

The application of commercial wearable technology and smartphone rehabilitation applications for enhancing individuals' level of activity after hip replacement surgery

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Abstract

Title: The application of commercial wearable technology and Smartphone rehabilitation applications for enhancing individuals' level of activity after hip replacement surgery

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Total hip replacement (THR) is one of the most common and successful orthopaedic operations worldwide that offers pain relief, even at week one post-surgery. However, many studies suggested that the aim should not only be to improve pain, but also lead to improving daily activity which currently does not follow the same positive trend.

Commercially available activity monitoring wearables and smartphone apps have the potential to engage patients as advocates in their personalised care, but the systematic review conducted in this integrated thesis identified that the evidence of their use in THR population is limited. Furthermore, findings from Patient and Public Involvement (PPI) study, showed that, in the absence of pain post-surgery, a major motivator for individuals undergoing THR surgery is their desire to participate in walking activities. Given the importance of walking to this group, an assessment of gait data 6-month post-surgery was carried out using a self-paced instrumented treadmill. Data indicated that despite gradual improvement from pre surgery to up to 6 months post-surgery, the walking speed and step length of the THR group remain statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence is improved and recovers, when compared to the control group, as early as the 6 weeks stage post-surgery. Indeed, it might even be earlier than that, but intervening measurements were not made. It then remains constant up to the 6-month assessment. However, it is important to note that, the step length and walking speed do not recover so quickly and only become closer to that of the control group over the first 6 months. This could be interpreted that as the patients rehabilitate, their range of movement only gradually improves and that although the number of steps might rapidly get back to the levels of the control group, the distance walked, and walking efficiency does not recover so quickly. Therefore, step count which has readily been identified as an indicator of walking ability and reported as a parameter for enhancing long-term activity levels and subsequently returning to walking freely, may not be the best indicator. Meanwhile, studies reported that an ability to walk even a short distance outdoors can be meaningful for successful and independent living at home among the THR group as well as enhancing their physical function.

On the other hand, despite commercial wearable activity monitors having been suggested as a possible motivator to enhance individuals' compliance to self-care and increase the chance of long-term quality of life, there was no evidence which activity monitor is most suitable for this population. Therefore, an exhaustive screening of the most popular wearable activity monitor with the most suitable interface was carried out. The Fitbit Charge 4 (FC4) activity monitor was selected as the most appropriate wearable activity monitor.

The findings prompted a mixed-method feasibility study to evaluate the feasibility of personalised outdoor walking which was referred to as a 'purposeful walk' intervention. The findings from this study suggested that the intervention was feasible and that it encouraged all participants to increase their daily activity. Outcome measures were also streamlined in order to inform a follow up study that aimed to evaluate the effectiveness of such an intervention. Designed as a randomised pilot trial, the final study aimed to determine the effect of an intervention where outdoor walking distance was used as a goal to increase daily

activity of older adults, using a commercial activity monitor, at 3 to 6 months post THR. The final study results suggested that the participants in the intervention group had higher activity levels after THR, compared to those in the control group. The Cohen's effect size was larger for the changes in the gait, HOOS, and PIADS data in the intervention group in contrast to the control group. However, further research with a larger sample size is suggested to provide tangible evidence on the significance of the effect of the purposeful walk in contrast to step count.

List of Contents

Abstrac	t		3
List of T	ables		13
List of F	igures	i	14
Integrat	ed Pa	pers	15
Acknow	ledge	ments	16
Glossar	y of Te	erms	17
Chapter	1 – Ir	ntroduction	19
1.1	Cha	pter overview	19
1.2	The	authors' research journey	19
1.3	Bac	kground	20
1.3.1	. Т	otal hip replacement surgery	20
1.3.2	. C	ommercial activity monitors	21
1.4	Aim	s and objective	22
1.5	Me	thodological overview and relevant justifications	24
1.5.1	G	ait analysis	25
1.5.2	Р	atient Reported Outcome Measure (PROMS)	25
1.5.3	A	ssessment of precision and accuracy of the activity monitor	26
1.5.4	C	Qualitative analysis	26
1.6	Cha	pter summary	27
Chapter	2 – L	iterature Review	29
2.1	Cha	pter overview	29
2.2	Rev	iew Article	29
2.3	Nev	v evidence, revision of aims and objectives	49
2.3	3.1	Introduction	49
2.3	3.2	New evidence	49
2.3	3.3	Reflection on the review	61
2.4	Cha	pter Summary	62
Chapter	3 – V	Vhy Do People Undergo THR - Patient and Public Involvement	65
3.1	Cha	pter overview	65
3.2	Pat	ent and public involvement (PPI) article	65
3.3	Ref	lection on the PPI study	76
3.4	Cha	pter summary	77
Chanter	· 4 – Т	he Covid-19 nandemic	80

	4.1	Chapter overview	80
	4.2	The timeline of Covid-19	80
	4.3	The impact of Covid-19 on research	81
	4.4	The impact of Covid-19 on research	82
	4.4.1	Early closure of lab-based research	82
	4.4.2	Suspension of research involving human participants	83
	4.5	Chapter summary	84
C	hapter 5	– Analysis of Walking in THR Population	86
	5.1	Chapter overview	86
	5.2	Spatio-temporal characteristics of THR individuals and their relevance to walking	86
	5.2.1	Introduction	86
	5.2.2	Methodology	88
	5.2.2.1	Participants	88
	5.2.2.2	Protocol	91
	5.2.2.3	Data processing and analysis	91
	5.2.2.4	Statistical analysis	91
	5.2.3	Results	92
	5.2.4	Discussion	94
	5.2.5	Chapter summary	95
C	hapter 6	Selection and Evaluation of Activity Monitors	97
	6.1.	Chapter overview	97
	6.2.	Evaluation of available technology	98
	6.2.1	Introduction	98
	6.2.2	Methodology	99
	6.2.2.1	Smartphone apps	99
	6.2.2.1.	1 Data extraction	99
	6.2.2.1.	1.1 The Mobile App Rating Scale (MARS)	. 100
	6.2.2.1.	1.2 Guideline's assessment	. 101
	6.2.2.1.	2 Outcome analysis	. 101
	6.2.2.2	Wearable activity monitor	. 104
	6.2.3	Results	. 104
	6.2.3.1	Smartphone apps	. 104
	6.2.3.2	Wearable activity monitors	. 109
	6.2.4	Summary	. 110
	6.3.	An Evaluation of Accuracy and Precision of Selected Commercial Activity Monitors to	
	Measur	e Walking Distance.	.113

6.3.1	Introduction	113
6.3.2	Methodology	114
6.3.2.1	Participants	114
6.3.2.2	Procedure	115
6.3.2.3	Data analysis	116
6.3.2.4	Data visualisation	116
6.3.2.5	Ethical approval	117
6.3.3	Results	118
6.3.4	Discussion	122
6.3.5	Summary	126
	n Evaluation of Accuracy, Consistency, and Precision of Fitbit Charge 4 in different	
settings		127
6.4.1	Introduction	
6.4.2	Methodology	
6.4.2.1	Settings	
6.4.2.1.1	, .	
6.4.2.1.2	FC4 accuracy and precision in an outdoor and indoor shuttle walk	135
6.4.2.1.3 with and	Consistency of different FC4 activity monitors in indoor and outdoor walk setting without GPS sensor	
6.4.2.1.4 and does	Does FC4 step length adjust automatically in an outdoor walk using the GPS sense this affect the algorithm-activated outdoor distance accuracy	
6.4.2.2	Outcomes	137
6.4.2.2.1	Statistical analysis	137
6.4.2.3	Results	138
6.4.2.3.1	FC4 accuracy and precision in long outdoor walks	138
6.4.2.3.2	FC4 accuracy and precision in an outdoor and indoor shuttle walk	138
6.4.2.3.3	Consistency of different FC4 activity monitors in an outdoor and indoor walk	139
6.4.2.3.4 based on	The accuracy of ALG indoor distance calculation using the FC4 step length estima the GPS sensor	
6.4.2.4	Discussion	145
6.4.2.5	Summary	147
6.5. Cl	napter summary	149
Chapter 7 –	A Feasibility Study to Evaluate a Purposeful Walk Intervention with a Distance Goal	using
a Commerc	ially Available Activity Monitor in Individuals Post Total Hip Replacement Surgery	151
7.1 Cl	napter overview	151
Abstract		152
Keywords:	Fotal hip replacement; Activity monitor; Walking activity; Gait analysis	153

	7.2	ntroduction	. 154
	7.3	Methods	. 157
	7.3.1	Study design	. 157
	7.3.2	Participants	. 157
	7.3.3	Setting	. 157
	7.3.4	Intervention	.160
	7.3.5	Sample Size	.161
	7.3.6	Statistical analysis	.161
	7.3.7	Qualitative analysis	.162
	7.3.7.1	Activity Diary	.162
	7.3.8	Quantitative analysis	.163
	7.3.8.1	Activity Monitor, FC4	.163
	7.3.8.2	Gait analysis	.163
	7.3.8.3	Patient reported outcome measures (PROMS)	.164
	7.3.8.3.	1 Hip-related disability	.164
	7.3.8.3.	2 Physical activity levels	.165
	7.3.8.3.	3 Gait efficacy	.165
	7.4	Results	.168
	7.4.1	Recruitment	.168
	7.4.2	Participant demographics	.168
	7.4.3	Feasibility and adherence of the intervention	.168
	7.4.4	Feasibility and practicality of different outcome measures	. 169
	7.4.4.1	Activity monitor:	. 169
	7.4.4.2	Gait analysis	. 170
	7.4.4.3	Patient reported outcome measures (PROMS)	. 172
	7.4.5	Qualitative findings	. 174
	7.4.5.1	Activity monitor	. 174
	7.4.5.2	Purposeful walking intervention	. 176
	7.4.5.3	Outcome measures	. 178
	7.4.5.4	Overall experience	. 180
	7.5	Discussion	. 182
	7.6	Chapter summary and conclusion	. 187
Αd	tivity M	 Can a Purposeful Walk Intervention with a Distance Goal using a Commercially Availage on the Improve Individuals' daily activity and function Post Total Hip Replacement Surguised Pilot Trial 	gery:
•		Chanter overview	189

Abstract.		192
Keywords	s: Total hip replacement; Activity monitor; Walking activity; Gait analysis	192
8.2	Introduction	193
8.3	Methods	195
8.3.1	Trial design	195
8.3.2	Participants	195
8.3.3	Setting	195
8.3.4	Intervention group	197
8.3.5	Control group	197
8.3.6	Outcomes	198
8.3.6.1	Primary outcome measure	199
8.3.6.1	.1 Walking activity	199
8.3.6.2	Secondary outcome measure	199
8.3.6.2	.1 Gait analysis	199
8.3.6.2	.2 Patient reported outcome measures (PROMS)	199
8.3.6.2	.2.1 Hip-related disability	199
8.3.6.2	.2.2 Psychosocial Impact of Assistive Devices Scale	200
8.3.7	Qualitative outcomes	201
8.3.7.1	Activity Diary	201
8.3.8	Sample Size	201
8.3.9	Randomisation	202
8.3.10	Statistical analysis	202
8.4	Results	203
8.4.1	Recruitment	203
8.4.2	Participant demographics	203
Allocat	tion	204
Assess	ment	204
Follow	⁻ -Up	204
Enroln	nent	204
Screen	ned	204
8.4.3	Activity Monitor	205
8.4.4	Gait analysis	207
8.4.5	Hip Disability and Osteoarthritis Outcome Score (HOOS)	210
8.4.6	Effect Sizes	210
8.4.7	The Psychosocial Impact of Assistive Devices Scale (PIADS)	211
8.4.8	Ancillary analyses of sample size	211

	8.4.9	Activity diary	213
	8.5	Discussion	214
	8.6	Chapter summary and conclusion	220
C	hapter 9	9 – Discussion	222
	9.1	Chapter overview	222
	9.2	Research objectives	222
	9.3	Results summary	222
	9.4	Impact of findings	226
	9.4.1	Purposeful walking	226
	9.4.2	Wearable activity monitor	227
	9.4.3	Adherence	228
	9.4.4	Gait	230
	9.5	Recommendation for clinical application	231
	9.6	Recommendation for future research	234
	9.7	Unanswered questions	235
	9.8	Limitations	236
	9.8.1	Data collection	236
	9.8.2	Participants	237
	9.9	Strength	237
	9.9.1	Study design	237
	9.9.2	Data collection	238
	9.10	Chapter summary	238
C	hapter 1	.0 – Conclusion	241
R	eferenc	es	246
Α	ppendic	es	261
	Appen	dix 1. Mobile Application Rating Scale (MARS)	261
	The Cla	ssification section is used to collect descriptive and technical information about the app).
	Please	review the app description in iTunes / Google Play to access this information	261
Α	pp Qual	ity Ratings	263
So	coring		267
	Appen	dix 2. Summary of the systematic search for the wearable brands	268
		dix 3. Evaluation of Activity Monitors for Walking Distance? - Bournemouth University checklist	269
		dix 4. Feasibility study of the purposeful walking intervention - Bournemouth University	274
	Appen	dix 5. Interview Topic Guide – Feasibility study	282

Appendix 6. Activity diary – Feasibility study	283
Appendix 7. Hip dysfunction and Osteoarthritis Outcome Score (HOOS)	300
Appendix 8. The Modified Gait Efficacy Scale (mGES)	305
Appendix 9. Randomised pilot trial of the purposeful walking intervention - Bournemouth University research ethics checklist	308
Appendix 10. Consort Checklist – Pilot trial	315
Appendix 11. The Psychosocial Impact of Assistive Devices Scale (PIADS)	318
Appendix 12. Activity diary – Intervention group – Pilot study	320
Appendix 13. Activity diary – Control group – Pilot study	337

List of Tables

Table 1. Study objectives	23
Table 2. Summary of 11 new studies	54
Table 3. Inclusion and exclusion criteria for the healthy control adults	89
Table 4. Inclusion and exclusion criteria for the THR group	89
Table 5. The mean and standard deviation of the spatio-temporal gait parameters for each group.	93
Table 6. Summary of the dimensions, their subsections, and checkpoints for selecting the	
appropriate smartphone apps for older adults using the guideline assessment	102
Table 7. Summary of the relevant information for the top 10 smartphone apps that met the inclus	sion
criteria	106
Table 8. Summary of the MARS score for the top 10 smartphone apps that met the inclusion crite	ria.
	106
Table 9. Summary of the guideline score for the top 10 smartphone apps that met the inclusion	
criteria	107
Table 10. Summary of different brands' usage in reach and their brand software development	
possibilities	111
Table 11. Summary of different FitbitTM products currently on the market with an average price	
below £130	
Table 12. Summary of the data for the accuracy and precision per device and smartphone app for	
three different walking speeds	
Table 13. Summary of the data for the accuracy and precision per device and smartphone app for	
three different heights (participant)	
Table 14. Summary of studies that utilised Fitbit activity monitors in their methodology	
Table 15. The FC4 data for long distances of 500m, 1000m, and 2000m outdoor walk	140
Table 16. Summary of data for shuttle walk of 2 laps (28.4m), 5 laps (71m) and 10 laps (142m) of	
indoor walks using the ALG function of the FC4 activity monitor.	140
Table 17. Summary of data for shuttle walk of 2 laps (28.4m), 5 laps (71m) and 10 laps (142m) of	
outdoor walks using the GPS sensor of the FC4 activity monitor	
Table 18. Summary of data for the 100 m shuttle walks and outdoor walks using the ALG function	
and GPS sensor at self-selected speed using the FC4 activity monitor.	
Table 19. Summary of three trials carried out with small steps.	
Table 20. Summary of three trials carried out with large steps.	
Table 21. Eligibility criteria	
Table 22: Visit schedule.	
Table 23: Participants' demographics information	
Table 24. Eligibility criteria	
Table 25. Participants' demographics information in the intervention group.	
Table 26. Participants' demographics information in the control group	205
Table 27. Within group and between group mean difference (pre to post intervention) (M_D) ,	210
standard deviation (SD), and the Cohen's effect size (d)	
Table 28. The PIADS scores for the intervention group Table 29. The PIADS scores for the control group	
Table 30. Recommendations for clinical application of purposeful intervention using a commercia	
) 233

List of Figures

Figure 1. Updated PRISMA flow diagram which includes searches of databases, and other sources. 50
Figure 2. 250 m Olympic standard outdoor tarmac track, Bournemouth116
Figure 3. Box Plots for Absolute Distance Error between the Gold Standard Distance121
Figure 4. Gold Standard Speed (250m divided by Time Measured by Stopwatch) versus absolute
error in metres for FC4 GPS readings
Figure 5. Three FC4 activity monitors were worn on the non-dominant wrist (personal collection).136
Figure 6. Bar plots illustrating data collected using three different FC4 activity monitors142
Figure 7. The GPS data recorded using the FC4 activity monitors in long distance walking trials146
Figure 8. Fitbit Charge 4 (FC4) (personal collection)160
Figure 9: Total amount of purposeful distance walked by each participant per week169
Figure 10. Walking speed gait data for each participant170
Figure 11. Cadence gait data for each participant171
Figure 12. Step length of the operated side gait data for each participant
Figure 13. Hip Disability and Osteoarthritis Outcome Score (HOOS) data for each participant 172
Figure 14. Physical Activity Scale for the Elderly (PASE) data for each participant
Figure 15. The modified Gait Efficacy Scale (mGES) data for each participant173
Figure 16. The codes and themes related to the subject discussion, activity monitor175
Figure 17. The codes and themes related to the subject discussion, purposeful walk177
Figure 18. The codes and themes related to the subject discussion, outcome measures179
Figure 19. Participant flow diagram204
Figure 20. The total amount of purposeful distance walked by each participant per week206
Figure 21. The total amount of steps taken by each participant per week206
Figure 22. Mean difference in gait data for each participant in the intervention and the control
group. A) Mean difference in walking speed for each participant in the control group209
Figure 23. Hip Disability and Osteoarthritis Outcome Score (HOOS) data for each participant in the
intervention and the control group

Integrated Papers

In line with the alternative formats of the thesis outlined within BU's Research Degree Code of Practice, this thesis follows an integrated format, where two published research articles and two submitted articles, are integrated into the thesis. The table below provides the details of the included research articles, publication status, and location within this thesis. For coauthored publications, I am the lead author and can confirm that I contributed over 75% of the substantive content of each article.

Paper	Reference	Chapter	Page	Publication
			numbers	status
1	Bahadori, S., Collard, S., Williams, J. M. and Swain, I., 2020a. A review of current use of commercial wearable technology and smartphone apps with application in monitoring individuals following total hip replacement surgery. <i>Journal of Medical Engineering & Technology</i> , 44 (6), 324-333.	Chapter 2	18-29	Published
2	Bahadori, S., Collard, S., Williams, J. M. and Swain, I., 2020b. Why Do People Undergo THR and What Do They Expect to Gain—A Comparison of the Views of Patients and Health Care Professionals. <i>Journal of Patient Experience</i> , 7 (6), 1778-1787.	Chapter 3	45-58	Published
3	Bahadori, S., Collard, S., Williams, J. M. and Swain, I., A Feasibility Study to Evaluate a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor in Individuals Post Total Hip Replacement Surgery. J Rehabil Assist Technol Eng. Dec 2022.	Chapter 7	123-155	Submitted (Under review). Journal of Rehabilitation and Assistive Technology
4	Bahadori, S., Collard, S., Williams, J. M. and Swain, I., Can a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor Improve Individuals' daily activity and function Post Total Hip Replacement Surgery: A Randomised Pilot Trial. J Aging Phys Act. Feb 2023.	Chapter 8	157-184	Submitted (Under review). Journal of Aging and Physical Activity

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Glossary of Terms

ALG	Algorithm Function	
COMET	The Connecting Outcome Measures in Entrepreneurship, Technology, and Science	
CoV	CoV Coefficient of Variation	
FC4	Fitbit Charge 4	
GPS	The Global Positioning System	
GRAIL	Gait Real-time Analysis Interactive Laboratory	
HCPs	Healthcare professionals	
HELLO	Health Outcomes After Robotic Hip Surgery Trial	
HOOS	Hip Disability and Osteoarthritis Outcome Score	
HRA	The Health Research Authority	
MAD	Mean Absolute Difference	
MARS	The Mobile Application Rating Scale	
MCID	Minimal clinically important differences	
mGES	The modified Gait Efficacy Scale	
ORI	Orthopaedic Research Institute	
PASE	Physical Activity Scale for the Elderly	
PIADS	The Psychosocial Impact of Assistive Device Scale	
PIADS	The Psychosocial Impact of Assistive Devices Scale	
PPI	Patient and Public involvement	
PRISMA	Program of Research to Integrate Services for the Maintenance of Autonomy	
PROMS	Patient Reported Outcome Measure	
RoB	Risk-of-Bias tool for Randomized Trials	
ROBINS-1	Risk Of Bias In Non-randomised Studies	
THR	Total Hip Replacement	
TKR	Total Knee Replacements	

"The miracle isn't that I finished, the miracle is that I had the courage to start"

John Bingham

Chapter 1 – Introduction

1.1 Chapter overview

The aim of this study is to explore the application of commercial activity monitors in improving individuals' daily activity after total hip replacement (THR) surgery. This is important because despite being one of the most successful operations for reducing pain and improving function, the postoperative activity level is disappointingly low in this patient group (Beaulieu et al. 2010; Beswick et al. 2012). This chapter provides an overview of the research background, the research objectives, the overview of the research methods, and the outline of this thesis.

1.2 The authors' research journey

My rational for undertaking this study came from my curiosity about the impact of using digital technology in orthopaedic medicine, while working as a researcher at the Bournemouth University Orthopaedic Research Institute (ORI). As a biomedical engineer, I was involved in various projects which included different medical devices since being employed as an ORI's Orthopaedic Researcher. Following my first year at ORI, I attended a conference in Sao Paulo, Brazil which included talks from world leaders on the impact of digital and smart technologies on the future of medicine. A particular talk by Professor. Stefano Bini, founder of modern digital orthopaedic intrigued me with how well orthopaedic medicine is placed for acceptance of digital pathways (Bini 2018). Subsequently, I started studying this field and exploring the current qualities of available activity monitors for monitoring individuals after hip and knee replacement surgeries (Bahadori et al. 2018a; Bahadori et al. 2018b; Bahadori et al. 2019c). Soon after researching this field, it was clear to me that activity monitors have the potential to improve user engagement and subsequently

their long-term recovery following total hip and total knee surgery, and they can be a viable adjuncts or replacements to traditional rehabilitation programmes. However, there was very limited evidence to support their efficacy and therefore I decided to follow my passion for digital health and explore new ways that activity monitors can support individuals in their surgical pathways and rehabilitation post-THR surgery.

1.3 Background

1.3.1. Total hip replacement surgery

THR is a procedure that removes a damaged hip joint and replaces it with prosthetic components (Bottai et al. 2015). The earliest recorded attempts at THR occurred by Professor Themistocles Glück in Germany in 1891 (Knight et al. 2011). Recognised as one of the most successful orthopaedic interventions of its generation, THR is an effective procedure for the treatment of hip osteoarthritis and is performed in an increasing number of individuals around the world (Learmonth et al. 2007).

The demand for THR surgery is rising worldwide and assuming rates of THR for the past two decades, it's predicted that by 2035 the number of this operation being performed worldwide will rise by 208% (Jones et al. 2005b; Marsh and Newman 2021). Meanwhile, with the cost of the operation around £7500 (Chen et al. 2012), combined with the time taken to return to normal activities and work, THR places a significant financial burden on any healthcare system worldwide. On average the post-acute care cost of THR surgery accounts for 36% of the total episode of care costs (Bozic et al. 2014).

While improvement in individuals' mobility and pain following this surgery are well documented, several challenges lie ahead to improve pre-surgical levels of physical activity

(Harding et al. 2014; Bandholm et al. 2018). Additionally, findings suggest that around 20% of individuals undergoing THR feel socially isolated following their surgery (Smith 2017). Given the negative physical and psychological consequences of these factors on outcomes such as all-cause mortality, return to work, and leisure activities (Smith 2017; Bandholm et al. 2018), there is a significant rehabilitation challenge for this population. Furthermore, it is also important to acknowledge that currently an optimal rehabilitation pathway post-THR has not been defined (Bandholm and Kehlet 2012), therefore the question of what rehabilitation programmes could help remains unanswered. Therefore, there is a need to develop alternative and innovative treatment regimens that could be used to enhance self-care, and daily activity, and, that are feasible for people after THR surgery.

1.3.2. Commercial activity monitors

Commercial activity monitors are electronic tracking devices that enable users to track and monitor their health-related physical fitness metrics including steps taken, level of activity, walking distance, heart rate, and sleep patterns (Shin et al. 2019). The term is primarily used for wearable smartwatches or smartphone apps and fundamentally are upgraded versions of pedometers (Constantinescu et al. 2022). The first commercial wearable activity monitor, the Polar PE2000, was introduced in 1981, combining an electrocardiogram and a radio chest strap. Trialled for monitoring athlete's heart rate, this was the first type of smartwatch capable of placing biometric information live onto the display (Bunn et al. 2018).

Similarly, while there is limited evidence on the exact date of the launch of the first smartphone app for daily activity tracking, Steve Jobs envisions of the App store began in 1983 (Dormehl 2012), and the first iPhone was launched in 2007. Subsequently, by 2015, over 80 apps were available on the Apple app store, and in a year after over three billion downloads

of various apps were recorded (Henriksen et al. 2018). The Health app for the iPhone was launched in September 2014 and it was the first smartphone app to track daily steps (Apple 2014).

A report in 2022 suggested that there are over 6.3 billion users of smartphones and over 216 million users of wearable smartwatches across the world (Statista 2022). With the pandemic having a tremendous effect on the popularity of activity trackers, this market is predicted to grow by 7.8% by 2028 (Market 2023).

Activity monitors offer a novel way to remotely monitor individuals and objectively measure their recovery. In particular, given the limitations around the recovery and financial burden that arises following THR surgery, it is simply negligence on behalf of the care provider if the availability of such technology isn't utilised for enhancing individuals' recovery. Activity monitors have the potential to engage patients as advocates in their personalised care, as well as offer health care providers objective assessments of their patients' daily activity patterns. However, there is currently very little evidence to support their long-term efficacy in enhancing rehabilitation pathways post-THR. Chapters 2, 3, and 6 further discuss the use of wearables in THR surgical pathways.

1.4 Aims and objective

The overall aim of this study was to examine the application of commercial activity monitor on improving individuals' daily activity after THR surgery. The objectives, plans to action them and related research method of this study are described in Table 1.

Table 1. Study objectives

Objectives	Plan	Methodology	Chapter
1. To gain insight into the use of activity monitors in THR surgery and	1a. To gain an understanding of the current evidence related to the use of commercial activity monitors in THR surgical pathways.	Literature review	Chapter 2
individuals' recovery goals	 1b. To gain insight into why individuals undergo THR surgery and their rehabilitation goals. 1c. To explore healthcare professionals' ((HCPs) (THR surgeons and THR physiotherapists)) views on THR surgery, and pre- and post-operative management of individuals. 1d. To learn whether an activity monitor is an acceptable technology to the common demographic of those undergoing THR surgery 	Patient and public involvement (PPI) group discussion	Chapter 3
	1e. To gain an understanding of pre to post gait	Gait analysis	Chapter 5
2. To evaluate the use of activity monitors and their functionality to inform objective recovery data	2a. To explore the best activity monitors that could enhance compliance with daily activity goal	The Mobile App Rating Scale (MARS) The usability and accessibility guidelines for smartphone apps for older adults Literature review	Chapter 6
	2b. To evaluate the accuracy and precision of activity monitors	Mixed-method lab-based study	Chapter 6

3.	To assess the feasibility of commercial activity monitors on improving the	3a. To assess the feasibility of an intervention where a personalised outdoor walking distance is monitored using a commercial activity monitor	Mixed-method feasibility study	Chapter 7
	daily physical activity and rehabilitation of individuals after THR surgery	3b. To determine the effect of an intervention where outdoor walking distance is used as a goal to increase the daily activity of older adults using a commercial activity monitor	Mixed-method randomised pilot study	Chapter 8

1.5 Methodological overview and relevant justifications

In order to integrate new technologies into the rehabilitation regimes of individuals after THR surgery, quantitative evaluation with qualitative insight is needed to create scientific objectivity and justification for their use (McCusker and Gunaydin 2015). Throughout this study, a mixed method approach, including both quantitative and qualitative research methods, was utilised in the assessment of the target population. Furthermore, in the planning of the feasibility and the pilot study designs, the Core Outcome Measures in Effectiveness Trials (The COMET) database was sought for selecting key outcome measures regarding the assessments of THR individuals, however, no results were found (COMET 2021). Therefore, where appropriate, a methodology with prior utilisation in THR studies and validity in this cohort was selected and evaluated. The feasibility study was then used to streamline outcome measures that are most appropriate for assessments of the objectives and used to determine the outcome measure used in the final study. Given the integrated format of this thesis, the full methodology for each research study in described within its respective chapter, however an overview of the main methodologies is provided here to avoid repetition throughout the thesis.

1.5.1 Gait analysis

Gait analysis was undertaken as it has proved to be a valuable tool in providing objective data on individual walking patterns and modalities before and after THR (Bhave et al. 2007). The Gait Real-time Analysis Interactive Laboratory (GRAIL, Motekforce Link, Amsterdam, the Netherlands) system was used to carry out the gait analysis. The gait analysis was carried out as per the protocol published on gait analysis using the GRAIL system (Bahadori and Wainwright 2020a). However, only spatio-temporal data (walking speed, cadence, and step length) were recorded for analysis (Chapters 5, 7, and 8). Chapters 6, 7, and 8 include gait analysis using the GRAIL system and discuss the methodology in further detail.

1.5.2 Patient Reported Outcome Measure (PROMS)

Patient Reported Outcome Measures (PROMS) were used in Chapters 7 and 8 studies. PROMS were selected to give a broad understanding of the level of daily activity, functional limitation, occupational activity, and level of confidence in walking 3 to 6 months post-THR surgery. The Hip disability and Osteoarthritis Outcome Score (HOOS) questionnaire (Nilsdotter et al. 2003) was utilised more than once in this thesis (Chapters 7 and 8), whereas other PROMS including the Physical Activity Scale for the Elderly (PASE) questionnaire (Washburn et al. 1993) (Chapter 7), the modified Gait Efficacy Scale (mGES) (Newell et al. 2012) (Chapter 7), and the Psychosocial Impact of Assistive Devices Scale (PIADS) (Jutai et al. 2002; Harada et al. 2014) (Chapter 8), were used only once. Further justification for the use of each PROMS and detailed information on the suitability of these outcome measure are explained in the methodological section of their respective chapters.

1.5.3 Assessment of precision and accuracy of the activity monitor

Given the limited evidence surrounding the precision and accuracy of the activity monitor suitable for the target population (Evenson et al. 2015; Henriksen et al. 2018), a series of small studies was planned (Chapter 6) to evaluate these parameters in order to inform the study design in Chapters 7 and 8. Accuracy was assessed based on the mean absolute difference (MAD) (difference between Gold Standard distance or manual step count and observed per device). The precision (variance) was assessed using the percentage of coefficient of variation (CoV) per device (standard deviation divided by the mean and multiplied by 100).

1.5.4 Qualitative analysis

The activity diary was utilised in the feasibility study (Chapter 7) and amended following the participants feedback for use in the final study (Chapter 8). Activity diaries have been recommended as one of the most powerful qualitative tools for researchers to get insights into their participant's behaviour while they are in their natural environment (Snowden 2015). It provides insight into individuals' responses to external factors such as a change in environment, time of day, and life events (Snowden 2015). Given the objective of this study was to help individuals with their daily activity, it was, therefore, essential to allow them an opportunity to remain engaged not solely by the use of the activity monitor but also by understanding which conditions may affect their daily activity. Studies in Chapters 7 and 8 utilised activity diaries to allow participants to document any feelings/conditions which may have affected their ability to complete their daily walk. In Chapter 3, a PPI was advocated. PPI is reported to have a positive impact in various stages of the study design including the selection of outcome measures, increasing the likelihood of timely recruitment, and

improving participant retention (Bagley et al. 2016). Lastly, as part of the evaluation of the feasibility of the study intervention (Chapter 7), a semi-structured interview was designed and carried out in order to understand which elements of the intervention and study, including the selection of outcome measures, worked well and were seen as relevant for the participants, and which needed adjustments and further development. The use of a semi-structure interview is proven to be an effective method to 1) collect qualitative, open-ended data; 2) explore participant thoughts, feelings, and beliefs about a particular topic; and 3) delve deeply into participant's challenges and experiences (DeJonckheere and Vaughn 2019). The justification for their use of all qualitative elements of this thesis, details on their suitability and impact of these methodologies are explained further in Chapters 3, 7 and 8.

1.6 Chapter summary

This introduction aimed to provide an overview of the reasons why I sought to explore this topic, introducing THR surgery, and the concept of activity monitors. Furthermore, I have outlined the objectives, and the methodological approaches used to explore those objectives through mixed-method research. Considering the overall aim, it is now necessary to review what evidence is available on the use of this technology in research related to the THR population.

"Nothing has such power to broaden the mind as the ability to investigate systematically and truly all that comes under thy observation in life." Marcus Aurelius

Chapter 2 – Literature Review

2.1 Chapter overview

This chapter provides an overview of the current literature on the use of commercial wearable technology and smartphone apps with applications for monitoring individuals following THR surgery. The main section of this chapter is in the form of a Systematic Review published as part of this study (Bahadori et al. 2020a), which includes the PRISMA diagram, inclusion and exclusion criteria, and databases searched (Section 2.2). However, due to the increase of research in this field since published Systematic Review, a further review process was undertaken. The chapter ends with outlining the aims and objectives of the next chapter based on the findings of the literature review (Section 2.3).

2.2 Review Article

A review of current use of commercial wearable technology and smartphone apps with applications in monitoring individuals following total hip replacement surgery.

