

# The prevalence of pain catastrophising in pregnancy and its influence on latent phase hospital admission

The RETHINK Study

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#### Abstract

Background: Women experiencing an uncomplicated pregnancy are at increased risk of interventions if admitted to hospital during the latent phase of labour. Women expecting their first child (nulliparous) are more likely to be admitted during the latent phase than women who have had one (primiparous) or more babies (multiparous). Pain and fear are cited as significant factors in early hospital admissions. Some women may have exaggerated, negative cognitions for their pain experience, which have been referred to as pain catastrophising. To date there have been no studies that have sought to use a screening tool to identify pain catastrophising in pregnancy and to understand if a positive screening result influences when nulliparous women seek hospital admission in labour.

**Study aim:** The primary aim of this study was to determine the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an uncomplicated pregnancy, and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour.

*Method*: This was a longitudinal cohort study. Nulliparous women, experiencing an uncomplicated pregnancy in England, were recruited between 25-33 weeks gestation. Participants completed two online questionnaires, (1) on recruitment, (2) at three weeks postnatal. The antenatal questionnaire included the Pain Catastrophizing Scale (PCS) and the Wijma Delivery Expectancy Questionnaire (WDEQ-A) to detect fear of childbirth (FOC).

**Results:** A total of 389 eligible participants entered the study. Pain catastrophising scores of ≥20 and ≥30 were considered. There were 28.1% of women who indicated PCS scores ≥20 and 7.6% who were in the group with PCS scores ≥30. There was no significant association between pain catastrophising and the timing of hospital admission. The percentage of women reporting FOC (WDEQ-A score ≥85) was 10.6%. FOC (WDEQ-A score ≥85) was highly associated with PCS scores (p<.001) at both the lower (≥20) and higher (≥30) thresholds. Other significant associations were found between pain catastrophising and the variables of ethnicity, age, antenatal pain, and postnatal mental health issues.

*Discussion*: Although there was no significant association found between pain catastrophising and the timing of hospital admission, there was a tendency identified for women who pain catastrophise to present to hospital for admission during the latent phase of labour. Since FOC is known to be associated with latent phase admission, the highly significant association between PCS and WDEQ-A scores has implications for the identification of these women. The findings suggest that the PCS can be used as a screening tool to identify those women who have exaggerated, negative cognitions around pain and who may also go on to develop clinically relevant FOC. Further studies are needed to confirm the acceptability of the PCS as a screening tool with women, and to confirm the tendency that women who pain catastrophise are more likely to present to hospital for admission during the latent phase of labour.

*Impact:* To date no studies have sought to measure the prevalence of pain catastrophising in a population of nulliparous women who are experiencing a healthy pregnancy at low obstetric risk. This is also the first study to explore the impact of pain catastrophising on nulliparous women's decision-making regarding when to seek hospital admission in labour. This thesis makes an original contribution to knowledge by addressing these gaps in knowledge and brings together pain catastrophising and the latent phase of labour, two areas that have not been studied together before. It paves the way with evidence to facilitate further work for early identification of vulnerable women and the development of a targeted support intervention.

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#### **List of Abbreviations**

ACOG The American College of Obstetricians and Gynaecologists

ANQ Antenatal questionnaire

cm Centimetres

CRN Clinical Research Network

DCH Dorset County Hospital NHS Foundation Trust

FOC Fear of childbirth

HRA Health Research Authority

NHS National Health Service

NICE The National Institute for Health and Care Excellence

NIHR National Institute for Health Research

NMC Nursing and Midwifery Council

ONS Office for National Statistics

PCS Pain Catastrophizing Scale (Sullivan et al. 1995)

PI Principle Investigator

PIS Participant information sheet

PNQ Postnatal questionnaire

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analysis

RCM Royal College of Midwives

SD Standard deviation

SPSS Statistical Package for the Social Sciences

TENS Transcutaneous electrical stimulation

WDEQ-A Wijma Delivery Expectancy/Experience Questionnaire version A (Wijma et al. 1998)

WHO World Health Organization

#### Glossary

Active labour or established labour is a period of time characterized by regular painful uterine contractions, a substantial degree of cervical effacement and more rapid cervical dilatation from 5 cm until full dilatation for first and subsequent labours. (WHO 2018a).

The period of time when there are regular contractions and there is progressive cervical dilatation from 4 cm towards full dilatation at 10 cm (NICE 2023a).

As the neck of the womb begins to soften and open, the mucus which has been protecting the entrance to your womb comes away. This is called a 'show'. It has a clear jelly-like appearance. It can often be streaked with blood, either bright red, pink or brown. When this happens, it is called a bloody show.

Doula In the United Kingdom a doula is a person who can support women during pregnancy, labour, and the postnatal period. A doula is not trained to provide clinical care, and they do not provide advice. Their role is to provide information for informed decision-making, advocacy, and emotional support to women.

Dystocia Labour dystocia encompasses a variety of concepts, ranging from abnormally slow dilatation of the cervix to descent of the fetus through the birth canal up until the point at which the baby is born.

Elective caesarean sections

An operation to deliver a baby through an incision made across the abdomen usually just below the bikini line. An elective caesarean section is a planned procedure. The decision for an elective caesarean section is taken if labour is considered too risky for mother or baby. Sometimes a mother may request to have an elective caesarean section because she may want to avoid labour. This decision will be agreed upon following discussion between the mother and her obstetrician.

Emergency caesarean sections

The same as for an elective caesarean section except the decision is not planned in advance but taken at a time when there is an immediate or imminent threat to the safety of the mother of baby. The urgency/speed at which the operation needs to occur is categorised as either category I, II or III.

Epidural Anaesthesia An anaesthetic technique used in maternity care. It typically involves the insertion of a fine catheter into the epidural space around the spinal cord. A mixture of medium duration local anaesthetic and opioid drugs are then administered to achieve a temporary sensory block, although some degree of motor block is inevitable.

Flesch Reading Ease

A readability test. The score on the test is a guide to what education level a person requires to be able to read a piece of text.

Scores usually range between 0-100. The higher the score means the text is more readable.

Flesch-Kincaid Grade

Similar to the Flesch Reading Ease in that is uses the same core measures (e.g. word length and sentence length), however, they have different weighting factors. The Flesch-Kincaid Grade formula calculates the reading grade level of the text. A text with a high score on the Flesch Reading Ease should have an opposite lower score on the Flesch-Kincaid Grade.

**Fluid loss**This occurs when the membranes surrounding the fetus have ruptured and the amniotic fluid is released passing out of the woman's body through the vagina.

Instrumental birth A vaginal birth assisted by the obstetrician who uses devices such as a ventouse (a suction cup applied to the baby's head) or forceps (smooth metal instrument that looks like large tongs curved to fit carefully around the baby's head). When the mother has a contraction and is pushing her baby out the obstetrician assists, using either a ventouse or forceps, and pulls at the same time to help the baby to be born.

Labour augmentation Augmentation of labour is the process of stimulating the uterus to increase the frequency, duration, and intensity of contractions after the onset of spontaneous labour. It has commonly been used to treat delayed labour when uterine contractions are assessed to be insufficiently strong (WHO 2015).

Latent Labour / Latent Phase Latent first stage of labour is a period of time, not necessarily continuous, when there are painful contractions and there is some cervical change, including cervical effacement and dilatation up to 4 cm (NICE 2023a).

The latent first stage is a period of time characterized by painful uterine contractions and variable changes of the cervix, including some degree of effacement and slower progression of dilatation up to 5 cm for first and subsequent labours (WHO 2018).

**Mode of birth**A baby can be born in different ways. It can be a spontaneous vaginal birth, an instrumental birth (see definition above), or a caesarean section.

**Multiparous** A woman who has carried more than one pregnancy to a viable stage.

**Nulliparous** A woman who has never given birth to a viable infant i.e. one that is 24 weeks or more gestation.

Oxytocin is a hormone. It can be either naturally occurring in the human body or as a synthetic medication used within obstetrics to induce or augment labour.

Postpartum/postnatal

These terms are often used interchangeably. Although postpartum relates to issues pertaining to the mother and postnatal refers to those pertaining to the baby. The postnatal period begins immediately after the birth of the baby and extends up to six weeks (42 days) after birth (World Health Organization (WHO) 2010). For this study postnatal is used as a

general term and postpartum when there is specific reference to the mother having recently given birth.

**Primigravid** 

A woman in her first pregnancy.

Second stage of labour The second stage is the period of time between full cervical dilatation and birth of the baby, during which the woman has an involuntary urge to bear down, as a result of expulsive uterine contractions (WHO 2018b).

Uterine contraction / Contraction pain A physiological process occurring within the body particularly affecting the uterus and cervix. Muscles of the uterus tighten and shorten causing the softening cervix to shorten, stretch and open. It is thought pain is felt by the mother during contractions due to contractions compressing the blood vessels and reducing blood flow. When blood flow is limited pain receptors are stimulated. Pain is also caused by the fetus pressing down on the birth canal, and then onto the vulva and perineum as labour progresses from the first stage to the second stage and finally at the point of birth.

#### **Integrated Published Papers**

This doctoral study is presented as an integrated thesis incorporating a published narrative review paper (Batholomew et al. 2023) and two peer-reviewed publications (Bartholomew et al. 2022; Bartholomew et al. 2024). Table 1 below shows the list and location of the three published integrated papers. For all three publications contained within this thesis, I am the first and lead author and I confirm that I contributed at least 75% of the substantive content of each paper. The Royal College of Midwives (RCM) have kindly granted permission to include my first and second integrated papers as they appeared respectively in the MIDIRS and Evidence Based Midwifery journals. My third integrated paper also appears as it was published in the Sexual & Reproductive Healthcare journal. This paper is available on open access and can be copied and redistributed in any medium or format under a Creative Commons license BY-NC-ND 4.0. The deed of the Creative Commons license BY-NC-ND can be found online at http://creativecommons.org/licenses/by-nc-nd/4.0

Table 1: Table of Integrated Papers

| Paper<br>Number | Reference   | Chapter | Page<br>Number |
|-----------------|---|---------|----------------|
| 1               | Bartholomew V, Hundley V, Clark CJ, Parris BA 2023.<br>Changing the way we think about pain. <i>MIDIRS</i><br><i>Midwifery Digest</i> 33:1  | 3       | 52             |
| 2               | Bartholomew V, Hundley V, Clark CJ, Parris BA 2022. The RETHINK study protocol: to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of labour. Evidence Based Midwifery 20(2):5-12 ENT412-MIDIRS-EBM-June-2022-Bartholomew JR.pdf        | 5       | 81             |
| 3               | Bartholomew V, Hundley V, Clark CJ, Parris BA 2024. The RETHINK Study: Could pain catastrophising explain why some women are more likely to attend hospital during the latent phase of labour. <i>Sexual Reproductive Healthcare</i> . Vol 39:100941. ISSN 1877-5756 doi: 10.1016/j.srhc.2023.100941. | 6       | 103            |

This doctoral study has also been presented at 3 Conferences. First the premise to the RETHINK study was presented at the Postgraduate Researchers Conference 2020 and then an online PowerPoint presentation was given at the Trinity Health and Education International Research Conference 2021. Finally, the results to the primary aim of the RETHINK study were presented as a poster at the International Labour and Birth Conference 2023 in Grange-over-Sands. Here all the posters were judged by the conference attendees and fortunately my poster was judged the scientific prize winner on the day it was first presented. It was then judged the overall scientific prize winner out of all the posters presented over the three day conference. As a result, a book, monetary gift and certificates were awarded. The posters and prize certificates are presented in Appendix 1.

#### Acknowledgements

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To Hazel who would have thought that our conversations in the maternity unit corridor would have led us here.

To my sister Fay just when you thought you couldn't fit any more work into your day, I come along, thank you.

To my mum and dad for making me feel like I can give anything a go, thank you.

To Sam and Gabrielle, I am so sorry that on many occasions I have been distracted or shut away in my office when I could have been spending time with you. Looking back, I cannot remember any time that you complained. Thank you, I love you.

To my husband Bart, a business studies degree, a midwifery degree, and a PhD you have supported me through them all, thank you. I won't do anymore.......I love you.

To you all I could not have done it without you 🦃

#### **Chapter 1** Thesis Introduction

Women experiencing an uncomplicated pregnancy are at increased risk of interventions if admitted to hospital during the latent phase of labour. Pain and fear are cited as significant factors in early hospital admissions. Some women may have exaggerated, negative cognitions for their pain experience, which have been referred to as pain catastrophising.

The latent phase of labour (latent labour) is often overlooked, and yet it plays a significant role in shaping women's birth experiences and outcomes. There is much debate surrounding the definition of latent labour (Hanley et al. 2016; Hundley et al. 2017) (see discussion in Chapter 2). However, in England it is common practice to follow the National Institute for Health and Care Excellence (NICE) (2023), which states that latent labour is:

"a period of time, not necessarily continuous, when there are contractions and there is some cervical change, including position, consistency, effacement and dilatation up to four centimetres" (NICE 2023a pg. 127).

What the existing literature tells us is that women experiencing a pregnancy at low obstetric risk of complications are exposed to an increased chance of interventions in labour and birth if they are admitted to hospital whilst in the latent phase (McNiven 1998; Bailit et al. 2005; Davey et al. 2013; Lundgren et al. 2013; Neal et al. 2014; Tilden et al. 2015; Kauffman et al. 2016; Mikolajczyk et al. 2016; Rota 2018; Miller et al. 2020; Schick et al. 2020). During this clinically important time women are advised to stay at home and to only seek hospital admission once they have passed through this phase and are in active (established) labour. This advice leaves women bearing the brunt of the responsibility for this important decision at a time when they are vulnerable and in pain. Research tells us that many women seek professional care during latent labour due to their contraction pain and their lack of confidence in their ability to cope with this, and with the anxiety and uncertainty surrounding this phase of labour (Bailit et al. 2005; Janssen and Wessinger 2014; Mikolajczyk et al. 2016; Henderson and Redshaw 2017; Seravalli et al. 2022). Women expecting their first child (nulliparous) being more

likely to seek early support in hospital and express more uncertainty and anxiety than women who have had one (primiparous) or more (multiparous) babies (Bailit et al. 2005; Janssen and Wessinger 2014; Mikolajczyk et al. 2016; Henderson and Redshaw 2017; Seravalli et al. 2022). For some women their anxieties and poorer coping strategies may be fuelled by them having exaggerated, negative cognitions surrounding their pain experiences. This has been referred to as pain catastrophising. Pain catastrophising can be defined as:

"an exaggerated negative mental set brought to bear during actual or anticipated painful experience" (Sullivan et al. 2001, p.4).

Pain catastrophising may be one explanation for why women seek early hospital admission during labour.

To date there are no known studies seeking to report on the prevalence of pain catastrophising in a UK population of nulliparous women at low obstetric risk and no studies that have considered how pain catastrophising impacts on the timing of hospital admission when these women are in labour. Further, there are no known support interventions that individualise care considering the psychological needs of women to help them cope with this clinically important phase of labour. The RETHINK study sought to address this gap in knowledge.

The aim of this doctoral study was to determine the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an uncomplicated pregnancy, and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour. It was proposed that an association between pain catastrophising and latent phase admission could be used to inform a supportive intervention for these women.

#### 1.1 Presentation and navigation of chapter 1

This chapter will now go on to present a narrative of existing literature. First, the motivation behind this doctoral study (section 1.2) is provided. Sections 1.3, 1.4 and 1.5 identify the knowledge gap that serves as the focal point for investigation. Section

1.6 concludes the narrative section of this chapter. Section 1.7 in bullet points, provides a summary of the problems identified. Section 1.8 pinpoints the original contributions of this study to maternity care before bringing the chapter to a close in section 1.9.

## 1.2 More work is needed to reduce the rising rates of obstetric intervention in labour to improve childbirth outcomes.

In 2018 the World Health Organization (WHO) called for a reduction in the routinised over medicalisation of childbirth (WHO 2018a; 2018b). This call was in response to the rising rates of obstetric intervention in childbirth in many high-income countries across the globe (Miller et al. 2016; Fox et al. 2019; Seijmonsbergen-Schermers et al. 2020a) including in England where interventions have recently been recorded at their highest levels (NHS Digital 2023). Obstetric intervention in childbirth may be lifesaving but it must be timely, necessary and appropriate to prevent the situation of routinised overmedicalisation of childbirth (Miller et al. 2016), which in itself increases the risk of morbidity and mortality for mothers and their babies (Belizán et al. 2007; WHO 2015; Miller et al. 2016; Sandall et al. 2018).

The issue of unnecessary obstetric interventions is complex and multifactorial making it a difficult issue to unpick (Betrán et al. 2015; Betrán et al. 2016; Chen et al. 2018; Darling et al. 2021). Factors that have been identified as contributing to rising rates of intervention are: an increasing medicalisation of childbirth (Al-Gailani & Davis 2014; Clesse et al. 2018; Miller et al. 2016; Olza et al. 2020), resourcing decisions that prioritise an obstetric framework of care (Darling et al. 2021), hierarchical decisions supporting an interventionist approach (Darling et al. 2021), the fear of litigation within maternity care providers leading them to opt for intervention as a way to mitigate risks and legal consequences (Zwecker et al. 2011; Elaraby et al. 2023), lack of time to fully discuss and explore options with the women and their partners (Darling et al. 2021), using obstetric intervention as a means to reduce time spent supporting women through birth and alleviate resource constraints (Darling et al. 2021), and finally, technological advancements and their use in the management of risk which have led to more intervention than is necessary (Topçu & Brown 2019).

To maintain and promote maternal and fetal wellbeing much of the attention in research and in clinical practice to date has been on the mechanistic aspects of labour and birth such as the progress of labour being measured by cervical dilatation or the division of labour into distinct phases with allotted timeframes (Zhang et al. 2010; Neal et al. 2017; Lavender et al. 2018; WHO 2018a; Bonet et al. 2019). But, as Olza et al. (2020) point out, childbirth is a physiological and psychological cohesive event with each phase affecting the other. Putting the mechanistic aspects as paramount (Olza et al. 2020) and not prioritising the wants and needs of the woman and her partner (Darling et al. 2021) may have helped to maintain dominance of a medicalised approach to childbirth. In turn this may have contributed to the rising rates of obstetric intervention and given rise to the current situation where professional guidance is needed to put women at the centre of their own care.

To help combat these issues the WHO (2018a) considers women's maternity care experience as vital to high-quality care and not just supplementary to clinical practices. They go further to say that childbirth should be both "clinically and psychologically safe". Women themselves have identified both these factors as being of high importance (Downe et al. 2018). Prominent organisations and reporting committees in England echo the sentiments of the WHO's (2018a; 2018b) call to reduce unnecessary obstetric intervention in labour and improve outcomes for women and their babies. To help achieve this goal they all advocate a common thread, which is the promotion of holistic, woman-centred care that actively and equally involve the woman in the decision-making process and respects her choices (NHS England 2016; Ockenden 2022; Department of Health and Social Care (DHSC) 2022; National Institute for Health and Care Excellence (NICE) 2023). To realise this goal women must be empowered so that they can fully and equally participate in decision-making about their own care. Empowerment involves a process of recognition, promotion and enhancement of women's own abilities so that they can meet their own needs, solve their own problems and mobilise the necessary resources in order to feel in control of their lives (Gibson 1991). Midwives are placed in a principal position to effect positive change in the sincere pursuit of women's empowerment.

Women have a right to maternity care that protects and promotes their physical and psychological wellbeing and healthcare providers have an obligation to meet this requirement. Having a more detailed understanding about the psychological effects on childbirth decision-making is one strategy to help achieve a high-quality, holistic, woman-centred focus, and is necessary for informing how women can be best supported through their childbirth experience. This thesis makes an original contribution by addressing a key gap in knowledge and paves the way with evidence to facilitate further work for the development of a targeted intervention to support pregnant women who pain catastrophise.

# 1.3 Spotlighting the latent phase: a clinically critical time in labour requiring research attention.

#### 1.3.1 The situation

In recent years, and particularly in the United Kingdom (UK), research focus has turned to the latent phase of labour. The latent phase has typically been seen as a preparatory stage of labour with women being advised to stay at home until the active phase begins (NICE 2023a). Evidence and current professional guidelines are clear: it is safe, judicious and cost effective to advise women to stay at home until active labour begins (Bailit et al. 2005; Tilden et al. 2015; Kauffman et al. 2016; Edmonds et al. 2018; NICE 2023a). What is not clear is how to support women in making this important decision (Eri et al. 2015; Kobayashi et al. 2017; Edmonds et al. 2018; Allen et al. 2020;), especially those experiencing anxiety and uncertainty and who find latent labour pain challenging to manage. Moreover, ensuring and promoting women's empowerment, their psychological safety and self-efficacy during latent labour presents additional complexities (Carlsson et al. 2009; Carlsson 2016).

## 1.3.2 A selection of the important and recent research work undertaken to support women during latent labour.

A systematic review by Kobayashi et al. (2017) examined various assessment and support interventions for women in latent labour. Interventions included latent labour assessment versus immediate hospital admission (McNiven 1998), home visit assessments and support by midwives versus usual care (telephone triage) (Janssen et

al. 2006), latent labour one-to-one midwifery care versus usual care (Hodnett 2008), and labour diagnosis by algorithm versus usual care (Cheyne 2008). The review found no high-quality evidence corroborating any assessment or support intervention in latent labour for reducing the rate of caesarean section or instrumental births. However, some evidence suggested potential benefits such as lower epidural use and lower rates of oxytocin for labour augmentation and increased maternal satisfaction in the latent labour assessment group versus immediate hospital admission. Those women receiving home visit assessments reported slightly higher satisfaction with their maternity care, an aspect of women's reflection of childbirth that is important and should not be overlooked.

Subsequent research has considered interventions such as using a birth ball (Mylod et al. 2024), a web-based education program, (Edwards et al. 2023), mobile phone applications (Apps) (Fritzon et al. 2023) and video-calling (Borrelli et al. 2023). Mylod et al. (2023) used a randomised control trial to assess the impact of the use of a birth ball during latent labour on participants' pain levels, assessed with a visual analogue scale (VAS) on admission to hospital. This study found no difference in the mean pain scores on admission in either the intervention or control arm. However, results indicated potential benefits in terms of delaying hospital admission and lowering the caesarean section rate, although these findings did not reach statistical significance. Another intervention, a web-based education program on coping strategies during latent labour, was considered cost-effective and accessible, but did not significantly affect women's emotional experience or timing of hospital admission (Edwards et al. 2023). But there was an indication of potential benefits to reduce oxytocin augmentation of labour for women who commenced labour spontaneously (Edwards et al. 2023). In a pilot study Fritzon et al. (2023) considered the feasibility of an app which aimed to strengthen pregnant women's inherent physical, emotional, and birth self-efficacy to achieve a confident birth. The app provided education and practical exercises centring around breathing, relaxation, vocalising and the mind. The app proved useful and comprehensible to women and interestingly significantly more women in the appgroup were satisfied with leaving the labour ward in latent labour compared to the control group. However, there were no significant differences found between hours

spent in latent labour, latent labour or childbirth experience, labour onset, epidural use, babies requiring neonatal care, and mode of birth. Nevertheless, although pregnant women appreciate having the option to access reliable information via the use of technology (Fritzon et al. 2023, Whitworth et al. 2024), when it comes to antenatal education, they prefer face to face/non-electronic interaction (Grimes et al. 2014; Kovala et al. 2016; Wright et al. 2020; Whitworth et al. 2024). Also considering the use of technology in maternity care, video-calling during latent labour has been explored with midwives (Spiby et al. 2018) and women (Faucher and Kennedy 2020). Both groups showed positivity towards the potential use of this technology. Midwives thought that utilising visual cues would help in making more accurate assessments for labour advice and seeing one another would enhance trust (Spiby et al. 2018). Whilst women thought that being able to see the midwife would improve human connections over a telephone call (Faucher and Kennedy 2020). But both raised issues about privacy (Spiby et al. 2018; Faucher and Kennedy 2020). A note of caution about the use of technology and digital interventions (e-health) in maternity care is that they carry the potential to perpetuate healthcare inequity by making some women vulnerable to a 'digital divide' created through e-health interventions (Grimes et al. 2014; Kovala et al. 2016; Arcia et al. 2019; Wright et al. 2020). Conditions that put women at risk to the 'digital divide' are: the lack of easy access to the technology required; 2) physical, intellectual, or educational barriers; 3), and not speaking the language used in the intervention (Grimes et al. 2014; Kovala et al. 2016; Arcia et al. 2019; Wright et al. 2020).

Despite ongoing efforts, there is still a lack of targeted interventions addressing the specific needs of women during latent labour to improve childbirth outcomes. Work continues to understand more about the symptoms of latent labour (Grylka-Baeschlin and Mueller 2023) which can inform woman-centred approaches to improve latent labour care and to direct the development of effective latent labour interventions. One example of an intervention currently being investigated is an evidence-based tool to provide structured advice to inform the joint decision, between the pregnant woman and the midwife, regarding the timing of hospital admission (Grylka-Baeschlin et al. 2022).

# 1.3.3 Potential explanations for the lack of success in effectively supporting women during latent labour and delaying hospital admission until active labour has commenced, and suggestions for improvement.

The lack of success of latent labour interventions in improving outcomes could be because many are offering service-driven interventions and innovations, generalised to the masses, rather than designing them from an understanding of women's needs and preferences. In a system that is operating at capacity (Care Quality Commission (CQC) 2023), many studies appear to women to be a professional response and gatekeeping activities (Eri et al. 2011; Ängeby et al. 2019) used as means to control and reduce latent phase admission with little attention focused on the individualised needs of pregnant and labouring women. Designing interventions purely for the purpose of delaying women's hospital admission diverts attention away from all the other intricacies that contribute to the increased risk of obstetric intervention. Such interventions do not tackle the root cause/s of the problem, and they carry the potential to disempower women, which can contribute to their traumatic reflections of childbirth (Thomson and Downe 2008; Elmir et al. 2010).

Where women choose to birth appears to be important. In England the system is not set-up for effective latent labour support and yet there is prevailing tacit acceptance that birth takes place in hospital, often in obstetric-led units, where there is an integral risk of obstetric intervention if women are admitted during latent labour. However, fundamentally switching the philosophy away from system drivers and turning the attention back to the needs of women during latent labour, and childbirth overall, can help to improve the:

"sensitivity and specificity of support for physiological labour and birth, as well as early recognition of when labouring women might want or need extra help". (Stone and Downe 2023 pg. 544).

Listening to women and focussing on their care needs and acting upon them are key national drivers to improve outcomes for women and their babies and have been discussed above. This approach remains high on the national agenda into 2024 and

beyond (NHS England 2023a) and is very relevant for directing research activities for pregnant women.

## 1.3.4 What women say they want: It is important to address women's pain and fear during latent labour

In high-income countries some studies have found 47-80% of nulliparous women present to hospital for admission during the latent labour (Bohra et al. 2003; Rota et al. 2018). Many women seek professional care during this time due to contraction pain and lack of confidence in their ability to cope with ongoing labour pain, anxiety and uncertainty (Beebe and Humphreys 2006; Cheyne et al. 2007; Barnett et al. 2008; Carlsson et al. 2009; Cappelletti et al. 2016; Carlsson 2016; Cliffe 2017; Kobayashi et al. 2017; Beake et al. 2018; Edmonds et al. 2018). It is important to address fear, anxiety and uncertainty because high levels of fear of pain and helplessness during pregnancy have been related to high levels of stress during the latent phase of labour (Wuitchik et al. 1989). High levels of stress during labour have been shown to delay the progress of labour (Alehagen et al. 2005; Adams et al. 2012; Handelzalts et al. 2015).

What most women have said they want is a psychological and physiological safe, positive childbirth experience for themselves and their baby, in-line with their personal and sociocultural beliefs and expectations. This includes conserving a personal sense of achievement, maintaining control through shared decision-making throughout labour and birth, continuity of practical and emotional support from birth companions, and kind technically competent clinical staff (Downe et al. 2018; WHO 2018). The latent phase is a particular time during labour when many women feel their care needs are not being met (Janssen and Wessinger 2014). This is likely due to women being offered a variety of methods to manage their pain with little understanding of the holistic nature of pain-related fear, and how this is affecting labour choices (Eri et al. 2011; Eri et al. 2015).

During early labour women want to feel that they are in a safe and secure environment; this might be at home or in hospital (Carlsson 2016). In both settings feeling empowered and autonomous, and having a sense of self-efficacy to cope with labour is important (Da Costa et al. 2000; Larsen et al. 2001; Stockman and Altmaier

2001; Lowe 2002; Callister et al. 2003; Tilden et al. 2016; Sánchez-Cunqueiro 2018; Whitburn et al. 2019). Reasons behind their decision for where childbirth takes place might include whether the woman views childbirth as a natural or medical life event (Carlsson 2016). Women choosing to go to hospital early may do so because they feel safest when they can hand over responsibility for monitoring and managing their labour and birth to the professionals (Carlsson 2016). In this situation care should be reassuring and meet women's expectations. If not, it can make women feel demotivated to continue with labour, feel that they are experiencing pain to no avail, and lead them to feel helpless, victimised, disempowered, and assess care as inadequate (Carlsson 2016).

The spotlight has been turned on to the latent phase highlighting it as a time in labour of critical importance (Grylka-Baeschlin and Hundley eds. 2023). It is an area requiring improvements in maternity care to prevent a cascade of costly interventions, a time that currently women are under-supported, and an area requiring more research. The shift towards latent labour research aligns with the broader maternity care policy to reduce unnecessary obstetric intervention and to provide more woman-centred, respectful care. More work is needed to fill the notable gap in understanding about women's attitudes surrounding contraction pain during latent labour and how this might affect their timing of hospital admission.

### 1.4 Pain Catastrophising: coping with labour pain, its role in the timing of hospital admission, in-labour choices, and influence over the perinatal period.

Pain is a sensory and emotional experience associated with or described in terms of tissue damage (International Association for the Study of Pain (IASP) 2020). However, labour pain perception is a unique physiological and psychological event notably because it is associated with tissue changes and not tissue damage (Whitburn et al. 2019). It is an "excellent model of acute pain" (Melzack 1993) that is associated with a normal and natural physiological process, but the experience of labour pain is both challenging and complex (Lowe 2002; Whitburn et al. 2019). For some women, labour

pain can be both excruciating and desirable (Lundgren and Dahlberg 1998) and an experience that many accept and wish to experience. Conversely, some women may not be reassured by the fact that labour pain is not associated with tissue damage, and they may feel threatened at the prospect of pain and find that managing labour pain during the event difficult. Interestingly, women's satisfaction with their birth experiences are not solely dependent on labour pain intensity or being pain-free (Anim-Somuah et al. 2011; Whitburn et al. 2019; Fumagalli et al. 2021; Borelli et al. 2023). This underpins the idea that it is a woman's mindset that influences how she perceives and copes with labour pain. Coping involves conscious thoughts and behaviours that a woman utilises to navigate and manage an external stressor (Lazarus and Folkman 1984; Folkman et al. 1986) like labour, highlighting the substantial influence of a woman's cognitive approach to the experience.

It has been shown above that many women seek professional care during latent labour due to contraction pain, anxiety and fear (Beebe and Humphreys 2006; Cheyne et al. 2007; Barnett et al. 2008; Carlsson et al. 2009; Carlsson 2016; Cliffe 2017; Edmonds et al. 2018). Some women can tend to amplify negative thoughts and emotions around an anticipated or actual painful event. This mindset or more specifically psychological construct is known as pain catastrophising (Sullivan et al. 2001). To a degree, fear of pain is natural and understandable. However, pain catastrophising is a maladaptive approach to coping with a painful experience. It is conceptualised as involving helplessness, rumination and magnification of pain (Sullivan et al. 1995), whereby people expect the worst in relation to a particular experience of pain (Sharpe and Johnson 2012).

While studies suggest that pain is important in preparing women for birth (Whitburn et al. 2019), the anticipation of pain including the role of pain catastrophising can trigger women to fear that they will not be able to cope with labour pain and that they may be overwhelmed by it. Early studies suggested that a woman's fear of pain had a high correlation with her pain levels during the first stage of labour (Lowe 1989; Wuitchik et al. 1990; Harrison 1991; Lowe 1991) and fear of pain, pain catastrophising, and anxiety might predict labour pain experience in women undergoing an induction of labour (Carvalho et al. 2014). Later studies have been more specific and considered pain

catastrophising which has been shown to affect women's in-labour pain management choices (Van den Bussche et al. 2007; Veringa et al. 2011; Tan et al. 2021) but this has been found to not always be the case (Van Den Bosche et al. 2020; Peralta et al. 2024) and influence their preferences relating to mode of birth (Veringa et al. 2011; Dehghani et al. 2014). Women who pain catastrophise may perceive labour pain as threatening and employ various strategies to help them cope with this stressful situation. The suggestion is that pain catastrophising could be one explanation underpinning why some women seek early hospital admission during labour.

Continued efforts are being made to improve understanding of how women's pain cognitions contribute to their escalating risk of labour interventions, their need for pain management throughout labour (Van den Bussche et al. 2007; Veringa et al. 2011; Van Den Bosche et al. 2020; Sim et al. 2021; Tan et al. 2021), their choice to avoid labour altogether and opt for an elective caesarean section (Saisto and Halmesmäki 2003; Dehghani et al. 2014; Ahmadi and Bagheri 2017; Wilson et al. 2023), and in their reflections of their childbirth experience and postnatal recovery (Flink et al. 2009; Van Den Bosche et al. 2020;) and depression (Soet et al. 2003; Ferber et al. 2005; Zeng et al. 2020; McKelvin et al. 2021; Sun et al. 2023).

Nevertheless, further research is needed, because there still exists a notable gap in understanding the influence of women's pain cognitions, particularly pain catastrophising, during latent labour. This includes understanding its association with women's hospital admission during this phase and the subsequent increased risk for obstetric interventions. (See Appendix 2 for an example literature search strategy underpinning this statement and contributing to this narrative).

Pain catastrophising is widely recognised in the field of musculoskeletal pain management (Petrini and Arendt-Nielsen 2020) but its role is less understood over the perinatal period despite pain being commonly reported during pregnancy (Liddle and Pennick 2015; Shah et al. 2015), it being a significant aspect of labour and birth that women think about before the event, a prominent feature they must manage during the event (Whitburn et al. 2019), and often an ongoing issue for some women postnatally (Komatsu et al. 2020). But work continues in the pursuit of understanding

more about the role of pain catastrophising in the symptomology of pain throughout the perinatal period and its effects on the biopsychosocial outcomes for women. With studies implicating pain catastrophising in lumbopelvic pain, dyspareunia, genito-pelvic pain, pain interference, pain intensity, depression, anxiety, postnatal recovery and physical ability (Flink et al. 2009; Chang et al. 2012; Olsson et al. 2012; Glowacka et al. 2014; Doğru et al. 2018; Zeng et al. 2020; Sim et al. 2021; Tan et al. 2021; Rosen et al. 2022; Jessa et al. 2024). What is encouraging is that pain catastrophising has been shown to be modifiable with an antenatal intervention such as mindfulness training (Ahmadi and Bagheri 2017; Veringa-Skiba et al 2022).

There is ongoing theoretical debate surrounding pain catastrophising. First, there has been discourse about the uniqueness of the construct of pain catastrophising and difficulty in disentangling and distinguishing pain catastrophising from negative affectivity (Sullivan 2009; Crombez et al. 2020; Petrini and Arendt-Nielsen 2020; Sullivan and Tripp 2024). Second, there is debate whether pain catastrophising is a unique, cognitive mind-set that can be assessed through recall of thoughts and feelings related to past painful experiences, and prior to exposure to a painful episode and therefore a dispositional 'trait' or, whether it is a reaction assessed during or immediately after a painful episode and therefore a situational 'state' (Leung 2012; Petrini and Arendt-Nielson 2020; Sullivan and Tripp 2024). Third and final, there is a lack of agreement on its definition, conceptual issues, and criteria for diagnosis (Sullivan 2009; Petrini and Arendt-Nielson 2020; Sullivan and Tripp 2024). Nevertheless, work continues in this area with substantial empirical evidence around acute (Leung 2012) and chronic pain highlighting pain catastrophising as a consistent predictor of almost all of the significant pain-related outcomes including intensity, disability and psychological functioning (Quartana 2009; Leung 2012; Theunissen et al. 2012; Angst et al. 2014; Doménech et al. 2014; Wertli et al. 2014; Schütze et al. 2018; Petrini and Arendt-Nielsen 2020; Sullivan and Tripp 2024).

In a pregnant population pain catastrophising has demonstrated its predictive utility of childbirth outcomes (Van Den Bussche et al. 2007; Flink et al. 2009; Dheghani et al. 2014; Ahmadi and Bagheri 2017) suggesting that, in this population of women, pain

catastrophising is akin to a dispositional trait that can be identified prior to a painful event such as childbirth. A view that is adopted in this thesis.

This doctoral study aims to build on the work of Whitburn et al. (2019) and others discussed in this chapter by seeking to address the gap and understand if pain catastrophising does impact on the choices of women in labour, and their decision-making about when to seek hospital admission.

# 1.5 Pain catastrophising and fear of childbirth

Pain and fear have been identified as two major factors causing women to seek professional support in hospital during latent labour (Barnett et al. 2008; Beebe and Humphreys 2006; Cheyne et al. 2007; Carlsson et al. 2009; Carlsson 2016). Pain-related fear has been shown to be a factor in women avoiding labour altogether with 40% of European pregnant women who request an elective caesarean section cite fear of pain as the reason (Sjögren and Thomassen 1997; Ryding 1998; Geissbuehler and Eberhard 2002). Furthermore, Dehghani et al. (2014) found pain catastrophising mediated the relationship between fear of pain and preference for elective caesarean section. However, there is little evidence for the role of pain catastrophising in the development of fear of childbirth. Pain catastrophising has been identified as a potential mechanism in women fearing childbirth, although it was suggested that study findings were to be viewed as preliminary (Rondung et al. 2019). Women themselves cite fear of pain associated with childbirth as a key element for their fear of childbirth (Greer et al. 2014; Fenwick et al. 2015; Sheen and Slade 2017; Demšar et al. 2018; Kanellopoulos and Gourounti 2022) and fear of childbirth has been found to increase as pregnancy progresses (Rouhe et al. 2009). From the evidence presented and the assumption that pain catastrophising is an identifiable mindset this study anticipated that women who experience antenatal pain catastrophising are more likely to also fear childbirth.

Fear of childbirth is a complex psychological phenomenon which can affect women's decisions to become pregnant (Alehagen et al. 2006; O'Connell et al. 2015) and their decisions to terminate a pregnancy (Hofberg and Brockington 2000; Tsui et al. 2006;

O'Connell et al. 2015). It can cause intense anxiety during pregnancy leading women to opt out of labour and choose to birth their baby by an elective caesarean section (Fenwick et al. 2010; Sydsjö et al. 2012; Salomonsson et al. 2013) and increase their risk of gestational diabetes (Mishra et al. 2020), preterm birth (Roy-Matton et al. 2011; Staneva et al. 2015; Tanpredit and Kaewkiattikun 2020), low fetal birthweight (Lau 2013), and lower childhood intelligence scores (Lamb et al. 2014). It has also been implicated in women having a higher chance of an induction of labour, birth by emergency caesarean section (Sydsjö et al. 2012), the occurrence of prolonged and labour dystocia (Laursen et al. 2009; Adams et al 2012; Handelzalts et al. 2015), and the increased risk of postnatal depression and post-traumatic stress disorder (PTSD) (Soderquist et al. 2009; Elmir et al. 2010; Garthus-Niegel et al. 2013; Grekin and O'Hara 2014; Monk et al. 2020).

Fear of childbirth encompasses a range of fearful thoughts and feelings, and it is widely accepted that it can be measured on a scale whereby women's fears of childbirth exist on a continuum from low to severe (O'Connell et al. 2017; Nilsson et al. 2018), and in some cases reaching levels of a phobia as classified by the DSM IV [3, p.141]. However, there are some problems in the conceptualisation, terminology, definition, and unification of measurement of fear of childbirth (O'Connell et al. 2017; Slade et al. 2021). First, women's fears of childbirth have been found to be multifactorial (O'Connell et al. 2019) and fear of childbirth has been demonstrated to be an overly broad term (Nilsson et al. 2018; O'Connell et al. 2021). Second, in the literature there is some interchange, inconsistency and ambiguity in terminology with some using 'fear of childbirth' and others using the term 'tocophobia', or both (O'Connell et al. 2017; Nilsson et al. 2018; Slade at al 2019; O'Connell et al. 2021). There is also a lack of consensus around its definition, there are no standard measurement or criteria for classification, and the demarcations between no fear, mild, moderate, and severe fear and tocophobia are very unclear (O'Connell et al. 2017; Nilsson et al. 2018; Slade at al 2019). As a consequence, the concept of fear of childbirth is used as a broad term encompassing various anxiety and fears that surround pregnancy and childbirth (Nilsson et al. 2018).

Usually, the term tocophobia is used to identify those women who have a distressing pathological condition. It has been defined as an 'unreasoning dread of childbirth' leading women to sometimes avoid pregnancy, and childbirth altogether (Hofberg and Brockington 2000). Although, there is discordance across the globe regarding the prevalence of clinically relevant tocophobia, in a recent meta-analysis by O'Connell et al. (2017) they estimated the pooled incidence of tocophobia as 14% worldwide. But this figure was based on studies using different measures and cut-off points for diagnosis which suggests a prevalence figure based on ranging levels of fear of childbirth up to and including tocophobia. Although the 14% prevalence figure is based on significantly heterogeneous data it is a figure that appears to be slowly increasing (O'Connell et al. 2017). Evidence also suggests the prevalence is higher in nulliparous women than multiparous women (O'Connell et al. 2017; Kanellopoulos and Gourounti 2022). Kanellopoulos and Gourounti (2022) in their systematic review of tocophobia and women's desire for a caesarean section identified the prevalence of tocophobia to be between 7-25% in nulliparous women and 7.7-16.25% among multiparous women. Although, like O'Connell et al's (2017) previous meta-analysis, Kanellopoulos and Gourounti's (2022) systematic review relies on heterogenous data. Nevertheless, Kanellopoulos and Gourounti (2022) go on to identify fear of pain as the "most important reason for the manifestation of tocophobia" with older age and assisted conception as being significant demographics for women avoiding labour altogether and opting for birth by elective caesarean section. Variations in the estimation of the prevalence of fear of childbirth/tocophobia have been explained by the various methods used to measure it. These measures included it being self-defined by the woman, screening for it by using different questionnaires, varying cut-off points determining a positive screening result, or estimated via physiological indices such as stress hormones in childbirth (Nilsson et al. 2018). In this doctoral study the term 'fear of childbirth' is used and encompasses tocophobia. Fear of childbirth is measured on a continuum and a positive screening result determined at a cut-off score. Methods are detailed further in Chapter 4.

Women's fear of childbirth can be influenced by insufficient knowledge of the process of labour (Wigert et al. 2020), but it has been found to be modifiable with antenatal

education (Karabulut et al. 2016; Serçekuş and Başkale 2016). Rouhe et al. (2013) also found that spontaneous vaginal births significantly increased when women were screened for fear of childbirth and given a course of psychoeducation. Similarly, antenatal education has been shown to reduce maternal stress, improve self-efficacy, lower the caesarean section birth rate and decrease epidural anaesthesia use (Hong et al. 2021). This aligns with the findings of Tang et al. (2021), whose study showed that antenatal education led to a reduction in the rate of elective caesarean sections requested by expectant mothers.

There is discussion in the literature about whether mental health conditions such as anxiety and depression coexist with fear of childbirth, and pain catastrophising (Rondung et al. 2018; Hildingsson 2021). However, some studies do not screen-out pre-existing mental health conditions, or account or control for them (Flink et al. 2009; Rondung et al. 2019; Jessa et al. 2024). This is an important activity when trying to identify a particular cohort of women with similar characteristics who might pain catastrophise and be at risk of developing fear of childbirth, and then subsequently designing a targeted support intervention to address these needs.

More understanding is required about the constituent characteristics and causes of fear of childbirth. More understanding is required about the role pain catastrophising has in causing or magnifying this fear. This knowledge could contribute to the design of an early support intervention for a cohort of pregnant women who catastrophise pain.

# 1.6 Summary of narrative review

It has been established that the rising rates of obstetric intervention in labour and birth are heavily influenced by a complex web of various factors including the medicalisation of childbirth, the fear of litigation, and resource constraints within the NHS maternity care system. Despite these challenges, women express that they want individualised maternity care that focuses on supporting them and their choices and promotes their psychological and physical wellbeing throughout childbirth and beyond. These are factors that are advocated by national and world organisations. To help meet requirements to improve maternity care, this PhD study has been driven by

the recognition that a more comprehensive understanding of pain catastrophising, its role in women's fear of childbirth, and its impact on the timing of hospital admission is essential. Greater understanding can help to identify opportunities for early support interventions for women during latent labour, which in turn can have significant implications for women, their childbirth outcomes, and clinical practice.

# 1.7 Summarising the problem and drivers for this doctoral study.

- Healthy women at low obstetric risk are advised to remain at home during the
  latent phase and be admitted to hospital during active labour, and yet many
  women seek hospital admission during the latent phase for midwifery support
  due to pain, fear and anxiety.
- Women being admitted to hospital during the latent phase of labour are more likely to receive obstetric intervention that may not always be necessary.
- Unnecessary obstetric intervention during labour and birth can lead to iatrogenic harm to mothers and their babies.
- Globally and in the UK, there has been a call to reduce unnecessary obstetric intervention.
- Holistic woman-centred care is high on the national agenda as one strategy to improve childbirth outcomes for women and their babies.
- A more detailed understanding of the effect of a woman's cognitions on childbirth, and how women can be best supported throughout for a positive experience, could contribute to fostering a high-quality, woman-centred approach to maternity care and empower women.
- Understanding the role of pain catastrophising in women's decisions surrounding labour and birth is limited. No studies have considered the influence of pain catastrophising on the timing of hospital during labour.
- To date there are no known interventions that have proven effective in reducing the number of women who are admitted to hospital during latent labour and no known latent labour support interventions for women who pain catastrophise.

 There are ambiguities surrounding the conceptualisation, definition, terminology used, and multidimensionality of the fear of childbirth. Preliminary studies have identified pain catastrophising as a potential mechanism in women fearing childbirth.

# 1.8 The Original Contribution of this Research

- 1. This doctoral study focuses on nulliparous pregnant women at low obstetric risk, the latent phase, and pain catastrophising. This project is important and has the potential to have high impact due to there being no existing studies that focus on pain catastrophising and the latent phase together.
- 2. No existing studies have considered identifying a specific need such as pain catastrophising in this target population of women, then how this may impact on this group of women's decision-making during labour, and then subsequently sought to fulfil that need with a targeted support intervention. This is different to other approaches that have provided universal support intervention to all.
- 3. This study is timely because:

It is coming at a point where there is little known about the best way to support women during latent labour, and when little is known about the influence of pain catastrophising on women's pregnancy, intrapartum and postnatal experiences.

It aligns with the broader maternity care policy aiming to reduce unnecessary costly obstetric intervention.

It aligns with broader maternity care policy to provide more woman-centred care.

4. By researching this under-investigated phase of labour this thesis provides the opportunity to improve maternal and neonatal wellbeing by reducing iatrogenic complications from unnecessary interventions.

- 5. It provides the opportunity to develop a support intervention that may improve women's reflections on their childbirth experience and contribute to their ongoing psychological wellbeing.
- 6. This study focusses upon one central area in midwifery care and that is supporting women through the pain of labour. As such it holds the potential to improve labour pain management for women.
- 7. Based on the work in this study a targeted support intervention has been designed.

This doctoral study is embedded in midwifery practice. It is focussed on contributing valuable insights to the field of maternity healthcare from a woman-centred perspective and ultimately aims to enhance the childbirth experience for women and improve their childbirth outcomes.

# 1.9 Moving on to chapter 2

Chapter 1 has provided the motivations and underpinnings for the RETHINK study. The next chapter embeds this doctoral work in a historical context and presents a discussion on the definition on latent labour.

# Chapter 2 Background context: historical and defining latent labour

# 2.1 Chapter introduction

This chapter provides context for the provision of latent labour care in the UK. First historical context of maternity care is presented (section 2.2). The focus in this section is on the developments within midwifery care and how history has shaped the care of women through latent labour. Understanding the historical context of maternity care in the UK is important to understanding midwifery research and practices today. This historical knowledge provides a particular lens through which it is possible to identify persistent challenges and identify potential areas for development or improvement, and where beneficial practices should be upheld. Section 2.3 presents an account of the discourse surrounding the definition of latent labour and why defining latent labour is important for researching and planning safe labour care and effective support of pregnant women during this period.

# 2.2 Taking a step back: understanding the historical underpinnings for the choice of hospital over homebirth, and the rise in obstetric intervention.

In England and Wales, the majority of pregnant women now choose to give birth in hospital when once the home was where childbirth took place. Over a recent 40 year period (1981 to 2021) the majority of births occurred in hospital, with a rate of 97.5%-98.1% (Nove et al. 2008; Office for National Statistics (ONS) 2021). The influences contributing to the shift in the place of childbirth are multifactorial and reflect societal attitudes towards childbirth. Important factors that shape culture and societal attitudes towards childbirth include advancements in medical knowledge (Al-Gailani & Davis 2014; Miller et al. 2016; Clesse et al. 2018; Olza et al. 2020), technology (Topçu & Brown 2019), the influence of the portrayal of birth in the media (Stoll et al. 2014; Luce et al. 2016), and an ever evolving healthcare system which is moulded by power structures within the socio-cultural, and political circumstances of the time (Benoit et al. 2005; Louden 2008; Ham et al. 2018; Nelson and Romanis 2021; Renfrew et al. 2022; Ham 2023).

For some women who are experiencing a pregnancy complicated by obstetric factors giving birth in hospital is recommended (NICE 2019a; 2023). However, when considering where to give birth, women at low obstetric risk can be reassured that no difference in perinatal or neonatal mortality exists "when birth was intended at home or in hospital" (Hutton et al. 2019). A similar finding for positive childbirth outcomes in planned homebirths was also reported in an earlier systematic review and metaanalysis by Scarf et al. (2018). They found that no statistically significant impact on neonatal mortality between home and hospital births, but there was a higher chance of maternal morbidity and obstetric intervention with planned hospital births and a lower chance of a 'normal' vaginal birth. In the case of Scarf et al's (2018) study they define normal vaginal birth as "births other than caesarean sections or instrumental birth, specifically stating there was no induction of labour, epidural or spinal analgesia, or episiotomy, and vertex presentations". For some the term 'normal' to define birth is contentious. Professionals and interested parties are now working towards reframing 'normal' into terminology that promotes a positive, responsive and safe birth experience that is woman-centred, away from the pursuit of the ideology of keeping birth 'normal' (Kirkup 2015; Independent Maternity Review 2022; Renfrew 2022; Edun 2023). Therefore, the term 'normal' will not be further expressed in relation to labour and birth. Olsen and Clausen (2023) summarise the issue by stating that "planned hospital births can do more harm than good" for healthy pregnant women at low obstetric risk receiving midwifery care in a well organised health care system. Despite this evidence, the majority of healthy pregnant women at low obstetric risk are preferring to give birth in hospital. A decision that is understandable when considering all the factors shaping this choice.

The shift from predominantly home birth to predominantly hospital birth was seismic with this shift predominantly occurring in the early 1970s (Peel 1970). But the maintenance of this choice can be accounted for by historical evolution within the midwifery and obstetric professions. Midwifery care in the U.K. spans centuries and has its roots in ancient practices where women supported other women during childbirth. Care was informal and based on knowledge passed through the generations. However, around the 18<sup>th</sup> century men started to involve themselves in

childbirth emphasising anatomical study and assisting birth with forceps (Stone 1737; Fores 1793; RCM 2020). They were expensive to hire and became a fashionable choice for the wealthy (Fores 1793). Although the appropriateness of men attending childbirth was contentious the move towards the rise of male dominated, professional medicine had begun taking midwifery care along with it and encompassing it under its umbrella.

In 1881 the Royal College of Midwives (RCM), although under a different name, was established in response, in part, to the significant mortality rate (Louden 1986), and the decline of female midwives and the rise of male obstetricians (RCM 2020). The 20<sup>th</sup> century saw the first Midwives Act (1902) being passed and the creation of the Central Midwives' Board after years of campaigning by the RCM for the regulation of midwifery practice and education, making the midwifery profession more structured and accountable (RCM 2020). The 1936 Act created the nationwide midwives service which further strengthened midwifery as a legitimate profession in its own right which was consolidated during World War II when midwifery became a 'national service' (RCM 2020) (the Royal College of Obstetricians and Gynaecologists was later founded in 1929).

Shortly after the end of the war factors such as antibiotic use, improved sanitation, blood transfusions, better maternal health and nutrition, improving maternity healthcare and surveillance, and finally greater understanding into maternal deaths began their substantial contribution towards reducing maternal mortality (Chamberlain 2006; RCM 2020). Then in 1948 the National Health Service (NHS) was formed. These aforementioned factors where vital in reducing maternal and perinatal morbidity and mortality. But the foundations for the medicalisation of childbirth were laid and were greatly strengthened by two proceeding reports. First the Cranbrook Report (Russell 1959) which advised that hospital provision should be made for 70% of all births and then the Peel Report (1970). The Peel Report (1970) recommended that all women should give birth in hospital and then stay for some days postnatal. Although Sir John Peel's (1970) intention was to improve maternal and infant mortality his evidence for hospital confinement for childbirth and postnatal stay was thought weak and his recommendation "cavalier over the wishes of the women" themselves

(Richmond 2006). Concurrently there was a continuing decline in maternal and perinatal mortality leading people to make the link that hospital births are safer than homebirths (Reitsma et al. 2020). Although there is a temporal association between hospital birth and improved outcomes there is not the evidence to demonstrate a causal link. What has been suggested, with compelling evidence is that improvements in maternity outcomes were the result of improving maternal health over the time period (Tew 1981, 1986). In fact, there is recent evidence suggesting that for healthy pregnant women who intend to birth at home with the support of a professional midwife who is integrated into a responsive healthcare system the maternity outcomes are more favourable than for this cohort of women birthing in hospital in an obstetric-led maternity unit (Scarf et al. 2018; Tew 1981, 1986; Reitsma et al. 2020).

The transition from primarily home births to the majority of women birthing in hospital altered the dynamics of childbirth and denoted a significant evolution in maternity care services. Prior to the change of place for labour and birth, care was usually provided in the home and typically at a later stage with the woman deciding when the care was needed (McIntosh 2013). But with the majority of women moving into hospitals to give birth obstetrically the optimum time for hospital admission during labour had to be determined. This shifted the power of influence over access to labour care to midwives who were placed in a position of power over enforcing the decision of when to grant access to hospital based on following recommendations provided by professional guidelines and pressures from maternity care providers (Eri et al. 2011; Eri et al. 2015; Ängeby et al. 2019). A situation that continues today with women bearing the burden of responsibility for determining the 'right' time to seek hospital admission whilst managing painful contractions and potentially navigating psychological factors such as anxiety and uncertainty (Cheyne et al. 2007; Eri et al. 2015; Edmonds et al. 2018). They must then make the journey to seek professional support in hospital, a journey that can be extremely uncomfortable due to labour pain and anxiety inducing because some women fear they may not get to hospital in time and have their baby on route. Once at hospital and prior to hospital admission for ongoing labour care women are usually required to meet the criteria for active labour (NICE 2023a).

# 2.3 Defining the latent phase

Providing safe and effective labour care for women requires careful balance between supporting the women in line with her needs, monitoring for and limiting potential complications, whilst upholding and promoting the natural process of childbirth (WHO 2018a, 2018b; 2018c; American College of Obstetricians and Gynecologists (ACOG) 2019; NICE 2023a). Careful balance and consideration are also required when dividing labour into distinct phases and defining those phases because labour care is planned around diagnosing each phase (WHO 2018; 2018b; ACOG 2019; NICE 2023a). In contrast, women tend to perceive labour on a continuum (Dixon et al. 2013) and there is debate whether such a complex physiological and emotional process throughout childbirth can be divided into distinct phases (Dixon et 2013) and whether the process of doing so is a professional construct (Carlsson 2016). However, dividing labour into distinct phases has become broadly accepted into clinical practice and research (Hundley et al. 2017; WHO 2018a; ACOG 2019; Mueller and Grylka-Baeschlin 2023; NICE 2023a; Tilden et al. 2023).

Knowing when to diagnose that latent labour has come to an end and the active phase has begun is important particularly when deciding the optimum time for admitting women to hospital when they are in labour. The optimum time centres around that which protects the physical safety of the woman and her fetus (McNiven 1998; Bailit et al. 2005; Davey et al. 2013; Lundgren et al. 2013; Neal et al. 2014; Tilden et al. 2015; Kauffman et al. 2016; Mikolajczyk et al. 2016; Rota 2018; Miller et al. 2020; Schick et al. 2020; NICE 2023a). However, this diagnosis can be problematic when there is a lack of consensus in definition and practice for when the latent phase finishes and the active phase begins (Cheyne et al. 2006; Hanley et al. 2016; Hundley et al. 2017; Tilden et al. 2019; Tilden et al. 2023).

The World Health Organization (2018a p.3) recommend for practice using the following definition for the latent phase of labour:

"The latent phase is a period of time characterised by painful uterine contractions of variable changes of the cervix, including some degree of

effacement and slower progression of dilatation up to 5cm for first and subsequent labours".

In the UK, the National Institute for Health and Care Excellence (NICE 2023a p.39) define early labour as:

"A period of time, not necessarily continuous, when there are contractions and there is some cervical change, including cervical position, consistency, effacement and dilatation up to 4 centimetres."

The obvious difference between these two definitions is cervical dilatation. Cervical dilatation is one the leading features in clinical practice for diagnosing labour progression and the distinction between latent and active labour. Following cervical dilatation, uterine contractions are the next most prominent indicator, while other physiological signs such as bloody show, fluid loss, and gastro-intestinal symptoms are less commonly featured (Hanley 2016). Observing cervical dilatation through labour is an idea founded by Friedman, an American obstetrician through his series of seminal works (Friedman 1954; Friedman 1955). Friedman developed the labour curve (Friedman 1954; Friedman 1955; Friedman 1969) which established specific criteria based on cervical dilatation and effacement and distinguished the transition from latent to active phase of labour, together called the first stage (Friedman 1955). Friedman's earlier work described the typical physiological evolution of labour in primigravid women (Friedman 1955) and provided objective measures around which decision-making regarding the timing of hospital admission and obstetric intervention have evolved. Although Friedman did later explain that the onset of active labour is the transition point when the rate of cervical dilatation significantly increases (Friedman 1978 cited by Hanley et al. 2016). Since Friedman's work there has been no consensus between researchers, academics or clinicians for defining the phases of the first stage of labour using one transitional cervical dilatation point. This benchmark is critical for assessing deviations from expected labour progress and identifying pathological changes (Dixon et al. 2013; Hanley et al. 2016; Cohen and Freidman 2023).

With some advocating the need to consider women's genetic and cultural differences which may indicate that defining one cervical dilatation as a pivotal parameter for all women inappropriate (Cohen and Freidman 2023; Watanabe 2023).

Currently, variation in opinion on the transition point from latent labour to active labour is reflected in the WHO (2018a) and NICE (2023) definitions with one suggesting a cervical dilatation of 5cm (WHO 2018a) and the other 4cm (NICE 2023a). Zhang et al. (2010) suggest using an even greater cervical dilatation measurement of 6cm as one of the clinical markers signalling the start of active labour. The American College of Obstetrics and Gynecology (ACOG 2014) changed its definition of labour phases in response to evidence suggesting many women may not enter active labour until 6cm. This led the ACOG (2019) to advise that if a woman's cervix is between 4-6cm and all other signs indicate she is still in latent labour, it is reasonable to wait for active labour to progress, provided there are no concerns about the wellbeing of the mother or baby. A plan for labour reassessment should be agreed upon between the woman and her maternity care provider. The American College of Nurse-Midwives have approved of the American College of Obstetricians and Gynaecologists statement for delaying hospital admission until at least 4 to 6cm of cervical dilatation, for women experiencing low-risk pregnancy and labour (ACOG 2019). Although it could be argued that in the United States of America (USA) the timing of hospital admission in practice is, to some degree, influenced by the varying maternity care provision structures and the different mechanisms through which women pay for their maternity care (Backes and Scrimshaw eds. 2020).

Grylka-Baeschlin and Mueller's (2023) conducted a scoping review to determine the frequency and description of symptoms described in the literature from onset and throughout latent labour to inform care. They found a diversity of symptoms including 'contractions, labour pain' to be the most frequently mentioned, then 'details about contractions'. They go to describe other symptoms including 'positive and negative emotions', and then 'fear and worries' with symptom descriptions ranging from both ends on a spectrum. Gastrointestinal symptoms were also described, and women themselves described other physical symptoms. For example, women described an increase or decrease in food or fluid intake, pressure in lower abdomen, perineal and

pelvic areas, swelling of the external genitalia, the vagina feeling hot and increased secretions, increased urinary frequency and urgency, difficulty in movement, and bending forward with contractions. They go on to suggest that from their findings of such a diverse and opposing array of symptoms and needs provides a basis for improving women-centred care and 'play a role in the discussion about the unclear definition' surrounding this phase of labour.

Furthermore, omitted from definition and description of the latent phase is a standardised timeframe for the expected duration. This is because a standard duration has not yet been established and can vary widely between each woman (Abalos et al. 2018; Oladapo et al. 2018; WHO 2018; Tilden et al. 2019). There appears little agreement in evidence on the duration of the latent phase with no consistency on how to identify the onset of labour (Hanley et al. 2016; Abalos et al. 2018) or the point of active labour onset (Janssen and Weissinger 2014; Abalos et al. 2018; Oladapo et al. 2018; Tilden et al. 2019; Shukla et al. 2020; Cohen and Friedman 2023). It is likely that this inconsistency is partially due to the complex nature of the physiology and mechanics that may or may not be involved in triggering spontaneous labour (Cohen and Friedman 2023). Nevertheless, based on the woman's own self-identification of labour onset Tilden et al. (2019) suggest the median duration to be nine hours and mean duration was 11.8 hours in nulliparous women, with fetal malposition being identified causing delay. Cohen and Friedman (2023) suggest a 95<sup>th</sup> percentile for the normal limit for nulliparous women should be around 20 hours and 14 hours for multiparous women. More work is needed to identify time parameters for latent labour before inclusion in the definition. To define time parameters there will need to agreement on what signifies the start of latent labour (Hanley et al. 2016; Abalos et al. 2018) and the point at which latent labour transitions into active labour (Janssen and Weissinger 2014; Abalos et al. 2018; Oladapo et al. 2018; Tilden et al. 2019; Shukla et al. 2020; Cohen and Friedman 2023). However, the thought is that inclusion is necessary because there is strong evidence to suggest that nulliparous women, experiencing a low-risk pregnancy, are at increased risk of a diagnosis of labour dystocia and associated interventions, and epidural use without it (Tilden et al. 2020).

To support women effectively and safely through latent labour it is important to understand its' distinctness within the whole process of labour. Having a clear definition may help woman accurately anticipate, prepare, and cope during this time. Although caution should be taken when defining and assimilating into practice guidelines that predicate and stipulate a certain cervical dilatation to identify the transition from latent to active labour. This practice does not address the issue of providing adequate latent labour support to women who require it. Using a specific cervical dilatation as a benchmark for hospital admission (Allen et al. 2020) and advising women to seek admission to hospital when active labour commences does not address the issue of the needs of women during this uncertain and often painful time (Grylka-Baeschlin et al. 2023). However, clarity and comprehensiveness in latent labour definition is required to ensure women are provided with individualised, evidence-based care (Hanley et al. 2016; Hundley et al. 2017), and unnecessary obstetric intervention avoided (Abalos et al. 2018; Oladapo et al. 2018; Tilden et al. 2020; Tilden et al. 2023).

# 2.4 Chapter summary

A history of maternity care, and midwifery care in particular, has been presented together with a discussion on the discourse surrounding the definition of latent labour. Together these topics have provided important context for understanding the current provision of maternity care in the UK and for navigating current discourse surrounding latent labour care provision and for identifying opportunities for improvement.

Historical reflection has provided valuable insight into the development of current maternity care services based on traditional practices, social, cultural and political influences over time, and how these factors have impact on women's decision-making surrounding childbirth today.

Whilst recent evidence strongly indicates that finding an agreed definition of latent labour remains a challenge, evidence points to the need for a holistic definition that reflects this critical time point in labour and promotes safe and effective womancentred care. Understanding the debate surrounding the definition of the latent phase

is important for navigating the current discourse accordingly informing research inquiry and shaping research methodology.

# 2.5 Moving on to Chapter 3

Chapter 3.0 presents an integrated published paper (Bartholomew et al. 2023) which delves into the current understanding about pain perception. It discusses the importance of effective psychological support for women during labour and considers the current education provision for student midwives surrounding this issue. Finally, consideration is given for how women could be supported in latent labour and encourage their timely admission to hospital.

# **Chapter 3** Pain

As highlighted in chapter 1, pain is cited by women as a major reason for latent labour hospital admission. This chapter explores theories around pain in preparation for the empirical work, and is presented as an integrated, published, narrative review paper (Bartholomew et al. 2023).

3.1 Why understanding pain theories is important for midwives and any health professional caring for pregnant women and their families.

A core aspect of midwives' clinical practice involves providing skilled, knowledgeable, respectful and compassionate care for women in preparing for childbirth, providing support during labour and birth, and postnatal as they recuperate (NMC 2018; 2021). Understanding the underlying mechanisms of pain holds potential for midwives to offer more effective pain management strategies to labouring women. This knowledge is crucial as it promotes holistic care tailored to individual women's needs throughout the perinatal period as required (NICE 2019a; 2019b; NMC 2021; NICE 2023a). Furthermore, midwives can share their understanding about pain with women facilitating empowerment and informed decision-making through education (NMC 2018; Yuill et al. 2020; NICE 2021c; Kloester et al. 2022), which aids women's understanding about their own pain experiences and contributes to a positive birth experience (Downe et al. 2018; Yuill et al. 2020). It is important that midwives can recognise and understand pain theories, however the literature suggests that this is an area for improvement (Klomp et al. 2014; Lally et al. 2014; Mankelow et al. 2022).

Based on my extensive experience as a practicing midwife, I have an in-depth understanding about midwives' knowledge, expertise, and clinical practice supporting women through labour pain. Consequently, I wanted to share the insights and knowledge I had acquired for this doctoral study with fellow midwives and raise awareness about the importance of evidence-based and individualised psychological assessment and support for pregnant women managing their labour pain. I chose to target my paper for publication in MIDIRS. I selected this journal because it aims to

provide evidence-based articles and research to support the continuous professional development or academic studies of midwives, student midwives, maternity support workers or any health professionals caring for women, babies and their families during their pregnancy, birth and the postnatal period, worldwide.

The literature on which this paper was based upon was informed by several sources including library searches, my own professional knowledge and experience, professional guidance, standards for midwifery education and proficiencies, and discussion with colleagues.

# 3.2 An integrated published narrative review paper 'Changing the way we think about pain'.

Bartholomew V, Hundley V, Clark CJ, Parris BA 2023. Changing the way we think about pain. *MIDIRS Midwifery Digest* 33:1. Available from:

https://www.midirs.org/informing/midirs-midwifery-digest/

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# Changing the way we think about pain

Vanessa Bartholomew, Carol J Clark, Vanora Hundley, Benjamin A Parris

#### **ORIGINAL**

#### Introduction

Pain and fear are high on the list of reasons that women give for seeking hospital admission when they are in labour (Cheyne et al 2007, Barnett et al 2008, Carlsson et al 2009, Carlsson 2016). The timing of admission to hospital is important because women experiencing an uncomplicated pregnancy are at increased risk of obstetric intervention if they are admitted to hospital during early labour (Bailit et al 2005, Lundgren et al 2013, Neal et al 2014). This knowledge causes many women, who might have benefited from professional psychological support, to be sent home and left to manage this period of labour alone (Barnett et al 2008, Eri et al 2015). More work is needed to understand how women can be effectively supported in managing their pain at this time and safely await active labour before coming to hospital (Eri et al 2015, Kobayashi et al 2017).

This paper is presented as one of two papers aimed at prompting our thinking and understanding around pain perception in labour. It provides a summary of our current understanding about pain, and highlights pain catastrophising and how it might affect childbirth. We discuss the importance of effective psychological support for women, and how hypnosis may be one intervention to support women in early labour and encourage their timely admission to hospital.

#### The science behind pain

#### Definition of pain

A widely accepted definition of pain is that it is 'an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage' (International Association for the Study of Pain (IASP) 2020). However, this definition may not adequately represent the uniqueness of labour pain.

For women at low obstetric risk, labour is a normal physiological event with labour pain being associated with normal tissue changes and not the threat of, or actual, tissue damage (Whitburn et al 2019). However, for other women, the fear and pain they experience during childbirth may be associated with the perceived potential for tissue damage. Nonetheless, in the absence of a specific definition for labour pain the IASP definition stands.

#### Nociception and pain differ

Nociception is a term used to describe how the human body encodes noxious (unpleasant) stimuli via its neural process in a normally functioning somatosensory nervous system (IASP 2011). Noxious stimuli are stimuli that damage, or threaten to damage, normal body tissues (IASP 2011) and can be in the form of mechanical stimulation (such as stretching, cutting, or pinching), intense heat exposure or exposure to noxious chemicals (Brodal 2010). However, it cannot be assumed that a person who is exposed to noxious stimuli will have a painful

experience — nor that the absence of noxious stimuli means the absence of pain (Mischkowski 2018). The experience of pain is subjective and fundamentally differs from nociception (Bendelow 2006, Kong et al 2006, Garland 2012, Atlas et al 2014, Nickel et al 2017, Woo et al 2017, Mischkowski 2018).

#### Pain is an individual experience

Pain is an individual, subjective experience and a complex phenomenon which is not fully understood. It is an experience resulting in a range of responses, in each individual and between individuals, in response to an identical stimulus.

Contemporary theories generally consider pain to be multidimensional (Melzack 1990, Melzack 1999, Melzack 2001, Moayedi & Davis 2013) and influenced, to varying degrees, by an interplay between biological, psychological, and socio-cultural factors (Anderson & Losin 2017, IASP 2020) that are partially dissociable (Moayedi & Davis 2013, IASP 2020). It is thought that, in its translation of nociception, the brain incorporates the person's pain beliefs, which have been learnt and conditioned throughout their life and drive the person's painmanaging behaviours.

#### Innervation of pain

The pain of labour has two component sources: visceral (related to the organs in the midline of the body), and somatic (related to muscles, skin, joints, and bones).

Throughout labour, pressure triggered by uterine contractions causes stretching and distension of the lower segment and cervix. Stretching and distension are translated as visceral pain, and these are often reported as a deep dull ache or pressure and not easily localised. Visceral pain is associated with the first stage of labour (including early and active labour) and is mediated by the T10 to L1 spinal segments.

Somatic pain is felt in the late first stage and second stage of labour and is carried by the T12 to L1, and S2 to S4 spinal segments. Somatic pain arises as a result of fetal descent through the birth canal causing distension, stretching, ischemia, and possible tearing of the vagina, pelvic floor muscles and the perineum (Labor & Maguire 2008).

#### A selection of pain theories

Pain perception has interested philosophers, researchers and scientists for hundreds of years and can be traced back to around 375 BC and Plato. Plato suggested the Intensity Theory (Plato cited in Moayedi & Davis 2013). Over time, and with increasing knowledge, a number of more modern theories have been put forward to explain how and why we feel pain. Prominent modern theories are: Specificity Theory (Bell 1868, Von Frey 1894 cited in Trachsel et al 2022, Sherrington 1903, Sherrington 1906, Sherrington 1947); Pattern Theory (Nafe 1929); Gate Control Theory (Melzack & Wall 1965); Neuromatrix Theory (Melzack 1990) and the Biopsychosocial model (Engel 1977, Loeser 1982).

#### Intensity Theory

Intensity Theory, first proposed by Plato (cited in Moayedi & Davis 2013), considered pain as an emotional experience, as opposed to pleasure, and experienced when the body is under threat from normal function or damage (Wolfsdorf 2015). This theory had backing into the twentieth century but lost support after Sherrington's (1947) proposal of a framework for Specificity Theory, and the discovery of the existence of the sensory receptors or 'nociceptors' (Moayedi & Davis 2013).

#### Specificity Theory

Specificity Theory (Bell & Shaw 1868, Von Frey 1894 cited in Trachsel et al 2022, Sherrington 1903, 1906, 1947) suggests pain is a specific modality with specific sensory receptors connected to associated pathways responsible for different sensations such as touch, cold, heat, and pain. However, this theory did not fully account for the complexities of pain perception and did not include neurons in the central nervous system that respond to both nociceptive and non-nociceptive stimuli.

#### Pattern Theory

Pattern Theory, presented by John Paul Nafe (1929), takes an opposite view, suggesting that there are no specific sensory receptors or associated pathways but that, instead, it is the pattern of neural firing in response to different sensations and intensity that are transduced to the brain where the pattern is then interpreted. However, this theory was disproved by the confirmation that there are unique nerve receptors for each type of sensation (Moayedi & Davis 2013, Trachsel et al 2022).

#### Gate Control Theory

In 1965, Melzack & Wall proposed the Gate Control Theory of pain that brought together ideas from both Specificity Theory and Pattern Theory and was one of the first modern theories to recognise the contribution of psychological aspects to the feeling of pain.

The original idea proposed a 'gate' control system, located in the substantia gelatinosa. The substantia gelatinosa is principally associated with transmitting and modulating touch, temperature and pain. Simplified, the Gate Control Theory suggests that, following a noxious stimulus, nociceptor impulses (signals) are transmitted along first-order neurons to the substantia gelatinosa where they synapse (communicate) with second-order neurons. These second-order neurons then decussate (cross over) to the opposite side of the spinal cord, before ascending up the spinal cord to the thalamus where they synapse with third-order neurons. The third-order neurons impulse to their final destination in the brain where conscious awareness and localisation of the pain occurs.

To trigger the body's own pain-reducing mechanisms, and inhibit the nociceptor impulses ascending to the brain, a non-noxious stimulus such as touch, warmth or cold can be simultaneously applied. The non-noxious stimulus causes mechanoreceptor impulses to be sent on their neuronal pathway to the brain.

En route to the brain, the mechanoreceptor impulses activate inhibitory neurons in the substantia gelatinosa, which block, or partially block (gate), the noxious nociceptor impulses passing through and ascending to the brain, therefore limiting the amount of pain perception.

Melzack & Wall (1965) additionally suggested that pain perception can be influenced by mechanisms descending from the brain. Once the output from the ascending impulses reaches a critical level the 'Action System' in the brain is activated. Critical levels and activation of the 'Action System' are based on past pain experiences, cognitive processes and current emotional state, making pain perception and behaviour an individualised experience.

Melzack & Wall (1965) suggest that some pain perception is so rapid and intense (for example,

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a myocardial infarction (heart attack)) that the individual is unable to exert any strategies to manage or control their pain effectively by closing the pain gate.

The Gate Control Theory significantly advanced the understanding of pain, but it was criticised for its oversimplification and failings in its neural model, and the existence of the gating system, which was incorrect (Mendell 2014).

It is largely on the premise of Gate Control Theory that transcutaneous electrical nerve stimulation (TENS) machines and massage are thought to ease a woman's labour pain. When a TENS machine is set to a high pulse rate during a contraction it is thought to stimulate the faster communicating non-nociceptive nerves, thus closing the gate to the slower nociceptive nerve messages to the brain. Set at a lower pulse rate, between contractions, it stimulates the body's production of endorphins. Endorphins are the body's own natural pain-relief chemical. Relaxing massage is, similarly, thought to reduce labour pain perception because it boosts endorphin release and provides a sense of touch which closes the gate to nociceptive transmission.

TENS is not considered an effective pain-relief method in active/established labour (National Institute for Health and Care Excellence (NICE) 2017). The evidence relating to its effectiveness in early labour has not been conclusively established. This may be, in part, because of the low-quality research (Jones et al 2012). There is only limited evidence suggesting that massage reduces measured pain and expressed anxieties during labour (Smith et al 2018).

#### Neuromatrix Theory

Melzack (1990) went on to develop the Neuromatrix Theory of pain. Past theories based on nociception suggested the spinal cord and brain as secondary message receivers with the primary focus on actual tissue damage and the peripheral nervous system. Melzack (1989) noticed that people with amputated limbs still felt phantom limb pain, that is, they felt pain in body parts that no longer existed. This suggested that tissue damage and the peripheral nervous system were not solely responsible for pain. Furthermore, the extent of tissue damage does not always match the amount of pain reported. Equally, people who experience similar pain-inducing conditions do not have similar pain experiences and some people go on to report long term/chronic pain with no apparent cause.

To explain these observations Melzack (1990) suggested the Neuromatrix Theory. This proposes that pain is a multidimensional experience shaped by multiple influences which create a neurosignature of pain experiences. The neurosignature is created by genetic and sensory influences and modulated

by cognitive events and sensory inputs. The flow of neurosignatures is converted by the sentient neural hub into a continual awareness of the whole body and instigates behaviour to bring about the desired goal of pain reduction.

#### Biopsychosocial models

The above-described models all focused on biomedical approaches to describing pain perception, which was the favoured approach to disease at the time. The first biopsychosocial model for health care, challenging the biomedical model, was introduced by Engel in 1977. Although not specifically designed as a pain theory, the biopsychosocial model is applicable to pain as it provides a framework for research, teaching, and treatment which puts the individual at the centre and addresses their needs in a holistic manner. Loeser (1982) and Waddell (1987) were also key in taking forward the application of a biopsychosocial approach in the assessment and treatment of certain pain conditions.

Considering the complexities of pain, the biopsychosocial model has been criticised for its simplicist conceptualisation — which can support fragmented and reductionist application of its elements (biological, psychological and social factors) and allow bias when assessing and treating pain conditions (Nicholas 2022). It has, however, proved useful in rehabilitation and functional restoration for chronic pain (Guzman 2001).

Despite these limitations, biopsychosocial models are important in midwifery. For pregnant women, social and cultural influences provide expectation, context, and meaning for labour pain. These influences are assimilated alongside the woman's own beliefs about childbirth: her pain cognitions; her past pain experiences (Linton & Shaw 2011, Noel et al 2015); the personal meaning she ascribes to her labour pain (Whitburn et al 2019); her emotional state (Shackman et al 2011); self-efficacy (Bandura 1977, Tilden et al 2016) and other features, such as her tendency to catastrophise (Van Den Bussche et al 2007, Flink et al 2009, Veringa et al 2011, Sullivan 2012).

In the absence of a more complete contemporary model, it is important that midwives understand that features of the biopsychosocial model are still relevant — but that the web of complexity linking the features together and underpinning a painful experience should be at the forefront in assessment and care planning when supporting each woman through childbirth.

#### Terminology and reductionism

The understanding of nociception would appear to be extensive in the literature, but an understanding of the complex processes underlying the subjective experience of pain perception is not. Unfortunately, pain research literature can confound our

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understanding of pain (Apkarian 2019). This is due to the frequent blending, or oversimplification, of terminologies from pain perception and the nociceptive system for example, 'pain fibres' (Labor & Maguire 2008) and 'pain pathways'.

Use of such blended terminology gives a false impression about the scientific understanding of the subjective experience and perception of pain (Apkarian 2019). This confusion can impact on how society understands pain (Apkarian 2019) and, arguably, how pain in childbirth is viewed. For example, if labour pain is thought to be the result of tissue changes, which are detected in pain fibres in pain pathways, then subsequently the presiding focus will be on targeting those pain fibres and pain pathways to reduce or eliminate pain.

In this situation the terminology suggests pain is a 'bottom-up' approach (that is, the noxious stimulus transmits 'pain' to the brain) and is reductive. It encourages focus on the biological process of nociception rather than on the woman's past pain experiences and how this affects her interpretation of her pain and her pain behaviours. Focus is diverted away from how the woman can be best supported psychologically, including support from her birth partner/s, her midwifery support, the support interventions offered, the organisation of, and responses from, the maternity system, maternity research, and wider society.

