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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ABSTRACT

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 pre-specified 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 $p \leq 0.05$.

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

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

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 achieved	Whether they have/had ongoing pain that has lasted more than 3 months
Postcode	A brief pain experience history, which also includes current pain and its severity
Ethnicity	

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 (WDEQ-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 experiencing an uncomplicated singleton pregnancy, and who are planning a hospital birth	Women who are receiving ongoing 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	Women with a current or pre-existing mental health condition requiring current medication and/or care by perinatal mental health team, e.g. specialist obstetrician, specialist midwife and/or local mental health services provision
Antenatal women who are between 25–33 weeks gestation	
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

Table 4. The four recruitment pathways

Recruitment pathway	Recruitment process
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

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 non-pharmacological interventions such as breathing exercises, music, hypnosis, baths, showers, birthing pool.

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

Study strengths

1. 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
2. It aims to fill the gap in knowledge about whether pain catastrophising is a risk factor for admission in the latent phase of labour
3. It will indicate the prevalence of pain catastrophising and fear of pain in the study group
4. 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
5. 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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