Title

A review of current use of commercial wearable technology and smartphone apps with application in

monitoring individuals following total hip replacement surgery.

Abstract

The advent of commercially available wearable activity monitors and smartphone apps allows objective

digital monitoring of daily activities of patients before and after THR surgery. A wide variety of

wearable activity monitors and smartphone apps are being marketed to assist with enhancing physical

activity following surgery. A systematic review of commercial wearable technology and smartphone

apps was undertaken to assess the evidence supporting their efficacy in assisting rehabilitation and

patient monitoring following THR. A search was conducted using the electronic databases including

Medline, CINAHL, Cochrane, PsycARTICLES and PubMed of studies from January 2000 to January

2019. Five studies met the eligibility criteria. A review of the studies found very little evidence to

support long term efficacy of the technology in enhancing rehabilitation and patient monitoring post

THR. Future work is required to establish which commercially available monitoring technology is most

valuable to patients, which ones improve clinical outcomes post THR, and what are the best economical

models for their deployment.

Keywords: Total hip replacement, wearables, smartphone apps, rehabilitation, patient monitoring.

30

Introduction

Total hip replacement (THR) is among the most successful operations and is performed in an increasing number of individuals around the world with the primary aim of reducing pain and improving function (Culliford et al. 2015). However, an objective evaluation of physical function and performance status post-surgery is difficult because patients spend the majority of their postoperative rehabilitation outside the clinic and self-report to providers using subjective methods such as patient reported outcomes measures (PROMs) (Siljander et al. 2018).

Despite concerns over standardization (Siljander et al. 2018), PROMs offer insight into an individual's daily, and results are generally positive. However, discrepancies are seen when PROMs are compared to performance based function (Luna et al. 2017a) and a number of studies have suggested caution with only using subjective data as the measure of recovery (Luna et al. 2017a; Bandholm et al. 2018; Holl et al. 2018). In addition, compared with pre-operative function, post-operative activity levels are low and many individuals become socially isolated following surgery (Harding et al. 2014; Smith 2017).

The launch of commercially available wearable devices such as activity monitors and smartphone apps allows objective monitoring of daily activities. In addition to their growing popularity (Henriksen et al. 2018), these devices are equipped with a wide variety of different sensors and algorithms to collect and display physical activity data. Different devices have advantages and disadvantages, including cost, comfort, ease of use, and immediacy of feedback provided. Some are likely to be more suited for research and others for clinical purposes working as a 'virtual trainer' to motivate people to complete an exercise programme (Gonzalez-Franco et al. 2014).

Several studies have compared activity tracking wearables and smartphone apps. Their aim is to analyse their reliability and assess their effectiveness on increasing rehabilitation adherence. A number of limitations in their performance have been identified. Fokkema et al. (Fokkema et al. 2017) identified the need for further validation of activity monitors in slower walking populations. Bahadori et al. (Bahadori et al. 2018b) also found that despite a wide range of apps currently available to individual following THR and total knee replacement (TKR), there was significant variability in their quality.

Sanders et al. (Sanders et al. 2016) reviewed the characteristics and measurement properties of currently available, self-monitoring wearables for health self-monitoring, sedentary behaviour and personal activity detection. They reviewed various aspects of these devices, and found that there is still a need for further development to self-monitor sedentary behaviour.

Although overall, advances in wearable technology has enabled several studies to use more valid and reliable objective measures of physical activity, the picture related directly to THR remains unclear (Lutzner et al. 2014; Alharbi et al. 2016; Schoenfelder et al. 2017) and to date, there has been no systematic review of studies objectively measuring personal activity after THR. Therefore, the aim of this review is to systematically identify all studies which utilised commercially available activity monitors or smartphone apps to measure physical activity in individuals both before and after THR.

Method

This review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (www.prismastatement.org/PRISMAStatement). A computer-based search was completed in January 2019 using the mySearch Database (Bournemouth University). This included Cochrane Database of Systematic Reviews library, CINAHL Complete®, Science Citation Index and Medline®. Articles published in the English language from January 2000 to January 2019 were reviewed. Search strategy terms are outlined in Table 1 and Table 2. Studies included were commercially available activity trackers and smartphone apps capable of providing feedback to the end user following THR surgery.

The most popular wearable devices on the market (Bunn et al. 2018) were chosen for this systematic review and included: Fitbit, Garmin, Apple, Misfit, Polar, Samsung Gear, TomTom, and Lumo. A second systematic search strategy was also employed to capture the smartphone apps across the five most popular smartphone app stores: iTunes; Google Play; Windows Mobile; Blackberry App World; and Nokia Ovi for analysis. Once the initial searches were completed, the results were manually filtered to remove duplicates. Two independent reviewers (SB and SC) then screened journal titles and abstracts for relevance until only 74 papers remained (see Figure 1 for flowchart). Any disagreements between reviewers were discussed with IS and resolved by consensus. Studies included were commercially available activity trackers and smartphone apps capable of providing feedback to the end user following THR surgery.

As this study utilised information that was available in the public domain and there was no interaction with patients or retrieval of personal data, the Health Research Authority (HRA) ethics database (Authority 2019) confirmed ethics approval was not required and therefore not sought.

Data extraction process

SB extracted data to a standardised table, details found in Table 3 and Table 4.

Data quality

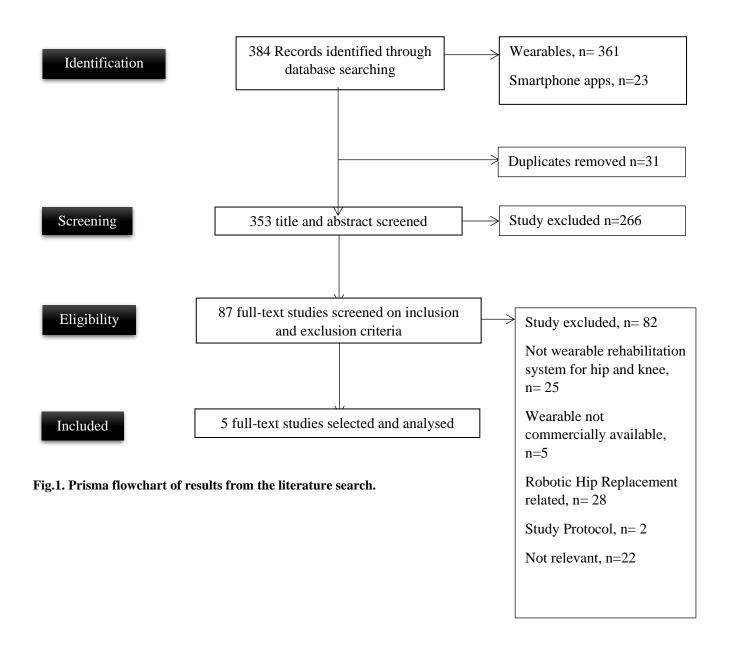
The Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) (Sterne et al. 2016) and Risk of Bias in Randomized trials (RoB 2.0) (Eldridge et al. 2016a) tool was used to assess the risk of bias. ROBINS-I includes seven domains including confounding, selection of participants into the study, classification of interventions, deviations from the intended interventions, missing data, measurement of outcomes, and selection of the reported result. The categories for risk of bias judgements for ROBINS-I are 'low risk', 'moderate risk', 'serious risk', and 'critical risk' of bias (Sterne et al. 2016). RoB 2.0 includes six domains including randomization process, timing of identification, recruitment of participants, deviations from intended intervention, missing outcome data and measurement of outcomes. The categories for risk of bias judgements for RoB 2.0 are 'low risk', 'high risk' and 'some concerns'.

(MM "Arthroplasty, Replacement, Hip") Ol	•	
(MM "Hip Prosthesis") Individual		
(Hip*) N5 (arthroplast* OR prosthes* OR	(Hip*) N5 (arthroplast* OR prosthes* OR	
replace*)		
AND		
Fitbit OR Garmin OR Apple OR Misfit OR		
Device Polar OR Samsung Gear OR TomTom OR		
Lumo		
AND		
Tracker*		
Device*		
Wearable Systems Wearable*		
Sensor*		

Table 1. Literature search strategy. MM (MeSh term). "" used to find exact phrase. *used to find all word with a common stem. N5 to find all articles containing the keywords within five words.

	(MM "Arthroplasty, Replacement, Hip") OR
To Africa Joseph	(MM "Hip Prosthesis")
Individual	(Hip*) N5 (arthroplast* OR prosthes* OR
	replace*)
	AND
	smartphone application* or mobile
Device	application* or app or apps

Table 2. Literature search strategy. MM (MeSh term). "" used to find exact phrase. *used to find all word with a common stem. N5 to find all articles containing the keywords within five words.



Reference	Study population	Activity monitor	What does it do?	Placement	Aim of study	Analysis	Outcomes of study
(Toogood et al. 2016)	33 THR patients	Fitbit	Step count	Ankle	To examine the feasibility (compliance) of a remote mobility monitoring programme in the early (first 30 days) post-operative period.	Correlation analysis between number of steps and objective factors such as, age, body mass index (BMI), surgical approach and destination of the patients at the time of discharge post THR.	The monitoring of the pattern of activity in patients who have undergone elective primary THR is possible. Step counts can provide an easily understood objective measure of mobility that may be more reliable than patients' subjective assessment.
(Van der Walt et al. 2018)	163 Patients (95 THR, 68 TKR)	Garmin Vivofit® 2	Step count	Wrist	To determine if feedback from a commercial activity monitor improves activity levels over the first 6 months after THR or TKR.	A randomized controlled trial, participants are divided into two groups where they were either able to view their daily step count, and were given a daily step goal or wore activity tracker with obscured display. The mean daily steps at 1, 2, 6, 21 weeks, and 6 months were monitored.	Patients who received feedback from a commercial activity tracker with a daily step goal had significantly higher activity levels after hip and knee arthroplasty over 6 weeks and 6 months, compared to patients who did not receive feedback.

 Table 3: Wearable Activity Monitor Article Summary

Reference	Study population	Smartphone app	What does it do?	Platform	Aim of study	Analysis	Outcomes of study
(Wang et al. 2018)	400 THR patients	WeChat	Home care platform for orthopaedic. The platform has two clients, namely the port for the nurse specialists in clinical orthopaedics and the port for the patients	iOS or Android	To evaluate the effectiveness of extended care based on Internet and home care platform for orthopaedics after THR on joint function, activities of daily living and quality of life.	Patients were randomised into control and intervention groups. In the control group, only routine nursing care was carried out after discharge. In the intervention group, continuous intervention was performed via the Internet-based (WeChat) orthopaedic care platform. The patients in the two groups were compared in terms of functional recovery, quality-of-life score and activities of daily living at 3 and 6 months after discharge.	There were no significant differences in the baseline data between the two groups. After 6 months of continuous intervention, all score in the intervention group were significantly higher than those in the control group.
(Krumsvik and Babic 2017)	3 participant (1 THR patient, 1 physician, 1 expert app designer)	SafeTHA	Pain levels and well-being	Android	To prevent the occurrence of severe post THR adverse events.	A user-centered design approach to allow collection of patient data out of a hospital setting.	The app is found to be practical, intuitive, sufficient and simple for users. It is recommended for optimising patient safety and recognizing adverse events.
(Crizer et al. 2017)	589 Patients (301 THR, 288 TKR)	Mobile step- tracking app	Step count	iOS or Android	To evaluate and compare an objective measure of postoperative recovery, daily step-count, with patient self-reported outcomes.	Steps were recorded for 4 weeks before surgery and 12 weeks, thereafter. Patient-reported lower extremity functional scale (LEFS) scores were recorded at 1, 6, and 12 weeks, postoperatively. LEFS scores were correlated to weekly median daily steps using the Spearman rank correlation coefficient.	Physical function improved over the first 12 weeks as measured by both steps and patient-reported assessments. Postoperative steps weakly correlated with LEFS scores, suggesting patient-reported outcomes may provide only part of the story.

Table 4: Smartphone Activity Monitor Article Summary

Results

Classification of technologies and application in patient monitoring

Five studies were identified which utilised currently available commercial wearable activity monitors and smartphone apps to measure physical activity before to after THR.

Wearable Activity Monitor Devices

Toogood et al. (2016) used an activity monitor (Fitbit) in a cohort of 33 patients undergoing elective primary THR, and aged above 60 years who were mobile pre-operatively. Age, gender, BMI, surgical approach, length of stay, and discharge disposition were extracted from the medical records. All patients wore a Fitbit wireless accelerometer on their operated side ankle for 30 days after discharge. A mean step count was obtained for all patients on each post-operative day. The patient computer or mobile device transmitted data to a web service that was accessible by investigators who reviewed the data each day. The mean compliance over 30 days was 26.7 days of use. There was a clear trend towards increased activity with passage of time. Additionally, Fitbit data showed correlation between age, BMI, surgical approach and destination of patient at the time of discharge from hospital. Toogood et al. (Toogood et al. 2016) concluded that at-home remote monitoring using Fitbit monitor is viable and can be a great help to those patient who recover slowly.

A randomized control study by Van der Walt et al. (Van der Walt et al. 2018) used Garmin Vivofit® 2 to assess the activity levels of 163 patient following THR and TKR surgery. Eligible patients were all adults undergoing primary elective hip or knee replacement surgery. Invited two week prior to their surgery, patients received a Garmin Vivofit® 2 upon acceptance to take part. On day 1 after arthroplasty, randomisation was performed, creating two equal numbered groups of 'Feedback Group' or 'No Feedback Group'. In the 'The Feedback Group', patients were able to see their step counts and were given a daily step goal. The goal of 7000 steps by week 6 was selected as this is the recommended daily step count for healthy older adults (>65). Participants in the "Non- Feedback Group" continued to wear the device with the display obscured for 2 weeks after surgery and were not given a daily step goal. In addition, all patients completed patient reported outcome questionnaires (PROMS)

preoperatively and at 6 months after surgery. Van der Walt et al. (2018) found that patients who received feedback from the Garmin Vivofit® 2 with a daily step goal were significantly more active than those in the 'No Feedback Group'. However there was no significant difference between the groups in PROMS at 6 months.

Smartphone Activity Monitor Apps

Wang et al. (2018) aimed to evaluate the effect of an Internet-based home orthopaedic care platform on patients' functional joint recovery, quality of life and activities of daily living after hip replacement. In this randomized clinical study, 400 THR patients were monitored by 18 local departments of Orthopaedic surgery using a free smartphone messaging app called WeChat. Patients were either given routine care or introduced to an intervention care using the WeChat platform. Using the platform, specially trained nurses interacted with patients on: Clinical Broadcast, Question and Answer Application, Appointment Application and Rehabilitation Exercise. Patients were able to upload pictures or videos from their rehabilitation exercises. The patients in the two groups were compared in terms of functional recovery (Harris hip score), quality-of-life score (MOS SF-36) and activities of daily living (Barthel index) at 3 and 6 months after discharge. This study found that after 6 months of continuous intervention, the scores for the intervention group were significantly higher than those in the control group. Overall, the smartphone app provided a platform for extended care management outside of the hospital, which can be extremely helpful for patients following THR surgery.

A study by Krumsvik and Babic (Krumsvik and Babic 2017) utilised a user-centred approach to report on the user experience of smartphone apps to reduce post-THR adverse event. The authors believed that the outcome of an adverse event has a huge impact on patient well-being, societal costs, as well as the reputation of healthcare. Therefore, an app which is capable of empowering patients, not only through providing general information, but also through capturing patient specific data such as pain level, anxiety, mobility, progress, and quality of recovery is also needed. A smartphone application designer, a female nurse who had recently undergone THR and a physiotherapist were invited to take part in the study. They were assessed with respect to the interaction flow, information content and self-reporting functionalities. SafeTHA app was designed to allow the patient to report any complication following a

THR surgery using a diary platform which the physiotherapist is able to check and reply to with any advice. The study concluded that the SafeTHA app is a practical, sufficient and intuitive way of monitoring patient post-THR, however one cannot solely rely on the application.

Crizer et al. (2017) used a mobile step-tracking application to record daily steps of 589 patients post THR (n=301) and TKR (n=288). The goal of this prospective, single-centre study was to evaluate and compare an objective measure of postoperative recovery, daily step-count with PROMS. Following consent from patients, the step-tracking app was downloaded to their smartphone. Steps were recorded and monitored by prospective surgeons for 4 weeks before surgery and 12 weeks thereafter. Patientreported lower extremity functional scale (LEFS) scores were recorded at 1, 6, and 12 weeks, postoperatively. LEFS scores were correlated to weekly median daily steps for a 4 week period just before surgery, as well as for each of the first 12 consecutive weeks after THR/TKR. Crizer et al.(Crizer et al. 2017) found that for THR patients, recovery of physical activity was rapid, as the median patient surpassed their baseline step counts after only 5 weeks, after which further functional improvement was slow and steady. Overall, in both THR and TKR patients, physical function improved over the first 12 weeks as measured by both steps and LEFS. There is a weak correlation between step counts and LEFS scores suggesting that subjective measures may provide only part of the story. Crizer et al. (Crizer et al. 2017) suggested that objective measures such as a step count using a simple smartphone app could be a helpful and practical addition to the surgeon's armamentarium for monitoring the recovery of their patients.

Risk of Bias in individual studies

The risk of bias for the five studies included for review is outlined in Table 5. Given the lack of studies available following screening process, quality assessment was not a factor for inclusion or exclusion within the systematic review, but was utilised to facilitate interpretation of findings. Two reviewers (SB and SC) completed the quality assessment, with any discrepancies resolved through discussion.

Reference	Tool	Risk of Bias	Judgement across domains
(Toogood et al. 2016)	ROBINS-I	Moderate risk	The study is judged to be at low or moderate risk of bias for all domains
(Van der Walt et al. 2018)	RoB 2.0	Some concern	The study is judged to be at some concern in at least one domain for this result.
(Wang et al. 2018)	RoB 2.0	Some concern	The study is judged to be at some concern in at least one domain for this result.
(Krumsvik and Babic 2017)	ROBINS-I	Serious risk	The study is judged to be at serious risk of bias in at least one domain, but not at critical risk of bias in any domain
(Crizer et al. 2017)	ROBINS-I	Moderate risk	The study is judged to be at low or moderate risk of bias for all domains

Table 5: Summary of risk of bias in included studies.

Discussion

Clinical assessments and the evidence of use

The main goal of activity monitor wearable and smartphone apps is to monitor and encourage patient activities during rehabilitation. Clinical trials are crucial to assess the success of the new technologies, in particular when additional clinical results show improvement in patient condition. However, many studies have relied primarily on subjectively reported personal activity levels, a method hampered by reporting biases and inadequate reliability and validity compared to objective methods, such as bodyworn accelerometers (Prince et al. 2008). Advances in technology have signalled the release of several studies in patients undergoing TKR surgery (Luna et al. 2017b), spinal surgery (Debono et al. 2016), stroke (Timmermans et al. 2010), and arm rehabilitation (Nguyen et al. 2011; Tsekleves et al. 2016) using more valid and reliable objective measures of physical activity, but the picture related to THR remains unclear.

The systematic search found five papers, of which two were adopting randomised trials to assess the commercially available technology for monitoring patients post THR. The papers generally had various levels of bias (Table 5); however, blinding of participants and personnel and blinding of outcome assessment were consistently reported to have a high risk of bias.

In general, all of the studies agreed that subjective measures (PROMS) alone may provide only part of the story and therefore, objective measures for tracking postoperative recovery should be utilised in the patients' surgical pathways. Patients who received feedback from a commercial activity tracker or smartphone app had significantly higher activity levels after THR compared to patients who did not receive feedback (Crizer et al. 2017; Van der Walt et al. 2018; Wang et al. 2018). It is also important to acknowledge that currently an optimal rehabilitation pathway post THR has not been defined (Bandholm and Kehlet 2012), therefore the question of what rehabilitation programmes wearables should help to facilitate and deliver remains unanswered. Therefore, in the meantime, simple, objective measures such as step count could be useful tool in managing patient expectation regarding their personal activity level post THR.

Evidence demonstrating changes at 1 year was not reported in any of the studies; therefore, it remains unclear what long-term changes may occur after THR. Of the studies reporting improvement in activity level after THR, the clinical significance was unclear and impacted by a risk of methodological bias. The accuracy of activity monitors at low speed has been previously questioned specially in the first days after surgery when activity level is expected to be at a slower rate (Le Masurier et al. 2004; Alinia et al. 2017b). There is also no evidence to support the reliability of the step-tracking application used in Crizer et al. (Crizer et al. 2017) and when mobile apps are used as the point of contact between patients and healthcare providers, reliability is dependent on the level of academic education and self-efficacy(Reychav et al. 2019) which were not considered in the interpretation of the study outcome.

Wang et al (Wang et al. 2018) reported a large effect in functional recovery, quality-of-life score and activities of daily living at 3 and 6 months after discharge. However, this study was vulnerable to bias regarding reporting of recruitment handling of potential factors confounding the measurement of personal activity. Furthermore, there are two major concerns, one related to the interpretation of data and the other on the impact of the innovation. Evidence shows that patient reported physical function after THR/TKR does not correlate with objectively assessed function (Aasvang et al. 2015; Luna et al. 2017a; Luna et al. 2018). More importantly, use of applications such as WeChat which have been designed primarily for messaging and social media to discuss patient data is forbidden in most European countries with implementation of GDPR (Kolah 2018). Therefore, despite agreeing with the effectiveness of an internet-based home orthopaedic platform, this innovation would be challenging to implement outside China.

It is worth noting that none of the studies examined or reported on the health economics aspects of introducing the technology. Even if evidence is collected that supports the clinical benefit of wearable devices, without such data, they are unlikely to be widely adopted in health care systems (Bahadori et al. 2018a).

Interestingly, wearable activity monitors are among the fastest growing area in consumer technology (Bunn et al. 2018) and in some cases by the time a study has gained approval, participants have been tested, data analysed, and reports have been written and gone through the peer review process, wearable

technology or smartphone app has been updated to the next model or has become obsolete (Bunn et al. 2018). Thus, the wearable activity monitors used in the studies reviewed here have also been marketed to have the potential to measure other activities in different clinical trials (Henriksen et al. 2018). Therefore, we have summarised the (Table 6) characteristics of different types including the sensor use, price, battery life and tracking features of the two products (FitbitTM, Garmin[®]) examined. This could be beneficial to readers whom are interested of using these trackers in future studies.

Availability of brands is another interesting topic. Since 2011, 432 unique devices from 132 different brands were introduced to the market (Henriksen et al. 2018). Out of the brands currently available, the five most often used in research projects are FitbitTM, Garmin[®], Misfit, Apple, and Polar(Bunn et al. 2018; Henriksen et al. 2018). In addition, these brands have all existed for several years and are likely to stay on the market for the immediate future. Nevertheless, it is worth considering that a high article count, clinical trials or reliability study of a particular device does not automatically imply suitability of that device for every study. FitbitTM and Garmin[®] which were utilised in the studies reviewed here, both allow third party programs to access, run and communicate on their devices (Ltd 2019a; Ltd 2019b). Nevertheless, Apple, Misfit, Polar and Samsung also offer similar capabilities(Henriksen et al. 2018). For projects that require remote access to patient's data such as THR trials, these features are essential.

Smartphone apps however are slightly more challenging to generalise. In the UK there is no official requirement to register smartphone or tablet apps either as software or devices with the Medicines and Healthcare products Regulatory Agency (MHRA)(Agency 2019). Whereas in the USA, Food and Drug Administration (FDA)(Food and Drug Administration 2019) have recently announced a regulatory program, aiming to ensure that the quality of the apps is sufficient before it is available to the public. The guidelines (Food and Drug Administration 2019) that are available are just that, so it depends on what the app does and the level of patient risk associated with it as to whether it should be classified as a medical device or not. Furthermore, at the time of writing, none of the apps included in our review have been included in the 'NHS approved' list (UK 2019) nor had any shown evidence that they had volunteered to take part in the FDA software and app precertification program. Nonetheless, new

possibilities are becoming available with the use of smartphones and apps to estimate as well as physical activity (Ferriero et al. 2013) but studies are required to assess their reliability for the measurement of activity and angles in different walking speeds.

The studies included in this review demonstrate that the technology (activity monitors, and smartphone apps) are safe and feasible, and that they show promise in measuring physical activity before and after THR. In contrast, there is lack of evidence supporting sustained use or effects on health outcomes, as studies have primarily focused on establishing the feasibility of monitoring activity and the association of measured activity with short-term benefits.

Recommendation for future research

As the wearable activity monitors and smartphone apps in THR research evolves, the challenges in clinical measurements, development, adherence, privacy, and clinical integration need to be addressed before these devices are broadly adapted as a clinical and self-assessment tools. Several of our key recommendations and clinical directions are as follow. First, we believe that involving patients in goal setting is essential and will define the use of the appropriate activity monitor. A good compliance is an important part of a well delivered clinical trial and greatly influenced by patients characteristics (Reychav et al. 2019). Second, the biggest deficit following THR surgery is the walking speed and step length among THR patients (Ewen et al. 2012). Activity monitors allow an objective measure of those parameters, and by only considering step count we are not addressing gait adaptations which persist after surgery. Third, a limitation from all of the studies reviewed here is the uncertainty around the accuracy of the activity trackers. The Consumer Technology Association (CTA) have developed protocols to evaluate devices for step count (ANSI 2016), sleep validity(ANSI 2017) and a standard for heart rate is expected to be released in 2020. More standards and protocols should be developed for other parameters such as heart rate, intensity and activity profiles. A guideline recommendation has been published recently (Bunn et al. 2018) and should be utilised to help evaluate devices in a standardize format. Fourth, wearables should be regarded as facilitators rather than drivers of change in health behaviour (Patel et al. 2015). Future research protocols should be designed with an aim to

develop a behaviour change program that utilise wearable activity monitors or smartphone apps to offer

a more organized and engaging experience than use of the device alone.

Limitations

There is limited data specifically investigating the use of commercial wearable technology and

smartphone apps with THR pathways. Although of good methodological quality, the studies employed

different protocols making generalisability difficult. In addition, the Krumsvik and Babic (2017) study

was a user design report which suffered from serious risk of bias. Furthermore, we only summarised

characteristics of the two brands (FitbitTM, Garmin[®]) and their current iteration of activity trackers which

is most used across all clinical research (Henriksen et al. 2018). We did not collect information about

all devices that have existed at some point. This was done with the aim to reduce the burden on

researchers with difficulties of selecting a suitable activity monitor for research.

Conclusion

Commercially available activity monitoring wearables and smartphone apps have the potential to

engage patients as advocates in their personalized care, as well as offer health care providers objective

assessments of their patients' daily activity patterns. However, this review finds very little evidence to

support their long term efficacy in enhancing rehabilitation pathways post THR. Future work is required

to establish which monitoring technology is most valuable to patients, which improve clinical outcomes

post THR, and what are the best economical models for their deployment.

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to this work

47

Device	Sensor	Price	Battery life	Tracking features
Fitbit zip TM	Accelerometer	£49.99	4-6 months	Steps, calories, distance
Fitbit alta™	Accelerometer, vibration motor	£99.99	Up to 5 days	Steps, calories, distance, sleep, gym activity profiles
Fitbit Charge 4 TM	Accelerometer, vibration motor, Barometric altimeter, GPS	£129.99 Up to 7 day		Steps, calories, distance, sleep, floors climbed, intensity minutes, stress, gym activity profiles, heart rate, swim profile
Garmin Vivofit® 4	Accelerometer	£69.99	12 months	Steps, calories, distance, sleep
Garmin Vivosmart® 4	Accelerometer, Garmin Elevate TM wrist heart rate monitor, Barometric altimeter, Ambient light sensor, Pulse Ox	£119.99	Up to 7 days	Steps, calories, distance, sleep, floors climbed, intensity minutes, stress, gym activity profiles, heart rate, swim profile
Garmin Vivosport®	Accelerometer, Garmin Elevate TM wrist heart rate monitor, Barometric altimeter, GPS	£149.99	Up to 7 days	Steps, calories, distance, sleep, floors climbed, intensity minutes, stress, gym activity profiles, heart rate, swim profile, biking
Garmin Forerunner® 35	Accelerometer, Garmin Elevate™ wrist heart rate monitor, GPS	£129.99	Up to 9 days	Steps, calories, distance, sleep, floors climbed, heart rate, biking, running profiles

 Table 6: Fitbit and Garmin product summary.

2.3 New evidence, revision of aims and objectives

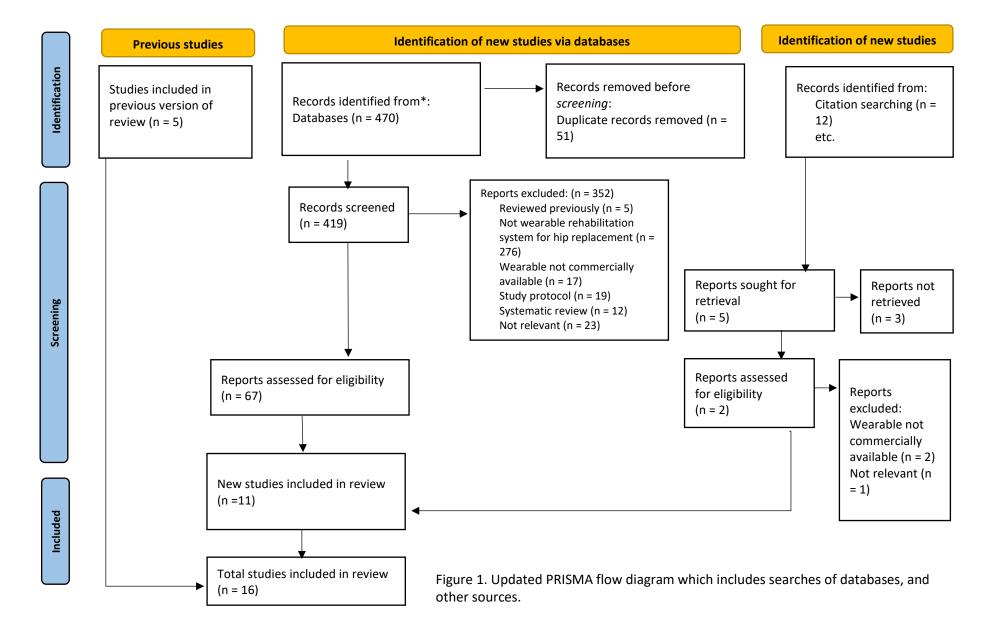
2.3.1 Introduction

Since our last review, the utilisation of commercial activity monitors for monitoring individuals after THR surgery has advanced rapidly. In an earlier review (Bahadori et al. 2020a), there were only five papers that met the eligibility criteria of which only two utilised wearable activity monitors. Three years on, a systematic search was carried out using the same strategy as the published review article, excluding the search terms related to smartphone apps. The justification behind the exclusion of smartphone apps is further discussed in Chapters 3 and 5. This chapter concludes with further reports on the reflections following the publishing of the literature review and the development of the overall study objectives as a result of the findings.

2.3.2 New evidence

A computer-based search was completed in December 2022 using the mySearch Database (Bournemouth University). The methodology for this search was exactly as per the systematic review study with two amendments: 1) The smartphone apps-related search terms were excluded; 2) The search date started from January 2019.

In addition to the database search, the references of the selected articles were screened and other studies that met the inclusion criteria were included. In total, 11 new papers were included for review. An updated PRISMA flow diagram including all papers is outlined in Figure 1.



The 11 new studies found are summarised in Table 2. A total of 913 THR participants, of which about 65% were female, took part in these 11 studies. The average age of the participants was 62.3 (±7.4) years old. The feasibility of the activity monitors for remote monitoring of individuals' daily activity (Bini et al. 2019; Madara et al. 2019; Mehta et al. 2020; Crawford et al. 2021), adherence to their rehabilitation programme (Goel et al. 2020; Karas et al. 2020; Goeb et al. 2021), and its effect on increasing individuals post-operative activity (Daskivich et al. 2019; Vaughn et al. 2019; Tang et al. 2021), were the main aims of the studies found.

Five brands of commercial wearable activity monitors were used, with Fitbit devices utilised in 7 out of 11 studies. All studies used wearable activity monitors to monitor individuals' number of steps, as a measure of their daily physical activity. Additionally, the number of floors, ascended and descended, sleeping hours, and minutes of daily activity were collected in four other studies (Bini et al. 2019; Madara et al. 2019; Karas et al. 2020; Tang et al. 2021). Two studies combined mobile-health applications like the MoveUp or Mymobility platform with activity monitors (Crawford et al. 2021; Lebleu et al. 2021). In two studies, the participants were divided into control and intervention groups. The control groups mostly received the usual care consisting of physiotherapy pre and post-surgery and a single session in which they received information about the operation, walking with crutches, and exercises that would be performed in the post-operative phase (Madara et al. 2019; Crawford et al. 2021). The interventions included personalised rehabilitation programme based on individual goals (a variety of vocational and recreational activities such as basketball, golf, jogging, and curling) (Madara et al. 2019; Lebleu et al. 2021), and educational materials pre and postoperatively including an eight-week home-based exercise programme (Crawford et al. 2021). Studies ranged from 3 to 112 days in duration, with an average length of 42 days.

The majority of the studies demonstrated an overall increase in the number of daily steps and individuals' level of activity, after their surgery. Goeb et al. (2021) found an improvement in pain for approximately every 1000 steps walked by individuals after their surgery. Lebleu et al. (2021), findings suggested that individuals reach their pre-operative physical activity level at week 7, with no significant additional improvement by three months post-surgery. It is also reported that post-THR individuals returned to near baseline levels over roughly three months (Karas et al. 2020; Tang et al. 2021). A factor for the variability of up to 35% in step count at three months was correlated to the number of days using crutches (Lebleu et al. 2021). Presurgery rehabilitation and home exercises were associated with better rehabilitation after surgery (Karas et al. 2020). Daskivich et al. (2019) claimed that up to 1000 steps on the first-day post-THR surgery can correlate with lower odds of prolonged length of stay.