#### Societal and caregivers' responses to pain

Individuals' pain experience, and their responses to pain, are influenced by psychological factors and societal influences. How caregivers provide support for the person in pain is complex and is shaped by multifactorial variables, which are not yet fully understood (Campbell & Edwards 2012). Factors such as sex (Bartley & Fillingham 2013); ethnicity (Campbell & Edwards 2012, Herbert et al 2017); socio-economic status (Macfarlane et al 2009, Public Health England (PHE) 2017) and cultural group (Lasch 2000) have not only been demonstrated to influence a person's evaluation and interpretation of pain, and their emotional and behavioural responses to it, but can also influence assessment and treatment decisions (Wandner et al 2013, Miller et al 2022).

Knowledge about pain, why and how we react and respond to pain, and awareness of inequalities in pain-related treatment, means that midwives need to be vigilant and reflective in their practice in order to provide skilful and equitable care.

#### Midwifery education and learning from experience

Midwives are experienced at preparing and supporting women through pregnancy, childbirth and postpartum, with women greatly valuing this care (Mattison et al 2018, Perriman et al 2018). But the majority of midwives may never have received formal training in how they can provide evidence-based, psychological support intervention for managing labour pain. To provide an anecdotal example, when discussing the concept of pain catastrophising with midwives the primary author noted that the vast majority did not recognise this term although, following an explanation, they recognised associated behaviours.

Current midwifery training for non-pharmacological methods of pain management includes touch, relaxation, mobility, and hydrotherapy, with no reference to any psychological support interventions (Nursing and Midwifery Council (NMC) 2019a). The recommended methods for psychologically supporting women through childbirth may be insufficient (Whitburn et al 2017). More research is needed to understand how women process and experience childbirth pain. This is imperative so that midwives are able to effectively assess, plan and provide individualised psychological support rather than relying on knowledge gained from learning from experience. While learning from experience is required (NMC 2019b), it does not provide student midwives and midwives with adequate, evidencedbased knowledge and skills on the assessment, planning and provision of effective psychological pain management strategies to support women through such a transformational life event as childbirth.

#### The importance of focusing on early labour

Despite the advice to stay at home until active labour commences many women seek out professional support in hospital during early labour (Bohra et al 2003, Lundgren et al 2013). This is commonly because of the labour pain they experience and fear (Cheyne et al 2007, Carlsson et al 2009, Lundgren et al 2013, Eri et al 2015, Carlsson 2016). However, women experiencing an uncomplicated pregnancy are at increased risk of obstetric intervention (Bailit et al 2005, Lundgren et al 2013, Neal et al 2014) and have a higher chance of caesarean section (Davey et al 2013, Yang et al 2013) if they are admitted to hospital during early labour. So, it is understandable that women at low obstetric risk are advised to stay at home until active labour begins.

Many who are turned away to await the start of active labour are given minimal guidance and support (Eri et al 2015). Knowing that obstetric intervention is reduced if hospital admission is delayed makes early labour a clinically relevant and sensitive stage (Wuitchik et al 1989), and staying at home an organisational target, with midwives wielding a powerful influence over whether to send women home until active labour commences (Eri et al 2010). Women are left feeling as if they must prove their credibility before they can be admitted to hospital

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and feel embarrassed and vulnerable if judged to have sought hospital admission 'too early' (Eri et al 2010).

So far, interventions to help optimise the timing of women's admission to hospital have proven unsuccessful (Kobayashi et al 2017). Women are generally offered a variety of support and assessment methods during early labour, but this is not always linked to an understanding of the holistic nature of pain-related fear, and how this might affect labour choices (Eri et al 2015, Kobayashi et al 2017). Pain-related fear is important: a study by Geissbuehler & Eberhard (2002) found that 40 per cent of pregnant women expressed a fear of pain, and fear has been associated with an increase in the risk of emergency caesarean section (Ryding et al 1998).

More work is needed to, first, understand which characteristics of women's fear and anxiety contribute to their need for professional support and pain relief during early labour (Clark et al 2022) and, second, how women can be best supported to manage their pain and fear during this time.

#### Pain catastrophising

Pain catastrophising can be defined as 'an exaggerated negative mental set brought to bear during an actual or anticipated painful experience' (Sullivan et al 2001:4). In the context of childbirth, knowledge about pain catastrophising and how women can be supported with this psychological distortion is important.

In a recent study by Clark et al (2022) the prevalence of pain catastrophising in women of reproductive age was high (ranging from 21.3 per cent to 47.5 per cent of participants, depending on the pain catastrophising cut-off score used). The few studies directly investigating pain catastrophising in relation to childbirth suggest that pain catastrophising is not only of importance for the anticipation of childbirth pain, but also associated with: fear of being overwhelmed by pain (Van den Bussche et al 2007); preferred mode of birth (Dehghani et al 2014); the experience of pain intensity during delivery, and poorer physical recovery following childbirth (Flink et al 2009).

In the childbirth setting a woman's interpretation of the significance of her labour pain, coupled with her views about the normality or pathology of childbirth and the responsibility she bears for determining 'the right time' to seek professional labour care, will affect her labour pain behaviours and the time she presents to hospital for admission (Lally et al 2008, Carlsson et al 2009, Carlsson and Edwards 2012, Lally et al 2014, Carlsson 2016).

#### Psychological support, hypnosis and self-hypnosis

There is limited literature on psychological interventions to support women who are at low obstetric risk during early labour. There is, however, evidence that increased self-efficacy is associated with a variety of improved perinatal outcomes (Tilden et al 2016), with pain-relief requirements being reduced for those women with greater autonomy and less anxiety (Tiran 2018).

Hong et al (2021) found that antenatal education can reduce maternal stress and increase self-efficacy, lower caesarean birth rate and reduce epidural analgesia use. A variety of antenatal education programmes including birth preparation courses, social support programmes, music therapy sessions, progressive relaxation programmes, self-hypnosis training, parenting skills, and cognitive coping were reviewed. There was evidence of lower birth interventions and improved mental health outcomes for women following better antenatal psychological preparation. Demirci et al (2021) also found that antenatal education is effective in promoting women's selfbelief, and the desired outcome of coping behaviour, which is effective in achieving a positive birth experience.

Childbirth self-efficacy can be modified through various efficacy-enhancing interventions (Tilden et al 2016) including self-hypnosis (Cyna et al 2006, Cyna et al 2013). In her review of the evidence Marsh (2021) concluded that hypnosis could reduce pharmacological methods of pain relief. Hypnosis, including self-hypnosis, has demonstrated its value in supporting people with pain in other fields (Kendrick et al 2016, Eason & Parris 2019). There is evidence that hypnosis reduces the overall use of pain medication in labour — but not that it reduces epidural use (Madden et al 2016). Hypnosis has shown potential benefit in reducing experiences of anxiety and fear associated with childbirth (Downe et al 2015) and a positive impact on women's reflection on their childbirth experience (Werner et al 2013, Marsh 2021).

Self-hypnosis might prove to be particularly useful in early labour. Harmon et al (1990) showed that adding self-hypnosis training to childbirth education classes produced shorter Stage-I labour (from cervical dilatation of 5cm to fully dilated) but did not affect Stage-II labour (from when the cervix was fully dilated), possibly because hypnotic analgesia, while effective, might be limited in its effect. Nevertheless, its potential, in terms of being a self-guided activity that requires no external intervention and the generally less intense pain experience in early labour, might make self-hypnosis a particularly useful tool in pain control during this phase.

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These are important factors which enhance the midwifery care model and promote women's satisfaction with their childbirth experience (Overgaard et al 2012, Mattison et al 2018) and their autonomy (Renfrew et al 2014). These psychological and emotional experiences of pregnancy, as well as the health of themselves and their growing baby, are valued by women (WHO 2016, Downe et al 2018) and are essential non-clinical aspects of care that should complement any necessary clinical interventions to optimise the quality of care provided (WHO 2016, WHO 2018a, WHO 2018b).

The lack of conclusive evidence on the benefits of self-hypnosis could be due to the methodology of the research. Eason & Parris (2019) pointed out that, in the studies reporting no effect of self-hypnosis in childbirth, self-hypnosis was defined as listening to audio recordings, but did not involve specific self-regulated self-hypnosis skills, a previous heterohypnosis session or tailoring training to the needs of the individual. In contrast, in Harmon et al (1990) self-hypnosis was practised in a self-directed way with an emphasis on skill mastery and resulted in a reduced period of early labour, reduced medication and higher Apgar scores.

This raises another issue, that of suggestibility.

Any form of hypnosis requires the subject to be able to adopt a hypnotic mindset and be suggestible. Hypnosis is not a skill that everyone will be proficient at, particularly in the face of such a potential physical and psychological challenge as childbirth, but it is a skill which can be improved by effective training.

Hypnosis is also an inexpensive, relatively simple intervention that has no known adverse side effects when used during pregnancy, labour or postpartum (Marsh 2021).

Childbirth studies have not yet considered using hypnosis for early labour to empower women and improve their self-efficacy and pain-coping strategies. A hypnosis intervention could prove valuable if combined with a tool to identify those women most concerned about pain. Any intervention should provide relevant knowledge and hypnotic skills and specifically target those women who are suggestible, who tend to pain catastrophise, and who are at low obstetric risk and therefore advised to experience early labour at home.

#### Conclusion

It is evident that supporting women through childbirth and optimising the time that women are admitted to hospital when in labour are complex and interwoven issues. Through better understanding of a woman's past pain experiences, her beliefs about childbirth, her attitudes towards childbirth pain and her individual care needs, individualised care can be created providing women with support through the psychological and physiological continuum of pregnancy and the postnatal period. Targeted and skilful implementation of self-hypnosis is one psychological adjunct that could benefit many women and improve birth outcomes.

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For more information on this topic see MIC database search packs: L9 Women's perceptions of pain and pain relief; P99 Hypnosis.

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# 3.3 Chapter summary and confirmation of the study aim

The evidence presented in this chapter and in chapters 1 and 2 have highlighted areas requiring further research. In particular it has been shown that more research is required to understand the role of pain catastrophising in the context of childbirth, and that women's experience of pain and fear during latent labour are important factors in their decision to seek professional support in hospital. For these reasons, the primary aim of this research was to assess the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an uncomplicated pregnancy (NICE 2023a), and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour. The prevalence of fear of childbirth (FOC) was also assessed, as was its relationship with pain catastrophising, and whether it had an impact on participants' timing of hospital admission when they were in labour. Other objectives and outcomes for research are detailed in methods presented in Chapter 5.0.

# **Chapter 4** Justification for methods

#### 4.1 Introduction

This chapter presents the theoretical framework for this thesis. The RETHINK study was designed to pursue the primary aim of this thesis which was to assess the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an uncomplicated pregnancy (NICE 2023a), and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour. The prevalence of FOC was also assessed, as was its relationship with pain catastrophising, and whether it had an impact on participants' timing of hospital admission when they were in labour. Additionally, the study sought to determine the impact of pain catastrophising on the labour experience over time. Reciprocally, the study aim informed the design. The chapter continues with justification for key methodological decisions (sections 4.1 to 4.6.2.1). Preparation was undertaken to ensure the study was designed to meet objectives (sections 4.7 to 4.8). Finally, rationalisation for amendments that occurred during the running of the RETHINK study are provided (section 4.9).

Study names are often an acronym derived from the full study title. However, I chose not to use an acronym because none fully captured the study's purpose. RETHINK was selected because it reflects my goals to reassess certain aspects of current maternity care. It was also chosen for its association with the word cognition and suggests reassessment and deeper examination into the psychological aspects influencing a woman's pain perception. Study methods are presented in Chapter 5.0.

## 4.2 The RETHINK study embedded in a positivist paradigm.

The scientific and methodological principles synonymous with a positivist approach were employed in this study (Comte 1798 - 1857 by cited Kivunja and Kuyini 2017).

Positivism is dominant in healthcare research and has influenced advances in science by generating empirical evidence through systematic inquiry in the pursuit of generating reliable, valid, predictable and replicable findings that can be generalised to

larger populations (Kivunja and Kuyini 2017; Park et al 2020). To achieve this, objectivity is a key element. This key element indicates how a positivist researcher perceives the world. Positivists assert a naïve realist view that there is a single tangible reality that exists and is discoverable independent of the individual participants (Kivunja and Kuyini 2017) and researchers (Bryman 2008, Howell 2013).

The following table highlights the philosophical assumptions underpinning the RETHINK study design:

Table 2: Tabulation of the philosophical assumptions underpinning the RETHINK study design together with examples of their practical employment in the study

|  | Elements of positivist paradigm   | Philosophical assumptions at work guiding the RETHINK study  |
|--|---|--|
| Ontology  (The nature of reality and study of being) | Through their senses people perceive the world around them as it exists. Therefore, phenomena can be viewed objectively, accurately measured and observed.        | Pain catastrophising is a psychological construct and cognitive distortion that is the result of women being exposed to similar experiences and information. Pain catastrophising is viewed as an objective phenomenon that can be identified, measured and observed. The study focussed on the quantifiable aspects of pain catastrophising and assumed pain catastrophising had a direct and deterministic effect on the timing of hospital admission. |
| Epistemology  (The study of knowledge)               | In order to obtain and communicate accurate knowledge about the phenomena in question it must be acquired without influence from the researchers or participants. | Pain catastrophising and the timing of hospital admission are identifiable and measurable variables. With objectivity and without bias there is the possibility to discover the impact of pain catastrophising on the timing of hospital admission. Quantifiable data were gathered, statistically analysed and communicated without bias which aligns with a positivist perspective and empiricism.   |

| Aviology   | Panaficance  | From the outset handfigures was  |
|--|--|--|
| Axiology  (The values that guide the research, behaviours and decision-making) | In healthcare axiology is intrinsically linked with ethics and moral principles.   | From the outset beneficence was upheld. It guided whether the phenomenon should be studied considering risks, benefits, and feasibility, and what behaviours, such as honesty, respect and open communication were valued.  Beneficent undertakings included:  * Self-judgement  * Gaining ethical approval  * Maintaining professional midwifery and research standards |
|  |  | (NMC 2018; NHS Health Research<br>Authority (HRA) 2023; National<br>Institute for Research (NIHR)<br>2024).  |
|  |  | * Involving women and their partners and relevant professionals in the study design  |
|  |  | * Team-working   |
|  |  | * Informed consent (NMC 2018)  |
| (How knowledge is obtained)  | Key factors of positivism are embodied within the methodology and methods. Study designs include objectivity, experimentation, observation, deductive logic, appropriate sample sizes, statistical analysis and reason. Studies should have internal and external validity, reliability, generalisability, rigour and aim to eliminate bias. | The hypothesis was formulated based on investigation of the literature. To test the hypothesis a study design was decided, aim, objectives formulated, and corresponding relevant statistical  |
|  |  | A sample size calculation was undertaken to ensure sufficient statistical power to answer the primary aim.   |
|  |  | Data were gathered by two structured, user-friendly questionnaires that employed strategies to limit bias, enhance response rate, provide valid and reliable data, and enhance   |

|  | understanding about the subject matter.  |
|--|--|
|  | Quantitative data were analysed using statistical software.  |
|  | Involvement of other people including experts, professionals, women and their partners were vital to ensure relevancy, accuracy and reduce bias. |

# 4.3 Pursuing a positivist approach in a real-world situation.

This study embodied a positivist approach. However, on occasion complimenting positivism with practical solutions was necessary to meet the demands and complexities of researching in the real-world setting and in particular researching maternity healthcare within the NHS. A situation that was complicated by the concurrent global COVID-19 pandemic. For example, a pragmatic approach to participant recruitment was taken and time constraints meant that a decision was made to close the RETHINK study before the target number of participants were recruited. Another example has been where quantitative data were supplemented by open-ended questions. Open-ended questions were included on both the antenatal and postnatal online questionnaires. This strategy and oblique (Pollack 2006; Torlak 2001) use of research techniques facilitated examination of the complex phenomena being studied through a different lens. This provided the opportunity for richer indepth understanding and allows participants to provide nuanced, context specific information. Combining different methods supports triangulation of data enhancing the relevancy, credibility and validity of the findings (Heale and Forbes 2013; Cohen et al. 2017), and the opportunity for the provision of a more balanced holistic explanation of the study findings. The use of open-ended questions is discussed in more detail in section 4.6.2.

## 4.4 Reflexivity, personal professional knowledge, and experience

"Reflexivity is the process of engaging in self-reflection about who we are as researchers, how our subjectivities and biases guide and inform the research process, and how our worldview is shaped by the research we do and vice versa" (Wilkinson 1988 cited Jamieson et al. 2023 pg. 2).

Traditionally qualitative research has actively engaged in reflexivity (Lazard and McAvoy 2020; Olukotun 2021) whereas quantitative research has usually avoided the idea and practice of it (Jamieson et al. 2023). However, reflexivity can foster transparency and be a tool to identify and mitigate researcher bias (Kingdon 2005).

Practicing reflexivity in a positivist approach I have drawn on my deep understanding of the intricacies of pregnancy and childbirth and the emotional experiences of labouring women to guide this study to ensure its applicability to midwifery care in the NHS today. My professional knowledge and experience as a midwife have been woven throughout. My firsthand involvement in caring for labouring women and my professional knowledge and experience have provided a valuable 'insider' perspective (Flemming 2018) which contributed to formulating the research question, study design, interpret qualitative data from open-ended questions, and assess the implications of the study results for clinical practice. Embracing reflexivity supported me to identify my own influence within the RETHINK study. To offset my influence, limit bias, and ensure suitability and practical relevance of this work I have continued to pursue the guiding principles of positivism, sought confirmation in the literature, and balanced my knowledge, influence and experience against what colleagues, pregnant women and their partners, and professional guidance advise.

# 4.5 Rationale for a longitudinal cohort study

The aim of the RETHINK study informed the study design. Ultimately if pain catastrophising can be and was identified during the antenatal period and it was shown to influence the timing of hospital admission when women are in labour then a support intervention could be targeted to this particular group of women.

A longitudinal cohort study follows a pre-defined sample of participants over a set period of time. By surveying low-risk nulliparous pregnant women at two key points, antenatal (between 25 and 33 weeks and 6 days gestation) and postnatal (3 weeks after childbirth), the study can investigate the impact of pain catastrophising on the labour experience over this time. Collecting data prospectively and observing participants in a 'real-world' setting through this temporal sequence of events is useful for identifying the risk factor (pain catastrophising) and assessing its association with the timing of hospital admission when the participants are in labour (Caruana et al. 2015).

The disadvantages of a longitudinal cohort design were considered. The disadvantage of attrition (Curtis and Drennan 2013; Caruana et al. 2015) was accounted for in the target sample size. An assessment of the time required to conduct the study was calculated and considered acceptable within the doctoral programme. The RETHINK study and this doctoral programme were resourced and supported by Bournemouth University, the National Institute for Healthcare Research (NIHR), and the participating NHS sites. These factors allowed for data to be collected from a large sample size, in a real-world context both online and through access to participants healthcare records. This support mitigated against the barriers of access to the target population, and financial costs (Curtis and Drennan 2013; Caruana et al. 2015) associated with research in the NHS and this study design. Relatively intrinsic to longitudinal studies is the potential for a 'cohort effect' (Curtis and Drennan 2013; Caruana et al. 2015). This is where results may be impacted due to shared experiences or characteristics of participants belonging to the same birth cohort of group over time. It reflects how factors such as historical events, societal changes or environmental influences unique to the group can affect their behaviours, attitudes or outcomes measured in the study (Curtis and Drennan 2013; Caruana et al. 2015).

# 4.6 A questionnaire for quantitative data collection

#### 4.6.1 Questionnaires

Questionnaires are an accepted, efficient, and key method for data collection in healthcare research (Crombie and Davies 1996; Karavadra et al. 2020; Harrison et al. 2021; Hildingsson 2021; NHS 2024). Collecting data via questionnaires meets the study aims due to its capacity to include a large number of participants and capture a diverse

range of perspectives efficiently and cost effectively (Jones et al. 2013). Questionnaires have a quantitative foundation, through a structured format and data collection, they allow for the control of variables, comparisons, and statistical analysis, factors which all fit within a positivist approach. Like all research there are challenges and sources for error when collecting data by questionnaire. Table 3 presents the main challenges (Safdar et al. 2016) and how the RETHINK study was designed to overcome such challenges.

Table 3: The challenges that confronted the RETHINK study and mitigating actions

| Challenges                            | Strategies to mitigate or eliminate       |
|---------------------------------------|---|
|                                       | challenges incorporated into the design   |
|                                       | of the RETHINK study                      |
|                                       |   |
| Questionnaire design offers limited   | Open-ended questions provided the         |
| capability to explore complex matters | opportunity for participants to provide   |
| and capture nuances that may have     | detailed and nuanced responses. A         |
| been discovered during in-depth       | strategy that offers depth and context to |
| qualitative research.                 | the quantitative data from closed         |
|                                       | questions. Together the quantitative and  |
|                                       | qualitative data offer a more             |
|                                       | comprehensive understanding of the        |
|                                       | participants' perspective, experiences,   |
|                                       | and motivations. This corroboration and   |
|                                       | triangulation of data helps to enhance    |
|                                       | the validity and reliability of the study |
|                                       | results.                                  |
|                                       |   |
| Response accuracy is reliant on       | The PCS was piloted, and the RETHINK      |
| participants' interpretation of the   | questionnaires were pretested to          |
| question and their commitment to      | maximise the potential of the             |
| answering appropriately.              | questionnaires and limit drop-out.        |
|                                       |   |

| Potential for a lack of response to questions within the questionnaire and/or a high drop-out rate of participants from the study.  | Participants were informed via a participant information sheet/leaflet about the importance of the study, and the commitment required from them to complete their participation in the study.  The optimum sample size to meet the study aim was calculated allowing for 50% attrition (Redshaw and Henderson 2015). |
|---|--|
| Study design could mean some potential participants will have zero chance of being included in the sample.  Participant characteristics may not be representative of the target population. | To employ various recruitment strategies to ensure adequate coverage of individuals within the target population.  To identify the target population and ensure the inclusion and exclusion criteria captured the appropriate participants with or without the specified characteristics.                            |
| Questions, instruments or tools included on the questionnaire do not accurately measure the topic of interest.  | Previously validated and reliable measures were used i.e., the PCS and the WDEQ-A.   |

# 4.6.2 Rationale for including open-ended questions on the questionnaire.

Understanding the drivers for latent phase hospital admission and the associated increased risk for obstetric intervention have been difficult suggesting that there are complex human phenomena involved. Employing a different methodological approach can provide insight into, enhance, or verify the findings from quantitative data (Rouder et al. 2021; Galura et al. 2022). Open-ended questions can provide a more holistic understanding and can help unravel and understand the complexity posed by the RETHINK study's primary aim (Zull 2016) and are usually well received by respondents (Riiskjær et al. 2012). To this end the quantitative data gathered from the antenatal and postnatal RETHINK questionnaires were supplemented by the inclusion of openended questions to generate qualitative data.

Open-ended questions invited RETHINK participants to add non-standardised, free-text comments (Reja et al. 2003; Riiskjær et al. 2012) allowing them to comment without prescription apart from suggested guidance in the question. This style of questioning is often a successful way to capture what is important to participants (Braun et al. 2020) and obtain "authentic and unexpected feedback" (Rouder et al. 2021). This is particularly useful when little is known on a topic (Singer & Couper 2017) which is the case for the effect of pain catastrophising on the labour experience particularly as it relates to timing of hospital admission. Having authentic responses from the RETHINK participants is important because it can provide a legitimacy and credibility for the quantitative data. Responses to open-ended questions provide access to the participants' language and terminology, both frequently claimed advantages of qualitative research (Frith, 2000). Furthermore, open-ended questions can highlight the diversity of opinions (Braun et al. 2020), are a feasible way to gain insights when timely research is required (Galura et al. 2022) and can add depth and context to the quantitative data (Rouder et al. 2021). These are all important features for consideration when researching an area where there is very little prior knowledge as is the case for the RETHINK study.

In the healthcare setting, including within maternity care, open-ended questions are repeatedly used in combination with closed questions to gain patient feedback, to understand their experiences and choices, and for example, to provide insight about

patient experiences of an intervention (Eriksson et al. 2006; Attanasio et al. 2015; Karavadra et al. 2020; Wilksa et al. 2021; Eri et al. 2022). Open-ended questions have previously demonstrated their utility in improving care worldwide via online surveys/questionnaires in a maternity, and healthcare setting (Crombie and Davies 1996; Eriksson et al. 2006; Porter et al. 2007; Riiskjær et al. 2012; Attanasio et al. 2015; Benet et al. 2020; Karavadra et al. 2020; Edmonds et al. 2021; Matsunaga et al. 2021; Eri et al. 2022; Pelak et al. 2023; CQC 2024a). Although closed questions offer the potential to gather insights, they will often miss the more nuanced story (Meadows 2003) that could exist and underlies the human behaviour.

Open-ended questions could be criticised for being insubstantial and "lacking robust insights" (LaDonna et al. 2018; Galura et al. 2022) when compared to other qualitative data collection methods such as interviews, and also for lacking the sufficient measurable qualities required for quantitative analysis (Rouder et al. 2021). Braun et al. (2020) would argue against this criticism and suggest that responses "can provide richness and depth, when viewed in their entirety, even if individual responses might themselves be brief". Criticism has also been lodged against the rigor employed in the qualitative analyses of open-ended questions, with suggestions that analyses can fall more into quantitative than qualitive methodology if analysis is based on frequency of key words alone (Stoneman et al. 2013; Gilles et al. 2017; LaDonna et al. 2018). To avoid this pitfall, reflexive thematic analysis was used to analyse open-ended questions where responses were likely to be in complete sentences and summative content analysis was used to analyse open-ended questions where responses were likely to be around only one or two words in length. Both these chosen methodologies are discussed in Chapter 5 Section 5.5.

# 4.6.2.1 Ensuring effective open-ended questions.

Compared to the literature on how to collect and analyse quantitative data there is a lot less knowledge on how to design, collect and uncover the meaning contained within responses to open-ended questions (Rouder et al. 2021) particularly within a maternity setting. Without clear methodology, methods, and analytical strategy the

inclusion of open-ended can appear perfunctory (Rouder et al. 2021) and can lead to problems such as:

- ambiguity in question design leading to ambiguity in responses,
- increased risk of introducing damaging bias which can distort findings,
- difficulty integrating the qualitative data with the quantitative data which can hinder the understanding of the research phenomenon,
- missed opportunities for insights,
- devaluing the time and effort given by respondents
- and overall, a reduction in the reliability, validity, and limited generalisability to the wider population.

(Marks and Yardley eds. 2003; Fowler 2009; Riiskjær et al. 2012; Iversen et al. 2014; Bourke et al. 2016;).

To avoid these pitfalls the following strategies and activities were undertaken:

- 1. A review of existing literature to confirm the study was timely and relevant.
- A review of existing literature to inform and confirm the questionnaire design.
   Then the review narrowed focus to studies undertaken within the field of midwifery and wider healthcare research that had included open-ended questions in their questionnaire design.
- 3. Sort guidance and advice from experts.
- Consultation with relevant stakeholders to ensure they backed the study design.
- 5. Questionnaire was pretested.
- 6. Established a clear coding scheme for analysing the open-ended responses, and ensured the coding scheme and analyses were consistent and reliable by sense checking with experts.
- 7. Used data analysis techniques that were appropriate to my skill level and had demonstrated applicability in similar settings in the literature.
- 8. Organised and interpreted the data systematically.
- Used both quantitative and qualitative data to corroborate and triangulate data.

10. Clear documentation of study design, data collection, organisation and analysis, and final discussion.

# 4.7 Study preparation

# 4.7.1 Peer Review

The doctoral research project was first peer reviewed by the Wessex Integrated Clinical Academic Training Programme. It was accepted to be part of the National Institute for Health Research's (NIHR) recognised Wessex Academic Clinical Pathway enabling it to be adopted on to the NIHR Clinical Research Network (CRN) portfolio. CRN funding facilitates high-quality research by making accessible the valuable support services of research midwives in participating NHS Trusts.

Next, The RETHINK study protocol was peer reviewed by:

- 1 The Sponsor
- 2 Three Research Midwives two from one of the potential participating NHS Trust sites and one from the leading participating NHS Trust site
- 3 One Head of Research, Lead Research Nurse, Clinical Trial Assistant from the leading participating NHS Trust site

Suggestions and comments offered by peer reviewers were incorporated within the RETHINK protocol and study design. Notably clarification was provided on:

- the inclusion and exclusion criteria
- outcome measures
- demographics
- how women are introduced to this study and by whom
- reducing the burden of study participation on midwives
- the addition of question 13 to the postnatal questionnaire
- more information on the Participant Information Sheet (PIS leaflet) as to what participants will be asked in the questionnaires

 adjusting the screening questions to avoid causing distress and confusion about their intention.

Concerns were raised about attrition and the number of participants that will be lost to drop-outs and follow-up, and one reviewer expressed an idea for conducting the questionnaire face to face or on the telephone. However, University Hospital Southampton NHS Foundation Trust and Hampshire Hospitals NHS Foundation Trust who had already expressed interest in running the RETHINK study did not question the online format and face to face was considered work intensive. The risk of attrition was considered and to achieve the target sample size of 384 and maintain scientific statistical analysis integrity 768 women was the target number pf participants to be recruited to the study. This increase from 30% to 50% is the anticipated number of participants lost to drop-outs/follow-up, or as a result of meeting exclusion criteria during the study period.

The protocol was then sent to each of the potential participating sites within the Wessex area prior to the application for NHS Health Research Authority (HRA) ethical approval. A suggestion was made to allow for midwives to approach potential participants soon after the midway point through their pregnancy. Professional guidance at the time (NICE 2019b) recommended that pregnant women, in their first pregnancy, should be seen at 25 weeks' gestation. Approaching women at this gestation allows time for a future support intervention to be implemented during pregnancy. Furthermore, research suggests as women progress through pregnancy fear increases (Rouhe et al. 2009). Surveying women too soon may not identify those that are later in need of support.

# 4.7.2 Patient and public involvement

The guidance of pregnant women and their partners, midwives, including research midwives, maternity support workers, doulas, and doctors was fundamental in the design of this study. Their active involvement was an invaluable contribution ensuring the study topic and aims were relevant, communication with the target population and participants was clear, and study design, data collection methods and dissemination of results agreeable.

# How PPI was undertaken:

- A presentation about the background to this study was given at a doula conference held in Bournemouth. Approximately fifty doulas were in attendance. A group discussion was held with attendees, and written feedback in response to three questions was invited.
- 2 Midwives attending a local midwifery conference 'Behind the Trauma', and midwives at Dorset County Hospital (DCH) were asked for their written feedback in response to the same three questions.

The three questions asked to groups 1 and 2 were:

- i. Do you recognise fear of pain or heightened pain experiences as an issue for women?
- ii. In your experience how does fear of pain or heightened pain experiences affect how women approach their labour?iii In your experience what sort of intervention do you think would best support women who have fear of pain or heightened pain experience?
- Four pregnant women and two birth partners, and three pregnancy healthcare providers at Dorset County Hospital (DCH) were approached and their opinions invited during antenatal classes. They were asked about their opinions on seven items:
  - i. The aim of the study
  - ii. Who, how and when women are approached to participate
  - iii. Study approach/methodology
  - iv. Participant Information Sheet
  - v. Questionnaire
  - vi. Gaining online consent and use of an online questionnaire
  - vii. Dissemination of results.

These same seven items were discussed with two DCH maternity unit support workers, four midwives and a doctor during quiet work periods.

All those who kindly gave their opinions agreed and recognised fear of pain or heightened pain experiences as an issue for women. Common themes raised concerned the link between anxiety and tension, making contractions seem worse and the adverse effect on labour hormones which can slow labour progress. With respect to how women can be supported, complementary therapies including hypnotherapy, education and communication were the most popular choices. Understandably, clinicians' answers and suggestions did vary slightly from those given by those people who do not work in maternity services. Clinicians' answers demonstrated they had more in-depth knowledge around the physiology of childbirth and the role of the professional care provider. However, the main themes in their answers converged.

The concerns raised during the antenatal education class were first that using words such as fear and pain catastrophising are very strong and could cause fear and anxiety when there was not any. Second, one thought was that identifying a specific group of women in this way could stigmatise or label them. This is particularly important when considering future healthcare and support interventions to ensure that both advocate individualised, woman-centred care. This issue was discussed, and the group decided that it is important to provide targeted support to those who need it. Furthermore, the group felt reassured and pleased that midwives will not be communicating about pain catastrophising and fear, in the manner in which we did in the consultation group, and that midwives will be guided about how they will invite women to participate.

Similarly, a suggestion was made that the wording in the questionnaire could be more subtle. This was discussed as a group. Together the group agreed it would not be suitable to moderate the tone and language of the questionnaire because the aim to determine fear and catastrophic thinking would be lost.

One suggestion was the Participant Information Sheet (PIS leaflet) was long and there was a thought that women would not read through it all. The importance of conveying all the information contained within the PIS was thought important. Following this comment the PIS was reviewed. Where possible the PIS was altered to improve its

readability in line with 'Flesch Reading Ease' (Flesch 1948) and 'Flesch-Kincaid Grade' (Kincaid et al. 1975).

The women and their partners at antenatal education classes, and the midwives who were asked, understood and agreed with the study approach and methods.

For those involved in this PPI who wished to receive the results of this study agreed to be informed via email.

Interestingly, the vast majority of people who took part in this PPI activity had not heard of pain catastrophising before, including midwives. However, once the concept was explained they understood and appeared familiar with this mind-set, just not familiar with the pain catastrophising terminology.

# 4.7.3 Pre-testing and Piloting

The Pain Catastrophizing Scale (PCS) (Sullivan et al. 1995) was to be the screening tool used to identify participants who catastrophise pain. To determine the sample size necessary to estimate the prevalence of pain catastrophising in the target population the PCS was piloted with, non-pregnant, nulliparous women, aged 18 to 45 years, studying at two university sites in the United Kingdom (Clark et al. 2022).

The complete RETHINK questionnaires were pre-tested online with four midwives, and on paper with one non-pregnant woman, two pregnant women, and two non-pregnant multiparous women. The pre-test was to:

- \* ensure adequate flow through the questions,
- \* assess the time it took to complete each questionnaire
- \* identify any problems with clarity and comprehension of the questions
- \* identify any unintended response bias as a result of question structure

Unintended response bias was considered during the study design phase and discussed with those involved in the PPI. Efforts were made in designing the study materials, including the PIS, posters and social media advertisements, antenatal and postnatal

questionnaires, and the participant email communications to ensure clear, open and honest communication and to limit any cues that might affect women's decisions to participate in the study or influence their questionnaire responses. For example, the PIS informed women about the overall goal of this study which was to see if it is 'possible to detect those women who may find extra support for latent labour useful, to help reduce their chance of a difficult labour and unnecessary intervention'. Although many women understand that contractions can be painful 'pain' was not emphasised. However, response bias was not tested for using statistical methods.

Piloting confirmed there was not a need to change the questionnaire further to the PPI work.

# 4.8 Ethical approval of the study

To protect the dignity, rights and welfare of research participants (WHO 2023) ethical standards and principles for scientific research with humans were upheld throughout this study.

To conduct research within the NHS involving patients NHS research ethics approval is required. Prior to seeking NHS HRA ethical approval BU gave its agreement on the study to proceed. On the 3<sup>rd</sup> June 2020 RETHINK received a favourable ethical opinion from an NHS HRA research ethics committee (see Appendix 3) and on the 4<sup>th</sup> June 2020 the NHS HRA followed with its' approval to commence the study at NHS sites (see Appendix 4).

# 4.9 Study amendments: Consequences of running a large multi-site study, and the effects of COVID-19 coronavirus pandemic.

The RETHINK study was dramatically affected by the COVID-19 coronavirus global pandemic which saw its first cases in the United Kingdom in January 2020. The effects of which meant that there was a seven-month delay (HRA 2020) to the opening of the RETHINK study at NHS sites. Once the RETHINK study opened at sites, research within the NHS continued to shift away from less urgent studies and towards understanding and combatting the virus, restarting other suspended studies, and on new studies with

an urgent healthcare focus. Research and clinical practice within the NHS were significantly affected and reshaped during this period and in some cases changed for good. As a result of government self-isolation rules there were ongoing staff shortages in both clinical and research departments. To plug the gaps appropriate research staff were redeployed to work clinically and away from their usual research duties. This not only affected the date which the RETHINK study could open at sites but was an ongoing challenge throughout RETHINK's data collection period. In response amendments were made to enhance the recruitment of participants to the study through additional recruitment strategies. These strategies reflected the shift from face to face working to the use of technology-based initiatives and practices. The study area was also widened from the Wessex area to include all of England, and the duration the study ran at sites was extended.

Other amendments to the RETHINK study were undertaken. These were either administrative, important for the management of the study, or to enhance the efficiency and effectiveness of the research. Where applicable research staff at sites were consulted about the proposed amendments relevant to them. As required by the NHS HRA all amendments were submitted for approval via the Integrated Research Application System (IRAS). As required all amendments were first reviewed by Bournemouth University before submission to the NHS HRA for ethical approval (see Appendix 5 for list of approved amendments).

# 4.10 Chapter summary

The rationale and justification for a longitudinal cohort study design using two questionnaires as the principal data collection method for the RETHINK study has been discussed and justified. Additionally, feedback from peer review and the PPI has been detailed and an explanation for how this feedback influenced the shaping of the study design has been evidenced. The methods employed to undertake and complete the study will be provided in Chapter 5.

# **Chapter 5** Methods

# 5.1 Introduction

Previously chapter 4 presented the theoretical framework and methodological principles that underpinned the RETHINK study. This chapter details the methods employed throughout the duration of the RETHINK study to its completion.

First the RETHINK study protocol is presented as an integrated peer-reviewed publication (Bartholomew et al. 2022) (section 5.2). This published protocol concentrates on the quantitative aspects of the study. Following publication some clarification, streamlining and modifications to the protocol were required. These changes reflect the learning over the period of this doctoral study, details of which can be found in section 5.3.

The qualitative aspects complete the methods followed by the RETHINK study and are located in section 5.5.

5.2 An integrated peer-reviewed published paper. The RETHINK study protocol: to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of labour.

Bartholomew V, Hundley V, Clark CJ, Parris BA 2022. The RETHINK study protocol: to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of labour. *Evidence Based Midwifery* 20(2):5-12. Available from: https://doi.org/10.1016/j.srhc.2023.100941

# **Evidence Based Midwifery**

# The RETHINK Study Protocol: to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of labour

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#### ARSTRACT

**Background:** Women experiencing an uncomplicated pregnancy are at increased risk of obstetric intervention if admitted to hospital during latent labour. Understanding which factors influence the time that women are admitted to hospital when in labour is crucial to reducing unnecessary obstetric intervention. There is evidence that some women seek early hospital admission for pain relief, and it is possible that women who pain catastrophise may be more likely to do this. Studies have yet to consider whether pain catastrophising impacts the timing of hospital admission. This study will consider the prevalence of pain catastrophising in the study group, and its sway on the timing of hospital admission, labour choices and birth outcomes.

**Aim:** This study aims to identify the prevalence of pain catastrophising during pregnancy and examine whether it has an impact on the timing of hospital admission when women are in labour.

**Ethics:** A favourable ethical opinion was received on 3 June 2020 by a National Health Service (NHS) local research ethics committee. Study approval was granted on the 4 June 2020 by the Health Research Authority (HRA) and Health and Care Research Wales (HCRW).

**Methods:** This is a pragmatic, quasi-experimental study. Primigravid women, experiencing an uncomplicated pregnancy and planning to birth in an NHS hospital trust in England, will be recruited between 25 and 33 weeks and 6 days gestation. To estimate prevalence, with five per cent precision, requires a target sample size of 384. This was based on a study of women of reproductive age, calculated with the aid of a statistician and verified using the app WinPepi. Participants will complete two online questionnaires, one antenatal and one postpartum. The antenatal questionnaire includes the Pain Catastrophizing Scale (PCS), and the Wijma Delivery Expectancy Questionnaire (WDEQ-A). Analysis will divide the sample according to whether participants catastrophise pain or not. The primary outcome measure is admission to hospital in latent labour. Secondary outcome measures include prespecified birth outcomes. Logistic regression will be used to assess if pain catastrophising is a predictor of hospital admission during latent labour. Other explanatory factors (for example, socio-economic) will be identified. The alpha level will be  $p \le 0.05$ .

**Discussion:** It is hypothesised that the PCS can be used as a predictive tool to identify who will seek hospital admission during latent labour. Identifying whether pain catastrophising is a risk factor for early hospital admission will facilitate early intervention to support and empower women to manage their labour pain.

**Keywords:** latent labour, pain, catastrophise, pain catastrophizing scale, hospital admission, Evidence Based Midwifery

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#### Introduction

Women experiencing an uncomplicated pregnancy are at increased risk of obstetric intervention if admitted to hospital during latent labour (Kobayashi et al 2017). However, definitions for latent labour vary considerably (Hanley et al 2016). The National Institute for Health and Care Excellence (NICE), for the United Kingdom, suggests a cervical dilatation of 4 cm signifies the end of latent labour (NICE 2017). The American College of Obstetricians and Gynecologists (ACOG) changed their definition of labour phases based on evidence which indicates that many women do not enter active labour until their cervix is 6 cm dilated (ACOG 2014). Both NICE (2017) and ACOG (2019) suggest that it is safe for pregnant women, at low obstetric risk, to stay at home until active labour begins. Nevertheless, many women seek professional care during latent labour because of the pain they experience, and their lack of confidence in their ability to cope (Barnett et al 2008, Kobayashi et al 2017).

More work is needed to understand how women can be effectively supported during latent labour (Hundley et al 2017, Kobayashi et al 2017). The latent phase is a complex, uncertain, and stressful time (Eri et al 2015) with women in labour bearing the responsibility for deciding the optimum time to go to hospital (Vik et al 2016). Turning women away from hospital before active labour begins can cause fear and anxiety (Barnett et al 2008). Higher levels of perceived pain and cognitive distress during latent labour have been associated with poorer labour efficiency and obstetric outcome (Wuitchik et al 1989), while fear of childbirth has been associated with a longer labour duration (Adams et al 2012).

Little is known about which characteristics of women's fear and anxiety contribute to their need for professional support and pain relief during the phases of labour. Greater understanding is needed, particularly when considering the prevalence of fear of childbirth among pregnant women. Comparing estimates of severe fear of childbirth is difficult, this is largely due to the variety of methods used in studies to measure it. However, in a recent meta-analysis by O'Connell et al (2017) they estimated the worldwide pooled prevalence of fear of childbirth to be 14 per cent. Women are being offered a variety of support and assessment methods during latent labour without comprehensive understanding of the holistic nature of pain-related fear, and how this affects labour choices (Eri et al 2015, Kobayashi et al 2017).

Pain catastrophising is a strong predictor of childbirth pain (Flink et al 2009). Pain catastrophising can be defined as an exaggerated negative mental set brought to bear during an actual or anticipated painful experience (Sullivan et al 2001). It is a subjective experience shaped by physiological, psychological, social and cultural influences mediated by previous pain experiences (Linton & Shaw 2011, Noel et al 2015). It is a multidimensional construct involving helplessness, rumination and magnification (Sullivan et al 1995) whereby people expect the worst in relation to a particular experience of pain (Sharpe & Johnson 2012). To a degree, fear of pain is natural and understandable. However, pain catastrophising may be considered a negative cognitive distortion.

Pain catastrophising is important in the anticipation of childbirth pain. It is also associated with fear of being overwhelmed by pain (Van den Bussche et al 2007), preferred mode of birth (Dehghani et al 2014), the experience of pain intensity during delivery, the need for epidural analgesia during labour (Veringa et al 2011), and poorer physical recovery following childbirth (Flink et al 2009). We have previously identified a high prevalence of pain catastrophising in women of reproductive age (Clark et al 2021). This paper reports a study to explore the impact of pain catastrophising in relation to latent phase labour.

#### Methods

This is a quasi-experimental study with nonprobability convenience sampling. The primary aim is to assess the prevalence of pain catastrophising among primigravid women with an uncomplicated pregnancy and determine how pain catastrophising affects the timing of women's admission to hospital in labour, and subsequently their birth outcomes. It is anticipated this will provide evidence for a future, targeted support intervention.

# Objectives

The following objectives are those determined to achieve the study aim:

- to test the utility of the PCS as a predictive tool for the identification of pregnant women who may require additional labour support
- to determine the prevalence of pain catastrophising in the target sample using the predictive tool
- to examine the relationship between pain catastrophising in pregnant women and the timing of admission to hospital when in labour
- to examine the relationship between pain catastrophising and the specified birth outcomes
- to examine whether women who catastrophise pain also fear childbirth and, if so, to understand the relationship between these two variables and their effects on the timing of admission to hospital when in labour, and birth outcomes
- to determine what pregnant women, find helpful and supportive, or unhelpful, with their pain management during labour

- to determine whether pain catastrophising acts as a predictor for mental health issues and/ or pain as self-defined by the participant at approximately three weeks postpartum
- to analyse who and what are the influencing factors that impact on a woman's decision to seek hospital admission when in labour and the relationship between these factors and pain catastrophising
- to examine the relationship between the demographics specified in this study, pain catastrophising, timing of admission to hospital when in labour and birth outcomes.

#### Design

The quasi-experimental aspect will occur during analysis, meaning groups will be constructed according to those who catastrophise pain, those who have fear of childbirth (FOC), those who both catastrophise pain and have FOC, and those who do neither. The control group will be women who do not catastrophise pain and do not have FOC. Comparisons and associations will then be made between groups to estimate the possible impact that pain catastrophising, FOC, or both, have on birth outcomes and the timing of admission to hospital when in labour.

# Setting

Maternity units in England will be invited to participate. The participating sites cover obstetric and midwife-led units, and rural and urban areas. This study will be undertaken concurrently at multiple sites with each site recruiting independently from each other.

# Outcomes

The primary outcome measure is the prevalence of pain catastrophising and its association with admission to hospital in latent labour. Secondary outcomes are listed in Table 1.

Table 1. Secondary outcomes

| Table 1. Secondary outcomes                                   |
|---|
| Prevalence of FOC   |
| Prevalence of FOC and PC                                      |
| Latent phase hospital admission                               |
| Premature or postmature (i.e. greater than 14 days over       |
| expected date for birth) labour                               |
| Spontaneous, augmented (including artificial rupture of       |
| membranes or oxytocin use) or induction of labour             |
| Analgesia use   |
| Mode of birth (i.e. spontaneous vaginal birth, ventouse or    |
| forceps birth, elective or emergency caesarean section birth) |
| Duration of latent labour (cervical dilatation <4 cm)         |
| Duration of active labour (cervical dilatation ≥4 cm)         |
| Duration of second phase of labour                            |
| Duration of third phase of labour                             |
| Total duration of labour                                      |
| Postpartum mental health issues                               |
| Postpartum pain   |
|   |

#### Measures

Demographics and additional relevant information The demographic profile of participants provides important context to help understand the findings from this study (Table 2).

Table 2. Demographics and additional relevant information

| Demographic information     | Additional relevant information  |
|-----------------------------|----------------------------------|
| Relationship/marital status | Previous miscarriage or          |
|                             | termination of pregnancy         |
|                             | before 24 weeks pregnant         |
| Employment status           | Gestation when answering         |
|                             | the first online antenatal       |
|                             | questionnaire                    |
| Highest level of education  | Whether they have/had            |
| achieved                    | ongoing pain that has lasted     |
|                             | more than 3 months               |
| Postcode                    | A brief pain experience history, |
| Ethnicity                   | which also includes current pain |
|                             | and its severity                 |

#### Pain Catastrophizing Scale (PCS)

The PCS was first introduced by Sullivan et al (1995) and is one of the most widely used psychometric measures of catastrophic thinking linked to pain (Leung 2012). The PCS is a self-report measure developed for both clinical and non-clinical use. It is composed of 13 items based on catastrophising definitions described in the literature, and previous experimental and clinical research on catastrophic thinking in connection to pain experience (Sullivan et al 1995). PCS scores have been found to correlate with other health measures, including pain intensity, pain-related disability, and psychosocial distress (Severeijns et al 2004).

The 13 PCS items are divided into three dimensions (subscales): helplessness, magnification and rumination. The correlational relationship between these dimensions has been replicated in several investigations demonstrating internal consistency and validity of the three subscales with total PCS Cronbach's coefficient alphas = 0.87; rumination = 0.87; magnification = 0.66; helplessness = 0.78 (Sullivan et al 1995; Osman et al 1997) and it has high test-retest correlation of r = 0.75 across 6 weeks (Leung 2012).

Participants are required to reflect on past painful experiences and score their thoughts or feelings between not at all (score 0), and all the time (score 4), about the painful experience for each of the 13 items (possible total score of 52). The higher the score the greater the catastrophic thinking. Although pain catastrophising scores have been shown to be normally distributed (Sullivan et al 1995) the PCS developers (Sullivan et al 1995) have predominantly taken a score of 30 or more to determine pain catastrophising as clinically relevant with other

studies finding lower cut-off scores as clinically relevant (Flink et al 2009).

The PCS was piloted with non-pregnant, nulliparous women, aged 18 to 45 years, studying at two university sites in the United Kingdom (Clark et al 2021). The study provided baseline data on the prevalence of pain catastrophising among women of reproductive age, identifying that over half of the sample catastrophised pain.

# Wijma Delivery Expectancy Questionnaire Part A (WDEO-A)

The Wijma Delivery Expectancy Questionnaire Part A (WDEQ-A) (Wijma et al 1998) is one of the most commonly used tools in assessing fear of childbirth (O'Connell et al 2017). It is a self-report measure with 33 items, each item rated on a six-point Likert scale ranging from 'not at all' (score 0) to 'extremely' (score 5). The higher the score the greater the fear. Questions refer to a cognitive and emotional belief about childbirth.

The WDEQ-A is a multidimensional psychometric measure to explore the fear of childbirth, therefore, the differential impact of the various aspects of WDEQ-A suggests a single score to diagnose FOC should not be used (Pallant et al 2016).

The WDEQ-A has been shown to correlate well with other fear of childbirth measures in identifying high childbirth fear in first-time mothers, previous emergency caesarean and women with self-reported anxiety and/or depression (Haines et al 2015). The correlation between the instruments was strong (Spearman's Rho = 0.66, p < 0.001) (Pallant et al 2016). The scale has been shown to have a high sensitivity (89%) and specificity (79%), with a positive predictive value of 85% and a negative predictive value of 79% (Pallant et al 2016).

# Postpartum questionnaire

Women will complete a second online survey at approximately three weeks postpartum, or three weeks after their expected due date if they had their baby earlier.

The postpartum questionnaire will gather the following data:

- data about the latent phase (which is not routinely collected), including the signs that signalled to the woman it was time to go to hospital
- data about pain relief received during labour
- whether participants are receiving treatment for persistent pain and/or mental health conditions
- comments from respondents on what they found helpful and supportive during their labour and what was unhelpful and potentially had a negative effect

 participants' concerns about their physical or mental health and if they would like to be referred for professional NHS support.

# Sampling method, sample size

Sampling will be nonprobability, convenience. This is an efficient and cost-effective way of achieving the required sample size.

Prevalence of pain catastrophising will be estimated using cut off points of 20 and 30, as indicated in the literature. A recent study by Clark et al (2021) found 21 per cent of their non-pregnant population had a pain catastrophising score over 30, and 48 per cent had a score above 20. Based on these findings, using a cut-off score of 30 and having five per cent precision in a pregnant population requires a sample size of 255 women. Using a cut-off score of 20 and having five per cent precision in a pregnant population requires a sample size of 384 women. Sample size calculations were conducted with the aid of a statistician and verified using the app WinPepi (Abramson 2011).

A sample size of 384 will have 90 per cent power to detect correlations between variables as small as -0.17 (coefficients (r) is = >0.17 at the 5% 2 sided significance level). To achieve this sample size, 768 women will be recruited to allow for 50 per cent of participants who are lost to drop-out or whose risk status changes from low to high during the antenatal period. For these participants their data will be included in relevant sensitivity analyses.

All women recruited to the study will be receiving normal pregnancy care with no intervention. Women who are 41 years or over at the time of childbirth are excluded. This is because of the range of risks for mother and baby with rising maternal age (Lean et al 2017). The inclusion and exclusion criteria are specified in Table 3.

# Participant recruitment

Eligible women will be recruited from hospitals in England. Participating sites can employ different recruitment pathways in their recruitment strategy (Table 4).

However, there is an overarching journey that participants follow through the study. The overarching journey is that eligible women will be invited to participate in this study and, at the same time, be given a Participant Information Sheet (PIS) which contains all the necessary information about the study to facilitate an informed choice about participation. The PIS also contains the Uniform Resource Locator (URL) for women to access this online study.

Participation is entirely voluntary, and participants can withdraw from the study at any stage. If data has been anonymised and used within analysis, then

Table 3. Inclusion and exclusion criteria

| Inclusion criteria                               | Exclusion criteria  |
|--|---|
| Healthy primigravid women who are                | Women who are receiving ongoing care from an obstetrician during their      |
| experiencing an uncomplicated singleton          | pregnancy   |
| pregnancy, and who are planning a hospital birth |   |
| Women aged 18 to ≤40 years at the time of study  | Women who are 41 years or over at the time of childbirth                    |
| Able to understand and read English              | Women with a current or pre-existing mental health condition requiring      |
| Antenatal women who are between 25-33 weeks      | current medication and/or care by perinatal mental health team, e.g.        |
| gestation  | specialist obstetrician, specialist midwife and/or local mental health      |
|  | services provision  |
| Have internet access and an email address for    | Pregnant women already participating in a different study that is providing |
| study correspondence                             | support with pain management or a labour support intervention of any        |
|  | kind. This includes the latent, active, second and third phases of labour   |

Table 4. The four recruitment pathways

| Recruitment | Recruitment process   |  |
|-------------|---|--|
| pathway     |   |  |
| 1           | Women are introduced to the study at one of their routine antenatal appointments                                |  |
| 2           | A member of the participating site's research team will screen and contact women to introduce them to the study |  |
| 3           | A member of the participating site's research team will screen and contact women to introduce them to the study |  |
|             | At least 24 hours later the research team member will again contact the woman and support her to complete       |  |
|             | the online questionnaire. The research team member will be responsible for contacting the participant at the    |  |
|             | appropriate time to support the participant to complete the online postpartum questionnaire                     |  |
| 4           | Participants will be recruited directly from social media, and poster advertisements                            |  |

withdrawal of participant's data from this part of the study will not be possible.

Eligibility will be checked online using a criteria checklist and women will be asked to consent. Those women who are not eligible to participate or who do not consent will be directed away from the questionnaire and will proceed no further.

Participants will be asked to provide their email address so that they can be contacted by the CI via secure email to request the personal identifiable information necessary to collect their labour and birth details. One reminder will be emailed if no reply is received to the first request.

Women who are approximately three weeks postpartum, or approximately three weeks after their expected due date if they had their baby beforehand, will be emailed the online link to the postpartum questionnaire. One reminder to complete the postpartum questionnaire will be sent.

# Data collection and management

Data will be collected via two online questionnaires, one antenatal and one postpartum, and by retrieving participants' routinely collected labour and birth details from participating sites' digitally held records.

The online survey will be managed via a secure online survey provider. All site level data will be managed by a nationally used, secure and fully auditable software system.

Participants will be asked to consent to the collection and storage of their data.

A unique participant identifier (study ID) will be allocated to each participant once the completed antenatal questionnaire has been received. Participants' personal identifiable information will be held separate to their questionnaire responses and labour and birth details. Only the CI and the CI's research team will have access to the complete data set.

# Data analysis

Data from the online questionnaires will be initially collated and organised in Microsoft Excel and then organised, summarised, and analysed using the statistical software package SPSS (v.26). Descriptive and inferential statistics will be used.

The association between the primary outcome measure (hospital admission in latent phase labour) and pain catastrophising will be examined using parametric statistics if the data are normally distributed, or non-parametric statistics if they are not. Logistic regression will be used to assess if pain catastrophising is a predictor of hospital admission during latent labour. Other explanatory factors (for example, socio-economic) will be identified. The alpha level will be  $p \leq 0.05$ .

Removal or inclusion of missing data, including data missing due to drop-out or withdrawal from the study, will be carefully considered to ensure inclusion or exclusion do not skew the data or create bias. Statistical analysis which has appropriate mechanisms and assumptions for the missing data will be conducted. Statistical analyses that tend to

<sup>1.</sup> Please note, in Table 4 of this published integrated paper (Bartholomew et al. 2022) Recruitment Pathway 3 should not have a white dividing line between the first line of this item and the remaining three lines. Recruitment Pathway 3 should read as: A member of the participating site's research team will screen and contact women to introduce them to the study. At least 24 hours later the research team member will again contact the woman and support her to complete the online questionnaire. The research team member will be responsible for contacting the participant at the appropriate time to support the participant to complete the online postpartum questionnaire.

work best with larger samples, such as multiple imputation or full maximum likelihood estimation, will be considered. All variables which present the potential mechanisms to explain the missing data will be included.

Inclusion or exclusion of data also has two other provisions. First, providing participants have not withdrawn their consent to participate and, second, providing the participants' data have not been anonymised. If a participant has dropped out, but not withdrawn from the study, their data will be analysed to see if they share significantly similar characteristics such as high or low pain catastrophising or fear of childbirth scores. This information will be conveyed in the final study report.

If on the postpartum questionnaire the participant indicates that they received ongoing care from a consultant obstetrician during their pregnancy and/or they did not experience latent labour at home, then their data will be included in relevant sensitivity analyses. The postpartum questionnaire will also collect data on what participants found helpful and supportive during their labour while at home, and then in hospital, and what was unhelpful and potentially had a negative effect. This data will be used to consider the potential mediating impacts of things such as antenatal education, birth partner, a health professional such as a midwife, pharmacological interventions, and nonpharmacological interventions such as breathing exercises, music, hypnosis, baths, showers, birthing

Written comments in response to relevant questions in the questionnaires will be coded and thematically analysed.

# Study strengths

- This is an original piece of work which brings together pain catastrophising and the latent phase. These two features together have not been studied before
- It aims to fill the gap in knowledge about whether pain catastrophising is a risk factor for admission in the latent phase of labour
- It will indicate the prevalence of pain catastrophising and fear of pain in the study group
- It is anticipated that future research, based on this work, could lead to a reduction in hospital admissions in the latent phase of labour and associated labour interventions, thus improving birth outcomes
- It creates the opportunity to work with women to develop support interventions.

# Limitations

The study is limited by its use of convenience

sampling, which opens it to sampling bias and the possibility that the sample is not representative of the whole population. The necessities of time, cost and accessibility to the required sample group mean nonprobability convenience sampling is the most appropriate to meet the aims and objectives of this study. The study sample will be compared with local population data to explore whether there are any differences and, where possible, to adjust for these in the analysis.

#### The measures

- 1 The PCS and the WDEQ-A may demonstrate predictive value for birth outcomes; however, causality cannot be determined.
- 2 Using the PCS as a predictive tool of poorer birth outcomes may prove ineffective.
- 3 Debate in the literature continues as to whether pain catastrophising is distinct from other constructs, such as negative affectivity. Therefore, women with a current or pre-existing mental health condition requiring care by a perinatal mental health team are excluded.
- 4 Lack of standardised routine data collection around the timing of admission to hospital when women are in labour means the women themselves will be asked to recall the details, which relies on correct recollection of events and that the appropriate information was passed to the woman at the time of her hospital admission
- 5 Women may become more fearful the closer they progress towards childbirth; therefore, screening at 25 weeks pregnant may appear too early. However, this gestation has been chosen to facilitate a future support intervention before women reach full-term pregnancy.

# Risks and safety

There are no foreseeable risks to the health of participants and their babies in participating in this study as participants should continue with their usual maternity care. If participants' responses raise safeguarding concerns for the woman or baby, then follow-up will be arranged by the Chief Investigator (who is also a registered midwife), and the information will be shared with their midwife.

Should an adverse event be identified it will be urgently reviewed by members of the research team and a decision made regarding the suspension or termination of this study. Adverse events are not anticipated for this study.

# Discussion

A woman's previous pain experiences and her cognitions about pain may adversely affect how she interprets her labour pain. In addition, how she remembers and reflects upon it postpartum will affect

her behaviour and attitude towards pain experiences in the future, including future childbirth. Some women are predisposed to pain catastrophising, which can adversely affect their pain-coping behaviour.

This study comes at a point where there is little known about the best way to support women during latent labour. It is hypothesised that the PCS can be used as a predictive tool to identify pregnant women who will seek hospital admission during latent labour. Identifying whether pain catastrophising is a risk factor for early hospital admission will facilitate early intervention to support and empower women to manage their labour pain.

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While the published paper above provides justification for the PCS used in the RETHINK study, additional details relevant to its use are presented here. These additional details address the sensitivity and specificity of the PCS. These factors were not fully explored in the published work and further support its use. Suggestions have also been made for its use in future research:

Sullivan et al (1995) in developing the scale confirmed that *PCS scores had high internal consistency (Cronbach*  $\alpha$  = 0.87) and high test–retest reliability ( $\mathbf{r}$  = 0.70 at 10-week interval). This has been confirmed by (Leung 2012). Sensitivity and specificity have not been reported for the 13 item scale but have been established for the short-form PCS. The short form has a sensitivity of 81.6% and a specificity of 78.3% (Cheng et al. 2019). Future research should consider establishing the test accuracy for the 13 item scale.

# 5.3 Clarification, streamlining, and modification of methods.

Clarification, streamlining and amendments of methods are listed below:

a) Most notably the study design was titled as a quasi-experimental study based on how the data were to be analysed. However, the title for the study design

was a misnomer. The design of the study was a longitudinal cohort study, and the title of the design was corrected to reflect this.

- b) For clarity, chi square tests of independence were used to determine association between categorical variables and most notably used to test the hypothesis and address the primary aim of the RETHINK study. In SPSS, where results for any of the cells where less than the expected count, Fisher's exact test was used.
- c) In the integrated peer-reviewed published paper presented above (section 5.2) objectives and secondary outcomes have both been presented. To avoid confusion and provide improved focus for the analysis the objectives and secondary outcomes were streamlined together and were uniformly referred to as objectives. Objectives were exploratory (Parker and Weir 2022). In some instances, for the analyses some of the sample groups were small and not adequately powered to note statistical significances. Therefore, in results where statistical significances are provided, they should be interpreted with caution (Parker and Weir 2022). Following streamlining, the objectives were as follows:

Objective i: To explore if there is an association between pain catastrophising and specified birth outcomes including whether pain catastrophising acts as a predictor for mental health issues, ongoing treatment or professional support, and/or pain as self-defined by the participant at approximately 3 weeks postnatal.

Objective ii: To explore whether there is an association between pain catastrophising, the timing of admission to hospital when women are in labour, and the specified birth outcomes.

Objective iii: To explore whether the simultaneous occurrence of pain catastrophising and FOC impact on the timing of hospital admission.

<u>Objective iv:</u> To assess, by frequency, the pain management choices women are making at home and at hospital, then explore if these choices are affected by low (<20) versus higher (≥20) PCS scores.

Objective v: To determine the factors that pregnant women find helpful and supportive, or unhelpful, with their pain management during labour.

Objective vi: To analyse who and what are the influencing factors that impact on a woman's decision to seek hospital admission when in labour and the relationship between these factors and pain catastrophising.

Objective vii: To explore the responses to open-ended questions provided on the two online questionnaires and consider the nuanced account of participants' experiences contained within the data, assess for triangulation of data, and consider for a balanced holistic explanation of the study findings.

d) The method to handle missing data was amended to complete case analysis. It was decided that complex multiple imputation was not required for analyses involving only 7 missing PCS scores. Using complete case analysis is valid when it is data missing in the outcome variable (Latent Vs Active labour) and data is missing at random (Sullivan et al. 2018; Austin et al. 2021). Complete case analysis is often the default method used in statistical software, is intuitive and has the advantage of simplicity over models such as multiple imputation limiting the potential for incorrect modelling causing bias or unreliable results (Little et al. 2022). Therefore, for attrition at the postnatal questionnaire response point and for the timing of hospital admission variable (Latent Vs Active) complete case analysis was used.

In the study, cervical dilatation was used to determine the timing of hospital admission and the distinguishing feature marking the transition from latent to active labour. This was a pragmatic decision and aligns with common practices in NHS hospitals in England, where cervical dilatation is often the primary

indicator of labour progression (see Chapter 2 section 2.3). It is acknowledged that women could decline to have a vaginal examination, and this would exclude them from the analyses requiring this data and could potentially have an impact on the study findings.

Prior to analyses demographics, Pain Catastrophising Scale (PCS) (Sullivan et al. 1995) scores and Wijma Delivery Expectancy Questionnaire (WDEQ-A) (Wijma et al. 1998) scores denoting FOC were compared between the antenatal questionnaire respondents, the postnatal questionnaire respondents, and the subset for whom the timing of hospital admission was available. The number of days postnatal that the participants responded on the postnatal questionnaire were also assessed. This was to identify if these factors were affected by those participants lost to follow-up through study progression and provide support for complete case analysis.

e) Postcode and social determinants of health were not analysed in this study and have been deferred to a post-doctoral study at Bournemouth University's discretion.

# 5.4 An NHS HRA ethically approved study protocol

A different form of study protocol was also necessary to fulfil NHS HRA requirements as part of the ethical approval process. This study protocol was used at participating NHS sites to guide their activities in relation to the study. This protocol had to meet certain standards and contain all necessary elements required by the ethics review body. The final study protocol used at sites is included in Appendix 6. Also available to view in this study protocol are all the standard study communications with the participants including the online questionnaires. As previously explained in Chapter 4 section 4.9, amendments were required to the administration and running of the RETHINK study. Some of these amendments required changes to this study protocol document. All amendments received relevant ethical approval (See Appendix 5 for list of approved amendments).

# 5.5 Open-ended questions: a qualitative method

It was anticipated that the open-ended questions in the two RETHINK questionnaires would generate distinct responses based on whether they prompted participants to describe symptom types or explain why they saw a consultant for example versus sharing thoughts, feelings, or opinions. These two distinct data types and their potential for unique insights facilitated two different analytical approaches.

For questions where participants might be describing symptom types or explaining why they saw a consultant summative content analysis (SCA) was used. The other data were brought together using reflexive thematic analysis (RTA). Although both qualitative approaches involve some overlap in methods, SCA enables a descriptive approach in coding and interpretation of data with the added dimension of quantification for the revelation of patterns and trends, and relationships between factors under investigation (Vaismoradi et al. 2013). In contrast, RTA is purely qualitative, flexible, and facilitates providing a nuanced account of data. Both these qualitative methodologies have grown in popularity in healthcare research (Hsieh 2005; Vaismoradi et al. 2013) and have been reported in previous perinatal studies (Eriksson et al. 2006; Porter et al. 2007; Attanasio et al. 2015; Ferguson and Davis 2019; Benet et al. 2020; Karavadra et al. 2020; Edmonds et al. 2021; Matasunaga et al. 2021; Eri et al. 2022; Keedle et al. 2023; Pelak et al. 2023; CQC 2024a; 2024b).

# 5.5.1 Reflexive Thematic Analysis

Reflexive thematic analysis (RTA) was chosen because it is a straightforward, flexible and interpretive qualitative research methodology (Braun and Clarke 2012) which aims for nuanced understanding of the data within the context, and the other methods used in this study. RTA is suitable to understand and draw meaning from messages communicated by participants about their thoughts, feelings, and opinions. RTA has versatility to analyse the qualitative responses to open-ended questions, and identify themes (Braun and Clarke 2012), fulfil triangulation of data, confirm findings, and determine completeness of data (Heale and Forbes 2013; Cohen et al. 2017; Noble and Heale 2019).

RTA involves "the researcher's reflective and thoughtful engagement with their data and their reflexive and thoughtful engagement with the analytic process" (Braun and

Clarke 2019, p. 594). It is a method that supports the researcher's role in knowledge production, and the participation of multiple researchers in the process in a collaborative manner for sense-check and ideas (Byrne 2022). By way of delineation from other thematic analysis approaches, RTA does not uphold the use of structured coding (Boyatzis 1998; Joffe 2011) that requires consensus on codes (Braun and Clarke 2013), or on structured codebook approaches that use templates (Brooks and King 2014) or framework analysis (Smith and Firth 2011). Rather coding in RTA is an organic, inductive process where codes are used as building blocks for the themes (Mayring 2000; Elo and Kyngäs 2008).

Data for RTA were collected through open-ended questions on the antenatal and postnatal RETHINK questionnaires. These questions on the antenatal questionnaire (ANQ) were:

Question 8. 'Please feel free to provide additional thoughts you may have about labour and birth'.

Question 18. 'Is there anything else you would like to tell us?'

The questions on the postnatal questionnaire (PNQ) were:

Question 17. 'Is there anything else you would like to tell us?'

Lincoln and Guba's (1985) six phase criteria for trustworthiness was adapted and adopted as a procedural guide for analysing these data. Researcher 'insider' knowledge and reflexivity was used to draw meaning and contextualise responses to the childbirth setting (Figure 1).

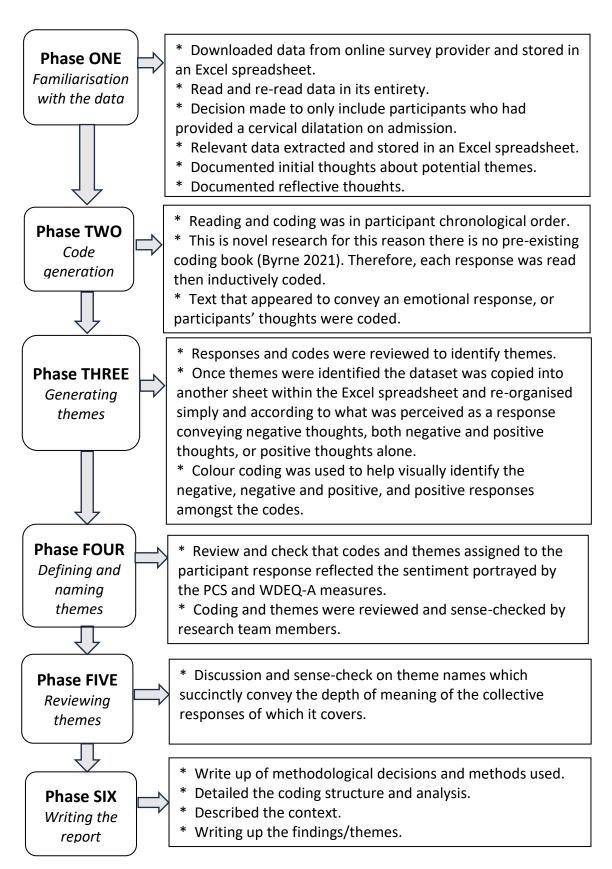


Figure 1: Lincoln and Guba's (1985) criteria for trustworthiness adapted for thematic analysis.

# **5.5.2** Summative Content Analysis

SCA was chosen to analyse the other distinct data set because it facilitates quantitative examination of specific, manifest (Berelson 1952 p.18; Potter and Levine-Donnerstain 1999) and latent (Holsti 1969), words, terms or phrases contained in the qualitative textual data. These words, terms or phrases are coded, quantified, and categorised. Quantification was not to infer statistical meaning but to help identify patterns and contextualise the data (Hsieh 2005). Expressing quantities within this qualitative approach can help reveal the magnitude of a particular phenomenon (Berg 2001; Morgan 1993). Manifest analysis was appropriate because question responses were expected to be short, descriptive and explicit, with examination of the latent content providing flexibility to allow for researcher interpretation of data (Bengtsson 2016) to discover underlying meanings (Catanzaro, 1988; Babbie, 1992; Morse & Field 1995).

Data for SCA were collected through open-ended questions on the antenatal and postnatal RETHINK questionnaires. The questions on the antenatal RETHINK questionnaire were 9a, 10a:

(Question 9. Have you ever had previous pain of any kind (e.g., back pain) that has lasted more than 3 months?).

Question 9a. If you answered yes to Q9 above, what type of pain have you experienced for more than 3 months?

(Question 10. Are you currently experiencing pain?).

Question 10a. If you answered yes to Q10 above what kind of pain are you currently experiencing?

The questions on the postnatal RETHINK questionnaire were:

Question 5. What were the signs that signalled to you that it was time to go to hospital when you were in labour?

Question 11. During your labour what did you find most useful and supportive to help you manage your pain? Please comment.

Question 12. During your labour what did you find not useful/or had a negative effect on helping you manage your pain? Please comment.

Participants were not directed on what factors they should consider or on the criteria for their decisions for questions 5, 11, and 12.

Although designed for thematic analysis, Lincoln and Guba's (1985) six phase criteria for trustworthiness was further adapted and adopted as a procedural guide for analysing SCA data. This was a pragmatic decision because these criteria provided a straightforward framework for the analytic method and provided description and clarity of the process to enhance trustworthiness of the study. It also fit with the organisation of all the qualitative data. As with RTA researcher 'insider' knowledge and reflexivity was used to draw meaning and contextualise responses to the childbirth setting (Figure 2).

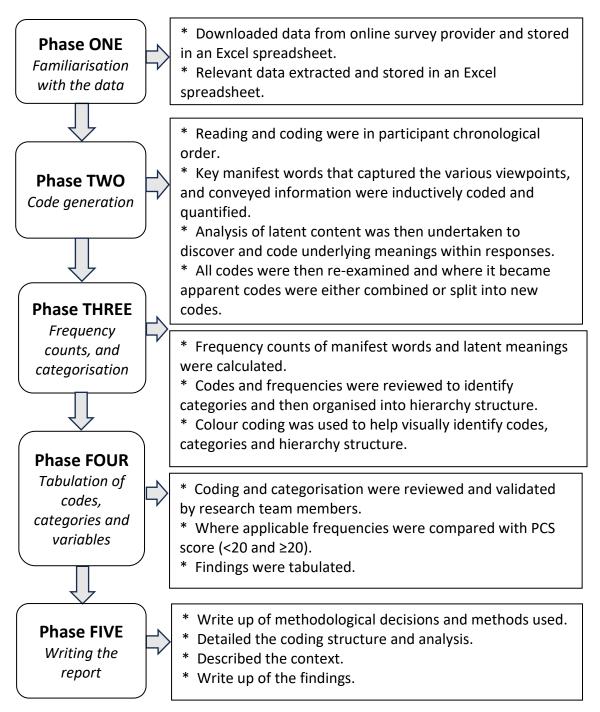


Figure 2: Lincoln and Guba's (1985) criteria for trustworthiness adapted for content analysis

# 5.6 Chapter summary

This chapter has presented the methods for the RETHINK study, including an integrated, peer-reviewed journal publication (Bartholomew et al. 2022) of the study protocol, and provided clarification and justification for modifications made to the methods employed in the RETHINK study.

The next 4 chapters present the results for the RETHINK study. Chapter 6.0 comprises of an integrated, peer-reviewed journal publication (Bartholomew et al. 2024) reporting the results to the primary aim of the RETHINK study. Chapters 6.0 and 9.0 report the results to the other objectives.

# Chapter 6 The RETHINK study: primary aim findings

# 6.1 Introduction to chapter

This chapter principally reports the results to the primary aim of the RETHINK study. These results are presented as an integrated, peer-reviewed publication (Bartholomew et al. 2024) (Section 6.2). Following the presentation of this paper, data on study progression and the results of an investigation into the effect of participants lost to follow-up are provided.

6.2 An integrated peer-reviewed published paper. The RETHINK study:

Could pain catastrophising explain why some women are more
likely to attend hospital during the latent phase of labour.

Bartholomew V, Hundley V, Clark CJ, Parris BA 2024. The RETHINK Study: Could pain catastrophising explain why some women are more likely to attend hospital during the latent phase of labour. *Sexual Reproductive Healthcare*. Vol 39:100941. ISSN 1877-5756. Available from: doi: 10.1016/j.srhc.2023.100941.

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# The RETHINK Study: Could pain catastrophising explain why some women are more likely to attend hospital during the latent phase of labour

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#### ARTICLE INFO

Keywords: Latent Labour Pain Catastrophising Fear Hospital

#### ABSTRACT

Objective: To examine the prevalence of pain catastrophising and identify whether it impacts on the timing of hospital admission when in labour.

Methods: A longitudinal cohort study. Nulliparous women, experiencing an uncomplicated pregnancy in England, were recruited between 25 and 33 weeks gestation. Participants completed two online questionnaires, (1) on recruitment, including the Pain Catastrophizing Scale (PCS) and the Wijma Delivery Expectancy Questionnaire (WDEQ-A) (2) at three weeks postnatal.

Results: A total of 389 eligible participants entered the study. The percentage of women who were pain catastrophisers (PCS  $\geq$  20) was 28.1 %, while 7.6 % had a high pain catastrophising score (PCS  $\geq$  30). There was no association between pain catastrophising and the timing of hospital admission. The percentage of women reporting fear of childbirth (WDEQ-A score of  $\geq$  85) was 10.6 %. Fear of childbirth was highly associated with PCS scores (p <.001) at both the lower ( $\geq$ 20) and higher ( $\geq$ 30) thresholds.

Conclusion: Although not statistically significant, there was a tendency for women who pain catastrophise to present to hospital in the latent phase. The highly significant association between PCS and WDEQ-A scores has implications for the identification of these women and suggests that the PCS can be used as a screening tool to identify those women who have heightened fear around pain and who may also go on to develop clinically relevant fear of childbirth. Further studies are needed to confirm the acceptability of the PCS as a screening tool with women.

# Introduction

# Background

Evidence and current professional guidelines are clear: it is safe, judicious, and cost effective to advise women, who are experiencing pregnancy uncomplicated by risks factors, to remain at home until active labour begins [1]. What is not clear is how these women can be supported holistically so that they can make an informed decision about when to come into hospital, and that this decision is not driven by fear [2]. Decisions made during labour contribute to birth outcomes [3] and choosing the ideal time to move from home to hospital is important because hospitalisation during the latent phase of labour (early labour) often leads to a cascade of interventions [3,4,5] such as caesarean section [4] with implications for maternal [6] and infant [4] wellbeing.

More work is needed to improve the health of women and their babies, and to answer the call from the World Health Organization to advance non-clinical interventions to help reduce the amount of non-urgent obstetric interventions during childbirth [7].

The latent phase of labour is a time "not necessarily continuous, when there are painful contractions and there is some cervical change, including cervical effacement and dilatation" up to the diagnosis of active labour [1]. Many women seek professional care during the latent phase due to pain and lack of confidence in their ability to cope [2,3,5]. Greater understanding is required of women's psychological experiences of labour pain and how this affects their labour choices [5], including their decisions on the timing of when to seek hospital admission.

Pain catastrophising is one psychological construct that may influence a woman's decision to seek early hospital admission. Pain catastrophising can be defined as "an exaggerated negative mental set brought

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to bear during actual or anticipated painful experience" [8]. Higher levels of cognitive distress and perceived pain have been associated with poorer labour efficiency and obstetric outcomes [9-11]. A recent study of women of reproductive age found high levels of pain catastrophising [12], however the prevalence among pregnant women is unknown. Studies have yet to consider whether pain catastrophising, identified in pregnancy, is a significant factor in hospital admission during the latent phase of labour.

Pain-related fear and fear of childbirth (FOC) are distinct yet interrelated concepts. Evidence suggests those women who fear pain also fear childbirth [13], with pain-related fear being a stimulus in the broader dimension of FOC and a factor that moderates women's childbirth decisions [14]. FOC has been shown to increase as pregnancy progresses [15] and it has also been linked with adverse childbirth outcomes such as prolonged labour, epidural use, obstetric complications, traumatic stress symptoms and the need for psychiatric care [9].