Daily activity metrics and heart rate data were generally observed to be less variable than sleep data (Karas et al. 2020). This is possibly due to poorer night time data coverage and the relatively low accuracy of current models for estimating sleep metrics from consumer wearables (Liang and Chapa-Martell 2019). Nevertheless, despite studies relying on daily step count to evaluate correlations to ambulation (Daskivich et al. 2019) or health outcomes (Bini et al. 2019; Karas et al. 2020; Tang et al. 2021), there were no prior reliability or validity evaluation of the wearables used. This is a major limitation of all studies given recent studies have highlighted a major limitation of current commercial activity monitors, to be a lack of accuracy at slower walking speeds (Le Masurier and Tudor-Locke 2003; Alinia et al. 2017a).

In general, all of the studies agreed that wearables can encourage the individual to increase their activities during rehabilitation. Furthermore, evidence enhanced the previous findings

that subjective measures (PROMS) may provide only part of the story, and therefore,

objective measures for monitoring postoperative recovery should be utilised in the individuals' surgical pathways.

Table 2. Summary of 11 new studies.

	REFERENCE	STUDY POPULATION	WEARABLE DEVICE	DEVICE FUNCTION	STUDY AIM	STUDY METHOD	RESULTS AND CONCLUSION
1	Bini et al. (2019)	22 THR, and 22 TKR participants	Fitbit Flex	Steps count, number of ascended and descended floors, and minutes of daily activity	To determine the feasibility and the accuracy of Fitbit device for prediction of health outcomes after TJR surgery.	Daily activities were monitored from 4 weeks before to 6 weeks following surgery. PROMS (HOOS, KOOS, VR-12) were collected at both endpoints.	Data derived from the Fitbit activity trackers can be used to predict individuals' recovery, however, there is no clear association between preoperative activity levels and postoperative PROMs.
2	Daskivich et al. (2019)	15 THR, and 85 other (various surgeries) participants	Fitbit Charge HR	Steps count	To determine the correlation between daily step count and physicians' accuracy of ambulation assessment, and individuals' length of stay.	Sociodemographic and clinical data via review of the medical record were collected. Daily step count was passively monitored for the duration of hospitalisation.	Findings suggested that there is an association between the number of daily steps in the early postoperative period and the length of stay. The Fitbit activity monitor improved the accuracy of the assessment of ambulation over the current standard of care.

3	Madara et al. (2019)	20 THR participants	FitBit Zip	Steps count, number of ascended and descended floors	To evaluate the feasibility of home exercise intervention after THR and individuals' long-term adherence to the intervention	The intervention group was prescribed a progressive home exercise program and generally, training in this group was tailored to individual patient goals. The control group participated in usual rehabilitation care after THR surgery. Results were compared between groups at 16 weeks after surgery.	The study suggested that a personalised rehabilitation goal that includes a period of homebased exercises, followed by supervised movement training may benefit individuals after THR surgery.
4	Vaughn et al. (2019)	23 THR, and 28 TKR participants	Fitbit Zip	Steps count	To determine if participants accurately report the distance walked compared to that measured by an accelerometer within a 50% margin of error.	Each participant wore a FitBit for 1 week and was blinded to its measurements. The participants reported their perceived walking distance in miles daily. Data were collected preoperatively and 6 to 8 weeks postoperatively.	The mean magnitude of error in self-reported walking milage was 69% preoperatively and 93% postoperatively. Providers should exercise caution when interpreting individuals' reported activity levels before and after THR.

5	Goel et al. (2020)	13 THR, and 12 TKR participants	Fitbit Charge HR and Apple Health Application	Steps count	Determine the optimal anatomical placement of activity monitoring devices and smartphones to accurately measure postoperative step count following TJR.	Two weeks after their joint replacement surgery, an activity monitor was placed at a different location on the participant's body during a 100m walk test.	Both trackers had unacceptable error levels early in the postoperative period, but the Fitbit on the contralateral ankle and iPhone on the contralateral hip showed acceptable error rates of less than 30% at 2 weeks postoperatively when gait is normalising.
6	Karas et al. (2020)	196 THR, and 1128 other (arthroscopy and bone fracture) participants	Fitbit Flex	Steps count, heart rate, and sleeping hours	To evaluate individuals' recovery and time scale to return to relative personal baseline levels	Data on steps count, heart rate, and sleep were derived by tracker up to 26 weeks before and after the surgery.	Fitbit was feasible in the collection of all daily behavioural measurements. The trajectory of recovery is relative to the individual, and it differs in different surgery.

7 Mehta et al. (2020)

80 THR, and 182 TKR participants

Withings

of activity monitoring and bidirectional text messaging on the rate of discharge to home and other clinical outcomes after TJR.

Steps count To assess the effect In the intervention group, participants received a wearable activity monitor to track step count and had postoperative goals and milestones, pain score tracking, and access to clinicians as needed. In the control group, they received the usual care.

There was no significant difference in the rate of discharge to home between the usual care group and the intervention group. There was a significant reduction in the rehospitalisation rate in the intervention arm, which may have resulted from goal setting and connection to the care team.

(198 control and remote monitoring group, 167 exercise platform. intervention time group)	such as physiotherapy use, outpatient visit, THR complications, and readmissions, were collected and outcomes between groups were compared before surgery, and at 30 days and 90 days postoperatively. Early outcomes including PROMS (HOOS, JR EQ-5D-5L)	physiotherapy use was statistically lower in the intervention group. However, there were no significant differences in complications, readmissions, outpatient visits, or
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and physical functions (SLS TUG)

were assessed.

early outcomes

between the groups.

9	Goeb et al. (2021)	72 THR participants	Letscom Plus HR	Steps count	To evaluate postoperative recovery and physical activity using an activity monitor.	Participants wore the tracker from 1-week pre to 6 weeks post-operation. participants reported their daily step count and HOOS-JR was used to assess individuals' hip-related outcomes.	A significant correlation was found between increased weekly steps and improved HOOS-JR scores post-THR. Although the use of wrist-based trackers was useful, several technical errors limit the ability of this wearable to accurately record data.
10	Tang et al. (2021)	41 THR participants	FitBit Flex	Steps count, and sleeping hours	To compare objective daily activity and sleep data from Fitbit to the PROMS subjective score.	HOOS-JR scores were collected at 1-day pre-surgery, and at 2 weeks, 1 month, and 3 months post-surgery. Subjective were compared to Fitbit objective data.	Patients reported remarkable improvements in activity level and sleep, whereas the objective did not correlate with that.

11	Lebleu et al. (2021)	66 THR, and 66 TKR participants	Nokia®Go	Steps count	To determine peri operative factors that could help predict individuals' post-operative recovery.	Participants received personalised daily exercises and feedback through a tablet. Nokia activity monitor was used to track individuals at one week before until 3 months after surgery. PROM (HOOS, KOOS), the number of days of anti-inflammatory drug intake, the number of days using crutches, and pre-operative symptoms were recorded.	The physical activity level at 3 months could be moderately predicted by preoperative step count, duration of using crutches postsurgery, and preoperative symptoms level.
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2.3.3 Reflection on the review

Findings from the systematic review and the new evidence, are in agreement over the possibility that wearable activity monitors may enhance the recovery process by providing various physical activity information such as the number of steps, quality of sleep, heart rate, and energy expenditure. In addition to helping individuals after their THR surgery, wearables could also provide valuable objective information for surgeons and physiotherapists. This is important as current practice relies mainly on PROMS self-reported subjective information and evidence have suggested discrepancies when these data are compared to objective and performance-based functions (Luna et al. 2017a; Holl et al. 2018; Bini et al. 2019; Tang et al. 2021).

The trajectory of the recovery in THR individuals also suggests that in addition to individuals feeling socially isolated post-surgery, it will take a minimum of three months for them to return to the level of activity pre-surgery (Bandholm et al. 2018). In many cases, data suggest that individuals do not reach their pre-operation level of activity even a year post-surgery. This may be due to the fact that all studies only focus on interventions where step count is used as a parameter for measuring or enhancing the level of activity.

Nevertheless, a reflection upon the findings of the review provided the followings direction and consideration. First, I believe that involving individuals in goal setting is essential and will define the use of the appropriate activity monitor. Good compliance is an important part of a successful surgical recovery pathway and it's greatly influenced by individuals' characteristics (Reychav et al. 2019). Second, a limitation of all of the studies reviewed here is the uncertainty around the accuracy and reliability of the activity monitors, in particular where a lack of

accuracy is used to make clinical decisions (Daskivich et al. 2019). Third, wearables should be regarded as facilitators rather than drivers of change in health behaviour (Patel et al. 2015). Future research protocols should be designed with an aim to utilise wearable activity monitors or smartphone apps to offer a more organised, realistic, easy, and engaging experience than the use of the device alone.

2.4 Chapter Summary

The findings suggest that commercially available activity monitoring wearables have the potential to engage individuals as advocates in their personalised care, as well as offer health care providers objective assessments of their patients' daily activity patterns. However, current evidence does not suggest a trajectory in which individuals' goals were explored before they were given a particular rehabilitation or home-based exercised programme. This has also led to data suggesting individuals are not returning to pre-op level of activity even a year post-THR surgery. Therefore, it is essential to explore that an individual undergoes THR surgery, but also does this goal remains after they had their operation. Additionally, there is evidence suggesting that individuals often experience social isolation and a sense of confusion regarding self-care following surgery (Bandholm et al. 2018). Therefore, what are their thoughts and feelings on the use of wearables which may allow them to have an objective assessment of their daily level of activity and subsequently their recovery. Conversely, where do healthcare professionals stand when it comes to personalised rehabilitation and the use of technologies such as wearable activity monitors?

The concept of using a commercial activity monitor for tracking individuals after THR is also shadowed by the lack of evidence on the accuracy and reliability of this technology. This may

also be the reason that healthcare professionals are hesitant in recommending such technology.

The following chapter discusses how I involved a group of individuals before and after THR surgery, and also Healthcare Professionals (HCPs) to explore their perspectives of THR surgery and the potential use of simple, commercially available activity monitors in rehabilitation by advocating a Patient and Public Involvement (PPI) approach.

"To learn through listening, practice it naively and actively. Naively means that you listen openly, ready to learn something, as opposed to listening defensively, ready to rebut. Listening actively means you acknowledge what you heard and act accordingly." **Betsy Sanders**

Chapter 3 – Why Do People Undergo THR - Patient and Public Involvement

3.1 Chapter overview

This chapter outlines the Patient and Public Involvement (PPI) approach undertaken to understand why individuals undergo THR surgery and their rehabilitation goals. Similarly, insight into the views and perspectives of orthopaedic surgeons and physiotherapists regarding the surgical pathway, use of wearables, and what objective measure will assist with their decision-making is reported. The main section of this chapter is in the form of a research report published as part of this study (Bahadori et al. 2020c). The chapter ends with reflecting on the PPI findings and summarising the aims and objectives of the next chapter based on the findings of the PPI.

3.2 Patient and public involvement (PPI) article

Why Do People Undergo THR and What Do They Expect to Gain-A Comparison of the Views of Patients and Health Care Professionals?



Why Do People Undergo THR and What Do They Expect to Gain—A Comparison of the Views of Patients and Health Care Professionals

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Abstract

Little concerted effort has been made to understand why individuals undergo total hip replacement (THR) surgery and their rehabilitation goals. Similarly, insight of views and perspective of health care professionals' (HCPs) regarding surgery and what objective measures help them with decision-making is lacking. This patient and public involvement report aimed to explore both patients' and HCPs' perspectives of THR surgery. Twenty patients, 10 pre-THR, 10 post-THR, 9 physiotherapists, and 6 surgeons took part. Results suggest a consensus among patients and HCPs on pain reduction being the main reason for undergoing THR. The inability to carry out simple daily activities such as dog walking and sleep deprivation had a significant effect on patients' mental and physical well-being. This article is the first to explore the views of THR patients and HCPs on reasons behind THR surgery amalgamated into a single report. As walking is important, wearable activity monitors are suggested as a possible motivator to enhance patient compliance to self-care rehabilitation and increase quality of life. A future research project on the use of such wearable activity monitors in enhancing mobility post-THR is therefore planned.

Keywords

patient and public involvement, patient experience, health care professionals, total hip replacement

Introduction

Patient and public involvement (PPI) in research has expanded rapidly, both nationally and internationally, with the aim of improving all aspects of the research process from commissioning to dissemination and evaluation (1). A PPI approach is recommended where researchers collaborate with the patient and/or public to help plan research projects, particularly where the focus is "new" knowledge about the lived experience (2,3). The aim of this article is to explore both patients' and HCPs' perspectives of THR surgery and the potential use of a simple, commercially available activity monitors in rehabilitation by advocating a PPI approach.

Theoretical Underpinnings

Total hip replacement (THR) is an effective treatment for most individuals who suffer from pain and loss of function due to end-stage symptomatic osteoarthritis (OA) of the hip (4). By 2030, the incidence of THR for OA is predicted to

rise by 208% in Australia (2) and 174% in the United States (5). Studies from the United Kingdom, Canada, Taiwan, and Denmark also predict increases in hip replacement surgery, although estimates vary widely (6–9). Eighty percent of those affected by hip OA report some degree of functional limitation and 25% cannot perform routine daily living activities such as getting dressed (10). The prevalence of hip OA is set to rise, along with its economic burden, both from high direct and indirect costs (11).

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2 Journal of Patient Experience

In 2016, the typical hip replacement patient in the United Kingdom was 69.8 years old (female) or 67.6 years old (male), and had a body mass index of 28.8 (12). Few studies have used PPI to explore a patient's decision to undergo THR (13,14). Dosanjh et al (13) conducted interviews with patients regarding their decision to undergo hip replacement, concluding that decisions to undergo surgery were based upon increasing severity of limitations affecting their basic quality of daily living, relationships, and psychological well-being (13).

Efforts to aid decision-making have centered on clinicians providing information to patients to make trade-offs between costs and benefits. Recent qualitative studies (15,16) have explored patients' unwillingness to consider total joint replacement (TJR) surgery due to negative presurgery perceptions. These studies highlighted the lack of patient knowledge and how discussions about TJR might be initiated (and by whom) as a major influence on patient unwillingness to consider TJR surgery (15,16).

Perspectives of orthopedic surgeons on patients' appropriateness for TJR have also been a subject of interest (17). In a qualitative study, surgeons were asked (1) what their criteria is for TJR; (2) do they use support tools to assess appropriateness for surgery; and (3) what role the patient plays in their decision-making (17). Surgeons agreed that pain and its impact on quality of life is key to determine appropriateness, however they also agreed that these concepts are complex, multifactorial, and do not always correlate with joint radiographs (17). Some surgeons used a wider range of criteria, including assessments of patient expectations, ability to cope, and readiness for surgery (17). While age was not a factor for decision-making, surgeons acknowledged that criteria may differ between younger and older patients (17). Most also agreed that there is a need for an appropriate decision-making tool, albeit that the final decision will always be based upon surgeons' discretion within the context of the doctor–patient relationship (17).

Concepts and Theory Development

Patient-reported outcome measures (PROMs) have been introduced by national health systems and quality networks to ensure clinical standards and to supervise outcome after THR (18). Despite concerns over standardization (19), studies have shown an association between presurgical values and postoperative outcomes (20–22). However, discrepancies between PROMs and performance-based function are seen (23) and a number of studies have suggested caution when only using subjective data as the measure of recovery (23–25). Additionally, compared with preoperative function, postoperative activity levels are low and many individuals become socially isolated following surgery (26,27). Specht et al (28) explored the experience of individual undergoing THR during 12 weeks postdischarge from hospital. They found that there was a feeling of uncertainty among THR

patients at being left on their own after discharge, which affected their self-management and recovery at home (28).

A paradigm shift in the management of patients preand postsurgery toward self-management has been advocated to improve patient surgical pathways (29). Thewlis et al (29) objectively measured 24-hour activity profiles (ie, walking activities and sleep) before and after THR, using a wrist-worn accelerometer (29). They found patients were inactive and slept poorly prior to THR and showed no improvement in 24-hour activity profiles 6 months postoperation. Commercial activity trackers and smartphone apps have been explored for monitoring and enhancing physical activity following surgery (30–34). However, very little evidence was found to support long-term efficacy of the technology in enhancing quality of life and patient monitoring post-THR (35).

Aim

Overall, there is a lack of evidence surrounding an individuals' pre and post-THR views and perspectives (36). No concerted effort has been made to advocate partnership with individuals undergoing THR to understand their reasons for undertaking surgery and their ultimate rehabilitation goals. Similarly, insight is lacking on the views of HCPs, such as surgeons and physiotherapists, to understand their perspectives on surgery and what objective measures will assist with decision-making. The aim of this article is to obtain HCPs' and patients' perspectives of THR surgery and the use of simple commercially available activity monitor in rehabilitation by advocating a PPI approach.

Methods

This article is reported with reference to the Guidance for Reporting Involvement of Patients and the Public (37) checklist.

Engagement Strategy and Individuals Involved

With a focus on digital technologies, it was decided to publish the "invitation to get involve" advert through a social media platform (Twitter). The lead author had Twitter followers, including local hospitals, local universities, NIHR INVOLVE, Chartered Society of Physiotherapy, British Orthopaedic Association, and International PPI and therefore reached a large number of patients, surgeons, and physiotherapists across a wide geographical area. An online approach was taken to recruit those who already use smartphone apps in their daily routine to minimize the gap between digital technology and the typical demography of those having received THR (over 65 years old). Moreover, there is evidence to support an increase in orthopedic patients (38), orthopedic surgeons (39), and physiotherapists (40) using social media. A topic guide, informed by previous literature (28) and

Bahadori et al 3

Before Surgery Patients

Age:

Gender:

Roughly how long you have had the hip pain:

- 1. In regards to your physical activity, what sort of things did you do prior to your hip arthritis?
- 2. What are your top three limitations?
- 3. How do you cope with these limitations?
- 4. Have you had professional help to manage these limitations (i.e. are you seeing a physiotherapist or others)? If so what have they suggested?
- 5. Are you or would you consider hip replacement surgery?
- 6. What do you hope that surgery will accomplish for you?
- 7. Would you like to be more active? How?
- 8. Do you have or use a smartphone or a mobile phone?
- 9. Have you owned an activity monitor or know anyone who owns one? If no, would you consider one to help you get more active? If yes, How do you find using one?
- 10. Any other comments:

Figure 1. Topic guide example—before total hip replacement group.

designed by the project team, was used to explore each group's thoughts on surgical and recovery pathways and their perspectives on the use of a simple commercially available activity monitor in rehabilitation (patients) and diagnosis (surgeons and physiotherapist). Figures 1–4 detail an example of topic guide questions.

Inclusion and Exclusion Criteria

The post-THR group included individuals who had undergone one or both hip replacements within a year. A year was chosen to represent the time frame to recovery post-THR. The group yet to receive THR included those who were diagnosed with symptomatic arthritis and were on the hospital list to have operation within a year. The surgeons group included were orthopedic specialists with over 5 years of experience and having performed at least 200 cases of THR surgery. The physiotherapist group included those who had over 2 years of experience working with patients within an orthopedic setting.

Results

Demographics

A total of 35 people were invited to take part in the PPI groups. Depending on participant preference, location, and availability, the lead author conducted face-to-face (n=15) and telephone (n=20) discussions lasting between 25 and 35 minutes with each individual group member between 4th and 30th of August 2019. Notes about the interactive discussion were made during the conversation by the lead author and subsequently transcribed. Demography and relevant information of all group members are summarized in Table 1.

Outcomes of PPI

The core concepts that emerged for each of the PPI groups are summarized below.

The views of individual yet to undergo THR (n = 10)

Physical activity. Seven group members reported pain was the trigger to decrease physical activity. The majority of the

Journal of Patient Experience

Post Surgery Patients

Age:

Gender:

Date of surgery:

- 1. In regards to your physical activity, what sort of things did you do prior to your hip arthritis?
- 2. What weren't you able to do after your hip arthritis worsened?
- 3. What were your top three limitations?
- 4. How did you cope with these limitations?
- 5. What factors led to your decision to consider the option of hip replacement?
- 6. What has surgery changed for you?
- 7. Have you been able to accomplish your goals post-surgery?
- 8. Do you feel more active? Would you like to be more active? How?
- 9. Do you have or use a smartphone or a mobile phone?
- 10. Have you owned an activity monitor or know anyone who owns one? If no, would you consider one to help you get more active? if yes, How do you find using one?
- 11. What would you change (if any) from your rehabilitation journey?
- 12. Any other comments:

Figure 2. Topic guide example—after total hip replacement group.

individuals (8 members) lived an active lifestyle which involved walking, carrying out professional/family-related activities, and sport.

Limitations and goals. Individuals had a strong sense of wishing to "help themselves" in the early stages of hip pain, but at the point of formal diagnosis, most could not carry out simple daily activities which required bending (ie, wearing socks), were unable to walk for long periods of time, and felt their sleep was affected. Anti-inflammatory painkillers were a common solution to managing the pain. Prior to undergoing THR, patients were treated with physiotherapy, hip block injections (a combination of a synthetic steroid and a local anesthetic), and a cycling program. Individuals particularly sought out THR with the goal to return to walking, become active, and generally get their "normal life back."

Activity monitors. All participants, except 2, currently use a smartphone, 4 people had wearable activity monitors, and 1 used a smartphone activity monitor app. There was agreement

that they were unsure of safe levels of activity. Individuals wanted to know what they could do to help themselves and, in particular, what simple task they could carry out before the THR operation to serve as prehabilitation.

Views of individuals after their THR (n = 10)

Physical activity. All group members were active individuals with the top 3 activities including walking, swimming, and playing golf. However, as their symptomatic hip arthritis worsened, their activities were reduced significantly. Their inability to carry out simple activities such as dog walking, moving around the house, and even engaging in sexual activities were affecting mental and physical well-being. The increasing restrictions upon their life were a main factor for them considering THR surgery.

Limitations and goals. The top 3 reported limitations were pain, the inability to walk, and lack of quality sleep. All group members had to compensate by stopping some of their activities or cope with the pain by taking anti-inflammatory

Bahadori et al 5

Orthopaedic Physiotherapists

Job Title:

Number of years working as a physiotherapist:

- 1. When do you see patients after surgery?
- What percentage of patients would you say attend pre-surgery physiotherapy clinic?
- 3. What is the initial assessment you carry out in the first clinic post-surgery?
- 4. What are the questions you tend to ask post-surgery?
- 5. How often do you see the patients and for how long?
- 6. Is there a common approach/check list to assess patient's rehabilitation pathway?
- 7. Do you encourage self-care? What are you recommendations?
- 8. What is an ideal yet simplest activity that you would recommend to your patients? Are they something we can measure with simple activity monitor (think Fitbit, Garmin etc.)?
- 9. Do you change your post-surgical rehabilitation to fit individual's goals? If so what are they?
- 10. Any other comments:

Figure 3. Topic guide example—physiotherapists group.

painkillers. However, for 9 group members, surgery was a revelation in terms of pain free movement, returning to work, being able to walk again, and regaining some level of normalcy. Three members still experienced some pain a year after their THR, but 6 said that they had fully accomplished their presurgery goal of mainly pain-free movement. All group members agreed that, a year after surgery, they are more active compared to the year before surgery, yet they would like to progress from "pain free" to "do more." This "do more" phrase referred to activities such as playing tennis, playing golf regularly, going hiking, and power walking.

Activity monitors. All group members, except 1, currently use smartphones. Three used an activity tracker for cycling and running prior to their operation. In general, they were not adverse to having an activity monitor but they felt there were limited opportunities to ask health professionals about what level of activity they are allowed to engage in, with 1 participant feeling that at times they were "fobbed off." Having a personalized rehabilitation program was the only thing they would change from their rehabilitation pathway.

Views of orthopedic surgeons (n = 6)

Patient demography. All surgeons described the most common demographic of those who attend their clinic as females

aged 65 to 80 years. All surgeons identified pain as the most common complaint from the patients, followed by loss of mobility and sleep deprivation.

Surgeons' approach and decision-making. All surgeons mentioned carrying out a physical assessment, in particular the Trendelenburg test (41), during their patient's visit to clinic. Surgeons expressed the opinion that as pain was difficult to measure and assess, pain scores needed to correspond with significant radiographic abnormalities. Similarly, a poor radiographic result was not deemed as the ultimate decision-maker, unless significant pain and limitations were being expressed. One surgeon expressed the decision-making as: It is a 'joint' decision between the patient and I. It's a journey we embark upon together. There is no single factor, but a culmination of a sensible discussion with the patient based on understanding the risk/benefit and the options available.

Furthermore, quality of life was mentioned by all surgeons but was interpreted differently. Three surgeons expressed it as performance of activities of daily living, while the other 3 surgeons included additional considerations, such as hobbies/sport.

Preoperative and postoperative service. None of the surgeons who took part in our group have a routine

Journal of Patient Experience

Total Hip Replacement Surgeons

Job Title:

Number of years working in Orthopaedics:

Number of hip replacements:

Assisted:

Performed:

- Could you please describe the most common demographic of the individuals who attend your clinic?
- 2. What are the most common complaints that you hear from patient?
- 3. Do you test patients in your clinic? If so how?
- 4. What are the factors most important to you when it comes to making a decision on whether or not an individual needs a THR surgery?
- 5. Do you have pre-surgery programme for your patients? If so what are they?
- 6. When do you see your patients after surgery (follow up clinic time-scale)?
- 7. Do you perform any tests in the follow up clinic? If so what test?
- 8. What is an ideal yet simplest activity that you would recommend to your patients? Are they something we can measure with simple activity monitor?
- 9. Is digital rehabilitation (e.g. apps or wearable's etc...) something that you would consider in your future patient pathways?
- 10. Any other comments:

Figure 4. Topic guide example—orthopedic surgeons group.

preoperative program for patients. One surgeon said he recommends weight loss and hip friendly exercises such as cycling, yoga, or walking. Five surgeons see the patients up to 6 weeks postsurgery in which they prominently focus on checking the wound for infection. One surgeon does not see his patients until 3 months postsurgery. Three surgeons said that they do a physical examination, such as watching patients walk.

Activity monitor. Because of difficulties quantifying patients' pain, surgeons tended to focus on the impact of pain on patient mobility or sleep. All surgeons agreed walking was a measurable activity which can be quantified with a simple activity monitor. Surgeons also recognized the benefit that simple activity monitors could have on improving

patient engagement, reassurance, and motivation. Moreover, they expressed their interest in using technology to monitor patients postoperatively.

The views of orthopedic physiotherapists (n = 9)

Preoperative management. Physiotherapists agreed that preoperative physiotherapy is not a usual pathway in the health care system and 6 said only 10% to 30% attended preoperative sessions. They also agreed that those sessions are normally around THR education and expectation during discharge.

Postoperative management. Postoperative management usually starts 1 day postsurgery for the patients. This normally takes around 30 minutes and involves review of the

Bahadori et al 7

Table 1. Demography and Relevant Information of all Group Members.

Group	Gender	Age	Date of surgery	Suffering from hip pain	Job title	Years in orthopedic	THR performed
After total hip replacement	Female	81	May 2018				
(THR) surgery	Female	61	Feb 2018				
	Female	71	Sep 2018				
	Male	66	Nov 2018				
	Male	74	Mar 2018				
	Male	44	Jul 2018				
	Male	69	Jan 2018				
	Male	69	Nov 2017				
	Male	70	Nov 2018				
	Male	79	Nov 2018				
Before total hip replacement	Female	59		3 Years			
(THR) surgery	Female	57		4 Years			
, , <u>,</u>	Female	51		2 Years			
	Female	55		3 Years			
	Female	45		3 Years			
	Male	66		2.5 Years			
	Male	71		4 Years			
	Male	64		l Year			
	Male	61		2 Years			
	Male	68		2 Years			
Surgeon	Male				Consultant orthopedic surgeon	>10	>600
_	Male				Hip fellow	10	453
	Male				Consultant orthopedic surgeon	10	800
	Male				Consultant orthopedic surgeon	16	823
	Male				Hip fellow	8	260
	Male				Consultant orthopedic surgeon	15	400
Physiotherapist	Female				Senior orthopedic physiotherapist	8	
,	Female				MSK/orthopedic physiotherapist	2	
	Female				Senior physiotherapist	11	
	Female				MSK/orthopedic physiotherapist	2	
	Female				Senior orthopedic physiotherapist	16	
	Female				Junior orthopedic physiotherapist	6	
	Female				Senior orthopedic physiotherapist	40	
	Male				Senior orthopedic physiotherapist	22	
	Male				Senior orthopedic physiotherapist	15	

Abbreviation: MSK, musculoskeletal.

operation notes, checking for infections, checking for signs and symptoms of blood clots in the leg, and carrying out basic functional assessment. Functional assessment includes gait and range of joint movement. Two members said that they discuss long-term goals and expectations with their patients at this point.

A further postoperative session is arranged from days 10 to 14. This session is a more comprehensive discussion to understanding an individuals' goals. Understanding pain levels, sleep deprivation, functional restrictions and precautions, short-term goals, long-term goals, and realistic expectations of physiotherapy is sought. A follow-up session is set up for weeks 5 to 6. Only 1 physiotherapist had a protocol, modified Iowa (42), for the follow-up sessions. All physiotherapists agreed that the current system only enables 10 to 30 minutes with each patient per visit, which they consider is insufficient and therefore there is a great reliance on patients' self-care and home exercises.

Activity recommendations and monitoring. A common recommendation from physiotherapists to patients is to "get active, stay active and exercise regularly but always listen to your body", "listen to your body," refers to hip pain, as pain is to be expected if patients have "exceeded" their exercises. All members agreed that walking is the best exercise to recommend. All members also agreed that activity monitors are very effective in self-management, facilitating compliance to home exercises.

Discussion

Outcomes

This is the first PPI report to explore THR patients' and HCPs' perceptions about THR surgery as well as the use of activity monitors as a tool for surgical decision-making and rehabilitation. The findings from this PPI report indicate an overall recognition of the importance of physical activity

8 Journal of Patient Experience

and that engagement in activity can be greatly improved by the use of activity monitors. In the absence of pain postsurgery, patients described their wish "to do more" to achieve personal enjoyment. These findings are in line with the study by Harding et al (43), which also recognizes individual beliefs and perceptions as important influencers to THR recovery and they should be given a high level of priority by HCPs when developing rehabilitation plans.

Shared decision-making is increasingly presented as the preferred model for patient care (44,45). However, HCP members suggested that the current health care setting makes this difficult, mainly due to lack of consultation time suggesting that service constraints drive clinical decision-making. In association with lack of preoperative programs from HCPs, patients are normally left with a level of psychological distress (45). It is important to recognize that patients want to help themselves, and a simple activity such as walking could enable them to feel involved and encourage compliance in home care rehabilitation (46).

All HCP members agreed that activity monitors could positively complement their role and enhance their relationship with patients. Perceived benefits of activity monitors included monitoring patients' progress, treatment evaluation, monitoring compliance, and informing clinical decision-making. Objective data on a simple activity such as walking could be a used alongside PROMs to achieve goals and allow patients to take ownership of their treatment.

Impact

The impact of PPI can be divided into several categories. Firstly, partnership with THR patients and HCPs to understand their perspective is established for the first time in a single report. Secondly, it is now understood that the main reason for undergoing THR surgery is relief of pain and desire to gain normal life activities. Thirdly, there is need for an objective tool to facilitate clinical decisions between HCPs and patients. Walking ability was recognized as a factor that would assist in better understanding patients' expectations and standardizing indications for surgery and rehabilitation. Fourthly, improving patient compliance and creating a patient centered program can be a positive intervention on the THR surgical pathway and the use of a simple activity monitor may be the path forward.

Reflections/Critical Perspective

There are limitations to this PPI report. The PPI group was recruited online and therefore responses in regard to the use of activity monitor are subject to bias. Nonetheless, recruiting online meant that group members were not limited. In order to achieve a broader generalization, in particular with patient groups, the findings may require more participants. Nevertheless, this report opens previously unexplored issues that could help develop new studies for THR patients.

Conclusion

This article is the first to explore the views of THR patients and HCPs on reasons behind THR surgery in a single report. As walking is important, wearable activity monitors have been suggested as a possible motivator to enhance patient compliance to self-care rehabilitation and increase chance of long-term quality of life. A future research project on the use of such wearable activity monitors in enhancing mobility post-THR is therefore planned.

Authors' Note

As this article utilized an approach in line with governance procedures on PPI, the Health Research Authority (HRA) ethics database (47) confirmed ethics approval was not required and therefore was not sought.

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10 Journal of Patient Experience

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3.3 Reflection on the PPI study

PPI in research refers to the inclusion of patients or members of public as partners in the various stages of the research process, or as "research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them" ((NHRA) 2023). We advocated PPI as it was recommended as a suitable approach where the focus is 'new' knowledge about the lived experience. Despite a rapid increase in their popularity, the use of commercial activity monitors in interventions to promote physical activity after THR surgery is a relatively new phenomenon and therefore it sat well within the scope a PPI (Shin et al. 2019; Babaei et al. 2022).

Prior to our report, no concerted effort was made to advocate partnership with THR population to understand their reasons for undertaking surgery and their ultimate rehabilitation goals. In addition, orthopaedic medicine was referred to as the most suitable sector for adaptation and integration of digital health tools such as wearables (Bini et al. 2020), but insight was lacking on the views of healthcare professionals (HCPs), such as surgeons and physiotherapists, to understand their perspectives on surgery and possibility that wearables may offer with their decision-making. Therefore, a PPI study was deemed essential to make an inform our decision and create a patient-centred study (Marsh and Newman 2021),

The findings from this PPI study indicated an overall recognition of the importance of physical activity, and that engagement in activity can be greatly improved by the use of activity monitors. Individuals particularly sought out THR with the goal to be pain free and become more active and generally get their "normal life back". Walking was a common dominator in all of the physical activities outlined (for example, outdoor dog walks, taking grandkids to

park, hiking, etc.). Individuals awaiting THR wanted to know what they could do to help themselves and, in particular, what simple task they could carry out before the operation to serve as pre-rehabilitation. Post-surgery and in the absence of pain, all THR groups described their wish "to do more" to achieve personal enjoyment.