There is little research that has looked at how pain catastrophising and fear of childbirth impact the latent phase of labour. A high proportion of mothers who are admitted into hospital in the latent phase of labour have unnecessary intervention [3,4,5]. The primary aim of this study was to assess the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an uncomplicated pregnancy, and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour. The prevalence of FOC was also assessed, as was its relationship with pain catastrophising, and whether it had an impact on participants' timing of hospital admission when they were in labour.

#### Methods

#### Study Design

This was a longitudinal cohort study. Over an 18 month period data were collected via two online questionnaires, one antenatal and one postpartum, and by retrieving participants' routinely collected birth data from participating sites' digitally held records.

# Setting

All National Health Service (NHS) Hospitals in England with an obstetric maternity unit, or alongside midwife-led units, or stand-alone midwife-led units were eligible to participate. A total of 24 primary care NHS Hospitals (sites) across England chose to be included. Participant recruitment took place concurrently at multiple independent sites.

The study opened to participant recruitment and data collection at the first participating site on 31st December 2020. This was following a delay caused by research measures imposed in the United Kingdom (UK) to help tackle the novel coronavirus pandemic. Data collection closed 30th June 2022.

# **Study Population**

# Eligibility Criteria

This study aimed to recruit healthy nulliparous women between 18 and  $\leq$  40 years of age, experiencing an uncomplicated pregnancy, and planning a hospital birth. Participants were required to understand and read English, be between 25 and 33 weeks and 6 days gestation and have internet access and an email address for study correspondence.

The age range was chosen to reflect the study focus on uncomplicated pregnancies. Women outside this age range are more likely to require medical assessment, intervention or, at the lower age range require additional support.

Women who chose to take up the invitation to be included accessed the study online either by themselves or with the assistance of the midwife researcher.

#### Exclusion Criteria

Women who were under ongoing care from an obstetrician, aged 41 or over, with current or pre-existing mental health condition requiring current medication or specialised care, or already participating in a study providing pain management or labour support interventions were excluded.

# Sampling Method, Sample Size

The sampling technique was nonprobability, convenience sampling. The sample size was determined by considering previous studies that used the PCS as an assessment tool [12,16,17]. Studies have used various cut-off scores of between  $\geq 20$  [12,16] and  $\geq 30$  [12,17] for diagnosis of pain catastrophising. Considering a 47.5 % prevalence of pain catastrophising found in a non-pregnant population using the cut-off point of  $\geq 20$  [12], a cut-off point also used with a pregnant population [16], a power calculation determined the sample size of 384 participants which would give us 90 % power to determine association with hospital admission.

This study aimed to recruit 768 women to allow for potential loss to follow-up or changes in risk status from low to high during the antenatal period.

#### The Measures

# Demographics

The demographic profile of participants helped provide context which aided understanding about the findings from this study. Demographic details, included:

- · Relationship/Marital status
- Ethnicity
- · Employment status
- · Highest level of education achieved

Supplement contextual questions included:

- If they had ever been pregnant before but unfortunately suffered a miscarriage or termination of pregnancy before 24 weeks pregnant.
- · Their current gestation
- A brief pain experience history, including antenatal pain level using an 11 point Numerical Rating Scale (NRS) for intensity ratings from 0 (no pain) to 10 (very severe pain). The NRS was chosen for its reliability and because it is easy to administer and score [18].

# The Pain Catastrophising Scale (PCS)

The PCS is one of the most widely used psychometric measures of catastrophic thinking linked to pain [8,17,19]. The PCS is a self-report measure developed for both clinical and non-clinical use. It is composed of 13 items based on catastrophising definitions described in the literature, and previous experimental and clinical research on catastrophic thinking in connection to pain experience [17]. PCS scores have been found to correlate with other health measures, including pain intensity, pain-related disability, and psychosocial distress [20]. The 13 items are divided into three dimensions (subscales): helplessness, magnification and rumination. The correlational relationship between these dimensions has been replicated in several investigations demonstrating internal consistency and validity of the three subscales with total PCS Cronbach's coefficient alphas = 0.87, rumination = 0.87, magnification = 0.66, and helplessness = 0.78 [21] and it has a high test-retest correlation of r = 0.75 across 6 weeks [17].

For each of the 13 items participants are required to reflect on past painful experiences and score their thoughts or feelings on a 5-point Likert scale between "not at all" (score 0), and "all the time" (score 4). The highest possible total score is 52. The higher the score the greater the catastrophic thinking. Although pain catastrophising scores have been shown to be normally distributed, the PCS developers have predominantly taken a score of 30 or more to determine pain catastrophising as clinically relevant [17] with other studies finding lower cut-off scores are clinically relevant [16].

#### The Wijma Delivery Expectancy Questionnaire WDEQ-A

The Wijma Delivery Expectancy Questionnaire Part A (WDEQ-A) [22] asks women about their cognitive and emotional beliefs about childbirth. It is a self-report measure with 33 items, each item rated on a 6-point Likert scale ranging from "not at all" to "extremely". The minimum total score is 0 and the maximum is 165. The higher the score the greater the fear with a cut-off point of 85 or above indicating clinically relevant FOC [10,23]. The internal consistency of the WDEQ-A has been found to be strong with a Cronbach's coefficient alpha of 0.87 [22] and 0.94 [10].

Although the WDEQ-A has been criticised for its multidimensionality [24] and its phraseology for use with UK women [25], the WDEQ-A was chosen in the absence of a more fitting measure of FOC. It is perceived by women as a thorough tool which captures most of women's fears [25] and has demonstrated good reliability and validity [26]. It is one of the most widely used tools worldwide in assessing FOC [26,27] and has also shown to correlate well with other FOC measures in identifying high childbirth fear in first time mothers, previous emergency caesarean and women with self-reported anxiety and/or depression [10].

#### Postnatal Questionnaire (PNQ)

Participants were asked to complete a second online survey at approximately 3 weeks postpartum, or 3 weeks after their expected due date if they had their baby early. The majority of woman completed the PNQ between 21 and 28 days.

Prior to its use the postnatal questionnaire was pretested with four pregnant women, two birthing partners, two non-pregnant multiparous women of childbearing age, four maternity support workers and nine clinical maternity experts.

For this study participants were asked to provide data on their latent phase (which is not routinely collected in the NHS), including cervical dilatation on admission.

# Recruitment

A pragmatic approach was taken for participant recruitment allowing sites to use various methods such as posters, social media, or direct invitation by relevant staff, or a combination of methods.

# Data Collection and Management

Online questionnaires were used for data collection and managed via a secure online survey provider (JISC Online Surveys). Routinely recorded birth outcome data was collected from sites.

Participants were asked to provide their email address to enable follow up with the postnatal online questionnaire. One reminder was emailed if no reply was received to the first request. Women's details were checked to confirm that there were no issues (such as the loss of a baby) in which it could be distressing if further study communication was sent to the participant.

The JISC Online Surveys tool is used for research and education by the majority of higher education institutions in the UK. It is certified to ISO 27001 (International Organization for Standardization (ISO) the world's best-known standard for information security management systems [28], and data is processed in compliance with the General Data Protection Regulation (2018) for organisations in the UK. Participants' personal identifiable information were held separate to all other study data. Personal identifiable information and study data were held securely on the study sponsor's secure mainframe and accessed via a password-protected laptop. All site level data were managed by NHS approved, secure and fully auditable software systems. Women's data were protected, stored, and used in line with the Data Protection Act 2018 and General Data Protection Regulation 2018 and the latest study sponsor's policies.

#### Data Analysis

Data were analysed using the statistical software package SPSS (v.28). For participants who indicated that they had an elective caesarean section, an induction of labour, received ongoing antenatal care from a consultant obstetrician, or that they did not experience latent labour at home, their data were included in relevant sensitivity analysis only.

Prevalence data, socio-demographics, and latent labour experiences were analysed using descriptive statistics. Chi-square tests were used to test independence between relevant categorised variables. Pain catastrophising scores (PCS scores) were categorised  $\geq 20$  [16] and  $\geq 30$  [17], and FOC scores (WDEQ-A scores) were categorised  $\geq 85$  [23]. Multiple variables were examined in relation to the timing of hospital admission and PCS scores. The alpha level for the RETHINK study was set at  $p \leq 0.05$ .

Participants with missing answers to Likert scales within the PCS or the WDEQ-A were removed from relevant analysis. 7 participants failed to complete the PCS, 30 participants failed to complete the WDEQ-A, and 1 participant failed to complete both the PCS and the WDEQ-A.

This study used a cervical dilatation of  $\geq 4$  cm to diagnose the start of active labour. This reflects current guidance from the National Institute for Health and Care Excellence [1] and the most commonly followed guidance in the UK.

#### Ethical Considerations

Ethical approval to conduct this study was obtained on the 4th June 2020 from the National Health Service (NHS), Health Research Authority (HRA) and Health and Care Research Wales (HCRW).

Participants consented to their data being collected and stored. Before online consent participants were informed that if they chose to withdraw from the study then their data would only remain in if their withdrawal came after their data had been anonymised.

# Results

# Participants and Demographics

Fig. 1 provides a graphic of the journey of the participants through the RETHINK study. A total of 389 eligible participants entered the study. Participants were aged between 22 and 40 years (mean age 31.43 years [±3.98]). The majority of participants were educated to degree standard or above (78.5 %), were in full-time employment (81.0 %), were married or had a partner (95.6 %), categorised their ethnicity as White (75.8 %), and, as per the preferred eligibility criteria, were in their third trimester of pregnancy (59.1 %) (Table 1).

Data gathered from the antenatal questionnaire showed 77.8 % had not experienced a pregnancy loss before they reached 24 weeks gestation. One fifth of participants reported having a previous pain experience that lasted more than 3 months (20.1 %), with just over a third (144/389, 37.5 %) reporting being in pain at the time they answered the antenatal questionnaire. Of these participants, 23 % were experiencing high pain (levels 6–10), although the duration of the antenatal pain was unknown. Out of those participants who were in pain most reported musculoskeletal pain and generally cited their lower back, hip, or pelvic regions as the sources of their pain.

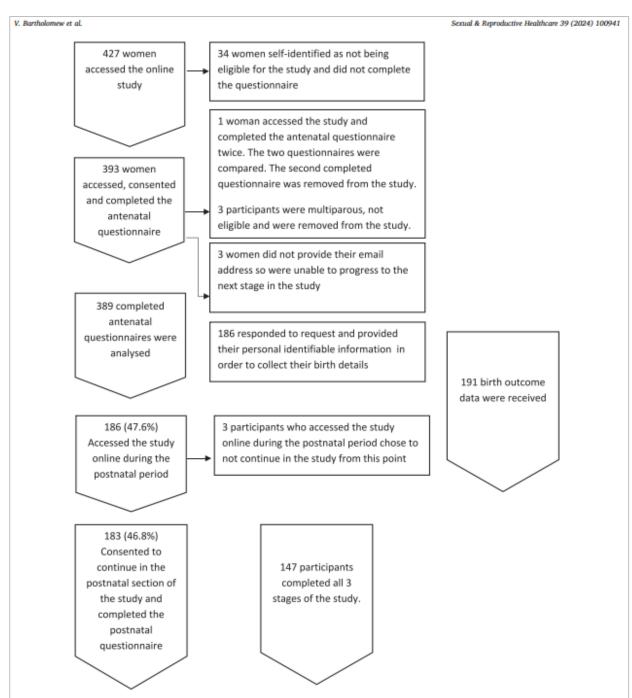


Fig. 1. Flowchart Displaying Participants' Journey Through the RETHINK Study.

Prevalence of Pain Catastrophising and FOC

The PCS was completed by 381 participants and the WDEQ-A by 358 participants (Table 2). The prevalence of pain catastrophising with a cutoff score of  $\geq 20$  was 28.1 % of participants. Prevalence of pain catastrophising with a cut-off score of  $\geq 30$  was 7.6 % of participants. The prevalence of FOC determined by WDEQ-A scores with a cut-off point of  $\geq 85$  was 10.6 % of participants. PCS scores at both the lower and higher

cut-off points were highly associated (p <.001) with FOC (WDEQ-A score  $\geq$  85).

Participants' Latent Labour Experience

Data on latent phase of labour experience is drawn from the PNQ (Table 3). The majority (128/183) of participants responded between 21 and 28 days postnatal.

Table 1
Demographic characteristics of sample.

|  |      | Percentage   | (n)  |
|--|------|--------------|------|
| Gestation (Trimesters*)                  | (n = |              |      |
|  | 389) |              |      |
| 1st Trimester                            |      | 0.3 %        | (1)  |
| 2nd Trimester                            |      | 40.6 %       | (158 |
| 3rd Trimester                            |      | 59.1 %       | (230 |
| Employment                               | (n = |              |      |
|  | 389) |              |      |
| Full-time                                |      | 81.0 %       | (315 |
| Self-employed                            |      | 4.4 %        | (17) |
| Part-time                                |      | 5.9 %        | (23) |
| Maternity leave                          |      | 2.6 %        | (10) |
| Unemployed                               |      | 3.6 %        | (14) |
| Prefer not to say                        |      | 1.5 %        | (6)  |
| Other** - Student MW, Shielding,         |      | 1.0 %        | (4)  |
| Student, FT undergrad                    |      |              |      |
| Highest level of academic achievement    | (n = |              |      |
|  | 377) |              |      |
| GCSE                                     |      | 7.7 %        | (29) |
| A Level or equivalent                    |      | 13.8 %       | (52) |
| Degree or equivalent                     |      | 46.9 %       | (17) |
| Masters or equivalent                    |      | 25.2 %       | (95) |
| PhD                                      |      | 6.4 %        | (24) |
| Relationship Status                      | (n = |              |      |
|  | 389) |              |      |
| Married                                  |      | 54.8 %       | (21) |
| Single                                   |      | 2.6 %        | (10) |
| Partner                                  |      | 39.8 %       | (15) |
| Widow                                    |      | 0            | (0)  |
| Prefer not to say                        |      | 1.8 %        | (7)  |
| Other — Civil partnership, Engaged,      |      | 1.0 %        | (4)  |
| Married common-law, Co-habiting          |      |              |      |
| Ethnic origin                            | (n = |              |      |
|  | 389) |              |      |
| White                                    |      | 75.8 %       | (29  |
| Mixed                                    |      | 4.9 %        | (19) |
| Asian or Asian British                   |      | 10.5 %       | (41) |
| Black or Black British                   |      | 4.4 %        | (17) |
| Arab or other ethnic group               |      | 0.5 %        | (2)  |
| Other - Kurdish, Chinese, Black African, |      | 3.9 %        | (15) |
| Japanese, Moroccan, Indian, Latin        |      |              |      |
| American, South East Asian, Brazilian,   |      |              |      |
| British Chinese                          |      |              |      |
| Age (years)                              | (n = |              |      |
|  | 183) |              |      |
| 22-25                                    |      | 9.3 %        | (17) |
| 26-30                                    |      | 28.4 %       | (52) |
| 31-35                                    |      | 45.4 %       | (83) |
| 36-40                                    |      | 16.9 %       | (31) |
| Mean [SD]                                |      | 31.43 [±3.98 |      |

 $<sup>^*</sup>$  1st trimester =1 to 12 completed weeks gestation, 2nd= trimester 13 to 27 completed weeks gestation, 3rd trimester =28 to 40+ weeks gestation

Only 44.8 % of participants who completed the PNQ (81/183) provided data on their timing of hospital admission when in labour, because a high proportion of participants reported having an induction of labour (38.2 %) or an elective cassarean section (9.3 %).

Approximately one third (32.9 %) of women with spontaneous onset of labour were admitted to hospital during the latent phase. Just over a fifth (21.6 %) reported that they were admitted on their first presentation to hospital, while the majority were sent home and admitted on their second (57.9 %) or subsequent (20.5 %) visits. Overall, the median duration of latent labour experienced at home before the first, or only time seeking hospital admission was 8.5 h, with a range of 0 to 72 h.

Factors Associated with the Timing of Hospital Admission

There was no statistically significant association between PCS scores or WDEQ-A scores and the timing of hospital admission (Table 4).

However, a tendency was observed for women with higher PCS scores (at both cut-off points) and WDEQ-A scores ( $\geq$ 85) to have latent phase hospital admission. There was a significant association between the timing of hospital admission and antenatal pain level, but participant numbers were very small.

Factors Associated with Pain Catastrophising and FOC

There was a significant association between antenatal pain level and both PCS cut-off points (Table 5). However, similar results were not seen with WDEQ-A scores.

Although antenatal pain lasting more than three months was not significantly associated with PCS scores (Table 5), there was a significant association with WDEQ-A scores. Participants who experienced pain that had lasted for more than three months were significantly more likely to have a high WDEQ-A score (20 % of those with pain compared to 8 % for those without, p=.004).

Age demonstrated a strong association (p=.007) with pain catastrophising at the lower pain catastrophising score ( $\geq 20$ ), with participants aged  $\geq 31$  years being more likely to pain catastrophise than those aged  $\leq 30$  years (Table 5). This association was not reflected between age and the higher PCS scores ( $\geq 30$ ). There were no associations found between age and WDEQ-A scores. Participants who classified their ethnicity as any other category other than white were more likely to pain catastrophise (score  $\geq 20$ ) than those who described themselves as white (p<0.038). There was no association found between ethnicity and WDEQ-A scores.

#### Discussion

This is the first study to report the prevalence of pain catastrophising in a population of pregnant nulliparous women in the UK, and to explore its association with the timing of hospital admission when in labour.

#### Prevalence of Pain Catastrophising

This study found a lower prevalence of pain catastrophising compared to a non-pregnant UK population [12]. One potential explanation is that in Clark et al's [12] study participants may have been self-selecting with an interest in engaging with a study about pain. In contrast, the participants for the RETHINK study were pregnant nulliparous women. The aim was to investigate if the PCS might predict those women who would benefit from extra pain management support in latent labour with a view to enabling them to arrive in hospital in active labour to help reduce their chance of unnecessary obstetric interventions. A study by Flink et al [16] with a similar sample group to the RETHINK study, reported the prevalence of pain catastrophising at a PCS cut-off point ≥ 20 to be nearly double at 46.3 % [16]. The most notable differences are that Flink et al [16] did not exclude women on mental health grounds or with obstetric risk factors (other than those women who were planning to have a caesarean section) [16]. Pain catastrophising has been shown to be influenced by negative emotions and thoughts in response to pain and those with high pain catastrophising and mental health symptoms report the worst pain intensity [30].

#### Prevalence of FOC

This study found the prevalence of FOC to be 10.6%, which is higher than the 3% found in a recent UK study [29] but below the worldwide estimate of 14% [27]. The variation in the estimation of FOC has been attributed to methodological flaws, and failure to account for, or control for confounding variables, including a broad conceptualisation of anxiety without specificity [31]. We attempted to reduce the confounding factors by recruiting low risk women and excluding those with mental health conditions, but we acknowledge that some undetected conditions

<sup>\*\* &#</sup>x27;Other' for Employment, Relationship status, and Ethnic origin is as participants specified and have not been re-categorised for purposes of demographic deniction.

Table 2
Frequency Table showing cut-off scores of PCS and FOC.

| Measure                   |         | Percentage (%) | n     | Mean  | Standard Deviation [±SD] | Overall<br>Range |
|---------------------------|---------|----------------|-------|-------|--------------------------|------------------|
| PCS<br>Out-off score < 20 | n = 381 | 71.9 %         | (274) | 14.62 | 9.41                     | 0-47             |
| Out-off score ≥ 20        |         | 28.1 %         | (107) |       |                          |                  |
| Total                     |         | 100.0 %        | (381) |       |                          |                  |
| Out-off score < 30        | n = 381 | 92.4 %         | (352) |       |                          |                  |
| Out-off score $\geq 30$   |         | 7.6 %          | (29)  |       |                          |                  |
| Total                     |         | 100.0 %        | (381) |       |                          |                  |
| WDEQ-A<br>FOC < 85        | n = 358 | 89.4 %         | (320) | 60.36 | 20.67                    | 10-14            |
| 2OC ≥ 85                  |         | 10.6 %         | (38)  |       |                          |                  |
| otal                      |         | 100.0 %        | (358) |       |                          |                  |

PCS = Pain Catastrophizing Scale [17] FOC = Fear of Childbirth WDEQ-A [22].

Table 3
Tabulation of Participants' Latent Labour Experience

| Characteristics  |           | (n)        | % of total PNQ<br>respondents |
|--|-----------|------------|-------------------------------|
| Total number of participants who   |           | 183        |                               |
| responded to the PNQ   |           |            |                               |
| How many times participants  | 0         | 19         | 21. 6 %                       |
| presented to hospital before<br>being admitted   | 1         | 51         | 58.0 9                        |
|  | 2         | 15         | 17.0 9                        |
|  | 3         | 3          | 3.4 9                         |
|  | Total     | 88         | 100 9                         |
|  | (n)       |            |                               |
| Admitted to hospital in latent<br>labour*  |           | 27         | 32.9 9                        |
| Admitted to hospital in active<br>labour**   |           | 55         | 67.1 9                        |
|  | Total     | 82         | 100 9                         |
| Minimum numbers of hours   | Total     | 88         |                               |
| participants said they were in   | (n)       |            |                               |
| labour before presenting to  | Median    | 8.50       |                               |
| hospital for admission   | IQR       | 4.00-14.75 |                               |
|  | Range     | 0-72       |                               |
| Number of participants who said<br>that they did have an IOL   | Yes       | 70         | 38.3 9                        |
| No or did n  | ot answer | 113        | 61.7 9                        |
|  | Total     | 183        | 100 9                         |
|  | (n)       |            |                               |
| Out of the total participants who<br>responded to the PNQ the<br>number who reported that they<br>had an elective caesarean<br>section |           | 17         | 9.3 9                         |
| Number of days postnatal that participants completed the PNO   | Median    | 25         |                               |
|  | IOR       | 22-29      |                               |
|  | 10-20     | 3          | 1.6 9                         |
|  | 21-28     | 128        | 70.0 9                        |
|  | 29-35     | 25         | 13.7 9                        |
|  |           |            |                               |
|  | 36-96     | 27         | 14.8 9                        |

\*Cervical dilatation ≤ 3 cm \*\*Cervical dilatation ≥ 4 cm.

might exist in the cohort. Nonetheless, this study adds to knowledge about FOC.

#### Factors Associated with the Timing of Hospital Admission

Approximately one third of the RETHINK study participants were admitted to hospital in the latent phase of labour. This is similar to the 32.4 % found in an Australian study by Miller et al [4]. In view of poorer birth outcomes associated with hospital admission during the latent phase of labour [3,4] it is important to consider the reasons why women present early.

Previous research has suggested that women seeking admission in the latent phase of labour do so because of pain [5,32]. This study found no statistically significant association between high PCS scores and latent phase hospital admission. However, the number of women admitted in spontaneous labour was much smaller than anticipated due to the high levels of induction, and the number of elective caesarean sections. Furthermore, participants who did experience the latent phase at home may have delayed their timing of hospital admission due to fears they may have had about attending hospital during a global pandemic, and the restrictions hospitals imposed on attending birth partners. Nonetheless, the tendency towards greater hospital admission during the latent phase of labour when women scored higher on the PCS, and higher on the WDEQ-A is noteworthy as this may indicate that these women may benefit from additional support in the future. Further studies with larger sample sizes are needed to confirm this.

The association between antenatal pain and hospital admission during the latent phase of labour is particularly noteworthy because those participants who rated their pain levels as high on the antenatal questionnaire were also those who were more likely to pain catastrophise. Taking a pain history on booking and/or later in pregnancy might be an important and simple way of identifying women who might benefit from targeted support prior to labour [33].

#### Factors Associated with Pain Catastrophising and FOC

The findings confirm previous research that indicates pain catastrophising is a predictor for pain intensity [19]. How women rate their pain level has been shown to be a strong predictor of childbirth pain [16]. It can be argued that women who rate their antenatal pain as high may also rate their labour pain as high. The potential then is that they

Table 4
Crosstabulation of timing of hospital admission against multiple variables.

|                                 | Latent | of Hospital Adn<br>Vs Active Labou | r   |        | df | Fisher's Exact 2-sided | Pearson<br>Chi-Square Asympt. Signif |
|---------------------------------|--------|------------------------------------|-----|--------|----|------------------------|--------------------------------------|
|                                 | No     |                                    | Yes |        |    |                        |                                      |
|                                 | n      | Row %                              | n   | Row %  |    |                        | p value                              |
| PCS score ≥ 20                  |        |                                    |     |        |    |                        |                                      |
| No (n - 57)                     | 17     | 29.8 %                             | 40  | 70.2 % | 1  |                        | 0.347                                |
| Yes (n - 22)                    | 9      | 40.9 %                             | 13  | 59.1 % |    |                        |                                      |
| PCS score ≥ 30                  |        |                                    |     |        |    |                        |                                      |
| No (n - 74)                     | 23     | 31.1 %                             | 51  | 68.9 % | 1  |                        |                                      |
| Yes (n = 5)                     | 3**    | 60.0 %                             | 2** | 40.0 % |    | 0.324                  |                                      |
| WDEQ-A score ≥ 85               |        |                                    |     |        |    |                        |                                      |
| No (n = 73)                     | 23     | 31.5 %                             | 50  | 68.5 % | 1  |                        |                                      |
| Yes (n = 6)                     | 4**    | 66.7 %                             | 2** | 33.3 % | -  | 0.173                  |                                      |
| 100 (11 - 0)                    | ,      | uoti ii                            | -   | 33.3 7 |    |                        |                                      |
| Previous pregnancy loss ≤ 24wks |        |                                    |     |        |    |                        |                                      |
| No (n - 59)                     | 17     | 28.8 %                             | 42  | 71.2 % | 1  |                        | 0.204                                |
| Yes (n = 23)                    | 10     | 43.5 %                             | 13  | 56.5 % |    |                        |                                      |
| Gestation                       |        |                                    |     |        |    |                        |                                      |
| $\leq 27 \text{wks (n} = 26)$   | 7      | 26.9 %                             | 19  | 73.1 % | 1  |                        | 0.431                                |
| ≥28wks (n = 56)                 | 20     | 35.7 %                             | 36  | 64.3 % |    |                        |                                      |
| Age/years                       |        |                                    |     |        |    |                        |                                      |
| ≤30 years (n = 19)              | 4      | 21.1 %                             | 15  | 78.9 % | 1  |                        | 0.250                                |
| ≥31 years (n = 36)              | 13     | 36.1 %                             | 23  | 63.9 % |    |                        |                                      |
| Education                       |        |                                    |     |        |    |                        |                                      |
| GCSE/ A Level (n = 18)          | 6      | 33.3 %                             | 12  | 66.7 % | 2  |                        | 0.317                                |
| Degree (n = 30)                 | 7      | 23.3 %                             | 23  | 76.7 % | -  |                        | 0.317                                |
| Post-Graduate (n = 34)          | 14     | 41.2 %                             | 20  | 58.8 % |    |                        |                                      |
| Post-draudate (n = 34)          | 14     | 41.2 %                             | 20  | 36.6 % |    |                        |                                      |
| Ethnicity                       |        |                                    |     |        |    |                        |                                      |
| White (n = 68)                  | 22     | 32.4 %                             | 46  | 67.6 % | 1  |                        |                                      |
| Not White (n = 14)              | 5**    | 35.7 %                             | 9   | 64.3 % |    | 1.000                  |                                      |
| Antenatal Pain Level            |        |                                    |     |        |    |                        |                                      |
| Level 0-5 (n = 28)              | 9      | 32.1 %                             | 19  | 67.9 % | 1  |                        |                                      |
| Level 6-10 (n - 4)              | 4**    | 100 %                              | 0** | 0.0 %  |    | 0.020*                 |                                      |
| Currently in pain               |        |                                    |     |        |    |                        |                                      |
| No (n = 49)                     | 13     | 26.5 %                             | 36  | 73.5 % | 1  |                        | 0.067                                |
| Yes (n = 30)                    | 14     | 46.7 %                             | 16  | 53.3 % | -  |                        |                                      |
| Ever had pain ≥ 3 months        |        |                                    |     |        |    |                        |                                      |
| No (n = 65)                     | 19     | 29.2 %                             | 46  | 70.8 % | 1  |                        | 0.164                                |
| Yes (n = 17)                    | 8      | 47.1 %                             | 9   | 52.9 % | -  |                        | 0.104                                |

df = Degrees of Freedom. Pearson Chi Square Asympt. Signif. = Pearson chi-square asymptotic significance.

will be affected by the fear of being overwhelmed by pain [34] and choose to avoid labour pain by requesting epidural analgesia [35] or opting for an elective caesarean section [11] and face poorer recovery following birth [16].

Age and ethnicity were significantly associated with pain catastrophising at the lower cut-off point. The evidence regarding age and pain catastrophising in a pregnant population is unclear with Flink et al finding no relationship [16]. However, ethnicity has been shown to influence a person's evaluation and interpretation of pain and their emotional and behavioural responses to it [36]. Caution is needed in interpreting this result considering the sample size in this study. It is recommended that future studies considering pain catastrophising examine the implications of ethnicity.

#### Predictive Value of FOC Based on PCS Scores

There was a strong association between pain catastrophising and FOC and with the PCS scores significantly predicting WDEQ-A scores. This mirrors previous work by Rondung et al [13]. The predictive relationship of pain catastrophising for FOC is pertinent because FOC has been shown to increase after 20 weeks gestation [15] and suggests that the PCS may be used as a predictor earlier in pregnancy to identify women who may later develop FOC and need additional support [33].

### Strengths and Limitations of The RETHINK Study

This is an original piece of work which brings together pain catastrophising and the latent phase of labour. It aims to fill the gap in knowledge about the prevalence of pain catastrophising in the target population and whether pain catastrophising is a risk factor for admission to hospital during the latent phase of labour.

The strengths of this study include the target sample size which was achieved and used to assess the prevalence of pain catastrophising at the higher cut-off point. This is a relatively high initial response rate compared to other studies considering a similar topic [11,16,34]. Another strength was that the study ran at multiple sites across England covering urban and rural areas and included obstetric-led maternity units and birth centres.

 $<sup>^{\</sup>circ}$  Significant finding (p=<0.05)  $^{\circ\circ}$ Cell has less than expected count for chi-square analysis.

PCS = Pain Catastrophizing Scale [17] WDEQ-A [22].

Table 5
Crosstabulation of PCS scores against multiple variables

|                         | PCS<br>score | ≥ 20   |     |        | df | Pearson<br>Chi-Square<br>Asympt, Signif. | PCS<br>score | ≥ 30   |        |        | df | Fisher's Exact<br>2-sided | Pearson<br>Chi-Square<br>Asympt. Signif |  |
|-------------------------|--------------|--------|-----|--------|----|--|--------------|--------|--------|--------|----|---------------------------|---|--|
|                         | No           |        | Yes |        | _  |  | No Yes       |        | No Yes |        |    | _                         |   |  |
|                         | n            | 96     | n   | %      |    | p Value                                  | n            | 96     | n      | 96     |    |                           | p Value                                 |  |
| WDEQ-A score ≥ 85       |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| No (n - 314)            | 242          | 77.1 % | 72  | 22.9 % | 1  | < 0.001*                                 | 302          | 96.2 % | 12     | 3.8 %  | 1  |                           | < 0.001*                                |  |
| Yes (n = 37)            | 14           | 37.8 % | 23  | 62.2 % |    |  | 24           | 64.9 % | 13     | 35.1 % |    |                           |   |  |
| Gestation               |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| ≤27wks (n = 154)        | 111          | 72.1 % | 43  | 27.9 % | 1  | 0.954                                    | 139          | 90.3 % | 15     | 9.7 %  | 1  |                           | 0.197                                   |  |
| ≥28wks (n = 227)        | 163          | 71.8 % | 64  | 28.2 % |    |  | 213          | 93.8 % | 14     | 6.2 %  |    |                           |   |  |
| Previous pregnancy loss | ≤ 24wks      |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| No (n = 296)            | 216          | 73.0 % | 80  | 27.0 % | 1  | 0.479                                    | 274          | 92.6 % | 22     | 7.4 %  | 1  |                           | 0.929                                   |  |
| Yes (n = 84)            | 58           | 69.0 % | 26  | 31.0 % |    |  | 78           | 92.9 % | 6      | 7.1 %  |    |                           |   |  |
| Age/years               |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| ≤30 years (n = 69)      | 58           | 84.1 % | 11  | 15.9 % | 1  | 0.007*                                   | 65           | 94.2 % | 4**    | 5.8 %  | 1  | 1.000                     |   |  |
| ≥31 years (n = 111)     | 73           | 65.8 % | 38  | 34.2 % |    |  | 104          | 93.7 % | 7      | 6.3 %  |    |                           |   |  |
| Education               |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| GCSE/A-Level (n = 79)   | 61           | 77.2 % | 18  | 22.8 % | 2  | 0.139                                    | 74           | 93.7 % | 5      | 6.3 %  | 2  |                           | 0.826                                   |  |
| Degree (n - 175)        | 128          | 73.1 % | 47  | 26.9 % |    |  | 160          | 91.4 % | 15     | 8.6 %  |    |                           |   |  |
| Post-Grad (n = 117)     | 76           | 65.0 % | 41  | 35.0 % |    |  | 108          | 92.3 % | 9      | 7.7 %  |    |                           |   |  |
| Ethnicity               |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| White (n - 291)         | 217          | 74.6 % | 74  | 25.4 % | 1  | 0.038*                                   | 272          | 93.5 % | 19     | 6.5 %  | 1  |                           | 0.152                                   |  |
| Not White (n = 90)      | 57           | 63.3 % | 33  | 36.7 % |    |  | 80           | 88.9 % | 10     | 11.1 % |    |                           |   |  |
| Antenatal Pain Levels   |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| Level 0-5 (n = 115)     | 87           | 75.7 % | 28  | 24.3 % | 1  | 0.006*                                   | 107          | 93.0 % | 8      | 7.0 %  | 1  |                           | 0.024*                                  |  |
| Level 6-10 (n = 35)     | 18           | 51.4 % | 17  | 48.6 % |    |  | 28           | 80.0 % | 7      | 20.0 % |    |                           |   |  |
| Currently in pain       |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| No (n = 233)            | 170          | 73.0 % | 63  | 27.0 % | 1  | 0.554                                    | 218          | 93.6 % | 15     | 6.4 %  | 1  |                           | 0.245                                   |  |
| Yes (n – 144)           | 101          | 70.1 % | 43  | 29.9 % |    |  | 130          | 90.3 % | 14     | 9.7 %  |    |                           |   |  |
| Ever had pain ≥ 3 month |              |        |     |        |    |  |              |        |        |        |    |                           |   |  |
| No (n = 303)            | 220          | 72.6 % | 83  | 27.4 % | 1  | 0.554                                    | 283          | 93.4 % | 20     | 6.6 %  | 1  |                           | 0.143                                   |  |
| Yes (n - 78)            | 54           | 69.2 % | 24  | 30.8 % |    |  | 69           | 88.5 % | 9      | 11.5 % |    |                           |   |  |

df = Degrees of Freedom. Pearson chi-square Asympt. Signif. = Pearson chi-square asymptotic significance.

\* Significant finding (p=<0.05) \*\*Cell has less than expected count for chi-square analysis.

PCS = Pain Catastrophizing Scale [17] WDEQ-A [22].

Excluding women from this study if they had a current or preexisting mental health condition requiring medication or specialised care is a strength of this study. This is because it isolates pain catastrophising and fear of childbirth from such conditions which has been a criticism of some studies in the past [31].

The study is limited by its use of convenience sampling with the potential for sampling bias and a sample that is not representative of the target population. The diverse nature of the participating sites may limit the impact of sampling bias. The necessities of time, costs and accessibility to the required sample group meant nonprobability convenience sampling was the most suitable method to meet the study aims and objectives.

Considering the target population in this study, an unexpected limitation was the high number of women undergoing induction of labour, coupled with those having an elective caesarean section which reduced the power to explore and conclude on associations between variables and the timing of hospital admission. The rate of induction is rising in England and yet there is much debate, and uncertainty surrounding the evidence for the optimum time, and in other particular instances the clinical need [37]. The percentage of the RETHINK study participants who said that they had an induction of labour (38.25 %) is slightly higher than national UK figure at 33.3 % for all singleton pregnancies at term [38].

This study was further limited by the unknown influence that the global pandemic, including fear about contracting the COVID-19 virus, and hospital measures aimed at minimising the transmission of the virus had on the participants' decisions about when to seek hospital admission when they were in labour. Furthermore, the pandemic had a major impact on study recruitment delaying the study start date as NHS staff were prioritised elsewhere.

Data about the latent phase and the timing of hospital admission are not routinely collected and were therefore collected from participants. The timing of hospital admission was based on cervical dilatation, which is usual practice in the UK [1] and excluded other factors that women would incorporate into their decision of when to move from home to hospital. This additional data may have advanced the findings about the influence of pain catastrophising on the timing of hospital admission decisions. Data collection could also have been hindered by relying on women's recollection of events [39]. Although women's memories about their childbirth experiences have been questioned in the literature [40] the evidence is not conclusive and recall of events has been shown to be excellent at four months postpartum [41]. Furthermore, to the authors' knowledge there is no evidence about the reliability of women's recall of events specifically around the latent phase of labour.

#### Conclusion

This is the first study to report the prevalence of pain catastrophising in a UK population of women at low obstetric risk and to consider how pain catastrophising impacts the timing of hospital admission in labour. Although this study was unable to identify a significant association between pain catastrophising and the timing of hospital admission, the findings suggest a tendency for women who pain catastrophise to present to hospital for admission during the latent phase of labour. The highly significant association between pain catastrophising and FOC has implications for the identification of these women. FOC has previously been shown to increase as pregnancy advances. This suggests that the PCS can be used as a screening tool to identify those women who have heightened fear around pain and who may also go on to develop clinically relevant FOC. Further studies are needed to confirm the acceptability of the PCS as a screening tool with women and identify the optimum gestation period to enhance its utility.

#### Author contributions

VH, CC and BP conceived the study and obtained funding to support the work. VB planned the study design, designed the data collection form and analysed the data with support from VH, CC and BP. All authors interpreted the data. All authors contributed to the discussion and interpretation of the findings. All authors contributed to the planning, conduct and reporting of this research article. VB is the guarantor. All authors contributed to the writing of the paper and approved the final version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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#### Transparency declaration

I, Vanessa Bartholomew, as the lead author of this work, affirm that this manuscript is an honest, accurate and transparent account of the study; no important aspects of the study have been omitted and that any discrepancies from the study as originally planned have been explained.

#### Role of the funding source

The RETHINK study was supported through a Wessex Clinical Academic Training Programme. The funding source has had no influence on the study findings.

#### Dissemination declaration

Findings will be made available to study participants and organisations promoting women's reproductive health and wellbeing.

#### Data sharing statement

A de-identified data set can be made available for research purposes following completion of the study and on application to the corresponding author.

#### Ethics statement

The study has been approved by a National Health Service (NHS) research ethics committee and the NHS Health Research Authority in England. The ethics committee was the Black Country Research Ethics Committee. The Health Research Authority (HRA) and Health and Care Research (HCRW) Approval was given on the 4th June 2020 and the IRAS project ID number is 270583.

In all instances participants' data are protected, securely stored and used in line with the Data Protection Act 2018 and General Data Protection Regulation 2018 and professional regulating bodies. Research data collected, managed, and stored at participating Trust level are retained in line with each Trust's data management policy.

#### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The RETHINK study was a doctotal study supported through the Wessex Clinical Academic Training Programme.

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# 6.3 Comparing participant characteristics between the antenatal questionnaire and postnatal questionnaire respondents, and the subset for whom the timing of hospital admission was available.

The integrated paper above (section 6.2) reports the results of the RETHINK study, with respect to the primary aim. The following sections present findings of an investigation into the impact that attrition may have had. In particular could the final sample group, after attrition, be considered representative of the main target sample. This was a visually comparative exercise.

#### Comparisons were between:

 Antenatal questionnaire (ANQ) respondents (main sample group) (n=389) and postnatal questionnaire (PNQ) respondents (n=183) (Table 4).

- Main sample group and the subset of respondents who provided data on their timing of hospital admission (subset) (n=82) (Table 5).
- PCS and WDEQ-A scores between main sample group and the total postnatal questionnaire respondents (Table 6).
- PCS and WDEQ-A scores between main sample group and subset (Table 7).
- The number of days postnatal between total PNQ respondents and subset (Table 8).

Visual inspection of the tabulated results shown below demonstrate that each group was relatively comparative, considered to be representative of the main sample group (n=389), and sufficient to meet the exploratory requirements of the study objectives.

Table 4: Comparison of demographics between main sample group and the total postnatal questionnaire respondents

|                                 | Mai     | n sample gr<br>(n=389) | oup        |         | ondents<br>(n=183) | to PNQ    |
|---------------------------------|---------|------------------------|------------|---------|--------------------|-----------|
|                                 |         | (n)                    | %          |         | (n)                | %         |
| Employment                      | (n=389) |                        | 100%       | (n=183) |                    | 100%      |
| Full-time                       |         | (315)                  | 81.0%      |         | (156)              | 85.2%     |
| Self-employed                   |         | (17)                   | 4.4%       |         | (10)               | 5.5%      |
| Part-time                       |         | (23)                   | 5.9%       |         | (10)               | 5.5%      |
| Maternity leave                 |         | (10)                   | 2.6%       |         | (2)                | 1.1%      |
| Unemployed                      |         | (14)                   | 3.6%       |         | (3)                | 1.6%      |
| Prefer not to say               |         | (6)                    | 1.5%       |         | (1)                | 0.5%      |
| Other** = Student MW,           |         | (4)                    | 1.0%       |         | (1)                | 0.5%      |
| Shielding, Student, FT          |         |                        |            |         |                    |           |
| undergrad                       |         |                        |            |         |                    |           |
| Highest level of academic       | (n=377) |                        | 96.9%      | (n=182) |                    | 99.5%     |
| achievement                     |         |                        |            |         |                    |           |
| GCSE                            |         | (29)                   | 7.7%       |         | (12)               | 6.6%      |
| A Level or equivalent           |         | (52)                   | 13.8%      |         | (21)               | 11.5%     |
| Degree or equivalent            |         | (177)                  | 46.9%      |         | (84)               | 46.2%     |
| Masters or equivalent           |         | (95)                   | 25.2%      |         | (50)               | 27.5%     |
| PhD                             |         | (24)                   | 6.4%       |         | (15)               | 8.2%      |
| Relationship Status             | (n=389) |                        | 100%       | (n=183) |                    | 100%      |
| Married                         |         | (213)                  | 54.8%      |         | (105)              | 57.4%     |
| Single                          |         | (10)                   | 2.6%       |         | (2)                | 1.1%      |
| Partner                         |         | (155)                  | 39.8%      |         | (74)               | 40.4%     |
| Widow                           |         | (0)                    | 0%         |         | (0)                | 0%        |
| Prefer not to say               |         | (7)                    | 1.8%       |         | (2)                | 1.1%      |
| Other = Civil partnership,      |         | (4)                    | 1.0%       |         | (0)                | 0%        |
| Engaged, Married common-        |         |                        |            |         |                    |           |
| law, Co-habiting                |         |                        |            |         |                    |           |
| Ethnic origin                   | (n=389) |                        | 100%       | (n=183) |                    | 100%      |
| White                           |         | (295)                  | 75.8%      |         | (147)              | 80.3%     |
| Mixed                           |         | (19)                   | 4.9%       |         | (5)                | 2.7%      |
| Asian or Asian British          |         | (41)                   | 10.5%      |         | (20)               | 10.9%     |
| Black or Black British          |         | (17)                   | 4.4%       |         | (5)                | 2.7%      |
| Arab or other ethnic group      |         | (2)                    | 0.5%       |         | (1)                | 0.5%      |
| Other = Kurdish, Chinese, Black |         | (15)                   | 3.9%       |         | (5)                | 2.7%      |
| African, Japanese, Moroccan,    |         |                        |            |         |                    |           |
| Indian, Latin American, South   |         |                        |            |         |                    |           |
| East Asian, Brazilian, British  |         |                        |            |         |                    |           |
| Chinese                         |         |                        |            |         |                    |           |
| Age (years)                     | (n=183) |                        | 47.0%      | (n=140) |                    | 76.5%     |
| 22-25                           |         | (17)                   | 9.3%       |         | (8)                | 5.7%      |
| 26-30                           |         | (52)                   | 28.4%      |         | (39)               | 27.9%     |
| 31-35                           |         | (83)                   | 45.4%      |         | (62)               | 44.3%     |
| 36-40                           |         | (31)                   | 16.9%      |         | (23)               | 16.4%     |
| Mean [SD]                       |         | 31.                    | 43 [±3.98] |         | 31.73              | 1 [±3.59] |

Table 5: Comparison of demographics between main sample group and the subset which includes those participants for whom the timing of hospital admission was available

|                                 | Main sam |       | (n=389)       |        | Subset | (n=82)     |
|---------------------------------|----------|-------|---------------|--------|--------|------------|
|                                 |          | (n)   | %             |        | (n)    | %          |
| Employment                      | (n=389)  |       | 100%          | (n=82) |        | 100%       |
| Full-time                       |          | (315) | 81.0%         |        | (69)   | 84.1%      |
| Self-employed                   |          | (17)  | 4.4%          |        | (4)    | 4.9%       |
| Part-time                       |          | (23)  | 5.9%          |        | (5)    | 6.1%       |
| Maternity leave                 |          | (10)  | 2.6%          |        | (1)    | 1.2%       |
| Unemployed                      |          | (14)  | 3.6%          |        | (1)    | 1.2%       |
| Prefer not to say               |          | (6)   | 1.5%          |        | (1)    | 1.2%       |
| Other** = Student MW,           |          | (4)   | 1.0%          |        | (1)    | 1.2%       |
| Shielding, Student, FT          |          |       |               |        |        |            |
| undergrad                       |          |       |               |        |        |            |
| Highest level of academic       | (n=377)  |       | 96.9%         | (n=82) |        | 100%       |
| achievement                     |          |       |               |        |        |            |
| GCSE                            |          | (29)  | 7.7%          |        | (6)    | 7.3%       |
| A Level or equivalent           |          | (52)  | 13.8%         |        | (12)   | 14.6%      |
| Degree or equivalent            |          | (177) | 46.9%         |        | (30)   | 36.6%      |
| Masters or equivalent           |          | (95)  | 25.2%         |        | (27)   | 32.9%      |
| PhD                             |          | (24)  | 6.4%          |        | (7)    | 8.5%       |
| Relationship Status             | (n=389)  |       | 1 <b>00</b> % | (n=82) |        | 100%       |
| Married                         |          | (213) | 54.8%         |        | (48)   | 58.5%      |
| Single                          |          | (10)  | 2.6%          |        | (1)    | 1.2%       |
| Partner                         |          | (155) | 39.8%         |        | (33)   | 40.2%      |
| Widow                           |          | (0)   | 0%            |        | (0)    | 0%         |
| Prefer not to say               |          | (7)   | 1.8%          |        | (0)    | 0%         |
| Other = Civil partnership,      |          | (4)   | 1.0%          |        | (0)    | 0%         |
| Engaged, Married common-        |          |       |               |        |        |            |
| law, Co-habiting                |          |       |               |        |        |            |
| Ethnic origin                   | (n=389)  |       | 100%          | (n=82) |        | 100%       |
| White                           |          | (295) | 75.8%         |        | (68)   | 82.9%      |
| Mixed                           |          | (19)  | 4.9%          |        | (0)    | 0%         |
| Asian or Asian British          |          | (41)  | 10.5%         |        | (10)   | 12.2%      |
| Black or Black British          |          | (17)  | 4.4%          |        | (1)    | 1.2%       |
| Arab or other ethnic group      |          | (2)   | 0.5%          |        | (1)    | 1.2%       |
| Other = Kurdish, Chinese, Black |          | (15)  | 3.9%          |        | (2)    | 2.4%       |
| African, Japanese, Moroccan,    |          |       |               |        |        |            |
| Indian, Latin American, South   |          |       |               |        |        |            |
| East Asian, Brazilian, British  |          |       |               |        |        |            |
| Chinese                         |          |       |               |        |        |            |
| Age (years)                     | (n=183)  |       | 47.0%         | (n=55) |        | 67.1%      |
| 22-25                           |          | (17)  | 9.3%          |        | (7)    | 12.7%      |
| 26-30                           |          | (52)  | 28.4%         |        | (12)   | 21.8%      |
| 31-35                           |          | (83)  | 45.4%         |        | (28)   | 50.9%      |
| 36-40                           |          | (31)  | 16.9%         |        | (8)    | 14.6%      |
| Mean [SD]                       |          | 31.4  | 13 [±3.98]    |        | 31.2   | 24 [±3.34] |

Table 6: Comparison of PCS and WDEQ-A scores between main sample group and the total postnatal questionnaire respondents

| Measure           | Main sample<br>group<br>(n=389) |         |         | Range    |         | Tot<br>Respond<br>PN<br>(n=1 | Range   |          |
|-------------------|---------------------------------|---------|---------|----------|---------|------------------------------|---------|----------|
|                   |                                 | %       | n       |          |         | %                            | n       |          |
| PCS               | (n=381)                         |         |         |          | (n=179) |                              |         |          |
| Cut-off score <20 |                                 | 71.9%   | (274)   |          |         | 74.9%                        | (134)   |          |
| Cut-off score ≥20 |                                 | 28.1%   | (107)   |          |         | 25.1%                        | (45)    |          |
| Cut-off score ≥30 |                                 | 7.6%    | (29)    |          |         | 5.6%                         | (10)    |          |
| Mean [SD]         |                                 | 14.62 [ | ±9.41]  | 0 – 47   |         | 14.26 [                      | ± 8.53] | 0 – 42   |
| WDEQ-A            | (n=358)                         |         |         |          | (n=172) |                              |         |          |
| FOC ≤85           |                                 | 89.4%   | (320)   |          |         | 91.3%                        | (157)   |          |
| FOC ≥85           |                                 | 10.6%   | (38)    |          |         | 8.7%                         | (15)    |          |
| Mean [SD]         |                                 | 60.36 [ | £20.67] | 10 - 148 |         | 59.80 [±                     | ±19.69] | 23 – 125 |

Table 7: Comparison of PCS and WDEQ-A scores between main sample group and the subset

| Measure           |         | gr    | sample<br>oup<br>:389) | Range    |        | Subset<br>(n=82)  | Range    |
|-------------------|---------|-------|------------------------|----------|--------|-------------------|----------|
|                   |         | %     | n                      |          |        | % n               |          |
| PCS               | (n=381) |       |                        |          | (n=79) |                   |          |
| Cut-off score <20 |         | 71.9% | (274)                  |          |        | 72.2% <i>(57)</i> |          |
| Cut-off score ≥20 |         | 28.1% | (107)                  |          |        | 27.8% (22)        |          |
| Cut-off score ≥30 |         | 7.6%  | (29)                   |          |        | 6.3% (5)          |          |
| Mean [SD]         |         | 14.62 | [±9.41]                | 0 – 47   |        | 14.00 [± 8.68]    | 0 – 39   |
| WDEQ-A            | (n=358) |       |                        |          | (n=79) |                   |          |
| FOC ≤85           |         | 89.4% | (320)                  |          |        | 92.4% <i>(73)</i> |          |
| FOC ≥85           |         | 10.6% | (38)                   |          |        | 7.6% <i>(6)</i>   |          |
| Mean [SD]         |         | 60.36 | [±20.67]               | 10 – 148 |        | 58.20 [±19.49]    | 23 – 125 |

Table 8: Comparison of the number of days postnatal between total PNQ respondents and the subset

|                                      | Total PNQ                         |                   | Subset     |                 |
|--------------------------------------|-----------------------------------|-------------------|------------|-----------------|
|                                      | respondents                       | 5                 | (n=82)     |                 |
|                                      | (n=183)                           |                   |            |                 |
|                                      |                                   |                   |            |                 |
| No of days postpats                  | al that narticinant               | s samplated the [ | NO         |                 |
| No. of days postnata                 |                                   | -                 |            |                 |
| No. of days postnata<br>10 – 20 days | al that participant<br><i>(3)</i> | s completed the I | PNQ<br>(2) | 2.44%           |
|                                      |                                   | -                 |            | 2.44%<br>69.51% |
| 10 – 20 days                         | (3)                               | 1.6%              | (2)        |                 |

# **6.4** Chapter summary

This chapter reported the results to the primary aim of the RETHINK study. It has also provided evidence contributing to the validity for using case complete analysis to handle missing data by demonstrating that the smaller sample group, caused by participants being lost to follow-up through study progression, were relatively comparative and sufficient to meet the exploratory requirements of the study objectives.

The following 3 chapters provide the findings to the remaining objectives defined for the RETHINK study.

# Chapter 7 The RETHINK study: objectives i and ii

#### 7.1 Introduction

This chapter reports the results from quantitative analyses of the first two objectives stipulated for the RETHINK study together with a discussion and recommendations for clinical practice and future research. All objectives were defined in Chapter 5 Section 5.3 together with the underpinning methods for analyses.

The objectives reported in this chapter are:

Objective i: To explore if there is an association between pain catastrophising and specified birth outcomes including whether pain catastrophising acts as a predictor for mental health issues, ongoing treatment or professional support, and/or pain as self-defined by the participant at approximately 3 weeks postnatal (see Section 7.2.1).

Objective ii: To explore whether there is an association between pain catastrophising, the timing of admission to hospital when women are in labour, and the specified birth outcomes (see Section 7.2.2).

Results in this chapter are presented in tabular and narrative form.

# 7.2 Results to Objectives i and ii.

7.2.1 Objective i: To explore if there is an association between pain catastrophising and specified birth outcomes including whether pain catastrophising acts as a predictor for mental health issues ongoing treatment or professional support, and/or pain as self-defined by the participant at approximately 3 weeks postnatal.

All respondents to the PNQ were included in the analyses for this outcome (n=183).

Overall, 21.2% of respondents to the PNQ reported a mental health issue since giving birth. Out of these respondents, 28.9% also reported receiving treatment or professional support for their mental health.

There was a significant association (p=.037) between mental health issues since giving birth and pain catastrophising at the higher cut-off point (PCS scores  $\geq$ 30), but this association was not seen at the lower cut-off point (PCS scores  $\geq$ 20) (Table 9).

Pain catastrophising, at either cut-off point (≥20 or ≥30), was not associated with participants reporting receiving treatment or professional support for mental health.

Participants reporting PCS scores  $\geq$ 30 appeared to be experiencing more ongoing pain since they gave birth for which they were receiving treatment, including taking regular pain relief medication, than those reporting PCS scores  $\geq$ 20. However, the alpha level for significance was not met for participants experiencing ongoing pain since giving birth for PCS scores at either cut-off point ( $\geq$ 20 or  $\geq$ 30).

Table 9: Crosstabulation of PCS scores against variables reporting postnatal issues of ongoing pain, ongoing mental health since birth and receiving treatment or professional support for mental health percentages by column

|               |         |            |       |          | Pearson    |     |       |     |       | Pearson | Fisher's |
|---------------|---------|------------|-------|----------|------------|-----|-------|-----|-------|---------|----------|
|               |         | PC         | S     |          | Chi-       |     | PC    | S   |       | Chi-    | Exact    |
|               |         | score      | ≥20   |          | Square     |     | score | ≥30 |       | Square  | 2-sided  |
|               |         |            |       |          | Asympt.    |     |       |     |       | Asympt. |          |
|               |         |            |       |          | Signif.    |     |       |     |       | Signif. |          |
|               |         | No         |       | Yes      |            |     | No    |     | Yes   |         |          |
|               | n       | %          | n     | %        | р          | n   | %     | n   | %     | р       | р        |
|               |         |            |       |          | Value      |     |       |     |       | Value   | Value    |
| Ongoing pain  | since   | birth      |       |          |            |     |       |     |       |         |          |
| No (n=102)    | 74      | 55.2%      | 28    | 62.2%    |            | 98  | 58.0% | 4   | 40.0% |         |          |
| Yes (n=77)    | 60      | 44.8%      | 17    | 37.8%    | .412       | 71  | 42.0% | 6   | 60.0% | .264    | -        |
| Mental healt  | h issue | s since bi | rth   |          |            |     |       |     |       |         |          |
| No (n=141)    | 109     | 81.3%      | 32    | 71.1%    |            | 136 | 80.5% | 5   | 50.0% |         |          |
| Yes (n=38)    | 25      | 18.7%      | 13    | 28.9%    | .146       | 33  | 19.5% | 5   | 50.0% | -       | .037     |
| Receiving tre | atmen   | t or profe | ssion | al suppo | rt for men | tal |       |     |       |         |          |
| health        |         |            |       |          |            |     |       |     |       |         |          |
| No (n=167)    | 124     | 93.2%      | 43    | 95.6%    |            | 158 | 94.0% | 9   | 90.0% |         |          |
| Yes (n=11)    | 9       | 6.8%       | 2     | 4.4%     | .732       | 10  | 6.0%  | 1   | 10.0% | -       | .481     |

There was only one other birth outcome that demonstrated a significant association with pain catastrophising and that was for those participants receiving prostaglandin for the induction of labour (Table 10). This significant association was only seen at the higher pain catastrophising score ( $\geq$ 30). There was no association between the variables artificial rupture of membranes, or oxytocin use (used in the process of induction of labour or augmentation of labour) and PCS scores at either cut-off point ( $\geq$ 20 or  $\geq$ 30).

Table 10: Crosstabulation of PCS scores against variables reporting induction of labour and/or augmentation variables % percentages by column

|                |         |          |               |       | Pearson |     |       |     |       | Pearson | Fisher's |
|----------------|---------|----------|---------------|-------|---------|-----|-------|-----|-------|---------|----------|
|                |         | P        | CS            |       | Chi-    |     | PC    | :S  |       | Chi-    | Exact    |
|                |         | score    | e ≥ <b>20</b> |       | Square  |     | score | ≥30 |       | Square  | 2-sided  |
|                |         |          |               |       | Asympt. |     |       |     |       | Asympt. |          |
|                |         |          |               |       | Signif. |     |       |     |       | Signif. |          |
|                |         | No       |               | Yes   | р       |     | No    |     | Yes   | р       | р        |
|                |         |          |               |       | Value   |     |       |     |       | Value   | Value    |
|                | n       | %        | n             | %     |         | n   | %     | n   | %     |         |          |
| Prostaglandi   | ns      |          |               |       |         |     |       |     |       |         |          |
| No (n=125)     | 96      | 71.6%    | 29            | 60.4% |         | 121 | 70.8% | 4   | 36.4% |         |          |
| Yes (n=57)     | 38      | 28.4%    | 19            | 39.6% | .150    | 50  | 29.2% | 7   | 63.6% | -       | .038     |
| Artificial rup | ture of | f membra | ines          |       |         |     |       |     |       |         |          |
| No (n=130)     | 98      | 73.1%    | 32            | 68.1% |         | 122 | 71.3% | 8   | 80.0% |         |          |
| Yes (n=51)     | 36      | 26.9%    | 15            | 31.9% | .508    | 49  | 28.7% | 2   | 20.0% | -       | .728     |
| Oxytocin       |         |          |               |       |         |     |       |     |       |         |          |
| No (n=123)     | 90      | 68.2%    | 33            | 70.2% |         | 114 | 67.9% | 9   | 81.8% |         |          |
| Yes (n=56)     | 42      | 31.8%    | 14            | 29.8% | .797    | 54  | 32.1% | 2   | 18.2% | .333    | -        |

Considering PCS scores ( $\geq 20$  or  $\geq 30$ ) and variables reporting participants' mode of birth, there were no results that reached the alpha level (p=0.05) (Table 11).

Table 11: Crosstabulation of PCS scores against variables reporting mode of birth % percentages by row

|               |         | P(<br>score |         |           | Pearson<br>Chi-<br>Square<br>Asympt. |     | PC<br>score |    |      | Pearson<br>Chi-<br>Square<br>Asympt. | Fisher's<br>Exact<br>2-sided |
|---------------|---------|-------------|---------|-----------|--------------------------------------|-----|-------------|----|------|--------------------------------------|------------------------------|
|               |         |             |         |           | Signif.                              |     |             |    |      | Signif.                              |                              |
|               |         | No          |         | Yes       | р                                    |     | No          | ,  | Yes  | р                                    | р                            |
|               |         |             |         |           | Value                                |     |             |    |      | Value                                | Value                        |
|               | n       | %           | n       | %         |                                      | n   | %           | n  | %    |                                      |                              |
| Spontaneous   | s vagin | al birth    |         |           |                                      |     |             |    |      |                                      |                              |
| No (n=89)     | 66      | 74.2%       | 23      | 25.8%     |                                      | 85  | 95.5%       | 4  | 4.5% |                                      |                              |
| Yes (n=96)    | 71      | 74.0%       | 25      | 26.0%     | .975                                 | 89  | 92.7%       | 7  | 7.3% | .421                                 | -                            |
| Forceps birth | 1       |             |         |           |                                      |     |             |    |      |                                      |                              |
| No (n=155)    | 116     | 74.8%       | 39      | 25.2%     |                                      | 145 | 93.5%       | 10 | 6.5% |                                      |                              |
| Yes (n=28)    | 20      | 71.4%       | 8       | 28.6%     | .704                                 | 28  | 100.0%      | 0  | 0.0% | -                                    | .364                         |
| Emergency c   | aesare  | an sectio   | n birt  | h         |                                      |     |             |    |      |                                      |                              |
| No (n=139)    | 104     | 74.8%       | 35      | 25.2%     |                                      | 132 | 95.0%       | 7  | 5.0% |                                      |                              |
| Yes (n=45)    | 33      | 73.3%       | 12      | 26.7%     | .842                                 | 42  | 93.3%       | 3  | 6.7% | -                                    | .708                         |
| Ventouse bir  | th      |             |         |           |                                      |     |             |    |      |                                      |                              |
| No (n=172)    | 126     | 73.3%       | 46      | 26.7%     |                                      | 162 | 94.2%       | 10 | 5.8% |                                      |                              |
| Yes (n=12)    | 11      | 91.7%       | 1       | 8.3%      | .302                                 | 12  | 100.0%      | 0  | 0    | -                                    | 1.000                        |
| Elective caes | arean   | section b   | irth    |           |                                      |     |             |    |      |                                      |                              |
| No (n=170)    | 127     | 74.7%       | 43      | 25.3%     |                                      | 160 | 94.1%       | 10 | 5.9% |                                      |                              |
| Yes (n=14)    | 10      | 71.4%       | 4       | 28.6%     | .756                                 | 14  | 100.0%      | 0  | 0.0% | -                                    | 1.000                        |
| Elective caes | arean   | section b   | irth fo | or materr | nal reques                           | t   |             |    |      |                                      |                              |
| No (n=181)    | 135     | 74.6%       | 46      | 25.4%     |                                      | 171 | 94.5%       | 10 | 5.5% |                                      |                              |
| Yes (n=3)     | 2       | 66.7%       | 1       | 33.3%     | 1.000                                | 3   | 100.0%      | 0  | 0.0% | -                                    | 1.000                        |

Data were gathered on the timing of each stage of labour for each participant.

However, these data did not appear reliable due to errors in reporting and omissions, therefore, these data were not analysed.

7.2.2 Objective ii: To explore whether there is an association between pain catastrophising, the timing of admission to hospital when women are in labour, and the specified birth outcomes.

Only respondents for whom the timing of hospital admission (Latent Vs Active variable) was available were applicable to answer this outcome (subset n=82), thus reducing the sample size considerably. When considering PCS scores  $\geq$ 30 the results were particularly affected by this smaller sample size, and it was unfeasible to draw conclusions. Therefore, where applicable, all remaining analyses in this chapter use the PCS cut-off points <20 or  $\geq$ 20, and tests for significance are not considered. Additionally, the remaining analyses in this chapter are limited by the very small sample size and should be considered with caution.

Above, Table 9 showed that out of the total number of responses to the question (n=179) 21.2% reported having ongoing mental health issues since giving birth, and that PCS scores ≥30 were significantly associated with these issues.

Table 12 and Table 13, below, added an additional layer by introducing the variable of timing of hospital admission (Latent Vs Active) into analyses. Out of those responding to the question (n=79) 19.0% reported an ongoing mental issue since birth.

On inspection of the results displayed in Table 12 reporting PCS scores <20, there appears to be a greater tendency for ongoing mental health issues postnatal for participants who were admitted during latent labour (35.3%) when compared to those who were admitted during the active labour (12.5%). This tendency is similarly reflected in Table 13 for those reporting PCS scores ≥20 which show that 22.2% of those participants admitted in latent labour report ongoing mental health issues since birth compared to 15.4% of those admitted in active labour. Relatedly, for participants reporting low (<20) and higher (≥20) PCS scores, there was a tendency for those

receiving treatment or professional support for mental health to have been admitted during latent labour.

The same consistent tendencies were not seen between PCS scores <20 and ≥20, the timing of hospital admission (Latent Vs Active) and those reporting ongoing pain since giving birth (Table 12 and Table 13).

Table 12: Crosstabulation of PCS scores <20, the timing of hospital admission (Latent Vs Active) and three postnatal variables % percentages by column

| PCS score   | Latent Vs Active phase hospital |       |        |       |  |  |  |
|---|---------------------------------|-------|--------|-------|--|--|--|
| <20   | admission                       |       |        |       |  |  |  |
|   | L                               | atent | Active |       |  |  |  |
|   | n %                             |       | n      | %     |  |  |  |
| Ongoing pain since birth                                      |                                 |       |        |       |  |  |  |
| (no=32)   | 9                               | 52.9% | 23     | 57.5% |  |  |  |
| (yes=25)  | 8                               | 47.1% | 17     | 42.5% |  |  |  |
| Ongoing mental health issues since birth                      |                                 |       |        |       |  |  |  |
| (no=46)   | 11                              | 64.7% | 35     | 87.5% |  |  |  |
| (yes=11)  | 6                               | 35.3% | 5      | 12.5% |  |  |  |
| Receiving treatment or professional support for mental health |                                 |       |        |       |  |  |  |
| (no=52)   | 14                              | 82.4% | 38     | 95.0% |  |  |  |

(yes=5)

3

17.6% 2

5.0%

Table 13: Crosstabulation of PCS scores ≥20, the timing of hospital admission (Latent Vs Active) and three postnatal variables % percentages by column

| PCS score   | Latent Vs Active phase hospital |             |        |       |  |  |  |
|---|---------------------------------|-------------|--------|-------|--|--|--|
| ≥20   | admission                       |             |        |       |  |  |  |
|   | L                               | atent       | Active |       |  |  |  |
|   | n %                             |             | n      | %     |  |  |  |
| Ongoing pain since birth                                      |                                 |             |        |       |  |  |  |
| (no=16)   | 7                               | 77.8%       | 9      | 69.2% |  |  |  |
| (yes=6)   | 2                               | 22.2%       | 4      | 30.8% |  |  |  |
| Ongoing men   | tal hea                         | alth issues | since  | birth |  |  |  |
| (no=18)   | 7                               | 77.8%       | 11     | 84.6% |  |  |  |
| (yes=4)   | 2                               | 22.2%       | 2      | 15.4% |  |  |  |
| Receiving treatment or professional support for mental health |                                 |             |        |       |  |  |  |
| (no=20)   | 8                               | 88.9%       | 12     | 92.3% |  |  |  |
| (yes=2)   | 1                               | 11.1%       | 1      | 7.7%  |  |  |  |

Women reporting PCS scores <20 appeared more likely to have an artificial rupture of membranes if admitted to hospital during latent labour than women who reported PCS scores ≥20 (Table 14 and Table 15).

Table 14: Crosstabulation of PCS scores <20, the timing of hospital admission (Latent Vs Active) and two augmentation of labour variables % percentages by column

| PCS score       | Latent Vs Active phase hospital |        |        |       |  |  |  |  |
|-----------------|---------------------------------|--------|--------|-------|--|--|--|--|
| <20             | admission                       |        |        |       |  |  |  |  |
|                 | I                               | Latent | Active |       |  |  |  |  |
|                 | n %                             |        | n      | %     |  |  |  |  |
| Artificial rupt | Artificial rupture of membranes |        |        |       |  |  |  |  |
| (no=32)         | 6                               | 66.7%  | 26     | 86.7% |  |  |  |  |
| (yes=7)         | 3                               | 33.3%  | 4      | 13.3% |  |  |  |  |
| Oxytocin        |                                 |        |        |       |  |  |  |  |
| (no=35)         | 8                               | 88.9%  | 27     | 90.0% |  |  |  |  |
| (yes=4)         | 1                               | 11.1%  | 3      | 10.0% |  |  |  |  |

Table 15: Crosstabulation of PCS scores ≥20, the timing of hospital admission (Latent Vs Active) and two augmentation of labour variables % percentages by column

| PCS score        | Lat   | Latent Vs Active phase hospital |         |        |  |  |  |
|------------------|-------|---------------------------------|---------|--------|--|--|--|
| ≥20              |       | adm                             | nission | ission |  |  |  |
|                  |       | Latent                          | Active  |        |  |  |  |
|                  | n %   |                                 | n       | %      |  |  |  |
| Artificial rupto | ure ( | of membra                       | nes     |        |  |  |  |
| (no=11)          | 5     | 71.4%                           | 6       | 66.7%  |  |  |  |
| (yes=5)          | 2     | 28.6%                           | 3       | 33.3%  |  |  |  |
| Oxytocin         |       |                                 |         |        |  |  |  |
| (no=15)          | 7     | 100.0%                          | 8       | 88.9%  |  |  |  |
| (yes=1)          | 0     | 0.0%                            | 1       | 11.1%  |  |  |  |

The tendency to not have a spontaneous vaginal birth if admitted during latent labour was greater for those participants who reported high PCS scores (≥20) (Table 17).

At both low (<20) and higher PCS scores (≥20) there appeared to be a slightly higher tendency for participants who were admitted to hospital during active labour to have a forceps birth when compared to those being admitted during latent labour (Table 16 and Table 17).

For participants who reported PCS scores <20 and ≥20 there appeared a higher tendency to have an emergency caesarean section if admitted to hospital during latent labour (22.2% and 28.6%) than those participants who were admitted during active labour (Table 16 and Table 17).

It was not possible to compare the results between PCS scores <20 and ≥20, the timing of hospital admission and ventouse assisted birth (Table 16 and Table 17) because for participants who reported PCS scores ≥20 (Table 17) there were no ventouse assisted births.

Table 16: Crosstabulation of PCS scores <20, the timing of hospital admission (Latent Vs Active) and four mode of birth variables % percentages by column

| PCS score <20                     | Latent Vs Active phase hospital admission |       |    |       |  |  |  |
|-----------------------------------|---|-------|----|-------|--|--|--|
|                                   | Latent                                    |       | A  | ctive |  |  |  |
|                                   | n   | %     | n  | %     |  |  |  |
| Spontaneous vaginal birth         |   |       |    |       |  |  |  |
| (no=8)                            | 2   | 22.2% | 6  | 20.0% |  |  |  |
| (yes=31)                          | 7   | 77.8% | 24 | 80.0% |  |  |  |
| Ventouse birth                    |   |       |    |       |  |  |  |
| (no=36)                           | 8   | 88.9% | 28 | 93.3% |  |  |  |
| (yes=3)                           | 1   | 11.1% | 2  | 6.7%  |  |  |  |
| Forceps birth                     |   |       |    |       |  |  |  |
| (no=32)                           | 8   | 88.9% | 24 | 80.0% |  |  |  |
| (yes=7)                           | 1   | 11.1% | 6  | 20.0% |  |  |  |
| Emergency caesarean section birth |   |       |    |       |  |  |  |
| (no=35)                           | 7   | 77.8% | 28 | 93.3% |  |  |  |
| (yes=4)                           | 2   | 22.2% | 2  | 6.7%  |  |  |  |

Table 17: Crosstabulation of PCS scores ≥20, the timing of hospital admission (Latent Vs Active) and four mode of birth variables % percentages by column

| PCS score                         | Latent Vs Active phase hospital |        |   |        |  |  |  |
|-----------------------------------|---------------------------------|--------|---|--------|--|--|--|
| ≥20                               | admission                       |        |   |        |  |  |  |
|                                   | Latent                          |        | A | ctive  |  |  |  |
|                                   | n %                             |        | n | %      |  |  |  |
| Spontaneous vaginal birth         |                                 |        |   |        |  |  |  |
| (no=4)                            | 3                               | 42.9%  | 1 | 11.1%  |  |  |  |
| (yes=12)                          | 4                               | 57.1%  | 8 | 88.9%  |  |  |  |
| Ventouse birt                     | Ventouse birth                  |        |   |        |  |  |  |
| (no=16)                           | 7                               | 100.0% | 9 | 100.0% |  |  |  |
| (yes=0)                           | 0                               | 0.0%   | 0 | 0.0%   |  |  |  |
| Forceps birth                     |                                 |        |   |        |  |  |  |
| (no=12)                           | 6                               | 85.7%  | 6 | 66.7%  |  |  |  |
| (yes=4)                           | 1                               | 14.3%  | 3 | 33.3%  |  |  |  |
| Emergency caesarean section birth |                                 |        |   |        |  |  |  |
| (no=13)                           | 5                               | 71.4%  | 8 | 88.9%  |  |  |  |
| (yes=3)                           | 2                               | 28.6%  | 1 | 11.1%  |  |  |  |

#### 7.3 Discussion

The following discussion will be sectioned under the main themes identified from the exploration of objectives i and ii. Each themed section will be followed by recommendations for clinical practice and future research.

# 7.3.1 Pain catastrophising is predictive of postnatal mental health issues.

The RETHINK study found a significant association (p=0.037) between high PCS scores (≥30) and mental health issues experienced since giving birth. Only two other recent studies have considered the impact of pain catastrophising on women's mental health postnatally (Ferber et al. 2005; Zeng et al. 2020). Both these studies first recorded PCS scores (Sullivan et al. 1995) once labour had commenced. However, the RETHINK study is the first study to explore whether pain catastrophising acts as an antenatal predictor

for mental health issues postnatally in a population of nulliparous women experiencing a pregnancy at low obstetric risk and who did not have a current or pre-existing mental health condition requiring medication or specialised care on antenatal entry into the study. Understanding how pain catastrophising impacts on women's mental health postnatally is important for the provision of preventive and intervention strategies to maintain well-being.

Mental health issues are of concern because they can have a harmful impact on the woman and her child (Thomas 2024). In the UK death attributed to mental health related concerns, including suicide, is the fourth leading cause of maternal death (Knight et al. 2023). Maternal mental health remains high on the national agenda for improving maternal and neonatal services (NHS England 2023a). There are associated concerns of poorer long-term health outcomes for women, a range of adverse outcomes for their child (Stein et al. 2014; Hutchens and Kearney 2020), there can be an impact on other family members including the woman's partner (Davey et al. 2006; Schumacher et al. 2008), and there can be associated socioeconomic costs both to the woman and her family, and wider society (Bauer et al. 2016; Bauer et al. 2022).

The exact nature of the mental health issue RETHINK study participants experienced was not asked but non-psychotic disorders are reported as the most common morbidities experienced by women during the perinatal period (Howard et al. 2014). During the postnatal period many women experience a postnatal mental health disorder, and this is primarily postnatal depression (Howard and Khalifeh 2020). Although many women also report experiencing the 'baby blues'. The 'baby blues' are thought to affect 50-80% of postnatal women and is a condition that is considered self limiting and includes transient, low mood or mild depressive symptoms. The 'baby blues' usually resolve in the first one to two weeks after giving birth (Howard et al. 2014; Jones and Shakespeare 2014). The RETHINK study participants were surveyed after they reached three weeks postnatal. Therefore, unlikely to be experiencing the 'baby blues' at the time of questioning but a limitation is that respondents to the question were not asked to specify their symptoms, when their symptoms commenced, the severity or duration of their symptoms, or the impact on their daily lives. However, respondents who answered positively to the question considered that

what they experienced was a mental health issue to them. Additionally, if participants were considering the 'baby blues' as being an issue there is the risk for the later development of postnatal depression (Beck 1996; Beck 2001). A suggestion supported by Ferber et al. (2005) who found that pain catastrophising was associated with the 'baby blues' and later social functioning. Ferber et al. (2005) chose to report on social functioning citing it as being considerably impaired in women with postnatal depression.

Multiple factors have been attributed to contributing to postnatal depression including biological factors, social and psychological factors, genetic factors and important life experiences (O'Hara and Swain 1996; Yim et al, 2015; Hutchens and Kearney 2020; Zhao and Zhang 2020; Gastaldon et al. 2022; Liu et al. 2022; Mo et al. 2022; Wang et al. 2021). In Hutchens and Kearney's (2020) review of evidence they identified 25 varied risk factors for postnatal depression. The strongest predictors were prenatal depression and abuse. Pain catastrophising does not feature in their list of identified risk factors for postnatal depression. One reason for pain catastrophising not being mentioned in Hutchens and Kearney's (2020) study is likely due to the lack of research available at the time that considered the impact of pain catastrophising on postnatal mental health.

In another review of evidence pain was considered. This study by Mo et al. (2022) considered the association between perinatal pain and postnatal depression. They define perinatal pain as pain that occurs from 28 weeks gestation to one week after childbirth. Again, pain catastrophising is missing as a specified predictor of postnatal depression but some studies that involved pain catastrophising as a measure are included in the review. The results of their review showed that perinatal pain increased the risk of postnatal depression, and labour epidural analgesia lowered it. However, Du et al. (2022) considered the evidence for labour epidural analgesia much less convincing citing heterogeneity between studies and methodological concerns for their doubt. They proposed that it would be better to switch focus from comparing the use or non-use of labour epidural on postnatal depression to instead examining pain and the complex intermediating factors on pain experience in the development of postnatal depression. The RETHINK study contributes to this area of knowledge by

identifying that high PCS scores ( $\geq$ 30) during the antenatal period were significantly associated with mental health issues postnatal. Furthermore, the RETHINK study identified that the demographic characteristics age and ethnicity were significantly associated with lower PCS scores ( $\geq$ 20) and experiencing higher levels of antenatal pain and FOC were significantly associated with PCS scores at both the lower and higher cut-off points ( $\geq$ 20 and  $\geq$ 30). This corroborates Du et al's (2022) earlier call for the need for greater holistic understanding about women's pain experience.

# 7.3.1.1 Recommendation for clinical practice and future research

The RETHINK study findings suggest that screening for women who pain catastrophise could also be part of an early support intervention for the prevention of postnatal mental health issues.

Future studies can confirm these findings and unpick the complexity surrounding intermediating factors, provide clarity on the specific postnatal mental health issues experienced, and identify how women at risk can be supported effectively. Maternity services should prioritise holistic screening and targeted support interventions, during pregnancy and the postnatal period, to prevent or limit the development of postnatal mental health issues.

# 7.3.2 An explanation for how pain catastrophising might be associated with postnatal mental health issues.

Ferber et al. (2005) found that pain catastrophising (PCS scores ≥25), assessed during active labour and before administration of analgesia or anaesthesia, significantly predicted the 'baby blues' and postnatal social functioning. Ferber et al. (2005) also used the visual analogue scale (VAS) to measure the intensity of labour pain that participants were experiencing. They concluded that, because higher VAS scores and PCS scores were correlated but that higher VAS scores did not alone predict later maternal adjustments, it is the emotional and cognitive factors at work during the pain experience that are relevant to later postnatal maternal adjustments. Furthermore, intensity of labour pain assessed by other means, such as the French version of the McGill pain questionnaire (Melzack 1975 cited Boudou et al. 2007), has been linked

with postnatal mood disorders (Boudou et al. 2007; Kwok et al. 2013). Consistent with Ferber et al's (2005) work, the RETHINK study also found an association between pain catastrophising (PCS scores ≥30) and mental health issues postnatally. These similar findings offer some support to the idea that it is a particular mindset (i.e. pain catastrophising) which processes the labour pain experience and later affects postnatal mental health. But the RETHINK study significantly differed in the timing of when pain catastrophising was measured. Ferber et al. (2005) measured once labour had started, and the RETHINK study assessed pain catastrophising during the antenatal period. The timing of the measurement in the RETHINK study suggests that pain catastrophising can be detected prior to the actual painful experience of labour, which allows for timely intervention for the prevention or mitigation of postnatal mental health issues.

Similar to Ferber et al's (2005) suggestion, Whitburn et al. (2017) propose that it is a woman's cognitive processes during labour that are important because they construct and give meaning to her pain experience. They suggest pain catastrophising as being adversely involved in this process (Whitburn et al. 2017). How women reflect on their birthing experience is also important. Even without intervention or obstetric concerns surrounding labour and birth women might perceive their experience as traumatic (Gribbin 2017). As Beck (2004) describes, 'birth trauma lies in the eye of the beholder'. Although likely to be multifactorial, pain catastrophising is potentially one psychological predictor that is mediating and moderating cognitive processes during the antenatal, intrapartum, and postnatal periods which is yet to be sufficiently explained (Soet et al. 2003; Beck 2004; Boudou et al. 2007; Kwok et al. 2013; Gribbin 2017; McKelvin et al. 2021; Sun et al. 2022; Whitburn et al. 2017).

Having a particular mindset such as pain catastrophising could mediate a woman's cognitive processes during the antenatal intrapartum period. An early support intervention provided during the antenatal period may subsequently demonstrate benefit for women in the postnatal period. The RETHINK study found a significant association between antenatal pain catastrophising and FOC, strengthening the notion that pain catastrophising is a particular mindset that can be used to predict those women who may later go on to fear childbirth (Bartholomew et al. 2024). Other studies have identified FOC as a risk factor for postnatal depression and post-traumatic

stress disorder (PTSD) (Soderquist et al. 2009; Elmir et al. 2010; Garthus-Niegel et al. 2013; Grekin and O'Hara 2014; Monk et al. 2020). The highly significant association between pain catastrophising and FOC has implications for the identification of these women at risk of developing a postnatal mental health issue. The significant association between pain catastrophising and FOC supports the ideas suggested by Whitburn et al. (2017) and Feber et al. (2005) that it is particular mindsets that underpin a woman's experience of labour, her reflections on childbirth, her postnatal mental health and adjustments.

Importantly, the RETHINK study adds new knowledge that the cognitive mindset of pain catastrophising can be measured during the antenatal period and is predictive of later postnatal mental health issues.

### 7.3.2.1 Recommendation for clinical practice and future research

Midwives should be aware of the different ways in which women psychologically process their pregnancy, labour and postnatal experiences and how these psychological processes could affect women's mental health irrespective of whether there were obstetric concerns or interventions.

A future direction for research is to further understand how pain catastrophising is involved in the construction of the meaning of labour pain, and how these meanings might affect decision-making during labour, impact upon childbirth reflections, and postnatal mental health. Improved understanding holds potential for the early identification of these women at risk of developing poorer postnatal mental health and facilitates the development of a support intervention. This greater understanding carries with it the potential for targeted strategies to promote individualised care.

#### 7.3.3 Prevalence of postnatal mental health issues and treatment

# 7.3.3.1 Prevalence

Out of those women who responded to the question asking if they had experienced a mental health issue since giving birth over one in five (21.2%) said that they had.

Among those women with high PCS scores (≥30) the rate was even higher with 50%

reporting an issue. Both these figures are surprisingly high given that women with preexisting mental health conditions were excluded on entry to the study.

In the literature postnatal mental health studies tend to focus specifically on postnatal depression. Two recent studies estimated the worldwide prevalence of postnatal depression to be 17% (Shorey et al. 2018) and 17.22% (Wang et al. 2021), with higher income and more developed countries occupying the lower rates of prevalence of postnatal depression. Both these studies excluded the 'baby blues'. They also excluded pre-existing psychiatric history or depression, which is a similar exclusion criterion to the RETHINK study. Interestingly, Wang et al. (2021) identified postnatal depression prevalence in the UK as 21.5%. An overall prevalence figure very similar to that found in the RETHINK study for women reporting a postnatal mental health issue. Although Wang et al. (2021) cite multiple factors as contributing to postnatal depression they do not cite pain catastrophising as a risk factor. NICE (2016) quote prevalence for 'depression and anxiety' to be 15% to 20% of women in the first year after giving birth. However, all these figures are higher than those given by the WHO (date unknown) which cites that globally 13% of women in developed countries who have just given birth experience a mental disorder and that disorder is primarily depression.

It is challenging to make direct comparisons between studies and draw conclusions about the prevalence of postnatal mental health issues due to the heterogeneity between studies. For example, there are differences in the study populations, inclusion and exclusion criteria, differences in how and when the data were collected, and differences in the measurement of postnatal mental health illness or postnatal maternal adjustments (Ferber et al. 2005; Flink et al. 2009; Shorey et al. 2018; Hutchens and Kearney 2020; NICE 2016; Zeng et al. 2020; Wang et al. 2021; WHO ca. 2024).

#### 7.3.3.2 Treatment for postnatal mental health issues

Just over a quarter (28.9%) of women in the RETHINK study reporting a postnatal mental health issue reported receiving treatment or professional support for their mental health. Participants were not questioned on their reasons for not receiving

treatment or professional support for the ongoing mental health issues that they were experiencing since the birth of their baby. The reasons for only 28.9% of RETHINK participants receiving treatment or professional support for their mental health could be that:

- the mental health issue may have already resolved without the requirement of treatment,
- not all women are asked about their mental health postnatal (Harrison et al. 2023) despite it being a professional recommendation (NICE 2021a) and are therefore not referred for treatment,
- some women might normalise their mental illness including attributing mental health to adjusting to parenthood and hormones, and 'baby blues', or fear of negative perception or stigma (Dolman 2013; Mule et al. 2022),
- women might not have reported their issues due to a lack of trust in professionals or an unpreparedness for the line of questioning at their postnatal appointment, or they might have felt that they had limited time to fully discuss their issues (Mule et al. 2022; Webb et al. 2023),
- women may be fearful about the consequences of disclosure (Darwin et al.
   2016), or not know how they should feel (Dolman et al. 2013; Mule et al. 2022),
- they may be unaware of how they can logistically access professional support, or waiting for appointments from overstretched, unintegrated services
   (Dolman et al. 2013; Webb et al. 2023), or through fear of intervention from social services (NICE 2024).

Finally, a particular factor that may have affected the RETHINK study participants from seeking support or treatment for their mental health could have been due to the negative effects from the COVID-19 pandemic.

Women with pre-existing mental health conditions were excluded on entry to the RETHINK study. However, since the COVID-19 coronavirus pandemic it is estimated that common mental health disorders have been on a continuing upward trend (NHS England Digital 2023a). This factor is likely to have had an impact on the participants of the RETHINK study who were surveyed whilst COVID-19 was a global concern. A time

that saw, to some extent, the delivery of maternity services and mental health services restructured to limit the spread of the virus, and in some instances affected access to care (British Medical Association (BMA) 2023; Kasaven et al. 2023). Therefore, women may have been adversely affected by postnatal mental health issues but found that accessing support or treatment problematic.

# 7.3.3.2.1 Recommendations for clinical practice and future research

Considering that there were 547,244 births in hospitals in England from April 2022 to March 2023 (NHS England Digital 2023b), and the percentage of women who will experience postnatal mental health issues, a significant number of women will be affected by these conditions each year. The findings of this study suggest that many of these women may be more likely to suffer from postnatal mental health issues due to pain catastrophising. Furthermore, previous studies suggest that national figures could be an underestimate because some women are not asked about their mental health (Harrison et al. 2023), or they may not disclose or seek treatment for their mental health issues (Dolman 2013; Mule et al. 2022; Webb et al. 2023; NICE 2024). Given the impact of postnatal mental health issues on the woman, her child, and family, as well as the broader socioeconomic costs, the RETHINK study underscores the importance of effective communication, education, and screening for all women, along with targeted support interventions for those who pain catastrophise.

Finally with regards to screening for postnatal mental health issues, currently the UK National Screening Committee (2019) advice given online is that "screening for postnatal depression is not currently recommended". This is based on their report that there is "no accurate screening tests for postnatal depression" and that "it is not known if screening and treatment would improve health outcomes for mothers or babies". As a result of the exploratory work The RETHINK study indicated that there is a possible association between pain catastrophising and postnatal mental health issues. Previous studies have demonstrated success for treatment-related reductions in pain catastrophising, which have led to reductions in pain severity, depression, and post-traumatic stress symptoms (Tripp and Sullivan 2024). Further studies would be required to provide greater understanding about the longer term benefits of using the

PCS as a screening tool for postnatal mental health issues. In particular, studies could consider the connection between pain catastrophising and postnatal mental health issues, how this knowledge could be included in an antenatal support intervention, and whether this is acceptable to women.

# 7.3.4 Impact of pain catastrophising on other specified birth outcomes

The RETHINK study did not find any significant associations between pain catastrophising and the birth outcomes including artificial rupture of membranes, oxytocin administration, spontaneous vaginal birth, ventouse or forceps birth, or birth by elective or emergency caesarean section. However, the study did find a significant association between high PCS scores (≥30) and the administration of prostaglandins. To the author's knowledge there are no studies reporting on pain catastrophising and this birth outcome. However, Sydsjö et al. (2012) found that induction of labour was more common among those who feared childbirth and FOC has been found to be strongly associated with pain catastrophising (reported in integrated paper Chapter 6 Section 6.3 Bartholomew et al. (2024). It is possible that those women in the RETHINK study who reported high PCS scores could have requested and received an induction of labour or could have been more inclined to readily accept an induction of labour earlier than those women reporting lower PCS scores who may have chosen to delay having an induction and went on to labour spontaneously. Those women who may have requested or readily accepted an induction of labour could have done so as a coping strategy with the aim to control the event of labour and/or as a way to bring the pregnancy to an end so that their anxieties and anticipation surrounding labour and birth also came to an end. This is supported by findings from two studies which found an association between pain catastrophising assessed during the antenatal period and women choosing an elective caesarean section birth (Dehghani et al. 2014; Wilson et al. 2023). Although in these studies the women opting for an elective caesarean section were employing a strategy to avoid labour altogether.

It should also be noted that the women in the RETHINK study may have been affected by the COVID-19 pandemic. Gurol-Urganci et al. (2022) found small increases in the percentage rates of obstetric interventions, including induction of labour, over the first

year of the COVID-19 pandemic period, March 2020 to February 2021, when compared to the previous year. The COVID-19 pandemic milieu could have been one moderating factor between higher PCS scores and prostaglandin administration.

### 7.3.4.1 Recommendation for clinical practice and future research

These results again suggest the usefulness of the PCS as a screening tool in clinical practice. Midwives should explore with women their reasons for requesting an induction of labour and ensure they have appropriate support if they express particular fears and anxieties.

There is a scarcity of evidence available to compare the RETHINK study results. Therefore, it is recommended that future studies investigate the impact of pain catastrophising on birth outcomes including induction of labour.

# 7.3.5 Certain birth outcomes appear affected by the timing of hospital when stratified by PCS scores.

When considering the association between the timing of hospital admission and the specified birth outcomes the RETHINK study reflect results previously found in other studies that women experiencing a pregnancy at low obstetric risk of complications are exposed to an increased chance of interventions in labour and birth if they are admitted to hospital whilst in latent labour (McNiven 1998; Bailit et al. 2005; Davey et al. 2013; Lundgren et al. 2013; Neal et al. 2014; Tilden et al. 2015; Kauffman et al. 2016; Mikolajczyk et al. 2016; Rota 2018; Miller et al. 2020; Schick et al. 2020).

In particular women in the RETHINK study were less likely to have a spontaneous vaginal birth, and more likely to have an emergency caesarean section if they were admitted to hospital during latent labour than if they were admitted to hospital during active labour. These observations were seen whether women pain catastrophised (PCS scores  $\geq$ 20) or not (PCS scores  $\leq$ 20). But those women who reported PCS  $\geq$ 20 tended to be more likely to experience these adverse birth outcomes. Higher pain catastrophising scores ( $\geq$ 20 or  $\geq$ 30) did appear to impact on the timing of hospital admission with women tending to be admitted during latent labour if they pain

catastrophised (reported in integrated paper Chapter 6 Section 6.3 Bartholomew et al. 2024). Taking a holistic view of these results suggests that pain catastrophising could be mediating the timing of hospital admission meaning women are more likely to be hospitalised during latent labour, reducing women's chances of having a spontaneous vaginal birth and increasing their risk of giving birth by emergency caesarean section.

Women reporting low and higher PCS scores (<20 and ≥20) in the RETHINK study did appear to be more likely to have a forceps birth if admitted to hospital during active labour. This result is in contrast to a previous study by Rota et al. (2018) and differing to Mikolajczyk et al's (2016) study who found a woman's risk of having an instrumental birth did not differ according to the timing of hospital admission. Inconsistencies between study results reporting on the timing of hospital admission and birth outcomes is likely due to the heterogeneity that exists between them. Nevertheless, the evidence indicating that latent labour is associated with obstetric interventions is strong (McNiven 1998; Bailit et al. 2005; Davey et al. 2013; Lundgren et al. 2013; Neal et al. 2014; Tilden et al. 2015; Kauffman et al. 2016; Mikolajczyk et al. 2016; Rota 2018; Miller et al. 2020; Schick et al. 2020).

# 7.3.6 Pain catastrophising and latent phase hospital admission appears to influence postnatal mental health.

The RETHINK study does not have sufficient power to draw conclusions with certainty, but results do appear to converge with previous studies. Women in this study were more likely to report having a mental health issue and be receiving treatment for their mental health if they were admitted to hospital during latent labour. An increased incidence of postnatal mental health issues is associated with traumatic events experienced during childbirth (Yildiz et al. 2017; Rodríguez-Almagro et al. 2019) which have a ripple effect for new mothers (Beck 2015). Women in the RETHINK study reporting low PCS scores (<20) were more likely to report experiencing augmentation of labour via artificial rupture of membranes or oxytocin infusion if they were admitted during latent labour. Labour augmentation has also been implicated in negative childbirth reflections (Waldenström et al. 2004). Emergency caesarean section has been associated with traumatic events during childbirth which can lead to PTSD

(Benton et al. 2019; Grisbrook et al. 2022; Hüner et al. 2023). Results suggest that all the women participating in the RETHINK study, regardless of PCS scores, were more likely to experience an emergency caesarean section and less likely to have a spontaneous vaginal birth if admitted during latent labour. However, it appears that it was those women reporting PCS scores ≥20 who were at the greater risk of having an emergency caesarean section and less likely to have a spontaneous vaginal birth. More work is needed to understand if pain catastrophising has a mediating role between latent labour hospital admission, adverse birth outcomes such as an emergency caesarean section and postnatal mental health issues.

# 7.3.6.1 Recommendations for clinical practice and future research

Midwives should be aware that a woman's negative cognitions, such as pain catastrophising can impact their decision-making throughout labour and birth, which can reduce their chance of having a spontaneous vaginal birth, increase their chance of having a caesarean section, and subsequent postnatal mental health issues.

Further research is needed to unpick the complex relationship between pain catastrophising, the timing of hospital admission and birth outcomes. Future studies should include larger sample sizes and employ strategies to increase participant recruitment and retention to support adequate statistical power and allow for the investigation of the impact of pain catastrophising at different cut-off points i.e.  $\geq 20$  and  $\geq 30$ .

# 7.4 Chapter summary

An interesting finding from the RETHINK study suggests that pain catastrophising acts as an antenatal predictor for mental health issues postnatal in a population of nulliparous women experiencing a pregnancy at low obstetric risk and who did not have a current or pre-existing mental health condition requiring medication or specialised care on antenatal entry into the study. The results presented have shown that women who reported high pain catastrophising scores (≥30) during the antenatal period were more likely to experience postnatal mental health issues. This finding supports the idea that a pain catastrophising mindset brought to bear during labour

can affect a woman's reflections on her childbirth experience and negatively impact her postnatal mental health. Additionally, findings also indicated that this group of women who reported high PCS scores were more likely to accept an induction of labour with prostaglandins. These findings indicate that the PCS can be used as a predictive tool to identify this group of women who may benefit from an early support intervention.

Although the sample group was small meaning strong conclusions cannot be drawn the RETHINK study raises interesting questions about pain catastrophising and its relationship with the timing of hospital admission and certain birth outcomes in a UK population of healthy, pregnant, nulliparous women at low obstetric risk. If women were admitted to hospital during latent labour, irrespective of PCS score, then they had a lower chance of having a spontaneous vaginal birth, a greater chance of having an emergency caesarean section, and greater chance of experiencing and be receiving treatment for a postnatal mental health issue. The associations between the timing of hospital admission and certain birth outcomes varied depending on PCS scores.

Women who reported PCS scores ≥20 had a lower chance of having a spontaneous vaginal birth and a greater risk of having an emergency caesarean section. Although the mechanisms governing the relationship between latent labour hospital admission and obstetric intervention are undoubtedly complex the RETHINK study suggests that pain catastrophising may play a role in these two birth outcomes.

Further research involving larger sample sizes is required to confirm these findings and reveal the nature of the complex relationship between pain catastrophising, the timing of hospital admission and birth outcomes.

# Chapter 8 The RETHINK study: objectives iii and iv

#### 8.1 Introduction

This chapter reports the results from quantitative analyses of the second two objectives stipulated for the RETHINK study together with a discussion and recommendations for clinical practice and future research.

The objectives reported on in this chapter are:

Objective iii: To explore whether the simultaneous occurrence of pain catastrophising and FOC impact on the timing of hospital admission. (see Section 8.2.1).

Objective iv: To assess, by frequency, the pain management choices women are making at home and at hospital, then explore if these choices are affected by low (<20) versus higher (≥20) PCS scores (see Section 8.2.2).

Results in this chapter are presented in tabular and narrative form.

# 8.2 Results to Objectives iii and iv.

8.2.1 Objective iii: To explore whether the simultaneous occurrence of pain catastrophising and fear of childbirth impact on the timing of hospital admission.

Only respondents for whom the timing of hospital admission was available were applicable to answer this objective (subset n=82).

There appeared a higher tendency to be admitted to hospital during latent labour (33%) if participants reported higher PCS scores (≥20) and had FOC (WDEQ-A scores ≥85) when compared to the 5.9% of those that reported low PCS scores (<20) but had FOC (WDEQ-A scores ≥85) (Table 18: .

Table 18: Crosstabulation of PCS scores, FOC (WDEQ-A scores) and timing of hospital admission % percentages by row

|                        | WDEQ-A score ≥85 |       |   |      |  |
|------------------------|------------------|-------|---|------|--|
|                        |                  | No    |   | Yes  |  |
|                        | n                | %     | n | %    |  |
| PCS score <20          |                  |       |   |      |  |
| Timing of hospital adm | nission          |       |   |      |  |
| (Latent labour = 17)   | 16               | 94.1% | 1 | 5.9% |  |
| (Active labour =38)    | 37               | 97.4% | 1 | 2.6% |  |
|                        |                  |       |   |      |  |
| PCS score ≥20          |                  |       |   |      |  |
| Timing of hospital adm | nission          |       |   |      |  |

8.2.2 Objective iv: To assess, by frequency, the pain management choices women are making at home and at hospital, then explore if these choices are affected by low (<20) versus higher (≥20) PCS scores.

3

1

33.3%

7.7%

Objective iv is assessed using descriptive and inferential statistics.

66.7%

92.3%

12

The questions asked of participants:

(Latent labour = 9)

(Active labour = 13)

Question 9: 'What methods of relaxation, and pain relief did you use during your labour at home? Please select all that apply.'

Question 10: 'What methods of relaxation, and pain relief did you use during your labour in hospital? Please select all that apply.'

All except one participant in the identified subset responded to question 9 (n=81) on the PNQ and indicated the various methods of relaxation, and pain relief that they chose to use during their labour at home (Table 19). All participants in the identified subset (n=82) responded to question 10 and indicated the various methods of relaxation, and pain relief that they chose to use during their labour in hospital. When responding to questions 9 and 10 participants could select as many options as were applicable to them. There was a total of 297 selections made by the 81 participants to question 9, and a total of 409 responses to question 10 made by 82 participants.

Out of the total number of participants (n=81) who responded to question 9 80.2% employed breathing techniques for relaxation or pain management making it the most popular method to use at home (Table 19). Using a birth partner for support came second (65.4%) and third was paracetamol (43.2%). These top three methods of relaxation and pain management used at home accounted for 51.5% of the total responses to this question (Table 19).

Although no participant in the identified subset used a birthing pool at home, they did choose to use water for relaxation or pain management either by having a bath (32.1%) and/or shower (21.0%) (Table 19). These two water options combined together (n=43) accounted for 14.5% of the total number of responses (n=297) to this question which places water as the third most popular option to use for relaxation and pain management (Table 19).

Table 19: Showing the frequencies in the identified set of the pain management techniques that participants used whilst experiencing labour at home

| Methods of relaxation and pain management strategies used at home  Total number of participants who responded to question in the identified set n=81 | (n) | % of respondents choosing method | % of total responses |
|--|-----|----------------------------------|----------------------|
| Total number of  |     |                                  |                      |
| Total number of selections made* n=  |     |                                  |                      |
| Breathing exercises  | 65  | 80.2%                            | 21.9%                |
| Support from birth partner   | 53  | 65.4%                            | 17.8%                |
| Paracetamol  | 35  | 43.2%                            | 11.8%                |
| TENS** machine   | 27  | 33.3%                            | 9.1%                 |
| Bath   | 26  | 32.1%                            | 8.8%                 |
| Mobilising   | 24  | 29.6%                            | 8.1%                 |
| Hypnobirthing  | 18  | 22.2%                            | 6.1%                 |
| Shower   | 17  | 21.0%                            | 5.7%                 |
| Music  | 13  | 16.0%                            | 4.4%                 |
| Massage  | 9   | 11.1%                            | 3.0%                 |
| Aromatherapy   | 7   | 8.6%                             | 2.4%                 |
| Birthing pool  | 0   | 0%                               | 0.0%                 |
| Homeopathy   | 0   | 0%                               | 0.0%                 |
| Other:   | 3   |                                  |                      |
| Sleeping   | 1   | 1.2%                             | 0.3%                 |
| Birth ball   | 1   | 1.2%                             | 0.3%                 |
| Heat pad   | 1   | 1.2%                             | 0.3%                 |

<sup>\*</sup>Other (n=3) was not included in the calculations but those 'Others' specified i.e. Sleeping, Birth ball, and Heat pad were included.

No one method for relaxation and pain management used at home showed significant association with PCS scores at the cut-off point ≥20 (Table 20).

<sup>\*\*</sup>TENS Transcutaneous electrical nerve stimulation.

Table 20: Crosstabulation of PCS Scores ≥20 compared to home pain management choices % percentages by column

|                         |          | PC:<br>score   |         |                | Pearson Chi-Square Asympt. Signif. | Fisher's Exact<br>2-sided |
|-------------------------|----------|----------------|---------|----------------|------------------------------------|---------------------------|
|                         |          | No Score       |         | Yes            | p value                            | p value                   |
|                         | n        | %              | n       | %              | P                                  | <b>p</b> :::::::          |
| Breathing technique     | ues      |                |         |                |                                    |                           |
| No (n=17)               | 11       | 19.3%          | 6       | 27.3%          |                                    |                           |
| Yes (n=62)              | 46       | 80.7%          | 16      | 72.7%          | -                                  | .543                      |
| Birth partner supp      | ort      |                |         |                |                                    |                           |
| No (n=26)               | 19       | 33.9%          | 7       | 31.8%          |                                    |                           |
| Yes (n=52)              | 37       | 66.1%          | 15      | 68.2%          | .859                               | -                         |
| Paracetamol             |          |                |         |                |                                    |                           |
| No (n=44)               | 31       | 55.4%          | 13      | 59.1%          |                                    |                           |
| Yes (n=34)              | 25       | 44.6%          | 9       | 40.9%          | .765                               | -                         |
| TENS* machine           |          |                |         |                |                                    |                           |
| No (n=52)               | 38       | 69.1%          | 14      | 63.6%          |                                    |                           |
| Yes (n=25)              | 17       | 30.9%          | 8       | 36.4%          | .644                               | -                         |
| Bath                    |          |                |         |                |                                    |                           |
| No (n=52)               | 36       | 64.3%          | 16      | 72.7%          |                                    |                           |
| Yes (n=26)              | 20       | 35.7%          | 6       | 27.3%          | .477                               | -                         |
|                         |          |                |         |                |                                    |                           |
| Mobilising<br>No (n=54) | 38       | 67.9%          | 16      | 72.7%          |                                    |                           |
| Yes (n=24)              | 18       | 32.1%          | 6       | 27.3%          | .675                               | _                         |
|                         | 10       | 32.170         | O       | 27.370         | .075                               |                           |
| Hypnobirthing           | 4.4      | 22.22/         | 4.5     | 60.20/         |                                    |                           |
| No (n=59)               | 44<br>11 | 80.0%<br>20.0% | 15<br>7 | 68.2%<br>31.8% | .268                               |                           |
| Yes (n=18)              | 11       | 20.0%          | ,       | 31.6%          | .200                               | -                         |
| Shower                  |          |                |         |                |                                    |                           |
| No (n=61)               | 45       | 80.4%          | 16      | 72.7%          |                                    | - 4-                      |
| Yes (n=17)              | 11       | 19.6%          | 6       | 27.3%          | -                                  | .545                      |
| Music                   |          |                |         |                |                                    |                           |
| No (no=64)              | 48       | 87.3%          | 16      | 72.7%          |                                    |                           |
| Yes (n=13)              | 7        | 12.7%          | 6       | 27.3%          | -                                  | .177                      |
| Massage                 |          |                |         |                |                                    |                           |
| No (n=69)               | 50       | 89.3%          | 19      | 86.4%          |                                    |                           |
| Yes (n=9)               | 6        | 10.7%          | 3       | 13.6%          | -                                  | .706                      |
| Aromatherapy            |          |                |         |                |                                    |                           |
| No (n=71)               | 53       | 94.6%          | 18      | 81.8%          |                                    |                           |
| Yes (n=7)               | 3        | 5.4%           | 4       | 18.2%          | -                                  | .094                      |
| Sleeping                |          |                |         |                |                                    |                           |
| No (n=77)               | 55       | 98.2%          | 22      | 100.0%         |                                    |                           |
| Yes (n=1)               | 1        | 1.8%           | 0       | 0.0%           | -                                  | 1.000                     |
| Birth ball              |          |                |         |                |                                    |                           |
| No (n=77)               | 55       | 98.2%          | 22      | 100.0%         |                                    |                           |
| Yes (n=1)               | 1        | 1.8%           | 0       | 0.0%           | -                                  | 1.000                     |
| Heat pad                |          |                |         |                |                                    |                           |
| No (n=77)               | 55       | 98.2%          | 22      | 100.0%         |                                    |                           |
| Yes (n=1)               | 1        | 1.8%           | 0       | 0.0%           | -                                  | 1.000                     |
| TENS Transcutaneous     |          |                |         | 0.070          |                                    | 1.000                     |

<sup>\*</sup>TENS Transcutaneous electrical nerve stimulation

Out of the total number of participants (n=82) who responded to question 10 78.0% used Entonox® in hospital (Table 21) replacing breathing exercises which was the most popular choice to use at home. Breathing exercises was the second most popular choice (72.0%) to use in hospital alongside support from birth partner. These top three methods of relaxation and pain management used in hospital accounted for 44.4% of the total responses to this question (Table 21).

Out of the total 22 different methods used for relaxation or pain management in hospital 8 (36.4%) were pharmacological and 14 (63.6%) were non-pharmacological methods (Table 21). Pharmacological methods accounted for 32.8% of the total responses (n=409) used for labour pain relief (analgesia) in hospital and non-pharmacological methods accounted for 66.8% of the total (Table 21). The 1.2% who had spinal anaesthesia were included in the pharmacological methods although it is possible spinal anaesthesia was administered for those participants who had an operative birth and was not for managing contraction pain during labour.

Table 21: Showing the frequencies in the identified set of the pain management techniques that participants used whilst experiencing labour in hospital

| Methods of relaxation and pain management strategies used in hospital | (n)  | % of respondents choosing | % of total responses |
|---|------|---------------------------|----------------------|
| Total number of participants who responded to                         |      | method                    |                      |
| question in the identified set n=82  Total number of                  |      |                           |                      |
| Total number of selections made* n=409                                |      |                           |                      |
| Total number of selections made 11–403                                |      |                           |                      |
| Entonox®*   | 64   | 78.0%                     | 15.6%                |
| Breathing exercises   | 59   | 72.0%                     | 14.4%                |
| Birth partner support   | 59   | 72.0%                     | 14.4%                |
| Health professional support   | 41   | 50.0%                     | 10.0%                |
| Birthing pool   | 25   | 30.5%                     | 6.1%                 |
| Paracetamol   | 22   | 26.8%                     | 5.4%                 |
| TENS*** machine   | 21   | 25.6%                     | 5.1%                 |
| Epidural  | 21   | 25.6%                     | 5.1%                 |
| Hypnobirthing   | 16   | 19.5%                     | 3.9%                 |
| Music   | 16   | 19.5%                     | 3.9%                 |
| Mobilising  | 13   | 15.9%                     | 3.2%                 |
| Pethidine   | 12   | 14.6%                     | 2.9%                 |
| Massage   | 9    | 11.0%                     | 2.2%                 |
| Aromatherapy  | 7    | 8.6%                      | 1.7%                 |
| Diamorphine   | 7    | 8.6%                      | 1.7%                 |
| Spinal  | 5    | 6.2%                      | 1.2%                 |
| Bath  | 4    | 4.9%                      | 1.0%                 |
| Shower  | 3    | 3.7%                      | 0.7%                 |
| Oramorph  | 3    | 3.7%                      | 0.7%                 |
| Homeopathy  | 0    | 0.0%                      | 0.0%                 |
| Remifentanil  | 1    | 1.2%                      | 0.2%                 |
| Othe  | r: 1 |                           |                      |
| *Other (n=1) was not included in the calculations but the             | 1    | 1.2%                      | 0.2%                 |

<sup>\*</sup>Other (n=1) was not included in the calculations but those 'Others' i.e. specified Flannel were

When exploring associations between PCS scores (<20 and  $\geq$ 20) and pharmacological (Table 22) and non-pharmacological methods (Table 23) used for pain management in hospital, only one method demonstrated a significant association (p=.017) with PCS scores and that was pethidine. This result suggests that those who do not pain catastrophise (PCS scores <20) are more likely to choose pethidine than those who do pain catastrophise (PCS scores  $\geq$ 20). Although as previously mentioned investigations are exploratory and should be considered with caution.

<sup>\*\*</sup> Entonox® Gas and air, 50% nitrous oxide and 50% oxygen

<sup>\*\*\*</sup>TENS Transcutaneous electrical nerve stimulation

Table 22: Crosstabulation of PCS scores ≥20 compared to pharmacological pain management choices in hospital % percentages by column

|              | PCS<br>score ≥20 |       |    |        | Pearson Chi-Square Asympt. Signif. | Fisher's Exact<br>2-sided |
|--------------|------------------|-------|----|--------|------------------------------------|---------------------------|
|              | ľ                | lo    | ,  | Yes    | <i>p</i> value                     | p value                   |
|              | n                | %     | n  | %      |                                    |                           |
| Entonox®*    |                  |       |    |        |                                    |                           |
| No (n=18)    | 14               | 24.6% | 4  | 18.2%  |                                    |                           |
| Yes (n=61)   | 43               | 75.4% | 18 | 81.8%  | .545                               | -                         |
| Paracetamol  |                  |       |    |        |                                    |                           |
| No (n=59)    | 42               | 73.7% | 17 | 77.3%  |                                    |                           |
| Yes (n=20)   | 15               | 26.3% | 5  | 22.7%  | .742                               | -                         |
| Epidural     |                  |       |    |        |                                    |                           |
| No (n=57)    | 42               | 75.0% | 15 | 68.2%  |                                    |                           |
| Yes (n=21)   | 14               | 25.0% | 7  | 31.8%  | .541                               | -                         |
| Pethidine    |                  |       |    |        |                                    |                           |
| No (n=67)    | 45               | 78.9% | 22 | 100.0% |                                    |                           |
| Yes (n=12)   | 12               | 21.1% | 0  | 0.0%   | -                                  | .017                      |
| Diamorphine  |                  |       |    |        |                                    |                           |
| No (n=72)    | 52               | 91.2% | 20 | 95.2%  |                                    |                           |
| Yes (n=6)    | 5                | 8.8%  | 1  | 4.8%   | -                                  | 1.000                     |
| Spinal       |                  |       |    |        |                                    |                           |
| No (n=73)    | 54               | 96.4% | 19 | 86.4%  |                                    |                           |
| Yes (n=5)    | 2                | 3.6%  | 3  | 13.6%  | -                                  | .133                      |
| Oramorph     |                  |       |    |        |                                    |                           |
| No (n=76)    | 55               | 96.5% | 21 | 95.5%  |                                    |                           |
| Yes (n=3)    | 2                | 3.5%  | 1  | 4.5%   | -                                  | 1.000                     |
| Remifentanil |                  |       |    |        |                                    |                           |
| No (n=78)    | 56               | 98.2% | 22 | 100.0% |                                    |                           |
| Yes (n=1)    | 1                | 1.8%  | 0  | 0.0%   | -                                  | 1.000                     |

<sup>\*</sup> Entonox® Gas and air, 50% nitrous oxide and 50% oxygen

Table 23: Crosstabulation of PCS scores ≥20 compared to non-Pharmacological Pain management in hospital % percentages by column

|                        |            | PCS<br>score ≥20 |         |               | Pearson Chi-Square Asympt. Signif. | Fisher's Exact<br>2-sided |
|------------------------|------------|------------------|---------|---------------|------------------------------------|---------------------------|
|                        |            | No Score         |         | Yes           | p value                            | p value                   |
|                        | n          | %                | n       | %             | p suiuc                            | <u> </u>                  |
| Breathing techniq      | ues        |                  |         |               |                                    |                           |
| No (n=23)              | 16         | 28.1%            | 7       | 31.8%         |                                    |                           |
| Yes (n=56)             | 41         | 71.9%            | 15      | 68.2%         | .742                               | -                         |
| Birth partner supp     | oort       |                  |         |               |                                    |                           |
| No (n=22)              | 16         | 28.1%            | 6       | 27.3%         |                                    |                           |
| Yes (n=57)             | 41         | 71.9%            | 16      | 72.7%         | .943                               | -                         |
|                        |            |                  |         |               |                                    |                           |
| Health profession      | al support |                  |         |               |                                    |                           |
| No (n=40)              | 28         | 49.1%            | 12      | 54.5%         |                                    |                           |
| Yes (n=39)             | 29         | 50.9%            | 10      | 45.5%         | .666                               | -                         |
| Birthing pool          |            |                  |         |               |                                    |                           |
| No (n=54)              | 40         | 70.2%            | 14      | 63.6%         |                                    |                           |
| Yes (n=25)             | 17         | 29.8%            | 8       | 36.4%         | .575                               | -                         |
| TENS* machine          |            |                  |         |               |                                    |                           |
| No (n=60)              | 45         | 78.9%            | 15      | 68.2%         |                                    |                           |
| Yes (n=19)             | 12         | 21.1%            | 7       | 31.8%         | .316                               | _                         |
| , ,                    | 12         | 21.170           | ,       | 31.070        | .510                               |                           |
| Bath                   | <b>5</b> 4 | 06.40/           | 20      | 00.00/        |                                    |                           |
| No (n=74)<br>Yes (n=4) | 54<br>2    | 96.4%<br>3.6%    | 20<br>2 | 90.9%<br>9.1% |                                    | .315                      |
|                        | 2          | 3.0%             | 2       | 9.1%          | -                                  | .515                      |
| Mobilising             |            |                  |         |               |                                    |                           |
| No (n=66)              | 47         | 82.5%            | 19      | 86.4%         |                                    |                           |
| Yes (n=13)             | 10         | 17.5%            | 3       | 13.6%         | -                                  | 1.000                     |
| Hypnobirthing          |            |                  |         |               |                                    |                           |
| No (n=63)              | 45         | 78.9%            | 18      | 81.8%         |                                    |                           |
| Yes (n=16)             | 12         | 21.1%            | 4       | 18.2%         | -                                  | 1.000                     |
| Shower                 |            |                  |         |               |                                    |                           |
| No (n=76)              | 54         | 94.7%            | 22      | 100.0%        |                                    |                           |
| Yes (n=3)              | 3          | 5.3%             | 0       | 0.0%          | -                                  | .556                      |
| Music                  |            |                  |         |               |                                    |                           |
| No (no=63)             | 45         | 78.9%            | 18      | 81.8%         |                                    |                           |
| Yes (n=16)             | 12         | 21.1%            | 4       | 18.2%         | -                                  | 1.000                     |
| Massage                |            |                  |         |               |                                    |                           |
| No (n=70)              | 51         | 89.5%            | 19      | 86.4%         |                                    |                           |
| Yes (n=9)              | 6          | 10.5%            | 3       | 13.6%         | -                                  | .703                      |
| Aromatherapy           |            |                  |         |               |                                    |                           |
| No (n=71)              | 53         | 94.6%            | 18      | 81.8%         |                                    |                           |
| Yes (n=7)              | 3          | 5.4%             | 4       | 18.2%         | -                                  | .094                      |
| Flannel                |            |                  |         |               |                                    |                           |
| No (n=77)              | 56         | 100.0%           | 21      | 95.5%         |                                    |                           |
| Yes (n=1)              | 0          | 0.0%             | 1       | 4.5%          | -                                  | .282                      |

#### 8.3 Discussion

The following discussion will be sectioned under each objective explored in this chapter (objectives iii and iv) and followed by recommendations for clinical practice and future research.

# 8.3.1 Objective iii: To explore whether the simultaneous occurrence of pain catastrophising and fear of childbirth impact on the timing of hospital admission. Discussion

Pain catastrophising has previously been identified as a predictor of FOC (Rondung et al. 2019). This study concurs with this previous finding and has shown that pain catastrophising and FOC are significantly associated, and pain catastrophising is predictive of FOC (reported in Chapter 6 integrated, peer-reviewed Bartholomew et al. 2024). Previous to this study there have been no studies investigating the impact of pain catastrophising on the timing of hospital admission when women are in labour. While there have been many studies undertaken that include the FOC (Dai 2020), there have been few that have considered FOC and latent labour (Dai 2020) together and none that have investigated the impact of FOC on the timing of hospital admission.

When pain catastrophising and FOC were investigated separately both appeared to impact on the timing of hospital admission with women being more likely to attend hospital during latent labour if either were present (reported in Chapter 6 integrated, peer-reviewed Bartholomew et al. 2024). Further analysis (reported in this chapter) supports these findings and indicates that women who pain catastrophise (PCS scores ≥20) and who have a FOC are more likely to be admitted to hospital during the latent phase of labour (Bartholomew et al. 2024).

### 8.3.1.1 Recommendation for clinical practice and future research

These results support the use of PCS as a predictive tool to identify women likely to seek hospital admission during latent labour due to their pain cognitions and fear and who may be at risk of unnecessary obstetric intervention. Utilising the PCS during pregnancy can pinpoint women who could benefit from an early support intervention.

Future research should involve larger sample sizes to confirm these findings and explore the efficacy of an early support intervention. Additionally, research should examine the types of support that are most effective for women who pain catastrophise and who have a FOC. Targeted interventions could reduce early hospital admissions and reduce unnecessary obstetric interventions.

# 8.3.2 Objective iv: To assess, by frequency, the pain management choices women are making at home and at hospital, then explore if these choices are affected by low (<20) versus higher (≥20) PCS scores. Discussion

The most popular choice for women in the study for relaxation and pain management overall were non-pharmacological techniques. These findings reflect previous studies (Heim and Makuch 2023; Zuarez-Easton et al. 2023). Apart from knowing what choices women are making it is important to understand what is impacting their decision. When considering the impact of pain catastrophising on the choices of relaxation and pain relief options available to women for their use during labour, whilst at home or in hospital, there was one significant association found between women who reported PCS scores <20 and pethidine use in hospital.

There is little evidence in the literature about the impact of pain catastrophising on women's choices for pain management during labour. The evidence that currently exists is inconclusive (Van den Bussche et al. 2007; Flink et al. 2009; Veringa et al. 2011; Peralta et al. 2024) suggesting that the relationship between pain catastrophising and pain relief choices during labour might not be straightforward. This inconsistency could be due to different factors.

First, the context of labour pain is unique and multidimensional, which influences how women interpret labour pain (Lowe 2002; Whitburn 2014; Whitburn et al. 2019). The highly variable nature of labour pain, influenced by physiological, psychological, and cultural factors, might weaken the impact of pain catastrophising on women's pain relief choices. Moreover, the support and guidance provided by healthcare professionals during labour can significantly influence women's pain management decisions (Veringa et al. 2011; Sandall et al. 2016; Thomson et al. 2019; Annandale et

al. 2022; CQC 2023) as can labour events (CQC 2023), potentially overshadowing the effects of pain catastrophising.

Second, some women might catastrophise their pain but still prefer non-pharmacological pain relief methods due to personal or cultural reasons, or due to a desire to avoid potential side effects of medications, or fear of the administration method i.e. needle insertion (Van den Bussche et al. 2007; Thomson et al. 2019).

#### 8.3.2.1 Recommendation for clinical practice and future research

Future research should explore the complex nature of labour pain management, focusing on psychological factors like pain catastrophising and how it influences women's pain management choices and experiences. Greater understanding about the factors influencing women's relaxation and pain management choices can lead to more individualised care, targeted education and information and effective strategies to manage labour pain.

### 8.4 Chapter summary

The results presented in this chapter have highlighted the significance of the relationship between pain catastrophising and FOC, and how these factors impact on the timing of hospital admission during labour. Women who report PCS scores ≥20 and experience FOC had a greater tendency to be admitted to the hospital during the latent labour, increasing their risk of unnecessary obstetric interventions. These findings support those presented in Chapter 6 and strengthen the proposal for the use of the PCS as a predictive tool during pregnancy to identify women who may benefit from early support interventions.

Unveiling that only pethidine was significantly associated with PCS scores (<20) underscores the multifactorial and complexity of pain management choices during childbirth and points to the need for greater understanding and psychological assessments with targeted support and education. Although studies with larger sample sizes would be needed to confirm these findings. These strategies may help optimise

| labour pain management, and ultimately improve childbirth outcomes and experiences |
|--|
| for women.   |

### Chapter 9 The RETHINK study: objectives v to vii

#### 9.1 Introduction

This chapter reports the results from the final three objectives stipulated for the RETHINK study together with and a discussion and recommendations for clinical practice and future research.

The objectives reported on in this chapter are:

Objective v: To determine the factors that pregnant women find helpful and supportive, or unhelpful, with their pain management during labour.

Objective vi: To analyse who and what are the influencing factors that impact on a woman's decision to seek hospital admission when in labour and the relationship between these factors and pain catastrophising.

Objective vii: Explore the responses from open-ended questions provided on the two online questionnaires consider the nuanced account of participants experience contained within the data, assess for triangulation of data, and consider for a balanced holistic explanation of the study findings.

9.2 Objective v: To determine the factors that pregnant women find helpful and supportive, or unhelpful, with their pain management during labour.

The questions asked of participants:

Question 11: 'During your labour what did you find most useful and supportive to help you manage your pain? Please comment.'

Question 12: 'During your labour what did you find not useful/or had a negative effect on helping you manage your pain? Please comment.'

In this section the manifest content analyses will be reported on first and the latent content analysis second and both will be presented in tabular and narrative format.

Table 24, Table 25, Table 26, and Table 27 depict the manifest content data which were inductively coded and quantified and reflect what participants found useful and supportive to help them to manage their labour pain and are tabulated according to PCS scores <20 or ≥20. On several occasions participants identified more than one technique as being most helpful and supportive in each instance the technique mentioned was coded and quantified.

Participants were given no other direction or criteria for their responses other than what was specified in the questions 11 and 12 above. However, from the differences in the categories and sub-categories presented in Table 24, Table 25, Table 26, and Table 27 it appears that the way women reflected on the positive and negative techniques was slightly different. For the positive 'most useful and supportive' techniques thoughts centred around pharmacological or non-pharmacological elements. However, for the negative 'not useful/or had a negative effect' participants also considered pharmacological or non-pharmacological elements but also brought into question other factors such as the support they received, and birthing in an NHS maternity care system which impacted on their labour pain management.

## 9.2.1 Manifest content - Useful: What participants found most useful and supportive to help them to manage their labour pain.

Comparing PCS scores <20 or ≥20 and the pain technique category, there was little variation in what participants found most useful and supportive to help them manage their pain during labour (Table 24 and Table 25). Although there were more choices available in the 'non-pharmacological' category compared to the 'pharmacological' category participants at both low and higher PCS scores (<20 and ≥20) were most frequently identifying methods in the 'non-pharmacological' category to be the most useful and supportive.

When considering all four main categories together pharmacology possesses distinct characteristics different from the categories 'environment', 'valuing support' and 'non-pharmacology' which are all intrinsically non-pharmacological. From this viewpoint participants found non-pharmacological pain management methods most useful and

supportive for pain management which outweighed pharmacological methods by much greater percentage differences (73.8% all non-pharmacological methods Vs 26.2% pharmacological methods Table 24Table 24; 73.0% all non-pharmacological factors Vs 27.0% pharmacological Table 25).

For participants who reported PCS scores <20 they referred to their 'supportive birth partners, supportive midwifery' (30.8%) second most frequently, and 'pharmacology' (26.2%) was cited the third most frequently (Table 24). The second and third order of frequency was slightly different for those participants who reported PCS scores ≥20 (Table 25). They indicated 'pharmacology' (27.0%) second and 'supportive birth partners, supportive midwifery' (24.3%) the third most frequently cited useful technique to help them to manage their pain during labour.

Comparing PCS scores <20 or ≥20 (Table 24 and Table 25 respectively) and the pain management technique by sub-category, the most frequently cited as useful and supportive for pain management in those with PCS scores <20 were 'breathing techniques' and 'birth partner' (n=18, 16.8%), with 'health professional (midwife)' and 'Entonox®' being equally second most frequently cited (n=15, 14.0%). However, for those participants reporting PCS scores ≥20 (Table 25) 'Entonox®' was the most frequently cited (n=7, 18.9%) followed by 'birth partner' (n=5, 13.5%) and 'health professional (midwife)' (n=5, 13.5%) in equal second.

Table 24: Manifest content analysis of useful and supportive relaxation and pain management techniques for participants with PCS scores <20. Some participants identified more than one technique.

| Category  | n      | % of total comments | Sub-category: useful & supportive relaxation and pain management techniques for participants with PCS scores <20 | n  | % of total comments |
|---|--------|---------------------|--|----|---------------------|
| Total number of p                               | artici | pants who ha        | nd a PCS score and who commented n=54  |    |                     |
| Total number of c                               | omm    | ents by categ       | ory n=107  |    |                     |
| Environment                                     | 1      | 0.9%                | Home   | 1  | 0.9%                |
| Supportive birth partners, supportive midwifery | 33     | 30.8%               | Birth partner<br>(husband, partner, mum)   | 18 | 16.8%               |
|   |        |                     | Health professional (midwife)  | 15 | 14.0%               |
| Pharmacology                                    | 28     | 26.2%               | Entonox®*  | 15 | 14.0%               |
| •   |        |                     | Epidural   | 7  | 6.5%                |
|   |        |                     | Opioid-based intramuscular injections (pethidine, morphine)  | 5  | 4.7%                |
|   |        |                     | Oral analgesia (codeine)   | 1  | 0.9%                |
| Non-<br>pharmacological                         | 45     | 42.1%               | Breathing techniques   | 18 | 16.8%               |
|   |        |                     | Birthing pool  | 9  | 8.4%                |
|   |        |                     | Hypnobirthing  | 5  | 4.7%                |
|   |        |                     | Zoning out, distraction, focus on end goal   | 5  | 4.7%                |
|   |        |                     | TENS** machine   | 3  | 2.8%                |
|   |        |                     | Bath or shower   | 2  | 1.9%                |
|   |        |                     | Position or being mobile   | 2  | 1.9%                |
|   |        |                     | Massage  | 1  | 0.9%                |
|   |        |                     | Hot water bottle   | 0  | 0%                  |
|   |        |                     | Birthing ball  | 0  | 0%                  |
|   |        |                     | Music  | 0  | 0%                  |
|   |        |                     | Cold flannel   | 0  | 0%                  |
| Nothing   | 1      | 0.9%                | Nothing  | 1  | 0.9%                |
| Comments not ap                                 | plicat | ole to questio      | n  |    |                     |
| Other   | 1      | 100%                | Other Miscellaneous  | 1  | 100%                |
| miscellaneous                                   |        |                     |  |    |                     |

<sup>\*</sup>Entonox® a mixture of gas 50% oxygen and 50% nitrous oxide \*\*TENS Transcutaneous electrical nerve stimulation

Table 25: Manifest content analysis of useful and supportive relaxation and pain management techniques for participants with PCS scores ≥20. Some participants identified more than one technique.

| Category  | n     | % of total comments | Sub-category: useful & supportive relaxation and pain management techniques for participants with PCS scores ≥20 | n    | % of total comments |
|---|-------|---------------------|--|------|---------------------|
| Total number of parti                           | cipan | ts who had a I      | PCS score and who commented i  | า=22 |                     |
| Total number of com                             | ment  | s by category r     | n=37   |      |                     |
| Environment                                     | 1     | 2.7%                | Home   | 1    | 2.7%                |
| Supportive birth partners, supportive midwifery | 9     | 24.3%               | Birth partner (husband, partner, mum)  | 5    | 13.5%               |
| , <b>.</b>                                      |       |                     | Health professional (midwife)  | 4    | 10.8%               |
| Pharmacology                                    | 10    | 27.0%               | Entonox®*  | 7    | 18.9%               |
|   |       |                     | Epidural   | 3    | 8.1%                |
|   |       |                     | Oral analgesia   | 0    | 0.0%                |
|   |       |                     | (codeine)  |      |                     |
|   |       |                     | Opioid-based intramuscular injections  | 0    | 0.0%                |
|   |       |                     | (pethidine, morphine)  |      |                     |
| Non-<br>pharmacological                         | 17    | 45.9%               | Breathing techniques   | 5    | 13.5%               |
|   |       |                     | Birthing pool  | 4    | 10.8%               |
|   |       |                     | Bath or shower   | 2    | 5.4%                |
|   |       |                     | Hot water bottle   | 1    | 2.7%                |
|   |       |                     | Cold flannel   | 1    | 2.7%                |
|   |       |                     | TENS** machine   | 1    | 2.7%                |
|   |       |                     | Zoning out, distraction, focus on end goal   | 1    | 2.7%                |
|   |       |                     | Music  | 1    | 2.7%                |
|   |       |                     | Birthing ball  | 1    | 2.7%                |
|   |       |                     | Massage  | 0    | 0%                  |
|   |       |                     | Hypnobirthing  | 0    | 0%                  |
|   |       |                     | Position or being mobile   | 0    | 0%                  |
| Nothing   | 0     | 0%                  | Nothing  | 0    | 0%                  |
| Comments not application                        |       | •                   |  |      |                     |
| Other miscellaneous                             | 1     | 100%                | Other Miscellaneous  | 1    | 100%                |

<sup>\*</sup>Entonox® a mixture of gas 50% oxygen and 50% nitrous oxide \*\*TENS Transcutaneous electrical nerve stimulation

## 9.2.2 Manifest content analysis – Not useful: What participants found to be not useful or had a negative effect on helping them to manage their labour pain.

The category participants most frequently cited as not useful or had a negative effect on helping to manage labour pain for both PCS scores (<20 or  $\ge20$ ) was 'pharmacology' (32.9% and 31.0% respectively). 'Entonox®' was the most cited sub-category for both PCS scores (<20 and  $\ge20$ ) (18.6% Table 26 and 17.2% Table 27 respectively). This makes Entonox® the:

- most frequently tried pain relief method in hospital (Table 21),
- the most frequently cited as being not useful or having a negative effect on labour pain management for participants reporting at PCS scores (<20 or ≥20) (Table 26 and Table 27),</li>
- the most frequently cited as being helpful or supportive during labour for participants reporting PCS scores ≥20 (Table 25),
- and the second most cited as being helpful or supportive during labour for participants reporting PCS scores <20 (Table 24).</li>

'Unsupportive labour care' was the second most cited category as being not useful or had a negative effect on managing labour pain for participants reporting PCS scores (<20 or ≥20) with frequent reference to communication, the attitude of staff, and delays in treatment (Table 26 and Table 27).

'Position: Certain body positions or imposed positions or restricted movement' was the third most frequently cited as being not useful or had a negative effect on their labour pain management for participants reporting at both PCS scores (<20 or ≥20) (Table 26 and Table 27).

Although non-pharmacological options were the most frequently chosen methods for relaxation and pain relief at home and hospital (Table 19 and Table 21 above), they were positioned fourth out of eight most frequently cited as being not useful or had a negative effect on helping participants to manage their pain for participants reporting PCS scores <20 and 20 (Table 26 and Table 27). The number and percentage of total

negative comments was low when compared to the total number of comments overall (n=3, 4.3% Table 26; n=3, 10.3% Table 27).

Table 26: Manifest content analysis of relaxation and pain management techniques that were not useful or had a negative effect for participants with PCS scores <20. Some participants identified more than one technique.

| Category  | N     | % of total comments | Sub-category: relaxation & pain management techniques not useful or had a negative effect for participants with PCS scores <20               | n  | % of total comments |
|---|-------|---------------------|--|----|---------------------|
| Number of participan  | ts wh | o had a PCS so      | ore and who commented n=53   |    |                     |
| Total number of comm  | ment  | s by category r     | n=70   |    |                     |
| Pharmacology  | 23    | 32.9%               | Entonox®*  | 13 | 18.6%               |
|   |       |                     | Epidural   | 3  | 4.3%                |
|   |       |                     | Oral analgesia   | 4  | 5.7%                |
|   |       |                     | (paracetamol, codeine, other: not specified) Opioid-based intramuscular injections (pethidine, morphine)                                     | 3  | 4.3%                |
| Non-<br>pharmacological   | 3     | 4.3%                | Massage  | 1  | 1.4%                |
| -   |       |                     | TENS** machine   | 2  | 2.9%                |
|   |       |                     | Hypnobirthing  | 0  | 0.0%                |
| Position: Certain<br>body positions,<br>imposed positions,<br>or restricted<br>movement | 8     | 11.4%               | Certain body positions<br>(certain body positions, standing, lying down,<br>lying on back, sat in triage, midwife request – on<br>all fours) | 4  | 5.7%                |
|   |       |                     | Position required for cardiotocograph  | 2  | 2.9%                |
|   |       |                     | Position required for VE   | 2  | 2.9%                |
| IA  | 0     | 0.0%                | Intermittent auscultation (IA)   | 0  | 0.0%                |
| VE  | 2     | 2.9%                | Vaginal examination (VE)   | 2  | 2.9%                |
| Unsupportive labour care  | 18    | 25.7%               | Partner The maternity service:   | 0  | 0.0%                |
|   |       |                     | Delays or not receiving labour support or treatment or pain relief   | 6  | 8.6%                |
|   |       |                     | Having lots of people do various things  | 1  | 1.4%                |
|   |       |                     | Other references to communication<br>and attitude of staff   | 4  | 5.7%                |
|   |       |                     | Explicit reference to poor support and poor communication around labour pain   | 7  | 10.0%               |
| Labour / labour<br>events affecting<br>cognitions                                       | 3     | 4.3%                | Labour / labour events affecting cognitions  | 3  | 4.3%                |
| Other   | 2     | 2.9%                | Other (Journey to hospital, uncomfortable bed  | 2  | 2.9%                |
| Nothing N/A none  | 7     | 10.0%               | Nothing N/A none   | 7  | 10.0%               |
| Miscellaneous other   | 4     | 5.7%                | Miscellaneous other  | 4  | 5.7%                |

<sup>\*</sup>Entonox® a mixture of gas 50% oxygen and 50% nitrous oxide \*\*TENS Transcutaneous electrical nerve stimulation

Table 27: Manifest content analysis of relaxation and pain management techniques that were not useful or had a negative effect for participants with PCS scores ≥20. Some participants identified more than one technique.

| Category                                     | n     | % of total comments | Sub-category: detailing relaxation & pain management techniques not useful or had a negative effect for participants with PCS scores ≥20 | n      | % of comments by sub-category |
|--|-------|---------------------|--|--------|-------------------------------|
| •  |       |                     | re and who commented n=18  |        |                               |
| Total number of comme                        | nts b | y category n=       | :29  |        |                               |
| Pharmacology                                 | 9     | 31.0%               | Entonox®*  | 5      | 17.2%                         |
|  |       |                     | Epidural   | 2      | 6.9%                          |
|  |       |                     | Oral analgesia (paracetamol, codeine, other - not specified)   | 2      | 6.9%                          |
|  |       |                     | Opioid-based intramuscular injections  | 0      | 0.0%                          |
|  |       |                     | (pethidine, morphine)  |        |                               |
| Non-pharmacological                          | 3     | 10.3%               | Massage  | 1      | 3.4%                          |
|  |       |                     | TENS** machine   | 1      | 3.4%                          |
|  |       |                     | Hypnobirthing  | 1      | 3.4%                          |
| Position: Certain body                       | 5     | 17.2%               | Certain body positions:  | 2      | 6.9%                          |
| positions or imposed positions or restricted |       |                     | Sat in triage, midwife request: on all fours   |        |                               |
| movement                                     |       |                     | Position required for cardiotocograph  | 1      | 3.4%                          |
|  |       |                     | Position required for VE   | 2      | 6.9%                          |
| IA   | 1     | 3.4%                | Intermittent auscultation (IA)   | 1      | 3.4%                          |
| VE   | 0     | 0.0%                | Vaginal examination (VE)   | 0      | 0.0%                          |
| Unsupportive labour                          | 6     | 20.7%               | Partner  | 1      | 3.4%                          |
| care   |       |                     | The maternity service:   |        |                               |
|  |       |                     | Delays in receiving  | 2      | 6.9%                          |
|  |       |                     | care or treatment including pain relief  | ^      | 0.00/                         |
|  |       |                     | Having lots of people do various things Other references to communication and  | 0<br>2 | 0.0%<br>6.9%                  |
|  |       |                     | attitude of staff  | _      | 0.570                         |
|  |       |                     | Explicit reference to Poor responses   | 1      | 3.4%                          |
|  |       |                     | to and communication around labour   |        |                               |
|  |       |                     | pain   |        |                               |
| Labour / labour events                       | 2     | 6.9%                | Labour / labour events affecting   | 2      | 6.9%                          |
| affecting cognitions                         |       |                     | cognitions   |        |                               |
| Other  | 1     | 3.4%                | Other (Bright lights, journey to hospital)   | 1      | 3.4%                          |
| Nothing N/A none                             | 1     | 3.4%                | Nothing N/A none   | 1      | 3.4%                          |
| Miscellaneous                                | 1     | 3.4%                | Miscellaneous  | 1      | 3.4%                          |

<sup>\*</sup>Entonox® a mixture of gas 50% oxygen and 50% nitrous oxide \*\*TENS Transcutaneous electrical nerve stimulation

### 9.2.3 Latent content analysis - Useful: What participants found most useful and supportive to help them to manage their labour pain.

There were no euphemistic terms used in place of manifest or the widely recognised terms or techniques used to support women with their labour pain.

Responses to the open-ended questions asking participants what they found most useful and supportive, or not useful/or had a negative effect on helping them to manage their pain during labour were predominantly manifest and have been tabulated and discussed above. Participants used the widely accepted and consistent terms when referring to pharmacological analgesia or to non-pharmacological methods such as breathing techniques or hypnobirthing with very little to no additional qualitative data sufficient for latent analysis. However, when participants commented on the support that they had received from their birth partner/s, healthcare provider (most frequently noted was the midwife), or the maternity service the data had latent qualities extending it to an interpretive level and is analysed below.

From the data it was apparent that support is an all-encompassing term used for labour support which does not reflect the composite elements that labouring women find useful to help them manage their labour pain. However, the latent data when discussing labour support revealed what components are contained within the construct of this support. There were two main themes identified. These were:

- Supportive birth partners
- Supportive midwifery

Analysis of the data uncovered the differences in how participants viewed the support given by birth partners and midwives. Results are presented below. Participants expressed the term 'support' from their birth partner or husband or partner 13 times and support from midwife 6 times. These multiple comments have been simply transcribed into codes and documented in each relevant table (Table 28 and Table 29).

#### 9.2.3.1 Supportive birth partners (Table 28)

When commenting about birth partners, participants identified birth partner, partner, husband and mum in the role and identified aspects of the support that they provided as being helpful to them when managing their labour pain. The usefulness to participants of having a person with them with whom they have a close or personal relationship was revealed through their comments and the coded categories:

- Just knowing that their birth partner was present with them whilst they were in labour was useful and supportive, "My partner being with me..." (RT12), "....the presence of my partner with me" (RT306).
- Participants felt it was useful and supportive when they felt they were
  experiencing labour together, "My partner breathing through contractions with
  me" (RT84), ".....my partner did the course too which was critical for the
  success. I found it 10 times easier when we managed the contractions
  together....." (RT378).
- Participants were also reassured by their birth partner conveying their support through touch, "My birth partner holding me during contractions" (RT155), "My partner holding my hand" (RT281).
- It was useful and supportive for some participants to have verbal coaching and reassurance from their birth partners, "My partner was incredibly supportive and motivating during my labour" (RT174), "My mum telling me to relax and unclench my hands" (RT394).
- Finally, women cited the 'support' they received from their husband, partner or birth partner as being most useful and supportive to help them to manage their labour pain.

Table 28: Latent content analysis: supportive birth partners

| Descriptive unit   | Code categories               | Theme          |
|--|-------------------------------|----------------|
| RT84: My partner breathing through contractions with me.   | Feeling in it together        |                |
| RT378:hypno- birthing course. I found this incredibly helpful to understand and the breathing exercises and back stroking were amazing for managing / distracting from pain - my partner did the course too which was critical for the success. I found it 10 times easier when we managed the contractions together | Feeling in it<br>together     |                |
| RT70:reassurance from birth partner  | Verbal coaching & reassurance |                |
| RT174: My partner was incredibly supportive and motivating during my labour.   | Verbal coaching & reassurance |                |
| RT370:supportive comments from staff and my partner.   | Verbal coaching & reassurance | Supportive     |
| RT379: Breathing and staying calm with the help of my partner  | Verbal coaching & reassurance | birth partners |
| RT394: My mum telling me to relax and unclench my hands  | Verbal coaching & reassurance |                |
| RT155: My birth partner holding me during contractions   | Touching support              |                |
| RT281: My partner holding my hand.   | Touching support              |                |
| RT12: My partner being with me   | Just be there                 |                |
| RT156: Presence of my partner  | Just be there                 |                |
| RT306:the presence of my partner with me.  | Just be there                 |                |
| Support from birth partner or husband or partner: referenced 13 times  | Support from birth partner    |                |

#### 9.2.3.2 Supportive midwifery (Table 29)

It was observed and interpreted that the coded categories constructing the supportive midwifery theme were distinct from the supportive birth partners theme by the absence of covert or overt indication that the person with them was one with whom they had a close or personal relationship. However, one participant did refer to knowing their midwife through having continuity of care through pregnancy and labour as being a useful and supportive aspect to managing their labour pain and how that may also have been translated into feeling her birth plan was respected, "....midwives respecting my birth plan. We had the same Midwife during labour that we had seen throughout the pregnancy". (RT130).

Participants did make similar comments about verbal coaching and reassurance to those that were made about supportive birth partners. However, supportive midwifery had the additional component of valuing knowledge alongside verbal coaching and reassurance, ".....midwives talking to me and telling me what to do" (RT28), "...midwife reassuring me / keeping me informed on the progress" (RT33), "Encouragement / coaching from midwife". (RT319).

Table 29: Latent content analysis: supportive midwifery

| Descriptive unit  | Coded categories                                 | Theme                   |
|---|--|-------------------------|
| RT130:midwives respecting my birth plan. We had the same Midwife during labour that we had seen throughout the pregnancy. | The importance of knowing one another            |                         |
| RT28: midwives talking to me and telling me what to do  | Valuing knowledge, verbal coaching & reassurance |                         |
| RT29: Midwife's reassurance   | Valuing knowledge, verbal coaching & reassurance | Supportive<br>midwifery |
| RT33:midwife reassuring me / keeping me informed on the progress  | Valuing knowledge, verbal coaching & reassurance |                         |
| RT143: my midwife updating me on progress.  | Valuing knowledge, verbal coaching & reassurance |                         |

| RT156: guidance and calmness of the midwife.                               | Valuing knowledge, verbal coaching & reassurance |
|--|--|
| RT252: Advice from midwife   | Valuing knowledge, verbal coaching & reassurance |
| RT266:coaching from midwife.   | Valuing knowledge, verbal coaching & reassurance |
| RT281:.contractions my midwives talking to me through them to distract me. | Valuing knowledge, verbal coaching & reassurance |
| RT306: The midwifes support and invite to follow my body.                  | Valuing knowledge, verbal coaching & reassurance |
| RT319: Encouragement / coaching from midwife                               | Valuing knowledge, verbal coaching & reassurance |
| RT321: and midwife advising on breathing through contractions.             | Valuing knowledge, verbal coaching & reassurance |
| RT370:supportive comments from staff                                       | Valuing knowledge, verbal coaching & reassurance |
| 'Support from midwife': referenced 6 times.                                | Support from midwife                             |

## 9.2.4 Latent content analysis – Not useful: What participants found not useful or had a negative effect on helping them to manage their labour pain.

Participants provided more latent content for analysis for what they found not useful or had a negative effect on helping them to manage their labour pain than they did for those positive aspects that they found most useful and supportive. The themes identified for what participants found not useful and had a negative effect were:

- Delays to receiving labour support, delays or non-provision of treatment including pain relief
- Poor communication and attitude of staff
- It's only pain: references to poor responses to and communication around labour pain.

There were two comments that did not fit with any over these themes but were notable. First one participant commented on "...Having lots of people do various things..." (RT340). It was evident that this participant experienced obstetric intervention in her labour due to increased risks which would have led to other staff being involved in her care. However, this participant was conveying that this aspect of care was not useful or had a negative effect on helping her manage her labour pain. This woman's comment reflects maternity care provision when obstetric intervention is indicated and how '...Having lots of people do various thing' can negatively impact on a woman, and potentially indicates that for this woman the situation could have been managed more respectfully. The second comment was about the birth partner support, "My partner! He was very scared and I had to reassure him". (RT33).

9.2.4.1 Delays to receiving labour support, delays or non-provision of treatment including pain relief (Table 30)

Three comments about delays to receiving labour support, delays or non-provision of treatment including pain relief were associated with staff shortages, ".....unavailability of a birthing pool (due to staff shortages and closure of both local birth centres), delays in receiving pain medication once agreed to by myself and the doctors" (RT283), understaffing, "The delivery ward was understaffed so not having a health professional or my birth partner with me from the beginning was scary". (RT374) or the unavailability of staff "Asked for epidural but did not get one because no anaesthetist available" (RT35). The effects of which meant participants were without timely and adequate pain relief, without timely labour care and were scared. Other delays in treatment caused a participant to become dehydrated due to the delay to receiving an anti-emetic medication, "No midwife attended for several hours. Was vomiting but not given anti emetics for hours and couldn't stay hydrated" (RT285). Participants also found that delays were caused by the provision of care being slow, "Arrival to hospital and triage process was slow and clinical and having to wait hours" (RT310), "Waiting hours in pain before they made the conclusion that first epidural didn't work" (RT377) with no explanation given.

Table 30: Latent content analysis: delays to receiving labour support, delays or non-provision of treatment including pain relief

| Descriptive unit  | Coded categories   | Theme   |
|---|--|---|
| RT285: No midwife attended for several hours. Was vomiting but not given anti emetics for hours and couldn't stay hydrated  | Delays to receiving labour support. Delays to receiving treatment.               |   |
| RT310: Arrival to hospital and triage process was slow and clinical   | Delays to receiving labour support.  |   |
| RT35: In triage I was sat a while whilst in considerable pain Asked for epidural but did not get one because no anaesthetist available  | Delays to receiving treatment.   |   |
| RT393: Delays in getting epidural   | Delays to receiving treatment.   | Delays to<br>receiving<br>labour<br>support,                            |
| RT283:unavailability of a birthing pool (due to staff shortages and closure of both local birth centres), delays in receiving pain medication once agreed to by myself and the doctors. | Unavailability of birthing pool. Staff shortages. Delays to receiving treatment. | delays or non-<br>provision of<br>treatment<br>including pain<br>relief |
| RT377: Waiting hours in pain before they made the conclusion that first epidural didn't work.   | Delays to receiving treatment.   |   |
| RT341:it was more 'here's the meds I'll be back in 4 hours'.  | Delays to receiving labour support.  |   |
| RT374: The delivery ward was understaffed so not having a health professional or my birth partner with me from the beginning was scary.   | Delays to receiving labour support. Staff shortages                              |   |

### 9.2.4.2 Poor communication and attitude of staff (Table 31)

Participants experienced poor communication, misjudged communication and attitude from staff which were not useful or had a negative effect on their labour pain management. Poor communication appeared to affect participants' ability to provide

informed consent and make informed decisions "Poor explanation of options for labour that was not progressing and benefits vs. risks from junior midwife" (RT40), and unhelpful attitude "First midwife allocated was not very helpful in explaining all available options or the impact of certain options...., and didn't engage with us in a way that meant we felt we had a plan in place,.... Looking back this was a really unhelpful way to be managed and did not feel supportive". (RT341). In other situations poor communication was evident in the manner the participant received the message and associated the communication with being not useful or having a negative effect, "Telling me they could see the head but it was only a tiny amount after it felt like i had been pushing effectively and more of the baby's head would have been out" RT28. One participant explained her encounter with a midwife who had an intimidating attitude, was dismissive and disrespectful in her care, and an unhelpful attitude and provided ineffective communication of information in the situation for the participant to make a later informed decision, "when I first went to the hospital (and sent home) the triage midwife was quite intimidating which I feel had a negative effect and impacted when I went to hospital the second time. I was left in the waiting room with my birth partner for an hour after which I was informed she'd been watching me on the cameras and said I hadn't experienced any contractions (despite me insisting that I had) and she wasn't sure she should check me. She did examine me.... at which point she advised I was 3 cm dilated and fully effaced. She did apologise for not noting my contractions saying I was 'discrete' in my contractions. She did send me home and told me to come back later, however the advice was limited as to when I should come back. When I did come back 6 hours later I was fully dilated. (RT365)

Table 31: Latent content analysis: poor communication and attitude of staff

| Descriptive unit  | Coded categories  | Theme                                     |
|---|---|---|
| RT28: Telling me they could see the head but it was only a tiny amount after it felt like i had been pushing effectively and more of the baby's head would have been out  | Poor communication.   |   |
| RT40: Poor explanation of options for labour that was not progressing and benefits vs. risks from junior midwife.   | Ineffective communication of information in the situation to make informed decisions.   |   |
| RT82: Poor communication. Rushed decisions.   | Poor communication. Ineffective communication of information in the situation to make informed decisions.   |   |
| RT341: First midwife allocated was not very helpful in explaining all available options or the impact of certain options, and didn't engage with us in a way that meant we felt we had a plan in place, Looking back this was a really unhelpful way to be managed and did not feel supportive  | Ineffective communication of information in the situation to make informed decisions. Unhelpful attitude.   | Poor                                      |
| RT365: when I first went to the hospital (and sent home) the triage midwife was quite intimidating which I feel had a negative effect and impacted when I went to hospital the second time. I was left in the waiting room with my birth partner for an hour after which I was informed she'd been watching me on the cameras and said I hadn't experienced any contractions (despite me insisting that I had) and she wasn't sure she should check me. She did examine me at which point she advised I was 3 cm dilated and fully effaced. She did apologise for not noting my contractions saying I was 'discrete' in my contractions. She did send me home and told me to come back later, however the advice was limited as to when I should come back. When I did come back 6 hours later I was fully dilated. | Intimidating attitude of midwife. Safety and security cameras used as to justify dismissive care. Inappropriately apportioning blame. Disrespectful care. Unhelpful attitude. Ineffective communication of information in the situation to make informed decisions. | communication<br>and attitude of<br>staff |
| RT368: People walking in  | Disrespectful care  |   |
| RT370: The midwife was very pushy at times and told me I needed to get into certain positions that I didn't feel particularly comfortable with (on all fours for example) and told me that some of my pushes weren't good enough. She meant well but her tone and style were demoralising and I didn't find the tough love helpful.   | Misjudgement about the style of communication. Unhelpful attitude.  |   |

### 9.2.4.3 It's only pain!: references to poor responses to and communication around labour pain (Table 32)

Although the question on the PNQ asked participants to provide comments on what they found not useful or had a negative effect on their labour pain management this theme specifically centres on care around pain relief, and the support midwives gave to the participants around pain management. Participants experienced care that was domineering or autocratic, with midwives telling participants how they should behave during the experience of contraction pain "A lady telling me I was breathing wrong", (RT12), "The midwife telling me not to scream when I needed a relief", (RT281) there were also instances where the participant's opinion was taken out of the decisionmaking process whilst the midwife and anaesthetist debated the administration of an epidural "...conflicting opinion between anaesthetist and midwife in whether or not I could have an epidural (RT393). Another participant experienced a similar situation where it appeared she was in active labour because she was eventually advised that she should be admitted into hospital and that a TENS machine would not be of use likely due to her being in active labour. The participant then suggested the pain relief she would like to try (Entonox®) the midwife recommended an epidural, but the participant received neither and was given codeine, "....may have been more comfortable with tens on..... I got told not of use anyway at this stage, although talk of me going home again....Got asked what pain relief As they decided I should stay. I suggested Entonox® as a starting point midwife advised she would recommend epidural as Entonox® would not help pain I was in. I got given codeine...." RT35:

Table 32: Latent content analysis: It's only pain: References to poor responses to and communication around labour pain

| Description unit  | Coded categories  | Theme  |
|---|---|--|
| RT6:midwives reluctant to give me pain relief   | It's only pain. Poor responses to and communication around labour pain.                       |  |
| RT12: A lady telling me I was breathing wrong.  | Poor responses to and communication around labour pain. Authoritative care.                   |  |
| RT35: may have been more comfortable with tens on I got told not of use anyway at this stage. although talk of me going home againGot asked what pain relief As they decided I should stay. I suggested Entonox® as a starting point midwife advised she would recommend epidural as Entonox® would not help pain I was in. I got given codeine | It's only pain. Poor responses to and communication around labour pain. Authoritative care.   | It's only pain! References to poor responses to and communication around labour pain |
| RT191: Midwife talking loudly asking questions during contractions  | It's only pain. Poor responses to and communication around labour pain.                       |  |
| RT233: Being told I needed to take deep breath in when I was still concentrating on my outward breath. Wanted to control the breathing myself but felt rushed to breath faster than what I had practiced. I wasn't really encouraged to get any other pain relief other than gas and air.   | It's only pain. Poor responses to and communication around labour pain. Authoritative care.   |  |
| RT266: Hearing from midwife that it could be another few more days of labour and that pain would get worse. Hearing that there was not much that they could do as I was not in active labour.   | It's only pain. Poor responses to and communication around labour pain.                       |  |
| RT281: The midwife telling me not to scream when I needed a relief  | It's only pain.  Poor responses to and communication around labour pain.  Authoritative care. |  |
| RT393:conflicting opinion between anaesthetist and midwife in whether or not I could have an epidural.  | It's only pain. Poor responses to and communication around labour pain. Authoritative care.   |  |

### 9.3 Objective vi: To analyse who and what are the influencing factors that impact on a woman's decision to seek hospital admission when in labour and the relationship between these factors and pain catastrophising.

Table 33 shows the quantitative data and descriptive statistics detailing by frequency those who were most influential in deciding when it was time to go to hospital to seek admission when in labour. In approximately two thirds of the cases the most likely person to decide to go to hospital is the participant herself (63.3%). However, in approximately one third of the instances it is someone else. This person is most likely to be the participants partner (27.8%) with only a healthcare professional being cited in 5.1% of cases.

When comparing results between PCS scores (<20 or ≥20) the most frequent person deciding remains the participant herself with little variation except the participant's mother or a healthcare professional does feature as being people who have some influence in the decision to seek hospital admission for participants reporting PCS scores <20.

Table 33: Tabulation by frequency those who were most influential in deciding it was time to go to hospital when in labour

| Who was most influential in deciding it was time to go to | Total | % of total responses | PCS<br>Score<br>≥20 | % of PCS<br>Score ≥20 | PCS<br>Score<br><20 | % of PCS<br>Score <20 |
|---|-------|----------------------|---------------------|-----------------------|---------------------|-----------------------|
| hospital  | (n)   | (%)                  | (n)                 | (%)                   | (n)                 | (%)                   |

### Total number of participants who responded to question in the identified set and who has a PCS score n=79

| You               | (50) | 63.3% | (15) | 68.2% | (35) | 61.4% |
|-------------------|------|-------|------|-------|------|-------|
| Your partner      | (22) | 27.8% | (7)  | 31.8% | (15) | 26.3% |
| A friend          | (0)  | 0.0%  | (0)  | 0.0%  | (0)  | 0.0%  |
| Your mother       | (3)  | 3.8%  | (0)  | 0.0%  | (3)  | 5.3%  |
| Your father       | (0)  | 0.0%  | (0)  | 0.0%  | (0)  | 0.0%  |
| Other (Healthcare | (4)  | 5.1%  | (0)  | 0.0%  | (4)  | 7.0%  |
| professional)     |      |       |      |       |      |       |

Participants were asked to comment on:

'What were the signs that signalled to you that it was time to go to hospital when you were in labour?'

Manifest content analysis was undertaken to reveal what the signs and signals were that signalled to participants' that it was time to seek hospital admission. Multiple influencing factors were revealed (Table 34). The most frequently appearing influencing factor was the frequency of contractions. The percentage remains similar between the total number of responses (38.0%) and by PCS scores (<20 or ≥20) (38.0% and 37.8% respectively). Approximately one quarter of responses are accounted for by pain or the intensity of contractions and this also remains relatively consistent across total response (26.3%), and PCS scores <20 (27.0%) and PCS scores ≥20 (24.3%). The third most frequently appearing influential factor in participants' decisions to seek hospital admission is a rupture of membranes (SROM/PROM/Mec) either during labour or pre-labour and for some the presence of meconium in the amniotic fluid influences the decision. The most likely to have this as an influencing factor are those who reported PCS scores <20 (22.0%) with much less having this as an influencing factor in those reporting PCS scores ≥20 (10.8%).

Table 34: Tabulation by frequency of the influencing or deciding factors for when it was time to seek hospital admission

|  | Number<br>of<br>responses | % of total responses | PCS<br>score<br><20 | % of PCS<br>Score<br><20<br>(Total<br>n=100) | PCS<br>score<br>≥20 | % of PCS Score ≥20 (Total n=37) |
|--|---------------------------|----------------------|---------------------|--|---------------------|---------------------------------|
|  | (n)                       | (%)                  | (n)                 | (%)  | (n)                 | (%)                             |
| Total number of resp<br>n=137  |                           |                      |                     |  |                     |                                 |
| Contraction frequency  | 52                        | 38.0%                | 38                  | 38.0%  | 14                  | 37.8%                           |
| Pain/intensity   | 36                        | 26.3%                | 27                  | 27.0%  | 9                   | 24.3%                           |
| SROM/PROM/Mec*   | 26                        | 19.0%                | 22                  | 22.0%  | 4                   | 10.8%                           |
| Bloody show  | 5                         | 3.6%                 | 4                   | 4.0%   | 1                   | 2.7%                            |
| PV bleeding/pink<br>liquor**   | 4                         | 2.9%                 | 2                   | 2%   | 2                   | 5.4%                            |
| Rectal pressure/pushing  | 2                         | 1.5%                 | 1                   | 1.0%   | 1                   | 2.7%                            |
| Reduced fetal movement   | 2                         | 1.5%                 | 1                   | 1.0%   | 1                   | 2.7%                            |
| Duration of latent labour  | 2                         | 1.5%                 | 2                   | 2.0%   | 0                   | 0.0%                            |
| Additional labour support  | 2                         | 1.5%                 | 1                   | 1.0%   | 1                   | 2.7%                            |
| Арр  | 1                         | 0.7%                 | 1                   | 1.0%   | 0                   | 0.0%                            |
| Midwife  | 1                         | 0.7%                 | 1                   | 1.0%   | 0                   | 0.0%                            |
| Vomiting   | 1                         | 0.7%                 | 0                   | 0.0%   | 1                   | 2.7%                            |
| Change in behaviour  | 1                         | 0.7%                 | 0                   | 0.0%   | 1                   | 2.7%                            |
| Wanting small dark cool space  | 1                         | 0.7%                 | 0                   | 0.0%   | 1                   | 2.7%                            |
| Booked for IOL<br>following week for<br>GDM wanted to be<br>checked out*** | 1                         | 0.7%                 | 0                   | 0.0%   | 1                   | 2.7%                            |

<sup>\*</sup>SROM = spontaneous rupture of membranes, PROM = Prelabour rupture of membranes, Mec = meconium present in the amniotic fluid. \*\*\* PV = per vaginum, pink liquor = blood staining in the amniotic fluid. \*\*\*IOL = induction of labour, GDM = gestational diabetes.