Seventeen out of twenty THR group members, owned a smartphone and in general, they were not averse to having an activity monitor, but there was mutual agreement that they preferred to wear a dedicated activity monitor rather than use a smartphone app, as they were not required to constantly carry their smartphone everywhere with them.

All surgeons described the most common demographic of those who attend their clinic as females aged 65 – 80 years old. All surgeons identified pain as the most common complaint from the patients, followed by loss of mobility and sleep deprivation. Walking ability was recognised as a factor that would assist in better understanding patients' expectations and standardising indications for surgery and rehabilitation. All members of the physiotherapy group agreed that walking is the best exercise to recommend, and activity monitors can be very effective in encouraging self-management.

3.4 Chapter summary

This PPI report provided insight into reasons behind people undergoing THR and their rehabilitation goals post-surgery. It is now understood that the main reason for undergoing THR surgery is the relief of pain and the desire to regain normal life. However, post-surgery and in the absence of pain, being able to undertake outdoor activities, such as long walks, are important. HCPs agreed that walking ability was a useful factor that would assist in better understanding THR individuals' expectations and standardising indications for surgery and rehabilitation. They also recognised that improving patient compliance and creating a patient-

centred programme can be a positive intervention on the THR surgical pathway and the use of a simple activity monitor may facilitate this.

Now that, the importance of walking has been highlighted, in the next chapter I aim to have an in-depth analysis of individuals walking after THR surgery through gait analysis. In this chapter, I investigate the key spatio-temporal gait parameters (walking speed, step length, and cadence) of THR patient's before and up 6 months after surgery and compare those results to gait data from age matched healthy volunteers, to identify the relevant parameters that can be improved, thereby enabling these patients desire to enhance their walking.

"The obstacle in the path becomes the i	path. Never forget, within emprove our condition."	every obstacle is an opportunity to
"The obstacle in the path becomes the i	path. Never forget, within e improve our condition." Ryan Holiday	every obstacle is an opportunity to
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"The obstacle in the path becomes the i	improve our condition."	every obstacle is an opportunity to

Chapter 4 – The Covid-19 pandemic

4.1 Chapter overview

Two years into this research project, the Covid-19 pandemic struck the world. This chapter summarises how the Covid-19 pandemic affected this research and the methodological changes made due to national lockdowns, the closure of universities, and the suspension of elective orthopaedic surgery such as THR.

4.2 The timeline of Covid-19

This project started in September 2018. In December 2019, the first case of coronavirus disease 2019 (Covid-19) emerged in China ((WHO) 2019). Covid-19 was declared a pandemic on the 22nd of March 2020 ((WHO) 2019) and on the 26th of March 2020, Prime Minster Boris Johnson legally declared a national lockdown in the United Kingdom (UK), ordering people to stay at home, with exception of essential outings such as food shopping or medical reasons (Government 2022). The UK government instructed the public to work from home where possible, with schools and Universities to close their campuses the staff and students. The ORI of Bournemouth University duly closed its doors for what would be six months at first, with all staff and students instructed to work from home. Elective orthopaedic surgery, including hip replacement, were cancelled to make bed space for patients with Covid-19, and all research was suspended so that all staff could focus on Covid-19 related trials.

The ORI team briefly returned to the Bournemouth University campus in August 2020, but unfortunately work from home was again ordered on 22nd September 2020. The second UK national lockdown was announced on the 5th of November 2020 (Government 2022). This lockdown was followed by a further lockdown due to wide spread of the Alpha variant which

saw the lockdown remain until July 2021 when a hybrid model of working was deployed for staff working at the University. All research studies were re-reviewed by university ethics committees and allowed to resume where considered safe and with appropriate Covid-19 precautions in place. All risk assessment procedures were re-reviewed and included extensive cleaning protocols and personal protective equipment.

With millions of orthopaedic surgeries cancelled across the globe, hospitals cautiously resumed their surgery lists, yet careful not to increase Covid-19 infection among hospital staff and patients. This approach saw NHS elective hip replacement fall from 330 cases per day to one or two between March and April 2020, resulting in 58,000 fewer hip replacement surgeries in 2020 (Foundation 2021). In response to the backlog, British Orthopaedic Association (BOA), introduced a three-phase approach based on the individual's urgency of surgery ((BOA) 2020). Further structural and organisation changes were also suggested to help the NHS deal with the massive backlog of those waiting for hip replacement surgery (Gammeri et al. 2020; Wainwright 2021). ORI is currently supporting a mass Outpatient assessment clinic, Dorset Health Village, whereby a Nightingale-style ward is deployed to tackle the backlog of diagnostic referrals for hip replacement surgery in University Hospital Dorset NHS Foundation Trust ((UHD) 2021).

4.3 The impact of Covid-19 on research

In March 2020, ORI suspended all its clinical trials due to national lockdown measures. Where possible, remote data collection was arranged, where data such as PROMS were collected over the telephone. Some of the staff were redeployed to support NHS, and others, such as myself, were instructed to work from home and focus on the analysis of previous data collected, and the preparation of academic papers.

As a result, it became very difficult to carry out undergraduate and postgraduate research projects during this period. Bournemouth University paused all research projects, in particular those with older adults. Research labs such as clinical gait assessment units were shut, and students were forced to create contingency plans and apply for funding extensions. It became almost impossible to deliver research studies within an NHS setting or at the University where the campus was locked. Furthermore, the suspension of orthopaedic surgeries both in the public and private sectors, in particular hip replacement surgeries, meant there were limited chances of being able to find volunteers to participate in trials. This impacted postgraduate students and their research projects, not just locally but also globally (Börgeson et al. 2021).

4.4 The impact of Covid-19 on research

4.4.1 Early closure of lab-based research

The first impact came in the shape of the early closure of lab-based projects. An area where most of my research is focused is gait analysis. I am the lead researcher in the ORI who, designs, delivers and analyses gait-related data collected on various orthopaedic related participants but mostly those undergoing THR surgery. The data presented in Chapter 5 is a secondary analysis of the data collected as part of two ORI projects. These studies are 1) An Evaluation of Health Outcomes for Mako Hip Replacement (HELLO) (ClinicalTrials.gov Identifier: NCT03846791) and 2) lower limb biomechanical analysis of healthy participants (BU reference ID 15005). Both studies commenced in 2019 and had planned to recruit 100 participants. However, they were suspended in March 2020 as per government advice on the closure of all university campuses. Hence both these studies were prematurely closed on the 15th of March 2020, and the analysis included the 18 THR participants and 18 health individuals who were recruited before the pandemic. The THR studies included timelines for

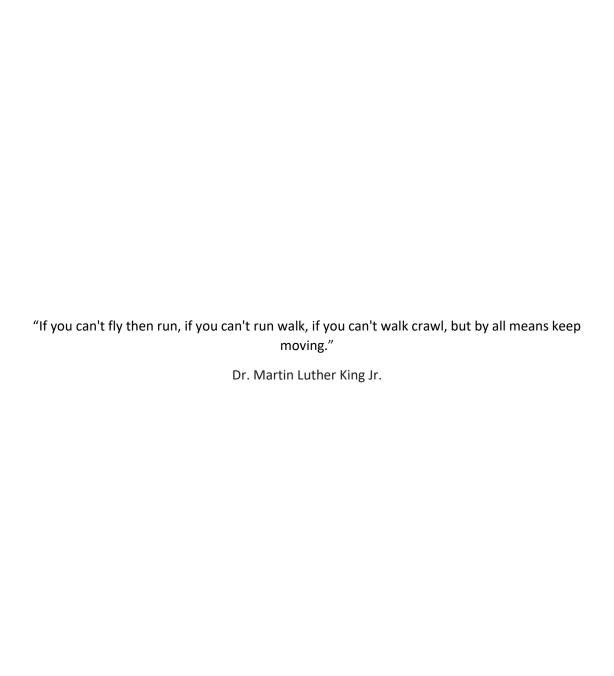
follow-up gait analysis at 6-weeks, 3-month, 6-month and 12-month post-surgery. Initially was aimed to continue with the study after the lockdown but the Covid-19 restrictions remained and delayed the follow-ups beyond 12-months and therefore a decision was made to carry out the secondary analysis with the data already available for up to 6 months post-surgery. Despite all effort to be COVID-19 compliant with health and safety measure, only 10 THR participants were able to attend their 6 months follow up appointments within their post operation timeline.

4.4.2 Suspension of research involving human participants

Despite relevant research ethics approvals prior to Covid-19 for studies described in Chapters 5 and 6, it was not possible to recruit human participants. In particular, given the common demographic of those undergoing THR surgery is 60 years old and over, the study aimed to recruit participants that are within the category of older adults. However, the older population fell within the category of vulnerable (NHS 2021) and were at high risk of getting COVID-19. Therefore, any studies requiring such participants were not allowed. Subsequently, understandably, both staff and students were not allowed to deliver non-essential research at Bournemouth University for around 18 months. Therefore, it was decided that I carry out studies with a minimal number of young healthy adults (three were recruited, section 6.2.2), and where possible I would be the participant of the study myself (sections 6.3.2.1 – 4). While this methodology was not originally planned, it provided a platform to carry out the assessment of the accuracy and precision of the wearables in a wide range of conditions and settings, and therefore greatly informed the design of the final studies in this research (Chapters 7 and 8).

4.5 Chapter summary

Although the pandemic resulted in a variety of new challenges and concerns to research, it also provided an opportunity to become more adaptable, creative, and resilient. Furthermore, it provided a platform to further assess the technical behaviour of wearable activity monitors in more settings than initially planned and prompted my critical thinking to create research protocols that can be applied to future research. Nevertheless, despite its challenges, the outcomes of the trials in this period greatly informed my final research study. The next two chapters describe studies that were modified in response to the pandemic and research challenges during this period.



Chapter 5 – Analysis of Walking in THR Population

5.1 Chapter overview

The findings from the PPI report showed that one of the main goals amongst those undergoing THR surgery is to be able to undertake more activities such as walking. This chapter outlines the secondary analysis of two studies' data which I collected as the gait analysis lead researcher for two projects at ORI. These studies are 1) An Evaluation of Health Outcomes for Mako Hip Replacement (HELLO) (ClinicalTrials.gov Identifier: NCT03846791) and 2) lower limb biomechanical analysis of 100 healthy participants (BU reference ID 15005). The complete dataset of the healthy individual's gait data (Bahadori et al. 2021), the protocol (Bahadori and Wainwright 2020a), and the reliability of the dataset (Bahadori et al. 2019b) have been already published elsewhere. However, the HELLO study is still ongoing and therefore has not been published yet.

This chapter reports the spatio-temporal data collected using a self-paced treadmill which is believed to be currently the best method to simulate free walking in a gait lab environment (Sloot et al. 2014; Plotnik et al. 2015). It concludes by discussing the spatio-temporal gait parameter that is least improved 6 months post-surgery and the possible interpretation of these parameters where they may halt individuals' desire to walk freely, without worrying about how far they can walk.

5.2 Spatio-temporal characteristics of THR individuals and their relevance to walking.

5.2.1 Introduction

The primary function of the hip in walking is to allow an adequate stride length and rapid limb advancement. The second function, that of mobile weight-bearing, is indicated by an

individual's single-stance duration (Wykman and Olsson 1992). Therefore, it is apparent that those individuals with hip disease often suffer from gait deficiencies. In comparison with healthy individuals, the THR population generally exhibits smaller hip adduction and extension angles, and thus generating lower hip adduction and extension moments during level walking (Bennett et al. 2008; Beaulieu et al. 2010; Ewen et al. 2012). The literature has also revealed that despite post-operative pain improvements that in long-term, the gait of individuals after THR surgery does not mirror that of the general healthy population, i.e. there are reductions in walking speed, stride length, sagittal hip joint range of motion (RoM) and peak hip abduction (Withers et al. 2017a; Moyer et al. 2018).

The often reported parameters in adults' biomechanical gait analysis for spatio-temporal parameters are walking speed, step length, and cadence (Roberts et al. 2017). Despite ample evidence of reports on these parameters, studies have been constrained to indoor treadmills where speed is controlled or collected over a small number of cycles (Hurwitz et al. 1997; van den Akker-Scheek et al. 2007). Hence the reference values for these spatio-temporal parameters are often reported at high magnitude differences.

The spatio-temporal measures data reported here is collected using a self-paced gait analysis system. To the best of my knowledge, no other studies to this date carried such analysis using the self-paced treadmill. Therefore, this chapter aims to investigate the key spatio-temporal gait parameters of THR patients before and after surgery and compare those results to normal healthy gait data to identify relevant parameters that could be improved to enhance individuals walking after THR surgery.

5.2.2 Methodology

5.2.2.1 Participants

Data for the first eighteen THR participants from the study (NCT03846791) (10 women, 8 men; age: 66.9 +/- 9.8 years; height 171.0 +/- 10.9; BMI: 28.7 +/- 5.9 kg/m²) and 18 healthy control participants over 65 from the study (BU reference 15005) (9 women, 9 men; age: 67.4 +/- 5.5 year; height 173.2 +/- 9.2 BMI: 25.7 +/- 4.9 kg/m²) were used for this secondary analysis. Full details on inclusion and exclusion criteria for the healthy control group and THR group can be found in Table 3 and Table 4 respectively. All THR operations were performed by one board-certified hip surgeon. All participants in the THR group received the same implant and followed the same rehabilitation programme involving both core and lower extremity strengthening as per a standard post-operative protocol. They were tested preoperatively, at 6 weeks, 3 months, and 6 months after THR (Wall et al. 1981; Madsen et al. 2004; Miki et al. 2004; van den Akker-Scheek et al. 2007).

 $\label{thm:control} \textbf{Table 3. Inclusion and exclusion criteria for the healthy control adults.}$

Healthy control group								
Inclusion	Participants meeting the following criteria will be considered for participation in							
Criteria:	the study:							
	 Safely ambulatory without assistive devices 							
	 Aged from 18 to 90 years old 							
	 Must be able to give written informed consent 							
Exclusion	Neurological or musculoskeletal conditions that might make the							
Criteria:	assessments dangerous							
	 A level of cognitive function that prevents participants from 							
	understanding the study							
	 Medical conditions that might be jeopardised by exercise 							

Table 4. Inclusion and exclusion criteria for the THR group.							
	THR group						
Inclusion Criteria:	Individuals meeting the following criteria will be considered for participation in the study:						
	 Male and female ≥18 years; Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, suitable for unilateral primary hip replacement; Correction of functional deformity; Voluntary written Informed Consent obtained; Participant able to complete study follow-up. 						
Participant able to complete study follow-up. Exclusion Pre-operative:							
Criteria:	 Prospect for recovery to independent mobility compromised by known coexistent medical problems; Requiring revision hip replacement; 						
	 Previous hip replacement (resurfacing or THR) on the contralateral side, with outcome achieving an Oxford Hip score <18 points; Likely post-operative leg length inequality >5cm; 						
	 Neuromuscular disease affecting hip (Parkinson's, cerebral palsy, other spasticity); 						
	 Primary or metastatic tumour involving this hip; 						
	 Loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint; 						
	 Previous arthrodesis or excision arthroplasty 						
	 Abnormal acetabulum: Acetabular deficiency - >2cm superior loss acetabular dome or >1.5cm protrusion acetabulae or wall deficiency> half a wall; Dysplasia (DDH) with >2.5cm subluxation or complete dislocation; Body mass index > 40kg/m²; 						

- Active or previous or suspected infection in this hip;
- Sepsis or osteomyelitis;
- Known sensitivity to device materials;
- Not physically able to use Grail gait lab;
- Women judged by the Investigator to be of childbearing potential who are pregnant, nursing, or planning to become pregnant, and those who do not agree to remain on an acceptable method of birth control throughout the entire study period;
- Unable to provide informed consent (insufficient English, cognitive disorder such as dementia, psychiatric illness);
- Unable to complete follow-ups (life expectancy <5 years, insufficient English, lives overseas, unable to return easily).

Intra-operative:

- Abnormal abductor mechanism trochanter escape > 1.5cm <u>or</u> gluteus medius totally non-functional <u>or</u> trochanter absence;
- Unavailability of required size of prosthesis;
- Abnormal acetabulum:
 - Acetabular deficiency >2cm superior loss acetabular dome or
 >1.5cm protrusion acetabulae or wall deficiency> half a wall;
 - Dysplasia (DDH) with >2.5cm subluxation or complete dislocation.

5.2.2.2 Protocol

As already introduced in section 1.5.1, the gait analysis was carried out as per the protocol published on gait analysis using the GRAIL system (Bahadori and Wainwright 2020a). Participants wore comfortable shoes and tight clothing (such as cycling shorts or leggings). They were fitted with 25 passive reflective markers using the Human Body Model (HBM) lower body marker set (van den Bogert et al. 2013; Bahadori and Wainwright 2020a). Participants were secured to a safety harness and following an acclimatisation period, three sets of 25 gait cycles were recorded.

5.2.2.3 Data processing and analysis

The reliability of the gait data, data processing, and analysis has been explored for the GRAIL system and carried out as per protocol (Bahadori et al. 2019b). Marker data were low-pass filtered with a second-order Butterworth filter with a cut-off frequency of 6 Hz. Gait event detection was calculated based on foot markers (Zeni and Higginson 2010). Key clinical spatio-temporal gait parameters (Beaulieu et al. 2010) including, walking speed, step length and cadence were exported to a .CSV file and analysed in Matlab R2017a (Mathworks Inc., Natick, MA, USA). Gait data was explored as an operated and non-operated side in the THR group.

5.2.2.4Statistical analysis

The statistical package for the Social Statistics for Windows (IBM) software, SPSS (version 26) was used in the analysis. The assumption of normal data was evaluated using the Shapiro-Wilk test. A series of Independent-Sample t-tests were executed to determine the presence of significant differences between the THR and control group. For the control group, only one side was analysed; therefore, the number of right and left sides matched the number of right

and left involved sides of the THR group. A *P* value lower than 0.05 was considered statistically significant for all analysis.

5.2.3 Results

A total of 18 control and 18 individuals with THR participated in the study, however, eight of the THR participants could not attend the 6 months follow-up due to COVID-19 pandemic restrictions for older adults as explained in Chapter 4. Therefore, the data reported here at 6 months post-surgery includes only 10 participants, whereas at the other timelines, the analysis includes 18 THR participants.

The mean and standard deviation of the spatio-temporal gait parameters for each group is represented in Table 5. Individuals in the THR group walked significantly slower preoperatively (P < 0.001), at 6 weeks (P = 0.026) and 3-month stages (P = 0.032), however, no significant differences were determined at 6 months (P = 0.518) post-THR. Cadence at the preoperative stage (P = 0.003) was significantly different from the control group, but no significant differences were determined in the post-operative period. Results from the Independent t-tests, revealed no significant difference between the THR group and control group at 6 months for any of the spatio-temporal parameters (P > 0.05).

Table 5. The mean and standard deviation of the spatio-temporal gait parameters for each group. Independent-Sample t-tests (P) were executed to determine the presence of significant differences between the THR and control group. (*) analysis based on ten participants.

Group	Healthy Control		ТН	IR								
		Preoperatively	6 Weeks	3 Months	6 Months		P Value					
Spatio-temporal parameters						Preop and Control	6 Weeks and Control	3 Months and Control	6 Months and Control			
Walking Speed (m/s)	1.43 (±0.23)	0.79 (±0.36)	1.20 (±0.34)	1.25 (±0.25)	1.36 (±0.27) *	<0.001	0.026	0.032	0.518			
Step Length (m)	0.73 (±0.09)	0.45 (±0.18)	0.61 (±0.15)	0.65 (±0.11)	0.69 (±0.12) *	<0.001	0.011	0.040	0.332			
Cadence (Step/Min)	58.30 (±5.16)	47.49 (±13.33)	58.56 (±20.97)	57.11 (±9.11)	59.05 (±3.55) *	0.003	0.959	0.635	0.772			

5.2.4 Discussion

The purpose of this chapter was to investigate the key spatio-temporal gait parameters of THR patient's before and up to 6 months after surgery and compare those results to normal healthy gait data in order to identify the optimal parameter that can enhance these patients' desire to walk freely.

It was previously reported that the greatest improvements in gait parameters (such as stride length and walking speed) occurred within the first six months after unilateral THR (Madsen et al. 2004; Miki et al. 2004). In line with other findings (Constantinou et al. 2014), the results here showed that, at the perioperative stage, the spatio-temporal gait of THR individuals is significantly different from that of the healthy control group. The main underlining factor which has been reported by several investigators is pain (Wall et al. 1981; van den Akker-Scheek et al. 2007). It is primarily because of the pain, that an arthritic patient has a reduced range of movement and a reduced capability to bear weight on the affected hip and these may in turn lead to abnormalities in gait (Wall et al. 1981; Ewen et al. 2012).

As also shown by our results (Table 5), despite gradual improvement from pre surgery to up to 6 months post-surgery, the walking speed and step length of the THR group remain statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence is improved and recovers, when compared to the control group, as early as the 6 weeks stage post-surgery. Indeed, it might even be earlier than that, but intervening measurements were not made. It then remains constant up to the 6-month assessment. However, it is important to note that, the step length and walking speed do not recover so quickly and only become closer to that of the control group over the first 6 months. This could be interpreted that as the patients rehabilitate, their range of movement only gradually

improves and that although the number of steps might rapidly get back to the levels of the control group, the distance walked, and walking efficiency does not recover so quickly. Therefore, step count which has readily been identified (Crizer et al. 2017) as a as an indicator of walking ability and reported as a parameter for enhancing long-term activity levels and subsequently returning to walking freely, may not be the best indicator.

A limitation of the data analysed was the missing data at 6 months period. Despite our best endeavours, we were not unable to collect these data due to COVID-19 pandemic; however, we believe that the small standard deviation within the results at 6 months stage provides confidence in our data analysis.

5.2.5 Chapter summary

The findings of this chapter indicate that, at the perioperative stage, the spatio-temporal gait of THR individuals is significantly different from that of the healthy control group. Regarding the spatio-temporal parameters that were directly measured in this research, the walking speed and step length remain statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence is improved at the 6 weeks stage. An interpretation of the results suggests that a step count which is readily reported in previous studies is not representation of THR population walking and other parameters such as, distance, may be a better indicator of individuals walking recovery after operation. The next chapter will divert focus on the selection and evaluation of the most suitable activity monitor for this population before outlining a feasibility study to assess the proposed intervention.

"In the kingdom of the blind, the one-eyed man is king."

Desiderius Erasmus

Chapter 6 – Selection and Evaluation of Activity Monitors

6.1. Chapter overview

Following the findings regarding the individual's gait and the possibility of distance as a parameter that may encourage daily activity in individuals post-THR surgery, this section will look to select and evaluate the most suitable activity monitors for this population. This section is divided into three main sections. The aim of section 6.2 is to utilise research evidence and guidelines to identify the top three commercially available smartphone apps and one wearable activity monitor brand that is best suited for research in the THR population. The aim of section 6.3 is to systematically evaluate the accuracy and precision of the selected wearable in section 6.2 for measuring walking distance at slow, medium, and fast walking speeds in an outdoor setting. The fourth section of the chapter (section 6.4) explores the accuracy, consistency, and precision of the activity monitor streamlined from section 6.3 for measuring distance walked in a variety of conditions. The structure of each section outlined as an aim for that section followed by the methodology, results, discussion, and summary of the objective of that particular section before providing a summary of the overall findings (section 6.5). The outcome of the findings from this chapter should provide a broader understanding of the most suitable activity monitor for a study involving the THR population. Unfortunately, as explained in Chapter 4, despite ethical approval, the studies in this section were restricted by the COVID-19 pandemic and sanctions imposed on university research studies involving the older adult population. Therefore, as a contingency plan, studies were mainly performed by young adults (section 6.3) or a young participant (section 6.4) as a series of a single-participant studies.

6.2. Evaluation of available technology

6.2.1 Introduction

Improving THR patient compliance and creating a patient-centred programme can be a positive intervention on the THR surgical pathway and the use of a simple commercially available activity monitor (wearables or smartphone apps) may be the path forward (Reychav et al. 2019). The most common demographic of hip replacement patients in the UK are those over-65 (Jones et al. 2005a; Ferguson et al. 2018; Bahadori et al. 2020b). Therefore, it is necessary to select an activity monitor that focuses on older adults' cognitive, perceptual, and psychomotor needs.

Most of the mobile interfaces are not designed optimally for older adults and there are no extensive research studies currently done that utilises commercially available smartphone apps in THR research (Bahadori et al. 2019a). Based on that, this chapter will utilise a recognised method of evaluating the quality of apps for researchers and clinicians, the Mobile App Rating Scale (MARS) (Stoyanov et al. 2015) assessment, as well as published usability and accessibility guidelines (Almao 2018) to find the best smartphone apps for older adults daily walking.

To select the correct wearable activity monitor brand for research in the THR population, we have shortlisted all of the health-related studies that utilised a commercially available wearable activity monitor for measuring a walking activity and evaluated their conclusion on the best brand for monitoring adults.

Therefore, the aim of this section is to utilise research evidence and guidelines to identify the top three commercially available smartphone apps and one wearable activity monitor that is best suited for common demographics undergoing THR surgery (adults over the age of 60 years old).

6.2.2 Methodology

6.2.2.1Smartphone apps

I searched the two most popular sources (Seabrook et al. 2014; Bahadori et al. 2018b) for relevant apps worldwide: the App Store (Apple 2020); and Google Play (Play 2020). These searches were conducted on the 28th of November 2020. Apps were retrieved for screening if they were identified using the search term "walking". Apps were subsequently included for evaluation if they were available in English and had more than 1000 reviews with a score of 4.5 out of 5 and above. Despite current trends in downloading free apps worldwide (Izahar et al. 2017; Research 2019); we also included apps that cost up to £130 which is an average price of wearable activity monitor (Bunn et al. 2018). Apps were excluded from evaluation if: they were not available in the UK; were not available in both Google Play and App store; were not in English; or did not have an option for measuring walking distance using a Global Positioning System (GPS) sensor.

Following the initial stage of identifying apps using the search term, the resulting apps were tabulated. The top 10 apps which met the inclusion criteria were downloaded onto an Apple iPhone SE smartphone device (iOS 14.3) through the App Store.

6.2.2.1.1 Data extraction

SB downloaded each of the apps included for evaluation. The quality assessment of each app was derived from two protocols. 1) through the MARS, with this approach being similar to

that used in similar app reviews (Ahmed et al. 2012; Bahadori et al. 2018b). 2) based on available usability and accessibility guidelines published on apps designed for older adults (Almao 2018).

Following the guidance from the creators of the MARS, SB undertook online video training in

6.2.2.1.1.1 The Mobile App Rating Scale (MARS)

the use of the MARS using sample rating exercises to practice (Stoyanov 2016), and compared results against creators' ratings (Stoyanov 2016). The MARS ratings from SB were then repeated by one of the other members of the research team (RS), with verification occurring by crosschecking for consistency. Where differences of greater than one point on the MARS scale existed, the third member of the research team (LB) was used to help reach a consensus. The MARS (Appendix 1) consisted of 19 items grouped into four sections: "Engagement" (entertainment, interest, customisation, interactivity, and target group); "Functionality" (performance, ease of use, navigation, gestural design);" Aesthetics" (layout, graphics, visual appeal); "Information quality" (accuracy of app description, goals, quality and quantity of information, visual information, credibility, evidence base). All items of the MARS were rated on a 5-point scale, from "1: Inadequate" to "5: Excellent". Section D also had not applicable (N/A) option for irrelevant components. Each of the four sections was rated by calculating the mean of the scores for questions in each of the sections (Stoyanov et al. 2015).

6.2.2.1.1.2 Guideline's assessment

A guideline was published by Almao (2018) for evaluating and/or designing mobile phone interfaces aimed at older adults. This guideline consisted of all information published by the smartphone app industry developers, and academic researchers, with a focus on elderly end users of the touchscreen-based mobile phone and/or smartphones.

The guidelines were grouped within four different dimensions associated with various interaction elements of a smartphone. The dimensions were: 1) screen; 2) touchscreen; 3) keypad; and 4) text. Table 6 summarised these dimensions, their subsections, and guideline checkpoints. Throughout the evaluation, each individual checkpoint for each dimension was tested manually for every app. To grade each checkpoint, a scale system that goes from 0 to 2 was employed as per other studies (Nielsen 1993; Almao 2018). In this system, 0 points were given to null or no-included checkpoints, 1 point was given to checkpoints not entirely considered, and 2 points were given to checkpoints fully included. For each list of checkpoints, there were individual preliminary results, and the final score of each app was the average between these preliminary scores.

6.2.2.1.2 Outcome analysis

In order to select the most appropriate apps, the apps with the highest MARS mean score, were shortlisted. Similarly, the apps with the highest score using the guideline assessment were shortlisted. The top three apps which were duplicated in each assessment were selected as the most suitable apps.

Table 6. Summary of the dimensions, their subsections, and checkpoints for selecting the appropriate smartphone apps for older adults using the guideline assessment.

Dimension	Subsections	Guideline Checkpoints
Screen	Display size	Elderly people prefer a larger screen for better readability
	Colour	It is suggested that older people favour conservative colours with high contrast between the foreground and the background. With that in mind, the colours that will be regarded as conservative are black; white; grey; blue; beige; and various shades, tones, or tints of one colour.
	Slower dimming	Screens should have slower dimming to allow older people to have sufficient time to understand and execute the necessary actions
	Zooming and	Fonts and screens should have the option to be magnified , that way if elderly people cannot
	magnification	see content well enough, at least they can zoom in or increase the font size.
Touchscreen	Touchscreen gestures	Gestures can create difficulties for elderly people since they are not familiarised with tapping on the screen. As a result, they need more time to comprehend and learn the movements required for gestures. Thus, it is highly recommended to keep gestures simple .
	Feedback	It is common that in digital interfaces, elderly people face problems trying to distinguishing whether if a button or target was pressed or not. Therefore, they constantly make mistakes by tapping for too long or not pressing the right buttons. Feedback within 3 seconds is preferable.
	Target/icon properties	Icons should be simple and clear, and properly designed for elderly people's mental models.

Keypad	Button type	Older people prefer large buttons with clear and immediate feedback that allows them to be more accurate when pressing the buttons. This is especially useful for older people when they are dialling or witting a text.
	Button size	Make buttons big enough so elderly people can perceive them.
	Button feedback	Include immediate visual, tactile, and/or auditory feedback , to help elderly people to avoid mistakes.
	Number of buttons	There is not enough explanation in the provided guidelines as to what this guideline entails. It could be assumed that since older people face cognitive skill issues, for them it is harder to focus on too many things at the same time. This means, that too many buttons should be avoided .
Text	Font size	With age visual skill starts degrading, which is why elderly people require a bigger font size . This gets worst, in the mobile context as the screen size is reduced. Thus, it is necessary to provide a suitable font size for elderly people.
	Font type	There is not enough explanation in the provided guidelines as to what this guideline entails, it could be assumed that there are certain family fonts such an Arial that is more suitable for elderly people, but font size should be considered a priority.

6.2.2.2 Wearable activity monitor

A computer-based search was completed in December 2020 using the mySearch Database (Bournemouth University). This included Cochrane Database of Systematic Reviews library, CINAHL Complete®, Science Citation Index, and Medline®. Articles published in the English language from January 2000 to February 2021 were shortlisted. The most popular wearable devices on the market (Bunn et al. 2018) were chosen for this search and included: Apple, FitbitTM, Garmin, Mio, Misfit, Polar, PulseOn, Samsung, TomTom, Withings, and Xiaomi.

In order to select the most appropriate brand, we focused on three categories: 1) brand usage: which brand has been used most in research; 2) status and trend: current status of the brand and its prospect and development; 3) brand developer possibilities: do brands have possibilities of software integration for remote access to individuals data and offer an application programming interface (API) and a software development kit (SDK). This could be essential in remote access to individual data. Information was collected from Google Play, Apple's App Store, and official brand websites. Information retrieval was done in December 2020.

6.2.3 Results

6.2.3.1 Smartphone apps

Table 7 summarises the relevant information for the top 10 apps found. All of the top 10 apps were free of charge. Table 8 is the MARS score for the listed apps. Pacer, Accupedo and StepsApp scored the highest mean MARS, 4.5, 4.4, and 4.3 respectively out of possible 5 scores. Table 9 is a summary of the guideline's assessment for the selected apps. Through

guideline assessment designed for older adults, Pacer, Accupedo, and StepsApp scored the highest, 21, 19, and 18 respectively out of a possible 26 score.

Table 7. Summary of the relevant information for the top 10 smartphone apps that met the inclusion criteria.

App name	Available on iOS and Android	Star Ratings	Review	Step count	Distance
Pacer	Yes	4.8	24000	Yes	Yes
Footpath Route Planner	Yes	4.7	8200	Yes	Yes
CharityMiles	Yes	4.7	1500	Yes	Yes
RunWalkJogg Goals	Yes	4.7	4000	Yes	Yes
MyFitnessPal	Yes	4.7	242000	Yes	Yes
MapMyWalk	Yes	4.8	64000	Yes	Yes
StepsApp	Yes	4.8	43000	Yes	Yes
ActivityTracker	Yes	4.7	13000	Yes	Yes
SweatCoin	Yes	4.5	32000	Yes	Yes
Accupedo	Yes	4.6	1100	Yes	Yes
Ranger	Yes	4.6	13000	Yes	Yes

Table 8. Summary of the MARS score for the top 10 smartphone apps that met the inclusion criteria.