9.4 Objective vii: Explore the responses from open-ended questions provided on the two online questionnaires to consider the nuanced account of participants' experiences contained within the data, assess for triangulation of data, and consider for a balanced holistic explanation of the study findings.

Finally, qualitative data resultant from three open-ended questions included on the antenatal questionnaire (ANQ) and the postnatal questionnaire (PNQ) were analysed using reflexive thematic analysis (RTA) (Braun and Clarke 2019). Analyses were per question and reported according to each question and the identified themes. For questions 8 and 17 a matrix was constructed depicting the coding strategies. These can be found in Appendix 7 and Appendix 8 respectively.

The questions reported on are:

ANQ Question 8: 'Please feel free to provide any additional thoughts you may have about labour and birth.'

ANQ Question 18 'Is there anything else you would like to tell us?'

PNQ Question 17 'Is there anything else you would like to tell us?'

## 9.4.1 ANQ Question 8: 'Please feel free to provide any additional thoughts you may have about labour and birth.'

Out of the 82 participants for whom cervical dilatation was available to denote the timing of hospital admission 25 (30.49%) provided textual responses to this question. The analysis of these responses resulted in identifying three prominent themes and two sub-themes:

- 1. The worriers included:
  - 1.1 Worried without a strategy
  - 1.2 Worried but with a strategy
- 2. The rationalisers, strategisers and planners

# 3. The positively optimistic

Table 35 provides context for the RTA findings. The largest group were 'The worriers' (total n=15). All participants gestation ranges were very similar ranging overall between 25 to 33 completed weeks pregnant, reasonably expected considering the inclusion criteria.

Table 35: Tabulation of the context for the reflexive thematic analysis for Question 8 and Question 18 on the ANQ

| Group   | Number<br>in group<br>(n=) | Gestation<br>range when<br>answering<br>ANQ<br>(completed<br>weeks) | PCS<br>score<br>range | FOC<br>score<br>range | Total admitted to hospital during latent phase (%) (n=) | Total admitted to hospital during active labour (%) (n=) |
|---|----------------------------|---|-----------------------|-----------------------|---|--|
| 1. The worriers                                 | 15                         | 26 – 33   | 7 – 35                | 47 – 103              | 33.33%<br>(n=5)   | 66.67%<br>(n=10)   |
| 1.1 Worried<br>without a<br>strategy            | 10                         | 26 – 33   | 7 - 30                | 52 – 103              | 40%<br>(n=4)  | 60%<br>(n=6  |
| 1.2 Worried<br>but with a<br>strategy           | 5                          | 26 – 32   | 14 – 24               | 47 – 71               | 20%<br>(n=1)  | 80%<br>(n=4)   |
| 2. The rationalisers, strategisers and planners | 7                          | 26 – 32   | 0 – 25                | 23 – 64               | 42.86%<br>(n=3)   | 57.14%<br>(n=4)  |
| 3. The positively optimistic                    | 3                          | 25 – 31   | 6-7                   | 24 – 57               | 0%<br>(n=0)   | 100%<br>(n=3)  |

#### 9.4.1.1 The worriers

#### 9.4.1.1.1 Worried without a strategy

Although question 8 did not provide guidance to the participant about how they should respond, other than providing additional thoughts that they may have had about labour and birth, all individuals responded by expressing their thoughts about their own approaching labour and birth.

The 'Worried without a strategy' group were characterised by their evident anxiety and worry about their own forthcoming labour and birth. Women expressed their apprehension often using the word 'worry or worries' and other words such as 'concerns or concerned', 'panic', 'terrified', or 'scared'.

'I'm terrified of the whole process, like from going in, what the expect, like basically, I feel like I need a run-down of start to finish of what's going to happen to me right up until after I give birth, and I'm more scared for after birth and what to expect from that. I need some reassurance of the unknown'.

[RT257, PCS score 30, WDEQ-A score 103, admitted to hospital in latent labour].

Analysis revealed that that women were often expressing apprehension and fear about the unpredictable nature of childbirth, about complications and obstetric interventions, fear for their baby's safety and wellbeing, managing pain, and the perceived potential for a loss of control of the situation and loss of self-control.

'Would prefer to give birth at midwife led centre away from doctors but concerned about things like shoulder dystocia or similar as very time critical intervention needed'. [RT322, PCS score 12, WDEQ-A score 70, admitted to hospital in active labour].

'I had had worries about child being born prematurely or something not going well or afraid of child not being healthy'. [RT117, PCS score 8, WDEQ-A score 68, admitted to hospital in latent labour].

'I have concerns about managing my pain and feeling like I won't know what is going on/is normal with labour since I've never done this before and think that may cause me to panic unnecessarily'. [RT118, PCS score 7, WDEQ-A score 80, admitted to hospital in active labour].

'I feel I might lose consciousness'. [RT306, PCS score 35, WDEQ-A score 66, admitted to hospital in active labour].

'I've dreamt that I gave birth (unplanned in hospital) and was not prepared!'. [RT11, PCS score 14, WDEQ-A score 58, admitted to hospital in active labour].

# 9.4.1.1.2 Worried but with a strategy

The other sub-theme that emerged in 'The worriers' group was 'Worried but with a strategy'. This group expressed similar worries and fears to the 'Worried without a strategy' group and also expressed concerns over the safety of childbirth. To convey how they felt they used similar descriptive words such as 'worry' and 'concerned' as used in the 'Worried without a strategy' group. But they also included their strategies to counterbalance their fears and worries or to maintain some sense of control and autonomy throughout the birthing experience. Whereas the 'Worried without a strategy' appeared to be bereft of any compensatory factors.

'I have been taking a hypnobirthing course to help me manage the delivery, and I have a doula. I am very concerned about medical intervention in my birth plan and worry that is where things could go wrong'. [RT157, PCS score 24, WDEQ-A score 64, admitted to hospital in active labour].

'Hoping for the best, with little niggles of worry- Mostly about my baby arriving safely, having experienced pregnancy loss prior to this pregnancy'. [RT247, PCS score 14, WDEQ-A score 59, admitted to hospital in latent labour].

'I have been looking into hypnobirthing and hope to use it whilst in labour, but I feel unable to surrender totally to this technique - for example, that I need to tell myself a relaxed and calm birth is 'best case scenario', and that I also need to prepare for the worst case. So despite learning how to relax, how to surrender to my body, there is a constant thought at the back of my mind that I probably won't get to use it - something might go wrong, I will probably require

intervention and it won't go to plan, etc'. [RT286, PCS score 23, WDEQ-A score 62, admitted to hospital in active labour].

'Want to be in a hospital setting as I feel it is the safest if something does go wrong'. [RT379, PCS score 16, WDEQ-A score 71, admitted to hospital in active labour].

## 9.4.1.2 The rationalisers, strategisers, and planners

This distinct theme emerged and exhibited how respondents rationalised the unknown and unpredictable nature of childbirth. Although individuals expressed their concerns, they were much less likely to use to communicate these thoughts using the same emotive language as 'The worriers' group. In fact, only one participant used the word worry in this group and no one used the words fear, panic, terrified or scared. Instead, this group were much more likely to communicate a proactive approach to childbirth and convey mixed emotions of both excitement and trepidation. To mitigate against the physical, mental and unpredictable nature of childbirth participants included their coping mechanisms, and their planning and preparation strategies to support themselves to feel equipped and in control when the time came.

'I feel it is going to be a painful process but once the baby is born I will forget about all the pain and feel so much love for my baby'. [RT12, PCS score 11, WDEQ-A score 64, admitted to hospital in latent labour].

'The unknown of labour fills me with excitement and trepidation all at once. I feel like I need to train for a marathon, but I have no clue about what my current fitness or running skills are like so can't predict how I will cope! I think knowledge and education will be my best tools'. [RT30, PCS score 10, WDEQ-A score 48, admitted to hospital in active labour].

'I have tried to keep mindful of all the options and stages of labour and delivery. With knowledge of options of what turns a labour and delivery can take. I have little expectations of a set plan of how it will go and want to try my best to keep as relaxed as I can. I also feel well supported for my delivery professionally with

the NHS, antenatal classes and my husband'. [RT35, PCS score 25, WDEQ-A score 55, admitted to hospital in latent labour].

'Some worries about my baby being stillborn or having some kind of dangerous disease or developmental disability. He was measuring on the 94th percentile at 20 weeks and I'm due a growth scan at 36 weeks but some worries about him being too big to have naturally and I've read that can cause injury to the baby. However, I don't spend a great deal of time thinking over these scenarios as I know they are unlikely/medical intervention is available if necessary. Overall, I'm mainly excited to be able to finally hold my baby and I'm curious about the whole labour process and aiming to go in with no expectations and just see how I get on'. [RT340, PCS score 8, WDEQ-A score 45, admitted to hospital in active labour].

#### 9.4.1.3 The positively optimistic

Although only three respondents comprised this theme all three portrayed a positive attitude. They expressed confidence in the language that they used and by the lack of communication of any negative emotion or thoughts towards childbirth. Only one of the respondents included a strategy for managing childbirth and that was relying on the midwives knowledge to guide them through the process. Overall, their responses communicated only positive sentiments towards the approaching childbirth event.

'I look forward to the experience'. [RT16, PCS score 7, WDEQ-A score 24, admitted to hospital in active labour].

'It's not something I've given much thought to, I trust the experience of my midwives to guide me when the time comes'. [RT156, PCS score 7, WDEQ-A score 57, admitted to hospital in active labour].

'I'm feeling fairly positive'. [RT368, PCS score 6, WDEQ-A score 49, admitted to hospital in active labour].

#### 9.4.2 ANQ Question 18:'Is there anything else you would like to tell us?'

There were only 6 responses to Question 18 in the dataset. The limited number of responses prevented conducting meaningful RTA. The challenges to RTA presented by this small dataset were that each of the responses contained diverse content impeding deriving cohesive themes, the responses were short and provided very little to no insight necessary for RTA, and some were divergent or unrelatable to the primary focus of the study. Furthermore, with such limited numbers and diverse content there were no means to defend the transferability of any potential findings to the target population.

Three out of the six topics participants covered included wishing good luck with the research, offering suggestions for modifications to the ANQ, and supplying information about participation in another study.

'Best of luck for your research project'. [RT370, PCS score 28, WDEQ-A 66, admitted to hospital in active labour].

'That the question about fantasies when sleeping should be open-ended and not so specific. If somebody has nightmares about birth for example and let the participant answer'. [RT377, PCS score 14, WDEQ-A 31, admitted to hospital in latent labour].

'Taking part in Preg-Cov trial'. [RT378, PCS score 5, WDEQ-A score 48, admitted to hospital in latent labour.

Two out of the six responses provided a brief insight into what the participants were thinking about when answering the closed questions on the ANQ. However, the participants did not elaborate on how these thought processes might have affected their answers.

'When relating to the pain section of the questionnaire, I was thinking of what I feel like when I have had a migraine. Luckily I have not had any during pregnancy'. [RT35, PCS score 25, WDEQ-A score 55, admitted to hospital in active labour].

'Not sure if being in the medical profession affects my answers'. [RT322, PCS score 12, WDEQ-A score 70, admitted to hospital in active labour].

Finally, one out of the six who responded to Question 18 provided information about the strategy that they were planning to use to help them manage labour pain and anxiety. Although interesting, this brief information in isolation does not provide enough qualitative information necessary for RTA.

'I am just about to start a hypnobirthing course to help with pain management and anxiety'. [RT181, PCS score 21, WDEQ-A score 52, admitted to hospital in latent labour].

#### 9.4.3 PNQ Question 17: 'Is there anything else you would like to tell us?'

27 out of the 82 participants responded and provided comments to this question. This was the final question on the PNQ and the final question asked of the participants in the study. The response rate was 32.93% (27/82), much higher than 7.32% (6/82) response rate to the same last question but asked on the ANQ. However, the response rate was similar to the response rate to the ANQ (30.49% (25/80) asking participants to: 'Please feel free to provide any additional thoughts you may have about labour and birth' which appeared approximately midway through the ANQ and guided the topic for response.

This postnatal open-ended question asking participants to share their thoughts ('Is there anything else you would like to tell us?') came at the end of the PNQ. A questionnaire that predominantly focussed on childbirth experiences and choices. There was no suggestion of a topic to guide responses. However, participants chose to predominantly comment on their experiences around childbirth. Participants shared a range of thoughts that centred around their emotions, obstetric interventions, and their encounters with healthcare providers. Five participants chose to take a more factual response style that held neither negative nor positive connotations and provided little insight into the participants thoughts, emotions, or opinions. One of these five commented on the questionnaire design in their response.

The analysis of participants' responses to this particular question resulted in identifying three prominent themes. Two themes were grouped around the sentiment communicated in the message and the third was characterised by the factual response style and lack of sentiment:

- 1. Positive reflections of childbirth attributed to the support received.
- 2. Childbirth pain is normal, so you deal with that yourself, we are in-charge of all the other things.
- 3. Just tell us the facts.

Table 36 provides context for these RTA findings. The largest group were 'The positive reflection of childbirth attributed to the support received' group (total n=14). The 'Childbirth pain is normal, so you deal with that yourself, we are in-charge of all the other things' group did have one participant outside of the upper gestation limit for inclusion criteria and three below the lower gestation limit (inclusion criteria 25 to 33 weeks and 6 days gestation). All participants gestation ranges were very similar ranging overall between 25 to 33 completed weeks pregnant, again reasonably expected considering the inclusion criteria.

Table 36: Tabulation of the context for the reflexive thematic analysis for Question 17 on the PNQ

| Group                        | Total<br>number<br>in group<br>(n=) | Postnatal<br>range when<br>answering<br>PNQ<br>(days) | PCS<br>score<br>range | How<br>many<br>PCS<br>≥20 | FOC<br>score<br>range | Total number admitted to hospital during latent phase (%) (n=) | Total number admitted to hospital during active labour (%) (n=) |
|------------------------------|-------------------------------------|---|-----------------------|---------------------------|-----------------------|--|---|
| 1. Positive<br>Reflection    | 14                                  | 21-30   | 2-30                  | 2                         | 31-80                 | 35.71%<br>(n=5)  | 64.29%<br>(n=9)   |
| 2. Childbirth pain is normal | 8                                   | 22-39   | 0-25                  | 1                         | 23-60                 | 75%<br>(n=6)   | 25%<br>(n=2)  |
| 3 Just tell us the facts     | 5                                   | 21-34   | 4-30                  | 2                         | 25-103                | 60%<br>(n=3)   | 40%<br>(n=2)  |

#### 9.4.3.1 Positive Reflection of Childbirth Attributed to the Support Received

Analysis revealed a recurring theme that revolved around the key role of the healthcare provider in the participants journey through pregnancy, childbirth and the postnatal period. Positive instances highlighted the invaluable support, guidance and expertise given by health professionals, even when there was obstetric intervention. Most often participants were referring to their midwives with some participants specifically acknowledging the team or midwife who they believed significantly contributed to their positive experiences:

'Continuity midwives have been amazing. For me it was a comfort and with visits for them whilst in hospital allowed me to open up about my mental health as they were a familiar face and safe space. Then the postnatal support has been brilliant as it's the same team if not the same midwife each time. I have had a brilliant experience with my continuity midwife team, the team'. [RT227, PCS score 12, WDEQ-A score 45, admitted to hospital in latent labour]. 'The maternity team were amazing'. [RT181, PCS score 21, WDEQ-A score 52, admitted during latent labour]. team were incredible, I feel so fortunate to have such a wonderful experience throughout pregnancy and labour'. [RT130, PCS score 6, WDEQ-A score 31, admitted to hospital in latent labour]. 'We had a fabulous birth experience once in the birthing suite. Our midwife was amazingly supportive, encouraging and made my husband also feel an important part of the birthing process. We cannot thank her enough for helping bring our first child and daughter into the world'. [RT341, PCS score 30, WDEQ-A score 62, admitted to hospital in latent labour]. 'I found the midwife who lead me through really helpful and calming. I am very

active labour].

birth centre and birth pool were amazing! Midwives made me feel very supported'. [RT378, PCS score 5, WDEQ-A score 48, admitted to hospital in latent labour].

Participants expressed their gratitude for midwives who were supportive and informative, and highlighted continuity of care as being an important factor in their journey to parenthood, and important in self-efficacy. Although 'support' was frequently expressed as a valued quality the elements constituting that support was often not communicated:

'During labour, I felt in control of the pain and through breathing and my birth partner support I found much better to control the pain. I only required epidural after I reached 9cm, nearly 12 hours after hospital admission because I needed to deliver my baby with forceps, otherwise I felt the pain was bearable and the support of the staff and my partner were crucial'. [RT117, PCS score 8, WDEQ-A score 68, admitted to hospital in latent labour].

'I have put that I did not suffer mental health issues but I had very low points in the first week, centred around feeding and difficulties with my baby latching. I have been given excellent support for the infant feeding team and now at 3 weeks, things have improved hugely'. [RT165, PCS score 15, WDEQ-A score 52, admitted to hospital in active labour].

However, one participant did go into more detail and explained what elements of the support that she valued. Being kept informed of labour progress was valued as were the opportunity to discuss potential care plans and interventions as labour progressed. Communication between this participant and her maternity care providers were valued but it also appears that this woman appreciated the midwives communicating between themselves to ensure the care they provided was optimal. These communications and the involvement of the woman in her own care contributed to her feeling 'well cared for':

'Once I was in labour and had been admitted to hospital, the midwife care was excellent and very supportive. The midwives kept me informed of my options at

all stages and talked me through the options as my labour progressed and things were not going to plan. For example, the 'pushing' phase was taking longer than anticipated and the baby kept moving backwards; they noted that they was limited space to get the baby out through the final stages and I was offered an episiotomy and they kept monitoring the baby throughout for signs of distress. When the baby came out, his arm was by his head (and the reason why pushing was so difficult); they ensured I had some brief skin-to-skin time before he was looked at by the paediatrician and talked me through this the entire time. I required stitches for the episiotomy as well as some awkwardly placed grazes which was checked by senior midwifes as needed. I felt very well cared for'. [RT365, PCS score not available, WDEQ-A score 47, admitted to hospital in active labour].

Participants often chose the words 'amazing' and 'incredible' to describe the care they received:

'Midwives we're amazing at coaching me'. [RT28 PCS score 2, WDEQ-A score 54, admitted to hospital in active labour].

'I loved my birth experience, even though it ended with a forceps delivery in hospital. I put this down to having the home birthing team service and wish more women were confident/aware of what an incredible option this is to have. [RT30, PCS score 10, WDEQ-A score 48, admitted to hospital in active labour].

'The NHS care I received was really amazing'. [RT118, PCS score 7, WDEQ-A score 80, admitted during to hospital in labour].

'Midwife unit was amazing, would have been much worse if on labour ward.

Also being discharged the same day and not having to leave the birthing suite until then was amazing'. [RT310, PCS score 14, WDEQ-A score 75, admitted to hospital in active labour].

'The midwives at were amazing......'. [RT127, PCS score 6, WDEQ-A score 63, admitted to hospital in active labour].

9.4.3.2 Childbirth pain is normal, so you deal with that yourself, we are in-charge of all the other things.

Responses that constructed this theme primarily centred around the negative experiences participants had during childbirth including reporting where the negative experience occurred, receiving inadequate pain management, feeling ignored, lack of staff, incorrect advice, or feeling pressured into certain obstetric interventions:

'I was upset for a few days following the birth as felt couldn't trust hospital to give pain relief and would not want to go through it again. I went from 3cm to 10 cm in short space so no time for it although almost sent home. Yeah ness in shock but also knew the pain I had been in after delivery was given epidural after birth due to retained placenta as injection didn't work, Entonox® tried first. When I went to theatre was so happy to receive pain relief at last then found recovery difficult offered birth counselling in future'. [RT35, PCS score 25, WDEQ-A score 55, admitted to hospital in latent labour].

'RLH need to fully reconsider the impact staffing has on outcomes in birth. I was not assessed for 16hrs and went from 2 to 10cm with little pain relief offered.

Ended up with potential sepsis risk and myself & baby on IV antibiotics for 1week PP. unacceptable level of 1:1 care. They convinced my husband I was not contracting. When I said I want to push I was ignored. [RT285, PCS score 11, WDEQ-A score 60, admitted to hospital in latent labour].

Baby born by emergency c section after becoming distressed following 52 hours of continuous labour. Admitted to MAU for 6 hours prior to c section, MAU had no available pain relief except paracetamol or dihydracodeine which didn't help. Unit incredibly short staffed, left alone for long periods of time which became stressful as pain intensified and the only furniture in the room was a bare hard exam couch or plastic chair. In the end the c section was by far the best bit as it finally took the pain away!' [RT96, PCS score 0, WDEQ-A score 23, admitted to hospital in active labour].

I phoned at 9 am and was told to stay at home until I couldn't talk through a contraction. I am not sure this was correct advice as I could always talk through my contractions throughout my labour and if I had come in earlier the car journey would not have been as uncomfortable as my contractions were coming thick and fast in the car by then as I stayed at home for a few hours and had a bath which slowed them down temporarily. [RT394, PCS score 8, WDEQ-A score 49, admitted to hospital in active labour].

Some participants communicated feelings of dissatisfaction with their care or trauma stemming from unexpected outcomes, such as emergency caesarean sections or prolonged labour leading to heightened pain and stress:

I was in labour for so long before I received intervention/stronger pain relief I feel it meant that I required more pain relief (epidural) to rest so I could then deliver vaginally. My baby was back to back and I wonder if earlier identification of the slow progress to established labour (despite strong and frequent contractions) might have reduced the amount of time I was in labour/the extent of the pain relief I required. [RT247, PCS score 14, WDEQ-A score 59, admitted to hospital in latent labour].

Felt pressured to have an induction if I hadn't given birth by 24 hours after waters breaking, this is not something I wanted and in the end didn't have to but felt no other options were discussed with me before it was booked in. I also was kept waiting in triage for over an hour in the waiting area as there was a shift change when we arrived, not ideal when I was trying to stay calm and work on my breathing. [RT85, PCS score 11, WDEQ-A score 41, admitted to hospital in latent labour].

Water was broken during vaginal examination so admitted even though only 1cm. Forceps delivery. Poor support during antenatal stay prior to being taken to delivery suite. [RT58, PCS did not complete, WDEQ-A score 35, admitted to hospital in latent labour].

My labour ended up being quite traumatic and needed an emergency c section as my babies heart kept dropping and not recovering. It was nothing I had planned for. [RT393, PCS score 10, WDEQ-A score 30, admitted to hospital in latent labour].

#### 9.4.3.3 Just tell us the facts.

Some participants chose to convey only factual accounts detailing events during their labour and child's birth. Participants predominantly reported obstetric interventions and outcomes without detailing emotions or sentiments or their subjective experience. Although participants reported in a factual style most linked obstetric intervention with an ongoing physical problem such as pain:

'I underwent forceps delivery with episiotomy so now my main problem is pelvic floor issues. I have been referred to physio'. [RT33, PCS score 22, WDEQ-A score 82, admitted to hospital in latent labour].

'Had the birth continued to progress as it had for the first 18hrs I wouldn't have had the epidural but things stalled at 8cm/around the first shift change. Pain since birth has been very manageable; I've only had to take the occasional paracetamol'. [RT34, PCS score 4, WDEQ-A score 34, admitted to hospital in active labour].

My labour was augmented. [RT377, PCS score 14, WDEQ-A score 31, admitted to hospital in latent labour].

Ongoing pain and discomfort from episiotomy. [RT380, PCS score 5, WDEQ-A score 25, admitted to hospital in active labour].

One participant did comment on the design of the PNQ which made it difficult to complete every question.

It was hard to answer some of the questions as I was induced due to prolonged rupture of membranes. [RT257, PCS score 30, WDEQ-A score 103, admitted to hospital in latent labour].

#### 9.5 Discussion

The following discussion will be sectioned under each objective explored in this chapter (objectives v, vi, and vii) and will be followed by recommendations for clinical practice and future research.

9.5.1 Objective v: To determine the factors that pregnant women find helpful and supportive, or unhelpful, with their pain management during labour. Manifest content analysis: Pain catastrophising versus non-pain catastrophising was there a difference in what they found useful and what they found not useful.

There are no past studies that have considered pain catastrophising scores and pain management options chosen by women when they are in labour.

There were very few differences between women with high and low PCS scores in terms of relaxation and pain management techniques that participants found useful and supportive. RETHINK participants frequently chose non-pharmacological relaxation and pain management techniques potentially supporting the idea that women more frequently choose to 'work with pain' and do not always want a pain-free labour (Leap et al. 2010). Or an alternate explanation could be that in choosing non-pharmacological techniques women are avoiding the potential side-effects of medications and/or are avoiding the method of administration e.g. needle insertion as previously discussed (Chapter 8 Section 8.3.2). The suggestion here is that women might select the same relaxation or pain management technique but for different reasons. This could dilute the impact of pain catastrophising on women's pain management choices. More work is needed to understand the reasons driving women's pain management choices.

Entonox® was the most frequently cited as being useful and supportive for those participants who reported PCS scores ≥20. Entonox® has been found to maintain maternal choice, empowerment and autonomy (Collins 2017). Entonox® is a frequent choice for women and has demonstrated its effectiveness in other studies (Pasha et al. 2012; Pita et al. 2012; Nodine et al. 2020).

Entonox® was also cited most frequently as being not useful or had a negative effective for labour pain management by all women irrespective of PCS scores. In the literature some examples to explain the negatives to its use could be due to women not managing the technique to draw and breath effectively with the gas, it not working effectively to reduce or remove contraction pain, or not liking the side effects of dizziness, nausea or vomiting (Bradfield et al. 2023).

Breathing techniques and birth partner support were most favoured by participants who reported low PCS scores (<20). Logically breathing techniques are the most accessible to all. This study supports Heim and Makuch (2023) who suggest that although there are some discrepancies in the literature breathing techniques have demonstrated their effectiveness to support women with their labour pain. Neither group, pain catastrophisers (≥20) or non-pain catastrophisers (<20), in the RETHINK study cited breathing techniques as being not useful or as having a negative effect on helping them to manage the labour pain. This being said, anecdotally women do not receive routinised advice on what breathing techniques actually are or how to do them. Heim and Makuch (2023) support this and propose women lack guidance on how to effectively use breathing techniques and how to integrate breathing techniques with other pharmacological and non-pharmacological pain management techniques throughout their labour (Heim and Makuch 2023).

RETHINK findings show women are choosing non-pharmacological techniques and finding them useful despite professional recommendations disregarding or advising against them (NICE 2023a). For example, participants chose hypnosis/hypnobirthing and those who pain catastrophise (PCS scores ≥20) tended to choose it more frequently based on percentage numbers. Although one out of the seven who did choose to use this method reported it as not useful. There were no reports of hypnosis/hypnobirthing being not useful out of those participants who do not catastrophise and chose to use it. These findings reflect those reported in other studies which suggest that although non-pharmacological techniques may not reduce obstetric intervention (Smith et al. 2018), they are important to women's positive reflections on the childbirth experience (Thomson et al. 2019). It has also been suggested that the lack of evidence to inform clinical practice, and for the reduction in obstetric

intervention may be due to study methodology and the level competence in the delivery of the intervention (Smith et al. 2018).

Overall women in the RETHINK study cited non-pharmacological relaxation and pain management techniques most frequently as being useful and supportive and cited pharmacological techniques most frequently as not being useful or having a negative effect in helping them to manage their labour pain. Although there were contradictions, with some individual techniques being cited as useful by some women and not useful by others. These contradictions are to be expected and are also reflected in the literature and point towards labour pain management being complex and multifaceted and requiring a holistic approach when supporting women through the experience (Jones et al. 2012; Boaviagem et al. 2017; Downe et al. 2018; Smith et al. 2018; Nori et al. 2023; Zuarez-Easton et al. 2023).

RETHINK study findings have been reported as pharmacological versus non-pharmacological. However, caution should be exercised around pursuing one approach over another because this can deflect or sustain childbirth practices which is not necessarily in the interests of women or their babies (Independent Maternity Review. 2022).

Childbirth experiences can range from positively transformative and empowering to traumatic and potentially psychologically damaging (Yildiz et al. 2017; Rodríguez-Almagro 2019; Olza et al. 2018; Kurz et al. 2022). Pain management in labour is an important contributory factor to a woman's childbirth experience which if ineffective can have a negative impact on a women's childbirth experience and her psychological wellbeing (Ghanbari-Homayi et al. 2019; Gathus-Niegel et al. 2014). Although not all women cite the same intensity, labour pain is one of the most intense forms of pain that can be experienced (Melzack 1984) and it is not up to others to assume whether the dimension of pain does or does not cause suffering (Turk and Wilson 2009).

A pain-free labour using pharmacological techniques does not always mean women report a greater degree of satisfaction with their childbirth experience (Hodnett 2002; Heinz and Sleigh 2003; Smith et al. 2006; Lally et al. 2008; Green et al. 2009). This is

also borne out in the findings in the RETHINK study. RETHINK participants frequently chose non-pharmacological techniques and report these as being not useful less frequently than non-pharmacological techniques. Perhaps there is an element of expectation at work here (Lally et al. 2014; Sutton et al. 2023). The RETHINK study contributes to existing literature calling for leading professional bodies to acknowledge the efficacy of non-pharmacological techniques to effectively support women to cope with their labour pain rather than eliminate it (Chaillet et al. 2014; Zuarez-Easton et al. 2023), and the requirement of fully informing and discussing pain relief options with women during the antenatal period (NICE 2023; Sutton et al. 2023). More work is needed to meet this objective.

Childbirth research and education, the provision and organisation of maternity care, pain management strategies, and one-to-one care provided by midwives reflects a societies' understanding and approach to childbirth pain. Midwives are not trained in how to support women with labour pain effectively and psychologically with evidenced-based strategies (Bartholomew et al. 2023) and they are trying to provide high quality labour care and pain management advice to women in a system that is already over-stretched. A system that has been heavily criticised in recent years (Zwecker et al. 2011; Kirkup 2015; Miller et al. 2016; Fox et al. 2019; Topçu & Brown 2019; Seijmonsbergen-Schermers et al. 2020a; Seijmonsbergen-Schermers et al. 2020b; Darling et al. 2021; Independent Maternity Review 2022; Elaraby et al. 2023). These factors appear to permeate through to the findings in the RETHINK study and may have contributed and underpin those things that participants cited as being not useful or had a negative effect on helping them to manage their labour pain.

Historically UK policies have been medically dominated and this approach persists, underpins, and influences midwifery practice today (Darling et al. 2021; Renfrew 2022). In England pain management for women in established labour is limited to pharmaceuticals and for women to labour in water (NICE 2023a). Outside of these provisions there is specific advice given about the very little evidence for the effectiveness of TENS devices, and midwives are advised to not offer acupuncture, acupressure or hypnosis during labour but if women choose to use any of these techniques, then their choices should be supported. Finally, it is advised that women

should be supported if they choose to play music or use massage techniques provided by their birth partner/s. For latent labour the advice is limited to breathing exercises, having a shower or bath, and massage which may help to reduce pain (NICE 2023a) Overall, there is little attention given to non-pharmacological interventions including no provision for psychological interventions (NICE 2023a) which appears at odds with what women reported in this study.

9.5.1.1 Latent content analysis: All participants reflections about what was useful to them and what was not useful or had a negative effect in helping them to manage their labour pain.

In describing what they found unhelpful participants brought into the fore elements such as the support they received through labour and birth, and their experiences of birthing in an NHS maternity care system. These experiences uphold the criticisms lodged above and were evident in the themes identified by the latent content analysis. The themes identified were 'delays to receiving labour support, delays or non-provision of treatment including pain relief', 'poor communication and attitude of staff' and 'its's only pain: references to poor responses to and communication around labour pain'. These themes are in direct opposition to what is recommended as part of a woman's labour care which is that she should feel empowered, informed and central to decision-making about her care (NICE 2023a). Fundamentally, midwives and maternity services should serve each woman's interests by providing respectful, kind, supportive, and responsive care which protects and promotes the psychological as well as the physical safety of childbearing women and their families. Women experiencing inadequate intrapartum care are significantly at risk of developing acute psychological trauma symptoms (Creedy et al. 2000; Thomas 2024) and poorer satisfaction and reflections surrounding childbirth experience (Goodman et al. 2004; CQC 2024a). Inadequate and disrespectful care falls short of professional guidelines and codes of practice (Nursing and Midwifery Council (NMC) 2018; NICE 2023a). McKelvin et al. (2021) highlight the significant impact of negative childbirth experiences which are a risk factor for developing postnatal depression and PTSD.

Since the RETHINK study data collection period (December 2020 to January 2022) the CQC (2024a) report that from a survey of 25,500 women there continued in a downward trend in women's satisfaction with care in some areas. There has also been a report on the first national inquiry in the UK Parliament to investigate reasons for birth trauma and make recommendations for improvement (Thomas 2024). This inquiry reports many traumatic stories, including but not limited to, the lack of attention given to women in pain throughout the perinatal period and the lack of sufficient pain relief in labour. Both the CQC (2023; 2024a) and the inquiry into birth trauma (Thomas 2024) are echoed in the negative reflections that RETHINK participants describe. The CQC (2024a) report that women were left alone at a time when it worried them, that they could not always get someone to help them when they needed it and sometimes not at all, and they were not always given the information they needed whilst in hospital after birth. Poor performance was also seen in women reporting that they were not treated with kindness or understanding. Although there were some areas of improvements with many women reporting more satisfaction around receiving "appropriate advice and support when they contacted a midwife or the hospital when in early labour". Women also reported their partners were involved more during labour, and "four out of five women felt their concerns during labour and birth were taken seriously by staff". Similar stories and concerns were also reported by the women in the inquiry into birth trauma (Thomas 2024).

For improvement it is important to not only know the negative, but to also understand what women find useful and supportive. This shift to a salutogenic perspective can contribute to a more comprehensive understanding about how women can stay psychologically well throughout the pregnancy and postnatal continuum (McKelvin et al. 2021).

In-labour 'support' is sometimes used as generic term when helping women their labour pain management without specification for what that support particularly entails for birth partners, and for midwives providing labour care and advice. The themes and coding categories contribute to knowledge in this area. For the theme 'supportive birth partners' women valued 'feeling in it together', which meant birth partners took an active role in some of the labour experience such as breathing

through contractions and undertaking a hypnobirthing course together. They appreciated verbal coaching and reassurance, and the presence of touch. In some instances, women were reassured just by the presence of their birth partner. In the 'supportive birth partners' theme the personal relationship they had with their birth partner underpinned those elements that they found supportive.

For the theme 'supportive midwifery' the participants valued the midwife's knowledge, verbal coaching and reassurance, and the importance of knowing one another. This theme embodies professional recommendations (NICE 2023a) which support the work of Olza et al. (2018) who concluded that physical, emotional and social support for women can maximise their sense of empowerment and benefit the psychological experience of childbirth. Numerous studies emphasise the importance of positive continuous support for women through labour and birth. Continuous support has been associated with greater chance of a shorter labour and a spontaneous vaginal birth, better pain management outcomes, reduced need for analgesia, higher satisfaction with the birth experience, and babies may be more likely to have better Apgar scores at five minutes post birth (Bohren et al. 2017). From a professional perspective continuous support for women during childbirth is recommended worldwide (WHO 2018) but as the RETHINK study findings underpin that support must be free from the burdens of an overstretched maternity care system, and it must be skilled, kind and respectful.

#### 9.5.1.2 Recommendations for clinical practice and research

Women have diverse experiences with non-pharmacological and pharmacological pain relief methods during labour, with some techniques being effective for certain women while less so for others. It is crucial for midwives to engage in thorough discussions with women about their pain management options, exploring the underlying thoughts and concerns driving their choices. This communication allows midwives to alleviate fears, manage expectations, and adapt pain management strategies to each woman's individual needs and preferences.

Through antenatal conversations and information sharing, women should feel empowered to make labour decisions aligned with their needs, supporting dynamic decision-making during the vulnerable time of labour.

To fully explore pain management strategies with women, midwives must understand the different drivers underpinning decisions, such as pain catastrophising, preferences to avoid pharmaceutical side effects, and desires to work with or avoid pain during labour.

Midwives should regularly reflect on their practice and evaluate their biases regarding non-pharmacological and pharmacological pain relief methods to provide unbiased, tailored care to each woman.

It is vital that midwives remain cognisant of the system pressures within the NHS that can impact care and ensure effective, timely communication with women when these pressures unavoidably affect care. Above all, kindness and respect should always be present in care provision and communications. When appropriate, midwives should advocate for women to management and influential stakeholders, urging for the improvement of maternity services. For example, through the relevant systems available within the NHS, always reporting when staffing levels are below safety standards.

Researchers should continue to explore the complex and multifaceted nature of labour pain. Studies should include how pain catastrophising may or may not influence a woman's labour pain management choices and the effectiveness of these choices during labour. The RETHINK study findings demonstrate that women are employing multiple relaxation or pain management techniques during labour. Therefore, future studies should investigate the effectiveness of combining different techniques including different combinations of non-pharmacological and pharmacological methods.

Researchers (and midwives) should stay informed about technological advancements.

One approach that did not feature in any woman's relaxation and pain management techniques in this study were digital solutions such as using virtual reality or mobile

phone applications (apps). Virtual reality is an emerging area in healthcare, showing promising results for pregnant women (Hajesmaeel-Gohari et al. 2021) and providing support during labour (Musters et al. 2023). Such approaches can often be combined with other, pre-existing relaxation or pain management techniques, enhancing their effectiveness.

- 9.5.2 Objective vi: To analyse who and what are the influencing factors that impact on a woman's decision to seek hospital admission when in labour and the relationship between these factors and pain catastrophising.
- 9.5.2.1 Who is most influential in deciding the time to go to hospital when in labour.

How individuals report their pain, societal influences and responses to pain, and how caregivers provide support for the person in pain is a complex network shaped by multifactorial variables which are not yet fully understood (Campbell and Edwards 2012). Socio-cultural groups have been demonstrated to influence a person's evaluation and interpretation of pain, their emotional and behavioural responses to it, and also influences the treatment given by care providers (Campbell and Edwards 2012; Mohammadi et al. 2017; Orhan et al. 2018; Sullivan and Tripp 2024). Considering the influence of pain catastrophising on pain behaviours, and how others respond to those pain behaviours, it is valuable to understand from a RETHINK participant's perspective where the locus of influence comes from in determining the time to move from home to hospital during labour. Knowledge about labour pain experience and behaviours and how we react and respond to it provides a basis for midwives to be vigilant and reflect about their own values and beliefs to ensure their care is equitable and individualised and supports the woman's choice (NICE 2023a).

There can be no conclusions drawn from the RETHINK study about the process of decision making, the information used in this process, or how the final decision was made. However, it appears that it was the participant herself who was most influential in the final decision to go to hospital when she was in labour. A study by Gehling et al. (2023) would concur with this finding. They also found that it is the woman herself who is most influential in this important decision.

# 9.5.2.2 What were the signs that signalled to you that it was time to go to hospital when you were in labour?

The participants in the RETHINK study reported an array of signs and symptoms that indicated to them to seek hospital admission. The most frequently cited sign was the frequency of contractions followed by corresponding pain and intensity, and then rupture of membranes. These influences reflect findings in the literature to date (Beebe and Humphreys 2006; Cheyne et al. 2007; Gross et al. 2009; Edmonds and Zabbo 2017; Edmonds et al. 2018) and suggest that women were following clinical advice. Outside of adverse signs and symptoms, women are often advised to phone for advice when contractions become regular and occur two or more in every 10 minutes (NHS England 2023b). Although the frequency of contractions is important (Leathersich et al. 2018) it appears that their frequency have become a main feature in the decision-making process. One possible reason for this proposition is because timing of contractions is a relatively tangible element based on objective fact upon which both women and midwife can base their decision. The timing of hospital admission in labour is one area where women have found that they must prove their credibility (Eri et al. 2010; Low and Moffat 2006; Henderson and Redshaw 2017; Allen et al. 2020) and women can defer to the tangible contraction frequency rather than having to justify their needs for support with pain or reassurance. From a midwife perspective decision-making under pressures from maternity services, in the absence of adverse events midwives use their own clinical assessment relying on tangible facts like frequency of contractions, and vaginal examinations rather than women's reports of their experiences of other signs and symptoms (Beake et al. 2018; Hundley et al. 2020).

However, in professional guidance diagnosing latent labour only the presence of contractions is required alongside other defining features. With the frequency of contractions not appearing in the current definition (NICE 2023a). Similarly, for active labour only regular contractions are required alongside other defining features (NICE 2023a). In Hanley et al's (2016) systematic review of definitions for the phases of labour it was contraction regularity rather than frequency that was more repeatedly described as a defining feature of the latent and active phases.

Previous studies have indicated that women find latent labour difficult to manage (Kobayashi et al. 2017; Ängeby et al. 2019) with many seeking support for contraction pain, anxiety and fear (Beebe and Humphreys 2006; Cheyne et al. 2007; Barnett et al. 2008; Carlsson et al. 2009; Carlsson 2016; Cliffe 2017; Edmonds et al. 2018). Women's experiences and duration of latent labour are highly variable (Friedman 1955; Gross et al. 2003; Zhang et al. 2010; Oladapo et al. 2018; Tilden et al. 2019; Grylka-Baeschlin and Mueller 2023) with different factors influencing the time to seek hospital admission (Cheyne et al. 2007; Carlsson et al. 2009; Eri et al. 2015; Kobayashi 2017). A limiting factor for the findings in the RETHINK study could have been the phrasing of the question which may have led to a certain type of responses. Women were asked to cite "the signs that signalled to you that it was time to go to hospital" which may have led to responses focussing on the clinical aspects rather than women expressing thoughts or feelings that were also present. Furthermore, women were surveyed at three weeks postnatal which may have hindered recall about their thoughts at the time, and women may have been less willing to share their thoughts and feelings through an online questionnaire.

#### 9.5.2.3 Recommendations for clinical practice and research

These findings suggest the need for midwives to adopt a more holistic approach when advising women about the timing of hospital admission during labour. While the frequency of contractions is most often cited as the reason for seeking hospital admission, midwives should also consider the psychological aspects, such as pain catastrophising, which may be impacting on a woman's decision to go to the hospital. Midwives should engage in thorough discussions with pregnant women about all the signs and symptoms of labour, including pain, regularity, and the intensity of contractions and emotional responses. This approach will help ensure that women's fears and anxieties are acknowledged and managed effectively, promoting individualised care.

Greater knowledge about diverse experiences during latent labour (Grylka-Baeschlin and Mueller 2023) and what are the influential factors in deciding when to seek hospital admission can contribute to underpinning woman-centred care, contribute to

a support intervention design, and inform education for women and midwives (Hanley et al. 2016). Future research should continue to explore the complex interplay between psychological factors like pain catastrophising and the decision-making process regarding hospital admission during labour. By widening the scope of research to include psychological dimensions such as pain catastrophising, can inform the development of more effective, evidence-based practices that address the diverse needs of women in labour.

9.5.3 Objective vii: Explore the responses from open-ended questions provided on the two online questionnaires consider the nuanced account of participants' experiences contained within the data, assess for triangulation of data, and consider for a balanced holistic explanation of the study findings.

The RTA fulfilled the objectives to triangulate the data and provide a nuanced account for enriching the quantitative findings. The RTA also triangulated with the content analysis findings.

The PCS scores, the WDEQ-A scores and the timing of hospital provided context for the analysis of the antenatal open-ended questions. These scores were notable by their approximation and tracking of themes from worry, through to optimism. Similar patterns between contextual factors and the postnatal themes were not apparent.

Participants did refer to their concerns about coping with labour pain although direct comparisons to the PCS (Sullivan et al. 1995) could not be made. Similarly direct comparisons between participants' concerns surrounding labour and birth and the fear of childbirth WDEQ-A (Wijma et al. 1998) tool could not be made but the concerns that participants did express echoed the items in the WDEQ-A (Wijma et al. 1998).

Worries and fears about childbirth expressed during the antenatal period by RETHINK participants reflect those that have been previously described in other studies and identified as important (Richens 2018; Downe et al. 2018). A woman's negative antenatal cognitions, her attitudes towards childbirth and her abilities to cope can be identified in her decision-making during labour, in her postnatal childbirth reflections, (Carlsson 2009; Carlsson et al. 2015; Hill and Firth 2018; McKelvin et al. 2021), and in

her increased chance of developing post-traumatic stress syndrome (PTSS) (Larsson et al. 2011).

With regards to a woman's management of latent labour, not coping with pain and having low levels of confidence have been cited as reasons why women seek early hospital admission (Low and Moffat, 2006; Cheyne et al. 2007). Cappelletti et al. (2016) recommended providing women with clear information and advice to increase their confidence and self-efficacy and decrease anxiety and fear. Some studies have explored the concept of self-efficacy (Bandura 1977) and have found that it relates to how women cope during latent labour at home and as a positive predicator for positive birth reflection (Beebe et al. 2007; Berentson-shaw et al. 2009; Carlsson 2015). However, fewer studies have considered the role of positive mental schema in childbirth satisfaction and childbirth outcomes and instead focus on causes of negative mindsets and pathology (McKelvin et al. 2021). It is important for woman to have the psychological tools they need to cope, confidently and resiliently, with the challenges of labour and birth. Studies that have considered interventions that build positive mental schemas through education and emphasise coping strategies, resilience, and building self-efficacy have found that they foster greater childbirth satisfaction, confidence, empowerment, and improve perinatal outcomes (Goodman et al 2004; Cyna et al. 2006; Cyna et al. 2013; Downe et al. 2015; Tilden et al. 2016; Demirci et al. 2021; Hong et al 2021).

The RETHINK participants' positive postnatal reflections summarised in the theme 'positive reflection of childbirth attributed to the support received' centred around the positive value participants ascribed to their healthcare provider (usually the midwife). Participants' reflections constructing this theme echo the sentiments of professional guidelines and standards (NMC 2018; NICE 2019a, 2021a; 2021b; 2021c; 2023) which underpin the importance of respectful, individualised, woman-centred care in a woman's childbirth experience. As participants looked to their midwife to guide them through labour and birth they identified the value of the midwife-woman relationship, continuity of care, and one-to-one continuous active labour support (Eri et al. 2015; Allen 2020; McKelvin et al. 2020).

Unfortunately, the negative reflections in the theme "Childbirth pain is normal, so you deal with that yourself, we are in-charge of all the other things" featured the abject opposite to 'positive reflection of childbirth attributed to the support received' which possibly indicated an overstretched maternity care system as reasons for poor care (Darling et al. 2021; Renfrew et al. 2022). The absence of effective pain management has been associated with traumatic birth (Ghanbari-Homayi et al. 2019) and coupled with a woman's overall negative reflections on her birth experience have been identified as precursors to PTSD (Garthus-Niegel et al. 2013).

# 9.5.3.1 Recommendations for clinical practice and research

Engaging in proactive discussions with pregnant women about their worries and fears is beneficial for fostering a positive childbirth experience (Hall et al. 2022). Prioritising respectful individualised care and instilling a sense of empowerment and greater self-efficacy through clear, and comprehensive information, and kind professional relationships is encouraged. Additionally, guidelines underscore the importance of sharing information, respectful individualised care, shared decision-making, and empowerment as key recommendations, guiding principles and standards (NMC 2018; NICE 2019a; 2021a; 2021b; 2021c; 2023).

Tools such as the Pain Catastrophizing Scale (PCS) could be useful for identifying negative cognitions early which can then be addressed before labour. The PCS has the potential to be used as a tool for stimulating conversations and provides an opportunity to listen to women and address their needs. Failure to listen to women is a key issue highlighted by the inquiry into birth trauma (Thomas 2024). Addressing pain management proactively and empathetically is vital, as ineffective pain relief can lead to traumatic birth experiences and subsequent PTSD (McKelvin et al. 2021; Thomas 2024).

To further support these recommendations, maternity services are encouraged to consider the impact of system pressures on care quality and strive toward respectful, woman-centred care in line with professional guidelines and standards (NMC 2018; NICE 2019a; 2021a; 2021b; 2021c; 2023).

Future research may find value in exploring the complex relationships between pain catastrophising, attitudes towards labour and birth, and intervening factors during labour and birth, that coalesce into postnatal childbirth reflections. Investigating ways to improve antenatal education, build childbirth self-efficacy, and assess the feasibility and acceptability of integrating interventions within NHS maternity services could contribute to improved maternity healthcare.

# 9.6 Chapter summary

Managing labour pain is a complex and multifaceted process that requires a comprehensive approach involving the woman, her birth partner, and her midwife. With midwifery care, particularly with care provided during labour and birth, often being instrumental in positive and negative childbirth reflections. Midwives are encouraged to be aware of system pressures within the NHS that can impact care quality and to ensure effective communication with women when these pressures affect service provision in real time.

Engaging in thorough discussions with women about their pain management options during labour is important, as it enables midwives to understand the underlying thoughts and concerns driving women's choices. It may be helpful for midwives to consider the various factors influencing women's decisions, such as pain catastrophising and preferences to avoid pharmaceutical side effects. Reflecting on their practice and addressing any biases can further aid midwives in providing unbiased, tailored care. Non-pharmacological pain management techniques, despite no difference in choices between women who do or do not pain catastrophise, offer valuable alternatives or complement traditional pharmacological methods. These techniques can enhance the labour experience by promoting relaxation and comfort, reducing anxiety, and increasing satisfaction with the birth experience. They also present minimal side effects and risks, making them appealing to many women. Integrating these methods into a plan of care offers the potential for a more positive and empowering labour experience for all women.

Effective communication between midwives and women provides on opportunity to help ease fears, manage expectations, and tailor pain management strategies to each woman's individual needs and preferences. Empowering women through antenatal conversations and information sharing supports dynamic decision-making during the vulnerable time of labour.

Ongoing research could further explore the complex nature of labour pain and the role of pain catastrophising in labour pain management choices, investigating the effectiveness of combining different pain relief techniques. Maintaining awareness of technological advancements, such as digital solutions, and their applicability to particular studies may prove beneficial. Interventions should be feasible and acceptable to women. This holistic approach may prove valuable for supporting midwives in providing respectful, individualised care that enhances self-efficacy and improves overall childbirth experiences for women.

# **Chapter 10 Discussion**

The chapter begins by bringing together and summarising the findings from this complete body of work and discusses this within the context of the wider literature.

In previous Chapters (6 to 9) there has been discussion presented alongside the relevant findings. This chapter concludes the discussions by returning to the key elements of the primary aim (1) prevalence of pain catastrophising, and (2) pain catastrophising and its' impact on the timing of hospital admission. A proposal for a support intervention is outlined, which is followed by implications for practice, future directions for research, strengths and weaknesses of the study, before closing with contributions to knowledge and conclusion.

# 10.1 Summary of key aims

This study has explored the impact of pain catastrophising within the context of childbirth. The primary aim was to assess the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an uncomplicated pregnancy (NICE 2023a), and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour. Similarly, the prevalence of FOC was also assessed, as was its relationship with pain catastrophising, and whether it had an impact on participants' timing of hospital admission when they were in labour. Additionally, the study sought to determine the impact of pain catastrophising on the labour experience over time.

## 10.2 Interpretation and Contextualization

This doctoral study is timely, and it addresses issues that have been identified as important to women (DHSC 2022) and fits with world (WHO 2018a; 2018b), national (NHS England 2016; Ockenden 2022, DHSC 2022; NICE 2023a; Thomas 2024) and professional (RCOG 2019; RCM date unknown) priorities. In March 2021 the DHSC launched an appeal for evidence to inform the first ever government-led Women's Health Strategy for England (DHSC 2022) because the government recognised the current health and maternity care was not adequately meeting women's needs.

Considering pregnancy and issues related to this doctoral study in particular, women said that they felt unheard during pregnancy, they were denied pain relief during labour, and they were not being given sufficient care and attention when reporting physical and mental health issues. The recently published report by The All-Party Parliamentary Group on Birth Trauma indicates that these are issues of national concern (Thomas 2024). Ethnicity and socioeconomic disparities in maternal and neonatal outcomes were also areas in maternity care that needed addressing. This has been recognised by the Department for Health and Social Care, as part of the Women's Health Care Strategy (DHSC 2022) designed to address women's needs, through the launch of a £50million challenge in 2024 to address inequalities in maternity care (NIHR 2024). In a ten-year ambition this Women's Health Care Strategy is aiming for the NHS to be the best place in the world to give birth through personalised, individualised, and high-quality care where women are treated equitably and as equal partners in planning their care throughout pregnancy, labour and the postnatal period. As part of this women's care plans must be dynamic and responsive to changes in clinical needs and choices, and women must be supported to make informed decisions during labour. This study addresses the specified needs of women and aligns with government priorities by directly engaging with women during the antenatal and postnatal periods to explore their fears and pain experiences. It has identified a negative mindset (pain catastrophising) and tracked its manifestation and impact on a woman's pregnancy, intrapartum, and postnatal journey. The insights gained from this study can inform and provide evidence for the necessity of targeted support interventions to improve childbirth outcomes.

A priority for this study was to assess the prevalence of pain catastrophising in a population of healthy, pregnant, nulliparous women. This has not been addressed before in this target population and finding that over a quarter of these women pain catastrophise (PCS scores ≥20) is important. Knowing the prevalence provides a basis for estimating the magnitude of the problem for these women who, as this thesis has shown, are at risk of adverse childbirth outcomes which can be both physical and psychological. Understanding the extent of pain catastrophising in this target population can provide persuasive evidence for tailored support interventions, drive

maternity care provision and policies, and guidance for the allocation of resources to mitigate the issues associated with this negative mindset. It is also important to note that during the antenatal period pain catastrophising was found to be associated with ethnicity, age, and antenatal pain meaning the prevalence of pain catastrophising could vary dependent on the presence of these factors.

This study aligns with current thinking about the influence of this negative cognitive mindset on pain experiences such as pain severity (Sullivan et al. 2001; Quartana et al. 2009; Leung 2012; Wertli et al. 2014) and outcomes (Quartana 2009; Leung 2012; Theunissen et al. 2012; Angst et al. 2014; Doménech et al. 2014; Wertli et al. 2014; Schütze et al. 2018; Petrini and Arendt-Nielson 2020; Sullivan and Tripp 2024). To demonstrate, this study found that at the time of antenatal questioning women who reported that they were experiencing higher levels of pain (described as musculoskeletal in origin) were significantly more likely to be those who pain catastrophised. Another novel finding from this study was that pain catastrophising during the antenatal period was predictive of postnatal mental health issues (see Chapter 7 Section 7.2.1). Although previous studies have considered the association between pain catastrophising and postnatal maternal adjustments (Ferber et al. 2005; Flink et al. 2009; Doğru et al. 2018; Zeng et al. 2020) none have specifically investigated the predictive value of screening for pain catastrophising during the antenatal period in the target population and mental health issues postnatal (see Chapter 7 Sections 7.3.1 to Section 7.3.3.2.1 for discussion and recommendations). However, this study adds a new dimension by bringing pain catastrophising and latent labour together and indicates that a positive screening for pain catastrophising during the antenatal period could be useful in predicting those women who will later have a higher tendency to be admitted to hospital during latent labour. As a result, having identified pain catastrophising as a risk factor for women who may go on to experience these poorer outcomes a comprehensive support intervention has been proposed in Section 10.4 below.

# 10.3 Conceptualising pain catastrophising as experienced by the RETHINK participants

This study has focussed on latent labour and pain catastrophising both of which lack consensus on their defining criteria (See Chapter 1 Section 1.4; Chapter 2 Section 2.2). The following discussion adds to the continuing interest and debate in pain management literature about the uniqueness of the construct of pain catastrophising. Consistently acknowledged is that it is complex and multilayered (Petrini and Arendt-Nielsen 2020). The discussion in this section considers how pain catastrophising from the perspective of this doctoral study relates and contributes to wider theoretical conceptualisation and understanding of this construct.

It is important to consider which conceptual model underpins pain catastrophising or if a new model to explain pain catastrophising is required. This is because different models offer different insights into the mechanisms and processes involved in pain catastrophising which can then guide activities such as prevention or targeted treatment interventions and strategies (Petrini and Arendt-Nielsen 2020), provide relevant education and information to both patient and clinician (Sullivan 2009; Sullivan and Tripp 2024), and direct research. Much of the existing work focuses on explaining the chronicity of pain (Petrini and Arendt-Nielsen 2020; Sullivan and Tripp 2024) whereas this study brings into the discourse the unique and acute pain experience of labour and birth which might be influenced by past pain experiences. It is vital that childbirth, such a common pain experience amongst women, is not left out of theoretical discussions and debates about pain. This is because pregnancy, labour and birth, and transition to motherhood is unique and differs from other acute and chronic pain experiences but it is one that a vast number of women experience everyday throughout the world. Contribution from the maternity care field could help address gaps and enhance pain catastrophising conceptual models making them more comprehensive, applicable and efficacious for pregnant women.

Considering whether pain catastrophising is a dispositional trait or situational state this study took the view that, for the target population, it was more akin to a trait. Traits can be summarised as "endogenous basic tendencies that interact with external influences to shape the characteristics of the functioning individual" (McCrae and Costa 2021 p.7). Like trait characteristics pain catastrophising is endogenous, it is relatively stable over time and influences cognitions and behaviour during pain

experiences (Sullivan et al. 2001). However, pregnancy is a unique experience. It has a beginning and then it ends with childbirth. It comes with potential risks to the pregnant woman and her developing fetus. As a result, the woman might worry that these potential risks will come to fruition, or that childbirth will be too challenging for her to manage, or she might have worries about becoming a mother. Arguably, although most women at the time of survey were not in pain they were in a state of pregnancy and worries surrounding this may have amplified their negative pain cognitions and subsequently affected her pain catastrophising scores. This idea leans towards pain catastrophising being a situational state as the women interlinked their pain cognitions with their fears about childbirth. But in a study by Clark et al. (2022) pain catastrophising was identified, in greater number, in a healthy, non-pregnant population and pain catastrophising was not associated with a pre-pregnancy fear of childbirth. The findings in Clark et al's (2022) study and highlighted in Sullivan et al's (2001) paper corroborate with the premise of this doctoral study which views pain catastrophising as an identifiable, distinctive, pre-existing tendency which has an effect on pain experiences and behaviours during the actual painful event and is more aligned with a trait-like characteristic.

Catastrophising itself has been suggested to be a transdiagnostic maladaptive process that spans across health and mental health conditions (Gellatly and Beck 2016). Pain catastrophising has often been characterised in these pathological terms (Sullivan 2009) and is often associated with negative affectivity (Sullivan and Tripp 2024). Catastrophizing involves "dwelling on the worst possible outcomes of any situation in which there is a possibility of an unpleasant outcome" (Beck and Emery 1985 cited Petrini and Arendt-Nielsen 2020). Flink et al. (2013) used the process of catastrophising and followed a transdiagnostic approach to explain problematic pain experiences. They proposed applying the 'catastrophic worry' model, emphasising that catastrophic worry and pain catastrophising have the same underlying mental processes. They argued that distinguishing between the two is unnecessary as they are functionally equivalent. This model is transdiagnostic with similar core processes of rumination, magnification and helplessness to pain catastrophising and contributing to various issues, including problematic pain experiences, depression, and sleep disorders.

Viewing catastrophic worry from a transdiagnostic perspective is beneficial for interventions, as targeting catastrophic worry could also address multiple comorbidities (Flink et al. 2013). Although it is tantalising and appears logical to employ a model that is universally and functionally equivalent across different situations it has as yet not demonstrated its worth in the pain management field (Petrini and Arendt-Nielsen 2020; Sullivan and Tripp 2024). As Sullivan and Tripp (2024) point out that to date there is very little empirical evidence to support this idea, and none examining the relationship between catastrophic worry and pain-related outcomes.

The idea that the RETHINK participants who pain catastrophised were those who would also dwell on the worst possible outcomes of 'any' situation where an unpleasant outcome is possible (Beck and Emery 1985 cited Petrini and Arendt-Nielsen 2020) seems less likely given that the exclusion criteria aimed to exclude mental health pathology. This assumption is based on catastrophic thinking being shown to span across mental health conditions (Gellatly and Beck 2016) and is also often associated with negative affectivity (Sullivan and Tripp 2024) which is a key personality trait of psychopathology especially anxiety and depression (Watson et al. 2011; Jeronimus et al. 2016). This doctoral study supports the idea that pain catastrophising is a distinct construct which can exist separate from other transdiagnostic catastrophising models. This finding is also supported in other pain studies which also excluded psychological disease or depression but reported pain catastrophising to be a feature in the pain experience (Sullivan and Neish 1998; Geisser et al. 1999; Kristiansen et al. 2014; Keefe et al. 2000).

Previously it has been suggested that a fear-avoidance pathway could explain how people develop and maintain chronic musculoskeletal pain (Vlaeyen and Linton 2000). The fear-avoidance pathway comprises of the injury leading into into a loop-cycle involving pain experience, attentional processes of catastrophising and fear of pain resulting in fear-avoidance and reduction in activity, disuse, disability and depression (Vlaeyen and Linton 2000). It has been suggested that a pregnant woman who has fears and anxiety about pain might follow a similar fear-avoidance pathway and employ one, two or three different strategies to help her to manage her pain. The

three strategies are to seek early hospital admission, to request pain relief or to request other interventions (Clark et al. 2023). This may be true for some women. The RETHINK study did find a tendency for women who pain catastrophise to be admitted to hospital during latent labour (Bartholomew et al. 2024 Chapter 6 Section 6.2). However, considering the lack of association between pharmacological and nonpharmacological pain management techniques and pain catastrophising, this study does not support the idea that pain catastrophising influenced the request for pain relief. Further studies with larger sample size would be required to confirm both findings. Although other studies have found that overall pain catastrophising did not appear to increase a woman's decision to have an epidural or neuraxial anaesthesia and in some cases pain catastrophising was suggested as the reason why women avoided some methods of pain relief (Van den Bussche et al. 2006; Peralta et al. 2024). Finally, previous studies have found an association between pain catastrophising and women's choice to completely avoid the pain of labour and vaginal birth and opt for an elective caesarean section birth (Dehghani et al. 2014). For these women the fearavoidance model may be more relevant.

Previous studies support the idea that the women in the RETHINK study were not necessarily following a fear-avoidance pathway when they sought early hospital admission. Findings from this doctoral study and previous studies suggest that for those women who are at low obstetric risk and who are planning to labour and give birth vaginally the influence of pain and fear on their birthing decisions and behaviour is likely more nuanced (Beebe and Humphreys 2006; Van den Bussche et al. 2006; Cheyne et al. 2007; Barnett et al. 2008; Carlsson et al. 2009; Eri et al. 2015; Carlsson 2016; Edmonds et al. 2018). For example, some women might be seeking reassurance that the pain they are experiencing is normal and not indicating a problem, or they might be looking to have a professional to watch over them and be in hospital 'just in case', or they might be looking for reassurance that the pain will not get worse, or they may want to have pain relief available just in case they struggle to cope but ultimately do not chose to accept it because they are fearful of the route of administration or side-effects, or their ultimate decision to go to hospital might be swayed by what their birth partners think, or it might be due to a combination of factors.

Findings reported in this study and those reported in previous studies can be used to point to the theoretical framework and mechanisms that link pain catastrophising to the pain cognitions, behaviours and experience. The following examples have been used because they report on 'fear' and 'pain' as being key factors in women seeking hospital admission. Also, the concerns and behaviours that women reported appear to provide solutions to the types of thoughts and feelings associated with a pain catastrophising mindset as detailed in the PCS (Sullivan et al. 1995). To date there are no studies specifically reporting on the reasons why women with pain catastrophising seek early hospital admission.

In Carlsson's study (2016) women who considered childbirth to be risky and a medical event, chose to go to hospital earlier. At hospital the woman can handover the responsibility for managing labour and birth and for keeping both herself and her baby safe to the professionals who have the skills and ready access to all the emergency medical interventions. For these women hospital is conceptualised as a safe and secure place (Carlsson 2016) with the women seeking professional help for reassurance and observation purposes. Other women said that the uncertainty of how their labour was progressing drove them to seek labour diagnosis and reassurance from professionals in the hospital (Cheyne et al. 2007; Eri et al. 2015; Edmonds et al. 2018). For these women hospital is a place where they can get answers to their questions, alleviate their fears, and be given reassurance.

For some women there was an expectation that pain should equate to labour progress, and 'something' could be done by professionals in hospital to advance labour and help it come to an end (Carlsson 2016). For these women it could be argued that they were exhibiting fear-avoidance behaviours. However, the hypothesis is that these women may not necessarily have been trying to totally avoid the pain but were seeking support from others who might be able to help them to control the length of time they were in pain by progressing their labour.

Cheyne et al. (2007) found that women's decision to go to hospital were based on the anticipation that labour pain would get worse, and women were concerned that they

would not cope and wanted reassurance that they would have ready access to pharmacological pain relief 'just in case'. In this example the intention to accept pharmacological pain relief does not appear to be the main focus for seeking early hospital admission rather the assessment of the threat that the pain might get worse and having pharmacological pain relief available was a reassuring factor and the strategy they employed to help them to manage their pain.

For these reasons, in the target population in this study, pain catastrophising could be seen as either a communal coping model (Sullivan 2009), a coping strategy, or an appraisal model or possibly a combination of all three. Perhaps women's decisions to seek the support of others in hospital, and the value women expressed about the support of their birthing partner/s, favours the communal coping model. Although relevant it does not account for all the thoughts and the strategies that both this study and others have indicated women employ in preparation for and during labour. Similarly, considering pain catastrophising as a person's coping strategy which influences subsequent behaviours and strategies does not accommodate all aspects of pain catastrophising. What this model primarily focusses on is the actual painful event which makes pain catastrophising itself the actual coping strategy rather than the result of an appraisal of the situation. This misses out other factors that could underlie the cause of the pain catastrophising; therefore, the appraisal model seems more appropriate for the women participating in the RETHINK study.

The appraisal model involves the individual assessing the threat of the situation then assessing their abilities to cope with the situation which then influences their cognitive, emotional and behavioural responses (Haythornthwaite and Heinberg 1999; Leung 2012; Petrini and Arendt-Nielsen 2020). An appraisal model fits with Whitburn et al's (2019) suggestion that the experience of labour pain is dependent on the meaning that a woman subscribes to it influenced by the cognitive, social and environmental determinants of labour pain. For the women in the RETHINK study who pain catastrophise, they may have assimilated all their environmental influences and knowledge that they have gained about childbirth and judged it to be a threatening

event. They may have lower levels of self-assessed coping abilities or feel unconfident in those close to them to keep them safe or unemboldened by their caregivers.

The hypothesis is that as a result of their appraisal women respond with corresponding strategies and behaviours such as seeking early access to hospital, a place that they may perceive as safe. During labour, pain can become the overwhelming feature that they must manage and one that, for women who are predisposed to pain catastrophising, triggers heightened attention to the pain and heightened anxiety and rumination about the meaning of this pain i.e. is the pain signalling something is going wrong. As a result, women may consciously, and in some cases unconsciously, employ strategies before and during the event to help them mitigate the risks and to try to maintain a sense of control and safety. Consciously employing strategies to help cope through labour was a feature for participants in the RETHINK study (see Chapter 9 Section 9.4.1.1.2 and Section 9.4.1.2).

It is vital that during the antenatal period midwives commence and continue discussions with women about their expectations for labour and birth. These discussions should be documented and can support effective communication with women throughout labour and birth. Effective communication throughout women's maternity care is not a new concept. It is recommended as one of the key principles of midwifery care (NICE 2021a; 2021b; NMC 2018) and it could potentially help mitigate a woman's pain catastrophising. In labour poor communication can make women feel demotivated to continue, feel that they are experiencing pain to no avail, and lead them to feel helpless, victimised, disempowered, and assess care as inadequate (Carlsson 2016; Whitburn et al. 2019). These thoughts can feed back into the helplessness of the pain catastrophising mindset and leave women feeling they can cope no longer with overwhelming pain, that they can do nothing about it, and feel like it is never-ending (Sullivan 2009). Such negative thoughts and feelings have been shown to feature in women's childbirth reflections in this study (see Chapter 9 Section 9.2.4 to Section 9.2.4.3 and Section 9.4.3.2).

While a strength of the appraisal model is that it brings into play the cognitive, social and environmental influences of labour and supports a more holistic assessment of the

painful event. It is limited by the fact that focus is on cognition with little attention given to the emotional responses within the appraisal process (Jones et al. 2003) which are included in the pain catastrophising mindset as identified by the PCS (Sullivan et al. 1995).

In summation, this study with supporting justification from previous studies points to pain catastrophising in the context of childbirth being an appraisal model that includes cognitive, social, and environment determinants with emotional and behavioural components. The PCS (Sullivan et al. 1995) then becomes a tool to help identify a typical mindset a person engages in during a painful event. How pain catastrophising is conceptualised helps determine the format for the treatment intervention.

# 10.4 Proposal for the format of an intervention for women who pain catastrophise.

This intervention proposal brings together the learning from this complete doctoral study and my professional knowledge. It is outlined here, but the intention is to develop the intervention and assess its acceptability and feasibility as part of a post-doctoral programme of work. The intervention would aim to target women with high PCS scores as a priority and would be commenced during the antenatal period.

The intervention will adopt a positive psychological approach emphasising empowerment rather than labelling women with high PCS scores as having a psychological problem. The focus for the intervention will be towards improving women's childbirth experiences and outcomes rather than framing childbirth and childbirth pain as a threat to be mitigated. The focus for the intervention is to build women's confidence, resilience and self-efficacy so that they feel prepared and empowered to cope through labour and birth. Meeting these goals provides the opportunity to enhance the childbirth experience and improve outcomes.

The intervention should be feasible and demonstrate that it is effective and efficacious. It should maintain a flexible approach to uphold the philosophy of individualised care aligning with national drivers (see Chapter 1 Section 1.2). The intervention should be delivered and supported by professionals skilled in the

intervention component. The proposal for the core elements to be included in the intervention are:

#### 1. Psychoeducation

Psychoeducation is a structured, systematic and evidence-based therapeutic intervention that has demonstrated its utility for women with FOC (Akgün et al. 2020; Alizadeh-Dibazari et al. 2024) and improvement in postsurgical pain outcomes in a more general population (Horn et al. 2020). Psychoeducation provides education and information, including psychological elements, and support for better understanding and coping skills to tackle a particular problem (Akgün et al. 2020; Alizadeh-Dibazari et al. 2024).

Psychoeducation as opposed to general antenatal education is preferred for its targeted and empowering approach to a problem and in this case adapted to tackle pain catastrophising in the context of childbirth (Rowe et al. 2014). It is an intervention that can be delivered to individuals, groups of individuals with similar issues (NICE 2023b) and can also include birth partners (Darwin et al. 2021; Tola et al. 2022).

This core element should also include education on:

#### a. Health literacy

- Providing information, education to improve health literacy are important factors in enhancing a woman's childbirth selfefficacy, and her decision-making.
- It is suggested that education includes health literacy to ensure all women have equitable access to knowledge so that women feel confident to 'communicate, assert and enact' their health decisions (NHS Health Education England 2020).
- Supporting an individual's health literacy is a philosophy that should be embodied throughout a woman's maternity care (NHS Health Education England 2020).
- b. Expectation and management of latent labour at home and in hospital.

- c. Relaxation and pain management techniques (suggestions are based upon results and discussion in this study see Chapter 8 Section 8.2.2 and Section 8.3.2 and Chapter 9).
  - Non-pharmacological and pharmacological techniques
  - How to practice and use breathing techniques
  - Distraction techniques
  - Use of technology e.g. virtual reality as and when it becomes available and has demonstrated its utility for women who pain catastrophise.
  - Managing expectations

### 2. Self-hypnosis

- Self-hypnosis requires self-induction into the hypnotic process produced by self-generated suggestions. Self-hypnosis is different to hetero hypnosis in that the latter requires the presence of a hypnotist or audio recording to guide thoughts and deliver suggestions to the individual in the context of hypnosis (Eason and Parris 2018).
- Self-hypnosis has been demonstrated to support women in managing their pain in childbirth (Madden et al. 2016; Eason and Parris 2018) increasing child-birth self-efficacy (Cyna et al. 2006; Cyna et al. 2013), lowering actual experiences of anxiety and fear associated with childbirth (Downe et al. 2015), shortening the time between cervical dilatation of 5cm to 10cm (Harmon et al. 1990), and positively impacting on women's reflection of their childbirth experience (Werner et al. 2013; Marsh 2021).
- Generally, the evidence is positive towards the efficacy of selfhypnosis in other clinical settings such as reducing stress and anxiety, pain management improving the quality of life in a group of women with metastatic breast cancer, insomnia amongst cancer survivors and it is a cost-effective technique,

and it can be used alongside the majority of other pain management techniques and obstetric intervention if required (Eason and Parris 2018). Although more high quality evidence is required for self-hypnosis to demonstrate satisfaction with pain relief in labour, improve a sense of coping with labour and increase the chance of spontaneous vaginal birth (Madden et al. 2016). However, it is important to note that the delivery of the self-hypnosis training should allow adequate time to practice mastery of the self-hypnosis skills (Eason and Parris 2018).

- 3. Sign-posting and access to targeted relevant support.
- 4. Postnatal follow-up.

## 10.5 Implications for practice and future research

Implications for practice and for future research have been included as they have been revealed throughout this thesis. These have been consolidated, summarised below.

## 10.5.1 Implications for practice

- Timely screening is an important first step in discovering a woman's thoughts
  around her pain experiences and should be introduced in England. This
  screening is relevant to all pregnant women, however, this study and the
  proposal for the intervention is applicable to women at low obstetric risk and
  who are advised and who are planning to experience latent labour at home.
- Alongside discussion the PCS (Sullivan et al. 1995) can be used to assess a
  woman's thoughts towards pain and pain experiences and assess for pain
  catastrophising which may later impact on a woman's pregnancy, childbirth and
  postnatal experiences. This provides a tool to identify those who pain
  catastrophise so that they can be provided with a targeted intervention (see
  Section 10.4).
- Midwives should be provided with the necessary education and knowledge to
  effectively assess for pain catastrophising and care for a woman if it is
  discovered and signpost her to support services if necessary. Relevant staff

- should be provided with the required training to effectively deliver the proposed intervention (see Section 10.4).
- Midwifery care should be provided in a kind, respectful, non-biased manner upholding the principles of the Code (NMC 2018) of practice.
- Providing information, education and improving health literacy are important factors in enhancing a woman's childbirth self-efficacy, her decision-making, and for managing expectations. Ongoing skilled woman-centred, individualised midwifery care is integral to this.
- Maintain and promote a holistic, individualised approach when advising women about the timing of hospital admission during labour and caring for women during latent labour.

#### 10.5.2 Future Research Directions

This doctoral study has provided several opportunities for future research. In response to the primary aim, this study has shown that there is a tendency for women who pain catastrophise to be admitted to hospital during latent labour. However, results from this study were undermined by attrition and the rate of induction of labour and elective caesarean sections (see Chapter 6 Section 6.2). Future longitudinal quantitative research should involve larger sample sizes with enough power to confirm the tendency towards latent labour hospital admission if women pain catastrophise, and to confirm the quantitative results that have been reported in this study. Quantitative research will also be required to confirm the acceptability of the PCS (Sullivan et al. 1995) as a screening tool with women and identify the optimum gestation period to enhance its utility. Once confirmations are completed it is recommended that pregnant women, their birth partners, midwives and other relevant public and professional stakeholders are consulted on the acceptability of the intervention and study before embarking on a small pilot study to test the research protocol and to identify any problem areas for remedy (Arain et al. 2010) in the intervention before conducting a rigorous, large, multicentre randomised control trial to examine the safety and effectiveness of the proposed intervention (McErlean et al. 2022). The Medical Research Council's (MRC) complex intervention framework is a useful tool for guiding the development, feasibility/piloting, evaluation and

implementation of the intervention. This framework helps ensure the intervention is rigorously tested, relevant to real-world settings and enhances the translation of the research into practice (Skivington et al. 2021).

It is also important to note that research should not occur in isolation from the people it aims to serve. Excellent collaborative patient and public involvement (PPI) is important at all stages and should be embedded within these recommendations for future research directions. This is because high quality PPI has demonstrated its utility in improving the quality, impact, and applicability of health care research (Health Research Authority (HRA) / INVOLVE 2016; Hughes 2023). To be meaningful the PPI should be inclusive, uphold equality and diversity principles, value all contributions, and involve those who hold a vested interest, concern or stake in the research activities or outcomes (Hughes 2023).

This study has produced some other interesting results and has highlighted several issues that might be beneficial to pregnant women if there were greater understanding. Issues that might benefit from further research and greater understanding about how pain catastrophising manifests in pregnant women's cognitions, emotions and decision-making over pregnancy, intrapartum and the postnatal period are listed below:

- Pain catastrophising was associated with higher levels of antenatal pain, higher levels of antenatal pain was associated with hospital admission during latent labour. In the first instance studies should investigate these associations further to gain greater understanding about the relationship between antenatal pain, pain catastrophising, and the timing of hospital admission.
- Develop deeper understanding about the latent labour experience and the
  factors influencing the timing of hospital admission in women who pain
  catastrophise. Greater understanding about these experiences and
  underpinning reasons for deciding to seek hospital admission can contribute to
  a support intervention and improvements in support and woman-centred,
  individualised care.

- Further understanding about how pain catastrophising is involved in the
  construction of the meaning of labour pain, and how these meanings might
  affect decision-making during labour, impact upon childbirth reflections, and
  postnatal mental health.
- In research remain abreast with advancing technology and knowledge about pain catastrophising and how these may be useful to pregnant women.
- Within the context of maternity care investigate the proposal that pain catastrophising is an appraisal model with cognitive, emotional and behavioural components with a view to constructing an evidence-based theoretical model.
- Investigate the complex nature of labour pain management, focusing on pain catastrophising and how it influences women's pain management choices and experiences.

# **10.6 Strengths and Limitations**

Methodological advantages, disadvantages and challenges have been presented in Chapter 4. Strengths and limitations have been presented in Chapter 6 Section 6.3 in an integrated, peer-reviewed publication (Bartholomew et al. 2024). These strengths and limitations are applicable to the whole RETHINK study but were focussed on the primary aim. Additional strengths and limitations applicable to the complete study are detailed below.

A strength of this study is considering and investigating pain catastrophising as an important and identifiable construct. Pain catastrophising is one of the most widely researched pain-related psychological variables which has repeatedly demonstrated its value in other pain-related healthcare (Sullivan and Tripp 2024); however few studies have considered it in relation to maternity care. The work and discourse that exists around it has helped provide compelling evidence about the importance of it in pain experiences (Quartana et al. 2009; Crombez et al. 2020; Petrini and Arendt-Nielsen 2020; Sullivan and Tripp 2024). This doctoral study extends the evidence of pain catastrophising within the context of pregnancy, intrapartum, and postnatal periods. Likewise, to identify pain catastrophising in pregnant women the PCS (Sullivan et al. 1995) was used. The PCS (Sullivan et al. 1995) is the most widely used measure and

most notable for its efficacy in research around chronic pain (Leung 2012; Petrini and Arendt-Nielsen; Sullivan and Tripp 2024).