App name	MARS	MARS	MARS	MARS	MARS mean
	Engagement	Functionality	Aesthetics	Information	score
Pacer	4.8	4.5	4.7	4.2	4.5
Footpath Route Planner	4.2	3.8	4.3	4.0	4.1
CharityMiles	4.2	4.0	4.3	4.0	4.1
RunWalkJogg Goals	4.0	4.5	4.7	3.8	4.2
MyFitnessPal	3.8	4.0	4.7	4.4	4.2
MapMyWalk	3.6	4.3	4.0	4.0	4.0
StepsApp	4.4	4.3	4.3	4.4	4.3
ActivityTracker	4.8	4.5	4.0	4.2	4.4
SweatCoin	3.8	4.5	4.0	4.0	4.1
Accupedo	3.8	4.0	4.7	4.0	4.1
Ranger	4.2	3.8	4.0	4.6	4.1

Table 9. Summary of the guideline score for the top 10 smartphone apps that met the inclusion criteria.

Dimension	Pacer	FootpathRoute Planner	CharityMiles	RunWalkJog Goals	MyFitnessPal	MapMyWalk	StepsApp	ActivityTracker	SweatCoin	Accupedo	Ranger
Screen											
Display size	2	2	2	2	0	0	2	2	2	2	2
Colour	2	1	1	2	0	0	2	1	1	2	1
Slower dimming	2	2	1	1	1	1	1	2	1	2	1
Zooming and magnification	0	0	1	1	0	0	0	0	1	0	1
Touchscreen											
Touchscreen gestures	2	1	1	1	1	2	2	1	1	1	2
Feedback	1	1	1	1	1	2	2	1	1	1	1
Target/icon properties	2	1	1	1	1	1	1	2	1	2	0
Keypad											
Button type	2	1	1	1	0	0	2	1	1	2	0
Button size	1	1	1	1	0	0	2	2	1	2	0
Button feedback	1	1	1	1	2	1	1	1	1	1	1
Number of button	2	1	1	0	0	0	0	1	0	1	2

Text											
Font size	2	1	2	1	1	1	1	1	1	2	1
Font type	2	2	2	1	2	2	2	1	1	1	1
Total	21	15	16	14	9	10	18	16	13	19	13

6.2.3.2Wearable activity monitors

Eighty-four studies were found in the systematic search (Appendix 2). Sixty-one studies investigating the reliability or validity of wearable activity monitors. Twenty-three studies were using wearable activity monitors for collecting data. Wearable activity monitors were used in 33 studies for assessing step count or distance walked. Table 10 summarises different brands' usage in research studies, and also specific brand software development possibilities. Out of the brands currently available, the two most often used in research projects were FitbitTM, and Garmin*. FitbitTM devices were used in 56 of which 28 studies were validation or reliability of step count/distance parameter. Garmin* devices were the second most used brand. In 23 of the studies, one or more Garmin devices were used. Of these, 11 were validation or reliability of step count/distance parameters. FitbitTM devices are currently utilised in 33 clinical trials, whereas all other devices were mentioned in four or fewer projects.

All brands had an app in the Apple App Store and could connect to the iPhone. Except for the Apple wearable, all other brands had an app in Google Play that could be used with Android phones. Eight out of 11 brands had a private cloud repository with an accompanying API, which allows third-party apps to access these data. Six brands had an SDK, which makes it possible to create custom programs to communicate with the device or create watch faces that can run on the device. FitbitTM offers three major SDKs (Device API, Companion API, and Settings API) for developing apps for FitbitTM devices. In addition, FitbitTM offers the Web API that can be used to access FitbitTM cloud-stored fitness data. The Web API exposes six types of data: physical activity (steps and distance walked), heart rate (HR), location, nutrition, sleep, and weight (Ltd 2019a). FitbitTM also has a solution for accessing high-resolution step

and HR data (i.e. intraday data), granted on a case-by-case basis. There is no cost for developing with the Fitbit™ SDKs or API.

6.2.4 Summary

The aim of this section was to utilised research evidence and guidelines in order to identify three mobile apps and one wearable activity monitor brand that is best suited for research in the THR population, which consisted of mainly over 60 years old adults. The findings suggest that the top three smartphone apps are Pacer, Accupedo and StepsApp with the highest scores in both MARS and also guidelines assessment. Furthermore, out of the brands currently available, the most often used in research projects is FitbitTM. Nevertheless, it is worth considering that a high article count, clinical trials or reliability study of a particular device do not automatically imply the suitability of that device for every study. However, further evidence shows that Fitbit™ is currently used the most (Bahadori et al. 2019a) in the THR-related studies. In addition, this brand allows third-party programs(Ltd 2019a) to access, run and communicate with their devices, and for projects that require remote access to patient data such as THR trials, this is of importance. Therefore, we have summarised the characteristics (Table 11) of different types including the sensor use, price, battery life, and tracking features of the Fitbit[™] products that cost less than a standard NHS physiotherapy session. The Fitbit[™] Charge 4[™] (FC4) (Fitbit, Inc., San Francisco, CA, USA), currently offers the most complete sensor package at a retail price of £129.99 which is less than a cost of a standard NHS physiotherapy session at £170 (Rivero-Arias et al. 2006).

In the following section, the accuracy, precision, and consistency of selected activity monitors are assessed in order to select the most suitable activity monitor for monitoring individuals' activity post-THR surgery.

Table 10. Summary of different brands' usage in reach and their brand software development possibilities.

				Validation- or re	eliability studi	es						
Brand	Devices	mySearch Database	Steps	Energy expenditure	Heart rate	Sleep	Other	Clinical Trials	SDK	API	Apple Health	Google Fit
Apple	3	8	1	3	4	0	0	2	Х	Χ	Х	
Fitbit	10	56	28	10	7	8	3	33	Χ	Χ		
Garmin	41	23	11	4	4	1	4	3	Χ	Χ		
Mio	3	5	0	2	5	0	0	3			Χ	Χ
Misfit	8	12	6	3	1	4	2	1	Χ	Χ	Χ	Χ
MyKronoz	18	0	0	0	0	0	0	0				
No.1	19	0	0	0	0	0	0	0				
Polar	11	6	2	3	1	1	1	4	Χ	Χ	Χ	Χ
PulseOn	1	4	0	2	4	0	0	1				
Samsung	12	5	2	1	2	0	0	2	Χ	Χ		
TomTom	7	2	0	0	2	0	0	1		Χ		
Withings	2	5	4	0	0	2	0	2		Х	Χ	Χ
Xiaomi	3	1	1	0	1	0	0	1			X	Χ

Table 11. Summary of different FitbitTM products currently on the market with an average price below £130.

Device	Sensor	Price	Battery life	Tracking features
Fitbit zip™	Accelerometer	£49.99	4-6 months	Steps, calories, distance
Fitbit alta™	Accelerometer, vibration motor	£99.99	Up to 5 days	Steps, calories, distance, sleep, gym activity profiles
Fitbit Charge 4™	Accelerometer, vibration motor, Barometric altimeter, GPS	£129.99	Up to 7 days	Steps, calories, distance, sleep, floors climbed, intensity minutes, stress, gym activity profiles, heart rate, swim profile

6.3. An Evaluation of Accuracy and Precision of Selected Commercial Activity Monitors to Measure Walking Distance.

6.3.1 Introduction

A number of commonly used activity monitors have been found to accurately count steps in active populations of younger (Adam Noah et al. 2013; Case et al. 2015) and older adults (Grant et al. 2008; Paul et al. 2015). However, the majority of these studies only focus on medium-paced indoor walking settings and do not explore the accuracy or precision of these devices at different walking speeds and outdoor environments (Bunn et al. 2018). This is a major deficiency as findings suggest that walking speed in older adults and those undergoing THR surgery may vary between 0.6 – 1.9 m/s (Carroll et al. 2012; Van Remoortel et al. 2012; Constantinou et al. 2014; Fulk et al. 2014). Furthermore, there is currently very limited evidence on the accuracy or precision of walking distance measured using any commercial activity monitor (Bunn et al. 2018; Babaei et al. 2022). This is perhaps due to the fact that step count has been the main focus of objective measures of physical activity across all research studies (Schmalzried et al. 2000; Tudor-Locke et al. 2011; ANSI 2016; Alinia et al. 2017b). Commercial activity monitors are often utilising two methodologies to calculate the walking distance performed by an individual. 1) Algorithm (ALG) function; and 2) GPS. In ALG measurement, the number of steps counted is multiplied by individuals' stride length. To measure step count, the majority of activity monitors have built-in Inertial Measurement Units (IMUs) which use the principles of linear acceleration and angular motion along with noise filtering algorithms to determine if the individual has taken a step (Khedr and El-Sheimy 2017). In the GPS method, the two location points are measured using the in-built GPS receiver, tracking the individual's position using satellite-based localisation (Merry and Bettinger 2019).

The aim of this section is to systematically evaluate the accuracy and precision of the FC4 wearable, and three smartphone apps (Pacer, Accupedo and StepsApp) for measuring walking distance, using both ALG and GPS sensors, at slow, medium and fast walking speed in an outdoor setting.

6.3.2 Methodology

6.3.2.1 Participants

Due to COVID-19 restrictions, recruiting a large sample size, and more importantly, older adult participants was not possible and therefore we were only able to recruit three young healthy adults. However, we attempted to pay attention to the participants' heights, as it was hypothesised varying stride lengths would influence the accuracy of the devices. Thus, we recruited three participants considerably different in body height with the assumption that their natural stride lengths would differ and therefore ALG accuracy may be influenced. The participants' height ranged from 152 cm to 192 cm, as studies (Barreira et al. 2010; Batzinger et al. 2019; Bumgardner 2020) have identified significant gait differences, in particular in the stride length can correlate to an individual's height. One participant was recruited for each height category: 1) 5 - 5ft 3 inch (152 - 161 cm); 2) 5 ft 5 - 5 ft 7 inch (167 - 173 cm); 3) 6 ft - 6.3 inches (182 - 192 cm).

Following the provision of written informed consent, three healthy individuals between 18 and 35 years of age participated in this study. Prior to testing, all subjects claimed no known neuromuscular, musculoskeletal, or cardiovascular pathology affecting their ambulatory capacity and were able to walk at least 5 kilometre (km) without the use of an assistive device.

6.3.2.2 Procedure

The participants were asked to complete 9 trials of one lap on a flat lane of 250 m Olympic standard outdoor tarmac track (Figure 2), repeating three times at slow, medium, and fast walking speeds. Walking speed between 0.6-0.8 m/s is recognised as a slow speed, 1.0-1.3 m/s is recognised as a medium speed, and 1.6-1.9 m/s is recognised as a fast speed for adults walking outdoor (Bohannon et al. 1996; Morio et al. 2019; Murtagh et al. 2020). A member of the research team walked alongside the participant and utilised a stopwatch to measure walking time which subsequently was used to calculate the Gold Standard Walking Speed. A digital hand tally number counter was used to manually count the number of the steps and used as the Gold Standard Step Count.

In the course of every trial, the wearable was placed on the non-dominant wrist and an Apple iPhone SE (version 14.1.1) was placed in the participant's front non-dominant pocket (Silsupadol et al. 2017) with the smartphone apps running concurrently in the background. The non-dominant wrist setting was selected for the wearable device as it has been shown to increase the sensitivity of step counting and was anticipated to reduce any under estimation of distance walked using step counts in ALG estimations (Alinia et al. 2017b). GPS of the apps and wearables were turned on and satellite signal connectivity was ensured, showing the correct starting location. Participants were instructed to stay still behind the starting line of the 250 m track. Then SB started the devices before the participant began each trial. After completion, participants stopped exactly behind the finish line of the track and stood still until SB stopped all devices. At least two minutes of recovery was allowed between trials. Data collation consisted of manual recording of step-count using a digital hand tally number

counter and lap time as well as screen-shots of the different activity monitors' software apps and were downloaded after every test day and were manually post-processed.



Figure 2. 250 m Olympic standard outdoor tarmac track, Bournemouth. Top left corner: Example data acquired from screenshot from one activity monitor app (personal collection).

6.3.2.3 Data analysis

All data were analysed using Microsoft Excel Version 2021 (Microsoft Corporation, Retrieved from https://office.microsoft.com/excel). Due to the small sample size, all data were presented descriptively, using appropriate summary statistics. Accuracy was assessed based on the mean absolute difference (MAD) (difference between Gold Standard distance (250 m) or manual step count and observed per device). The precision (variance) was assessed using the percentage of coefficient of variation (CoV) per device (standard deviation divided by the mean and multiplied by 100).

6.3.2.4 Data visualisation

Box plots were used to illustrate the accuracy and precision of each device for each participant for the three different walking speeds. The overall height of the box plots (i.e. range of data) denotes precision, and the mean/median denotes accuracy (i.e the closer to 0m, the more accurate the device). For data visualisation, Python, Jupyter Notebooks (Fernando 2016) and

the Numpy (Harris 2020) Pandas and Plotly (Inc 2015) libraries were used. The Scikit-Learn module was also used to fit lines using simple least-squares linear regression to the 9 data points for each participant, with the infrastructure in place for more involved machine learning techniques for larger datasets in the future.

6.3.2.5 Ethical approval

The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki. Informed written consent, approved by Bournemouth University's (approval number: 37817) research ethics boards (Appendix 3), was obtained from each participant prior to their involvement in the study.

6.3.3 Results

One female and two males with a body height of 160, 171, and 182 cm (age: 28.6 ± 6.1 years) respectively, and all without any walking disabilities, were recruited to participate in this study.

Tables 12 and 13 present the data for the accuracy and precision per device and smartphone app for each walking speed and each participant (different height) respectively. The FC4 had the best accuracy in both GPS and ALG distance walked with the lowest MAD across all heights. Regarding precision, the FC4 yielded the lowest CoV in all heights for both GPS and ALG, except GPS walking distance recorded for the tallest height which was reported more precisely by the StepsApp smartphone app.

MAD was the highest across all activity monitors when participants walked at a slow pace with Accupedo app and FC4 recording the lowest MADs in GPS and ALG distance walked respectively at this speed band. At a medium and fast pace, the FC4 had the best accuracy among all activity monitors. At a fast pace, Accupedo app record was the most precise, however, FC4 was superior in measuring walking distance using the GPS. Furthermore, Figure 3 demonstrates the error trends seen over all four activity monitors. From simple visual observation, it is clear to see that the FC4 plots show that the device is more precise than other activity monitors.

Table 12. Summary of the data for the accuracy and precision per device and smartphone app for three different walking speeds.

	Accuracy	,					Precision	า				
	Short		Medium		Tall	Short			Medium	1	Tall	
	Mean	MAD	Mean	MAD	Mean	MAD	SD	% Cov	SD	% Cov	SD	% Cov
Distance (m) GPS												
FC4	256.67	8.00	265.56	9.78	262.22	6.67	26.46	10.31	25.55	9.62	22.24	8.48
Pacer	271.11	10.22	286.67	14.67	266.67	6.67	20.28	7.48	41.23	14.38	14.14	5.30
StepsApp	288.89	38.89	254.44	19.56	268.89	12.00	14.53	5.03	55.03	21.63	31.40	11.68
Accupedo	230.00	15.56	241.11	14.22	230.00	8.00	16.58	7.21	41.67	17.28	17.32	7.53
Distance (m) ALG												
FC4	261.11	8.00	263.33	7.11	276.67	10.67	25.22	9.66	20.62	7.83	24.49	8.85
Pacer	322.22	28.89	295.56	27.11	282.22	21.78	44.10	13.68	69.66	23.57	60.37	21.39
StepsApp	285.56	15.11	264.89	23.73	280.00	14.67	20.68	7.24	65.99	24.91	29.58	10.56
Accupedo	277.78	19.11	261.11	20.44	271.11	18.22	53.80	19.37	74.07	28.37	56.67	20.90

Table 13. Summary of the data for the accuracy and precision per device and smartphone app for three different heights (participant).

	Accuracy	,					Precision	า				
	Slow		Medium		Fast		Slow	Slow		1	Fast	
	Mean	MAD	Mean	MAD	Mean	MAD	SD	% Cov	SD	% Cov	SD	% Cov
Distance (m) GPS												
FC4	285.56	14.22	261.11	5.33	237.78	4.89	18.10	6.34	12.69	4.86	10.93	4.60
Pacer	288.89	15.56	263.33	7.11	272.22	8.89	38.87	13.46	16.58	6.30	19.86	7.30
StepsApp	286.67	16.44	270.00	15.11	255.56	15.56	31.22	10.89	37.42	13.86	44.47	17.40
Accupedo	241.11	7.11	221.11	11.56	238.89	11.56	19.65	8.15	15.37	6.95	38.87	16.27
Distance (m) ALG												
FC4	288.89	15.56	265.56	6.22	246.67	4.00	20.28	7.02	13.33	5.02	15.00	6.08
Pacer	316.67	31.11	308.89	28.00	274.44	18.67	68.19	21.53	60.92	19.72	43.33	15.79
StepsApp	296.00	22.84	280.00	16.44	254.44	14.22	45.81	15.48	33.17	11.85	41.57	16.34
Accupedo	337.78	37.78	247.78	9.78	224.44	10.22	51.67	15.30	30.73	12.40	8.82	3.93

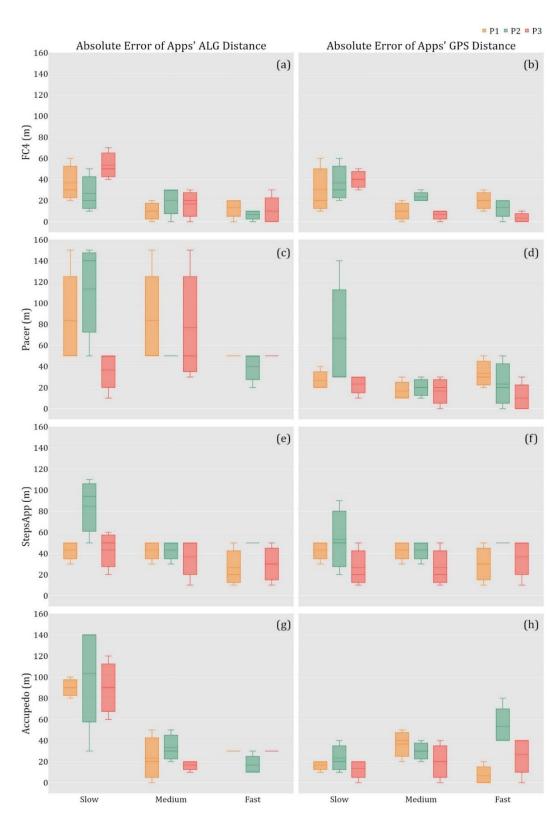


Figure 3. Box Plots for Absolute Distance Error between the Gold Standard Distance of 250m and distance recorded using the app's algorithm (Left column) and distance displayed within app using GPS (Right Column) vs. speed bands for Participants P1, P2 and P3. Mean is denoted by dotted lines inside boxes.

6.3.4 Discussion

The aim of this section was to evaluate the accuracy and precision of the selected activity monitors, for measuring walking distance at three walking speeds and heights, with the intention to have a broader understanding of these activity monitors' functionality and selecting the best option for future studies.

It was expected that due to using the same hardware modules, the step count and GPS distance readings would be reported the same for all iPhone apps (Pacer, StepsApp, and Accupedo) but different for the FC4, due to separate GPS receiver and IMU. However, although this was true for the step count (all apps were using the iPhone's IMU in the same manner), it was not true for the GPS distance data. We speculated this was due to the apps 'pinging' or 'querying' the iPhone's GPS receiver data at different frequencies/ intervals and, therefore, resulting in different distance values.

In line with other studies (Sjöberg and Persson 2014; Orr et al. 2015; Balto et al. 2016) our result found the iPhone's Motion Coprocessor sensor to have an overall lower accuracy and precision, in particular at the lower speed, in contrast to Triaxial accelerometer found in FC4. This can be attributed to the app's inaccurate application of users' stride length and its ALG to estimate walking distance. StepsApp for instance always uses a constant (0.415) to estimate individuals step stride based on height, whereas, according to the manufacturer information, the FC4 utilises the individual steps and automatically calculates stride length over every 20 steps, which has resulted in a higher accuracy across all heights. Moreover, we speculate that at the slower pace of 0.8 m/s and below, due to the individual taking smaller steps, over a longer period of time, the FC4 GPS sensor may misjudge small changes in movement to be noise and assume the individual is in a stationary position. Despite this, FC4

had the highest precision (lowest SD and CoV percentage) in contrast to all other activity monitors. However, the author recognises the severe limitations of only using three participants and having nine data points per participant, however, this research can act as a starting point for distance error estimations.

Furthermore, in agreement with other studies (Cummins et al. 2013) our results suggest that an outdoor walking activity is more accurate when measured using GPS in contrast to the ALG estimate. This is important, as monitoring individuals in the early stage of recovery will require an accurate estimation of both indoor and outdoor parameters related to walking activities. This is because, during the recovery process, the first steps outside the home may be taken at the porch, patio, backyard, or driveway. Walking for a longer distance, such as 500 meters or one block, is, however necessary for participation in common societal activities such as the use of services, shopping, or leisure time activities. For this the FC4 activity monitor can be suggested as a viable, objective motivator.

Figure 4 allows researchers to estimate absolute error values given the walking speed and height of their participants using the FC4 activity monitor. A slight decrease in absolute error as walking speed increased was observed amongst all heights. It was also observed that the gradient of error reduction as speed increased was steeper as the participant's height increased, i.e. the taller the participant the more effect increasing speed seems to have on reducing error. We recognise that the error estimation in this study is only over a distance of 250m and that increasing the distance walked may impact accumulated error values.

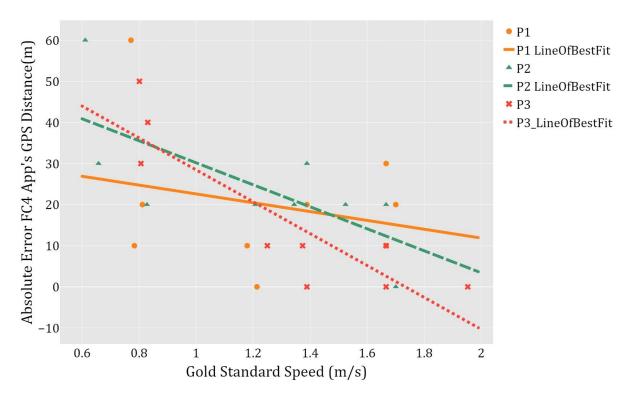


Figure 4. Gold Standard Speed (250m divided by Time Measured by Stopwatch) versus absolute error in metres for FC4 GPS readings. Trendlines were plotted using linear regression and training of all 9 sample points for each participant.

It should be noted that the accuracy and precision assessment study was conducted on healthy adults and not on an individual before or after THR surgery who may suffer from gait impairment. However, these activity monitors were identified as the activity monitors best suited for research in the THR population which mainly consists of adults over the age of 60 years old. The main achievement of this study was to compare the influence of walking speed and individual heights on the accuracy and precision of activity monitors identified in previous section. To the best of my knowledge, this is the first study to evaluate the distance walked in an outdoor setting with a particular focus on slow, medium, and fast walking speeds, and Figure 4 may act as a guide to researchers for estimating walking errors in their population of interest.

In the THR population, the first weeks after surgery have been found to be critical for recovery (Aasvang et al. 2015; Poitras et al. 2016). However, the lack of supported discharge, long-term follow-up, and planned individualised long-term rehabilitation is acknowledged (Salpakoski et al. 2014). Furthermore, walking outdoor was identified as a main activity goal in THR groups both before and after surgery. It was also agreed by both surgeons and physiotherapists as the best objective exercise to enhance patient recovery (Bahadori et al. 2020b). Additionally, all of the activity monitors identified were able to provide immediate feedback and this may be of benefit to patients and therapist, in a THR rehabilitation setting, who require immediate objective measures and feedback on the distance travelled or steps taken.

We acknowledge that a limitation of our study is the small sample age and size. However, like many other studies, the recruitment was carried out during the COVID-19 pandemic and therefore there were restrictions on studies involving humans and in particular older adults. Furthermore, given the small sample size, any statistical analysis would not provide a viable

contribution to analysis of the data reported by the activity monitors. Therefore, the conclusions drawn about the influence of body heights on the walking step and distance must be treated with caution. However, the protocol for device validation and infrastructure for data analysis was put in place to encourage more data collection amongst researchers in the future, so that better accuracy information for these devices may be ascertained.

6.3.5 Summary

Following the evaluation of the selected activity monitors, we can conclude that the activity monitors were the least accurate at a slow walking speed, and the best accuracy was seen at the medium speed. Furthermore, the walking distance was measured with the highest precision and accuracy by FC4's GPS sensor over an outdoor distance of 250 m. However, for the FC4 activity monitor to be considered in any future study, the precision, accuracy, and consistency of this device will be further explored in the following section in a variety of settings and walking speeds.

6.4. An Evaluation of Accuracy, Consistency, and Precision of Fitbit Charge 4 in different settings.

6.4.1 Introduction

In the previous section, Fitbit was found to be the brand which was used the most in clinical trials and research studies. An evaluation of the selected commercially available activity monitors suggested that FC4 is the most suitable device for study including THR participants. Furthermore, to the best of our knowledge, no validation studies on the accuracy of the distance and step count exist as of today. In contrast, there are plenty of studies that utilised earlier versions of Fitbit. Table 14 summarises all studies published up to July 2021, looking at the validation of different types of Fitbit devices in different settings. Only one study (Hollandsworth 2019) looked at the validity of outdoor distance walking when monitored using a Fitbit device. This study did not specify which version of Fitbit was used for the evaluation and included only eight healthy participants. The study found that the Fitbit device underestimates outdoor distance covered on a golf course by approximately 6.3%. A study by Huang et al. (2016) evaluated the reliability of a Fitbit device for tracking healthy individual walking distance in an indoor treadmill environment at medium and fast walking speeds. The findings suggested that the Fitbit flex overestimates 400 meters treadmill walk by an average of 26% in medium paced and 20% for a fast-paced walk. Two studies (Toth et al. 2018; Tedesco et al. 2019) looked at the validity of Fitbit devices for measuring daily step count in free living conditions. The results of these studies indicated that, in general, Fitbit Charge wearable tend to overestimate daily steps. It is important to note, however, that these studies represented a limited body of evidence regarding the accuracy of activity monitors in free-living conditions.

Overall, there are various methodologies used for evaluating validity of the Fitbit devices in different conditions. In summary, free-living validation against a gold standard ground truth involved comparing an activity monitor directly against a highly accurate reference measure to evaluate its validity. The aim was to determine how well the activity monitor performed in capturing the true values of activity, and it contributed to understanding the accuracy and reliability of activity monitors. On the other hand, using other devices as criterion measures involved comparing the measurements of the activity monitor against those of established, validated devices to assess its agreement with existing standards. This approach helped in evaluating the performance of the activity monitor and understanding its accuracy and reliability. Both approaches contributed to the understanding of the accuracy and reliability of activity monitors, but they employed different methods to assess the performance of the devices.

The aim of this section was to explore the accuracy, consistency, and precision of the FC4 activity monitor for measuring distance walked in a variety of conditions. The outcome of our findings should provide a broader understanding of the FC4 and its functionality in both indoor and outdoor environments, in order to allow informed decision-making on the design of any future study, as well as assist in interpreting the level of accuracy of the data collected.

Table 14. Summary of studies that utilised Fitbit activity monitors in their methodology.

Reference	Study population	Type of Fitbit	Aim	Setting	Walking parameter	Outcome of study
Hollandsworth (2019)	8 healthy adults	Unknown	To examine the accuracy of the Fitbit for measuring distance walked in an outdoor setting	Distance reported by the Fitbit against a known distance on a golf course	Distance	Fitbit underestimated the distance by about 6.3%
Tedesco et al. (2019)	20 healthy adults	Charge 2	To examine the validity and reliability of the Fitbit Charge 2 for step counts in free-living conditions	Charge 2 was worn for 24 hours and compared against the gold standard Actigraph	Steps	Charge 2 overcount steps by 12.36%
Burton et al. (2018)	31 healthy adults	Flex and Charge HR	To test the reliability and validity of two Fitbit activity monitors by step count when worn by older adults	Two 2-meter walk tests were completed while wearing the Fitbits. Participants were then given one fitness tracker and a GENEactiv accelerometer to wear at home for 14-days.	Steps	Charge HR was more accurate and more reliable in the laboratory and free- living conditions in contrast to Flex
Toth et al. (2018)	12 healthy adults	Charge and Zip	To examine the validity of the Fitbit Charge and Zip for step counts in 1 day of free-living conditions	The data collected with various commercial activity monitors were compared against a real-time data recorded using a GoPro camera.	Steps	Across all waking hours of 1 day, step counts differ between devices. Fitbit Charge overestimated the number of daily step whereas Fitbit Zip underestimated

Fokkema et al. (2017)	31 healthy adults	Charge HR	To examine the test- retest reliability and validity of ten activity trackers for step counting at three different walking speeds	Participants walked twice on a treadmill at slow, medium, and fast speeds for 30 min while wearing the activity monitors.	Steps	the number of daily steps. 0.9, 1.7, and 5.7 % Errors for slow, medium, and fast speed respectively. Reliability was moderate for the Fitbit Charge HR.
Modave et al. (2017)	60 healthy adults	Surge	To assess the accuracy of Fitbit Surge and other mobile app devices for counting steps, across three different age groups	1000-step walks on a treadmill at a self-selected speed	Steps	Fitbit Surge significantly undercounted steps across all age groups
Floegel et al. (2017)	99 older adults of varying ambulatory abilities	Flex and One	To assess the accuracy of step detection in activity monitors in older adults with varied ambulatory abilities	Walking at a self- selected pace for 100 m	Steps	Steps were underestimated by 1.7% by Fitbit One and 16.3 % by Flex
Reid et al. (2017)	22 healthy female adults	Flex and One	To investigate the accuracy of Fitbit One and Flex activity monitors in measuring steps against a gold standard ActiGraph GT3X	Activity monitors were worn for seven consecutive days	Steps	Regardless of wear- location, all Fitbit devices provide similar accuracy and users can wear the devices wherever best accommodates their lifestyle or needs
Voss et al. (2017)	30 children with heart disease	Charge HR	To examine the validity of activity monitors in Children	Activity monitors were worn for seven days in a free-living	Steps	Charge HR overestimated the

				environment. Data was compared against a gold standard Actigraph		number of steps by 7%
Treacy et al. (2017)	166 stroke patients	Charge HR and One	To explore the influence of gait parameters, activity monitor position, and use of walkers on activity monitor accuracy	Activity monitors worn in different positions simultaneously during a 6-minute and a 6-meter walks	Steps	Fitbit One worn on the ankle showed excellent agreement with the observed step count. Charge HR error percentage 52%
Chu et al. (2017)	104 healthy adults	Flex	To compare the average number of steps per day using the wrist-worn Fitbit Flex and waistworn ActiGraph (wGT3X-BT) in free-living conditions.	Activity monitors were worn for seven days in a free-living environment. Data was compared against a gold standard Actigraph	Steps	The median average steps/day recorded by Fitbit Flex was 10193 and it was in strong correlation with the gold standard
Leth et al. (2017)	22 healthy adults	Charge HR, One, Zip	To evaluate five commercially available self-monitoring devices for further testing in clinical applications	100-meter outdoor track at slow and medium walking speeds and compared to gyroscope data	Steps	Fitbit Charge performed the best with 26.8 % error at slow, -0.7% error at medium walking speed
Alinia et al. (2017b)	15 healthy adults	Flex, One, Zip	To determine the accuracy, best positioning, and performance in the free living condition of Fitbit activity monitor	Wearing positions (pants pocket, chest, and wrist) Treadmill walks for slow, medium and fast walking speed Number of steps in a day of a free-living environment	Steps	Wrist - Walking with a walker 73.1% error, walking at a slow 6.8%, walking with a shopping cart at 19.8%, walking at a medium speed

Dominick (2016)	et	al.	19 healthy adults	Flex	To assess the measurement congruence between Fitbit Flex and Actigraph GT3X for quantifying steps in sedentary activity and light, moderate, and vigorous-intensity physical activity in free-living conditions	Participants concurrently wore the Fitbit Flex for a period of two weeks	Steps	3.9%, walking at a fast speed 4.4% Fitbit Flex provides accurate measures of steps for daily activity and minutes of reported exercise
Sushames (2016)	s et	al.	22 healthy adults	Flex	To examine the validity and reliability of the Fitbit Flex against an Actigraph for step counts in free-living conditions and for moderate-to-vigorous physical activity	Flex worn during a laboratory-based protocol (including walking, incline walking, running, and stepping) and one-day free-living conditions	Steps	Flex has moderate validity relative to direct observation and the Actigraph
(Alharbi 2016)	et	al.	48 cardiac patients	Flex	To validate Fitbit-Flex against Actigraph accelerometer for monitoring physical activity	Activity monitors were worn for four days in a free-living environment. Data was compared against a gold standard Actigraph	Steps	Fitbit-Flex is strongly correlated with Actigraph for measuring step counts among all examined subgroups, but the device appeared to progressively overestimate the step count as the

Diaz et al.	. (201	16)	13 healthy female adults	Flex and One	To provide evidence concerning the validity of the Fitbit One attached to the upper torso in contrast to Flex worn on the wrist for measuring step counts	The treadmill walks at four different speeds	Steps	number of steps increased Fitbit One was more accurate than Flex in steps counts at all speeds
Nelson (2016)	et	al.	30 healthy adults	Flex, One, Zip	To examine the validity of different Fitbits for measuring steps in 10 activities (sedentary, household, ambulatory)	Participants wore the Fitbits in three sedentary, four household, and four ambulatory/exercise activities and step count data was compared against Omron HJ-720IT pedometer	Steps	One and Zip, monitors significantly underestimated steps by 35%–74% for the household category. The Flex correctly recorded 0 steps during sedentary activities in all but five participants
(Huang 2016)	et	al.	40 healthy adults	Flex, One, Zip	To assess step count and distance accuracy for various activity monitors	Participants walked on flat ground (400 m), upstairs (176 steps), and downstairs (176 steps), and a subset of 10 subjects performed treadmill walking trials to assess the influence of walking speed on	Steps and distance	Fitbits Overestimated 400m ground walk by 5%, 4% and 17% for Zip, One and Flex respectively
Kooiman (2015)	et	al.	89 health adults	Flex and Zip	To examine the reliability of	accuracy. In free-living conditions, 56	Steps	The reliability and validity of most

ten consumer activity monitors for measuring step count in both laboratory and free- living conditions	volunteers wore the same activity trackers for one working day. 33 participants walked twice on a treadmill at a slow pace for 30 min	trackers for measuring step count were good. The Fitbit Zip was the most valid
	a slow pace for 30 min	
	while wearing the activity monitors	

6.4.2 Methodology

To evaluate the FC4 activity monitor, four tests were carried out. Due to COVID-19 restrictions, it was not possible to recruit participants outside the lead researcher (SB) household and so all of the tests were carried out by SB as a participant.