However, a potential limitation is the complex nature of pain catastrophising which is predominantly framed by the use of the PCS (Sullivan et al. 1995) but has no consensus on the conceptual model underpinning or explaining it (Petrini and Arendt-Nielsen 2020). Without a common theoretical grounding the translation of these findings into a support intervention is potentially hindered.

Failure to achieve a sample size of 768 with an in-built allowance for 50% attrition limited the extent of statistical analysis. For example, it was not possible to use multiple logistic regression to test if more than one variable predicted the timing of hospital admission.

The following limitations caused by the COVID-19 pandemic have previously been discussed in (see Chapter 6 Section 6.3) but are expanded here. The influences associated with this pandemic on women's decisions of when to seek hospital admission in labour is unknown. However, throughout this period pregnancy and childbirth were associated with increased anxiety and uncertainty (Ahlers-Schmidt et al. 2020; Davenport et al. 2020; Moyer et al. 2020; Aydin et al. 2022). At the time of data collection women were contending with an ongoing threat of contracting the COVID-19 virus, they faced inconsistent (Ambihaipahan et al. 2023) hospital measures and disruption of services (Brigante et al. 2022) aimed at minimising the transmission of the virus, and maternity staff shortages (RCM 2020) when they did seek support. For a time, these measures included limiting a woman's birthing to one person and delaying birth partner support until active labour was confirmed. A difficult measure for women to deal with considering the importance of birth partners in a woman's childbirth experience as highlighted in this and other studies (Bohren et al. 2019). As a result of being faced with these threats and measures some women were choosing to avoid labour and opt for a caesarean section birth (Betteley 2020; Aydin et al. 2022) and there was some evidence to show that the number of women who were considering 'freebirth' (birthing without the presence of a midwife or doctor) increased (Greenfield et al. 2021). Additionally, women were reporting negative birth

experiences (Aydin et al. 2022) which may have also impacted on the birth reflections that the participants in the RETHINK reported.

At this time, it is not possible to clarify the impact that the pandemic had on participants' decision-making. However, it is useful to consider the pandemic timeline (Institute for Government 2022). This timeline details the lockdowns and measures used to control the spread of the virus and can be compared against when the participants were recruited to the study. Across England severe restrictions limiting all non-essential face-to-face interactions to reduce the spread of the COVID 19 virus commenced from the 23<sup>rd</sup> March 2020. The term 'lockdown' was coined to indicate that people were ordered to stay at home. Lockdowns and other measures restricting movement and face-to-face contact of people continued in earnest and in various formats until 29<sup>th</sup> March 2021. Most legal limits on social contact were removed in England on the 19<sup>th</sup> July 2021 but measures to prevent virus transmission, such as the wearing of facemasks, were compulsory until the 1<sup>st</sup> April 2022 but facemasks was one measure that remained a requirement under infection prevention and control guidance in healthcare settings.

Over the study period, and prior to any participants being excluded from the study, approximately 17% (n=67) of participants were recruited during the first half of the study period ranging from December 2020 to the June 2021. During this time only 5 participants were recruited from December 2020 to March 2021. The remainder (n=62) were recruited between April and June 2021. 63% (n=244) were recruited during the second half of 2021, and approximately 20% (n=81) were recruited in January 2022.

Although the impact of the pandemic on the RETHINK participants' labour and birth decisions is unknown it should be acknowledged that it is an unquantified, contextual, confounding variable.

## 10.7 Contribution to knowledge and conclusion

This thesis has presented a novel study to determine the prevalence of pain catastrophising in a population of nulliparous women who were experiencing an

uncomplicated pregnancy, and to determine whether pain catastrophising had an impact on their timing of admission to hospital when they were in labour. The study also sought to determine the impact of pain catastrophising on the labour experience over time. Additionally, the prevalence of FOC was assessed, as was its relationship with pain catastrophising, and whether it had an impact on participants' timing of hospital admission when they were in labour.

Previous research underscores the complexity of the labour pain experience. To date no one defining feature cuts through this complexity, likely because labour pain is influenced by multiple factors. However, where this study makes significant and novel contributions is by identifying a known negative mindset, pain catastrophising, and show that it affects a significant number of pregnant women in the target population. Consequently, these women face increased risks of adverse experiences throughout the antenatal, intrapartum and postnatal periods. This study underscores the pervasive impact of pain catastrophising on maternal health, offering valuable insights for targeted interventions to improve women's overall childbirth experiences.

Demographic vulnerabilities for pain catastrophising were also identified these included age and ethnicity.

Furthermore, pain catastrophising was confirmed to be significantly associated and predictive of FOC and women who had a FOC also had a higher tendency to be admitted to hospital during latent labour. When pain catastrophising and FOC are both present then the tendency to be admitted to hospital during the latent phase of labour appears to increase.

The findings from both the quantitative and qualitative aspects of this study, combined with the existing literature on women's latent labour experiences, and pain catastrophising, have been brought together to outline the components of a future theoretical model that underpins pain catastrophising.

This study emphasises the critical importance of maintaining focus on latent labour in both research and clinical practice. It reintegrates latent labour into the framework of

maternity care through a wraparound intervention and highlights the need for timely screening for pain catastrophising during pregnancy to facilitate early intervention.

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# **Appendices**

# Appendix 1 The RETHINK Study poster presentations

## **Postgraduate Researchers Conference 2020**



# The RETHINK Study



A study to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of labour

| PGR: Vanessa Bartholomew Professors: Vanora Hundley, Carol Clark & Ben Parris

#### Background

 Women who are experiencing an uncomplicated pregnancy are at increased risk of obstetric intervention if they are admitted to hospital during the latent phase of labour (the time when the cervix is dilating up to 4-5cm approximately).







 Women's experiences of latent labour point to pain and fear as significant factors in early hospital admission.



 Exaggerated negative feelings toward an anticipated painful event, known as pain catastrophising, are a strong predictor of childbirth pain.



#### Aims



To assess the prevalence of pain catastrophising in the target sample.
 To determine how pain catastrophising affects the timing of admission to hospital when in labour, and subsequently birth outcomes.

## Methods



<u>Design</u>: A pragmatic, quasi-experimental study.

<u>Sample:</u> Primigravid women experiencing an uncomplicated pregnancy will be recruited from National Health Service (NHS) Hospitals in England. The target sample is 384 women.

<u>Data collection</u>: Two online questionnaires; the first completed when participants are between 25 and 33 weeks pregnant, and the second at approximately 3 weeks postnatal.

<u>Measures:</u> The Pain Catastrophizing Scale (PCS), and the Wijma Delivery Expectancy Questionnaire (WDEQ-A).

The primary outcome measure is admission to hospital in the latent phase of labour. Secondary outcome measures include pre-specified birth outcomes.

<u>Analysis:</u> Participants will be divided according to whether they catastrophise pain or not. Logistic regression will be used to assess if pain catastrophising is a predictor of hospital admission during latent labour. Other explanatory factors (e.g. socioeconomic variables) will also be identified. The significance level will be set  $\underline{to}$  p  $\leq 0.05$ .

#### Originality & Contribution to Knowledge

This study aims to investigate whether pain catastrophising and fear of childbirth are risk factors for early hospital admission in latent labour.

The study will provide data relating to the prevalence of pain catastrophising in the sample group.

There is potential for high impact because pain catastrophising and latent labour have not been considered before in research.

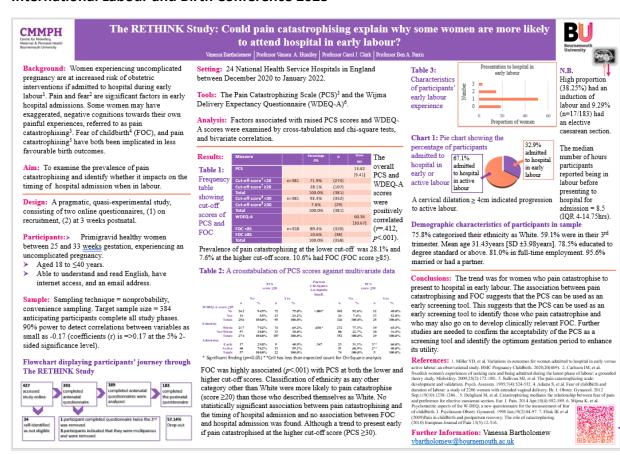
The outcomes could lead to the development of individualised care, helping women identify their own behaviour in coping with labour pain.

The outcomes could also create the opportunity to work with women to develop a support intervention to improve birth outcomes.

#### Discussion

66 It is hypothesised that the PCS can be used as a predictive tool to identify pregnant women who catastrophise pain and who seek hospital admission during latent labour. This could facilitate early support for pregnant women.

#### **International Labour and Birth Conference 2023**



## Scientific prize winning certificates





# Appendix 2 Literature search strategy

# Scoping review title

Does pain catastrophising increase the likelihood of hospital admission during latent phase of labour, and change labour outcomes? A scoping review.

#### Rationale

Women experiencing an uncomplicated pregnancy are at increased risk of interventions if admitted to hospital during latent labour. Pain and fear are cited as significant factors in early hospital admissions. Some women may have exaggerated, negative cognitions for their pain experience which have been referred to as pain catastrophising. From initial investigation, the literature considering the impact of pain catastrophising on labour outcomes appeared sparse and there were no studies considering the impact of pain catastrophising on the timing of hospital admission during labour. To support this preliminary finding that there was a gap in knowledge a scoping review of the literature was undertaken. For transparency, accuracy and completeness the principles and checklist of the PRISMA-ScR 2018 were used to guide the search. The results have been reported in a narrative style was adopted to report on the findings. A pragmatic approach was used to finalise the search terms in order to strike a balance between generalised terms and those that were specific.

#### Methods

The search was undertaken using the PRISMA Extension for Scoping Reviews (PRISMA-ScR) reporting checklist (Tricco et al. 2018).

## **Primary objective**

This scoping review sought to provide an overview of the evidence to date and understand if pain catastrophising increases the likelihood that women are admitted to hospital during the latent phase of labour, and impacts labour outcomes.

#### **Primary outcome**

Timing of hospital admission (latent or active stage of labour).

#### Secondary outcomes

Obstetric interventions were considered, for example births by caesarean section; epidural; analgesia; anaesthesia; nitrous oxide and oxygen; instrumental births (forceps or ventouse).

## **Protocol and registration**

This scoping review has not been registered and is not available for access outside of this thesis.

## **Eligibility criteria**

All primary research studies.

#### Inclusion criteria

Women in labour; women in early/latent phase of labour, with cervical dilatation of less than 5cm; participants demonstrating cognitions or psychological mindset outside of 'normal' expected behaviour; a change in the expected mode of delivery due to participant or health professional choice.

#### Exclusion criteria

Women with co-morbidities/obstetric concerns, including concerns about the fetus, who would be advised, during the antenatal period or intrapartum, against experiencing labour and birth without enhanced obstetric surveillance or intervention (see NICE guidelines NG235 Intrapartum Care (2023) and NG121 Intrapartum care for women with existing medical conditions or obstetric complications and their babies (2019)).

#### Context

Studies in hospital maternity units. Countries where women can opt or have the right to give birth in a hospital.

## Search strategy

To derive search terminology to meet the primary objective a PEO (i.e., population or problem, exposure, outcome) framework was used (Bettany-Saltikov 2016). Using Boolean operators AND, and OR search strings were developed applicable to the

requirements of the databases. The search strategy was originally derived with the support of an expert librarian.

The table below represents the concepts included in the keyword framework.

Table 1: PEO framework

| (P) Population/Problem   | (E)Exposure   | (O) Outcome  |  |  |
|--|---|--|--|--|
| Latent phase of labour   | Pain catastrophising  | Labour and birth outcomes  |  |  |
| Latent N5 labo#r  (Labo#r OR childbirth OR birth*) AND (early OR onset OR "first stage")  + Database specific subject headings | <ul> <li>Catastroph*</li> <li>anxi*</li> <li>fear*</li> <li>"psychological stress"</li> <li>(anxi* OR fear* OR concern* OR toleran*) N3 pain*</li> <li>panic*</li> <li>"central sensiti?ation"</li> <li>allodyni*</li> <li>hyperalgesi*</li> <li>kinesiophobi*</li> <li>To?ophobi*</li> </ul> | <ul> <li>(hospital* OR ward OR unit OR centre* OR center*) N5 (admiss* OR admit*)</li> <li>caesarean</li> <li>cesarean</li> <li>c-section</li> <li>hospitali?ation</li> <li>"mode of delivery"</li> <li>"mode of birth"</li> <li>choice*</li> <li>epidural</li> <li>analgesia</li> <li>anaesthe*</li> <li>"introus oxide"</li> </ul> |  |  |
|  | + Database specific subject<br>headings   | <ul> <li>entonox</li> <li>"n2o"</li> <li>"gas and air"</li> <li>instrument*</li> <li>deliver*</li> <li>+ Database specific subject</li> <li>headings</li> </ul>  |  |  |

A literature search was first conducted in March 2019 and was repeated in April 2024 prior to completion of this thesis. Between these two time periods there was a change made to the library catalogue search system 'mySearch'. Therefore, the updated search in April 2024 used the EBSCOhost database search system. EBSCOhost s a similar database to the previous 'mySearch'. The following databases were searched:

EBSCOhost – without edit to the databases this system searches:

EBSCOhost searches Academic Search Ultimate; APA PsycArticles; APA
PsycBooks; APA PsycInfo; Art & Architecture Complete; Business Source
Ultimate; Communication Source; eBook Collection (EBSCOhost); eBook
Academic Collection (EBSCOhost); eBook Open Access (OA) Collection
(EBSCOhost); Education Source; Environment Complete; ERIC; European Views of
the Americas: 1493 to 1750; Green FILE; Hospitality & Tourism Complete; Library,
Information Science & Technology Abstracts; MEDLINE Complete; Regional
Business News; SocINDEX with Full Text; SPORT Discus with Full Text; CINAHL
Ultimate.

Cochrane Library; PROSPERO; MEDLINE; Scopus; CINAHL. With reference lists of eligible studies and review articles, key journals, trials register.

Included: All published articles presenting scientific results (e.g. RCT, controlled trial, observational trial, cohort studies, case control).

Excluded: Conference abstracts, editorial or review articles, literature reviews commentaries, general articles, book chapters and internet resources.

References lists from systematic reviews will be hand searched for eligible studies.

No date or language limiters were applied at the database stage, because initial scoping identified few papers. The search scope then was primarily limited by the population/problem group by way of defining the latent stage of labour as closely as possible and not searching for labour more widely.

Table 2: Sample search – Medline

|     |   | 14 <sup>th</sup> Mar | 25 <sup>th</sup> April |
|-----|---|----------------------|------------------------|
|     |   | 2019                 | 2024                   |
| S1  | (MH "Anxiety+")   | (76,596)             | 117,111                |
| S2  | (MH "Fear+")  | (32,665)             | 41,158                 |
| S3  | (MH "Stress, Psychological+")   | (119,812)            | 155,884                |
| S4  | (MH "Hyperalgesia")   | (10,630)             | 14,391                 |
| S5  | (MH "Kinesthesis")  | (3,167)              | 3,329                  |
| S6  | (MH "Patient Admission")  | (22,702)             | 26,205                 |
| S7  | (MH "Cesarean Section+")  | (42,301)             | 54,379                 |
| S8  | (MH "Hospitalization+")   | (215,717)            | 299,539                |
| S9  | (MH "Delivery, Obstetric+")   | (75,120)             | 93,139                 |
| S10 | (MH "Anesthesia, Epidural+")  | (13,271)             | 14,256                 |
| S11 | (MH "Analgesia, Obstetrical")   | (3,787)              | 4,434                  |
| S12 | (MH "Anesthesia, Obstetrical")  | (12,719)             | 13,606                 |
| S13 | (MH "Analgesia, Epidural")  | (7,830)              | 9,160                  |
| S14 | (MH "Nitrous Oxide")  | (13,563)             | 16,055                 |
| S15 | (MH "Labor Onset+")   | (3,868)              | 4,475                  |
| S16 | (MH "Labor Stage, First")   | (1,284)              | 1,480                  |
| S17 | (MH "Parturition+")   | (15,309)             | 23,036                 |
| S18 | (MH "Perinatal Care+")  | (9,121)              | 11,740                 |
|     | TI catastroph* OR anxi* OR fear* OR "psychological stress" OR (anxi* OR fear* OR concern* OR toleran*) N3 pain* OR panic* OR "central sensiti?ation" OR allodyni* OR hyperalgesi* OR kinesiophobi* OR To?ophobi* OR AB catastroph* OR anxi* OR fear* OR "psychological stress" OR | (359,605)            | 466,114                |

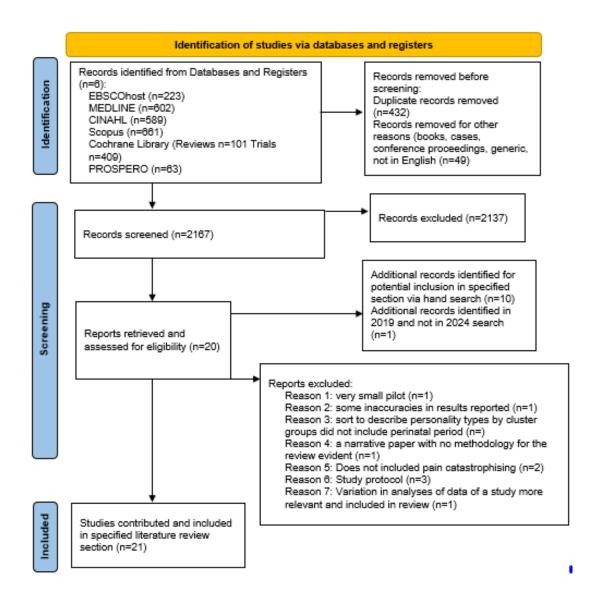
|     | (anxi* OR fear* OR concern* OR toleran*) N3 pain* OR<br>panic* OR "central sensiti?ation" OR allodyni* OR<br>hyperalgesi* OR kinesiophobi* OR To?ophobi*   |             |           |
|-----|--|-------------|-----------|
| S20 | TI (hospital* OR ward OR unit OR centre* OR center*) N5 (admiss* OR admit*) OR caesarean OR cesarean OR csection OR hospitali?ation OR "mode of delivery" OR "mode of birth" OR choice* OR epidural OR analgesia OR anaesthe* OR "nitrous oxide" OR "n2o" OR "gas and air" OR Entonox OR instrument* N3 deliver* OR AB (hospital* OR ward OR unit OR centre* OR center) N5 (admiss* OR admit*) OR caesarean OR cesarean OR "c section" OR hospitali?ation OR "mode of delivery" OR "mode of birth" OR choice* OR epidural OR analgesia OR anaesthe* OR "nitrous oxide" OR "n2o" OR "gas and air" OR Entonox OR instrument* N3 deliver* | (939,829)   | 1,094,638 |
| S21 | TI (Latent N5 labo#r) OR (Labo#r OR childbirth OR birth*) N3 (early OR onset OR "first stage") OR AB (Latent N5 labo#r) OR (Labo#r OR childbirth OR birth*) N3 (early OR onset OR "first stage")   | (11,607)    | 14,580    |
| S22 | S1 OR S2 OR S3 OR S4 OR S5 OR S19  | (457,718)   | 625,312   |
| S23 | S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR<br>S14 OR S20  | (1,053,757) | 2,310,451 |
| S24 | S15 OR S16 OR S17 OR S18 OR S21  | (37,159)    | 38,043    |
| S25 | S22 AND S23 AND S24  | (550)       | 602       |

# **Screening and selection process**

This review includes qualitative, quantitative and mixed method studies.

In March 2019 the sources were screened in Endnote by VB to identify those that met the inclusion criteria, CC provided advice throughout the screening process and the review of the selected papers. Papers selected for possible inclusion were then screened in full text following the same process as for title and abstract sifting.

In April 2024 a further literature search was conducted by VB. The database search systems EBSCOhost, MEDLINE, CINAHL, Cochrane Library, and Scopus were searched online. Papers selected for possible inclusion were then screened in full text following the same process as for title and abstract sifting. All records found in these searches were then downloaded and managed in Endnote. PROSPERO was searched, and records reviewed online.



Page, MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

# **Charting the results**

Data charting was managed in Excel. Data were organised under the following headings:

- 1) Study identification- authors, publication date, title, country
- 2) Study design
- 3) Study aims
- 4) Measures
- 5) When was data collected specifically when was data on pain catastrophising collected.
- 6) Was the timing of hospital admission when in labour measured
- 7) Sample size and participant characteristics
- 8) Results
- 9) Conclusions

Table 3: Details of studies included in the narrative review

| No | Authors, year of   | Title             | Study design  | Country | Timing of | Measures            | Participants      | Results                |
|----|--------------------|-------------------|---------------|---------|-----------|---------------------|-------------------|------------------------|
|    | publication        |                   |               |         | hospital  |                     |                   |                        |
|    |                    |                   |               |         | admission |                     |                   |                        |
|    |                    |                   |               |         | included  |                     |                   |                        |
| 1  | Dahahasi Charra    | Catactus ubisis a | Overtinancias | Lana    | No        | Childhimth attitud  | 300 nulliparous   | Dain antastuanhisina   |
| 1  | Dehghani, Sharpe   | Catastrophising   | Questionnaire | Iran    | No        | Childbirth attitude | ,                 | Pain catastrophising,  |
|    | and Khatibi (2014) | mediates the      | cohort        |         |           | questionnaire       | and multiparous   | fear of pain and       |
|    |                    | relationship      |               |         |           | (CAQ), fear of pain | women, 4-36       | choice of delivery     |
|    |                    | between fear of   |               |         |           | questionnaire       | weeks gestation   | were all measured      |
|    |                    | pain and          |               |         |           | (FPQ-III),          | attending their   | during pregnancy.      |
|    |                    | preference for    |               |         |           | depression anxiety  | regular prenatal  | Women who opted        |
|    |                    | elective          |               |         |           | stress scale        | care appt. 150    | for ECS had higher     |
|    |                    | caesarean         |               |         |           | (DASS), pain        | from public       | levels of fear of      |
|    |                    | section.          |               |         |           | catastrophising     | hospital and 150  | childbirth, fear of    |
|    |                    |                   |               |         |           | scale (PCS),        | from private.     | pain and catastrophic  |
|    |                    |                   |               |         |           | catastrophic        | Persian-speaking. | cognitions than        |
|    |                    |                   |               |         |           | cognition           |                   | women who chose        |
|    |                    |                   |               |         |           | questionnaire       | During            | vaginal delivery. Fear |
|    |                    |                   |               |         |           | (CCQ).              | pregnancy, 58%    | of childbirth and fear |
|    |                    |                   |               |         |           |                     | planning ECS      | of pain                |
|    |                    |                   |               |         |           |                     | while 42% vaginal | independently          |
|    |                    |                   |               |         |           |                     | delivery.         | predicted preference   |
|    |                    |                   |               |         |           |                     |                   | for ECS and this was   |

|   |                 |                 |               |        |    |                    | Mean age: 27.5    | mediated by            |
|---|-----------------|-----------------|---------------|--------|----|--------------------|-------------------|------------------------|
|   |                 |                 |               |        |    |                    | years.            | catastrophising, but   |
|   |                 |                 |               |        |    |                    |                   | not by negative        |
|   |                 |                 |               |        |    |                    |                   | affectivity. Did not   |
|   |                 |                 |               |        |    |                    |                   | measure pain relief    |
|   |                 |                 |               |        |    |                    |                   | nor actual delivery    |
|   |                 |                 |               |        |    |                    |                   | method.                |
|   |                 |                 |               |        |    |                    |                   |                        |
| 2 | Ferber, Granot, | Catastrophizing | Observational | Israel | No | VAS and PCS in     | maternal age was  | This study             |
|   | Zimmer (2005)   | labor pain      | cohort        |        |    | active labour, VAS | 29.56 G 4.97      | demonstrates that      |
|   |                 | compromises     |               |        |    | and EPDS PCS 2     | years. and mean   | higher levels of labor |
|   |                 | later maternity |               |        |    | days postnatal,    | number of         | pain catastrophizing   |
|   |                 | adjustments.    |               |        |    | then 6 weeks       | previous labors   | are associated with a  |
|   |                 |                 |               |        |    | postnatal Social   | was 1.42 G 1.42.  | decrease in            |
|   |                 |                 |               |        |    | Functioning (SF36) | Multips and       | postpartum maternal    |
|   |                 |                 |               |        |    | (social            | primips. The      | adjustment. The PCS    |
|   |                 |                 |               |        |    | functioning)       | infants were born | that was measured      |
|   |                 |                 |               |        |    |                    | at 39.43 G 1.69   | during active labor    |
|   |                 |                 |               |        |    |                    | weeks.            | was found to be a      |
|   |                 |                 |               |        |    |                    |                   | significant predictor  |
|   |                 |                 |               |        |    |                    |                   | for maternity blues    |
|   |                 |                 |               |        |    |                    |                   | and social             |
|   |                 |                 |               |        |    |                    |                   | functioning at 6       |
|   |                 |                 |               |        |    |                    |                   | weeks. The             |
|   |                 |                 |               |        |    |                    |                   | correlation between    |

|  |  |  |  | the VAS scores and      |
|--|--|--|--|-------------------------|
|  |  |  |  | PCS levels agrees       |
|  |  |  |  | with previous studies   |
|  |  |  |  | that evaluated these    |
|  |  |  |  | relationships in        |
|  |  |  |  | various healthy, sick,  |
|  |  |  |  | and experimental        |
|  |  |  |  | pain conditions.12,13   |
|  |  |  |  | The finding that VAS    |
|  |  |  |  | scores did not predict  |
|  |  |  |  | later maternal          |
|  |  |  |  | adjustment points to    |
|  |  |  |  | the possibility that it |
|  |  |  |  | is not the pain         |
|  |  |  |  | intensity alone, but    |
|  |  |  |  | rather the emotional    |
|  |  |  |  | and cognitive factors,  |
|  |  |  |  | attributed to the pain  |
|  |  |  |  | experience are          |
|  |  |  |  | relevant to the future  |
|  |  |  |  | emotional               |
|  |  |  |  | adjustment of the       |
|  |  |  |  | women after             |
|  |  |  |  | childbirth.             |
|  |  |  |  |                         |

| 3 | Clark, Kalanaviciute, | Exploring pain     | Prospective   | UK | No | PCS, Pain Anxiety  | 122 nulliparous | Identified that        |
|---|-----------------------|--------------------|---------------|----|----|--------------------|-----------------|------------------------|
|   | Bartholomew,          | characteristics in | observational |    |    | Symptoms Scale     | women aged 18-  | healthy young          |
|   | Cheyne, Hundley       | nulliparous        |               |    |    | short form (PASS-  | 48 years, mean  | women show levels      |
|   | (2022)                | women; a           |               |    |    | 20), Fear of Pain  | 22.55 years     | of pain                |
|   |                       | precursor to       |               |    |    | Questionnaire      |                 | catastrophising which  |
|   |                       | developing         |               |    |    | (FPQ), the         |                 | are highly correlated  |
|   |                       | support for        |               |    |    | Childbirth Fear-   |                 | to anxiety and fear of |
|   |                       | women in the       |               |    |    | Prior to Pregnancy |                 | pain. The prevalence   |
|   |                       | latent phase of    |               |    |    | (CFPP) scale.      |                 | of pain                |
|   |                       | labour             |               |    |    |                    |                 | catastrophising with   |
|   |                       |                    |               |    |    |                    |                 | a cut-off score of 20  |
|   |                       |                    |               |    |    |                    |                 | and above was 47.5%    |
|   |                       |                    |               |    |    |                    |                 | (58/122 participants). |
|   |                       |                    |               |    |    |                    |                 | Prevalence of pain     |
|   |                       |                    |               |    |    |                    |                 | catastrophising with   |
|   |                       |                    |               |    |    |                    |                 | a cut-off score of 30  |
|   |                       |                    |               |    |    |                    |                 | and above was 21.3%    |
|   |                       |                    |               |    |    |                    |                 | (26/122). The sample   |
|   |                       |                    |               |    |    |                    |                 | average score was      |
|   |                       |                    |               |    |    |                    |                 | 20.36 (SD=9.95) and    |
|   |                       |                    |               |    |    |                    |                 | the scores ranged      |
|   |                       |                    |               |    |    |                    |                 | from 16 to 49 overall  |
|   |                       |                    |               |    |    |                    |                 |                        |

| 4 | Glowacka, Rosen,    | Genito-pelvic pain | Observational | Canada | No | pain-related      | Low-risk, First- | Of 150 women, 49%    |
|---|---------------------|--------------------|---------------|--------|----|-------------------|------------------|----------------------|
|   | Chorney, Snelgrove- | during pregnancy   | cohort        |        |    | anxiety,          | time expectant   | reported genito-     |
|   | Clarke, George      | and postpartum:    |               |        |    | catastrophizing,  | mothers (N =     | pelvic pain in       |
|   | (2014)              | the prospective    |               |        |    | hypervigilance to | 150)             | pregnancy. The pain  |
|   |                     | impact of pain-    |               |        |    | pain              |                  | resolved for 59% of  |
|   |                     | related anxiety    |               |        |    |                   |                  | women, persisted for |
|   |                     | and                |               |        |    |                   |                  | 41%, and 7% of       |
|   |                     | hypervigilance to  |               |        |    |                   |                  | women reported a     |
|   |                     | pain.              |               |        |    |                   |                  | new onset of genito- |
|   |                     |                    |               |        |    |                   |                  | pelvic pain after    |
|   |                     |                    |               |        |    |                   |                  | childbirth. Pre-     |
|   |                     |                    |               |        |    |                   |                  | pregnancy non-       |
|   |                     |                    |               |        |    |                   |                  | genito-pelvic pain   |
|   |                     |                    |               |        |    |                   |                  | was associated with  |
|   |                     |                    |               |        |    |                   |                  | an increased         |
|   |                     |                    |               |        |    |                   |                  | likelihood of        |
|   |                     |                    |               |        |    |                   |                  | postpartum onset of  |
|   |                     |                    |               |        |    |                   |                  | genito-pelvic pain.  |
|   |                     |                    |               |        |    |                   |                  | Greater pain-related |
|   |                     |                    |               |        |    |                   |                  | anxiety was          |
|   |                     |                    |               |        |    |                   |                  | associated with      |
|   |                     |                    |               |        |    |                   |                  | greater average      |
|   |                     |                    |               |        |    |                   |                  | genito-pelvic pain   |

|   |                      |                   |             |           |    |                   |                     | intensity at 3 months |
|---|----------------------|-------------------|-------------|-----------|----|-------------------|---------------------|-----------------------|
|   |                      |                   |             |           |    |                   |                     | postpartum.           |
|   |                      |                   |             |           |    |                   |                     |                       |
| 5 | Tan, Agarthesh, Tan, | Perceived stress  | Cohort      | Singapore | No | Perceived stress  | 801 women           | Results               |
|   | Sultana,             | during labor and  | prospective |           |    | (Perceived Stress | generally low-risk  | demonstrated that     |
|   | Chen,                | its association   | study       |           |    | Scale, PSS, high  | nulliparous         | the presence of       |
|   | Chua, Sng (2021)     | with depressive   |             |           |    | PSS ≥ 16),        | women aged 20–      | depressive            |
|   |                      | symptomatology,   |             |           |    | depressive        | 46 years, with      | symptomatology,       |
|   |                      | anxiety, and pain |             |           |    | symptomatology    | singleton           | increasing trait      |
|   |                      | catastrophizing.  |             |           |    | (Edinburgh        | pregnancies over    | anxiety, and          |
|   |                      |                   |             |           |    | Postnatal         | 36 weeks'           | increasing pain       |
|   |                      |                   |             |           |    | Depression Scale, | gestation, and      | magnification were    |
|   |                      |                   |             |           |    | EPDS, high        | who requested       | independently         |
|   |                      |                   |             |           |    | EPDS ≥ 10), and   | for epidural        | associated with       |
|   |                      |                   |             |           |    | pain              | analgesia in early  | elevated perceived    |
|   |                      |                   |             |           |    | catastrophizing   | labor (cervical     | stress levels in      |
|   |                      |                   |             |           |    | (Pain             | dilatation ≤ 5 cm). | laboring women        |
|   |                      |                   |             |           |    | Catastrophizing   |                     | receiving epidural    |
|   |                      |                   |             |           |    | Scale, PCS, high  |                     | analgesia.            |
|   |                      |                   |             |           |    | total PCS ≥ 25).  |                     |                       |
|   |                      |                   |             |           |    | Anxiety (State-   |                     |                       |
|   |                      |                   |             |           |    | trait Anxiety     |                     |                       |
|   |                      |                   |             |           |    | Inventory, STAI). |                     |                       |
|   |                      |                   |             |           |    |                   |                     |                       |

| 6 | Sim, Tan, Yeam,   | Association of     | Cohort,     | Singapore | No | Short-form McGill | 712 women.          | Increased sensory        |
|---|-------------------|--------------------|-------------|-----------|----|-------------------|---------------------|--------------------------|
|   | Tan, Sultana, Sng | Pain               | prospective |           |    | pain              | Recruited           | intermittent and         |
|   | (2021).           | Catastrophizing    | study       |           |    | questionnaire–2   | nulliparous         | neuropathic subsets      |
|   |                   | and Depressive     |             |           |    | (SF-MPQ-2), pain  | women aged 21–      | of early labor pain      |
|   |                   | States with        |             |           |    | catastrophizing   | 50 years, 36        | are significantly        |
|   |                   | Multidimensional   |             |           |    | scale (PCS), and  | gestational weeks   | correlated with          |
|   |                   | Early Labor Pain   |             |           |    | Edinburgh         | or more, with a     | increased pre-           |
|   |                   | Assessment in      |             |           |    | postnatal         | singleton fetus ,   | delivery pain            |
|   |                   | Nulliparous        |             |           |    | depression score  | the American        | catastrophizing and      |
|   |                   | Women Having       |             |           |    | (EPDS), obstetric | Society of          | depressive states in     |
|   |                   | Epidural Analgesia |             |           |    | data from medical | Anesthesiologists'  | nulliparous women.       |
|   |                   | – A Secondary      |             |           |    | records.          | physical status II, | This positive            |
|   |                   | Analysis           |             |           |    |                   | and in early labor  | association may be       |
|   |                   |                    |             |           |    |                   | (defined as         | useful for pre-          |
|   |                   |                    |             |           |    |                   | cervical dilatation | delivery risk            |
|   |                   |                    |             |           |    |                   | <5 cm) who had      | stratification for early |
|   |                   |                    |             |           |    |                   | requested labor     | interventions            |
|   |                   |                    |             |           |    |                   | epidural            | towards a more           |
|   |                   |                    |             |           |    |                   | analgesia.          | holistic care            |
|   |                   |                    |             |           |    |                   |                     | management.              |
|   |                   |                    |             |           |    |                   |                     |                          |
| 7 | Komatsu, Ando,    | Factors associated | Narrative   |           |    |                   |                     |                          |
|   | Flood (2020)      | with persistent    | review.     |           |    |                   |                     |                          |
|   |                   | pain after         |             |           |    |                   |                     |                          |

|   |                      | childbirth: a     |             |           |    |                     |                     |                         |
|---|----------------------|-------------------|-------------|-----------|----|---------------------|---------------------|-------------------------|
|   |                      | narrative review. |             |           |    |                     |                     |                         |
|   |                      |                   |             |           |    |                     |                     |                         |
| 8 | Zeng, Tan, Sultana,  | Association of    | Cohort,     | Singapore | No | Predelivery         | 805 generally       | No significant          |
|   | Chua, Chen, Sia, Sng | Pain              | prospective |           |    | questionnaires,     | low-risk            | association was         |
|   | (2020)               | Catastrophizing   | study       |           |    | including the Pain  | nulliparous         | found between high      |
|   |                      | with Postnatal    |             |           |    | Catastrophizing     | women aged 20–      | pain catastrophizing    |
|   |                      | Depressive States |             |           |    | Scale (PCS) and     | 46 years, with      | and probable PND;       |
|   |                      | in Nulliparous    |             |           |    | Edinburgh           | singleton           | however, high           |
|   |                      | Parturients: A    |             |           |    | Postnatal           | pregnancies over    | predelivery pain        |
|   |                      | Prospective Study |             |           |    | Depression Scale    | 36 weeks'           | catastrophizing,        |
|   |                      |                   |             |           |    | (EPDS), were        | gestation, and      | presence of             |
|   |                      |                   |             |           |    | administered        | who requested       | breakthrough pain       |
|   |                      |                   |             |           |    | during early labor. | for epidural        | during epidural         |
|   |                      |                   |             |           |    | A phone survey at   | analgesia in early  | analgesia, and lower    |
|   |                      |                   |             |           |    | 5- 9 weeks          | labor (cervical     | BMI at term were        |
|   |                      |                   |             |           |    | postdelivery was    | dilatation ≤ 5 cm). | associated with         |
|   |                      |                   |             |           |    | conducted to        | Then 518 lost to    | increased               |
|   |                      |                   |             |           |    | determine           | follow-up.          | postdelivery EPDS       |
|   |                      |                   |             |           |    | postdelivery EPDS   |                     | scores. Further         |
|   |                      |                   |             |           |    | and Spielberger's   |                     | research will be        |
|   |                      |                   |             |           |    | State-Trait-Anxiety |                     | needed to validate      |
|   |                      |                   |             |           |    | Inventory scores.   |                     | this association in the |
|   |                      |                   |             |           |    | The primary         |                     | context of the risk of  |
|   |                      |                   |             |           |    | outcome was a       |                     | PND development.        |

|  |  |  | binary variable of  | his suggests that pain |
|--|--|--|---------------------|------------------------|
|  |  |  | postdelivery EPDS   | severity and pain      |
|  |  |  | with cutoff of ≥10, | vulnerability have an  |
|  |  |  | whereas the         | important association  |
|  |  |  | secondary           | with increased         |
|  |  |  | outcome was a       | depressive symptoms    |
|  |  |  | continuous          | and may contribute     |
|  |  |  | variable on         | to PND states.         |
|  |  |  | increases in EPDS   | Prospective studies    |
|  |  |  | score.              | to validate our        |
|  |  |  |                     | findings are needed    |
|  |  |  |                     | to confirm the impact  |
|  |  |  |                     | of the proposed        |
|  |  |  |                     | association model.     |
|  |  |  |                     | Future research will   |
|  |  |  |                     | also evaluate the      |
|  |  |  |                     | usefulness of this     |
|  |  |  |                     | model to be            |
|  |  |  |                     | implemented for risk   |
|  |  |  |                     | stratification and     |
|  |  |  |                     | early interventional   |
|  |  |  |                     | therapy to reduce      |
|  |  |  |                     | PND and PND states.    |
|  |  |  |                     |                        |

| 9  | Doğru, Özsoy,         | Catastrophizing ,   | Cross-        | Not stated | No | Pain                | 365 pregnant      | PCS cut off 17.        |
|----|-----------------------|---------------------|---------------|------------|----|---------------------|-------------------|------------------------|
|    | Doğru, Karaman,       | depression and      | sectional     |            |    | Catastrophizing     | women. The        |                        |
|    | Şahin, Özsoy,         | anxiety during      |               |            |    | Scale, Beck         | mean age was      | The study              |
|    | Çakmak, Süren         | pregnancy:          |               |            |    | Anxiety Inventory,  | 25.94 ± 5.03. The | demonstrated that      |
|    | (2018)                | relation between    |               |            |    | Beck Depression     | mean gestational  | catastrophizing level  |
|    |                       | lumbopelvic pain    |               |            |    | Inventory-II, and   | week was          | shows an alteration    |
|    |                       | and physical/       |               |            |    | Short Form-36.      | 16.59 ± 8.14 (%95 | throughout the         |
|    |                       | social functioning. |               |            |    | VAS Pain intensity  | CI 15.91–17.51;   | pregnancy period,      |
|    |                       |                     |               |            |    |                     | minimum–          | and variation in       |
|    |                       |                     |               |            |    |                     | maximum: 4–40).   | catastrophizing        |
|    |                       |                     |               |            |    |                     |                   | shows an               |
|    |                       |                     |               |            |    |                     |                   | approximately similar  |
|    |                       |                     |               |            |    |                     |                   | course with pain       |
|    |                       |                     |               |            |    |                     |                   | intensity, depression  |
|    |                       |                     |               |            |    |                     |                   | and anxiety.           |
|    |                       |                     |               |            |    |                     |                   |                        |
| 10 | Chang, Jensen,        | Risk factors of     | Descriptive   | Taiwan     | No | Brief Pain          | 183 pregnant      | Indicated that lower   |
|    | Yang, Lee, Lai (2012) | pregnancy-related   | Cross-        |            |    | Inventory-Short     | women who:        | education level was    |
|    |                       | lumbopelvic pain:   | sectional     |            |    | Form Taiwanese      | (1)were adults    | associated with        |
|    |                       | a biopsychosocial   | correlational |            |    | version (BPI-T)Pain | (‡18 years); (2)  | higher pain intensity. |
|    |                       | approach            |               |            |    | intensity and pain  | were in the 35th- | Higher pain intensity  |
|    |                       |                     |               |            |    | interference were   | 41st gestational  | during pregnancy and   |
|    |                       |                     |               |            |    | assessed using      | week, (3)         | catastrophising        |
|    |                       |                     |               |            |    | items from the      | reported current  | cognitions were        |
|    |                       |                     |               |            |    | BPI-T. we initially | pain in the area  | associated             |

|    |                    |                  |             |        |    | measured           | ranging from the   | significantly with    |
|----|--------------------|------------------|-------------|--------|----|--------------------|--------------------|-----------------------|
|    |                    |                  |             |        |    | catastrophising    | 12th rib to        | higher pain           |
|    |                    |                  |             |        |    | using the 6-item   | gluteal fold       | interference.         |
|    |                    |                  |             |        |    | catastrophising    | and/or the         | Moreover, age         |
|    |                    |                  |             |        |    | subscale in the    | pubic-symphysis;   | moderated the         |
|    |                    |                  |             |        |    | CSQ-CATA.          | (4) the reported   | strength of the       |
|    |                    |                  |             |        |    | Physical           | pain had lasted    | association between   |
|    |                    |                  |             |        |    | Workload           | for more than      | pain intensity and    |
|    |                    |                  |             |        |    | Questionnaire      | one week; and (5)  | pain interference.    |
|    |                    |                  |             |        |    | (PWQ), and         | had no obstetric   | This association was  |
|    |                    |                  |             |        |    | background         | or psychiatric     | stronger for older    |
|    |                    |                  |             |        |    | demographics,      | severe disease     | than for younger      |
|    |                    |                  |             |        |    | BMI and            | for controlling    | women.                |
|    |                    |                  |             |        |    | pregnancy data.    | potential          |                       |
|    |                    |                  |             |        |    |                    | confounding        |                       |
|    |                    |                  |             |        |    |                    | factors.           |                       |
|    |                    |                  |             |        |    |                    |                    |                       |
| 11 | Rosen, Dawson,     | Trajectories of  | Prospective | Canada | No | VAS for            | 582 attrition to   | Identified two        |
|    | Binik, Pierce,     | dyspareunia from | cohort      |        |    | dyspareunia pain,  | 492 pregnant       | distinct trajectories |
|    | Brooks, Pukall,    | pregnancy to 24  |             |        |    | daily energy scale | Women were, on     | of dyspareunia across |
|    | Chorney, Snelgrove | months           |             |        |    | rated on a scale,  | average, 29 years  | pregnancy and         |
|    | Clarke, George     | postpartum.      |             |        |    | EPDS, PCS, and     | old at the time of | postpartum from       |
|    | (2022)             |                  |             |        |    | sexual goals       | recruitment        | mid-pregnancy to 24   |
|    |                    |                  |             |        |    | questions.         |                    | months postpartum:    |
|    |                    |                  |             |        |    | _                  |                    | 21% of women were     |

|  |  |  | (range 18–45    | in the class with      |
|--|--|--|-----------------|------------------------|
|  |  |  | years, SD54.4). | moderate               |
|  |  |  |                 | dyspareunia and 79%    |
|  |  |  |                 | were in the class with |
|  |  |  |                 | minimal dyspareunia.   |
|  |  |  |                 | In both classes, pain  |
|  |  |  |                 | increased from mid-    |
|  |  |  |                 | pregnancy to 3         |
|  |  |  |                 | months postpartum,     |
|  |  |  |                 | decreased between 3    |
|  |  |  |                 | and 12 months          |
|  |  |  |                 | postpartum, and        |
|  |  |  |                 | then was relatively    |
|  |  |  |                 | stable to 24 months    |
|  |  |  |                 | postpartum. One in     |
|  |  |  |                 | five nulliparous       |
|  |  |  |                 | women experienced      |
|  |  |  |                 | moderate               |
|  |  |  |                 | dyspareunia. Pain      |
|  |  |  |                 | catastrophizing at 3   |
|  |  |  |                 | months postpartum      |
|  |  |  |                 | was associated with    |
|  |  |  |                 | experiencing           |
|  |  |  |                 | moderate relative to   |
|  |  |  |                 | minimal levels of      |

|    |                      |                   |             |        |    |                   |                  | dyspareunia. Also     |
|----|----------------------|-------------------|-------------|--------|----|-------------------|------------------|-----------------------|
|    |                      |                   |             |        |    |                   |                  | identified critical   |
|    |                      |                   |             |        |    |                   |                  | timepoints to assess  |
|    |                      |                   |             |        |    |                   |                  | pain catastrophizing  |
|    |                      |                   |             |        |    |                   |                  | to identify those at  |
|    |                      |                   |             |        |    |                   |                  | risk for moderate     |
|    |                      |                   |             |        |    |                   |                  | dyspareunia.          |
|    |                      | _                 |             |        |    |                   |                  |                       |
| 12 | Jessa, Tomfohr-      | Trajectories of   | Observation | Canada | No | PCS >30. Patient- | 142 attrition to | Findings may help to  |
|    | Madsen , Dhillon,    | pain intensity,   | cohort      |        |    | Reported          | 117 pregnant     | identify women who    |
|    | Walker, Noel,        | pain              |             |        |    | Outcomes          | women who can    | are at high risk for  |
|    | Sedov, Miller (2024) | catastrophizing,  |             |        |    | Measurement       | read and can     | experiencing pain     |
|    |                      | and pain          |             |        |    | Information       | access computer  | symptoms during       |
|    |                      | interference in   |             |        |    | System Pain       | to participate.  | pregnancy and could   |
|    |                      | the perinatal and |             |        |    | Intensity short   |                  | aid in developing     |
|    |                      | postpartum        |             |        |    | form (3 items),   |                  | targeted              |
|    |                      | period            |             |        |    | Patient-Reported  |                  | management            |
|    |                      |                   |             |        |    | Outcomes          |                  | strategies to prevent |
|    |                      |                   |             |        |    | Measurement       |                  | mothers from          |
|    |                      |                   |             |        |    | Information       |                  | developing chronic    |
|    |                      |                   |             |        |    | System Pain       |                  | pain during their     |
|    |                      |                   |             |        |    | Interference      |                  | pregnancy and into    |
|    |                      |                   |             |        |    | subscale short    |                  | the postpartum        |
|    |                      |                   |             |        |    | form (4 items) ,  |                  | period.               |
|    |                      |                   |             |        |    | Insomnia Severity |                  |                       |

|    |                    |                   |                 |      |    | Index, Generalized Anxiety Disorder, Edinburgh Postnatal Depression Scale. |                   |                        |
|----|--------------------|-------------------|-----------------|------|----|--|-------------------|------------------------|
|    |                    |                   |                 |      |    |  |                   |                        |
| 13 | Ahmadi and Bagheri | The effectiveness | Clinical trial, | Iran | No | State-Trait Anxiety  | 38 nulliparous    | Pain catastrophising   |
|    | (2017)             | of educating      | single blind    |      |    | Inventory,   | women who had     | and fear of pain were  |
|    |                    | mindfulness on    | pre-test post-  |      |    | Hartman's  | selected          | measured during        |
|    |                    | anxiety, fear of  | test            |      |    | Childbirth   | caesarean         | pregnancy.             |
|    |                    | delivery, pain    |                 |      |    | Attitudes  | section, 18-28    |                        |
|    |                    | catastrophising   |                 |      |    | Questionnaire  | weeks gestation,  | Mindfulness            |
|    |                    | and selecting     |                 |      |    | (CAQ), and Pain  | higher than       | improved the score     |
|    |                    | caesarean section |                 |      |    | Catastrophising  | median score of   | of anxiety, fear of    |
|    |                    | as the delivery   |                 |      |    | Scale (PCS).   | fear and anxiety. | labour pain and        |
|    |                    | method among      |                 |      |    |  | Iranian           | catastrophising pain   |
|    |                    | nulliparous       |                 |      |    |  | nationality.      | and consequently       |
|    |                    | pregnant women.   |                 |      |    |  | Randomly          | changed the attitude   |
|    |                    |                   |                 |      |    |  | allocated into    | toward selecting       |
|    |                    |                   |                 |      |    |  | mindfulness       | caesarean section. A   |
|    |                    |                   |                 |      |    |  | intervention or   | significant difference |
|    |                    |                   |                 |      |    |  | control group.    | in the score of        |
|    |                    |                   |                 |      |    |  | Mean age: 28.24   | catastrophising pain   |
|    |                    |                   |                 |      |    |  | years.            | in the intervention    |
|    |                    |                   |                 |      |    |  | ,                 | group after the        |

|    |                      |                    |             |             |    |                   |                  | intervention            |
|----|----------------------|--------------------|-------------|-------------|----|-------------------|------------------|-------------------------|
|    |                      |                    |             |             |    |                   |                  | compared to before      |
|    |                      |                    |             |             |    |                   |                  | the intervention and    |
|    |                      |                    |             |             |    |                   |                  | also compared to the    |
|    |                      |                    |             |             |    |                   |                  | control group. Did      |
|    |                      |                    |             |             |    |                   |                  | not measure actual      |
|    |                      |                    |             |             |    |                   |                  | delivery method.        |
|    |                      |                    |             |             |    |                   |                  |                         |
| 14 | Veringa, Buitendijk, | Pain cognitions as | Prospective | Netherlands | No | Labour pain       | 177 low-risk     | Pain catastrophising    |
|    | de Miranda, de       | predictors of the  | cohort      |             |    | coping and        | nulliparous      | measured during         |
|    | Wolf and Spinhoven   | request for pain   |             |             |    | cognition list    | women, 34-36     | pregnancy. Women        |
|    | (2011)               | relief during the  |             |             |    | (LPCCL), NPS-     | weeks gestation. | with high scores for    |
|    |                      | first stage of     |             |             |    | anticipated       | Dutch-speaking.  | catastrophising were    |
|    |                      | labor: a           |             |             |    | measured most     | Mean age: 29.1   | more than two and a     |
|    |                      | prospective study. |             |             |    | intense           | years.           | half times as likely to |
|    |                      |                    |             |             |    | imaginable labour |                  | request pain relief     |
|    |                      |                    |             |             |    | pain, NPS-during  |                  | during labour as        |
|    |                      |                    |             |             |    | labour measured   |                  | women with lower        |
|    |                      |                    |             |             |    | experienced       |                  | scores.                 |
|    |                      |                    |             |             |    | labour pain       |                  | Catastrophising was     |
|    |                      |                    |             |             |    | (numerical pain   |                  | the most powerful       |
|    |                      |                    |             |             |    | intensity scale). |                  | predictor of the        |
|    |                      |                    |             |             |    |                   |                  | request for pain relief |
|    |                      |                    |             |             |    |                   |                  | during the first stage  |
|    |                      |                    |             |             |    |                   |                  | of labour. Fear of      |

|    |                     |                    |             |        |    |                     |                  | pain and choice of     |
|----|---------------------|--------------------|-------------|--------|----|---------------------|------------------|------------------------|
|    |                     |                    |             |        |    |                     |                  | delivery were not      |
|    |                     |                    |             |        |    |                     |                  | measured. 73% of all   |
|    |                     |                    |             |        |    |                     |                  | requests for pain      |
|    |                     |                    |             |        |    |                     |                  | treatment were         |
|    |                     |                    |             |        |    |                     |                  | made in the latent     |
|    |                     |                    |             |        |    |                     |                  | phase of labour.       |
|    |                     |                    |             |        |    |                     |                  |                        |
| 15 | Flink, Mroczek,     | Pain in childbirth | Prospective | Sweden | No | Pain                | 82 nulliparous   | Pain catastrophising   |
|    | Sullivan and Linton | and postpartum     | cohort      |        |    | Catastrophising     | women, at least  | measured during        |
|    | (2009)              | recovery – The     |             |        |    | Scale (PCS),        | 34 weeks         | pregnancy. Doesn't     |
|    |                     | role of            |             |        |    | Present Pain        | gestation, in    | measure fear of pain   |
|    |                     | catastrophising.   |             |        |    | Intensity scale     | Sweden.          | or choice of delivery. |
|    |                     |                    |             |        |    | (PPI) to assess     | Excluded: women  | No differences         |
|    |                     |                    |             |        |    | anticipated and     | who had planned  | between                |
|    |                     |                    |             |        |    | experienced         | to have          | catastrophisers and    |
|    |                     |                    |             |        |    | labour pain, and    | caesarean.       | non-catastrophisers    |
|    |                     |                    |             |        |    | Activities of Daily | Included: women  | for use of analgesics  |
|    |                     |                    |             |        |    | Living (ADL) to     | who had an acute | during delivery.       |
|    |                     |                    |             |        |    | assess physical     | caesarean in     | Women who              |
|    |                     |                    |             |        |    | recovery.           | advanced labour. | catastrophised about   |
|    |                     |                    |             |        |    |                     | Mean age: 29.6   | labour pain            |
|    |                     |                    |             |        |    |                     | years.           | anticipated (large     |
|    |                     |                    |             |        |    |                     |                  | difference) and        |
|    |                     |                    |             |        |    |                     |                  | experienced            |

|    |                     |                  |               |         |    |                      |                 | (moderate              |
|----|---------------------|------------------|---------------|---------|----|----------------------|-----------------|------------------------|
|    |                     |                  |               |         |    |                      |                 | difference) more pain  |
|    |                     |                  |               |         |    |                      |                 | than non-              |
|    |                     |                  |               |         |    |                      |                 | catastrophisers. Non-  |
|    |                     |                  |               |         |    |                      |                 | catastrophisers rated  |
|    |                     |                  |               |         |    |                      |                 | their recovery after   |
|    |                     |                  |               |         |    |                      |                 | childbirth             |
|    |                     |                  |               |         |    |                      |                 | significantly better   |
|    |                     |                  |               |         |    |                      |                 | than catastrophisers.  |
|    |                     |                  |               |         |    |                      |                 |                        |
| 16 | Van den Bussche,    | Why women        | Observational | Belgium | No | Pain                 | 114 nulliparous | Pain catastrophising   |
|    | Crombez, Eccleston  | prefer epidural  | cohort        |         |    | Catastrophising      | (57%) and       | measured during        |
|    | and Sullivan (2006) | analgesia during |               |         |    | Scale (PCS), Beliefs | multiparous     | birth. Pain            |
|    |                     | childbirth: The  |               |         |    | about Epidural       | (43%) women.    | catastrophising was    |
|    |                     | role of beliefs  |               |         |    | Analgesia            | Mean age: 28.74 | positively             |
|    |                     | about epidural   |               |         |    | Questionnaire        | years.          | interrelated with a    |
|    |                     | analgesia and    |               |         |    | (BEAQ) and the       |                 | fear of pain during    |
|    |                     | pain             |               |         |    | Childbirth           |                 | the beginning of the   |
|    |                     | catastrophising. |               |         |    | Experience           |                 | contractions in both   |
|    |                     |                  |               |         |    | Questionnaire        |                 | groups. Pain           |
|    |                     |                  |               |         |    | (CEQ). The BEAQ      |                 | catastrophising was    |
|    |                     |                  |               |         |    | and CEQ were         |                 | not predictive of      |
|    |                     |                  |               |         |    | specifically         |                 | epidural use. But it   |
|    |                     |                  |               |         |    |                      |                 | was related to some    |
|    |                     |                  |               |         |    |                      |                 | epidural beliefs. Pain |

|    |                    |                    |                |             |    | developed for this |               | catastrophising was    |
|----|--------------------|--------------------|----------------|-------------|----|--------------------|---------------|------------------------|
|    |                    |                    |                |             |    | study.             |               | positively related to  |
|    |                    |                    |                |             |    |                    |               | recommendations to     |
|    |                    |                    |                |             |    |                    |               | use epidural by        |
|    |                    |                    |                |             |    |                    |               | midwives and           |
|    |                    |                    |                |             |    |                    |               | gynaecologist. Two     |
|    |                    |                    |                |             |    |                    |               | questions on BEAQ      |
|    |                    |                    |                |             |    |                    |               | measure fear of pain.  |
|    |                    |                    |                |             |    |                    |               | Pain catastrophising   |
|    |                    |                    |                |             |    |                    |               | was related to the     |
|    |                    |                    |                |             |    |                    |               | fear of pain during    |
|    |                    |                    |                |             |    |                    |               | insertion of epidural  |
|    |                    |                    |                |             |    |                    |               | needle and the fear    |
|    |                    |                    |                |             |    |                    |               | of being               |
|    |                    |                    |                |             |    |                    |               | overwhelmed by         |
|    |                    |                    |                |             |    |                    |               | pain. Did not          |
|    |                    |                    |                |             |    |                    |               | measure choice of      |
|    |                    |                    |                |             |    |                    |               | delivery.              |
|    |                    |                    |                |             |    |                    |               |                        |
| 17 | van den Bosch,     | Variables          | Two center,    | Netherlands | No | Beliefs About      | Women (n=446) | Pain catastrophizing   |
|    | Goossens, Winkens, | Contributing to    | randomized,    |             |    | Epidural           | who were      | is the most important  |
|    | Nijhuis, Roumen,   | Women's            | noninferiority |             |    | Questionnaire      | randomly      | factor associated      |
|    | Wassen (2020)      | Prelabor Beliefs   | trial.         |             |    | (BEAQ) and Pain    | allocated to  | with beliefs about EA  |
|    |                    | about Epidural     |                |             |    | Catastrophizing    | routine EA or | and the feelings       |
|    |                    | Analgesia: Results |                |             | _  | Scale (PCS) before | analgesia on  | about childbirth after |

|    |                  | of a Randomized     |               |        |    | randomization,       | request. 18 years  | delivery, which        |
|----|------------------|---------------------|---------------|--------|----|----------------------|--------------------|------------------------|
|    |                  | Controlled Trial in |               |        |    | and the Child Birth  | and older,         | should especially be   |
|    |                  | Dutch Women.        |               |        |    | Experience           | pregnant with a    | accounted for in       |
|    |                  |                     |               |        |    | questionnaire        | singleton in       | young, nulliparous     |
|    |                  |                     |               |        |    | (CEQ) six weeks      | vertex             | women with lower       |
|    |                  |                     |               |        |    | after delivery.      | presentation at    | education. These       |
|    |                  |                     |               |        |    |                      | 36 weeks           | results contribute to  |
|    |                  |                     |               |        |    |                      | gestation or       | make a tailor-made     |
|    |                  |                     |               |        |    |                      | more.              | pain management        |
|    |                  |                     |               |        |    |                      |                    | plan for women         |
|    |                  |                     |               |        |    |                      |                    | during pregnancy       |
|    |                  |                     |               |        |    |                      |                    |                        |
| 18 | Olsson, Grooten, | Catastrophizing     | Prospective   | Sweden | No | PCS and disability   | 242 pregnant       | A total of 242 of 324  |
|    | Nilsson-Wikmar,  | during and after    | questionnaire |        |    | rating index. Non-   | women who          | women were             |
|    | Harms-Ringdahl,  | pregnancy:          |               |        |    | catastrophizing      | completed the      | categorized            |
|    | Lundberg (2012)  | Associations with   |               |        |    | (below or equal to   | Pain               | according to reported  |
|    |                  | lumbopelvic pain    |               |        |    | the highest tertile, | Catastrophizing    | levels of              |
|    |                  | and postpartum      |               |        |    | 17) and              | Scale (PCS) on all | catastrophizing. A     |
|    |                  | physical ability.   |               |        |    | catastrophizing      | 3 occasions.       | majority of women      |
|    |                  |                     |               |        |    | (above the highest   |                    | (57.9%) reported not   |
|    |                  |                     |               |        |    | tertile, 17)         |                    | catastrophizing at all |
|    |                  |                     |               |        |    |                      |                    | test occasions,        |
|    |                  |                     |               |        |    |                      |                    | whereas 10.3%          |
|    |                  |                     |               |        |    |                      |                    | reported               |
|    |                  |                     |               |        |    |                      |                    | catastrophizing at all |

|    |                    |                  |               |             |    |                      |                   | occasions. For the    |
|----|--------------------|------------------|---------------|-------------|----|----------------------|-------------------|-----------------------|
|    |                    |                  |               |             |    |                      |                   | remaining 31.8%, the  |
|    |                    |                  |               |             |    |                      |                   | levels of             |
|    |                    |                  |               |             |    |                      |                   | catastrophizing       |
|    |                    |                  |               |             |    |                      |                   | varied over time.     |
|    |                    |                  |               |             |    |                      |                   | Women who             |
|    |                    |                  |               |             |    |                      |                   | catastrophized at 1   |
|    |                    |                  |               |             |    |                      |                   | or more of the        |
|    |                    |                  |               |             |    |                      |                   | occasions reported    |
|    |                    |                  |               |             |    |                      |                   | higher proportions of |
|    |                    |                  |               |             |    |                      |                   | postpartum            |
|    |                    |                  |               |             |    |                      |                   | lumbopelvic pain and  |
|    |                    |                  |               |             |    |                      |                   | had more restricted   |
|    |                    |                  |               |             |    |                      |                   | postpartum physical   |
|    |                    |                  |               |             |    |                      |                   | ability than women    |
|    |                    |                  |               |             |    |                      |                   | who did not           |
|    |                    |                  |               |             |    |                      |                   | catastrophize.        |
|    |                    |                  |               |             |    |                      |                   |                       |
| 19 | Carvalho, Zheng,   | A Prospective    | Observational | California, | No | Anxiety Sensitivity  | Nulliparous       | Findings suggest that |
|    | and Tagaloa (2014) | Observational    | cohort        | USA         |    | Index (ASI), Fear of | women aged 18     | the psychological     |
|    |                    | Study Evaluating |               |             |    | Pain Score           | to 40 years, with | (ASI, FPQ, PCS)       |
|    |                    | the Ability of   |               |             |    | (FPQIII), Pain       | a singleton term  | questionnaires,       |
|    |                    | Prelabor         |               |             |    | Catastrophizing      | or post-term (37– | Eysenck personality   |
|    |                    | Psychological    |               |             |    | Scale (PCS),         | 42 weeks'         | assessments           |
|    |                    | Tests to Predict |               |             |    | Eysenck              | gestation)        | (psychoticism,        |

| Labor Pain,        | Personality    | pregnancy,      | extroversion,        |
|--------------------|----------------|-----------------|----------------------|
| Epidural Analgesic | Questionnaire- | admitted for    | neuroticism, and     |
| Consumption, and   | Short Scale    | scheduled       | lying), and other    |
| Maternal           |                | induction of    | psychosocial         |
| Satisfaction       | (EPQR-S)       | labour and      | evaluations          |
|                    |                | planning to     | completed before the |
|                    |                | request labour  | onset of labour may  |
|                    |                | epidural        | help predict the     |
|                    |                | analgesia were  | labour pain          |
|                    |                | enrolled in the | experience.          |
|                    |                | study.          | Personality traits   |
|                    |                |                 | (psychoticism,       |
|                    |                |                 | extroversion, and    |
|                    |                |                 | lying), as well as   |
|                    |                |                 | scaled ratings of    |
|                    |                |                 | anxiety, confidence, |
|                    |                |                 | and analgesia        |
|                    |                |                 | expectations, show   |
|                    |                |                 | some potential to    |
|                    |                |                 | predict labor pain,  |
|                    |                |                 | epidural local       |
|                    |                |                 | anesthetic use, and  |
|                    |                |                 | time to epidural     |
|                    |                |                 | analgesia request.   |
|                    |                |                 | Although ASI was     |

|                         |                    |               |             |    |                    |                    | included in the final |
|-------------------------|--------------------|---------------|-------------|----|--------------------|--------------------|-----------------------|
|                         |                    |               |             |    |                    |                    | model for labor pain  |
|                         |                    |               |             |    |                    |                    | AUC, and FPQ and      |
|                         |                    |               |             |    |                    |                    | PCS were not, further |
|                         |                    |               |             |    |                    |                    | study is required to  |
|                         |                    |               |             |    |                    |                    | determine whether     |
|                         |                    |               |             |    |                    |                    | ASI is a better       |
|                         |                    |               |             |    |                    |                    | predictor than FPQ or |
|                         |                    |               |             |    |                    |                    | PCS.                  |
|                         |                    |               |             |    |                    |                    |                       |
| 20 Veringa-Skiba, de Fe | ear of childbirth, | Randomised    | Netherlands | No | catastrophising    | Low-risk, nulli-,  | MBCP for pregnant     |
| Bruin, van Steensel, no | nonurgent          | control trial |             |    | labour pain        | and multi-parous   | couples reduces       |
| Bögels (2022) ol        | obstetric          | (RCT)         |             |    | catastrophising    | pregnant women     | mothers' fear of      |
| in                      | nterventions, and  |               |             |    | labour pain (CLP), | (n=141) aged ≥18   | childbirth, nonurgent |
| no                      | newborn            |               |             |    | WDEQ-A, labour     | years without a    | obstetric             |
| Of                      | outcomes: A        |               |             |    | pain acceptance    | priori restriction | interventions during  |
| ra                      | randomized         |               |             |    | (LPAQ),            | on having an       | childbirth and may    |
| СС                      | controlled trial   |               |             |    | willingness to     | unmedicated        | improve childbirth    |
| СС                      | comparing          |               |             |    | accept obstetric   | childbirth         | outcomes. MBCP        |
| m                       | mindfulness-       |               |             |    | interventions      | (spontaneous,      | adapted for pregnant  |
| ba                      | pased childbirth   |               |             |    | (WAOI).            | without any        | women with high       |
| ar                      | and parenting      |               |             |    |                    | obstetric          | FOC and their         |
| w                       | with enhanced      |               |             |    |                    | intervention),     | partners appears an   |
| Са                      | care as usual.     |               |             |    |                    | experiencing a     | acceptable and        |
|                         |                    |               |             |    |                    | high FOC (W-       |                       |

|    |                    |                 |               |              |    |                    | DEQ-A ≥ 66 and  | effective intervention |
|----|--------------------|-----------------|---------------|--------------|----|--------------------|-----------------|------------------------|
|    |                    |                 |               |              |    |                    | self-confirmed  | for midwifery care.    |
|    |                    |                 |               |              |    |                    | FOC) severe (W- |                        |
|    |                    |                 |               |              |    |                    | DEQ-A ≥ 85),    |                        |
|    |                    |                 |               |              |    |                    | and phobic      |                        |
|    |                    |                 |               |              |    |                    | (WDEQ-A ≥ 100). |                        |
|    |                    |                 |               |              |    |                    |                 |                        |
| 21 | Peralta FM, Condon | Association of  | Prospective   | Illinois USA | No | Brief Pain         | 138 Women       | No greater labor or    |
|    | LP, Torrez D,      | pain            | observational |              |    | Inventory (BPI),   | experiencing a  | post-delivery pain or  |
|    | Neumann KE, Pollet | catastrophizing |               |              |    | Pain               | singleton full- | increased analgesic    |
|    | AL, McCarthy RJ    | with labor pain |               |              |    | Catastrophizing    | term pregnancy  | use in high-           |
|    | (2024)             | and analgesia   |               |              |    | scale (PCS),       | (≥37 weeks'     | catastrophizing        |
|    |                    | consumption in  |               |              |    | Anxiety and        | gestation) and  | parturients. High      |
|    |                    | obstetrical     |               |              |    | depression         | induction of    | catastrophizers        |
|    |                    | patients.       |               |              |    | screened for using | labour.         | reported greater pain  |
|    |                    |                 |               |              |    | the Patient Health |                 | when requesting        |
|    |                    |                 |               |              |    | Questionnaire-4    |                 | analgesia, which is    |
|    |                    |                 |               |              |    | (PHQ-4). A pain    |                 | consistent with the    |
|    |                    |                 |               |              |    | score recorded at  |                 | role of                |
|    |                    |                 |               |              |    | request for        |                 | catastrophizing in     |
|    |                    |                 |               |              |    | analgesia using    |                 | intensifying the       |
|    |                    |                 |               |              |    | the numeric rating |                 | experience of pain.    |
|    |                    |                 |               |              |    | scale. Obstetric   |                 |                        |
|    |                    |                 |               |              |    | Quality of         |                 |                        |

|  |  |  | Recovery 10-item  |  |
|--|--|--|-------------------|--|
|  |  |  | tool (ObsQoR-10). |  |
|  |  |  |                   |  |

## References

Bettany-Saltikov, J. and McSherry, R. (2016) How to do a systematic literature review in nursing: a step-by-step guide. 2nd edn. London: Open University Press

A.C. Tricco, E. Lillie, W. Zarin, K.K. O'Brien, H. Colquhoun, D. Levac, et al., PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and Explanation, Ann. Intern. Med. 169 (2018) 467–473, https://doi.org/10.7326/ M18-0850.

Page, MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

# Appendix 3 NHS ethics committee approval



#### West Midlands - Black Country Research Ethics Committee

The Old Chape Royal Standard Place Nottingham NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

03 June 2020

Mrs Vanessa Bartholomew R202 Royal London House Faculty of Health and Social Sciences, Bournemouth University Christchurch Road, Bournemouth BH1 3LT

#### Dear Mrs Bartholomew

| Study title:     | The RETHINK Study - A study to determine if pregnant   |
|------------------|--|
|                  | women who pain catastrophise are more likely to attend |
|                  | hospital during the latent phase of labour             |
| REC reference:   | 20/WM/0100   |
| Protocol number: | N/A  |
| IRAS project ID: | 270583   |

Thank you for your correspondence, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

### Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

#### Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. <u>Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs)</u>, except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee ( see here for more information on requesting a deferral:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: <a href="https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/">https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/</a>

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

#### After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

#### Ethical review of research sites

#### NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

## Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

| Document   | Version | Date             |
|--|---------|------------------|
| Copies of advertisement materials for research participants<br>[Poster/Advert]   | 1.3     | 26 February 2020 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance & Department of Sponsors only) [Insurance & Department only) [Insurance & Department of Sponsors only) [Insurance & Depa |         | 01 August 2019   |
| IRAS Application Form [IRAS_Form_10032020]   |         | 10 March 2020    |
| Letter from funder [Portfolio adoption letter]   |         | 29 January 2020  |
| Letter from sponsor [Sponsor letter]   |         | 21 January 2020  |
| Non-validated questionnaire [Non-validated questions]  | 1.3     | 26 February 2020 |
| Other [CI Declaration]   | 1.0     | 26 February 2020 |
| Other [Carol Clark CV]   |         | 19 February 2020 |
| Other [Ben Parris CV]  |         |                  |
| Other [REC Required Amendments]  | 1       | 05 May 2020      |
| Participant consent form [Participant Consent]   | 1.4     | 05 May 2020      |
| Participant information sheet (PIS) [PIS]  | 1.4     | 05 May 2020      |
| Research protocol or project proposal [Study Protocol]   | 1.4     | 05 May 2020      |
| Summary CV for Chief Investigator (CI) [CI CV]   |         | 13 February 2020 |
| Summary CV for supervisor (student research) [Professor Hundley CV]  |         | 17 February 2020 |
| Summary of any applicable exclusions to sponsor insurance<br>(non-NHS sponsors only) [Professional Indemnity]  | 1.0     | 01 August 2019   |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Participant flowchart]   | 1.3     | 26 February 2020 |
| Validated questionnaire [The Fear of Childbirth Scale]   |         |                  |
| Validated questionnaire [Pain Catastrophizing Questionnaire]   |         |                  |

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/guality-assurance/

#### **HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <a href="https://www.hra.nhs.uk/planning-and-improving-research/learning/">https://www.hra.nhs.uk/planning-and-improving-research/learning/</a>

## IRAS project ID: 270583 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

# Appendix 4 NHS HRA ethical approval





Mrs Vanessa Bartholomew R202 Royal London House Faculty of Health and Social Sciences, Bournemouth University Christchurch Road, Bournemouth BH1 3LT

Email: approvals@hra.nhs.uk HCRW.approvals@wales.nhs.uk

04 June 2020

Dear Mrs Bartholomew

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title: The RETHINK Study - A study to determine if pregnant

women who pain catastrophise are more likely to attend

hospital during the latent phase of labour

IRAS project ID: 270583 Protocol number: N/A

REC reference: 20/WM/0100

Sponsor Bournemouth University

I am pleased to confirm that <u>HRA and Health and Care Research Wales (HCRW) Approval</u> has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, <u>in line with the instructions provided in the "Information to support study set up" section towards</u> the end of this letter.

# How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see <u>IRAS Help</u> for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

### How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

## What are my notification responsibilities during the study?

The standard conditions document "<u>After Ethical Review – guidance for sponsors and investigators</u>", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- · Registration of research
- Notifying amendments
- · Notifying the end of the study

The <u>HRA website</u> also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

#### Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 270583. Please quote this on all correspondence.