6.4.2.1 Settings

6.4.2.1.1 FC4 accuracy and precision in long outdoor walks

SB completed two laps (500 m), four laps (1000 m), and eight laps (2000 m) on a flat lane of 250 m Olympic standard outdoor tarmac track (Figure 2), repeated three times at a walking speed of between 0.6 – 0.8 m/s which is recognised as a slow speed for adults walking outdoor (Bohannon et al. 1996; Morio et al. 2019; Murtagh et al. 2020). SB utilised a stopwatch to measure walking time which subsequently was used to calculate the Gold Standard Walking Speed. In the course of every trial, the wearable was placed on the non-dominant wrist.

6.4.2.1.2 FC4 accuracy and precision in an outdoor and indoor shuttle walk

A clear marked rectangular parking space in an urban environment was utilised. The perimeter of the parking space was 14.2 m (length 4.7 m x width 2.4 m). To assess the indoor environment, SB clearly marked a rectangular space with a 14.2 m perimeter in a room inside a building. SB completed two laps (28.4 m), five laps (71 m), and 10 laps (142 m) of the perimeter, repeating five times at a slow walking speed in both the outdoor urban environment and indoor setting. SB utilised a stopwatch to measure the walking time which subsequently was used to calculate the Gold Standard Walking Speed. In the course of every trial, the wearable was placed on the non-dominant wrist.

6.4.2.1.3 Consistency of different FC4 activity monitors in indoor and outdoor walk settings with and without GPS sensor

Three FC4 activity monitors were placed on the non-dominant wrist of SB and were marked 1, 2, 3 (Figure 5). A 10 m walkway was marked on the floor with bright coloured tape at each end. To assess the consistency in an indoor setting, the FC4s were worn as per Figure 5, and data were collected using the ALG. To assess the consistency in an outdoor setting, a similar 10 m walkway was created outside on the pavement. During the first outdoor trial, the ALG only was activated to measure the outdoor distance walked using the ALG function only. In the second outdoor trial, only the GPS was activated to measure the distance walked. SB repeated each trial five times. In all three trials, SB walked at a self-paced speed without running, along the 10 m walkway and then turned around a mark at the end of the walkway, and returned to the starting point for a total distance of 100 m (9 turns). SB utilised a stopwatch to measure walking time which subsequently was used to calculate the Gold Standard Walking Speed.



Figure 5. Three FC4 activity monitors were worn on the non-dominant wrist (personal collection).

6.4.2.1.4 Does FC4 step length adjust automatically in an outdoor walk using the GPS sensor and does this affect the algorithm-activated outdoor distance accuracy

An FC4 was placed on the non-dominant wrist of SB. The GPS sensors on the FC4 were activated and SB did approximately 3.5 minutes of outdoor walking. According to the FC4 user guide and manufacture information, FC4 automatically adjusts to individuals' step length after 20 steps and therefore 3.5 minutes was determined to be a sufficient amount of time. In the first trial, SB purposefully took very small steps (less than 0.3 m) and after completion of the time, turned the GPS off and immediately went indoors and completed 200 steps and recorded the distance measure using the ALG function. In the second trial, SB purposefully took very large steps (above 0.7 m) and immediately moved indoor and took 200 steps, and recorded the distance using the ALG function. SB repeated each trial three times and utilised a stopwatch to measure walking time which subsequently was used to calculate the Gold Standard Walking Speed.

6.4.2.2 Outcomes

For all of the tests carried out, data on time, number of steps, speed, and distance using the GPS sensors and also the ALG function were collected.

6.4.2.2.1 Statistical analysis

All data were analysed using Microsoft Excel Version 2108 (Microsoft Corporation, 2022, Retrieved from https://office.microsoft.com/excel). This was a single-participant study and therefore all data were presented descriptively, using appropriate summary statistics. Accuracy was assessed based on the mean of the trials compared to the Gold Standard.

Precision (variance) was assessed using the standard deviations of the means. Consistency was assessed using the absolute values plotted on a bar chart.

6.4.2.3Results

6.4.2.3.1 FC4 accuracy and precision in long outdoor walks

Table 15 summarises the data collected for the outdoor long walk using the FC4 activity monitor. The mean distance was lower across 500, 1000, and 2000 m data sets when collected using the GPS sensor in contrast to ALG function, however, both ALG and GPS sensors overestimated the mean distance walked in contrast to the actual distance. The standard deviation of the means was smaller for the 500m, and 1000m data collected using the ALG function.

6.4.2.3.2 FC4 accuracy and precision in an outdoor and indoor shuttle walk

Tables 16 and 17 summarise the data collected for the shuttle walks carried out in an indoor and outdoor setting respectively. Both ALG function and GPS sensor of the FC4 overestimated the distance walked during slow shuttle walks. The FC4 overestimated the distances by 183% in 2 laps, 155% in 5 laps, and 192% in 10 laps using the GPS sensor. ALG function of the FC4, overestimated the distance for the indoor walks by 162% for 2 laps, 144% in 5 laps, and 154% in 10 laps. Standard deviations were lower across all walking distances measured in indoor settings using the ALG function.

- 6.4.2.3.3 Consistency of different FC4 activity monitors in an outdoor and indoor walk Table 18 summarises the data collected using three FC4 activity monitors. Figures 6A, 6B, and 6C bar plots illustrate the consistency of the data collected using different FC4s. Bar plots suggest FC4s are most consistent when used in an outdoor setting using the GPS sensor at self-selected walking speed.
- 6.4.2.3.4 The accuracy of ALG indoor distance calculation using the FC4 step length estimation based on the GPS sensor

 Tables 19 and 20 summarise the data collected using the FC4 to analyse the step length estimation of the GPS sensor for automation of step length size in the ALG function. Data suggests the step length was estimated irrespective of the actual step length performed in an outdoor walk using the GPS sensor. The ALG function estimated a mean distance of 134.67±1.15 m and step length of 0.67±0.05 m in the small step trials, and a mean distance of 134.0±8.71m and step length of 0.67±0.04 m in the large step trial and therefore did not perform as suggested by the manufacturer information.

Table 15. The FC4 data for long distances of 500m, 1000m, and 2000m outdoor walk.

Actual Distance	500	500	500	1000	1000	1000	2000	2000	2000
Time (s)	748	751	759	1417	1537	1485	2954	2937	2881
Actual Steps	781	787	790	1450	1430	1427	2835	2804	2839
Speed (m/s)	0.67	0.67	0.66	0.71	0.65	0.67	0.68	0.68	0.69
FC4 Step	780	785	788	1440	1432	1439	2825	2828	2890
Distance (m) GPS	490	510	510	1110	980	1170	2290	1920	2130
Mean (m) GPS	503.33			1086.67			2113.33		
SD (GPS)	11.55			97.13			185.56		
Distance (m) ALG	500	510	510	1110	990	1170	2300	1930	2480
Mean (m) ALG	506.67			1090.00			2236.67		
SD (ALG)	5.77			91.65			280.42		

Table 16. Summary of data for shuttle walk of 2 laps (28.4m), 5 laps (71m) and 10 laps (142m) of indoor walks using the ALG function of the FC4 activity monitor.

Actual distance (m)	28.4					71				142					
Time (s)	67	60	62	57	72	161	166	164	153	163	310	318	300	298	312
Steps	60	65	62	57	65	152	147	147	149	156	296	304	300	308	301
Speed	0.42	0.47	0.46	0.50	0.39	0.44	0.43	0.43	0.46	0.44	0.46	0.45	0.47	0.48	0.46
Distance (m) ALG	40.00	40.00	50.00	50.00	50	90	110	110	110	90	240	220	210	220	210
Mean	46.00	•		•		102.00					220.00	•			
SD	5.48					10.95					12.25				

Table 17. Summary of data for shuttle walk of 2 laps (28.4m), 5 laps (71m) and 10 laps (142m) of outdoor walks using the GPS sensor of the FC4 activity monitor.

Actual distance (m)			28.4				7	142							
Time (s)	54	62	57	63	61	138	134	148	144	131	237	236	238	237	221
Steps	50	58	51	54	55	135	126	135	132	132	254	258	259	260	257
Speed (m/s)	0.53	0.46	0.50	0.45	0.47	0.51	0.53	0.48	0.49	0.54	0.60	0.60	0.60	0.60	0.64
Distance (m) GPS	50	60	60	40	50	100	110	90	120	130	240	240	270	310	300
Mean	52					110					272				
SD	8.00					15.81					32.71				

Table 18. Summary of data for the 100 m shuttle walks and outdoor walks using the ALG function and GPS sensor at self-selected speed using the FC4 activity monitor.

ALG										GPS						
Indoor (Shuttle walk)							Outdoor (Shuttle walk)					Outdoor (Straight line)				
Gold Distance	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	
Time (s)	108	129	134	128	118	91	102	101	102	102	115	90	95	97	96	
Steps	154	187	192	191	169	134	156	155	157	154	150	138	153	144	153	
Speed	0.93	0.78	0.75	0.78	0.85	1.10	0.98	0.99	0.98	0.98	0.87	1.11	1.05	1.03	1.04	
FC4 1	130	140	150	130	130	90	110	100	110	100	90	100	100	100	110	
FC4 2	120	140	140	140	120	90	90	90	90	100	100	110	100	110	120	
FC4 3	120	140	150	140	130	80	110	100	110	110	100	90	100	90	110	

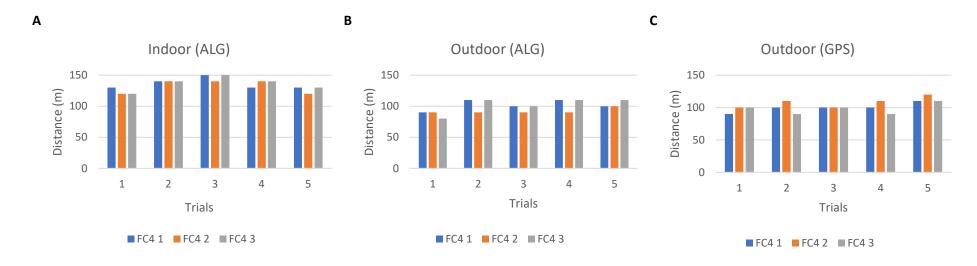


Figure 6. Bar plots illustrating data collected using three different FC4 activity monitors. 6A) Data collected in an indoor setting using the ALG function. 6B) Data collected in an outdoor setting using the ALG function. 6C) Data collected in an outdoor setting using the GPS sensor.

Table 19. Summary of three trials carried out with small steps.

Actual step length (m)		<0.3	Mean	SD			
GPS distance (m) (time (s))			140 (20				
FC4 Distance Indoor (m)	140	130	140	130	130	134	4.90
Time (s)	143	125	141	125	123	131.4	8.71
Steps	200	200	200	200	200	200	
Step Length (m)	0.70	0.65	0.70	0.65	0.65	0.67	0.02
GPS distance (m) (time (s))			170 (20	02)			
FC4 Distance Indoor (m)	120	140	140	140	140	136	8.00
Time (s)	114	132	145	150	148	137.8	13.45
Steps	200	200	200	200	200	200	
Step Length (m)	0.60	0.70	0.70	0.70	0.70	0.68	0.04
GPS distance (m) (time (s))			150 (20	06)			
FC4 Distance Indoor (m)	120	140	140	130	140	134	8.00
Time (s)	114	134	145	142	144	135.8	11.57
Steps	200	200	200	200	200	200	
Step Length (m)	0.60	0.70	0.70	0.65	0.70	0.67	0.04

Table 20. Summary of three trials carried out with large steps.

Actual step length (m)			>0.70	Mean	SD		
GPS distance (m) (time (s))			200 (20				
FC4 Distance Indoor (m)	130	130	110	120	130	124	8.00
Time (s)	109	128	128	117	130	122.4	8.11
Steps	200	200	200	200	200	200	
Step Length (m)	0.65	0.65	0.55	0.60	0.65	0.62	0.04
GPS distance (m) (time (s))			200 (20	06)			
FC4 Distance Indoor (m)	130	150	130	150	140	140	8.94
Time (s)	123	132	134	136	143	133.6	6.47
Steps	200	200	200	200	200	200	
Step Length (m)	0.65	0.75	0.65	0.75	0.70	0.70	0.04
GPS distance (m) (time (s))			230 (22	18)			
FC4 Distance Indoor (m)	130	140	140	140	140	138	4.00
Time (s)	121	132	131	131	134	129.8	4.53
Steps	200	200	200	200	200	200	
Step Length (m)	0.65	0.70	0.70	0.70	0.70	0.69	0.02

6.4.2.4Discussion

The aim of this single-participant study was to have a more in-depth understanding of the accuracy, precision, and consistency of the FC4 activity monitor, in order to inform decision-making on the design of any future study as well as to assist in interpreting the level of accuracy of the data that will be collected.

The findings from the long outdoor walk suggested that the accuracy and precision decrease greatly as the distance increase. Figure 7 outlines the GPS data recorded using the FC4 activity monitors in long-distance walking trials, showing signs of signal loss in distance measurement resulting in an overall overestimation or underestimation of the outdoor distance walked. As eluded to in the previous section, I speculated this was due to the 'pinging' or 'querying' of the FC4's GPS receiver data at different frequencies/ intervals and, therefore, resulting in different distance values. Moreover, we speculate that at the slow pace of 0.8 m/s and below, due to the individual taking a smaller step, over a longer period of time, the FC4 GPS sensor may misjudge small changes in movement to be noise and assume the individual is in a stationary position.

The findings showed that the outdoor distance measured using the GPS sensor was more accurate and more precise in contrast to the distance measured using the ALG function. Despite no evidence directly related to the FC4, and GPS sensor, our findings are in line with other evidence in the literature suggesting that at a slow walking speed the accuracy of Fitbit activity monitors decreases significantly in an indoor setting (Alinia et al. 2017b; Fokkema et al. 2017; Leth et al. 2017). Similarly, in a series of indoor and outdoor shuttle walks, the FC4 showed an overestimation of the distance walked using the ALG function and GPS sensor. However, findings were in favour of consistency in both outdoor and indoor settings using the



Figure 7. The GPS data recorded using the FC4 activity monitors in long distance walking trials. The first row (top) outlines the three trials of the 500m (two laps) of the outdoor velodrome. The second row (middle) outlines the three trials of the 1000m (four laps) of the outdoor velodrome. The third row (bottom) outlines the three trials of the 2000m (eight laps) of the outdoor velodrome (personal collection).

GPS sensor and ALG function respectively. The best consistency was seen across distance data collected in an outdoor setting using the GPS sensor of the FC4 activity monitor.

The ALG function and its subsequent built-in algorithm claimed that following 20 outdoor steps using the GPS, the FC4 automatically adjusts to an individual's step length. However, our findings suggest that the FC4 ALG does not carry out such a process and it is likely that it follows a simple analysis where individual self-inputted height in cm is divided by a constant, 2.4.

Due to COVID-19 restrictions, this study was a single-participant study and therefore there are limitations on the statistical analysis that was carried out. Hence, all findings should be treated with caution, nevertheless, the findings provide insight into the accuracy, precision, and consistency of the FC4 to inform future study design. Overall, the findings suggested that the FC4 activity monitor is not accurate in indoor or outdoor settings at a slow walking pace. However, FC4 precision is better when walking distance is measured using the GPS sensor in contrast to the ALG. It is also important to point out that the FC4 significantly overestimated a shuttle-like walk in indoor and outdoor settings. A factor for such overestimation may be the 'stop and start' manner of the shuttle walk causing the ALG and GPS to misjudge the movement or lose the satellite signal and constantly make an assumption about the position of the individual.

6.4.2.5Summary

The FC4 activity monitor showed a satisfactory level of precision in particular when the walking distance was measured using the GPS sensors in an outdoor environment. However, its accuracy remains questionable and further studies with a larger sample size are required to estimate the degree of the inaccuracy across different walking speeds. Therefore, any

future study design should consider an intervention in which the accuracy of FC4 activity monitor is not a significant factor in determining an individual's recovery post-THR surgery. Future studies should focus on designing a study where the precision of FC4 is the indicator of the individual recovery data (i.e. personalised and not generalised plan).

6.5. Chapter summary

The aim of this section was to utilise research evidence and guidelines in order to identify and evaluate the accuracy of the most suitable activity monitor for research in the THR population, which consists mainly of people over 60 years old adults. The findings from the exhaustive screen of the available wearables and smartphones found that the top three smartphone apps are Pacer, Accupedo, and StepsApp and the most used brand of wearables in research is Fitbit. Out of all of the available Fitbits on the market, FC4 offered the most complete sensor package at a price that is less than a cost of a standard NHS physiotherapy session. Following the evaluation of the selected activity monitors, the findings suggested that the activity monitors were least accurate at the slow speed of walking, and the best accuracy was seen at the medium speed. Furthermore, the walking distance was measured with the highest precision and accuracy by FC4's GPS sensor over an outdoor distance of 250 m. However, for the FC4 activity monitor to be considered in any future study, the precision, accuracy, and consistency of this device was further explored in a variety of settings and walking speeds. The FC4 activity monitor showed a satisfactory level of precision in particular when the walking distance was measured using the GPS sensors in an outdoor environment. However, its accuracy remains questionable and further studies with a larger sample size are required to estimate the percentage of the inaccuracy across different walking speeds. The following chapter describes the feasibility study designed to evaluate an outdoor walking intervention using the FC4 wearable activity monitor.

"The impediment to action advances action. What stands in the way becomes the way."

Marcus Aurelis

Chapter 7 – A Feasibility Study to Evaluate a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor in Individuals Post Total Hip Replacement Surgery

7.1 Chapter overview

Chapter 7 of this thesis describes the feasibility study, where the potential of a purposeful walking intervention, designed to increase daily activity in the THR population, was tested. This study also aimed to explore the barriers and facilitators to implement such intervention through qualitative analysis as well as assessing the appropriateness of different outcome measures so they inform the final pilot study of this research. This chapter is prepared in accordance with STROBE guidelines for reporting feasibility studies (Von Elm et al. 2007; Lancaster and Thabane 2019) as the research is currently under re-review at the Journal of Rehabilitation and Assistive Technology following a peer reviewed feedback.

Title

A Feasibility Study to Evaluate a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor in Individuals Post Total Hip Replacement Surgery.

Authors

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Abstract

Introduction: Total hip replacement (THR) is performed in an increasing number of individuals around the world and while improvements in pain reduction and long-term enhancement of muscle strength are well documented, the improvement in a daily activity does not follow the same trend. This study aimed to determine the feasibility of a five-week intervention where a personalised outdoor walking distance is monitored using a commercial activity monitor (Fitbit Charge 4).

Method: Data was collected on gait and activities of daily living using patient-reported outcome measures. Following the completion of the intervention period, participants took part in a semi-structured interview to voice their opinion on the use of the activity monitor, their experiences, and any challenges in order to assess the feasibility of the intervention. All quantitative data were presented descriptively, using appropriate summary statistics. Interviews were analysed using thematic analysis.

Results: Five participants who had undergone total hip replacement surgery within the postoperative period of 3 to 6 months were recruited from the local community.

Conclusion: The findings suggest that the intervention was feasible and that it encouraged all participants to increase their daily activity. Therefore, it can be concluded that a follow-up effectiveness trial is warranted.

Keywords: Total hip replacement; Activity monitor; Walking activity; Gait analysis.

7.2 Introduction

Total hip replacement (THR) is performed in an increasing number of individuals around the world with the primary aim of reducing pain and improving function (Culliford et al. 2015). The National Joint Registry (NJR)(National Joint Registry 2022) reported that over the last three years, 250,278 total hip replacement procedures were performed in the UK on individuals with a median age of 69, and this figure is predicted to rise by 208% by the year 2035. Meanwhile, with the cost of the operation being around £7500 (Chen et al. 2012), combined with the time taken to return to normal activities and work, THR places a significant financial burden on the National Health Service.

While improvements in pain reduction, range of motion of hip joints, and long-term improvement of muscle strength are well documented (Beswick et al. 2012; Smith et al. 2018; Astephen Wilson et al. 2019), the improvement in gait and in particular the walking ability does not follow the same trend (Beaulieu et al. 2010). A recent study monitored the first 3 months of the recovery post THR and data showed that the number of steps after THR decreases temporarily after surgery and does not reach pre-surgery levels even at 3-months post-surgery (Tang et al. 2021). Other studies looked at a longer period and found that this deficit even remains at 1-year post-surgery (Crizer et al. 2017; Withers et al. 2017b; Holl et al. 2018) and also few meet the physical activity guidelines recommended by the World Health Organization (WHO) (Harding et al. 2014).

There are currently no recommendations for the optimal amount of walking that should be recommended after THR surgery. A recent report (Bahadori et al. 2020c) including both groups of THR patients (before and after surgery) and healthcare professionals (physiotherapists and surgeons) concluded that walking freely i.e. long outdoor walks without

pain, is one of the main reasons that people undergo THR surgery, and therefore should be recognised and monitored as a factor to a positive long-term outcome measure. Furthermore, another study (Salpakoski et al. 2014) reported that an ability to walk even a short distance outdoors can be meaningful for successful and independent living at home among the THR group, as well as enhancing their physical function (Simonsick et al. 2005).

The availability of commercially available wearable devices, such as activity monitors, allows objective monitoring of daily activities such as walking. In addition to their growing popularity (Henriksen et al. 2018), these devices are equipped with a wide variety of different sensors such as the Global Positioning System (GPS), and algorithms to collect and display physical activity data in indoor and outdoor settings. In an earlier study (Bahadori 2021b), Fitbit Charge 4 (FC4) was identified as the most suitable activity monitor for a study involving the elderly population, and with the best accuracy and percision in measuring the distance walked using the GPS sensor. Whilst, research has provided evidence to support the use of wearable activity monitors in maintaining good health in older adults (Gartner 2018; Kononova et al. 2019), when it comes to THR studies (Toogood et al. 2016; Van der Walt et al. 2018), there is limited evidence to support its benefits. Furthermore, for all of these studies, the focus has been merely on step count and has not addressed the main gait adaptations e.g. shortened stride length, (Beaulieu et al. 2010; Ewen et al. 2012; Bahadori 2020) which persist long term after surgery. The benefits of distance-based walking in contrast to time or step count has already shown benefits in reducing cardiovascular disease (Morris et al. 2017), improving stride length in older adults (Troosters et al. 1999; Camarri et al. 2006) as well as increasing the walking efficiency pre and post-THR surgery (Brown et al. 1980). Therefore the concept of monitoring the distance walked in an outdoor setting, using the GPS sensors of a commercially available activity monitors, emerges as a potentially motivating factor.

However, before implementing new methods to promote outdoor walking, it is important to gain understating of the feasibility (uncertainties around recruitment, outcome measure, adherence, and acceptability etc.) of such a proposition.

This study aimed to determine 1) the feasibility of an intervention where walking distance is used as a parameter to increase daily walking activity using a commercially available activity monitor (FC4) in THR patients 3-6 months post-surgery, 2) explore the barriers and facilitators to implement the intervention, and 3) assess the feasibility of the recruitment and the adherence to the use of the FC4 activity monitor, and appropriateness of different outcome measures. Throughout this paper, we will refer to the outdoor walk that is recorded with a GPS sensor as a 'purposeful walk'.

7.3 Methods

7.3.1 Study design

This was an investigator-initiated, single-center feasibility trial with full ethical approval granted by the Bournemouth University Research Ethics Committee (ref: 42236) and prepared in accordance with STROBE guidelines for reporting feasibility studies (Von Elm et al. 2007; Lancaster and Thabane 2019).

7.3.2 Participants

Table 21 provides full eligibility criteria for the participants in the study. Participants were all recruited through publicising tools such as Twitter posts, and posters shared on the University channels (Bournemouth University research blogs, the Public Involvement in Education and Research (PIER) group), University of Third Age, and communities of older adults (e.g. local indoor bowling clubs). Those interested in the study were asked to contact the lead researcher (SB) for more information. Once an individual had expressed an interest in taking part, the lead researcher emailed the individual a copy of the participant information sheet. To comply with Good Clinical Practice (GCP) guidelines, the participant was given 48 hours to consider their participation in the study. The lead researcher then contacted the participant to undertake initial eligibility screening and to attend a baseline assessment.

7.3.3 Setting

The study was carried out at the Orthopaedic Research Institute at Bournemouth University. Following taking informed consent, data were collected on gait, and on activities of daily living using patient reported outcome measures (PROMS) questionnaires. Participants were invited to attend a final assessment at 5 weeks from their baseline appointment where their baseline

measures were repeated. In addition, participants were asked to keep a diary of their daily walking activities and the intensity of their walk. After the intervention period was complete, participants were invited to attend a semi-structured interview with the lead researcher in which they were able to openly express their thoughts on the use of the activity monitor, their compliance, practicality, and the usefulness of the intervention.

Table 21. Eligibility criteria

Inclusion Criteria

- Male and female, aged 60 years and over;
- 3 to 6 months post unilateral total hip replacement surgery for osteoarthritis;
- Can provide verbal confirmation that they have been discharged from their surgical care;
- Capable of independent walking;
- Capable of completing the activity diary independently;
- Have access to a smartphone or computer;
- Willing to complete the trial protocol.

Exclusion Criteria

- Unable to provide informed consent;
- Unable to complete follow-up (insufficient English, lives overseas, unable to return easily);
- Not physically able to use Grail gait lab;
- Systematic disease affecting walking ability (chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), chronic kidney disease (CKD), Parkinson's Disease, cerebral palsy, multiple sclerosis etc.);
- Requiring revision hip replacement;
- Previous hip replacement (resurfacing or THR) on the contralateral side;
- Known metastatic tumour involving the hip.

7.3.4 Intervention

The purposeful walking intervention in this study was monitored using the FC4 activity monitor (Figure 8). Participants wore the FC4 activity monitor for 5 weeks in total. In the first week, participants wore their FC4 activity monitor in order to understand the participant's post-surgical walking distances. In week two, a target distance was calculated to increase the previous weekly walking distance achieved by 10% and was divided by seven to calculate a daily distance for that week. In the weeks thereafter, if participants met their target, a new purposeful distance target was calculated to increase the participant's walking distance by a factor of 10% from the previous target. If the participant did not meet their target, the daily distance goal they were assigned the previous week remained in place. Participants were contacted through the FC4 Fitbit app on a weekly basis throughout the study and were given their daily goals for the upcoming week. The FC4 activity monitor was worn on the wrist of the non-dominant hand continuously during the study period. Participants were shown how to charge and operate the FC4 activity monitor and were given a copy of a simple instruction manual to take with them.



Figure 8. Fitbit Charge 4 (FC4) (personal collection).

7.3.5 Sample Size

Five participants were chosen to take part in this feasibility study. Given this was a feasibility trial, a convenience sample size was selected, and a formal calculation was not carried out.

7.3.6 Statistical analysis

All data were analysed using Microsoft Excel Version 2108 (Microsoft Corporation, 2022, Retrieved from https://office.microsoft.com/excel). As this is a feasibility study, all quantitative data (gait, and PROMs scores) was presented descriptively, using appropriate summary statistics. In the absence of any direct guidance associated with the development of walking post THR surgery over a period of weeks, the feasibility for using a purposeful walk with target distances in individuals post THR was determined if individuals managed to increase their baseline purposeful walk by more than 40% (4 weeks multiply by 10%) from their baseline. Adherence to the intervention was assessed in terms of the daily purposeful walk amount that was recorded using FC4 and reported through the Fitbit App. Full adherence was achieved if all participants reported their daily purposeful walk amount, and no data were missed. Recruitment was assessed based on the time needed to recruit the study participants, with 1 participant per week being an acceptable recruitment rate (Walters et al. 2017). The feasibility of different outcome measures was assessed through appropriations of collected data, and the practicality of delivering the assessments such as the time it took for each assessment.

7.3.7 Qualitative analysis

Following the intervention completion, in order to qualitatively explore the feasibility of the intervention, all participants were invited for a semi-structured interview held at Bournemouth University. The use of a semi-structure interview is proven to be an effective method to 1) collect qualitative, open-ended data; 2) explore participant thoughts, feelings, and beliefs about a particular topic; and 3) delve deeply into participant's challenges and experiences (DeJonckheere and Vaughn 2019). A topic guide (Appendix 5) was designed to inform the study design of any future trial by determining which elements of the intervention worked well for participants, and which needed adjustment or further development. Participant feedback was analysed using thematic analysis (Braun and Clarke 2006; Vaismoradi et al. 2016). The six phases of the thematic analysis (Vaismoradi et al. 2016), 1) familiarisation with the data, 2) generating codes, 3) searching for themes, 4) reviewing themes, 5) defining, and 6) naming themes, were followed. The recording was anonymised, and transcribed discussions were read through several times by the lead researcher to become familiar with the data and were organised using Microsoft Excel Version 2018. Codes were thereafter created, and similar codes were organised into potential themes. The sessions took around 25 to 35 minutes and were conducted in June 2022.

7.3.7.1 Activity Diary

Participants were given an activity diary to record their daily walking activity (Appendix 6). They were asked to record the amount of distance walked in kilometers (km) as reported on their activity monitor after each purposeful walk. They were also asked to rate the intensity of their walking using the Borg scale (Oosting et al. 2012) following each purposeful walking session. The activity diary also had sections where participants were able to document their

feelings/conditions which may have affected their attempts to do their daily purposeful walk.

Participants brought their activity diary to the interview in order to remind themselves of any challenges or positive experiences they faced during the 5 week intervention.

7.3.8 Quantitative analysis

The study period and visit schedules are summarised in Table 22. The choice of key outcome measures was sought by a search conducted on The COMET database (Core Outcome Measures in Effectiveness Trials; www.comet-initiative.org). However, no results were found in regard to the studies including THR participants.

7.3.8.1 Activity Monitor, FC4

Adherence was assessed in terms of the usage and repeated usage of the FC4. This data were downloaded by the lead researcher at the end of each day using the Fitbit app which has been connected to the study's Fitbit account.

7.3.8.2 Gait analysis

The Gait Real-time Analysis Interactive Laboratory (GRAIL, Motekforce Link, Amsterdam, the Netherlands) system was used to carry out the gait analysis. GRAIL combines a fully instrumented treadmill with a self-paced option, as described by Sloot et al. (Sloot et al. 2014). The treadmill is feedback-controlled, which allows participants to walk at their preferred speed. It compromises a virtual environment, 10-camera Vicon MX optical infrared tracking system (Oxford Metrics, UK), and a split-belt instrumented treadmill. The gait analysis was carried out as per the protocol published on gait analysis using the GRAIL system(Bahadori and Wainwright 2020b). However, only Spatio-temporal data (walking speed, cadence and step length of the operated side) which are directly related to the walking pattern of participants were recorded for analysis. Participants were asked to wear comfortable shoes

and tight clothing (such as cycling shorts or leggings). They were fitted with 25 passive reflective markers using the Human Body Model (HBM) lower body marker set (van den Bogert et al. 2013). Following an acclimatisation period, three sets of 25 gait cycles were recorded (Bahadori and Wainwright 2020b). The reliability of the GRAIL system in self-paced mode walking speed (Bahadori et al. 2020d) has been previously reported and it is recommended that a minimum of 23 gait cycles should be captured to attain the characteristics of individuals' walk (Kribus-Shmiel et al. 2018). Spatial-temporal gait parameters for all participants were exported as a . CSV file and analysed in Matlab R2019b (The Mathworks Inc., USA). Gait analysis was undertaken as it has proved a valuable tool in identifying objective data on individual walking patterns and modalities before and after THR (Bhave et al. 2007).

7.3.8.3 Patient reported outcome measures (PROMS)

PROMs were selected to give a broad understanding of the level of daily activity, functional limitation, occupational activity, and level of confidence in walking 3 to 6 months post-THR surgery.

7.3.8.3.1 Hip-related disability

Hip-related disability was assessed using the Hip Disability and Osteoarthritis Outcome Score (HOOS) questionnaire (Nilsdotter et al. 2003) (Appendix 7). The tool is validated in a sample of participants after THR surgery (Goodman et al. 2020) and was perceived as relevant and is intended to be used to assess the individual's opinion about their hip and associated problems, and to evaluate symptoms and functional limitations related to the hip during a therapeutic process. To provide meaningful information to support the clinical effect of the

five-week programme on individuals, the minimal clinical important difference (MCID) for the HOOS was considered to be 24 (Soh et al. 2022).

7.3.8.3.2 Physical activity levels

Activity levels were measured using the Physical Activity Scale for the Elderly (PASE) questionnaire (Washburn et al. 1993). The self-administered questionnaire is a valid and reliable tool for adults with hip osteoarthritis, that consists of 12 questions regarding the duration, frequency, exertion level, and amount of physical activity undertaken during a seven-day period (Svege et al. 2012). It was perceived relevant as it was designed to assess a broad range of activities, including household tasks, occupational activities, active transport, and sports and exercise in older adults, and therefore given our inclusion criteria it provides an insight into such age range who undergone THR surgery. It uses frequency, duration, and intensity level of activity over the previous week to assign a score, ranging from 0 to 791, with a higher score indicating greater physical activity (Washburn et al. 1993).