# Appendix 5 List of approved amendments for the RETHINK study

| No. | Summary and Justification                                | No. | Amendment                                      | Substantial | Date       |
|-----|--|-----|--|-------------|------------|
|     |  |     |  | or Non-     | approved   |
|     |  |     |  | substantial |            |
|     |  |     |  |             |            |
| 1   | These amendments have been made: 1 to incorporate a      | 1   | Addition of Trust. Wording has been amended at | Non-        | 14/08/2020 |
|     | Trust that was previously omitted but would like to      |     | relevant points through the protocol.          | substantial |            |
|     | participate, 2. to improve efficiency of the management  |     |  |             |            |
|     | of the study, 3. to retain participants who were         |     |  |             |            |
|     | unnecessarily excluded if they met exclusion criteria    |     |  |             |            |
|     | during the study period, 4. to aid participants' memory  |     |  |             |            |
|     | recall by reducing the time period when they can expect  |     |  |             |            |
|     | to be contacted postnatal, 5. for participants'          |     |  |             |            |
|     | convenience when completing the survey, 6. with the aim  |     |  |             |            |
|     | to improve this study's findings about the social        |     |  |             |            |
|     | determinants of health, 7. to avoid leading participants |     |  |             |            |
|     | through thoughts about pain before they contemplate      |     |  |             |            |
|     | childbirth, 8. to provide participants with increased    |     |  |             |            |
|     | opportunity to provide comment and contribute their      |     |  |             |            |
|     | thoughts when completing the survey.                     |     |  |             |            |
|     |  |     |  |             |            |

| 2 | During discussion with a potential participating site, it was         |  |
|---|---|--|
|   | highlighted that it would not be practical or feasible for the sites' |  |
|   | research team to identify those women whose risk status changes       |  |
|   | from low to high during the study period. The impact and effects of   |  |
|   | this on the study were considered. It has been decided that those     |  |
|   | women who are eligible will continue, as planned, to be invited to    |  |
|   | participate in the study, however, they will not be excluded if       |  |
|   | during the study period they later meet any of the exclusion          |  |
|   | criteria. Relevant wording changes have been made throughout the      |  |
|   | protocol to reflect this change, and additional questions included    |  |
|   | into the postnatal questionnaire to facilitate this amendment. (see   |  |
|   | Change 3 below).  |  |
| 2 | Detected was time in a second and the ill all and a sixty             |  |
| 3 | Postnatal questionnaire amendments will allow women whose risk        |  |
|   | status has changed to be identified and, the additional knowledge     |  |
|   | gained from these questions supports a sensitivity analysis.          |  |
|   | Relevant updates to PIS and Consent Form                              |  |
|   | Amendments to improve study efficiency: The time when women           |  |
|   | would be sent the postnatal questionnaire is 'approximately' four     |  |
|   | weeks postnatal the aim is to be nearer 3 weeks. This small timing    |  |
|   | adjustment will improve the efficiency of the management of the       |  |
|   | study and has the potential to support participant's recall of the    |  |

| <br><del>-</del> | <u></u>  |  |
|------------------|--|--|
|                  | recent childbirth event and potentially, very slightly reduces the   |  |
|                  | duration some participants are involved in the study. The estimated  |  |
|                  | due date (EDD) is important because it informs Trusts when they      |  |
|                  | should begin checking for when the woman gave birth, and for         |  |
|                  | when to send the postnatal email. It will also contribute to process |  |
|                  | efficiency and study management. The EDD is more accurate and        |  |
|                  | less susceptible to error than asking how many weeks pregnant a      |  |
|                  | participant is.  |  |
|                  |  |  |
|                  | Amendments to improve study efficiency: To reflect the change in     |  |
|                  | timing from when women will be sent the postnatal questionnaire,     |  |
|                  | to improve the efficiency of the management of the study, aid        |  |
|                  | participant memory recall and very slightly reduce the time          |  |
|                  | participants are involved in the study the PIS and follow-up email   |  |
|                  | communication has been amended. One question on the antenatal        |  |
|                  | questionnaire has been amended to ask for the participant's EDD      |  |
|                  | rather than how may weeks pregnant she is. This will support the     |  |
|                  | efficient management of the study and has the potential to           |  |
|                  | improve the accuracy of the data collected.                          |  |
|                  |  |  |
|                  | Small notice onto PIS requesting for it to be retained in maternity  |  |
|                  | notes. The same eligibility questions are presented to the potential |  |
|                  | participant but in a slightly different format for the potential     |  |
|                  |  |  |

|  | participant's convenience when taking part online. For the           |  |
|--|--|--|
|  | participant's convenience, when online, the presentation of the      |  |
|  | Consent Form has changed. The same questions are presented           |  |
|  | apart from question 6 as previously mentioned in Change 3 above.     |  |
|  |  |  |
|  | Participants will be asked to provide their postcode and the highest |  |
|  | academic level they have achieved. This is included to improve this  |  |
|  | study's findings about the social determinants of health.            |  |
|  |  |  |
|  | Antenatal questionnaire minor amendments: The order of the           |  |
|  | questions has been changed to avoid leading participants' through    |  |
|  | thoughts about pain before they contemplate labour and birth. To     |  |
|  | enable participants to provide further comment, contribute their     |  |
|  | thoughts, and to provide flexibility in the answer provision for     |  |
|  | multiple choice questions The antenatal questionnaire has been       |  |
|  | amended with a 'free text' box (Q8), and the option of 'Other -      |  |
|  | please specify ' has been included. These amendments will also       |  |
|  | provide additional qualitative data and allows flexibility for the   |  |
|  | participant to interpret include their own choice of answer to an    |  |
|  | otherwise predetermined criterion. One question on the antenatal     |  |
|  | questionnaire has been amended to more readily encompass the         |  |
|  | meaning of ethnicity   |  |
|  |  |  |

|   |  | Postnatal questionnaire minor amendments: Following assessment of the postnatal questionnaire it appeared unnecessary to limit women to completed weeks since birth. Furthermore, women may be, for example 3 weeks and 5 days postnatal in which case they are nearer 4 weeks. Rounding down of time could unnecessarily impact on analyses. At the end of the postnatal questionnaire participants are informed where they can see the results of this study once they have been prepared.   |                     |            |
|---|--|--|---------------------|------------|
| 2 | These amendments have been made to amend an error in the duration required to store research data and provide clarity around study management at participating NHS Trust level including: 1. Research data is stored, at participating NHS Trust level, in line with their local NHS research policy and to amend the time research data is stored by the sponsor in line the Sponsor's standard operating procedures (SOPs) and with Good Clinical Practice (GCP); 2. to provide clarity about adverse event reporting. | Protocol point 8.0 Data Collection and Data Management: The words 'Research data collected, managed, and stored at participating Trust level will be retained in line with each Trust's data management policy' have been added. This only affects research data and supports individual Trust's to store research data in line with their NHS Trust's policy. Furthermore, the responsibility for Bournemouth University, the sponsor, to protect and store research data has been amended in line with BUs SOPs and GCP. These amendments do not affect the NHS maternity services policy to store a woman's pregnancy records for 25 years. | Non-<br>substantial | 08/10/2020 |
|   |  | Protocol point 9.0 Risks and Safety: The words 'Should an adverse event be identified by a participating Trust this should be communicated to the Chief Investigator with urgency and as soon  |                     |            |

|   |   | The second like the second second settle to the second settle to the second sec |             |            |
|---|---|--|-------------|------------|
|   |   | as possible. An adverse event affecting a participant is one that is   |             |            |
|   |   | thought to be caused or likely to be caused as a result of   |             |            |
|   |   | participating in this study. An adverse event is one that is likely to   |             |            |
|   |   | affect a participant's safety, including the safety of their personally  |             |            |
|   |   | identifiable information, or their physical or mental integrity' have  |             |            |
|   |   | been added. This additional wording provides clarity to the Case   |             |            |
|   |   | Report Form which facilitates documentation around the very  |             |            |
|   |   | unlikely event of an adverse event.  |             |            |
|   |   |  |             |            |
|   |   | Protocol point 14.13 Appendix 13: Case Report Form has had the   |             |            |
|   |   | words added 'see section 9.0 Risks and Safety in the study protocol.   |             |            |
|   |   | These words have been added so that the user can find the  |             |            |
|   |   | relevant point in the protocol where they can clarify what sort of   |             |            |
|   |   | adverse event they should record. (For this study an adverse event   |             |            |
|   |   | is not anticipated and is very unlikely as it is an online survey and  |             |            |
|   |   | not a clinical trial of an investigational medicinal product).   |             |            |
|   |   |  |             |            |
|   |   | The Participant Information Sheet has been amended to reflect the  |             |            |
|   |   | amended duration that research data records will be stored. This   |             |            |
|   |   | information is now in line with BU's SOPs and GCP.   |             |            |
|   |   |  |             |            |
| 3 | The purpose of this amendment is to inform potential    | Social media advertisement supplied to participating hospitals. The  | Non-        | 10/02/2021 |
|   | participants about this study and aid recruitment. This | recruitment process is not affected by this advertisement. Potential   | substantial |            |
|   |   |  |             |            |

|   | amendment provides a social media advertisement about      |   | participants are informed via this advertisement to contact their |             |            |
|---|--|---|---|-------------|------------|
|   | The RETHINK Study which is additional to the existing      |   | midwife if they are interested in participating.                  |             |            |
|   | advertising resource already included in the study design. |   |   |             |            |
|   | This amendment is not a significant change and does not    |   |   |             |            |
|   | alter the design of this study. This social media advert   |   |   |             |            |
|   | may aid recruitment, but it does not alter the             |   |   |             |            |
|   | recruitment process because potential participants are     |   |   |             |            |
|   | not provided with details of how to access this study in   |   |   |             |            |
|   | this advert. As with the pre-existing advertising resource |   |   |             |            |
|   | already provided, potential participants are informed      |   |   |             |            |
|   | that they should speak to their midwife if they are        |   |   |             |            |
|   | interested in participating in The RETHINK Study.          |   |   |             |            |
|   |  |   |   |             |            |
| 4 | 1 & 2) These amendments are required to improve the        | 1 | To improve the efficiency of the accrual payments to NHS Trusts,  | Non-        | 01/03/2021 |
|   | efficiency of the accrual payments to NHS Trusts, the      |   | the question asking participants to provide the name of the       | substantial |            |
|   | question asking participants to provide the name of the    |   | hospital where they intend to give birth has been moved from the  |             |            |
|   | hospital where they intend to give birth has been moved    |   | antenatal email (including the one reminder) to the antenatal     |             |            |
|   | from the antenatal email to the antenatal questionnaire.   |   | questionnaire.  |             |            |
|   | Therefore, this change affects the antenatal               |   |   |             |            |
|   | questionnaire, the antenatal email, the antenatal email    |   |   |             |            |
|   | reminder, and the Participant Information Sheet. 3) The    |   |   |             |            |
|   | closing date for this study has been extended to 31st      |   |   |             |            |
|   | August 2021. This extension is required because the        |   |   |             |            |

| coronavirus pandemic delayed the start date for the study, and also site recruitment. This extension is required to ensure the necessary number of participants are recruited the study and maintain scientific integrity.  4) This amendment is required to add a new participating site to this study. |   |   |  |
|--|---|---|--|
|  | 2 | To ensure the participants are aware of what they can expect if they participate in this study the Participant Information Sheet, the antenatal email and antenatal reminder email have been brought in-line to reflect the above amendment.                                    |  |
|  | 3 | The closing date for the study has been extended to 31st August 2021 due to the effects of the coronavirus pandemic which delayed the start date and site recruitment. This extension is required to support participant recruitment and the scientific integrity of the study. |  |
|  | 4 | Trust would like to become a participating site for The RETHINK Study. This additional site will be undertaking the same activities as existing sites.  |  |

| 5 | Bournemouth University is the sponsor for this study. The    | 1 | Bournemouth University is the sponsor for this study. The person     | Non-        | 01/03/2021 |
|---|--|---|--|-------------|------------|
|   | person authorised on behalf of Bournemouth University        |   | authorised on behalf of Bournemouth University for this study has    | substantial |            |
|   | for this study has been moved address. This amendment        |   | been moved address. This amendment notifies of this address          |             |            |
|   | notifies of this address change.                             |   | change.  |             |            |
|   |  | 2 | Change in Sponsor address from Melbury House to Studland House,      |             |            |
|   |  |   | 12 Christchurch Road, Bournemouth, BH1 3NA so documents              |             |            |
|   |  |   | amended to reflect this.   |             |            |
|   |  | 3 | Change to Sponsor postal address.                                    |             |            |
| 6 | 1) This amendment is required to add new participating       |   | Sites that would like to be included as participating sites are: 1)  | Non-        | 01/04/2021 |
|   | sites to this study. 2) Relevant Principal Investigators for |   | Trust  | substantial |            |
|   | sites have been added. 3) The study protocol has been        |   | including their sites -  |             |            |
|   | amended to reflect that The RETHINK Study is open to all     |   | Hospital. 2)   |             |            |
|   | relevant Trusts across England. 4) One already approved      |   | including their sites - Hospital, and                                |             |            |
|   | eligibility criterion was missed off the online survey. This |   | Infirmary. 3)  |             |            |
|   | amendment corrects this. 5) Wording on the PIS has been      |   | Trust. 4) Trust including their                                      |             |            |
|   | slightly amended to separate the different usage of a        |   | site - Hospital. 5)  |             |            |
|   | participant's personally identifiable information and their  |   | Trust including their site - Hospital. These                         |             |            |
|   | postcode.  |   | additional sites will be undertaking the same activities as existing |             |            |
|   |  |   | sites.   |             |            |
|   |  |   |  |             |            |

| 1) will be the PI for  Trust. 2) will be the PI for  Trust. 3) will be the  PI Trust. 4)  will be the PI for  Trust. 5) is the PI for  Trust. 6)  will be the PI for the  Trust. 7) will be the PI for the  Trust. Trust. Trust.  The study protocol has been amended to reflect that The RETHINK   |
|---|
| Study is open to all relevant Trusts across England.  One of the approved eligibility criteria was missed off the online survey. Therefore, the online eligibility criteria have been corrected to include 25 to 33 weeks and 6 days pregnant.  Wording on the PIS has been changed from: 'This information is optional, but it can help us to learn more about what affects the group of women who take part in this research'. To: 'Postcode information is optional, but it can help us to learn more about what affects the group of women who take part in this research'. |

| 7 | 1) The postcode for the Chief Investigator, two of the Key | The postcode for the Chief Investigator, two of the Key Protocol   | Substantial | 20/04/2021 |
|---|--|--|-------------|------------|
|   | Protocol Contributors and the person who is designated     | Contributors and the person who is designated on the PIS to handle |             |            |
|   | on the PIS to handle study complaints on behalf of the     | study complaints on behalf of the study Sponsor has been           |             |            |
|   | study Sponsor has been corrected (The approved             | corrected (The approved postcode is allocated to Bournemouth       |             |            |
|   | postcode is allocated to Bournemouth University, but it is | University, but it is not right for those study team members       |             |            |
|   | not right for those study team members mentioned here      | mentioned here and therefore corrected). The postcode has been     |             |            |
|   | and therefore corrected). This affects the study protocol  | amended from BH1 3LT to BH1 3NA. This affects the protocol and     |             |            |
|   | and PIS. 2) Three different pathway options have been      | PIS.   |             |            |
|   | added to improve the recruitment of participants to this   |  |             |            |
|   | study. This affects the study protocol, the PIS, the Case  |  |             |            |
|   | Report Form, and necessitates a new social media           |  |             |            |
|   | advertisement. 3) The closing date for data collection was |  |             |            |
|   | incorrectly amended to 31st August 2021 it should have     |  |             |            |
|   | read closing date for recruitment is 31st August and a     |  |             |            |
|   | closing date for data collection 31st January 2022 and     |  |             |            |
|   | anticipated date for publication June 2022. This           |  |             |            |
|   | amendment corrects this error and takes account of the     |  |             |            |
|   | delays incurred as a result of the coronavirus pandemic    |  |             |            |
|   | and supports those sites who would like to participate     |  |             |            |
|   | and who are now in a position to do so. This affects the   |  |             |            |
|   | study protocol. 4) Since the study area has been widened   |  |             |            |
|   | to include relevant NHS Trusts in England it has now       |  |             |            |

| become necessary to accommodate those NHS Trusts         |   |  |
|--|---|--|
| who use digital/electronic records only. Therefore point |   |  |
| 7.4.3 in the study protocol has been amended to allow    |   |  |
| NHS Trusts to digitally upload the PIS to a woman's      |   |  |
| pregnancy record.  |   |  |
|  |   |  |
|  | As mentioned in 'Change 1' above, the postcode has been amended     |  |
|  | on the PIS for the person who is designated to handle study         |  |
|  | complaints on behalf of the study Sponsor and the Chief             |  |
|  | Investigator. The postcode has been amended from BH1 3LT to BH1     |  |
|  | 3NA.  |  |
|  |   |  |
|  | As mentioned in 'Change 1' above, the postcode has been amended     |  |
|  | in the study protocol for the Chief Investigator, two members of    |  |
|  | the research team and the person designated on the PIS to handle    |  |
|  | study complaints on behalf of the study Sponsor. The postcode has   |  |
|  | been amended from BH1 3LT to BH1 3NA.                               |  |
|  |   |  |
|  | To improve the recruitment of participants to this study three      |  |
|  | additional pathways have been added. Participating Trusts can       |  |
|  | decide if they wish to employ 1, 2, 3 or all 4 recruitment pathways |  |
|  | in their recruitment strategy. The recruitment pathways are:        |  |
|  | Pathway 1) Remains the same as already specified in the protocol.   |  |

| Pathway 2) Makes clear that appropriate participating Trust staff members can screen, receive referrals and contact potential participants directly to introduce them to the study. Pathway 3) Allows for an appropriate staff member to complete the online antenatal and postnatal questionnaires with the participant. Pathway 4) Allows for participants to be recruited directly from Trust's social media pages. |
|--|
| Amendments to the recruitment strategy have been detailed in the protocol. All four pathways have been described. Participating  Trusts can decide if they wish to employ 1, 2, 3 or all 4 recruitment pathways in their recruitment strategy. Where relevant changes have be made throughout the protocol to accommodate these new recruitment pathways.  |
| Wording in the PIS has been adjusted or added to accommodate the amendment to the recruitment strategy   |
| A social media advertisement has been provided that supports participants being recruited directly from the advertisement.   |

|   |   | The Case Report Form has been slightly amended to ensure that if a woman or baby sadly dies then no further study correspondence will be sent whichever recruitment pathway the woman following.  The closing date for data collection has been amended to 31st January 2022. This amendment has been necessary due to effects of the coronavirus pandemic. |                     |            |
|---|---|---|---------------------|------------|
|   |   | Since the study area has been widened to include relevant NHS  Trusts in England it has now become necessary to accommodate those NHS Trusts who use digital/electronic records only. Therefore point 7.4.3 in the study protocol has been amended to allow NHS  Trusts to digitally upload the PIS to a woman's pregnancy record.                          |                     |            |
| 8 | 1) This amendment is required to add new participating sites to this study. 2) Relevant Principal Investigators for sites have been added, and one PI for an existing site has been changed. 3) The inclusion criteria specifying eligible gestation for participation in this study has been clarified. The relevant documents have been amended to include this clarification. 4) The PIS has been removed from the social media advertisement which calls for new participants. This is to ensure that it is only ever the | Trust,  Hospital. 2) The  Trust, site Hospital. 3)  Trust. 4)  Trust. 5)  Hospital and  Hospital. 6)  Hospital.   | Non-<br>substantial | 11/05/2021 |

| current version of the PIS which is available to potential participants. 5) The process for sites checking a participant and their baby's records postnatal has been clarified to prevent unnecessary checking. 6) A QR code has been added to the recruiting advertising poster for participants' convenience. |   |  |
|---|---|--|
|   | 1) Trust the PI is  Trust the PI is |  |
|   | Inclusion criteria specifies 33 weeks gestation as the maximum gestation women can take part in this study. This has now been clarified to ensure participants are included up to 33 weeks and 6 days. Where applicable this clarification has been reflected in the  |  |

| study protocol and other relevant documents (see Change 4 and 5        |
|--|
| below).  |
|  |
| The study protocol has been amended to clarify and ensure              |
| participants are included up to 33 weeks and 6 days as detailed in     |
| 'Change 3' above.  |
| The PIS, the eligibility criteria, the posters advertising this study, |
| and the social media advertisements have been amended to reflect       |
| the clarification in the maximum gestation for when women can          |
| participate in this study i.e. 33 weeks and 6 days, as per 'Change 3'  |
| above.   |
|  |
| To prevent the CI from sending any postnatal study communication       |
| inappropriately the checking process which sites should undertake      |
| has been specified in a flowchart.                                     |
|  |
| To prevent the CI from sending any postnatal study communication       |
| inappropriately the checking process which sites should undertake      |
| has been specified in a flowchart (Appendix 14.12.1) and minor         |
| wording clarifications have been made in the protocol and              |
| recruitment pathway flowcharts where relevant                          |
|  |

|   |   | To prevent the CI from sending any postnatal study communication       |             |            |
|---|---|--|-------------|------------|
|   |   |  |             |            |
|   |   | inappropriately the checking process which sites should undertake      |             |            |
|   |   | has been specified in a flowchart. Wording in the CRF has been         |             |            |
|   |   | included as a reminder to sites to ensure this process is adhered to.  |             |            |
|   |   |  |             |            |
|   |   | Removed the PIS from the social media advertisement. This is to        |             |            |
|   |   | ensure the correct version is always accessible to the participant. In |             |            |
|   |   | the social media advertisement, the participant will be advised to     |             |            |
|   |   | read the PIS before they agree to take part in the study.              |             |            |
|   |   |  |             |            |
|   |   | A QR code has been added to the recruiting advertising poster for      |             |            |
|   |   | participants' convenience.   |             |            |
|   |   |  |             |            |
| 9 | 1) This amendment is required to add a new participating      | 1) Trust - site  | Non-        | 27/07/2021 |
|   | site to the study, and to add a location for research         | is Hospital 2) The addition of the location                            | substantial |            |
|   | activities at an existing participating site. 2) The relevant | Hospital to the already participating site                             |             |            |
|   | local collaborator for the new site has been added. 3)        | Trust  |             |            |
|   | This study is open to all NHS Trusts in England. Some sites   |  |             |            |
|   | do not use EDGE software but use other NHS approved           |  |             |            |
|   | Local Portfolio Management Systems (LPMS). Wording            |  |             |            |
|   | has been amended in the study protocol to reflect this. 4)    |  |             |            |
|   | A participating site has requested that the contact details   |  |             |            |
|   | of their research team be added to study advertising          |  |             |            |

| materials. This amendment meets this request. The        |  |  |
|--|--|--|
| appropriate document version numbers have also been      |  |  |
| added to the relevant social media advertisements and to |  |  |
| the Recruiting RETHINK poster. 5) Due to the pressures   |  |  |
| and the negative impact that the coronavirus pandemic    |  |  |
| has had on many studies conducted in the NHS the         |  |  |
| closing date for recruiting new participants is now      |  |  |
| amended to 31st January 2022 and the closing date for    |  |  |
| all research activities at sites is 30th June 2022.      |  |  |
|  |  |  |
|  | The named local collaborator for                                     |  |
|  | Trust is   |  |
|  | This study is open to all NHS Trusts in England. Some sites do not   |  |
|  | use EDGE software but use other secure Local Portfolio               |  |
|  | Management Systems (LPMS) e.g. ReDA. The wording in the study        |  |
|  | protocol has been amended to reflect this change.                    |  |
|  |  |  |
|  | A participating site has requested that the contact details of their |  |
|  | research team be added to study advertising materials. This          |  |
|  | amendment meets this request. The appropriate document version       |  |
|  | numbers have also been added to the relevant social media            |  |
|  | advertisements and to the Recruiting RETHINK poster.                 |  |
|  |  |  |

| Two potential answer options were missed off, in error, from           |
|--|
| question 9 and question 10 on the online postnatal questionnaire.      |
| These are already both multiple answer questions. This                 |
| amendment rectifies this oversight. The potential answer options       |
| now included are: Question 9 - 1) Hypnosis including hypnobirthing     |
| Question 10 - 1) Gas and air (also known as Entonox, or 50% oxygen     |
| and 50% nitrous oxide) 2) Hypnosis including hypnobirthing             |
|  |
| The effects of the coronavirus pandemic delayed the start date of      |
| The RETHINK Study. Unfortunately, the pandemic continues to            |
| negatively impact on NHS sites with some struggling with capacity      |
| to take on new studies because staff are supporting vaccine hubs.      |
| Furthermore, there are general pressures related to the pandemic       |
| which are affecting the amount of time research staff have to          |
| recruit participants and manage this study at site level. Although     |
| the number of recruited participants is steadily increasing the        |
| target sample will not be reached by the current closing date and      |
| the scientific integrity of this study is in jeopardy. Therefore, the  |
| closing date for recruiting new participants is now set to 31st        |
| January 2022 and the closing date for all research activities at sites |
| is 30th June 2022.   |
|  |

| 10 | This amendment is required to: 1) Add new participating      | 1) Hospital 2)  | Non-        | 10/09/2021 |
|----|--|---|-------------|------------|
|    | sites to the study. 2) To add the relevant lead staff at the | Trust 3)  | substantial |            |
|    | participating sites. 3) To update the Schedule of Events to  | Trust 4)  |             |            |
|    | bring it in-line with the changes previously made to the     | Trust 5) Hospitals NHS 6)                                       |             |            |
|    | participant recruitment pathways.                            | Trust 7)  |             |            |
|    |  | Trust   |             |            |
|    |  | 1) Local  |             |            |
|    |  | Collaborator 2)   |             |            |
|    |  | Trust - PI 3)   |             |            |
|    |  | Trust - PI 4  |             |            |
|    |  | Trust - PI 5)   |             |            |
|    |  | Hospitals NHS - PI  |             |            |
|    |  | Trust - PI 7)   |             |            |
|    |  | Trust - PI  |             |            |
|    |  | Due to additional recruitment pathways being added to the study |             |            |
|    |  | the Schedule of Events has now been amended to incorporate      |             |            |
|    |  | these previous changes.   |             |            |
| 11 | This amendment is required to: 1) Amend the Principal        | 1) Trust have had a change of PI                                | Non-        | 28/09/2021 |
|    | Investigator at a one of the participating sites because     | from  | substantial |            |
|    |  | Consultant Obstetrician   |             |            |
|    |  |   |             |            |

|    | the person in post has changed. 2) Add new participating   |   |                     |            |
|----|--|---|---------------------|------------|
|    | sites to the study   |   |                     |            |
|    |  | 1) Trust  |                     |            |
| 12 | 1. Trust formally acquired Hospital, Hospital and Infirmary services which became Hospitals.  Trust is already a site participating in The RETHINK study. The name of the group has now formally changed to the Trust. This amendment reflects this change. 2. Infirmary services now part of the Trust (see amendment 1) was not included as a location for research activities at this | Trust formally acquired  Hospital,  Infirmary services which became  Trust is already a site participating in  The RETHINK study. The name of the group has now formally  changed to the  amendment reflects this change. | Non-<br>substantial | 30/09/2021 |
|    | existing participating site. This amendment corrects this omission.  | services now part of the  Trust (see amendment 1) was not included as a location for research activities at this existing participating site. This amendment corrects this omission.                                      |                     |            |

| 13 | 1) Add two new participating sites to the study.             | 1)                   | Trust. 2)                                   |             | 09/11/2021 |
|----|--|----------------------|---|-------------|------------|
|    |  |                      | Trust.                                      |             |            |
|    |  | 1) The PI for        | Trust is                                    |             |            |
|    |  | . 2) T               | he PI for                                   |             |            |
|    |  | Trust is             |   |             |            |
| 14 | 1). The PI at the  | The PI at the        | Trust site is                               | Non-        | 19/01/2022 |
|    | Trust site is leaving the post and replacement has been      | leaving the post and | d replacement has been made. This amendment | substantial |            |
|    | made. This amendment reflects this change in Pl. 2). This    | reflects this change | in PI.                                      |             |            |
|    | is a survey study. Participants self-select and are required |                      |   |             |            |
|    | to complete two online questionnaires and reply by email     |                      |   |             |            |
|    | to the CI for this study supplying their personal            |                      |   |             |            |
|    | identifiable information so that sites can collect their     |                      |   |             |            |
|    | labour and birth details. To date participants have been     |                      |   |             |            |
|    | treated as anonymous and dropouts from this study if         |                      |   |             |            |
|    | they did not provide their identifiable information. The     |                      |   |             |            |
|    | participant consent form, the participant information        |                      |   |             |            |
|    | sheet (PIS), the means that participants can withdraw        |                      |   |             |            |
|    | from the study, and Section 6 on the antenatal online        |                      |   |             |            |
|    | questionnaire do not inform the participants that they       |                      |   |             |            |
|    | will be considered as dropouts or removed for the            |                      |   |             |            |
|    | subsequent parts of the study if they do not supply their    |                      |   |             |            |

personal identifiable information, participants are also informed that their email address will be used to send them a link to the online postnatal questionnaire. 3 points of reference (personal identifiable information) are required to retrieve a participant's labour and birth outcomes, and this will remain in place, if no personal identifiable information is supplied then no labour and birth outcomes can be collected. The protocol only will be adjusted to allow sites to use the unique email address, and the estimated date the participant can expect to birth their baby which participants provide on the online questionnaire, to check when a participant's baby has been born and inform the CI so that the CI will know when is the correct time to email the link to the online link to the postnatal questionnaire, thus allowing the participant to remain in the study should they wish. Participants will continue to have the same options available to them to withdraw from the study, including not responding to the emails and accessing the online questionnaire, and still have the opportunity to provide their ongoing consent to continue at the start of the postnatal questionnaire should they so wish.

This is a survey study. Participants self-select and are required to complete two online questionnaires and reply by email to the CI for this study supplying their personal identifiable information so that sites can collect their labour and birth details. To date participants have been treated as anonymous and dropouts from this study if they did not provide their identifiable information. The participant consent form, the participant information sheet (PIS), the means that participants can withdraw from the study, and Section 6 on the antenatal online questionnaire do not inform the participants that they will be considered as dropouts or removed for the subsequent parts of the study if they do not supply their personal identifiable information, participants are also informed that their email address will be used to send them a link to the online postnatal questionnaire. 3 points of reference (personal identifiable information) are required to retrieve a participant's labour and birth outcomes, and this will remain in place, if no personal identifiable information is supplied then no labour and birth outcomes can be collected. The protocol only will be adjusted to allow sites to use the unique email address, and the estimated date the participant can expect to birth their baby which participants provide on the online questionnaire, to check when a participant's baby has been born and inform the CI so that the CI will know when

|  | is the correct time to email the link to the online link to the postnatal questionnaire, thus allowing the participant to remain in the study should they wish. Participants will continue to have the same options available to them to withdraw from the study, including not responding to the emails and accessing the online questionnaire, and still have the opportunity to provide their |  |
|--|--|--|
|  |  |  |

| Appendix 6 The RETHINK study: study protocol  |
|---|
| 1.0 TITLE   |
| 1.1 The RETHINK Study – Long Title  |
| The RETHINK Study – A study to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of |
| labour  |
|   |
| 1.2 The RETHINK Study – Short Title   |
| RETHINK – Can we reduce hospital admission in latent labour?  |
|   |
| 1.3 IRAS Number:  |
| T.5 INAN INUITING   |

**IRAS Number:** 270583

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## 3.0 Trial Overview

## 3.1 Key Contacts

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|                           | Training Programme                     |
|                           | Dorset County Hospital NHS Foundation  |
|                           | Trust                                  |
|                           |  |
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# 3.2 Study Summary

Table 2 Study Summary

| Study Summary                         |  |  |
|---------------------------------------|--|--|
| IRAS Number                           | 270583   |  |
| Date of Submission/Registration       | 10 <sup>th</sup> March 2020  |  |
| Funders                               | Bournemouth University   |  |
|                                       | Dorset County Hospital NHS Foundation Trust  |  |
| Chief Investigator                    | Vanessa Bartholomew  |  |
| Full Study Title                      | The RETHINK Study - A study to determine if pregnant women who pain catastrophise are more likely to attend hospital during the latent phase of labour |  |
| Short Public Title                    | RETHINK - Can we reduce hospital admission in latent labour?   |  |
| Country and Local Area of Recruitment | England  |  |
| Issue Studied                         | Latent labour, pain catastrophising, timing of admission to hospital, birth outcomes   |  |
| Inclusion Criteria                    | Healthy primigravid women who are experiencing an uncomplicated singleton pregnancy, and who are planning a hospital birth.                            |  |

- •Women aged 18 to ≤40 at the time of study.
- •Able to understand and read English.
- •Antenatal women who are between 25 and 33 weeks and 6 days gestation.
- •Internet access and email address for study correspondence.
- Pregnant women who are under
   ongoing care from an obstetrician during the study period.
- •Women who will be aged 41 years or over at the time of childbirth.
- •Women with a current or pre-existing mental health condition requiring current medication and/or care by perinatal mental health team i.e. specialist obstetrician, specialist midwife and/or local mental health services provision or community mental health team.
- Pregnant women already participating in a different study that is providing support with pain management or a labour support intervention of any kind.
   This includes the latent, active, second and third phases of labour.

**Exclusion Criteria** 

| Study Type   | A quantitative study with data being    |
|--|---|
|  | collected from participants in          |
|  | questionnaire format, and their labour  |
|  | and birth outcomes.                     |
| Closing date for participant recruitment   | 31 <sup>st</sup> January 2022           |
| and the same services are same services are same services and the same services are sa |   |
| Anticipated Period for Data Collection   | May 2020 to 30 <sup>th</sup> June 2022  |
| Anticipated Date for Publication   | October 2022                            |
| Target Sample Size   | Aiming to recruit 768 to achieve final  |
|  | target sample of 384 women completing   |
|  | all phases of the study.                |
| Primary Aims   | To assess the prevalence of pain        |
|  | catastrophising among primigravid       |
|  | women who are experiencing an           |
|  | uncomplicated pregnancy.                |
|  | To determine how pain catastrophising   |
|  | affects the timing of women's admission |
|  | to hospital when in labour, and         |
|  | subsequently their birth outcomes.      |

#### 4.0 ABSTRACT

### 4.1 Background

Deciding the optimum time to move from home to hospital when in labour is important to prevent a cascade of costly interventions which statistically correlate to mode of birth. The fear of pain is one of the most common reasons women fear childbirth and points to pain as a significant factor for early hospital admission. Studies have found that up to 80% of nulliparous women are admitted to hospital when not in the active phase of labour and many women request pain relief during this latent phase of labour (cervical dilatation of 3cm-6cm).

Some women have exaggerated negative feelings toward an actual or an anticipated painful event known as pain catastrophising. In the childbirth setting pain catastrophising is a strong predictor of childbirth pain, and the need for epidural analgesia in labour.

In a recent study the prevalence of pain catastrophising in a non-pregnant population of women of reproductive age was high, providing evidence of this phenomenon occurring before pregnancy. Studies are now required to consider the prevalence of pain catastrophising, in pregnant women, and how this may affect the timing of admission to hospital when in labour, and subsequent birth outcomes.

Using the pain catastrophising scale as a predictive tool, this study aims to ascertain the prevalence of pain catastrophising in primigravid women experiencing an uncomplicated pregnancy, and to determine if this is associated with admission to hospital during the latent phase of labour and subsequently poorer birth outcomes. To date, there has been limited predictive utility demonstrated by other assessment tools, and new models designed to support women in the latent phase of labour have not had clear impact on specified birth outcomes.

### 4.2 Study Design

This is a quasi-experimental study. This means there will be a comparison made between two groups to estimate the possible impact that pain catastrophising has on the timing of admission to hospital when in labour and birth outcomes. In this study the quasi-experimental aspect will occur during analysis of the groups only. The groups will be divided according to those who pain catastrophise and those who do not. There will be no control group and no randomisation. This is consistent with this methodological approach.

Pregnant women who are eligible to participate will be invited into this study by appropriate staff (midwife or other appropriately trained healthcare worker) at each participating NHS Trust (see point 7.4.3 Recruitment for more details). Data collection will be made on three separate occasions:

- first, by participants completing an online questionnaire when they are between 25 and 33 weeks and 6 days pregnant (point 14.4 Appendix 4)
- second, routine birth outcome data will be collected by research staff at each individual NHS Trust, and
- third, at approximately three weeks postnatal participants will be asked to complete a second online questionnaire (point 14.9 Appendix 9).

Quantitative data will be analysed using the statistical software package SPSS (v.26) software. When completing the questionnaires women are invited to provide written comment in response to relevant questions. This qualitative data will be coded and analysed thematically.

### 4.3 Discussion

Identifying whether pain catastrophising is a risk factor for admission in the latent phase of labour and subsequent predetermined birth outcomes will enable early support for women. The intention is to use this information, in a future study, to identify women who would benefit from a targeted support intervention.

#### 5.0 BACKGROUND

#### 5.1 Why the Latent Phase

Over recent years, and particularly in many of the world's high-income countries, research and clinical practice has turned attention to the latent phase of labour. The latent phase is clinically relevant because it is a sensitive stage that might affect birth as a whole (Wuitchik et al. 1989). However, as yet, more work is needed to understand how women can be effectively supported at this time (Cheyne et al. 2006; Hundley et al. 2017; Kobayashi et al. 2017).

The World Health Organization (WHO 2018a) recommends using the following definition for the latent phase of labour:

"The latent phase is a period of time characterised by painful uterine contractions and variable changes of the cervix, including some degree of effacement and slower progression of dilatation up to 5cm for first and subsequent labours".

However, there is a lack of consensus in definition, and practice, of when early labour finishes and the active phase begins, varying from cervical dilatation of 3 centimetres (cm) to 6cm (ACOG 2014; Hanley et al. 2016; NICE 2014; Zhang et al. 2010). Common practice in the United Kingdom is that a cervical dilatation of 4cm denotes the start of active labour.

Cervical dilatation remains the predominant attribute for defining both the latent and active phases of labour closely followed by painful uterine contractions. Less likely to be included are other physiological symptoms such as bloody show, fluid loss and gastro-intestinal symptoms (Hanley et al. 2016). Furthermore, omitted from definition and description of the latent phase is a standardised timeframe for the expected duration. This is because a standard duration has not yet been established and can vary widely between each woman (WHO 2018a).

The lack of clarity around definition of the latent phase is likely to be attributed to the varying needs of women, lack of knowledge about the relationship between women's physiology and psychology and the subsequent effects on the progress of labour, the different ways women present in labour, influences of the maturing fetus (Liao 2005), and the unlikely need for intervention in healthy pregnant women who are at low-risk of complications (WHO 2018a). These factors are all balanced with expert opinion of the most likely safe point for mother and baby to commence one-to-one skilled labour care.

From a recent systematic review of the literature, and a small study of health professionals' views, clarity around the latent phase is required to ensure woman-centred, evidence-based care is provided (Hanley et al. 2016; Hundley et al. 2017). This is brought into sharper focus by Zhang et al. (2010) and more recently the WHO (2018a) guidelines, which suggest varying definitions could be contributing to rising rates of intervention. For uniformity of data this study will use a cervical dilatation of 4cm as a marker for the end of the latent phase and the start of the active phase. This reflects current guidance from the National Institute for Health and Care Excellence (2014).

During labour the decision on the ideal time to move from home to hospital is important to prevent a cascade of costly interventions (Holmes et al. 2001; Cheng et al. 2010, Lundgren et al. 2013; Janssen and Weissinger 2014; Janssen et al. 2017). However, reliably identifying the optimum time to move from home to hospital is a multifaceted issue involving the needs of the woman, the influence of birth partners, and guidance set at world, national and local NHS Trust levels which are subsequently translated into clinical practice. All these factors are also shaped by sociocultural, economic, and political influences (WHO 2018a).

Evidence and current professional guidelines are clear: it is safe, judicious, and cost effective to advise women to stay at home until active labour begins (Bailit et al. 2005; Edmonds et al. 2018; Kauffman et al. 2016; NICE 2017; Tilden et al. 2015). What is not

clear is how women are best supported to make this optimal decision (Edmonds et al. 2018), and how to protect and promote their psychological safety and self-efficacy during the latent phase (Carlsson et al. 2009; Carlsson 2016).

In England, policy puts women firmly at the centre of decision-making. National Health Service (NHS) strategies continue to move towards greater woman-centred care, where every woman should have access to information to empower her to make decisions about her own care, and professional support befitting her and her baby's individual needs and circumstances (NHS England 2016). Decisions made during labour contribute to birth outcomes (Johnson and Slade 2003; Van den Bussche et al. 2007; Veringa et al. 2011; Dehghani et al. 2014).

Pregnant women often have difficulties identifying the onset of active labour (Beebe and Humphreys 2006; Carlsson et al. 2009; Cheyne et al. 2007; Dixon et al. 2013) and seek out the support given in hospital. Studies have found that up to 80% of nulliparous women present to hospital for admission during the latent phase of labour (Bohra et al. 2003).

Advising women to stay at home until active labour begins, providing they are healthy and at low risk of complications, can appear to be a professional reaction in favour of organisational goals. It is not woman-centred and does not meet the need for support during the latent phase which is a time that is complex, uncertain, and stressful (Nolan and Smith 2010; Eri et al. 2010; Eri et al. 2014). Turning women away from hospital admission before active labour can cause fear and anxiety (Vik et al. 2016; Dixon et al. 2013; Low and Moffat 2006, Barnett et al. 2008, Cheyne et al. 2007, Carlsson et al. 2009) and; can create a 'revolving door' effect with some women repeatedly presenting to hospital seeking admission (Cheyne et al. 2008) and professional support.

Many women seek professional care during the latent phase due to contraction pain and lack of confidence in their ability to cope with ongoing labour pain, and anxiety (Barnett et al. 2008; Carlsson et al. 2009; Cheyne et al. 2007; Kobayashi et al. 2017). Women are being offered a variety of methods to manage their pain with little

understanding of the holistic nature of pain-related fear, and how this is affecting labour choices (Eri et al. 2010; Eri et al. 2014). High levels of fear of pain and helplessness during pregnancy have been related to high levels of stress during the latent phase of labour (Wuitchik et al. 1989). High levels of stress during labour have been shown to delay the progress of labour (Adams et al. 2012; Alehagen et al. 2005). 5.2 Why the Need for Specificity

Very little is known about which specific characteristics of women's fear and anxiety contribute to the escalating risk of labour interventions, their need for pain relief during the latent and active phases of labour, emergency caesarean sections, and women's choice for elective caesarean section (Saisto et al. 2001; Johnson and Slade 2003, Veringa et al. 2011; Van den Bussche et al. 2007; Dehghani et al. 2014). For this reason, this study will specifically consider the issue of pain catastrophising.

# 5.3 Pain Catastrophising

Pain is a subjective experience shaped by physiological, psychological, social, and cultural influences mediated by previous pain experiences (Linton and Shaw 2011; Noel et al. 2015). Consequently, in the context of childbirth, a woman's previous pain experiences and her cognitions about pain may adversely affect how she interprets her labour pain. In addition, how she remembers and reflects upon it postnatal, will affect her behaviour and attitude towards pain experiences in the future.

Pain catastrophising can be defined as "an exaggerated negative mental set brought to bear during actual or anticipated painful experience" (Sullivan et al. 2001, p.4).

To a degree fear of pain is natural and understandable. However, pain catastrophising is a cognitive distortion. It is conceptualised as involving helplessness, rumination, and amplification of pain (Abramson et al. 1989; Keefe et al. 2004), whereby people expect the worst in relation to a particular experience of pain (Sharpe and Johnson 2012). There has been some debate about the uniqueness of the construct of pain catastrophising over and above negative affectivity, or other negative cognitive processes around pain such as fear of pain. Furthermore, there is debate whether pain

catastrophising is a unique, cognitive mind-set that can be assessed through recall of thoughts and feelings related to past painful experiences, and prior to exposure to a painful episode and therefore a dispositional 'trait' or, whether it is a reaction assessed during or immediately after a painful episode and therefore a situational 'state' (Leung 2012). Nonetheless, substantial empirical evidence around acute (Leung 2012) and chronic pain highlight pain catastrophising as a consistent predictor of almost all the significant pain-related outcomes including intensity, disability and psychological functioning (Leung 2012; Domenech et al. 2014; Angst et al. 2014; Wertli et al. 2014) and it has demonstrated its predictive utility in birth outcomes in a pregnant population (Dheghani et al. 2014; Flink et al. 2009).

The few studies directly investigating catastrophising in relation to childbirth suggest that pain catastrophising is not only of importance for the anticipation of childbirth pain, but also associated with fear of being overwhelmed by pain (Van den Bussche et al. 2007), preferred mode of birth (Dehghani et al. 2014), the experience of pain intensity during delivery, and poorer physical recovery following childbirth (Flink et al. 2009). Pain related fear has been shown to be a factor in women avoiding labour altogether with 40% of European pregnant women who request an elective caesarean section cite fear of pain as the reason (Sjogren and Thomassen 1997; Ryding 1998; Geissbuehler and Eberhard 2002). Furthermore, in a study by Deghani et al. (2014) they found pain catastrophising mediated the relationship between fear of pain and preference for elective caesarean section.

In the childbirth setting catastrophising is a strong predictor of childbirth pain (Flink et al. 2009) and the need for epidural analgesia during labour (Veringa et al. 2011). A key factor that regulates the perception of pain during childbirth is women's own beliefs about their ability to cope or control pain (Nettelbladt et al. 1976). In a study by Veringa et al. (2011) they found that those women who remain at home until active labour commences are those who feel more confident, have higher self-efficacy, reflect more positively on their labour and are less likely to have interventions during labour than those who are anxious, fearful and present to hospital before active labour commences. Furthermore, out of those women who requested pain relief 73 percent

(%) of them did so in the latent phase of labour. They concluded catastrophising appeared to have significant influence on women's cognitions and pain-coping behaviour, even in low-risk pregnant women (Veringa et al. 2011). These findings highlight possible risk factors for hospital admission during the latent phase and could indicate that early intervention for these women might reduce their pain-related fear and might be effective to reduce the admissions to hospital during the latent phase and improve their birth outcomes.

The method for managing women's labour pain is long established in literature and in practice. However, management is usually characterised by a paternalistic, medical-model of care. Women are being offered various non-pharmacological and pharmacological methods to help them cope with their pain, with little understanding of the holistic, multifaceted nature of pain-related fear.

The suggestion is that if specific psychological factors such as pain catastrophising can be reliably identified as a risk factor, and an independent predictor for labour and birth outcomes, then through antenatal psychological screening and a woman-centred, latent phase support intervention, normal birth and women's wellbeing can be promoted (Johnson and Slade 2003, Veringa et al. 2007; Dehghani 2014; Vermelis et al. 2010; Ferber et al. 2005).

### 5.4 Tocophobia and Fear of Childbirth

Pain-related fear is one of the most common reasons women fear childbirth (Wuitchik et al. 1989, Guzkowska 2014). Empirical evidence is conflicting with respect to whether fear of pain and fear of childbirth are independent variables contributing to birth outcomes or dependent variables arising from these outcomes. This study will consider those women who have more severe pain-related fear (i.e. pain catastrophising) and who are likely to fear giving birth as a result. Therefore, it will consider two constructs pain catastrophising and fear of childbirth.

Tocophobia is a distressing pathological condition, defined as an 'unreasoning dread of childbirth' (Hofberg and Brockington 2000, p.83) leading women to sometimes avoid pregnancy, and childbirth altogether (Hofberg and Brockington 2000). Although, there is discordance across the globe regarding the prevalence of clinically relevant fear of childbirth, in a recent meta-analysis by O'Connell et al. (2017) they estimated the pooled incidence of tocophobia as 14% worldwide. Although this is a figure based on significantly heterogeneous data it is a figure that appears to be slowly increasing (O'Connell et al. 2017). Evidence also suggests the prevalence is higher in nulliparous women than multiparous women (O'Connell et al. 2017).

The last thirty years has seen growing interest around the fear of childbirth. However, ambiguity exists in the literature, between tocophobia and fear of childbirth. This is perpetuated by the lack of consensus around definition and no standard criteria for classification. The demarcations between no fear, mild, moderate, and severe fear and tocophobia are very unclear.

Comparison studies show the prevalence of the fear of childbirth varies widely (Areskog et al. 1981; Nieminen et al. 2009; Haines et al. 2010; Johnson and Slade 2003; Waldenstrom et al. 2006). The incidence of the fear of childbirth appears to depend on several factors such as cultural context, definition, and the measurement tools used to determine the condition (Raisanen et al. 2014; Nilsson et al. 2018). These issues are also present in tocophobia (O'Connell et al. 2017).

Fear of childbirth is important considering of the number of people experiencing it, and is important when considering the sequelae of longer labour durations (Adams et al. 2012; Lederman et al. 1977; Lederman et al. 1978; Lederman et al. 1985) such as higher rates of birth interventions and adverse effects in the neonate (Crandon 1978; Istvan 1986; Standley et al. 1979), caesarean births (Areskog et al. 1983; Areskog et al. 1984; Saisto & Halmesmäki 2003), and the interrelationship between women's assessment of their birth experience and mental health postnatal (Ballard et al. 1995; Räisänen et al. 2013; Soderquist et al. 2009; Wijma et al. 1997). Again, findings vary

between studies with some results demonstrating no relationship between fear of childbirth and adverse sequelae (Johnson and Slade 2003).

Several factors may account for inconsistencies. For example, there has been no standard in the timing of measurement of women's fear. Moreover, some studies have involved flawed methodological designs, in particular inadequate measurement tools, insufficient sample sizes, and failure to account for, or control for confounding variables, including a broad conceptualisation of anxiety without specificity (Johnson and Slade 2003). Without specificity the various characteristics of anxiety, and how each one interrelates with obstetric outcomes, cannot be identified. Therefore, this study focuses specifically on pain catastrophising, an identifiable negative thought process, in the context of childbirth where pain is a major feature. Fear of childbirth will also be analysed because it is hypothesised that those women who have heightened anxiety around pain are likely to report childbirth fear. Therefore, pain catastrophising may moderate fear of childbirth.

## 6.0 STUDY AIM AND OBJECTIVES

#### 6.1 Study Aim

The aim of this study is to assess the prevalence of pain catastrophising among primigravid women who are experiencing an uncomplicated pregnancy, and to determine how pain catastrophising affects the timing of women's admission to hospital when in labour, and subsequently their birth outcomes.

# 6.2 Objectives

The following objectives pertain to the target sample of women in this study and guide the activities in this study to meet the study aim. The primary and secondary outcome measures can be found in point 7.4.4 below.

- To test a predictive tool in the early identification of women who catastrophise pain (greater and perturbing anxiety and fear cognitions around pain) and who may require additional support.
- 2 To determine the prevalence of pain catastrophising in the target sample.
- To examine the relationship between pain catastrophising (as identified by the predictive tool) in pregnant women and the timing of admission to hospital when in labour.
- To examine the relationship between pain catastrophising and the specified birth outcomes.
- To examine whether women who catastrophise pain also have a fear of childbirth, and if so to understand the relationship between these two variables and their effects on the timing of admission to hospital when in labour, and birth outcomes.
- To determine what pregnant women find helpful and supportive, or unhelpful, with their pain management during labour.
- To determine whether pain catastrophising acts as a predictor for mental health issues and/or pain as self-defined by the participant at approximately 3 weeks postnatal.
- To analyse who and what are the influencing factors that impact on a woman's decision to seek hospital admission when in labour and the relationship between these factors and pain catastrophising.
- To examine the relationship between the demographics specified in this study, pain catastrophising, timing of admission to hospital when in labour and birth outcomes.

#### 7.0 METHODS

### 7.1 Preparation

The research project has been peer reviewed by the Wessex Integrated Clinical Academic Training Programme. This doctoral project is part of the National Institute for Health Research's (NIHR) recognised Wessex Academic Clinical Pathway enabling it to be adopted on to the NIHR Clinical Research Network (CRN) portfolio. CRN funding facilitates high-quality research by making accessible the valuable support services of research midwives in participating NHS Trusts. Midwives or other appropriate healthcare worker at each NHS Trust in the Wessex area (point 7.4.5.1 Table 4) will face to face or verbally via the telephone, or other technology invite women to this study. This invitation will be supported by the Participant Information Sheet (PIS; point 14.1 Appendix 1). The PIS will be passed to women at the same time as the verbal introduction. Each NHS Trust's research staff will collect the data for specified outcomes and manage this study at NHS Trust level and then communicate the required study data to the Chief Investigator. (Please see point 7.4 Study Design for more details).

A predictive tool, in questionnaire format, has been developed (point 14.4 Appendix 4) and tested in a healthy female, nulliparous population aged 18 to 45 years. Its aim was to identify the prevalence of pain catastrophising in this group of women. This tool consists of a series of questions that have previously been tested for reliability, validity, and robustness. The predictive tool was piloted on a non-pregnant population of women of reproductive age studying at two university sites (Clark et al. 2022). Crucially, this study found over half of the sample population catastrophised pain. Findings from this study may be limited by the relatively small sample size of 122, and results may be skewed due to self-selection for inclusion bias. Nevertheless, it indicates high prevalence of pain catastrophising in a healthy female population of reproductive age. This is important considering studies suggest pain catastrophising has an influence on pain coping behaviour for women during and after childbirth (Flink et al. 2009; Van den Bussche et al. 2007), requests for pain relief during the latent

phase of labour (Veringa et al. 2011), and preference for elective caesarean section (Dehghani et al. 2014).

## 7.2 Patient and Public Involvement (PPI)

The guidance of pregnant women and their partners, midwives, including research midwives, maternity support workers, doulas, and doctors has been fundamental in the design of this study. Their active involvement has been an invaluable contribution to ensuring the study topic and aims are relevant, communication with the target population and participants is clear, and study design, data collection methods and dissemination of results are agreeable.

#### How PPI was undertaken:

- A presentation about the background to this study was given at a doula conference held in Bournemouth. Approximately fifty doulas were in attendance. A group discussion was held with attendees, and written feedback in response to three questions was invited.
- Midwives attending a local midwifery conference 'Behind the Trauma', and midwives at Dorset County Hospital (DCH) were asked for their written feedback in response to the same three questions.

The three questions asked to groups 1 and 2 were:

- i. Do you recognise fear of pain or heightened pain experiences as an issue for women?
- ii. In your experience how does fear of pain or heightened pain experiences affect how women approach their labour?iii In your experience what sort of intervention do you think would best support women who have fear of pain or heightened pain experience?
- Four pregnant women and two support partners, and three pregnancy healthcare providers at Dorset County Hospital (DCH) were approached

and their opinions invited during antenatal class. They were asked about their opinions on seven items:

- i. The aim of the study
- ii. Who, how and when women are approached to participate
- iii. Study approach/methodology
- iv. Participant Information Sheet
- v. Questionnaire
- vi. Gaining online consent and use of an online questionnaire
- vii. Dissemination of results.
- These same seven items were discussed with two DCH maternity unit support workers, four midwives and a doctor during quiet work periods.

All those who kindly gave their opinions agreed and recognised fear of pain or heightened pain experiences as an issue for women. Common themes people made concerned the link between anxiety and tension making contractions seem worse and the adverse effect on labour hormones which can slow labour progress. With respect to how women can be supported, complementary therapies including hypnotherapy, education and communication were the most popular choices. Understandably, clinicians' answers and suggestions did vary slightly from those given by those people who do not work in maternity services. Clinicians' answers demonstrated they had more in-depth knowledge around the physiology of childbirth and the role of the professional care provider. However, thematically their answers converged.

The concerns raised during an antenatal education class were first that using words such as fear and pain catastrophising are very strong and could cause fear and anxiety when there was not any. Second, one thought was that identifying a specific group of women in this way could stigmatise or label them. This is particularly important when considering future healthcare and support intervention to ensure it advocates individualised, woman-centred care. This issue was discussed, and the group decided

that it is important to provide targeted support to those who need it. Furthermore, the group felt reassured and pleased that midwives will not be communicating about pain catastrophising and fear, in the manner in which we did in the consultation group, and the midwives will be guided about how they will invite women to participate. Similarly, a suggestion was made that the wording in the questionnaire could be more subtle. This was discussed as a group. Together the group agreed it would be not be suitable to moderate the tone and language of the questionnaire because the aim to determine fear and catastrophic thinking would be lost.

One suggestion was the Participant Information Sheet was long and there was a thought that women would not read through it all. The importance of conveying all the information contained within the Participant Information Sheet was thought important. Following this comment the Participant Information Sheet was reviewed. Where possible the Participant Information Sheet was altered to improve its readability in line with 'Flesch Reading Ease' and 'Flesch-Kincaid Grade'.

The women and their partners at antenatal education classes, and the midwives who were asked understood and agreed with the study approach/study methodology.

For those involved in this PPI who wished to receive the results of this study agreed to be informed via email.

Interestingly, the vast majority of people who took part in this PPI activity had not heard of pain catastrophising before, including midwives. However, once the concept was explained they understood and appeared familiar with this mind-set, just not familiar with the pain catastrophising terminology.

## 7.3 Peer Review

This research project has been peer reviewed as part of the funding for the Wessex Integrated Clinical Academic Training Programme. This study protocol has been peer reviewed by:

- 4 The Sponsor
- 5 Three Research Midwives two from one of the potential participating NHS Trust sites and one from the leading participating NHS Trust site
- One Head of Research, Lead Research Nurse, Clinical Trial
  Assistant from the leading participating NHS Trust site

Suggestions and comments offered by peer reviewers have been incorporated within this protocol and study design. Notably clarification has been provided on:

- the inclusion and exclusion criteria
- outcome measures
- demographics
- how women are introduced to this study and by whom
- reducing the burden of study participation on midwives
- the addition of question 13 to the postnatal questionnaire
- more information on the PIS as to what participants will be asked in the questionnaires
- adjusting the screening questions 3 and 4 (point 14.2 Appendix 2) to avoid causing distress and confusion respectively.

Concerns were raised about the number of participants that will be lost to dropouts/follow-up, and one reviewer expressed an idea for conducting the questionnaire
face to face or on the telephone. However, University Hospital Southampton NHS
Foundation Trust and Hampshire Hospitals NHS Foundation Trust who have already
expressed interest in running this study did not question the current online format and
face to face was considered work intensive. However, the risk of attrition has been
considered and to achieve the target sample size of 384 and maintain scientific
statistical analysis integrity 768 women will be recruited to the study. This increase
from 30% to 50% is the anticipated number of participants lost to drop-outs/follow-up,
or as a result of meeting exclusion criteria during the study period.

The protocol has been sent to each of the potential participating sites. Currently three of the potential sites have expressed strong interest of participation and they are:

- 1 Dorset County Hospital NHS Foundation Trust
- 2 Hampshire Hospitals NHS Foundation Trust
- 3 University Hospital Southampton NHS Foundation Trust

A suggestion was made to allow for midwives to approach potential participants soon after the midway point through their pregnancy. Professional guidance (NICE 2019) recommends that pregnant women, in their first pregnancy, should be seen at 25 weeks gestation. Approaching women at this gestation allows time for a future support intervention to be implemented during pregnancy. Furthermore, research suggests as women progress through pregnancy fear increases (Dehghani et al. 2014). Surveying women too soon may not identify those that are later in need of support.

Since NHS ethical approval was granted on the 4<sup>th</sup> June 2020 the study area was widened from the Wessex area to England and the closing date for recruitment extended from May to 31<sup>st</sup> January 2022, and data collection to 30th June 2022. This is because of the effects of the current coronavirus pandemic which has meant that NHS Trusts have had their workload directed to COVID-19 studies, and some research staff have been redeployed to working clinically. Slowly this is resolving and now Trusts are starting to start or recommence other research studies outside of those with a COVID-19 focus. Since widening the area to England some Trusts have requested that the recruitment strategy be enhanced to allow more involvement for NHS research Trust's staff. The amendments requested have been:

- to allow research staff to accept referrals from midwives,
- \* for research staff to screen clinic lists and patient records for eligible participants
- \* for research staff to approach women either face to face or via the telephone or via the use of other technology
- \* for research staff to approach women (as above) and to complete the questionnaire with women.

The requested amendments above have been discussed with research staff, midwives and pregnant women from the leading participating NHS Trust site and opinions have been invited via email and/or discussed over the telephone with some of the NHS Trusts who have expressed a strong interest in participating in this study or who are already participating.

All comments and opinions are in favour of these additional options for recruitment because they are in line with the more traditional means of participant recruitment within the NHS, and provide the opportunity for women to have someone to support them at the time of questionnaire completion should they wish it, and it may help reduce the rate of drop-out.

### 7.4 Study Design

## 7.4.1 Sampling Method, Sample Size and Participants

All women recruited to the study will be receiving normal pregnancy care with no intervention as specified by the inclusion and exclusion criteria. The sampling method for this study will be nonprobability, convenience sampling. Women in the target population will meet certain criteria including convenient geographical proximity of the NHS Trusts in Wessex to the research team. Nonprobability convenience sampling is an efficient and cost-effective way of achieving the required sample size during the study period. Although the most apparent potential limitation of convenience sampling is sampling bias and the sample not being representative of the whole population, the knowledge gained will be representative of the population from which this sample was taken. The sample size will be large enough to provide an indication of the prevalence of pain catastrophising and enable the vital comparisons between those healthy primigravid women who pain catastrophise and those who do not. Therefore, convenience sampling is a suitable method to meet the study aim.

Studies using the Pain Catastrophizing Scale (PCS) as an assessment tool have had a varied cut off score of between 20 and 30 (Flink et al. 2009; Sullivan et al. 2009) for diagnosis of pain catastrophising. For this study prevalence of pain catastrophising will

be estimated using both cut off points and these will be presented with 95% confidence intervals. The recent study by Clark et al. (2022) found 21% of their non-pregnant population had a pain catastrophising score over 30 and 48% had a score above 20. Based on these findings using a cut off score of 30 and having 5% precision in a pregnant population requires a sample size of 255 women. Using a cut off score of 20 and having 5% precision in a pregnant population requires a sample size of 384 women.

This study aims to achieve the higher sample size of 384. This ensures the sample size in this study will have 90% power to detect correlations between variables as small as -0.17 (coefficients (r) is =>0.17 at the 5% 2-sided significance level).

For scientific statistical analysis integrity, a target sample size of 384 is required. To ensure this is achieved 768 women will be recruited to the study. This allows 50% of participants who are lost to drop-out/follow-up or whose risk status changes from low to high during the study period.

# 7.4.2 Inclusion and Exclusion Criteria

At recruitment to this study, women should be healthy, primigravid and aged 18 to ≤40 years at the time of birth, experiencing a low risk pregnancy, and should not present with any of the exclusion criteria. The Inclusion and exclusion criteria have predominantly been chosen to reduce the known factors that may obscure the results of this study. Inclusion criteria aims to meet the needs of this study and future care planning such as allowing for screening and supporting women prior to labour. If the participant indicates on the postnatal questionnaire that they received ongoing care from a consultant obstetrician during their pregnancy and/or they did not experience latent labour at home, then their data will be included in relevant sensitivity analyses.

# 7.4.2.1 Table 3 Inclusion and Exclusion Criteria

| Inclusion Criteria  | Exclusion Criteria   |
|---|--|
| Healthy primigravid women who are experiencing an uncomplicated singleton pregnancy, and who are planning a hospital birth. | Women who are under <b>ongoing</b> care from an obstetrician during their pregnancy.   |
| Women aged 18 to ≤40 years at the time of study.  | Women who are 41 years or over at the time of childbirth.  |
| Able to understand and read English.  Antenatal women who are between 25 and 33 weeks and 6 days gestation.                 | Women with a current or pre-existing mental health condition requiring current medication and /or care by perinatal mental health team i.e. specialist obstetrician, specialist midwife and/or local mental health services provision. |
| Have internet access and an email address for study correspondence  | Pregnant women already participating in a different study that is providing support with pain management or a labour support intervention of any kind. This includes the latent, active, second and third phases of labour.            |

# 7.4.3 Recruitment

There will be a pragmatic approach to recruitment. This meets the aims of the nonprobability convenience sampling method. This study will be undertaken concurrently at multiple sites with each site recruiting independently from each other.

The relevant NHS Trust staff will be briefed prior to recruiting participants and they will determine and invite eligible women to participate. Briefing staff about this study prior to the start date ensures they can effectively communicate an invitation to participate in this study and answer women's questions. It also respects the vital contribution of staff to this study.

Posters advertising the study will be offered to participating NHS Trusts for display in relevant public and staff spaces.

Before they invite eligible women to participate in this study it is the responsibility of the midwife, research staff member or other appropriate trained healthcare worker to assess whether the woman meets any of the exclusion criteria (see point 7.4.2.1 Table 3 Inclusion and Exclusion Criteria). If any exclusion criteria are met the woman should not be invited into this study.

There are 4 pathways for recruitment.

PATHWAY 1 - Recruitment of participants at their routine antenatal appointment:

If it is a community midwife who is inviting a potential participant to the study it is a usual requirement that when they have a healthcare appointment with a pregnant woman that they review her past and present health and wellbeing and address any ongoing needs. Therefore, as part of the midwives' usual professional role she/he will be required to know whether the woman is experiencing an uncomplicated pregnancy or whether the woman may require additional care. This clinical assessment is helpful in determining a woman's eligibility to participate in this study. Backup to this process is when women independently determine their eligibility to participate online (point 14.2 Appendix 14.2).

Eligible women between 25 to 33 weeks and 6 days pregnant and attending their antenatal appointment will be verbally invited to participate in this study. At the same

time these women will be provided with a paper copy of the PIS (point 14.1 Appendix 1) which contains the Chief Investigator's contact details, an online link for this study, and administrative box. This paper copy will be given to women to attach to and at the front of their handheld pregnancy record (women look after their own handheld pregnancy record and take it to all their maternity appointments). Attaching the PIS at the front of the woman's handheld pregnancy record helps prevent her from being repeatedly invited to the study and facilitates sites recording invitation to the study. If the woman is not issued with a handheld pregnancy record because the NHS Trust only use digital records, then a PIS can be attached to the woman's records digitally. The NHS Trust staff who verbally invite eligible women to the study are not taking consent at this introductory time. Consent to participate is an online process and will be undertaken by the woman (participant) when she chooses to go online and access the study. The Chief Investigator will be available, at specified times by phone and email, to discuss this study with women and staff should they wish.

For all participants when they access the study online, on the landing page, there will be the PIS as a back-up if they have not read the online PIS or if they do not have their paper copy to refer to. There will also be an eligibility criteria checklist where women are asked a set of questions to confirm that they do not meet any of the exclusion criteria. If they answer yes to any of the exclusion criteria, they will be directed away from the questionnaire to a page thanking them for their time, and they will proceed no further. These questions support the process of ensuring correct participation and reduce the burden on NHS staff who introduce the study. If women are eligible to participate, they will continue to the consent page (point 14.3 Appendix 3) where they can either agree or decline to participate in this study. Women will give their informed consent online by selecting 'I agree to participate' and then selecting 'Finish and proceed to questionnaire' (point 14.3 Appendix 3). Once consent is obtained participants will continue to the online antenatal questionnaire (point 14.4 Appendix 4). Participation is entirely voluntary.

On the antenatal questionnaire participants will be informed why and asked to provide their email address. If the participant is following recruitment pathway 1, 2 or 4 as specified below then the Chief Investigator will then contact them, by a secure NHS

email account containing a short, standardised letter, requesting three points of personal identification i.e. full name, date of birth, and hospital number or NHS number (point 14.5 Appendix 5), and one requesting their postcode which will be used for demographic analyses. One reminder (point 14.6 Appendix 6) will be sent if no reply is received to this email request. Participant personal identifiable information is necessary to collect the participant's labour and birth details. It is usual within the NHS to provide three points of personal identifiable information. Three points of identity provides safety to collecting the correct data and supports triangulation of data.

PATHWAY 2 - A member of the participating Trust's research team or other suitably trained healthcare professional introduces eligible, potential participants to the study

An appropriate member of staff i.e. a research team member or other suitably trained healthcare professional will:

- identify potentially eligible participants by screening electronic records,
   paper records, or clinic lists. Referral can also be received from community
   midwives or other relevant healthcare professional.
- They will then telephone call, face to face, or via other technology approach the eligible potential participant to introduce them to the study.
- Participants will be asked for their identifiable information and email address. This information will be stored by the research team and used to support the NIHR Clinical Research Network's accruals process should the potential participant become an actual participant.
- Following on from this discussion they will post, email, or hand the PIS to the potential participant should they wish to accept it.

PATHWAY 3: A member of the participating Trust's research team or other suitably trained healthcare professional introduces eligible, potential participants to the study and completes both the antenatal and postnatal questionnaires with the participant

An appropriate member of staff i.e. a research team member or other suitably trained healthcare professional will:

- identify potentially eligible participants by screening electronic records,
   paper records, or clinic lists. Referral can also be received from community
   midwives or other relevant healthcare professional.
- They will then telephone call, face to face, or via other technology approach the eligible potential participant to discuss the study.
- Following on from this discussion they will post, email, or hand the PIS to the potential participant should they wish to accept it.
- With the potential participant's consent, the member of staff will contact them again a minimum of 24 hours later, either by telephone call, face to face, or virtually.
  - o This follow up contact pathway will be:
    - i. to discuss any questions the potential participant may have and
    - ii. to support the participant as they complete the online questionnaire or,
    - iii. for the staff member to access the study online where they will read out the questions to the participant and enter their responses online on their behalf.
- B. If the participant chooses to follow pathway ii. or iii. as specified above then an appropriate staff member will, with the consent of the participant,
- take and record the participant's identifiable information (see 8.0 Data
   Management and Data Management Plan) and,
- be responsible for contacting the participant at approximately and no sooner than 3 weeks postnatal or, 3 weeks from the expected date the participant's baby was due if the baby was born prematurely to either
  - iv. support the participant as they complete the postnatal online questionnaire or,

v. for the staff member to access the postnatal questionnaire online read out the questions to the participant and enter their responses online on their behalf.

NB If the participant chooses to follow pathway 3 ii. or iii. as specified above then the member of staff will immediately inform the CI of this woman's participation including her email address to help prevent the CI requesting this participant's identifiable information via email as specified in point 7.4.3 (Recruitment) of this study protocol. It will also ensure the CI can record the data in line with the specifications in this protocol (see 8.0 Data Management and Data Management Plan). If the participant decides to access the online study by themselves and in their own time after following Pathway 3 i. then from this point it is the same as Pathway 2 and they can continue in the study following Pathway 2.

PATHWAY 4: Participant accesses the study directly from a social media advertisement (see Appendix 14.14 Social Media Advertisement).

The participating Trust will display the social media advertisement, together with an uploaded version of the PIS on their social media pages. Once the participant accesses the study online, they will then follow pathway 1.

If the participant is following recruitment pathway 1, 2 or 4 as specified above then when they are approximately three weeks postnatal, or approximately 3 weeks after their expected due date if they had their baby prematurely, they will be sent the online link to the postnatal questionnaire (point 14.7 Appendix 7). This online link will be sent from the Chief Investigator's secure NHS email account. One reminder to complete the postnatal questionnaire will be sent (Appendix 9). Participants who access the online link, will be given the option to continue, or decline to continue (point 14.8 Appendix 8) to the postnatal questionnaire (Appendix 8). If they choose to decline to participate,

they will be directed away from the postnatal questionnaire page and thanked for their antenatal participation.

Participants can withdraw from the study by simply closing the browser page before selecting 'finish' at the end of the antenatal questionnaire. Participants who withdraw at this stage ensure their data will not be used. If either the antenatal or the postnatal questionnaire has been completed, by selecting 'finish', then the participant can contact the Chief Investigator who will withdraw all their data from the study. If the data has been anonymised and used within analysis, then withdrawal of their data from this part of the study will not be possible. This issue will be explained prior to consent in the Participant Information Sheet and at the time of withdrawal request.

Should any woman feel mentally distressed by this study and requires mental health support she will be signposted, via the PIS, antenatal and postnatal questionnaire (point 14.1 Appendix 1, point 14.4 Appendix 4, point 14.9 Appendix 9) to her 24 hour local NHS Trust's midwifery support.

Women who choose to withdraw from the study or wish to decline to be contacted postnatal are given the information on how they can do so in the Participant Information Sheet.

A poster advertisement for the RETHINK Study can be found in Appendix 11 (point 14.11). A flowchart depicting a participant's journey through the study can be found in Appendix 12 (point 14.12).

#### 7.4.4 Outcome Measures

Primary Outcome Measure:

The study is designed to identify the prevalence of pain catastrophisation (defined as a score of 20 or more) and its association with admission to hospital in latent phase labour.

## Secondary Outcome Measures:

- Labour outcomes: such as cervical dilatation on admission, labour augmentation, duration of labour
- Birth outcomes: such as mode of birth and pain relief
- Postnatal: postnatal mental health issues and persisting postnatal pain (as selfdefined by the woman)

## 7.4.5 Setting

All Maternity units in England will be invited to participate. Hospital settings cover obstetric, and midwifery led units, and rural and urban areas.

#### 7.4.6 Measures

The demographic profile of participants provides important context to help understand the findings from this study. Following informed consent participants will be asked to provide demographic details, including:

- Relationship/Marital status
- Ethnicity
- Employment status
- Highest level of education achieved
- Postcode

## Participants will also be asked:

- If they have ever been pregnant before but unfortunately suffered a miscarriage or termination of pregnancy before 24 weeks pregnant
- How pregnant they are, measured in weeks
- if they have had ongoing pain during pregnancy that has lasted for 4 weeks or more
- about a brief pain experience history

This study aims to assess the prevalence of pain catastrophising among primigravid women and how this affects their timing of admission to hospital when in labour, and subsequently their birth outcomes. This study will use the Pain Catastrophizing Scale (PCS) as a predictive tool. It will examine its effectiveness in the early identification of women who have pain catastrophisation and who may require additional support to improve their birth outcomes.

# 7.4.6.1 The Pain Catastrophizing Scale (PCS)

The PCS was first introduced by Sullivan, Bishop and Pivik in 1995 and is one of the most widely used psychometric measures of catastrophic thinking linked to pain (Sullivan 2009; Leung 2012). The PCS is a self-report measure and was developed for both clinical and non-clinical use. It is composed of 13 items based on catastrophising definitions described in the literature, and previous experimental and clinical research on catastrophic thinking in connection to pain experience (Chaves and Brown 1987; Spanos et al. 1979; Rosenstiel and Keefe 1983). Scores on the PCS have been found to correlate with other health measures, including pain intensity, pain-related disability, and psychosocial distress (Severeijins et al. 2001).

The 13 items of the PCS are divided into three dimensions (subscales) including helplessness, magnification, and rumination. The correlational relationship between these three dimensions has been replicated in several investigations demonstrating internal consistency and validity of the three subscales with total PCS Cronbach's coefficient alphas = 0 .87, rumination = 0.87, magnification = 0.66, and helplessness = 0.78 (Osman et al. 1997; Sullivan et al. 1995, and 2000; Van Damme et al. 2002); and it has high test-retest correlation of r=0.75 across 6 weeks (Leung 2012).

Participants are required to reflect on past painful experiences and score their thoughts or feelings between not at all (score 0), and all the time (score 4), about the painful experience for each of the 13 items. There is a possible total score of 52. The higher the score the greater there is catastrophic thinking present. Although pain catastrophising scores have been shown to be normally distributed (Sullivan 2009)

previous studies have predominantly taken a score of 30 or more to determine pain catastrophising as clinically relevant.

## 7.4.6.2 The Wijma Delivery Expectancy Questionnaire WDEQ-A

Currently, the Wijma Delivery Expectancy Questionnaire Part A (WDEQ-A) (Wijma et al. 1998) is the most commonly used tool for assessment for the fear of childbirth (O'Connell et al. 2017; Nilsson et al. 2018). It is a self-report measure with thirty-three items with each item rated on a 6-point Likert scale ranging from "not at all" (score 0) to "extremely" (score 5). Each question refers to a cognitive and emotional belief about the approaching childbirth and are either presented in a positive or negative format with reverse scoring of positively formulated questions. In some studies the WDEQ-A has been shown to find prevalence rating of intense fear of childbirth in approximately 10-15% of pregnant women (Lukasse et al. 2014; Nieminen et al. 2009; Söderquist et al. 2004) and very intense fear in 5-6% (Heimstad et al. 2006; Nieminen et al. 2009).

Recent studies have suggested the WDEQ-A is a multidimensional psychometric measure to explore the fear of childbirth, therefore, the differential impact of the various aspects of WDEQ-A suggests a single score to diagnose FOC should not be used (Pallant et al. 2016). The WDEQ-A has been shown to correlate well with other fear of childbirth measures in identifying high childbirth fear in first time mothers, previous emergency caesarean and women with self-reported anxiety and/or depression (Haines et al. 2015). The correlation between the instruments was strong (Spearman's Rho = 0.66, p < 0.001). The scale has shown to have a high sensitivity 89% and specificity 79%, with a positive predictive value of 85% and negative predictive value 79% (Haines et al. 2015).

#### 7.4.6.3 Postnatal Questionnaire

Women will be asked to complete this second online survey at approximately 3 weeks postnatal, or approximately 3 weeks after their expected due date if they had their baby prematurely. Depending on which recruitment pathway has been followed (see 7.4.3 Recruitment) will determine how the participant accesses the online postnatal

questionnaire. Should a baby have sadly died at any point during the antenatal period, labour, or postnatal period then the women will not be contacted for this second time. The Chief Investigator will be informed of this sad event by the relevant NHS Trust (See point 8.0 for more details). Likewise, in the unlikely event that a woman sadly dies the relevant NHS Trust will inform the Chief Investigator and no further study communication will be sent. The Chief Investigator will be informed, in a timely manner, about either of these sad events via secure email from the relevant participating site.

The postnatal questionnaire will gather necessary information including:

- request email address
- gather data about the latent phase which is not routinely collected to complete the data set, including what the signs were that signalled to the woman it was time to go to hospital
- gather data about any pain relief medication received during labour
- ask if participants are receiving treatment for persistent pain and/or mental health conditions
- invite comment from respondents on what they found helpful and supportive during their labour and what was unhelpful and potentially had a negative effect. In the first instance this information will start to inform future support interventions
- ask participants if they have any concerns about their physical, or mental health and would like to be referred for professional NHS support and would like to be contacted to arrange this.

# 7.5 Data Analysis

Data from the online questionnaires will be initially collated and organised in Microsoft Excel and then organised, summarised, and analysed using the statistical software package SPSS (v.26). Descriptive and inferential statistics will be used. In all analysis the significance level will be set to a maximum of  $p \le .05$ .

First relevant data will be summarised and visualised to assess for normality.

Relationships between variables and their predictive powers will be analysed.

For example, pain catastrophising will be summarised using descriptive statistics to:

- measure the central point (typical value or average) of the data
- report on the prevalence of pain catastrophising scores ≥ 20
- present the variability (spread of pain catastrophising scores) including the statistical range, variance, and standard deviation across the sample group
- present the frequency distribution of pain catastrophising across the sample group
- relationships between variables and their predictive powers will also be analysed.

The association between the primary outcome measure (hospital admission in latent phase labour) and pain catastrophisation will be examined using parametric statistics if the data are normally distributed or non-parametric statistics if the data are skewed.

Removal or inclusion of missing data including missing due to drop-out or withdrawal from the study will be carefully considered to ensure inclusion or exclusion do not skew the data or create bias. Statistical analysis which has appropriate mechanisms and assumptions for the missing data will be conducted. Statistical analyses that tend to work best with larger samples such as multiple imputation, or full maximum likelihood estimation will be considered. All variables which present the potential mechanisms to explain the missing data will be included.

Inclusion or exclusion of data also has two other provisions. First, providing participants have not withdrawn their consent to participate, and second, the participant's data have not been anonymised. If the participant has dropped out, but not withdrawn from the study, their data will be analysed to see if they share significantly similar characteristics such as high or low pain catastrophising or fear of childbirth scores. This information will be conveyed in the final study report.

Written comments in response to relevant questions in the questionnaires will be coded and thematically analysed.

#### 7.6 Limitations

## 7.6.1 Nonprobability convenience sampling disadvantages:

- Can only make weak statements about some characteristics of the sample itself rather than a formal inductive inference concerning the whole population of interest
- Is open to bias including subjective bias by midwives and depending on how the aims of the study are communicated by the midwives and by the participants self-selecting due to their specific interest in the aims.
- Hidden bias and outliers are unknown i.e. those women in the study population may be homogenous but they may be different to those in the target population. Such differences will not be discovered using this type of sampling method. This may undermine generalisations made from this sample group to the population.
- The women agreeing to participate may not be representative of the target population (selection bias) and may not be applicable to the research problem.

# 7.6.2 The Measures

The PCS and the WDEQ-A may demonstrate predictive value for birth outcomes; however, causality cannot be determined. These two variables may demonstrate association with birth outcomes but may be confounded by other factors that are not considered in this study. However, this study is specifically looking to identify a certain group of women who pain catastrophise, and those who may fear childbirth and assess the effects on their birth outcomes.

- There is uncertainty in the literature, and it is an ongoing debate around whether pain catastrophising is a 'state' or 'trait'. Using the PCS as a predictive tool of poorer birth outcomes may prove ineffective.

  Nonetheless, this study aims to accept or reject its null hypothesis through sound research methodology.
- Debate in the literature continues as to whether pain catastrophising is distinct from other constructs such as negative affectivity. This study will not be questioning women about their mood. However, women with a current or pre-existing mental health condition requiring care by perinatal mental health team are excluded. These exclusion criteria should assist in demonstrating that pain catastrophising can be identified as a unique construct.
- 4 Lack of standardised routine data collection around the timing of admission to hospital when women are in labour means the women themselves will be asked to recall the details, this relies on correct recollection of events and that the appropriate information was passed to the woman at the time of her hospital admission. However, previous studies show that women recall these events clearly.
- Women may become more fearful the closer they progress towards childbirth; therefore, screening at 25 weeks pregnant may appear too early. However, this gestation has been chosen in order to facilitate intervention in future studies, before the women reaches full term pregnancy i.e. 37-42 weeks pregnant. It is also in line with antenatal appointment schedule.

## 8.0 DATA COLLECTION AND DATA MANAGEMENT PLAN

Women will be approached by appropriate participating NHS Trusts' staff. This will be a telephone, virtual or face to face discussion with the participant and the staff member will introduce the study. NHS Trust staff will also give the woman the Participant Information Sheet and link to the online survey once the participant is

happy to proceed. By achieving NIHR portfolio adoption, sites can be adequately supported in releasing their staff to support the research project. Participants can also access the study directly from the NHS Trust's social media pages (see 7.4.3 Recruitment).

The online survey will be managed via <a href="www.onlinesurveys.ac.uk">www.onlinesurveys.ac.uk</a> for which Bournemouth University has a licence. The online link will provide the women with study information for their convenience, an eligibility criteria checklist, and a consent page. When consent is agreed participants will automatically proceed to the questionnaire. The questionnaire will request the participant's email address and participating NHS Trust and explain the reasons for this. Whichever recruitment pathway is followed (see 7.4.3 Recruitment) will determine how the participant's name, date of birth and hospital or NHS number, and postcode are requested once the antenatal questionnaire has been completed. If pathway 1, 2 or 4 is followed then the CI will be contact the participant using a secure NHS email account. This email will be sent to the participant requesting their name, date of birth and hospital or NHS number, and postcode once the completed antenatal questionnaire has been received. If pathway 3 is followed it will be the Trust's member of staff who asks the participant for their identifiable information and informs the CI of participation via secure NHS email.

A unique participant identifier (study I.D.) will be allocated to each participant once the completed the antenatal questionnaire has been received. The study I.D. will be digitally filed together with the questionnaire responses and labour and birth details. Another file will also be held. This file will include participants' personal identifiable information together with a record of when the relevant specified emails were sent. These are two separate files and will not be linked together. Emails will be saved separately and filed alongside the study's electronic documentation.

This study I.D. will be held on the hospital's instance of the Local Portfolio

Management System (LPMS) and held separately to their questionnaire answers which
will only be accessible to the Chief Investigator and the relevant Bournemouth

University research team for this study. Identifiable information is required for the Chief Investigator to be able to link the participant questionnaire data and their birth outcomes and to appropriately manage the data over the course of the study. Participants will consent to the collection and storage of their data.

A case report form (point 14.13 Appendix 13) has been provided for each participating NHS Trust site to manage the study at an individual participant level.

In such tragic circumstances as the death of a woman (participant) and/or her baby then this will be communicated via email from the relevant Trust to the Chief Investigator who also has a secure NHS email account. This will prevent any further study communication being sent to the participant by the Chief Investigator

If on the postnatal questionnaire the participant indicates that they received ongoing care from a consultant obstetrician during their pregnancy and/or they did not experience latent labour at home, then their data will be included in relevant sensitivity analyses.

By using the LPMS system, each participant's study I.D. will be recorded alongside their three identifiers, as is commonly done on this system by Sponsors and NHS sites. If the participant does not respond to the Cl's antenatal email request for further identifiable information, then the participant can be recorded as anonymous on the LPMS. Furthermore, providing sites check and are assured the unique email address provided by the woman on the antenatal questionnaire matches what they have recorded on their Trust's records then this email can be used to identify the participant for the purposes of monitoring for when the participant gives birth and informing the Cl, via secure email, of this birth date only. No other labour and birth outcomes will be collected for these participants. Sites will then follow the usual postnatal checking process (Appendix 14.12.1). This allows participants who have not withdrawn to remain in the study should they chose to.

The LPMS system's features such as attributes, workflows, safety reporting and notes will be utilised to record any pertinent details such as incidents or circumstances that

would mean approaching the participant would be inappropriate. Having this record is especially important once the participant has given birth, so that a short postnatal questionnaire can be sent for completion. This postnatal questionnaire will be sent to a participant once the hospital has informed the Chief Investigator that she has given birth. The postnatal questionnaire will contain free text comment boxes so that participants can write about their time in hospital – this will reduce the burden on midwifery staff and give the participant the opportunity to collaborate on the project.

LPMS is a secure and fully auditable system that is subscribed to by the study Sponsor and likewise the NHS Trusts in England. Participant safety and study management will be improved through the use of LPMS which is why it has been adopted as the project and participant management system for this project.

Any information relevant to women's NHS care is outside of the remit of this study and is the responsibility of the NHS. Therefore, usual NHS practice requirements for safely managing and storing women's pregnancy, labour and postnatal information and documentation will continue.