7.3.8.3.3 Gait efficacy

The modified Gait Efficacy Scale (mGES) (Newell et al. 2012) is a 10-item measure that addresses older adults' perception of their level of confidence in walking during challenging circumstances. The items include walking on a level surface and on grass, stepping over an obstacle, stepping up and down a curb, ascending and descending stairs (with and without a handrail), and walking over a long distance (Appendix 8). The items are scored individually on a 10-point Likert scale, with 1 denoting no confidence and 10 representing complete confidence, giving a total score range of 10 to 100, with 100 representing complete confidence in all tasks (Newell et al. 2012). This questionnaire was particularly relevant as it provided a subjective insight into participants walking capabilities to compliment the gait

analysis objective evaluation. The mGES is validated in studies including older adults (Weijer et al. 2020), total knee replacement patients (Fransen et al. 2021), and individuals undergoing lower limb fixation surgery (Xia et al. 2020) and is perceived feasible in other orthopaedic related studies such as THR.

Table 22: Visit schedule.

	STUDY PERIOD									
	Enrolment	Allocation	Study intervention					Post- intervention		
TIMEPOINT	Call 1	Visit 1 Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Visit 2 - Follow up assessment		
Eligibility screen	Х	Х								
Informed consent		Х								
Enrolment		Х								
INTERVENTION										
Purposeful intervention			4				-			
ASSESSMENTS										
Gait analysis		Х						х		
HOOS		Х						Х		
PASE		Х						х		
mGES		Х						х		
Activity Diary			•				-	Х		
Fitbit Charge 4								х		
Interview								х		

7.4 Results

7.4.1 Recruitment

Thirteen participants contacted the lead researcher over a period of 59 days of which, eight did not meet the inclusion criteria. Reasons for exclusion were: four did not have a smartphone, one suffered from systematic disease, one did not speak English, and two were under the age of 60 years old.

7.4.2 Participant demographics

Five adults (2 Male, 3 Females, average age 68 ± 5.7 years old, average BMI 27.8 ± 7.2 kg/m²) were recruited to take part in this study. Table 23 summarises the participant's demographic information.

Table 23: Participants' demographics information.

Participant	Age	Months Post Op	Height (cm)	Weight (kg)	BMI (kg/m²)	Gender
1	73	5	178.5	88.0	27.6	Male
2	74	4	163.4	58.0	21.7	Female
3	66	3	164.5	64.6	23.9	Female
4	60	4	178.4	127.6	40.1	Male
5	67	5	164.1	68.8	25.5	Female

7.4.3 Feasibility and adherence of the intervention

Figure 9 outlines individuals' weekly total purposeful walk. Results suggest a weekly increase of 10% to individuals' baseline walking distance was achieved, with all participants adherent to the use of FC4 and reporting a maximum purposeful walking distance of more than 40%

from their baseline amount. Except Participant 1 who achieved his maximum purposeful walk at week 3 (70% increase from baseline), all participants achieved their maximum walking amount at week 5.

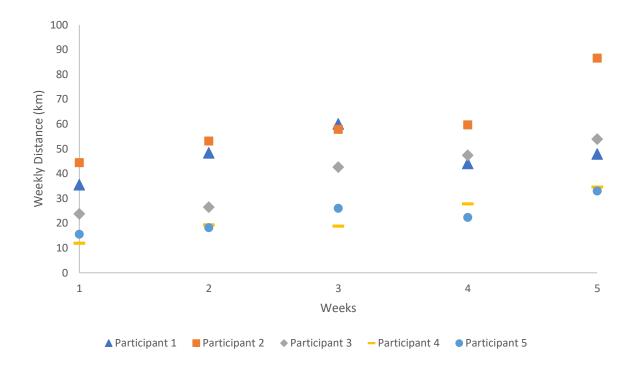


Figure 9: Total amount of purposeful distance walked by each participant per week.

7.4.4 Feasibility and practicality of different outcome measures

The feasibility of the various outcome measures was assessed through the appropriateness of collected data, and the practicality of delivering the assessments. On average it took approximately 45 minutes for the baseline and follow-up assessment sessions.

7.4.4.1 Activity monitor:

The purposeful walking intervention in this study was monitored using the FC4 activity monitor. In an earlier study (Bahadori 2021b), FC4 was identified as the most suitable activity monitor for a study involving the elderly population, and with the best accuracy in measuring

the distance walked using the GPS sensor. Throughout the study, participants were able to use the FC4 easily, record all of their purposeful walks, and report the distance of their daily purposeful walks. Thus, it can be concluded that as an activity monitor, the selection of FC4 with the target population is appropriate.

7.4.4.2 Gait analysis

Gait parameters (walking speed, cadence, step length) were recorded as per the protocol, using the GRAIL system, and took approximately 20 minutes to complete. Figures 10, 11, and 12 outline each participant's gait changes from pre to post-intervention. These findings suggest improvement of step length (operated side), walking speed, in all participants and cadence in four out of five participants following the purposeful walk intervention.

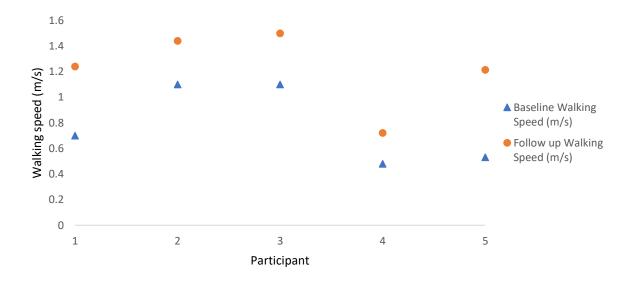


Figure 10. Walking speed gait data for each participant.

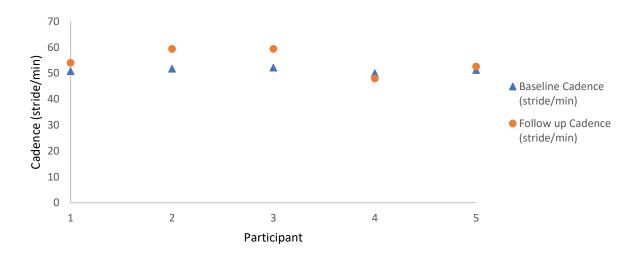


Figure 11. Cadence gait data for each participant.

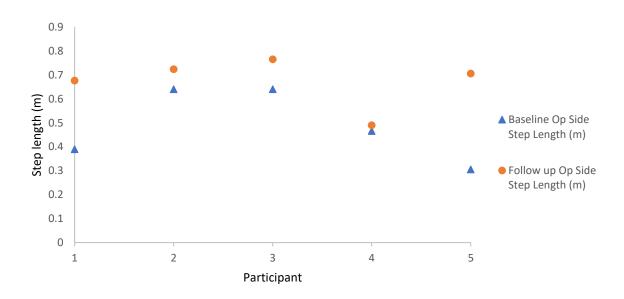


Figure 12. Step length of the operated side gait data for each participant.

7.4.4.3 Patient reported outcome measures (PROMS)

Figures 13, 14, and 15 show participants' data for HOOS, PASE, and mGES respectively. All participants were able to complete all of the questionnaires as per the protocol. Except for the PASE score for participant 3, and the mGES score for participant 4, PROMs data indicated an improvement in all participants. The MCID for pre to post-intervention was not seen in the HOOS score in any of the participants.

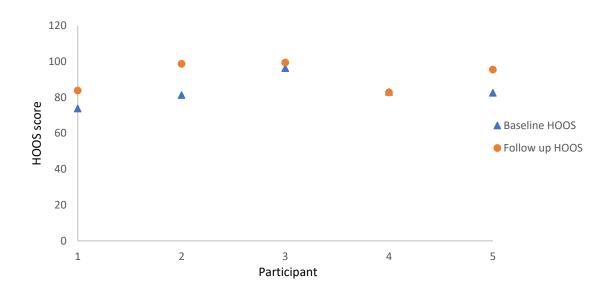


Figure 13. Hip Disability and Osteoarthritis Outcome Score (HOOS) data for each participant

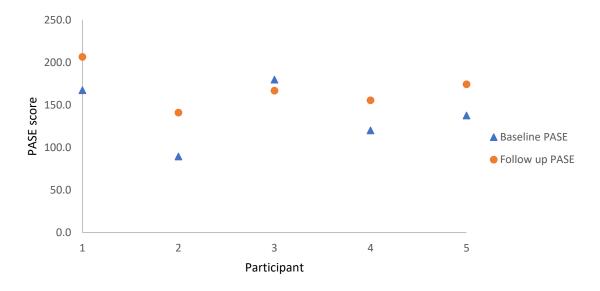


Figure 14. Physical Activity Scale for the Elderly (PASE) data for each participant.

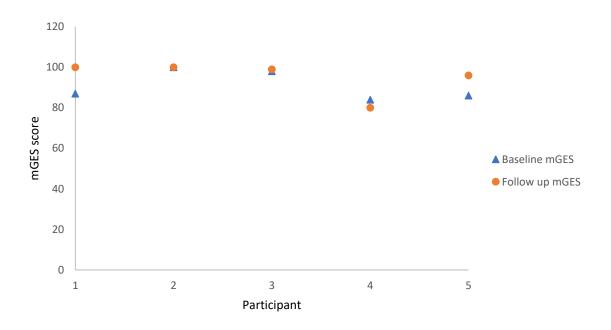


Figure 15. The modified Gait Efficacy Scale (mGES) data for each participant.

7.4.5 Qualitative findings

7.4.5.1 Activity monitor

The codes and themes relating to the activity monitor, are illustrated in Figure 16. Participants expressed that the FC4 was comfortable to wear on the wrist and encouraged them to walk further and increase their daily physical activity. The theme for the overall use of the FC4 was satisfaction. However, there were suggestions concerning the difficulties around the GPS signalling (Participants 1, 3). Subsequently, there were positive comments in relation to the use of GPS and pleasure in accessing the daily map of the purposeful walk (Participant 2). Additionally, being able to show others how much distance they had walked during the day was highly valued by participants. It provided evidence and reason for their need for rest, regardless of whether they needed to put their feet up after a day at work or to stop walking after an entire day of sightseeing while on vacation. Previous experience regarding the use of such activity monitors was also discussed and participants mentioned "trepidation" (Participant 5) feelings in relation to this matter. However, post participation in the study, they all enjoyed using the FC4 and would consider the future purchase of such activity monitors. The codes and themes related to the activity monitor, are illustrated in Figure 9. Quotes from participants concerning the activity monitor are outlined below.

"I would not say it encouraged us to walk (wife & I) as we usually have a daily walk. I would say however it encouraged us to have a longer walk - & we tried our best to meet my set target for that

week."

Participant 1

"Yes I think I would (consider buying one). I will miss wearing it and seeing the maps of my walks."

"The activity monitor did encourage me to walk and achieve my daily goals. It is an excellent piece of kit and I enjoyed the email feedback when my goals had been achieved. I was very impressed with the activity monitor."

Participant 3

"I hadn't given them any thought before the study at all. I intend to get one after I have given yours back to you."

Participant 4

"No, I don't think I would buy one. But it proved a point about exercising to return to fitness, as it renewed my cognisance of the benefits of moving more, and sitting down less."

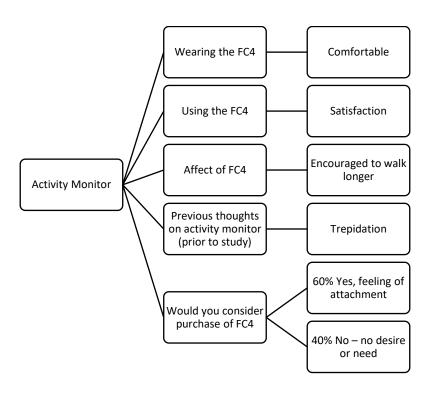


Figure 16. The codes and themes related to the subject discussion, activity monitor.

7.4.5.2 Purposeful walking intervention

Participants felt enthusiastic, excited, and enjoyed the purposeful outdoor daily walks. Personalised daily distance targets were manageable for most of the participants and the weekly gradual increase allowed the participant to push beyond their self-believed limit. Allowing time and having the purposeful walk planned into the daily schedule was also deemed feasible by all except one (Participant 1). This participant's (Participant 1) target was 9.4km on week three and they found it challenging to fit it into the daily schedule. Conversely, another participant (Participant 2) reached 9.4km on week five and she was able to achieve this daily distance and expressed her joy in doing so. The purposeful walk allowed participants to feel they had regained the muscles that they had lost post-surgery, as well as feeling fitter physically and mentally by being connected with outdoor nature again. The codes and themes related to the purposeful walking intervention, are illustrated in Figure 17. Quotes from participants concerning the purposeful walking intervention are outlined below.

"The beginning (4km) was easily manageable but 9km a day a long time to fit into my daily schedule"

Participant 1

"I really enjoyed going out for my outdoor walks and I really enjoyed my early morning walks as it was so therapeutic to listen to the birds singing early morning. Part of my study was carried out on a cruise ship, to be at sea and completing an outside walk is quite magical, listening to the waves lapping the water and the sun shining off a clear blue sea, combined with a gentle breeze was very exhilarating."

"The daily distance goals were extremely helpful in increasing my daily activity. It made me feel fitter, encouraged me to walk further daily and I feel healthier in myself plus I feel more toned up. It has encouraged me to walk on a daily basis."

Participant 3

"Early ones (daily distance goals) were very manageable. The 4.4km per day I think at the moment is my limit for a while, easily achieved at work not so out of work but I'm stubborn and I had to finish my given goal."

Participant 4

"Yes, they were helpful (daily distance goals). As my leg muscles strengthened, my hip gave me less pain, so I was able to look at my goal as a challenge to aim for and surpass, and grow more confident in realising that I still had the ability to move nearly as well as before the hip replacement. I felt safe in the knowledge that I would not be asked to do something that was too much for me to achieve after the operation, I was unsure if I would damage my new joint if I did too much, or too little moving around."

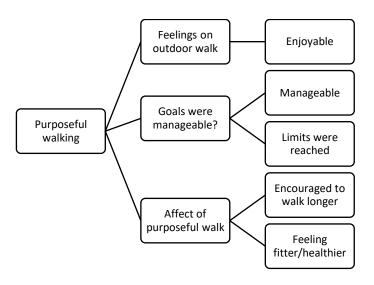


Figure 17. The codes and themes related to the subject discussion, purposeful walk.

7.4.5.3 Outcome measures

Participants were interviewed about their feeling on the time spent during the testing sessions, the duration of the intervention (5 weeks), the layout of the activity diary, their feelings on completing it as well as the styles of its questions. All participants were happy with the duration of the baseline and follow-up testing sessions at the Institute. Participants also were happy with the duration of the whole intervention and felt it passed by very quickly. They felt five weeks was a small amount of time commitment in comparison to the benefit they gained in taking part in this study. However, they found the Likert scale of the activity diary irrelevant and difficult to complete and preferred the section in which they can openly write any condition or feeling which may affect their daily outdoor walk. Overall, there was a mixture of feelings about the layout of the activity diary. One of the participants (Participants 1) did not enjoy paperwork and therefore found the activity a chore. Participant 2 also provided feedback on the layout design and suggested leaving more spaces in the diary table where they can express their daily feeling on conditions affecting their outdoor walk. All others expressed that the layout was simple, questions were clear, and completion was easy. The codes and themes related to the Outcome measures are illustrated in Figure 18. Quotes from participants concerning the Outcome measures are outlined below.

"I am afraid I don't do very well with paperwork & although keen at first - need to report my attitude
has not changed."

Participant 1

"I was happy to spend the baseline and follow-up daytime. Very enjoyable."

"Completing the daily activity diary was no problem. It was also good to keep a record so that I could go over past events."

Participant 3

"The questions were relevant to the different factors affecting the ability to carry out the exercise.

Pain, lifestyle and time can all be factors in the willingness to do differing amounts of exercise on any given day."

Participant 4

"(5 weeks) Perfectly acceptable. The aim of the study is to improve the patient's ability to move better and feel less discomfort. 5 weeks is a small amount of time to commit, compared to the quality of life that I feel I have regained."

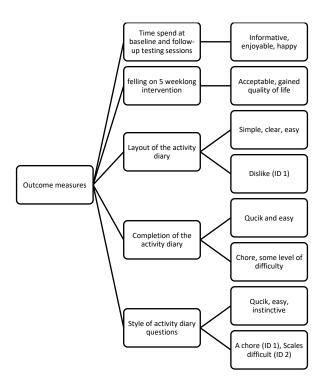


Figure 18. The codes and themes related to the subject discussion, outcome measures.

7.4.5.4 Overall experience

Participants also had an opportunity to share any further thoughts, challenges, or positive experiences that may have occurred during their purposeful outdoor walks or throughout the study but have not been discussed so far in the interview. An interesting point was raised in relation to the wearability of the FC4 and Participant 1 expressed he would wear the activity monitor only when had the intention to go for his outdoor walk. Others felt the study created a positive and beneficial habit to their daily routine and gained better self-confidence. Quotes from participants concerning their experience are outlined below.

"I enjoyed looking at the map when I got back seeing the distance we had covered, where we had been and the time it had taken. I would put the monitor on and have it on my right hand - I would notice it had switched off, this puzzled me for a few days and was frustrating - that I knew I had done the mileage but it had not registered as it had turned off. I worked out if I flexed my wrist the back of my hand would sometimes turn the monitor off. So I started to wear it on my left hand & that's my watch hand, so felt a bit foolish wearing (what appeared to be two watches) I like to wear my watch & as I had difficulty reading the screen of the monitor (in the sunshine) did not want to not wear my watch."

Participant 1

"I think this was a fantastic experience for me. It made me realise that I can do far more than I had thought I could, and with every week I felt stronger, faster, fitter, more stable and much more confident. When I did the baseline questions I thought I felt pretty confident, but I now realise I wasn't anywhere near as confident as I needed to be."

Participant 2

Having the activity monitor definitely made this study very enjoyable. I was determined to recover as quickly as possible from my hip surgery and completing this study gave me that extra

determination. I will definitely make daily outdoor walking part of my daily life. I have walked kilometres that I never did before and I will definitely continue to exercise on a daily basis and hopefully in the near future I will be able to get back on my bike and include this as part of my daily fitness activity.

Participant 3

"Well my operated leg has definitely improved a lot, which I found out on this past Saturday my colleague got diagnosed with covid so I had to go into work early doors, I cant drive the van at the moment so I had to push 1200ltr bins to the compactor area from all over the sight to empty them it involves most having to go through the link tunnel and that means pushing them uphill on part of the journey, my hips both hurt but next day it was only my right hip that's giving me any pain. I know if this had happened a month ago I would have been sunk, so it has been a good thing for me."

Participant 4

"It made me more communicative again, by passing the time of day with other walkers, particularly dog walkers as I love dogs, and cannot resist patting a friendly canine. Many happy little chats to brighten the day took place on my walks, hence my GPS shows several pauses on various days. It certainly brightened my mood."

Participant 5

7.5 Discussion

This study was a small feasibility trial, to inform a follow up randomised pilot trial, with a convenience sample, that aimed to evaluate the appropriateness of outcome measures, recruitment, and adherence to the purposeful outdoor walking intervention monitored using a commercial activity monitor device to decide whether an effectiveness trial is warranted. Five adults who had had THR surgery at least 3 months and at most 6 months ago, due to symptomatic hip osteoarthritis were recruited from the local community. Given the timeline and inclusion/exclusion criteria, the recruitment took almost two months. It is suggested that 1 or 2 participants per week are an acceptable recruitment rate for a clinical trial (Walters et al. 2017). Thus, the rate of our recruitment was below the average. Therefore, it should be emphasised that for a study of 12 participants with inclusion criteria, such as the one outlined here, recruitment may take up to 4 months to complete.

Current studies have provided evidence to support the use of wearable activity monitors in maintaining good health in older adults (Gartner 2018; Kononova et al. 2019). Our findings also showed that the five weeks of outdoor walking intervention was accepted by the participant and full adherence was achieved.

Additionally, there was large variability between the weekly purposeful distance walked by the participants. The minimum purposeful walking distance increase was 69% and the maximum was 191% from the individuals' baseline distance. A minimum of 4.7 km per day was achieved by all participants.

Given there is currently no data available on the average outdoor distance walked for a healthy elderly adult or people post THR surgery, we compared our findings to studies by Schimpl et al. (2011), Tang et al. (2021), and Althoff et al. (2017). It is important to

acknowledge that these studies are not restricted to outdoor walks only and did not utilise GPS to measure the daily distance walked. Schimpl et al. (2011) reported that an average healthy adult over the age of 60 years old, walks a mean of 5.5 km per day. However, the study by Althoff et al. (2017) which consisted of 68 million days of physical activity for 717,527 people, in 111 countries across the globe suggests that female adults over the age of 60 only achieve a daily distance of approximately 2.61 km per day and male achieve around 3.63 km per day. This distance was calculated using an arbitrary estimation (distance = step length x step count) data from an earlier study on the average step length of healthy adults and a group of THR patients. The estimation calculation is based on converting the 3,600 steps for females and 5,000 daily steps for males reported by Althoff et al. (2017) et al. by average step length of 0.725 m for adults over an age of 60 years old. Similarly, Tang et al. (2021) reported that at 3 months post THR, individuals were walking approximately 3 km (4,526 steps multiplying by 0.652 m step length). Overall, all our study participants achieved beyond the estimated daily distance reported for healthy elderly adults. Further investigation on the data may also provide a platform to compare our findings to previous research which suggests that the risk of mortality is reduced with 7,000 steps or more per day (Paluch et al. 2021). Similarly, an arbitrary calculation converts this number of steps to a distance estimation of 5 km per day. At baseline only 2 participants (Participants IDs 1, and 2) were achieving this target, however, final week results showed that all participants were able to achieve this target on solely purposeful outdoor activity without taking any other indoor walking activity into account. Therefore, it may be concluded that increasing individuals' baseline walking distance amount by 10% is feasible and beneficial to individuals, however, its efficacy should be assessed in a follow-up pilot study with a larger sample size compared against a control group.

Furthermore, evidence showed that there was a wide spread of distance that was achieved by individuals depending on their baseline abilities. Therefore, it is worth acknowledging that for any future pilot efficacy study with similar sample size, it is likely that we will again find very high variability in daily purposeful walk results. Thus, we should be prepared to carry out statistical analysis based on individual changes, to estimate any future effect size for a clinical trial.

When it comes to THR studies (Toogood et al. 2016; Van der Walt et al. 2018), the focus has been merely on the step count parameter and has not addressed the main gait adaptations e.g. shortened stride length, (Beaulieu et al. 2010; Ewen et al. 2012; Bahadori 2020) which persist even at 1-year after surgery. Bhave et al. (2007) found that gait analysis is valuable in identifying problems before and after THR. The visual, accurate, and reliable data obtained by gait analysis technology provide important objective data on individual walking patterns and modalities. Given the study design and its small sample size, we cannot statistically comment on the significant effect of the purposeful outdoor walking intervention on the gait parameters. However, our findings provide support to viability of a purposeful walk given there are improvements seen across almost all gait parameters (step length (operated side), walking speed, and cadence) in all participants. Therefore, the gait analysis using the GRAIL system was an appropriate test for such a study.

As stated earlier, a purposeful walk was the term that we used to refer to the outdoor walk that is recorded with a GPS sensor using the FC4 activity monitor. Therefore, compliance with the use of GPS was essential. All participants of our study admitted that FC4 encouraged them to go further and do a long daily walk. They also enjoyed looking at the map of the route they have walked daily and preferred it to simply seeing a daily step count. This finding is also in line with a recent survey on the perception of wearable technologies, which concluded that

one of the new technologies that the majority of THR patients are willing to utilise in daily routine activities is the use of GPS (Kurtz et al. 2022).

Another aim of this study was to help determine the feasibility of the outcome measures best suited to both participants and the objectives of this study. Hence, we selected a series of PROMS that were validated questionnaires and were previously utilised in THR studies. We considered only the MCID for the HOOS to be appropriate and findings showed that the average difference in HOOS outcome measures in the intervention group was 8.6±7.2, which was below the reference for MCID suggesting a lack of clinically relevant meaningful difference from pre to post intervention. All three PROMs questionnaires provided different information. However, given the timeline post-surgery, and age (mostly retired), HOOS provided a more comprehensive set of detailed health outcome measures. HOOS has sections on physical activity level as well as specific questions on walking and therefore, it provides equivalent insight to mGES and PASE questions. Therefore, even though, all participants express their happiness about the time spent during the testing sessions, it was determined to use only the HOOS questionnaire in any upcoming efficacy studies.

Regarding the activity diary outcome measure, findings suggested that the participants found the questions straightforward and were able to answer them with ease and instinctively. However, completion of the activity diary was a challenge for one participant (Participant 1). This was not due to the layout or type of questions, but mainly due to this individual's reluctance to complete a writing task. One other person (Participant 2) also found scales difficult to complete and further explained that this was because the intensity of a walk and his fatigue changed over the course of the walk and it was hard to judge an average. Furthermore, we did not comment on the intensity of the daily walks measured with the Borg scale as all participants felt their outdoor walk never passed beyond moderate activity level,

regardless of their daily targets. All feedback regarding the activity diary will be considered for any future design of a daily diary to ensure it is easier to complete.

The limitations in this study are mainly inherent to the study methodology. There was no formal power calculation and therefore the sample size was too small for statistical analysis or inadequate to reach a saturation in qualitative analysis. Moreover, the participants recruited in our study had their THR completed by different surgeons using different techniques and surgical approaches, which may influence their early post-operative recovery time (Aggarwal et al. 2020). Furthermore, the exclusion criteria included other comorbidities and joint replacement, putting the sample at the risk of being homogenous. Outlined methodological limitation, in particular, small sample size, were adhered due to the timing of the study post COVID. Furthermore, we added an exclusion criterion such as, systematic disease effecting walking activity such as COPD, so we can reduce the chance of individuals being at risk while performing an outdoor walk at the timeline post THR. Furthermore, all included participants who were at least 3 months post-operation and could confirm they are discharged from their surgical care. Additionally, studies suggest that regardless of surgical approach or technique, at 3 months post-THR surgery, patients are ready to return to their normal activity (Jones et al. 2005b). Importantly, in the absence of COMET guidelines on relevant outcome measure for evaluating individuals after THR surgery, we selected various outcome measures informed by previous publication and national reporting. A future patient and public involvement study is planned to include THR population in submission of an outcome measure best suited to assessment of THR population undergoing digital health related interventions. Lastly, there is limited evidence to support the accuracy and precision of the FC4 for monitoring individuals post THR. However, the intervention was designed based on individual walking amount in the first week and then a subsequent target was calculated

for the individual wearing the same FC4 activity monitor. This approach was undertaken to limit the risk of the FC4 inaccuracy effecting the outcome of individuals daily walking amount.

7.6 Chapter summary and conclusion

The objective of this small feasibility trial was to test the feasibility of the study methods and intervention delivery as well as the adherence to the personalised outdoor purposeful walking intervention in preparation for future trials. Although the PROMS selected were all relevant to this cohort, future research will only include the HOOS questionnaire, as it provides the most comprehensive and relevant set of subjective outcomes. Gait analysis was well received by all participants and the gait parameters selected provided great insight into the effects of the intervention on walking recovery post-THR surgery. Furthermore, the purposeful walking intervention was acceptable to all participants and should be considered without being amended in any future efficacy trials. Lastly, it is important to note that there was a wide spread of distance that was achieved by individuals and therefore a future trial with a similar sample size and variability in data should consider statistical analysis based on individual changes, in order to estimate an effect size for a clinical trial. In the following chapter, the final study designed as a randomised pilot trial is outlined.

"Walking outdoor is a bit like life: The journey only requires you to put one foot in front of the other...again and again and again. And if you allow yourself the opportunity to be present throughout the entirety of the trek, you will witness beauty every step of the way, not just at the summit."

Rosalia de Castro

Chapter 8 – Can a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor Improve Individuals' daily activity and function Post Total Hip Replacement Surgery: A Randomised Pilot Trial

8.1 Chapter overview

Chapter 8 of this thesis describes the final study, where a purposeful walking intervention designed to increase daily activity and improve function in the THR population was tested, as an accumulation of this research to date. This study was the first randomised trial to report the effect of the outdoor purposeful walk, monitored using a commercial activity monitor. The aim of this study was to determine the effect of an intervention where walking distance was used as a goal to increase daily walking activity using a commercially available activity monitor in people 3-6 months after THR surgery. It was our aim to compare this intervention group against a control group who reported their daily steps as opposed to a daily distance outdoor walk. This chapter is prepared in accordance with CONSORT guidelines for reporting randomized pilot studies (Eldridge et al. 2016b) and the paper is currently under review in the Journal of Aging and Physical Activity.

To date, this research has drawn the following conclusions:

- 1. The incidence of THR surgeries is increasing (National Joint Registry 2022), and many patients do not return to their pre-surgery level of daily activity or function in the weeks or years after their surgery (Smith et al. 2018; (Tang et al. 2021).
- 2. A PPI report (Bahadori et al. 2020c) including both groups of THR patients (before and after surgery) concluded that in the absence of pain following surgery, walking freely

- i.e. long outdoor walks without pain is the main reason that people undergo THR surgery.
- 3. The HCPs (THR surgeons and orthopaedic physiotherapists) agreed that walking is an ideal and very effective form of exercise post-THR surgery and the activity monitors are very effective in self-management and ensuring compliance with home exercises (Bahadori et al. 2020c).
- 4. There are currently no recommendations for the optimal amount of walking that should be recommended after THR surgery and THR population adherence to their rehabilitation programme is low as they often do not meet the individual's recovery goals (Wainwright and Burgess 2018). Individuals also feel socially isolated following their surgery and are often reluctant to participate in outdoor activities following their surgery (Bandholm et al. 2018). Therefore, innovations are required to address the deficit currently seen in the daily activity level post-THR surgery.
- 5. Walking speed and step length remain statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence is improved at the 6 weeks stage. This can be explained by the fact that during the recovery, as patients start to take more steps per minute, the shorter those steps become in order to maintain the walking speed (Chapter 5).
- 6. The commercially available activity monitoring wearables have the potential to engage individuals as advocates in their personalised care, as well as offer health care providers objective assessments of their patients' daily activity patterns. However, the current evidence in this area is limited, and where utilised, the parameter to enhance daily activity was step count (Bahadori et al. 2020a).

- 7. The benefits of distance-based walking in contrast to time or step count have already shown benefits in reducing cardiovascular disease (Morris et al. 2017), improving stride length in older adults (Troosters et al. 1999; Camarri et al. 2006) as well as increasing walking efficiency pre and post-THR surgery (Brown et al. 1980) but to date, it has not been tested in THR surgical pathway and recovery plan.
- 8. Commercial activity monitors are capable of measuring distance both indoor and outdoor using ALG and GPS functionality. A systematic search found that the top three most suitable smartphone apps are Pacer, Accupedo, and StepsApp with the highest scores in both MARS and also guidelines assessment. Furthermore, out of the brands currently available, the most often used in research projects is the Fitbit brand. The FC4 was selected as the most suitable Fitbit (Chapter 6).
- 9. In a series of single-participant studies, out of the selected activity monitors, the best precision and accuracy were observed by the FC4. The FC4 accuracy (high mean difference) at slow speed is questionable in short-distance and long-distance walks in GPS and ALG. Yet they show precision (low SD) and utilisation of such devices should be used to inform a programme where personalised data is used for creating an intervention (Chapter 6).
- 10. A feasibility study found that an outdoor walk intervention (purposeful walk) using an FC4 activity monitor is an acceptable method to address the lack of daily activity and function. An evaluation of the most suitable set of outcome measures for assessing this population for such intervention also suggested that HOOS is the best form or PROMS, and gait analysis was well received as a quantitative method for measuring the walking parameters.

Title

Can a Purposeful Walk Intervention with a Distance Goal using a Commercially Available

Activity Monitor Improve Individuals' daily activity and function Post Total Hip Replacement

Surgery: A Randomised Pilot Trial

Authors

Shayan Bahadori, Jonathan Mark Williams, Sarah Collard, Ian Swain

Abstract

Individuals have increasingly high expectations of return to activity following THR. The current

literature demonstrates marked improvements in pain following THR. However, there is

limited evidence showing objective improvement in daily activity. This randomised pilot trial

aimed to determine the effect of an intervention where outdoor walking distance is used as

a goal to increase daily activity of older adults using a commercial activity monitor at 3 to 6

months post THR. Findings suggested that the participants in the intervention group had

higher activity levels after THR, compared to those in the control group. The Cohen's effect

sizes were larger for the changes in the gait, HOOS, and PIADS data in the intervention group

in contrast to the control group. However, further research with a larger sample size is

required to provide tangible evidence on the significance of the effect of the purposeful walk

compared to step count.

Keywords: Total hip replacement; Activity monitor; Walking activity; Gait analysis.

192

8.2 Introduction

THR is one of the most common and successful orthopaedic operations worldwide (Ferguson et al. 2018; National Joint Registry 2022) that offers pain relief even at week one post-surgery (Learmonth et al. 2007; Ewen et al. 2012; Culliford et al. 2015). However, a recent report (Bahadori et al. 2020c) suggested that the aim should not only be to improve pain, but also lead to improving physical activity. This activity should preferably meet the recommended daily activity levels (at least 150–300 min of moderate-intensity physical activity per week) by the World Health Organization (WHO) (Harding et al. 2014).

Despite the recommendations and evidence showing the benefit of physical activity, previous research has reported that most individuals undergoing THR are not physically active enough after their surgery (Beaulieu et al. 2010). Recent studies (de Groot et al. 2008; Crizer et al. 2017; Holl et al. 2018; Tang et al. 2021) monitored the recovery of individual post-THR surgery and they found that the number of steps decreases and does not reach the same level as before surgery even at 24 months post-surgery period.

Activity monitors have been extensively used as an incentive to encourage people in the wider population to become more active through walking (Bunn et al. 2018). For example, Simonsick et al. (2005) and Geurts et al. (2019), carried out large longitudinal studies in a group of female older adults and individual with Multiple Sclerosis (MS) respectively, and found that the activity monitor increases walking distance amongst their cohorts. These studies utilised different types of activity monitors, but the major incentive for such enhancement were the targets that were set for the individual throughout the study. However, when it comes to the THR cohort, the evidence of distance-based interventions is limited, in particular when it comes to outdoor walking (Toogood et al. 2016; Van der Walt et al. 2018; Bahadori et al.