Only the Bournemouth University research team for this study will have access to all women's data including that collected via <a href="www.onlinesurveys.ac.uk">www.onlinesurveys.ac.uk</a>, personal identifiable information collected via secure NHS email and labour and birth details supplied by the participating NHS Trust. Women's data will be protected, stored, and used in line with the Data Protection Act 2018 and General Data Protection Regulation 2018 and the latest Bournemouth University's policies. Master copies of sensitive data will be stored on Bournemouth University's mainframe and be password protected. A Bournemouth University laptop will also be used by the Chief Investigator. This encrypted device is password protected and the password is known only to the Chief Investigator. It has a maximum of 10 minutes' inactivity until this device locks. It has a secure remote connection to access files and will not be used for storage of master copies of vital records, and will not be used in public areas, be shared with non-university staff, left logged in or unattended.

Research data will be protected and stored for 5 years, and used in line with Bournemouth University policies, the Data Protection Act 2018, General Data Protection Regulation 2018, and professional regulating bodies. Research data collected, managed, and stored at participating Trust level will be retained in line with each Trust's data management policy.

When this study is complete all necessary information pertaining to this study will be appropriately stored and managed by Bournemouth University, but data and information held on the laptop will be erased. No participant personal identifiable information will be stored on a laptop or other data storage devices other than what is specified here. Participant contact details will be destroyed once they are no longer required for research.

Necessary communication between the Chief Investigator and the participating NHS Trusts, about women, will be conducted via NHS email. Should any woman communicate, via this study, that she requires additional healthcare support then this personal healthcare requirement will be emailed to the appropriate midwife at the relevant NHS Trust.

The relevant NHS Trusts are responsible for storing each woman's maternity records and are kept for 25 years after she has had her baby. This process will not be affected.

#### **RISKS AND SAFETY**

There are no foreseeable risks to the health of participants and their babies in participating in this study. Participants should continue with their usual maternity care. The main disadvantage is they will be donating their time to complete the two questionnaires and respond to the email with their personal identifiable information. PPI work demonstrated this time is acceptable to women.

If any of the participants' responses on the questionnaire raise safeguarding concerns for the baby and the safety of the woman then the Chief Investigator, who is also a

practising midwife, will contact the woman and discuss this with them and share this with their midwife.

Participants will be asked to comment if they have concerns about their physical or mental health and would like to be referred for professional support. Should a participant have concerns about their wellbeing then the local NHS service will contact them to arrange this.

In the very sad but unlikely event that a woman's baby dies during the study period then this will be communicated to the Chief Investigator and no further study communication will be sent to the participant.

Should an adverse event be identified by a participating Trust this should be communicated to the Chief Investigator with urgency and as soon as possible. An adverse event affecting a participant is one that is thought to be caused or likely to be caused as a result of participating in this study. An adverse event is one that is likely to affect a participant's safety, including the safety of their personally identifiable information, or their physical or mental integrity.

The usual NHS indemnity arrangements will provide protection for negligent harm caused to a woman or her baby. Bournemouth University has insurance for non-negligent harm associated with the protocol. This will include cover for additional health care, compensation or damages whether awarded voluntarily by the Sponsor, or by claims pursued through the courts.

# 10.0 DISSEMINATION

This study will be held on the Bournemouth University Research Online (BURO) this is the University's open access Institutional Repository, and the anonymised data set on BORDaR which is Bournemouth University's online research data repository.

#### Results will also be available:

- Submitted for publication in applicable peer-reviewed journals
- Presented to relevant national or international professional conferences
- On completion of the trial and following data analysis a Final Study Report will be prepared and submitted to REC.
- On Bournemouth University website. Bournemouth.ac.uk/projects/RETHINK
   (Website address to be confirmed).

The plans for dissemination were agreeable to the PPI groups. All participants in this study and those people who have contributed their advice, opinions and feedback for study design will be informed of the results of the study via email should they wish. This email will contain details of how participants can gain access to the full study report and will also contain a summary of findings in lay person's terms. For those people who contributed their advice, opinions and feedback in a group, or conference e.g. the doulas, they will have access to the full study report and summary in lay person's terms via their event organiser. All those who contributed their advice, opinions and feedback in their work setting i.e. midwives, maternity support workers and doctors will have access to the full study report in both lay person's and professional terms at their work setting.

All participating sites will receive a copy of the final report and be given the relevant details how they can access the study when it is published.

### **11.0 ABBREVIATIONS**

ACOG The American College of Obstetricians and Gynaecologists

ARM Artificial Rupture of Membranes (Amniotomy)

cm Centimetres

CRN Clinical Research Network

DCH Dorset County Hospital NHS Foundation Trust

NICE The National Institute for Health and Care Excellence

NIHR National Institute for Health Research

NHS The National Health Service

PCS Pain Catastrophizing Scale

SPSS was once known as Statistical Package for the Social Sciences

WHO World Health Organization

#### 12.0 DEFINITIONS

Active Labour Active Labour is a period of time characterized by regular painful uterine contractions, a substantial degree of cervical effacement and more rapid cervical dilatation from 5 cm until full dilatation for first and subsequent labours. (WHO 2018a).

The period of time when progressive cervical dilatation is expected to occur in normal labour towards full dilatation at 10 cm. Current UK guidelines, this is defined as from 4 cm cervical dilatation (NICE 2014).

Amniotomy

A procedure undertaken by a midwife or obstetrician, whereby, an amnihook is inserted through the dilated cervix to puncture the membranes and release the amniotic fluid surrounding the fetus.

This can stimulate uterine contractions to induce or augment labour.

and open, the mucus which has been protecting the entrance to your womb comes away. This is called a 'show'. It has a clear jelly-like appearance. It can often be streaked with blood, either bright red, pink or brown. When this happens, it is called a bloody show.

Local Portfolio Management Systems are used by Local Clinical Research Networks (LCRNs) and their Partner

Organisations to manage local research delivery and associated processes. A number of different Local Portfolio Management Systems have been procured by the Local Research Networks e.g. EDGE, ReDA, R-Peak, Studyline/Siteline, Documas.

Elective caesarean sections

An operation to deliver a baby through an incision made across the abdomen usually just below the bikini line. An elective caesarean section is a planned procedure. The decision for an elective caesarean section is taken if labour is considered too risky for mother or baby. Sometimes a mother may request to have an elective caesarean section because she may want to avoid labour. This decision will be agreed upon following discussion between the mother and her obstetrician.

## Emergency caesarean sections

Category I, II and III The same as for an elective caesarean section except the decision is not planned in advance but taken at a time when there is an immediate or imminent threat to the safety of the mother of baby. The urgency/speed at which the operation needs to occur is categorised as either category I, II or III.

Epidural Anaesthesia/c An anaesthetic technique used in maternity care. It typically involves the insertion of a fine catheter into the around the spinal cord. A mixture of medium duration local epidural space anaesthetic and opioid drugs are then administered to achieve a temporary sensory block, although some degree of motor block is inevitable (Obstetric Anaesthetists Association 2013).

Flesch Reading Ease A readability test. The score on the test is guide to what education level a person requires to be able to read a piece of a Scores usually range between 0-100. The higher the score means the text is more readable.

Flesch-Kincaid Grade Similar to the Flesch Reading Ease in that is uses the same core measures (e.g. word length and sentence length), however, they have different weighting factors. The Flesch-Kincaid Grade formula calculates the reading grade level of the text. A text with a high score on the Flesch Reading Ease should have an opposite lower score on the Flesch-Kincaid Grade.

#### Fluid loss

This occurs when the membranes surrounding the fetus have ruptured and the amniotic fluid is released passing out of

the woman's body through the vagina.

Instrumental birth

A vaginal birth assisted by the obstetrician

uses devices such as a ventouse (a suction cup applied to the baby's head) or who (smooth metal instrument that looks like large tongs curved to fit forceps carefully around the baby's head). When the mother has a contraction and is pushing her baby out the obstetrician assists, using either a ventouse or forceps, and pulls at the same time to help the baby to be born.

Labour augmentation

Augmentation of labour is the

process of stimulating the uterus to increase the frequency, duration, and intensity of contractions after the onset of spontaneous labour. It has commonly been used treat delayed labour when uterine contractions are assessed to be insufficiently to strong (WHO 2015).

Latent Labour / Latent Phase

The latent first stage is a period of

characterized by painful uterine contractions and variable changes of the cervix, including some degree of effacement and slower progression of dilatation up to for first and subsequent labours (WHO 2018).

Latent first stage of labour is a period of time, not necessarily continuous, when there are painful contractions and there is some cervical change, including cervical effacement and dilatation up to 4 cm (NICE 2017)

Mode of birth

A baby can be born in different

can be a spontaneous vaginal birth, an instrumental birth (see definition ways. It above), or a caesarean section.

## **Multiparous**

A woman who has carried more

than one pregnancy to a viable stage.

**Nulliparous** 

A woman who has never given

birth to a viable infant i.e. one that is 24 weeks or more gestation.

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Nonprobability convenience sampling

A subgroup of the population is

used to represent the whole population. Nonprobability sampling is where the chances of a participant being selected cannot be calculated. Participants are

gathered either by convenience or the judgement of the researcher.

Oxytocin

Oxytocin is a hormone. It can be

either naturally occurring in the human body or as a synthetic medication used within

obstetrics to induce or augment labour.

**Pain Catastrophising** 

Is a maladaptive cognitive process

involving irrational negative assessment during an actual or anticipated painful

event.

**Primigravid** 

A woman in her first pregnancy.

**Quasi-experimental study** 

A scientific experiment which

involves selecting groups upon which a variable is tested. Quasi-experimental

studies do not have the random assignment of participants to groups. In this

study the quasi- experimental aspect will occur during analysis of the groups

only. The groups will be divided according to those who pain catastrophise and

those who do not.

Second stage of labour

The second stage is the period of

time between full cervical dilatation and birth of the baby, during which the woman

has an involuntary urge to bear down, as a result of expulsive uterine contractions (WHO 2018b).

Tocophobia

Is an intense anxiety or significant

fear of childbirth.

Within the body particularly affecting the uterus and cervix. Muscles of the uterus tighten and shorten causing the softening cervix to shorten, stretch and open. It is thought pain is felt by the mother during contractions due to contractions compressing the blood vessels and reducing blood flow. When blood flow is limited pain receptors are stimulated. Pain is also caused by the fetus pressing down on the birth canal, and then onto the vulva and perineum as labour progresses from the first stage to the second stage and finally at the point of birth.

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## 14.1 Appendix 1 Participant Information Sheet for Recruitment Pathways 1,2 & 3



Please retain in maternity notes for

## Participant Information Sheet for The RETHINK Study

### v1.11

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more help.

### What is the purpose of the study?

This study aims to see if we can detect those women who may find extra support for early labour useful, to help reduce their chance of a difficult labour and unnecessary intervention. To date research has not shown the best way to support women who are in early labour at home. Some women say they went to hospital during early labour because of their contractions and were looking for support to help them cope with this. Women who stay in hospital during the early stage of labour are more likely to have difficult labours and interventions such as having their waters broken, a hormone drip to speed up contractions, epidural anaesthesia and caesarean sections.

This study will follow participants through pregnancy, labour and birth, and into the postnatal period to see if we can identify those women who might benefit from additional support in early labour to reduce their chance of a difficult labour and unnecessary intervention. To help us do this we would like you to complete two questionnaires, one whilst you are pregnant and the other one after you have had your baby. We will also be asking for your permission for your hospital to tell us some details about your labour and birth.

### Why have I been chosen?

We would value your views because you are expecting your first baby, you have no known health problems that could affect you or your baby, and you plan to be at home during early labour then to go to hospital to give birth.

We aim to recruit 768 women in this research study.

What will happen to me if I take part?

If you decide to take part, you will need to be able to access the study questionnaire online and have an email address for correspondence. We would like you to complete the online questionnaire when you are between 25 and 33 weeks and 6 days pregnant.

Before you start the online questionnaire there are two important steps, we would like you to complete. The first involves reviewing five questions to confirm that you are eligible to take part. Second, we ask for you to consent to take part in this study. This involves reviewing seven questions and asks you to consent to each one. Once this is done you will be directed to the questionnaire and included in this study.

Near the end of the questionnaire you will also be asked to provide your email address and the name of your hospital. We would like your email address so that we can contact you to ask you for your full name, your date of birth, and your hospital number or NHS number and so that we can tell your hospital that you are taking part. The information that identifies you is important so that we can ask your hospital for details about your labour and birth. We will also ask for your full postcode. Postcode information is optional, but it can help us to learn more about what affects the group of women who take part in this research. If we do not hear from you in approximately one week after we have sent the email, we will send you one reminder. If you completed the questionnaire with a member of staff from your hospital, they will have asked for this information and you will not be emailed requesting this information again.

When you have finished the first online questionnaire your hospital will be told that you are taking part in this study. If you completed the questionnaire with a member of staff from your hospital, they would already know this. Then when you have had your baby your hospital will look at your hospital records and tell us some details about your labour and birth, such as what pain relief you had, if you had a doctor's help to give birth, how long you were in labour, if you had your waters broken or a hormone drip, or if you had a caesarean section.

A second online questionnaire will be sent to your email address about 3 weeks after having had your baby, or approximately 3 weeks after when you baby was due.

Each questionnaire should take no more than 20 minutes to complete. The second questionnaire is shorter than the first. The first antenatal questionnaire asks you about your thoughts about your approaching labour and birth, and your thoughts about pain. The second postnatal questionnaire asks you about your labour and birth, and what factors might have influenced your labour and birth choices.

## Do I have to take part?

It is up to you whether or not you take part in this study. If you decide to withdraw you do not have to give a reason and your care will not be affected in any way.

There are four different ways you can withdraw from taking part in this study.

1. You can withdraw from the study by simply closing the online browser page for the first (antenatal) questionnaire and you will receive no further contact and we will not collect your labour and birth information. If you are completing the antenatal

questionnaire with a member of staff from your hospital you will need to inform them of your decision at the time.

- 2. If you have completed the antenatal questionnaire, or both the antenatal and the postnatal questionnaires, and you do not wish to continue in this study you will need to contact the Chief Investigator to be withdrawn (contact details below).
  - If we are informed in time this will also stop us from collecting your labour and birth information and we will not send you an online link to the second questionnaire.
- 3. If you do not withdraw from this study and you receive the online link to the second questionnaire, but you decide you no longer wish to take part you do not need to do anything. However, the answers you gave on the first questionnaire and your labour and birth information may still be used in this study.
  - If you choose not to access the online link you will be sent **one** reminder to complete the postnatal questionnaire before you are withdrawn from this part of the study.
- 4. You can access the second questionnaire via the online link, and you can tell us here that you do not want to take part in the postnatal section of The RETHINK Study. However, the answers you gave on the first questionnaire and your labour and birth information may have already been collected and may still be used in this study.

If we have already anonymised any of your answers to the questionnaires or your labour and birth information, we will not be able to remove you from this anonymised part of the study.

If you do decide to withdraw from this study your future pregnancy care will not be affected in any way.

# What will happen to my responses and will taking part in this project be kept confidential?

All the information that you give will be kept strictly private under the General Data Protection Regulations and Data Protection Act 2018. You will not be identified in any reports or in publicly available information.

Bournemouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your maternity records in order to undertake this study. Bournemouth University is responsible for looking after your information securely and using it properly. Bournemouth University uses BORDaR <a href="http://bordar.bournemouth.ac.uk/">http://bordar.bournemouth.ac.uk/</a> a central secure location for research data. Bournemouth University will keep the research information that identifies you for 5 years after the study has finished. This does not affect the information your NHS hospital must keep about your health care.

By consenting to take part in this study you will be agreeing that your hospital can securely pass on details from your labour and birth records to the Bournemouth University Research Team for purposes of this study. Your hospital has a strict duty to protect your personal information. Your hospital will not pass on any other details other that what you have agreed to for this study.

Certain authorised individuals from Bournemouth University and regulatory organisations may look at the research records to check the accuracy of this study. These research records will be anonymised. This means the authorised individuals and regulatory organisations will not have access to the personal information that identifies you. This activity is required to make sure this study is being conducted properly and to ensure the quality and integrity of the research.

Other than what you agree to we will not collect other information that identifies you such as your Internet Protocol address known as your IP address. Your IP address is like a postal address. It is a long number label given to each device connected to a computer network such as the internet. This address makes it possible to communicate using the internet. The data you provide online will be transferred to Bournemouth University computers. All data collected for this study will be stored in a password protected electronic format on university secure computers. Within three weeks of the close of the data collection period for this study data held online will be destroyed. More information about online surveys can be found here: https://www.onlinesurveys.ac.uk/gdpr/

If any of your answers on the questionnaire cause concerns about you or your baby's safety then the Chief Investigator, who is also a practising midwife, will contact and discuss this with you and share this with your midwife.

Also, if it appears from your responses to the questionnaire that you require extra support, for example for a mental health issue, the Chief Investigator, a member of the research team, or local NHS service will contact you to discuss with you the best person to help you. The best person to help you may be your General Practitioner (GP). We will ask for your consent so that we can refer you to your GP when you access the study online.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- the leaflet available at <a href="https://www.hra.nhs.uk/patientdataandresearch">www.hra.nhs.uk/patientdataandresearch</a>
- by asking one of the research team
- by sending an email to <u>DPO@bournemouth.ac.uk</u>
- by reading Bournemouth University's <u>Research Participant Privacy Notice</u> which
  sets out more information about how we fulfil our responsibilities as a data
  controller and about your rights as an individual under the data protection
  legislation. We ask you to read this Notice so that you can fully understand the
  basis on which we will process your personal information.

#### What are the possible disadvantages and risks of taking part?

There are no expected risks to the health of you or your baby in taking part in this study. You should continue with your usual maternity care. The main disadvantage is that you will be donating around a total of 40 minutes of your time to complete the two questionnaires

and 5 minutes to provide your name, address, hospital or NHS number and hospital you have chosen to give birth in, and your postcode.

If you have any health issues that you feel have been caused by taking part in this study, and you would like support with this please contact your 24-hour local maternity service.

### What are the advantages of taking part?

There are no direct benefits to taking part in this study. However, your participation will be valuable in helping us to understand if we can find women who may require additional support, particularly during early labour. This may be important information to help reduce labour and birth interventions and improve birth experiences for these women.

## Who is organising and funding this study?

This study is an educational project in part fulfilment of a clinical midwifery doctorate (PhD) programme being undertaken by midwifery researcher Vanessa Bartholomew. It is funded by the Wessex Integrated Clinical Academic Training Programme.

### Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The Black Country Research Ethics Committee.

### Can I find out the results of this study?

Yes, you can find out the results of this study. Results will be posted on the Bournemouth University website available from:

https://www.bournemouth.ac.uk/research/projects/rethink-study

### Contacts

If you would like to talk to the researchers to help you decide whether or not you would like to take part and answer any questions you may have, then please contact:

Chief Investigator Vanessa Bartholomew <u>vbartholomew@bournemouth.ac.uk</u>

and contact for Faculty of Health and Social Sciences

more information Bournemouth University

about this study: Studland House

Christchurch Road

Bournemouth BH1 3NA Tel: 07735 388820

Study Sponsor is: Bournemouth University

Study Identifier: IRAS 270583 Version 1.13 07/01/2022

Sponsor Contact: Suzy Wignall researchethics@bournemouth.ac.uk

Research Development and Support

Studland House

12 Christchurch Road Bournemouth Dorset BH1 3NA

Your Local {Contact details/delete as applicable}

NHS Research Team:

#### **Complaints**

If you wish to complain about any aspect of this research, please contact the Chief Investigator or alternatively:

Executive Dean of the Faculty of Health and Social Sciences:

Professor Stephen Tee research
governance@bournemouth.ac.uk

Bournemouth University

Studland House

Christchurch Road

Alternatively, you can contact your local Patient Advice and Liaison Service (PALS). For details of your nearest PALS office you can go to the NHS website:

Bournemouth BH1 3NA

https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/

OR:

You can also ask your GP surgery, hospital or phone NHS 111

## Online link to **THE RETHINK STUDY**:

# https://bournemouth.onlinesurveys.ac.uk/rethink-study-270583

Email address from which you will receive the request for your personal identification information, the online link to the postnatal questionnaire, and one reminder:

vanessa.bartholomew@dchft.nhs.uk

You may wish to check how to prevent this email from going to your junk/spam folder with your personal email service. Alternatively, please check your junk/spam folder regularly.

## Thank you very much for considering taking part in this research study.

For administrative use only: NHS Trust site:

Date and time when the RETHINK Study was introduced:

Staff Signature: Print Name and Designation:

## 14.2 Appendix 2 Eligibility Criteria

(Word Document Version for Protocol)



No

## **Eligibility Criteria**

| To be eligible to take part in this study you should be:   |
|--|
| at least 25 weeks and no more than 33 weeks and 6 days pregnant,   |
| between 18 and 40 years old,   |
| you should not have given birth to a baby after you reached 24 weeks pregnant,   |
| you are <b>not</b> receiving <b>ongoing</b> care from an obstetrician in this pregnancy,   |
| you <b>do not</b> have a current or pre-existing mental health condition requiring <b>ongoing</b> care from a perinatal mental health team i.e. specialist obstetrician, specialist midwife and/or local mental health services provision, |
| and you are not already participating in a different study that is providing support with pain management or a labour support intervention of any kind.  |
| Are you eligible?  |
| O Yes  |

(If No is answered to the above question the woman will be directed away from the questionnaire to the 'Final page' thanking them for their time and participation. If they answer Yes to the question above, they will proceed to the online consent form).



# The RETHINK Study - IRAS Number: 270583

13% complete

## Are you eligible to take part in The RETHINK Study?

## To be eligible to take part in this study you should be:

at least 25 weeks and no more than 33 weeks and 6 days pregnant,

between 18 and 40 years old,

you should not have given birth to a baby after you reached 24 weeks pregnant,

you are **not** receiving **ongoing** care from an obstetrician in this pregnancy,

you **do not** have a current or pre-existing mental health condition requiring **ongoing** care from a perinatal mental health team i.e. specialist obstetrician, specialist midwife and/or local mental health services provision,

and you are not already participating in a different study that is providing support with pain management or a labour support intervention of any kind.

Are you eligible? \* Required

| <ul><li>Yes</li><li>No</li></ul> |  |  |        |
|----------------------------------|--|--|--------|
|                                  |  |  |        |
| < Previous                       |  |  | Next > |

(Word Document Version for Protocol)



# **CONSENT FORM**

|             | nemouth<br>ersity  |  |
|-------------|--|--|
| IRAS        | SID: 270583 Protocol Version 1.13: 07/01/2022Title of Project: The                 |  |
| RET         | HINK Study   |  |
| Nam         | ne of Chief Investigator: Vanessa Bartholomew                                      |  |
|             | Please tick the box  |  |
|             | to confirm you agree   |  |
| 1.          | I confirm that I have read the paper or online version of the Participant          |  |
| Info        | rmation Sheet for this study 'The RETHINK Study'. I have had the opportunity to    |  |
| cons        | sider the information, ask questions and have had these answered satisfactorily.   |  |
| 2.<br>any   | I understand that my participation is voluntary and that I am free to withdraw at  |  |
| time        | e, up until anonymisation, without giving any reason, without my medical care or   |  |
| legal       | I  |  |
| right       | ts being affected.   |  |
| 3.<br>birth | I give permission for my NHS Hospital to share information about my labour and     |  |
| with        | the Bournemouth University Research Team for purposes of this study.               |  |
| 4.          | I give permission for the information collected about me, for the purposes of this |  |
| stud        | y, to be looked at by authorised individuals from Bournemouth University and       |  |
| othe        | er regulatory organisations so that they can check the accuracy of this study. I   |  |
| unde        | erstand this information will be anonymised before the authorised individuals and  |  |
| regu        | latory organisations see it and they will not have access to the personal          |  |
| infor       | rmation that identifies me.  |  |

| 5.     | I understand that the information collected about me for purposes of this study  |
|--------|--|
| will k | be anonymised and then shared in various formats, including online, with the     |
| publ   | ic.  |
|        |  |
| 6.     | I consent to my General Practitioner (GP) being contacted if I indicate on the   |
| ques   | tionnaire that I require extra support, for example for a mental health issue. I |
| unde   | erstand that the Chief Investigator, a member of the research team, or local NHS |
| servi  | ce will contact me to discuss this first.  |
|        |  |
| 7.     | I agree to take part in The RETHINK Study.                                       |
| Pleas  | se enter today's date either in the format dd/mm/yyyy or by clicking on the      |
| caler  | ndar symbol and selecting today's date.  |
|        | Date format DD/MM/YYYY   |
|        |  |
|        |  |
|        |  |
|        |  |
|        | FINISH AND PROCEED TO  |

## Consent Form (Online Version for Participant)



## The RETHINK Study - IRAS Number: 270583

| 21% complete  |
|---|
| Consent Form  |
| To consent to participate in The RETHINK Study it is important that you agree with all of the following statements below. |
| This part of the survey uses a table of questions, <u>view as separate questions instead?</u>                             |

Please click in the appropriate box to indicate you agree with the following 8 statements. If you decide to not participate in The RETHINK Study you can simply close the browser page.

I agree Q1. I confirm that I have read the paper or online version of the Participant Information Sheet for 'The RETHINK Study'. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. Q2. I understand that my participation is voluntary and that I am free to withdraw at any time, up until anonymisation, without giving any reason, without my medical care or legal rights being affected. Q3. I give permission for my NHS Hospital to share information about my labour and birth with the Bournemouth University Research Team for purposes of this study. Q4. I give permission for the information collected about me, for the purposes of this study, to be looked at by authorised individuals from Bournemouth University and other regulatory organisations so that they can check the accuracy of this study. I understand this information will be anonymised before the authorised individuals and regulatory organisations see it and they will not have access to the personal information that identifies me. Q5. I understand that the information collected about me for purposes of this study will be anonymised and then shared in various formats, including online, with the Q6. I consent to my General Practitioner (GP) being contacted if I indicate on the questionnaire that I require extra support, for example for a mental health issue. I understand that the Chief Investigator, a member of the research team, or local NHS service will contact me to discuss this first. Q7. I agree to take part in The RETHINK Study.

Please enter today's date either in the format dd/mm/yyyy or by clicking on the calendar symbol and selecting today's date. \* Required

| Dates need to be in the format 'DD/MM/YYYY', for example 27/03/1980.  (dd/mm/yyyy) |        |
|--|--------|
|  |        |
| < Previous   | Next > |

14.4 Appendix 4 Antenatal Questionnaire (Word document version for Protocol)



## **Antenatal Questionnaire**

IRAS ID: 270583 Protocol Version 1.13: 07/01/2022Title of Project:

The

**RETHINK Study** 

Name of Chief Investigator: Vanessa Bartholomew

## **SECTION 1:**

Q1. What is the estimated due date that you have been given by your hospital for the birth of your baby? Please enter the date in the format dd/mm/yyyy or by clicking on the calendar symbol, scrolling forward and selecting the appropriate date.



Q2. Have you ever experienced a pregnancy loss before you reached 24 weeks pregnant?

| No | Yes |  |
|----|-----|--|
|    | L.  |  |

## **SECTION 2: Your Thoughts About Labour and Birth**

This next section is about feelings and thoughts you may have at the prospect of labour and birth. The answers appear as a scale from 1 to 6. The lowest number (1) and the highest number (6) correspond to the opposite intensity of a certain thought or feeling. Please complete <u>each</u> question by clicking on one circle/radio button that most closely corresponds to how you imagine your labour and birth will be. <u>Please</u> answer how you imagine your labour and birth will be not how the way you hope it will be.

| Q3.        | How do you th | a whole? |         |         |            |  |
|------------|---------------|----------|---------|---------|------------|--|
|            | Q3a.          |          |         |         |            |  |
| 1          | 2             | 3        | 4       | 5       | 6          |  |
| $\bigcirc$ | $\circ$       | $\circ$  | $\circ$ | $\circ$ | 0          |  |
| Extrem     | ely           |          |         |         | Not at all |  |
| fantasti   | ic            |          |         |         | fantastic  |  |

## Q3. How do you think your labour and delivery will turn out as a whole?

| C         | Q3b.       |            |            |            |            |
|-----------|------------|------------|------------|------------|------------|
| 1         | 2          | 3          | 4          | 5          | 6          |
| 0         | $\bigcirc$ | $\bigcirc$ | $\bigcirc$ | $\bigcirc$ | $\circ$    |
| Extreme   | ely        |            |            |            | Not at all |
| frightful |            |            |            |            | frightful  |

|        | Q4a.       |         |            |            |            |
|--------|------------|---------|------------|------------|------------|
| 1      | 2          | 3       | 4          | 5          | 6          |
|        | $\bigcirc$ | $\circ$ | $\bigcirc$ | $\bigcirc$ | $\circ$    |
| Extrem | ely        |         |            |            | Not at all |
| lonely |            |         |            |            | lonely     |

|         | Q4b.       |   |   |   |            |
|---------|------------|---|---|---|------------|
|         | $\bigcirc$ | 3 | 4 | 5 | 6          |
| Extreme | ely        |   |   |   | Not at all |
| strong  |            |   |   |   | strong     |

# Continued: -

| Q4c.  |                    |            |                    |                 |
|---|--------------------|------------|--------------------|-----------------|
| 1 2 C   | 3                  | 4          | 5                  | 6<br>Not at all |
| confident   |                    |            |                    | confident       |
|   |                    |            |                    |                 |
| Q4d.  |                    |            |                    |                 |
| $ \begin{array}{ccc} 1 & & 2 \\ \hline \end{array} $                | 3                  | 4          | 5                  | 6               |
| Extremely   |                    |            |                    | Not at all      |
| afraid  |                    |            |                    | afraid          |
|   |                    |            |                    |                 |
| Q4e.  |                    |            |                    |                 |
| $ \begin{array}{ccc} 1 & & 2 \\ \bigcirc & & \bigcirc \end{array} $ | 3                  | 4          | 5                  | 6               |
| Extremely   |                    |            |                    | Not at all      |
| deserted  |                    |            |                    | deserted        |
|   |                    |            |                    |                 |
| Q4f.  |                    |            |                    |                 |
| 1 2   | 3                  | 4          | 5                  | 6               |
| 0 0   | $\bigcirc$         | $\bigcirc$ | $\bigcirc$         | $\circ$         |
| Extremely   |                    |            |                    | Not at all      |
| weak  |                    |            |                    | weak            |
| Q4g.  |                    |            |                    |                 |
| 1 2   | 3                  | 4          | 5                  | 6               |
|   | $\tilde{\bigcirc}$ | $\bigcap$  | $\tilde{\bigcirc}$ |                 |
| Extremely   |                    | $\bigcup$  | $\bigcirc$         | Not at all      |
| safe  |                    |            |                    | safe            |

# Continued: -

| Q4h.  1 2  Extremely independent   | 3 | 4 | 5 | 6<br>O<br>Not at all<br>independent |
|--|---|---|---|-------------------------------------|
| Q4i.  1 2  Extremely desolate  | 3 | 4 | 5 | 6<br>O<br>Not at all<br>desolate    |
| Q4j.  1 2  Extremely tense   | 3 | 4 | 5 | 6<br>Not at all<br>tense            |
| Q4k.  1 2  Capacitan Control C | 3 | 4 | 5 | 6<br>O<br>Not at all<br>glad        |
| Q4I.  1 2  Extremely   | 3 | 4 | 5 | 6<br>O<br>Not at all                |

# Continued: -

| Q4m.  1 2  Extremely abandoned | 3 | 4 | 5 | 6<br>O<br>Not at all<br>abandoned |
|--------------------------------|---|---|---|-----------------------------------|
| Q4n.  1 2  Totally composed    | 3 | 4 | 5 | 6<br>O<br>Not at all<br>composed  |
| Q4o.  1 2  Extremely relaxed   | 3 | 4 | 5 | 6<br>O<br>Not at all<br>relaxed   |
| Q4p.  1 2  Extremely happy     | 3 | 4 | 5 | 6<br>O<br>Not at all<br>happy     |
| Q4q.  1 2  Extreme panic       | 3 | 4 | 5 | 6<br>O<br>No panic<br>at all      |

# Continued: -

# Q4. How do you think you will feel in general during the labour and delivery?

| Q4r.            |            |            |            |               |
|-----------------|------------|------------|------------|---------------|
| 1 2             | 3          | 4          | 5          | 6             |
|                 | $\bigcirc$ | $\bigcirc$ | $\bigcirc$ | $\bigcirc$    |
| Extreme         |            |            |            | No            |
| hopelessness    |            |            |            | hopelessness  |
|                 |            |            |            | at all        |
|                 |            |            |            | at an         |
| Q4s.            |            |            |            |               |
| 1 2             | 3          | 4          | 5          | 6             |
|                 | $\bigcirc$ | $\bigcirc$ | $\bigcirc$ | $\bigcirc$    |
| Extreme         |            |            |            | No longing    |
| longing for     |            |            |            | for the child |
| the child       |            |            |            | at all        |
|                 |            |            |            |               |
| Q4t.            |            |            |            |               |
| 1 2             | 3          | 4          | 5          | 6             |
|                 | $\bigcirc$ | $\bigcirc$ | $\bigcirc$ | $\bigcirc$    |
| Extreme         | •          |            |            | No self-      |
| self-confidence |            |            |            | confidence    |
|                 |            |            |            | at all        |
|                 |            |            |            |               |
| Q4u.            |            |            |            |               |
| 1 2             | 3          | 4          | 5          | 6             |
|                 | $\bigcirc$ | $\bigcirc$ | $\bigcirc$ | $\circ$       |
| Extreme         |            |            |            | No trust      |
| <br>  trust     |            |            |            | at all        |

# Continued: -

# Q4. How do you think you will feel in general during the labour and delivery?

| Q4v.              |                  |               |                  |              |
|-------------------|------------------|---------------|------------------|--------------|
| 1 2               | 3                | 4             | 5                | 6            |
|                   | $\bigcirc$       | $\bigcirc$    | $\bigcirc$       | O            |
| Extreme           |                  |               |                  | No pain      |
| pain              |                  |               |                  | at all       |
| Q5. What do you   | think will happe | en when labou | r is most intens | e?           |
|                   |                  |               |                  |              |
| Q5a.              |                  |               |                  |              |
| 1 2               | 3                | 4             | 5                | 6            |
|                   | $\bigcirc$       | $\bigcirc$    | $\bigcirc$       | $\circ$      |
| I will behave     |                  |               |                  | I will not   |
| extremely badly   |                  |               |                  | behave badly |
|                   |                  |               |                  |              |
|                   |                  |               |                  | at all       |
|                   |                  |               |                  |              |
| Q5b.              |                  |               |                  |              |
| 1 2               | 3                | 4             | 5                | 6            |
|                   | $\bigcirc$       | $\bigcirc$    | $\bigcirc$       | $\bigcirc$   |
| I will dare to    |                  |               |                  | I will not   |
| totally surrender |                  |               |                  | dare to      |
| control to        |                  |               |                  | surrender    |
| my body           |                  |               |                  | control to   |
|                   | my               |               |                  |              |

body at all

# **Continued:**

# Q5. What do you think will happen when labour is most intense?

| Q5c.           |             |                  |                |                |              |
|----------------|-------------|------------------|----------------|----------------|--------------|
| 1              | 2           | 3                | 4              | 5              | 6            |
|                | $\bigcirc$  | $\bigcirc$       | $\bigcirc$     | $\bigcirc$     | $\bigcirc$   |
| I will totally | ,           | <b>O</b>         | J              |                | I will not   |
| lose contro    | I           |                  |                |                | lose control |
| of myself      |             |                  |                |                | of myself    |
|                |             |                  |                |                | at all       |
| Q6. Hov        | v do you im | agine it will fe | el the very mo | ment you deliv | er the baby? |
|                |             |                  |                |                |              |
| Q6a.           |             |                  |                |                |              |
| 1              | 2           | 3                | 4              | 5              | 6            |
| 0              | $\bigcirc$  | $\circ$          | $\bigcirc$     | $\bigcirc$     | $\circ$      |
| Extremely      |             |                  |                |                | Not at all   |
| funny          |             |                  |                |                | funny        |
| Q6b.           |             |                  |                |                |              |
| 1              | 2           | 3                | 4              | 5              | 6            |
|                | $\bigcirc$  | $\bigcirc$       | $\bigcirc$     | $\bigcirc$     | $\bigcirc$   |
| Extremely      | O           | O                |                |                | Not at all   |
| Natural ,      |             |                  |                |                | natural      |
|                |             |                  |                |                |              |
| Q6c.           |             |                  |                |                |              |
| 1              | 2           | 3                | 4              | 5              | 6            |
|                | $\bigcirc$  | $\bigcirc$       | $\bigcirc$     | $\bigcirc$     | $\bigcirc$   |
| Extremely      |             |                  |                |                | Not at all   |
| self-eviden    | t           |                  |                |                | self-evident |

### **Continued:**

| Q6. | How do | you imagine | it will feel t | he very m | noment yo | ou deliver t | the baby? |
|-----|--------|-------------|----------------|-----------|-----------|--------------|-----------|
|-----|--------|-------------|----------------|-----------|-----------|--------------|-----------|

| 1          | 2            | 3               | 4               | 5               | 6                   |
|------------|--------------|-----------------|-----------------|-----------------|---------------------|
| $\circ$    | $\bigcirc$   | $\circ$         | $\bigcirc$      | $\circ$         | $\bigcirc$          |
| Extremely  |              |                 |                 |                 | Not at all          |
| dangerous  |              |                 |                 |                 | dangerous           |
| Q7. Ha     | ve you, duri | ng the last mor | ith, had fantas | ies about the l | abour and delivery, |
| for examp  |              |                 | ·               |                 |                     |
| O7a        | fantasies    | that your child | will die during | labour/deliver  | <i>1</i> ?          |
| 1          | 2            | 3               | 4               | 5               | 6                   |
| Ō          | Ō            | Ö               | $\circ$         | Ö               | Ö                   |
| Never      |              |                 |                 |                 | Very often          |
| Q7b        | fantasies    | that your child | will be injured | during labour/  | delivery?           |
| 1          | 2            | 3               | 4               | 5               | 6                   |
| $\bigcirc$ | $\bigcirc$   | $\bigcirc$      | $\bigcirc$      | $\bigcirc$      | $\circ$             |
|            |              |                 |                 |                 | Very often          |

# **SECTION 3: About Current Pain**

| Q9. H   | ave y | ou ever   | had pro  | evious p | oain of    | any kind | d (e.g. b | ack pair | n) that has la | ısted    |
|---------|-------|-----------|----------|----------|------------|----------|-----------|----------|----------------|----------|
| more    | than  | 3 montl   | ns?      |          |            |          |           |          |                |          |
| No      |       |           |          |          |            |          | Yes       |          |                |          |
|         | -     | answer    | -        | to the ( | Q9 abov    | e what   | type of   | pain ha  | ve you expe    | rienced  |
|         |       |           |          |          |            |          |           |          |                |          |
|         |       |           |          |          |            |          |           |          |                |          |
| Q10. A  | Are y | ou curre  | ntly ex  | perienc  | ing pair   | 1?       |           |          |                |          |
| No      |       |           |          |          |            |          | Yes       |          |                |          |
| Q10a.   | If yo | u answe   | ered yes | s to Q10 | ) above    | what k   | ind of p  | ain are  | you currentl   | y        |
|         |       |           |          |          |            |          |           |          |                |          |
|         |       |           |          |          |            |          |           |          |                |          |
| O10h    | ı£ 🗤  | nu hava   | ancuvor  | od voc   | to 010     | ahovo t  | hat you   | aro cur  | rently exper   | rioncina |
|         | -     |           |          | -        |            | above t  | nat you   | are cur  | rently exper   | iencing  |
| pain, i | now : | severe is | s your p | am tou   | <u>ayr</u> |          |           |          |                |          |
|         | 1     | 2         | 3        | 4        | 5          | 6        | 8         | 9        | 10             |          |
|         | 0     | 0         | 0        | 0        | 0          | 0        | 0         | 0        | 0              |          |
|         | No    | pain      |          |          |            |          |           |          | Very           |          |

severe pain

### **SECTION 4: Your Thoughts About Pain**

Everyone experiences painful situations at some point in their lives. Such experiences include headache, tooth pain or muscle pain. We are interested in the types of thoughts you have when you are in pain. Below are thirteen statement describing different thoughts and feelings that may be associated with pain. Using the scale below please indicate (by clicking in one circle/radio button for each row) the degree to which you have these thoughts and feelings when in pain.

| Q11. When I am in    | Not at all | To a slight | То а     | To a great | All the |
|----------------------|------------|-------------|----------|------------|---------|
| pain                 |            | degree      | moderate | degree     | time    |
|                      |            |             | degree   |            |         |
|                      |            |             |          |            |         |
| Q11a. I worry all    |            |             |          |            |         |
| the time about       | O          | 0           |          | O          |         |
| whether the pain     |            |             |          |            |         |
| will end             |            |             |          |            |         |
|                      |            |             |          |            |         |
| Q11b. I feel I can't | 0          | 0           | 0        | 0          | 0       |
| go on                |            |             |          |            |         |
| Q11c. It's terrible  |            |             |          |            |         |
| and I think it's     |            |             |          | 0          | O       |
| never going to get   | O          |             |          |            |         |
| any better           |            |             |          |            |         |
| Q11d. It's awful and |            | _           |          | _          |         |
| I feel that it       | O          | 0           | 0        | 0          | $\cup$  |
| overwhelms me        |            |             |          |            |         |
| Over whelms me       |            |             |          |            |         |
| Q11e. I feel I can't | 0          | 0           | 0        | 0          | 0       |
| stand it anymore     | •          |             |          |            |         |
|                      |            |             |          |            |         |

| Q11f. I become<br>afraid that the pain<br>will get worse               | 0 | 0 | 0 | 0 | 0 |
|--|---|---|---|---|---|
| Q11g. I keep<br>thinking of other<br>painful events                    | 0 | 0 | 0 | 0 | 0 |
| Q11h. I anxiously want the pain to go away                             | 0 | 0 | 0 | 0 | 0 |
| Q11i. I can't seem<br>to keep it out of my<br>mind                     | 0 | 0 | 0 | 0 | 0 |
| Q11j. I keep<br>thinking about how<br>much it hurts                    | 0 | 0 | 0 | 0 | 0 |
| Q11k. I keep<br>thinking about how<br>badly I want the<br>pain to stop | 0 | 0 | 0 | 0 | 0 |
| Q11I. There's nothing I can do to reduce the intensity of the pain     | 0 | 0 | 0 | 0 | 0 |

| Q11m. I wonder if | 0 | 0 | 0 | 0 | 0 |
|-------------------|---|---|---|---|---|
| something serious |   |   |   |   |   |
| may happen        |   |   |   |   |   |
|                   |   |   |   |   |   |

### **SECTION 5: About You**

| Q12. W | /hat is your present employment situation?   |
|--------|--|
|        | Full time Self-employed Part time Maternity leave Unemployed Prefer not to say Other If other, please specify:   |
|        |  |
|        | /hat is your highest level of academic achievement? For example, GCSE, A<br>Higher National Diploma, Degree etc. |
| Q14. W | /hat is your relationship status?  |
|        | Married  |
|        | Single   |
|        | Partner  |
|        | Widow  Profer not to say   |
|        | Prefer not to say Other  |
| Ш      | If other, please specify:  |
|        |  |

| Q15. How would you descr     | ribe your ethnic   | origin?                             |             |
|------------------------------|--------------------|-------------------------------------|-------------|
| White Mixe                   | d                  | Asian or Asian British              |             |
| Black or Black British       |                    | Arab or other ethnic group          |             |
| Not known                    |                    | Other                               |             |
| If other please spec         | ify:               |                                     |             |
|                              |                    |                                     |             |
|                              |                    |                                     |             |
|                              |                    |                                     |             |
|                              |                    |                                     |             |
| <b>SECTION 6: YOUR EMA</b>   | IL ADDRESS A       | AND YOUR HOSPITAL                   |             |
| We would like your email:    | addrass so that    | we can contact you soon after yo    | OU          |
| -                            |                    | from the Chief Investigator for t   |             |
| -                            |                    | _                                   | -           |
|                              |                    | request for you to provide us wit   | -           |
| •                            | -                  | al number or NHS number. We v       |             |
| •                            | -                  | viding your pregnancy, labour an    |             |
| •                            | •                  | portant for this research and will  |             |
|                              |                    | our labour and birth details are    |             |
|                              | •                  | r full postcode. This is optional b |             |
| help us to learn more abou   | ut what affects t  | the group of women who take pa      | art in this |
| research. Your email addre   | ess will also be ι | used to send you a link to the po   | stnatal     |
| questionnaire after you ha   | ve had your bal    | by. In no circumstances will your   | personal    |
| details be made public. Inf  | ormation that y    | ou provide will be anonymised o     | during the  |
| analysis phase and before    | publication. On    | ly the Bournemouth University F     | Research    |
| Team for this study will ha  | ve access to the   | e complete set of information yo    | u provide   |
| for this study.              |                    |                                     |             |
| Q16. Please tell us your pro | eferred email ac   | ddress for purposes of this resea   | rch?        |

| Q17. Which hospital is providing your pregnancy, labour and birth, and postnatal |  |  |  |  |  |
|--|--|--|--|--|--|
| care?  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

| Q18. Is there anything else you would like to tell us?                                |                      |  |  |
|---|----------------------|--|--|
|   |                      |  |  |
|   |                      |  |  |
|   |                      |  |  |
|   |                      |  |  |
| If you have been affected by anything in this questionnaire, or you have any          |                      |  |  |
| concerns about your physical, or mental health please contact your midwife.           |                      |  |  |
|   |                      |  |  |
| Soon you will receive an email from Vanessa Bartholom                                 | new who is the Chief |  |  |
| Investigator for the RETHINK Study as specified in the Participant Information Sheet. |                      |  |  |
| You may wish to check how to prevent this email from going to your junk/spam folder   |                      |  |  |
| with your personal email service. Alternatively, please check your junk/spam folder   |                      |  |  |
| regularly. The email address of the Chief Investigator is                             | :                    |  |  |
| vanessa.bartholomew@dchft.nhs.uk  | 1                    |  |  |
| Thank you for your participation  | FINISH               |  |  |



#### The RETHINK Study

IRAS ID: 270583 Protocol Version 1.13: 07/01/2022

#### **Dear Participant**

Thank you very much for participating in the RETHINK Study. Please will you now tell us some details about you so that we can collect your labour and birth details when the time comes. We will email you again with an online link to a short postnatal questionnaire approximately three weeks after you have had your baby, or approximately three weeks after your expected due date. You may wish to check how to prevent this email from going to your junk/spam folder with your personal email service. Alternatively, please check your junk/spam folder regularly. The email address of the Chief Investigator is:

Q1. What is your full name? Please include your first name and surname / family

vanessa.bartholomew@dchft.nhs.uk

| Q2. What is your date of birth? Please write it in the format dd/mm/yyyy. |  |
|---|--|
|   |  |
|   |  |

| Q3. What is you hospital or NHS number? You may find either of these numbers on a |
|---|
| printed label on your 'handheld pregnancy record'.                                |
|   |
|   |
|   |
|   |
|   |
|   |
|   |
|   |
| Q4. Please will you tell us your postcode?  |
|   |
|   |
|   |
|   |
|   |
| Thank you.  |
|   |
| Yours faithfully  |
|   |
| Vanessa Bartholomew   |
| Desistant d Midwife and Chief Investigator for the DETUNIX Chief.                 |
| Registered Midwife and Chief Investigator for the RETHINK Study                   |



### The RETHINK Study

**IRAS ID:** 270583 **Protocol Version 1.13**: 07/01/2022

### **Request for Information**

#### **REMINDER**

**Dear Participant** 

Thank you very much for participating in the RETHINK Study. Please will you now tell us some details about you so that we can collect your labour and birth details when the time comes. We will email you again with an online link to a short postnatal questionnaire approximately three weeks after you have had your baby, or approximately three weeks after your expected due date.

| Q1. What is your full name? Please include your first name and surname / family |
|---|
| name.   |
|   |
|   |
|   |
|   |
|   |
|   |
| Q2. What is your date of birth? Please write it in the format dd/mm/yyyy.       |
|   |
|   |

| O4. Please will you tell us your postcode?  Thank you.  Yours faithfully | Q3. What is you hospital or NHS number? You may find either of these numbers on a |
|--|---|
| Thank you.   | printed label on your 'handheld pregnancy record'.                                |
| Thank you.   |   |
| Thank you.   | OA Planes III as hall as a constant 2   |
|  | Q4. Please will you tell us your postcode?  |
|  |   |
|  |   |
|  |   |
|  |   |
|  |   |
|  | Thank you.  |
| Yours faithfully   |   |
|  | Yours faithfully  |
|  |   |
|  |   |
| Vanessa Bartholomew  | Vanessa Bartholomew   |
| Registered Midwife and Chief Investigator for the RETHINK Study          | Registered Midwife and Chief Investigator for the RETHINK Study                   |

14.7 Appendix 7 Email to Participant – Postnatal Online Link



#### The RETHINK Study

**IRAS ID:** 270583 Protocol **Version 1.13**: 07/01/2022

**Online Link to the Postnatal Questionnaire Dear Participant** Congratulations on the birth of your baby. Thank you very much for participating in the RETHINK Study. Please will you now complete the final part of the study by completing the Postnatal Questionnaire. To access the Postnatal Questionnaire please click on the link below. This is a short questionnaire and should not take too long to complete. Your link to the RETHINK postnatal questionnaire: https://bournemouth.onlinesurveys.ac.uk/rethink-study-270583-postnatal Thank you. Yours faithfully

Vanessa Bartholomew

Registered Midwife and Chief Investigator for the RETHINK Study

14.8 Appendix 8 Postnatal Questionnaire Ongoing Consent



# The RETHINK Study

IRAS ID: 270583 Protocol Version 1.13: 07/01/2022

# **POSTNATAL QUESTIONNAIRE CONSENT**

| Plea | se select below either option 1 or 2 whichever applies to you.                   |  |
|------|--|--|
| 1.   | I agree to continue participating in the postnatal section of The RETHINK study. |  |
|      |  |  |
| 2.   | I do not wish to continue participating in this postnatal section of The RETHINK |  |
| Stud | dv   |  |

FINISH AND PROCEED TO

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# POSTNATAL QUESTIONNAIRE v1.6

| IRAS ID: 270583 Protocol Version 1.13: 07/01/2022 Title of the Project: The RETHINK Study   |
|---|
| SECTION 1: About You  |
| The next question will be used to match the answers you provide here to your labour and birth details and to the answers you gave on the antenatal questionnaire. This is important for the purposes of this research. Information that you provide will be anonymised during the analysis phase and before publication. Only the Bournemouth University Research Team will have access to the complete information collected for the purposes of this research. In no circumstances will your personal details be made public. |
| Q1. Please tell us the email address you have been using for correspondence for this research?  |
| SECTION 2: About Your Pregnancy  Q2. Did you receive care from a consultant obstetrician during your pregnancy?  No Yes   |

| Q2a. Please will you tell us why you received care from a consultant obstetrician |  |  |  |  |
|---|--|--|--|--|
| during your pregnancy?  |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |

| Q2b. Were you advised to have an induction of labour?                                     |  |  |  |  |
|---|--|--|--|--|
| No Yes  |  |  |  |  |
|   |  |  |  |  |
| Q2c. Did you have an induction of labour?   |  |  |  |  |
| No Yes  |  |  |  |  |
| SECTION 3: Your Thoughts About Labour And Birth   |  |  |  |  |
| Q3. How long ago did you have your baby? Please state the number of completed             |  |  |  |  |
| weeks and days in the following format e.g. 3w 4d.  |  |  |  |  |
|   |  |  |  |  |
| Q4. How long were you in labour before you went to hospital? This question relates to     |  |  |  |  |
| the first (or only) time you went to hospital. Please specify, in numbers, to the nearest |  |  |  |  |
| hour.   |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
| Q5. What were the signs that signalled to you that it was time to go to hospital when     |  |  |  |  |
| you were in labour?   |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |

| Q6. Who was <u>most</u> influential in deciding the time to go to hospital when you were in labour?   |          |              |  |
|---|----------|--------------|--|
| You   |          | Your partner |  |
| A friend  |          | Your mother  |  |
| Your father   |          |              |  |
| Other. Please   | specify: |              |  |
|   |          |              |  |
| Q7. How many times did you go to hospital, in labour, before the midwife decided it was time to stay to have your baby?   |          |              |  |
| Q8. When you were finally admitted to hospital to stay to have your baby the midwife may have undertaken a vaginal examination to determine how many centimetres your cervix was dilated (open). This important examination may have helped decide it was time to stay in hospital. If you know how many centimetres your cervix was dilated on this examination, please specify in numbers only. |          |              |  |

| home? Please select all that apply.   |    |                                  |  |  |
|---|----|----------------------------------|--|--|
| Breathing exercises   |    | Aromatherapy                     |  |  |
| Homeopathy  |    | Massage                          |  |  |
| TENS Machine  |    | Music                            |  |  |
| Shower  |    | Bath                             |  |  |
| Birthing Pool   |    | Paracetamol                      |  |  |
| Support from birth partner  |    | Hypnosis including hypnobirthing |  |  |
| Other. Please specif  | у. |                                  |  |  |
|   |    |                                  |  |  |
|   |    |                                  |  |  |
| Q10. What methods of relaxation, and pain relief did you use in hospital? Please select all that apply. |    |                                  |  |  |
| Breathing exercises   |    | Aromatherapy                     |  |  |
| Homeopathy  |    | Massage                          |  |  |
| TENS Machine  |    | Music                            |  |  |
| Shower  |    | Bath                             |  |  |

Q9. What methods of relaxation, and pain relief did you use during your labour at

| Birthing Pool  |  | Paracetamol        |  |  |
|--|--|--------------------|--|--|
| Gas and air (also  |  | Pethidine          |  |  |
| Known as Entonox or  |  |                    |  |  |
| 50% oxygen and 50%   |  | Oramorph           |  |  |
| nitrous oxide)   |  |                    |  |  |
| Diamorphine  |  | Epidural           |  |  |
| Spinal   |  | Support from       |  |  |
| •  |  | birth partner      |  |  |
|  |  |                    |  |  |
| Support from   |  | Hypnosis including |  |  |
| health professional  |  | hypnobirthing      |  |  |
| e.g. midwife   |  |                    |  |  |
| Other. Please specify.   |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
| Q11. During your labour what did you find most useful and supportive to help you manage your pain? Please comment. |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |
|  |  |                    |  |  |

| helping you manage your p   | -               |                            | iau a negative enect on       |
|-----------------------------|-----------------|----------------------------|-------------------------------|
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
| Q13. Did you attend antena  | atal classes? P | lease select all th        | nat annly                     |
| Q13. Dia you attend antene  | No              | Yes                        | ис арргу.                     |
| NHS antenatal classes       |                 |                            |                               |
| National Childbirth Trust   |                 |                            |                               |
| Other please specify        |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            |                               |
|                             |                 |                            | ngoing pain for which you are |
| receiving treatment includi | ng taking regu  | ılar pain relief mı<br>Yes | edication.                    |
|                             |                 | 163                        |                               |

| Q15. Since the birth of your baby have you experienced mental health issues? |                                    |                           |  |  |  |  |  |
|--|------------------------------------|---------------------------|--|--|--|--|--|
| No   | Yes                                |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
| Q16. If you answered yes to  | Q15, are you receiving treatmen    | t or professional support |  |  |  |  |  |
| for your mental health?  |                                    |                           |  |  |  |  |  |
| No   | Yes                                |                           |  |  |  |  |  |
| Q17. Is there anything else you would like to tell us?                       |                                    |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
| If you have any concerns abo   | out this questionnaire, or your ph | nysical or mental health  |  |  |  |  |  |
| please contact your midwife.   | please contact your midwife.       |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
| You can also contact the Chie  | ef Investigator if you have questi | ons with regards to this  |  |  |  |  |  |
| study. If so please contact the Chief Investigator at                        |                                    |                           |  |  |  |  |  |
| <u>vbartholomew@bournemouth.ac.uk</u> or telephone on 07735 388820.          |                                    |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
| Thank you very much for your participation in the RETHINK study              |                                    |                           |  |  |  |  |  |
|  |                                    |                           |  |  |  |  |  |
| When they are ready the results from this study will be posted on the        |                                    |                           |  |  |  |  |  |
| Bournemouth University website available from:                               |                                    |                           |  |  |  |  |  |
| https://www.bournemouth.ac.uk/research/projects/rethink-study                |                                    |                           |  |  |  |  |  |
|  | FINISH                             |                           |  |  |  |  |  |



#### The RETHINK Study

**IRAS ID:** 270583 Protocol **Version 1.13**: 07/01/2022

#### Online Link to the Postnatal Questionnaire

### **Reminder**

Dear Participant

We would like to take this opportunity to congratulate you again on the birth of your baby.

Thank you very much for participating in the RETHINK Study. We know this is a very busy time for you, but we are hoping you can spare a few minutes to complete the final part of this study. If you can, please will you now click on the link below. This is a short questionnaire and should take approximately 20 minutes to complete.

Your link to the RETHINK postnatal questionnaire:

https://bournemouth.onlinesurveys.ac.uk/rethink-study-270583-postnatal

Thank you.

Yours faithfully

Vanessa Bartholomew

Registered Midwife and Chief Investigator for the RETHINK Study

#### **Directly Recruiting from Poster:**

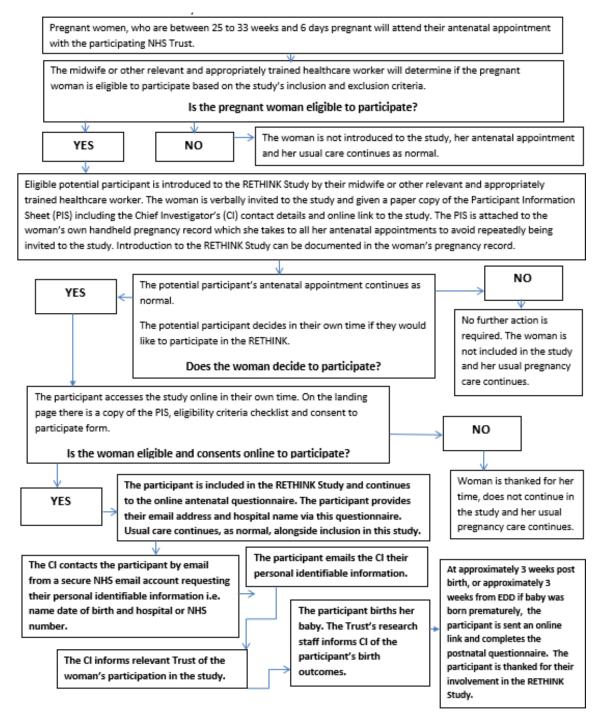


### **Poster Advertising Only and Not Directly Recruiting:**

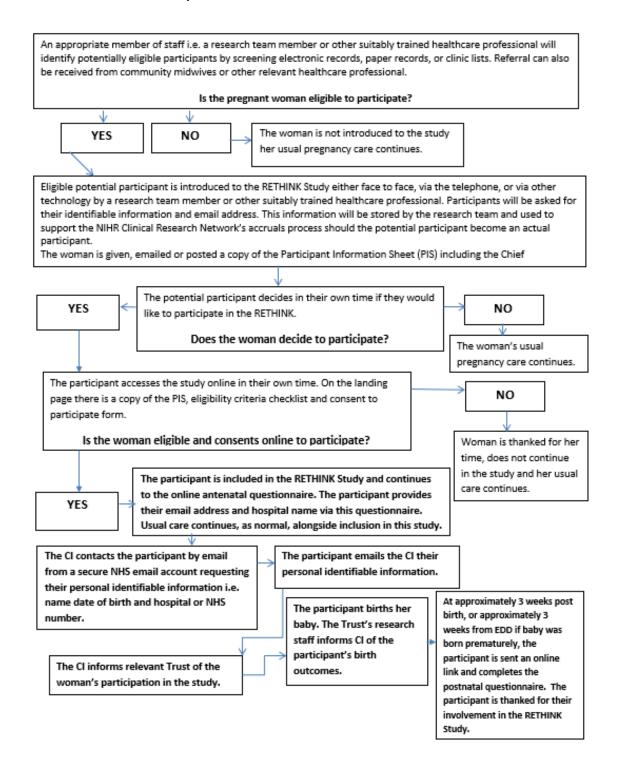


#### 14.12 Appendix 12 Flowcharts

### Recruitment Pathway 1



### Recruitment Pathway 2



#### Recruitment Pathway 3

including her email address.

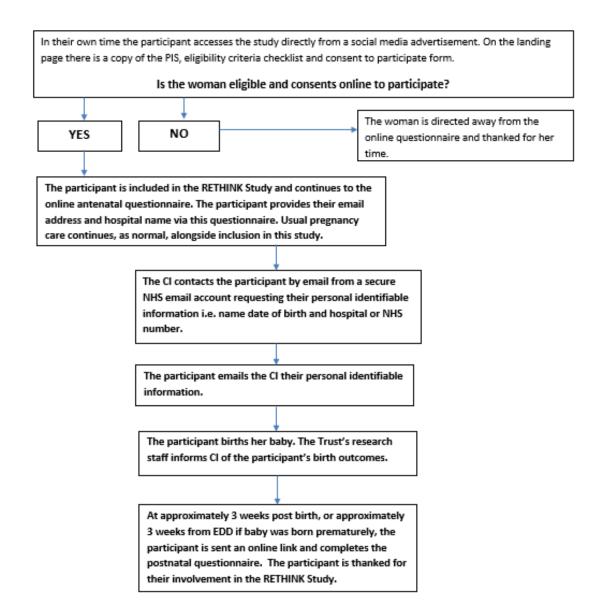
Usual care continues, as normal, alongside inclusion in this study.

An appropriate member of staff i.e. a research team member or other suitably trained healthcare professional will identify potentially eligible participants by screening electronic records, paper records, or clinic lists. Referral can also be received from community midwives or other relevant healthcare professional. Is the pregnant woman eligible to participate? The woman is not introduced to the study. YES NO The research team member or other suitably trained healthcare professional will then telephone call, face to face, or via other technology approach the eligible potential participant to discuss the study and offer to post, email or hand the PIS to the potential participant should they wish to accept it. Does the participant accept the PIS and agree to be contacted a minimum of 24 hours later to discuss the study? The woman is thanked for her time and YES NO proceeds no further. This introduction is documented by the introducing staff As agreed, the member of staff contacts the woman again either member to prevent this woman from by telephone call, face to face, or virtually. receiving further contact about this study. This follow up contact pathway will be: i.to discuss any questions the potential participant may have, Usual pregnancy care continues, as normal. ii.to ask the potential participant if they would like to take part in the study. Does the woman consent to participate? The woman is thanked for her time and proceeds no further. This introduction is documented by the introducing staff YES NO member to prevent this woman from receiving further contact about this study. The staff member will, with the consent of the participant either support the participant as they access and complete the online questionnaire or, the staff member will access the study online where they will read out the questions to the participant and enter their responses online on their behalf. The participant births her baby. The Trust's research staff inform CI of the Furthermore, with the consent of the participant, the staff participant's birth outcomes. member will record the participant's identifiable information and then immediately inform the CI of this woman's participation

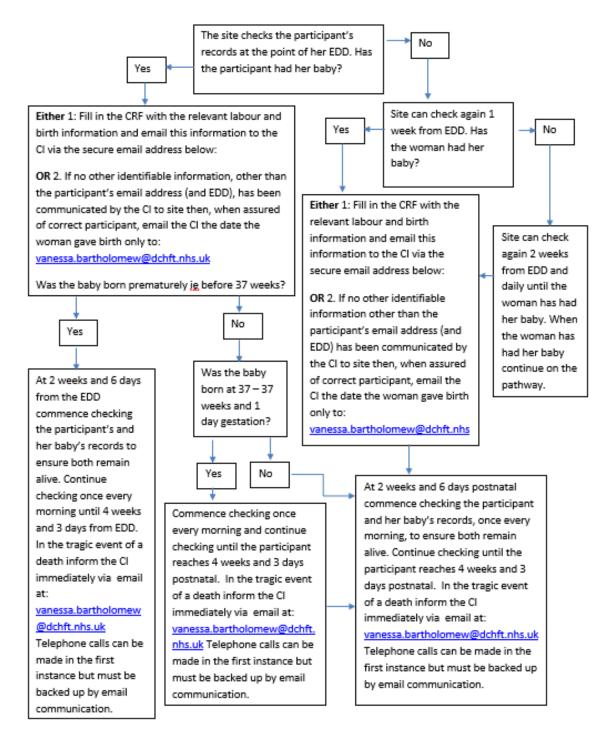
The Trust's research team is responsible for contacting the participant at approximately and no sooner than 3 weeks postnatal or, 3 weeks from the expected date the participant's baby was due if the baby was born prematurely to either support the participant as they complete the postnatal online questionnaire or, for the staff member to access the postnatal questionnaire online read out the questions to the participant and enter their responses online on their behalf.

The participant is thanked for their involvement in the RETHINK Study.

#### Recruitment Pathway 4



#### 14.12.1 Flowchart Depicting the Postnatal Checking Process Version 1.1



**NB** Please note sites are checking once in the morning before 12pm. The CI will not be sending the first or reminder postnatal email containing the link to the online questionnaire until after 12pm. The CI will not be sending any postnatal email communication on a Saturday, Sunday, Bank Holidays, Christmas Eve, Christmas Day or Boxing Day; therefore, sites will not be required to check a participant's or her baby's records on these days.

# 14.13 Appendix 13 Case Report Form



# The RETHINK Study

IRAS: 270583

| Participant Information     |  |
|-----------------------------|--|
| la. First name:             |  |
| lb. Middle name/s:          |  |
| .c. Family/last name:       |  |
| 2. Hospital number:         |  |
| 8. NHS number:              |  |
| i. Date of birth dd/mm/yww: |  |
| 5. Study I.D. number        |  |

|            | e particip<br>otocol Ap |           | ? Please (<br>.4.12.1 Pl |                |          |          |          | •       |        |
|------------|-------------------------|-----------|--------------------------|----------------|----------|----------|----------|---------|--------|
|            | articipan               | -         |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
| 6b. Is the | l<br>e particip         | ant's bab | v alive?                 | l<br>Please er | sure the | relevant | checks a | re made | as per |
|            | y protoco               |           | •                        |                |          |          |          |         |        |
| checked    | on the p                | articipan | t's hospit               | al record      | ls.      |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |
|            |                         |           |                          |                |          |          |          |         |        |

6c. If the participant is following recruitment pathway 1, 2 or 4 please complete.

If either the participant or the participant's baby has sadly died please initial in the box to confirm the Chief Investigator for this study has been informed by NHS emails?

6d. If the participant is following recruitment pathway 3 please complete.

If either the participant or the participant's baby has sadly died, please initial in the box to confirm all action has been taken to prevent all future correspondence being sent to the participant and that the Chief Investigator for this study has been informed by NHS emails?

| 7. Has there been an adverse event (see section 9.0 Risks and Safety in the study |  |  |  |  |
|---|--|--|--|--|
| protocol)? Yes  | No   |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
| Q M/hat was the nature of th  | a advarca avent?   |  |  |  |
| 8. What was the nature of th  | e adverse event?   |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
| 9. What action was taken? As  | s part of your action please inform the Chief Investigator |  |  |  |
| urgently of any adverse even  | t.   |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
| Labour and Birth Details  |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
| <ol><li>Estimated date for delivery:</li></ol>                                    |  |  |  |  |
|   |  |  |  |  |
| 11. Actual date of delivery:  |  |  |  |  |
|   |  |  |  |  |
| 12. Was the outcome of delivery a live birth:                                     | Yes No   |  |  |  |
|   |  |  |  |  |
| 13. Spontaneous vaginal birth:  | Yes No No  |  |  |  |
|   |  |  |  |  |
| 14. Induction of labour:  | Yes No No  |  |  |  |
|   |  |  |  |  |
| 15. Indication for induction of labour:   |  |  |  |  |
|   |  |  |  |  |
| 16. Augmentation of labour:   | Yes No   |  |  |  |
|   |  |  |  |  |
| 17. Indication for augmentation of labour:  |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |

19. Amniotomy:

| 20. Oxytocin or syntocinon infusion:    | Yes | No   |  |
|---|-----|------|--|
|   |     |      |  |
| 21. Duration of labour (hh:mm):         |     |      |  |
| 21a. 1st stage/active labour:           |     |      |  |
|   |     |      |  |
| 21b. 2 <sup>nd</sup> stage of labour:   |     |      |  |
|   |     |      |  |
| 21c. 3 <sup>rd</sup> stage of labour:   |     |      |  |
| -                                       |     |      |  |
| 21d. Total duration:                    |     |      |  |
|   |     |      |  |
| 22. Spontaneous vaginal birth on land:  | Vac | No   |  |
| 22. Sportaneous vaginar birtir on land. | 163 | 140  |  |
| 03.0                                    | v   |      |  |
| 23. Spontaneous vaginal birth in water: | res | No   |  |
|   |     |      |  |
| 24. Ventouse:                           | Yes | No   |  |
|   |     |      |  |
| 25. Forceps:                            | Yes | No   |  |
|   |     | [    |  |
| 26. Elective caesarean section:         | Yes | No   |  |
|   |     |      |  |
| 26a. If Yes to Q26 please give reason:  |     |      |  |
|   |     | <br> |  |
| 27. Emergency caesarean section:        | Yes | No   |  |
|   |     |      |  |
| 27a. If Yes to Q27 please give reason:  |     |      |  |

| 28. Birthing pool:   | Yes    | No |  |  |  |
|--|--------|----|--|--|--|
| 29. TENS machine:  | Yes    | No |  |  |  |
| 30. Paracetamol:   | Yes    | No |  |  |  |
| 31. Oramorph:  | Yes    | No |  |  |  |
| 32. 50% nitrous oxide & 50% oxyge<br>(i.e. gas and air / Entonox):   | en Yes | No |  |  |  |
| 33. Pethidine:   | Yes    | No |  |  |  |
| 34. Diamorphine:   | Yes    | No |  |  |  |
| 35. Epidural:  | Yes    | No |  |  |  |
| 36. Spinal:  | Yes    | No |  |  |  |
| 37. Other: Please specify  |        |    |  |  |  |
| 38. Please enter the date (dd/mm/yyyy) the Chief Investigator for The RETHINK Study was informed about the woman's delivery date and labour and birth details: |        |    |  |  |  |
|  |        |    |  |  |  |

#### **Recruitment Pathway 4**

#### The RETHINK Study - Can we reduce hospital admission in early labour? v1.2

Maternity care research Recruiting participants now!

The RETHINK Study is a study that aims to see if we can detect those women who may find extra support for early labour useful, to help reduce their chance of a difficult labour and unnecessary intervention. To date research has not shown the best way to support women who are in early labour at home.

This study will follow participants through pregnancy, labour and birth, and into the postnatal period to see if we can identify those women who might benefit from additional support in early labour. To help us do this we would like you to complete two questionnaires, one whilst you are pregnant and the other one around 3 weeks after you have had your baby, or 3 weeks from your expected due date if you give birth to your baby earlier than anticipated. We will also be asking for your permission for your hospital to tell us some details about your labour and birth.

This study is open to 18 to 40 year old women who are expecting their first baby, and are planning a hospital birth, and who are expecting an uncomplicated pregnancy. You will be asked to complete the first questionnaire when you are between 25 and 33 weeks and 6 days pregnant. Participants must be able to understand and read English, have internet access and an email address for study correspondence.

If you are planning to have your baby at {INSERT TRUST DETAILS HERE} you can get involved by either accessing the study directly by clicking on the link below or, you can contact your midwife directly, or you can contact your local research team. But before you decide, it is important for you to understand why this research is being carried out and what it will involve. This information to help you decide is in the Participant Information Sheet. You will be given the opportunity to read the Participant Information Sheet when you first access The RETHINK Study online. Please take time to read this information before you agree to take part.

To access The RETHINK Study online please click the link below:

## https://bournemouth.onlinesurveys.ac.uk/rethink-study-270583

If you would like more information please ask your midwife, your local research team, or the Chief Investigator for this study.

Local Research Team contact information: {INSERT DETAILS HERE}

Chief Investigator for this study is Vanessa Bartholomew: <a href="mailto:vbartholomew@bournemouth.ac.uk">vbartholomew@bournemouth.ac.uk</a>

Thank you ☺



#### The RETHINK Study - Can we reduce hospital admission in early labour? v1.2

Maternity care research Recruiting participants now!

The RETHINK Study is a study that aims to see if we can detect those women who may find extra support for early labour useful, to help reduce their chance of a difficult labour and unnecessary intervention. To date research has not shown the best way to support women who are in early labour at home.

This study will follow participants through pregnancy, labour and birth, and into the postnatal period to see if we can identify those women who might benefit from additional support in early labour. To help us do this we would like you to complete two questionnaires, one whilst you are pregnant and the other one around 3 weeks after you have had your baby, or 3 weeks from your expected due date if you give birth to your baby earlier than anticipated. We will also be asking for your permission for your hospital to tell us some details about your labour and birth.

This study is open to 18 to 40 year old women who are expecting their first baby and are planning a hospital birth at {HOSPITAL NAME}, and who are expecting an uncomplicated pregnancy. You will be asked to complete the first questionnaire when you are between 25 and 33 weeks and 6 days pregnant. Participants must be able to understand and read English, have internet access and an email address for study correspondence.

To get involved please contact your midwife directly{, or alternatively you can contact your Local Research Midwife at: {enter contact details or delete as applicable}.

For more information you can contact Vanessa Bartholomew who is the Chief Investigator for this study by email at: <a href="mailto:vbartholomew@bournemouth.ac.uk">vbartholomew@bournemouth.ac.uk</a>

Thank you ©





# Let's RETHINK Early Labour

Are you expecting your first baby, planning to experience early labour at home, and under midwifery care?

Will you take part in research exploring support for women in early labour?

Complete one online questionnaire when you are between 25 and 33 weeks and 6 days pregnant and a second online questionnaire about 3 weeks after you have had your baby.

We would also like to collect some details about your labour and birth.

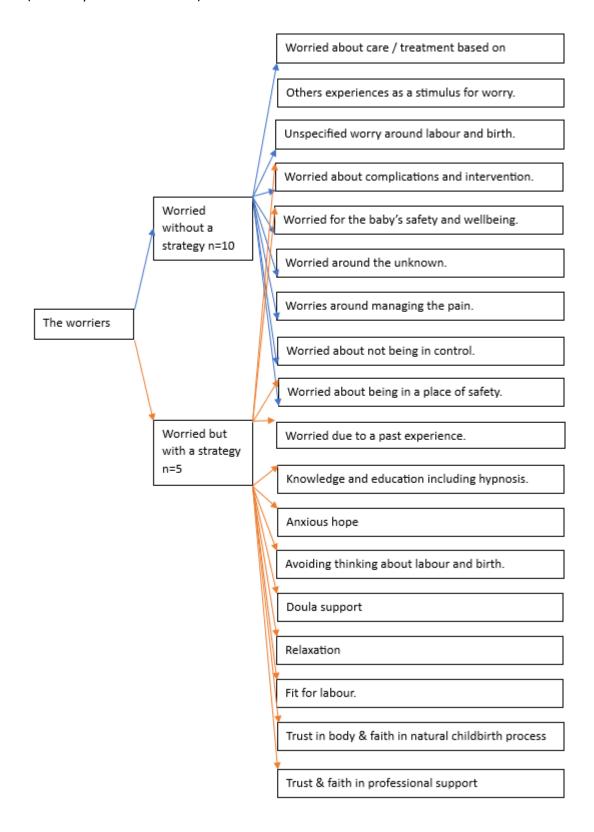
For more information please ask your midwife or contact:

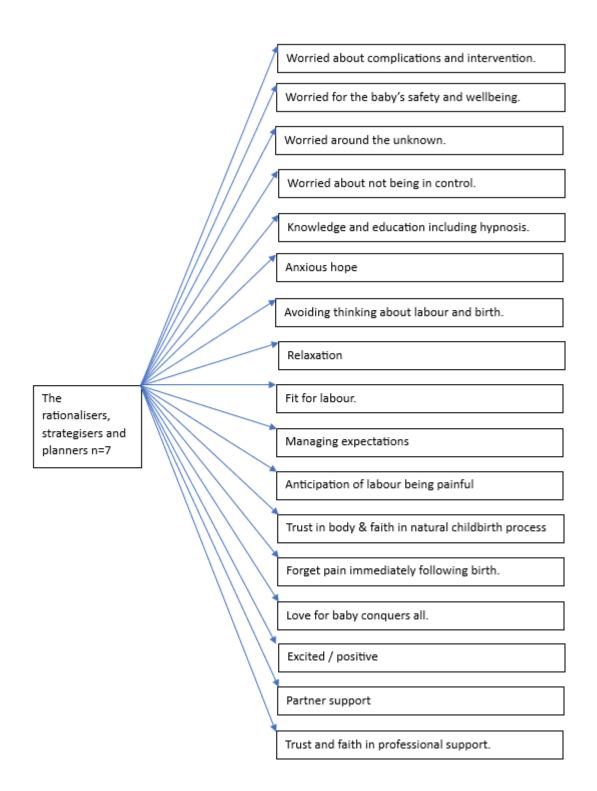
Chief Investigator: Vanessa Bartholomew <a href="https://www.bartholomew@bournemouth.ac.uk">wbartholomew@bournemouth.ac.uk</a>
Or contact your Local Research Team: <a href="team">(Contact details/delete as applicable)</a>
The RETHINK Study Protocol Version 1.12 19/07/2021 IRAS: 270583

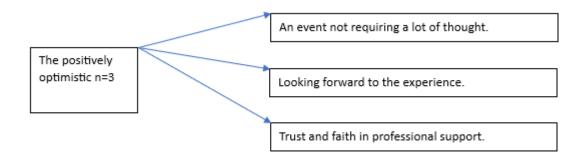


### Appendix 7 Coding strategy matrices for Question 8.

(See Chapter 9 Section 9.4)

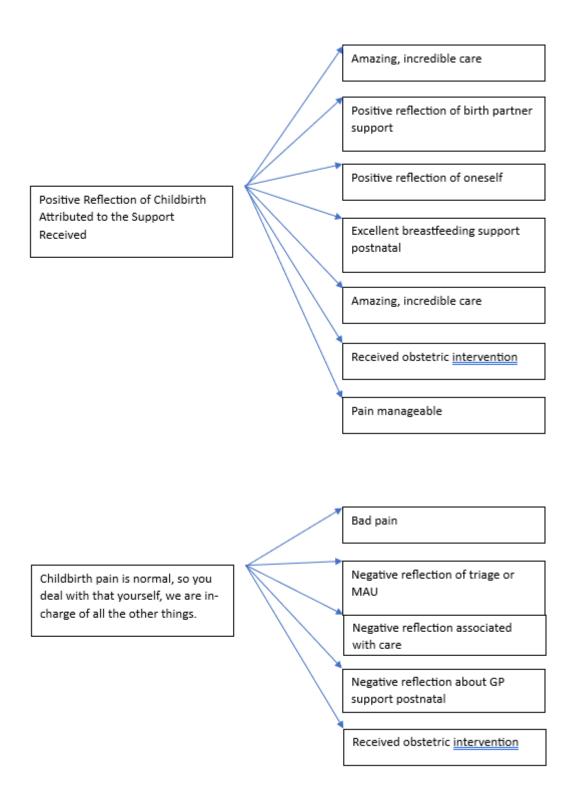


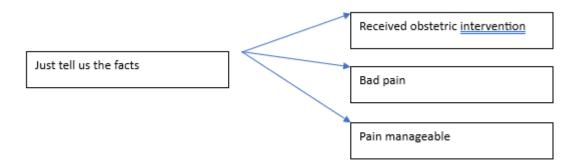




## Appendix 8 Coding strategy matrices for Question 17.

(See Chapter 9 Section 9.4)





Amendments

Prize winner