2019a; Babaei et al. 2022). The focus of current studies has been merely on monitoring or enhancing the amount of walking using the step count parameter. This is a shortcoming because a recognised technical problem with the activity monitors is their diminishing accuracy in step counting associated with decreased walking speed (Ehrler et al. 2016) which is often a gait characteristic associated with people after THR operation. Additionally, there is currently a lack of attention for personalised plans in the post operative period which is against the desire of individuals undergoing THR surgery (Robinson et al. 2021). Further evidence also suggest that individuals undergoing THR surgery are interested and receptive of wearable technologies and in particular enjoy the outdoor elements where sensors such as GPS technology are used to track their daily outdoor activities (Bahadori et al. 2019a; Bahadori et al. 2020c; Robinson et al. 2021; Babaei et al. 2022; Kurtz et al. 2022).

This study aims to determine the effect of an intervention where an outdoor walking distance is used as a goal to increase daily walking activity, using a commercially available activity monitor, in people after THR 3 to 6 months post THR surgery. Throughout this protocol, we will refer to the outdoor walk that is recorded with a GPS sensor as a 'purposeful walk'.

8.3 Methods

8.3.1 Trial design

This was an investigator-initiated, single-center randomised pilot trial with full ethical approval granted by the Bournemouth University Research Ethics Committee (ref: 45499) (Appendix 9) and prepared in accordance with CONSORT guidelines for reporting randomised pilot studies (Eldridge et al. 2016b). A CONSORT checklist of information is included in the appendices (Appendix 10).

8.3.2 Participants

Table 24 provides full eligibility criteria for the participants in the study. Participants were all recruited through publicising tools such as Twitter posts, and posters shared on the University channels (Bournemouth University research blogs, the Public Involvement in Education and Research (PIER) group, University of Third Age, and communities of older adults (e.g. local indoor bowling clubs). Those interested in the study contacted the lead researcher, were provided with an information sheet and to comply with Good Clinical Practice (GCP) guidelines (GCP 2005), were given 48 hours to consider participating.

8.3.3 Setting

The study was carried out at the Orthopaedic Research Institute at Bournemouth University. Following informed consent, participants were assigned to either the intervention or the control group. Details on randomisation process is explained in section 8.3.9.

Inclusion Criteria

- Male and female, aged 60 years and over;
- 3 to 6 months post unilateral total hip replacement surgery for osteoarthritis;
- Can provide verbal confirmation that they have been discharged from their surgical care;
- Capable of independent walking;
- Capable of completing the activity diary independently;
- Have access to a smartphone or computer;
- Willing to complete the trial protocol.

Exclusion Criteria

- Unable to provide informed consent;
- Unable to complete follow-up (insufficient English, lives overseas, unable to return easily);
- Not physically able to use Grail gait lab;
- Systematic disease affecting walking ability (chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), chronic kidney disease (CKD), Parkinson's Disease, cerebral palsy, multiple sclerosis etc.);
- Requiring revision hip replacement;
- Previous hip replacement (resurfacing or THR) on the contralateral side;
- Known metastatic tumour involving the hip.

8.3.4 Intervention group

The purposeful walking intervention group in this study was monitored using the FC4 activity monitor. Participants wore the FC4 activity monitor for 5 weeks in total. In the first week, participants wore their FC4 activity monitor in order to understand the participant's post-surgical purposeful walking distances. In week two, a target distance was calculated to increase the weekly walking distance by 10% and was divided by seven to calculate a daily distance for that week. In the weeks thereafter, if participants achieved their target, a new purposeful distance target was calculated to increase the participant's walking distance by a factor of 10% from the previous target. If the participant did not meet their target, the daily distance goal they were assigned the previous week remained in place. Participants were contacted through the FC4 Fitbit app on a weekly basis throughout the study and were given their daily goals for the upcoming week. The FC4 activity monitor was worn on the wrist of the non-dominant hand continuously during the study period. Participants were shown how to charge and operate the FC4 activity monitor and were given a copy of a simple instruction manual to take with them.

8.3.5 Control group

Participants in the control group wore the FC4 activity monitor for 5 weeks in total but were not given any weekly distance target and were asked to report their daily number of steps. The benefits of distance-based walking, in contrast to step count, have already shown benefits in reducing cardiovascular disease (Morris et al. 2017), but to our knowledge, this is the first study to examine the efficacy of outdoor distance-based walking in a group of THR patients. Furthermore, it cannot be guaranteed that the control group will walk outside

without any purposeful targets and therefore relying on GPS sensor data for indoor data is not possible. The daily steps were measured using the FC4 built-in accelerometer sensor (i.e. GPS sensor is not used). They were advised with a set paragraph. "During the next 5 weeks, walk as much as you feel able. Any amount of walking is better than none. But please listen to your body and walk to a distance and pace level that you feel comfortable." This paragraph was adopted in line with National Health Service (NHS) advice for promoting walking among adults (Service 2022).

8.3.6 Outcomes

In the absence of any direct guidance associated with the choice of key outcome measures on The COMET database (Core Outcome Measures in Effectiveness Trials; www.comet-initiative.org), the outcome measures selected here were streamlined from an earlier feasibility study conducted for such an intervention. During the baseline assessment, data were collected on gait, and hip-related disability using the Hip Disability and Osteoarthritis Outcome Score (HOOS) questionnaire (Nilsdotter et al. 2003). The final assessment was carried out 5 weeks after the baseline appointment and in addition to repetition of the baseline outcome measures, participants were also asked to complete the Psychosocial Impact of Assistive Devices Scale (PIADS) questionnaire (Jutai et al. 2002). Participants were also asked to keep a diary of their daily walking activities and the perceived intensity of their walk.

8.3.6.1 Primary outcome measure

8.3.6.1.1 Walking activity

The walking activity was measured via the difference in the amount of daily walking pre- to post-intervention as reported by the FC4 activity monitor. In the intervention group, this difference is assessed in terms of the amount of purposeful walking distance in kilometers, whereas in the control group the difference is based on daily step counts measured using the FC4 built-in accelerometer sensor. This data was downloaded by the lead researcher at the end of each week using the Fitbit app which was connected to the study's Fitbit account.

8.3.6.2 Secondary outcome measure

8.3.6.2.1 Gait analysis

The Gait Real-time Analysis Interactive Laboratory (GRAIL, Motekforce Link, Amsterdam, the Netherlands) system was used to carry out the gait analysis. GRAIL combined a fully instrumented treadmill with a self-paced option, as described by Sloot et al. (2014). The treadmill was feedback-controlled, which allowed participants to walk at their preferred speed. The gait analysis was carried out as per the protocol published on gait analysis using the GRAIL system (Bahadori and Wainwright 2020a). However, only Spatio-temporal data (walking speed, cadence, and step length) were recorded for analysis.

8.3.6.2.2 Patient reported outcome measures (PROMS)

8.3.6.2.2.1 Hip-related disability

Hip-related disability was assessed using the Hip Disability and Osteoarthritis Outcome Score (HOOS) questionnaire (Nilsdotter et al. 2003). The tool was validated in a sample of

participants after THR surgery (Goodman et al. 2020) and intended to be used to assess the individual's opinion about their hip and associated problems, and to evaluate symptoms and functional limitations related to the hip during their recovery process. To provide meaningful information to support the clinical effect of the five-week programme on individuals, the minimal clinical important difference (MCID) for the HOOS was considered to be 24 (Soh et al. 2022).

8.3.6.2.2.2 Psychosocial Impact of Assistive Devices Scale

The Psychosocial Impact of Assistive Devices Scale (PIADS) (Appendix 11) was utilised to measure the effectiveness of the assistive device, in this case, the FC4 (e.g., all categories of assistive technology and not limited to any one type) on quality of life and sense of well-being (Jutai et al. 2002; Harada et al. 2014). This self-administered questionnaire is a valid and reliable tool in adults undergoing hip replacement surgery (Tofani et al. 2019) and consists of 26 items, including 3 subscales (competence, adaptability, and self-esteem) (Jutai et al. 2002). Scores ranged from –3 (maximum negative impact) through zero (no perceived impact) to +3 (maximum positive impact).

8.3.7 Qualitative outcomes

8.3.7.1 Activity Diary

Participants were provided with an activity diary to record their daily walking activity. They were asked to record the distance walked in kilometres (km) (Appendix 12) or the number of steps taken (Appendix 13), depending on the group they were randomised to. The activity diaries for both the intervention and control groups had a section where participants were able to document their feelings or reasons which may have affected their attempts to do their daily walk. For the content of the activity diary, we used content analysis (Graneheim and Lundman 2004). The content of the activity diary was read line by line and coded by the lead researcher (SB), whereby meaning components were categorised. The content was further coded to interpret the meaning within their topic. These topics can be understood as the latent content of the text (Graneheim and Lundman 2004). The purpose of this analysis was to explore the reasons why an individual was unable to perform their daily walk. However, the different topics were scrutinised for content that encompassed a reason beyond condition or feelings. Two topics (i.e. back to work and hobbies) were eligible for content analysis as the barriers to do a daily walk. Where appropriate, evidence from the activity diary was reported as a quotation to support the quantitative outcome measures.

The activity diary also included a quantitative section in which the participants were asked to rate the intensity of their daily walks using the Borg scale (Oosting et al. 2012).

8.3.8 Sample Size

Twelve participants were chosen to take part in this pilot study. Six were randomised to the intervention group and 6 were randomised to the control group. Given this was a pilot trial, a

convenience sample size was selected, and a formal sample size calculation was not carried out.

8.3.9 Randomisation

The study used simple randomisation. Each group in the study had 6 participants randomised to either the intervention or the control group, with a 1:1 allocation ratio. Randomisation was done using a Sealed Envelope web-based system (reference number: 237466787579592) (https://www.sealedenvelope.com). The lead researcher undertook the randomisation process and then informed participants of their group during the baseline visit.

8.3.10 Statistical analysis

All data were analysed using Microsoft Excel Version 2018 (Microsoft Corporation, 2022, Retrieved from https://office.microsoft.com/excel). As this was a pilot study all quantitative data (gait, and PROMS) were presented descriptively, using appropriate summary statistics. Given the differences in measurement units for the amount of walking completed by the intervention group (i.e., km), and the control groups (i.e., steps), data were percentage normalised to the baseline walking levels. Due to the small sample size in each group, no statistical testing was completed. Within group and between group Cohen's d effect sizes (Cohen 2013) were calculated for all variables having converted walking amount into percentage improvement. A sample size calculation to inform future studies was carried out using G*Power software (version 3.1.9.2).

8.4 Results

8.4.1 Recruitment

The participants' flow diagram (Figure 19) outlines the number of participants who contacted the lead researcher over a period of approximately 8 weeks, were assessed for eligibility, went through the randomisation process, and were assessed.

8.4.2 Participant demographics

Twelve adults were recruited to take part in this study. Tables 24 and 25 summarise the participant's demographic information for the intervention and the control group respectively. The trial was completed by all participants and there were no missing data. On average, the data on age, BMI, and months post-operation were similar for both the intervention and the control group.

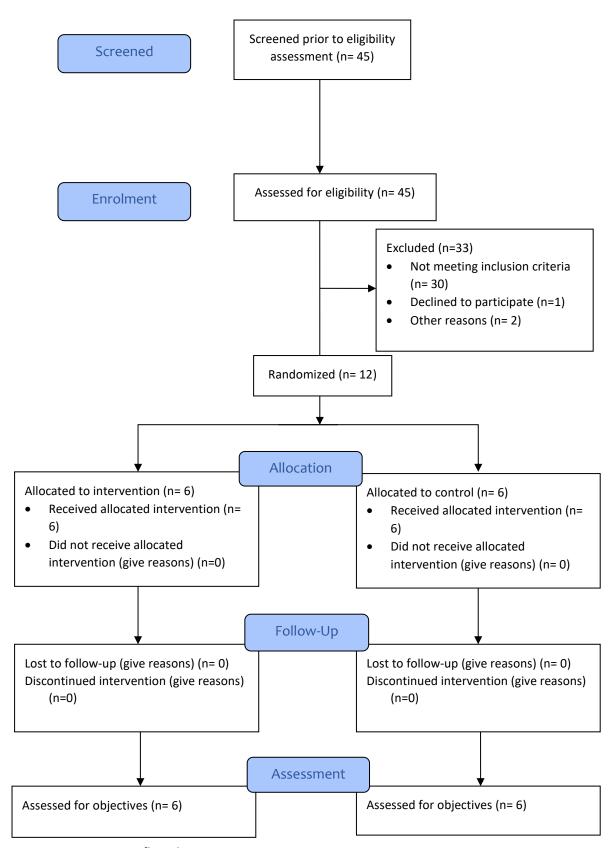


Figure 19. Participant flow diagram.

Table 25. Participants' demographics information in the intervention group.

			Intervention Group)		
	Months Post			Weight		
ID	Ор	Age	Height (cm)	(kg)	BMI (kg/m²)	Gender
101	3	64.00	171.10	88.40	30.20	Female
102	5	77.00	165.30	82.60	30.23	Male
103	5	70.00	178.00	115.60	36.49	Male
104	5	66.00	182.30	101.40	30.51	Male
105	3	60.00	182.00	108.90	32.88	Male
106	4	73.00	161.20	85.10	32.75	Female
Mean	4.17	68.33	173.32	97.00	32.17	
SD	0.98	6.22	8.88	13.64	2.44	

Table 26. Participants' demographics information in the control group.

Control Group						
	Months Post					_
ID	Ор	Age	Height (cm)	Weight (kg)	BMI (kg/m²)	Gender
C01	5	76.00	173.50	79.60	26.44	Male
C02	5	77.00	174.00	116.40	38.45	Male
C03	4	72.00	172.50	100.40	33.74	Male
C04	4	75.00	169.00	65.60	22.97	Female
C05	4	60.00	166.50	100.60	36.29	Female
C06	6	66.00	180.00	102.40	31.60	Male
Mean	4.67	71.00	172.58	94.17	31.58	
SD	0.82	6.69	4.64	18.28	5.91	

8.4.3 Activity Monitor

Figures 20 and 21, outline individuals' weekly total purposeful walk and step count for the intervention and the control group respectively. Participants IO4, IO5, and IO6 achieved all of their weekly targets. Participants IO2 and IO3 managed to achieve five out of six targets. Participant IO1 achieved three out of six weeks of their targets. All participants increased their baseline (week 1) purposeful walking distance amount with participant IO1 having the lowest percentage (66.3%) and participant IO4 having the highest percentage increase (183.8%).

In the control group C01 and C03 increased their baseline (week 1) weekly steps by 25.9% and 22.1% respectively by the end of week five, however, all other participants did not achieve more steps in the weeks after the baseline week.

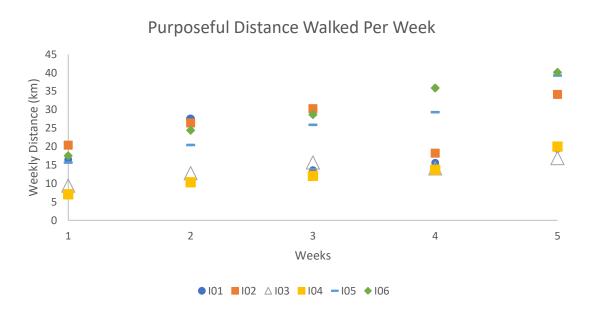


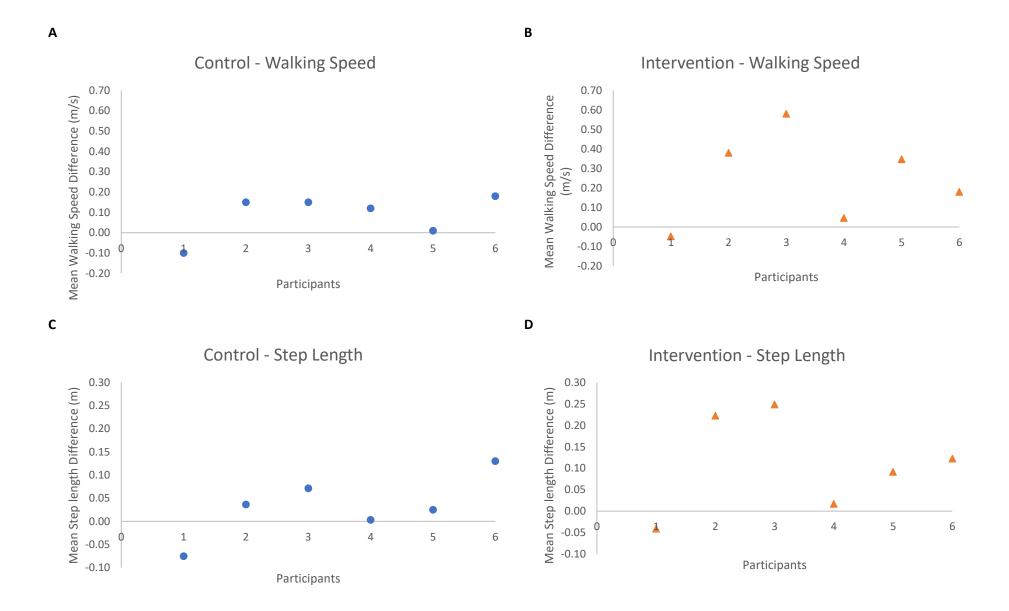
Figure 20. The total amount of purposeful distance walked by each participant per week.



Figure 21. The total amount of steps taken by each participant per week.

8.4.4 Gait analysis

Figure 22 outline individuals' mean difference from pre to post intervention for the walking speed, step length of the operated side, and cadence of the intervention and the control group. Except for participant IO1, and cadence data on participant IO2, the walking speed, step length, and cadence increased across all other participants in the intervention group.



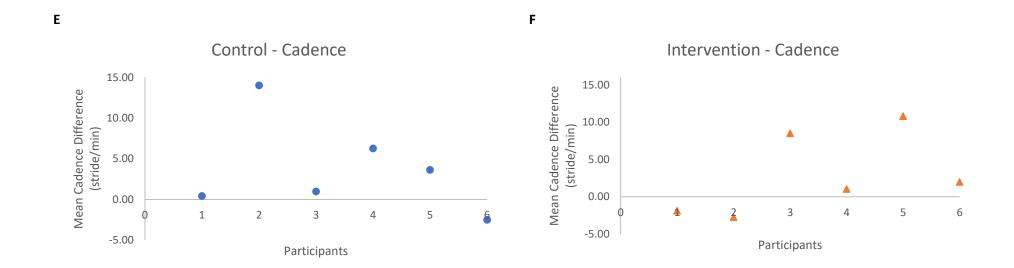


Figure 22. Mean difference in gait data for each participant in the intervention and the control group. A) Mean difference in walking speed for each participant in the control group. B) Mean difference in walking speed for each participant in the intervention group. C) Mean difference in the step length of the operated side for each participant in the control group. D) Mean difference in the step length of the operated side for each participant in the intervention group. E) Mean difference in the cadence for each participant in the intervention group.

8.4.5 Hip Disability and Osteoarthritis Outcome Score (HOOS)

Figure 23 shows the data related to HOOS subjective mean score difference from pre to post intervention for the intervention and the control group. The MCID for pre to post-intervention was not seen in the HOOS score in any of the participants in the control group. However, a change beyond the MCID was seen in the HOOS outcomes, 41.2 and 31.2, for participants IO3 and IO4 respectively.

8.4.6 Effect Sizes

Table 27 shows the Cohen's effect size (*d*) for the normalised walking amount, gait, and HOOS data.

Table 27. Within group and between group mean difference (pre to post intervention) (M_D), standard deviation (SD), and the Cohen's effect size (d).

		Intervention			Control		Between group
	M_{D}	SD	d	M_{D}	SD	d	d
Walking	104.68	60.98	1.72	-9.80	25.08	-0.39	1.27
Step length (m)	0.11	0.11	0.98	0.03	0.07	0.47	0.87
Walking speed (m/s)	0.25	0.23	1.06	0.09	0.11	0.79	0.89
Cadence (stride/min)	2.96	5.53	0.54	3.80	5.83	0.65	-0.15
HOOS	17.68	15.12	1.17	5.12	3.81	1.34	1.14

8.4.7 The Psychosocial Impact of Assistive Devices Scale (PIADS)

Tables 28 and 29 shows the PIADS scores for the intervention and control groups respectively. The PIADS subscale for competence, and self-esteem, were better in the intervention group by more than 50%, in contrast to the control group. The adaptability score was 39% more positive for the intervention group in contrast to the control group.

Table 28. The PIADS scores for the intervention group.

	Intervention				
ID	Competence	Adaptability	Self-Esteem		
101	1.75	1.83	0.88		
102	2.55	3.00	2.50		
103	2.17	2.33	1.25		
104	1.45	2.17	1.38		
105	1.8	2.67	1.88		
106	2.64	3.00	2.13		
Mean	2.07	2.50	1.67		
SD	0.47	0.47	0.60		

Table 29. The PIADS scores for the control group.

		Control				
ID	Competence	Adaptability	Self-Esteem			
C01	0.33	0.83	0.63			
C02	0.17	0.17	0.00			
C03	1.18	2.00	0.75			
C04	1.67	2.00	1.38			
C05	1.55	3.00	1.00			
C06	1.08	1.17	0.88			
Mean	1.00	1.53	0.77			
SD	0.62	1.01	0.46			

8.4.8 Ancillary analyses of sample size

A sample size calculation was carried out for walking distance based on the effect size of 1.27 from this pilot study, with alpha at 0.05 and power at 90%, a sample size of 24 is required.

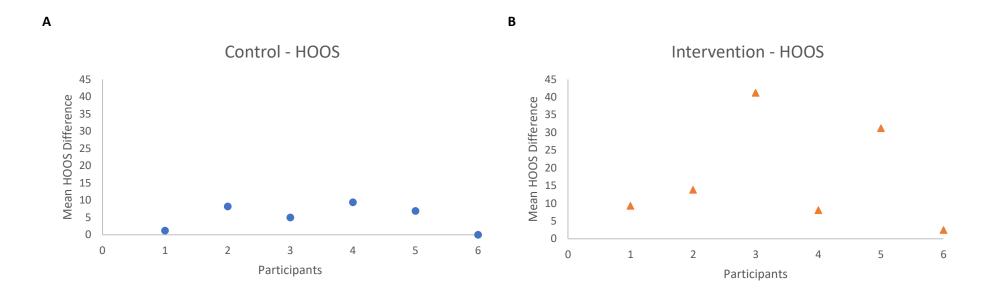


Figure 23. Hip Disability and Osteoarthritis Outcome Score (HOOS) data for each participant in the intervention and the control group. A) Mean difference in HOOS for each participant in the intervention group.

8.4.9 Activity diary

The walking intensity of participants in either the intervention or the control group, reported through Borg scale, did not exceed the moderate activity level for the duration of the five weeks. The main theme derived through analysis of the activity diary for the intervention group was the 'enjoyment' of walking outdoors and 'exceeding expectations' (i.e. going beyond the level they felt capable of). Other factors beyond the condition or feelings were outlined by individual participants and were explored further. For example, IO1 returned to work from week 3 onwards doing a daily 8 hours shift in a supermarket. Furthermore, she suffered from left knee pain:

"Started back at work today after 14 weeks off, 7297 steps at work, couldn't manage a long dog walk, hip felt like it had done enough and left knee hurting".

Similarly, participant IO2, was a keen fisherman and on week four he returned to his usual long fishing sessions. He camped by a river for the entire week and some of the fishing sessions were a full-day's activity:

"Went back fishing, not much walking today. Hip joint gets stiff when sitting for a long length of time. Got up walking about for a few minutes and it got easier."

The main themes found in the control group's responses were 'bad weather', 'felt down', 'not a good day', 'busy', and 'did my physio only today'. Exploring topics beyond the condition or feelings, showed 'gardening' as a main theme amongst the control group as it was repeated 13 times on different occasions. Participant CO1 did not report any condition or feeling that may have affected his walk.

8.5 Discussion

This study was the first randomised trial to report the effect of the outdoor purposeful walk, monitored using a commercial activity monitor. The aim of this study was to determine the effect of an intervention where walking distance was used as a goal to increase daily walking activity using a commercially available activity monitor in people 3-6 months after THR surgery. It was our aim to compare this intervention group against a control group who reported their daily steps as opposed to a daily distance outdoor walk. No target on increasing step count was set. Our findings suggest that the purposeful walking intervention was successful in increasing daily walking activity and function in contrast to the control group.

Although commercial activity monitors in interventions to promote physical activity in the form of walking is a relatively new phenomenon, there has been a rapid increase in their popularity and use in research during the last decade (Shin et al. 2019; Babaei et al. 2022). However, when it comes to THR studies (Toogood et al. 2016; Van der Walt et al. 2018), the focus for monitoring or enhancing the amount of walking has been merely on the step count parameter. Despite some benefit in enhancing daily activity (Van der Walt et al. 2018), the evidence shows that the counting step isn't a stimulus for enhancing long-term functional and gait recovery in THR patients' rehabilitation (Lebleu et al. 2021). Additionally, reports have outlined the importance of individualised support and how an individual would appreciate a continuous personalised goal (Bahadori et al. 2020c; Östlind et al. 2022). This is perhaps why the results from the control group in this study showed that despite full adherence to using the FC4, the number of steps decreased during the intervention. This is in line with findings from Ostlind et al., 2021

(Östlind et al. 2021), where despite achieving up to 7000 daily steps initially, over a period of 12 weeks, the number of steps taken by individuals with hip osteoarthritis decreased slightly, but gradually over time, in the absence of a personalised daily goal. Therefore, it can be suggested that an activity monitor may aid in the optimisation of daily walking, but it is not a panacea and other factors such as goal setting could play a crucial role in enhancing daily walking activity. Goal setting could also provide a motivation (Wade 2009) as there was evidence of low-level mood amongst the control group and repetition of themes such as "lazy day" and "felt down" was seen in four out of six participants in this group.

Age, BMI and post-surgical period have previously been suggested as the factors associated with the level of activity post-THR surgery (Kinkel et al. 2009; Toogood et al. 2016). Fortunately, the average age, BMI and months post operation for the intervention and control groups were similar in this study. However, given there are currently no comparable data available on the average outdoor walking distance for individuals post THR surgery, we compared our control group data to the Tang et al. (2021) study that had participants with similar age and BMI, (that is 61.6±10.2, BMI 25.5±5.9). This study reported that at 3 months post operation, the THR participants did an average daily step of 4526±2721. Another study reported a similar number of steps, 4632± 2246, in a group of 61 year old Japanese females 6 months post THR surgery (Fujita et al. 1997). Participants in this study exceeded these numbers and suggested that except for participant CO2 (2811 steps per day), participants in the control group took 7090±2739 steps per day during the five weeks of the study. However, this number of steps is comparable with the data from the healthy population of the Tang et al. (2021) with a similar age group. Our findings, in congruence with the literature, suggest that individuals may expect to return to the level of activity similar to the healthy matched aged group following THR as early as 3 months and may improve in the later postoperative periods (for example, 5 months and onward).

The gait parameters showed improvement for both the control and intervention groups. This is to be expected as participants gradually recover from their surgery regardless of their individualised rehabilitation programmes. However, despite the lack of statistical analysis, on average, the mean walking speed improved by 0.09±0.1 m/s in the control group in contrast to 0.25±0.2m/s in the intervention group. Furthermore, the step length of the operated leg was improved by 0.03±0.06m in the control group in contrast to 0.11±0.1m in the intervention group. Furthermore, as suggested by Cohen (2013), effect sizes may be categorised as small (0.2), medium (0.5), and large (0.8). Except for the cadence, the effect size for all quantitative outcome measures were large. Given the effect size provides insight into the magnitude of the difference between groups, the large effect size observed here may act as an indicator that the findings from this study have practical significance. Therefore, it may be suggested that a purposeful walking intervention could be a more effective stimulus than step count in improving selected gait spatiotemporal parameters post-THR surgery. However, further studies with larger sample sizes and longer follow-up are needed to assess the evidence on the significance of the effect of the purposeful walk in contrast to step count.

Participants' characteristics, hobbies, psychological feelings, and comorbidities influenced the level of activities in either group. Recognising pain and discomfort elsewhere (e.g. knee) and extended factors such as returning to work at 3 months post-surgery reduced the amount of outdoor walking which was carried out by

participant IO1. The diary information suggested that on average participant IO1 was doing over 7000 steps per day during her indoor working hours. However, she couldn't continue with the progress she made during the first 3 weeks and was unable to achieve her daily outdoor purposeful walks. It could possibly be suggested, that as participant IO1 was the only participant who did not improve in any of her gait parameters, the lack of outdoor walks may have had an influence.

The average difference in HOOS outcome measures in the intervention group was 23.8±14.9 (excluding two participants, IO4 and IO6, who score more than 90 in their baseline assessment) in contrast to the average difference of 6.14±3.2 (excluding one participant, CO6, who also scored more than 90 at the baseline) suggests that intervention had a bigger impact on the subjective self-perceived outcome measure.

Studies have reported that an ability to walk even a short distance outdoors can be meaningful for successful and independent living at home among the THR group as well as enhancing their physical function (Simonsick et al. 2005; Salpakoski et al. 2014). There was evidence of a greater psychological effect on participants within the intervention group with all subscales of PIADS showing greater improvement in contrast to subjective answers from the control group. Participants mainly saw the benefit of the FC4 and its GPS functionality upon seeing the maps of the routes they have walked. Meanwhile the outdoor walk provided a platform for further interactions, whether that was with their pets, friends, family, or even members of the public during their daily walks. This is significant, as current evidence suggests that majority of THR patients feel socially isolated even at 12 months post their surgery (Bandholm et al. 2018).

The limitations in this study are mainly inherent to the study methodology. There was no formal power calculation and therefore the sample size in each group was too small for other than minimal statistical analysis. However, we strengthened our methodology by adopting the randomisation process for assigning the study participants to each group. The study had an additional significant limitation regarding the comparison of metrics used to measure daily activity. The intervention group's daily activity was assessed based on walking distance, while the control group's activity was measured by step count. This discrepancy in measurement methods raises concerns about the fairness of directly comparing the two groups. To establish a more robust basis for evaluating the impact of FC4 on daily activity, it would be advantageous to include both walking distance and step count metrics for both groups in future studies. This approach would offer more substantial evidence for comparing the effects of FC4 on daily activity. Moreover, the participants recruited in our study had their THR completed by different surgeons using different techniques and surgical approaches, which may influence their early post-operative recovery time (Aggarwal et al. 2020). To address this limitation, we included participants who were at least 3 months post-operation and could confirm they are discharged from their surgical care. Additionally, studies suggest that regardless of surgical approach or technique, at 3 months post-THR surgery, patients are ready to return to their normal activity (Jones et al. 2005b).

Unfortunately, studies have suggested that despite precision, the FC4 is not accurate in slow-walking participants (Fokkema et al. 2017; Bahadori 2021a). Therefore, when it came to our analysis of mean changes, the effect size, and also sample size calculation, the data should be approached with caution. The effect size was large and therefore

sample size calculation may be underpowered with only 24 samples per group. Additionally, there was a wide spread of data across both the control and intervention group for daily walking activity. Thus, we reported individual data as well as an average across all outcome measures to provide more comprehensive access to the outcomes. Finally, a follow-up period of five weeks may be too short to assess any significant changes in our study outcomes, as other studies have shown improvement in physical activity with a longer follow-up time (de Groot et al. 2008; Brandes et al. 2011).

8.6 Chapter summary and conclusion

In a randomised controlled trial, participants who received the purposeful intervention using a commercial activity monitor with a daily outdoor distance goal had higher activity levels after THR, compared to participants who were in the control group and reported daily step counts. The data for gait, HOOS, and PIADS appeared to be better in the intervention group in contrast to the control group. However, further research with a larger sample size is required to provide tangible evidence on the significance of the effect of the purposeful walk in contrast to step count.

"The great enemy of knowledge is not error, but inertness. All that we want is discussion; and then we are sure to do well, no matter what our blunders may be. One error conflicts with another, each destroys its opponent, and truth is evolved."

Henry Thomas Buckle

Chapter 9 – Discussion

9.1 Chapter overview

This chapter provides a discussion of the accumulated research, including a synthesis of the results in relation to the thesis aim and objectives. The main and novel findings of this research are discussed in relation to the existing recovery pathways in THR surgery and unanswered questions are highlighted. In addition, this chapter discusses the collective strength and limitations of the research conducted, and how it can be progressed and improved in the future.

9.2 Research objectives

The aim of this study was to explore the application of commercial activity monitors to improve individuals' daily activity after THR surgery. To do this, the following objectives were formulated:

- To gain insight into the use of activity monitors in THR surgery and individuals' recovery goals
- 2. To evaluate the use of activity monitors and their functionality to provide objective recovery data
- 3. To assess the feasibility of commercial activity monitors on improving the daily physical activity and rehabilitation of individuals after THR surgery

9.3 Results summary

This research began by highlighting individuals' desire to be more active following THR surgery, the limitations of current practice and its lack of evidence to support the use of wearable activity monitors in THR surgical recovery pathway (Chapter 2). In Chapter 3,

the PPI approach was taken, and the finding emphasised the importance of walking to this population after their surgery. The findings prompt a need to better understand the possible factors halting individuals' desire to walk post-surgery. Thus, in Chapter 4, a secondary analysis of the spatio-temporal data, collected using a self-paced treadmill, which is believed to be the best method for resemblance of a free walking was carried out. Analysis showed that the walking speed and step length remain statistically significantly different from that of the healthy group with similar age at 3 months after surgery. In contrast, the cadence is improved at the 6 weeks stage. This was explained by the fact that despite gradual improvement from pre surgery to up to 6 months postsurgery, the walking speed and step length of the THR group remain statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence is improved and recovers, when compared to the control group, as early as the 6 weeks stage post-surgery.. Furthermore, as the patients rehabilitate, they will naturally gain a better range of movement which increases their capability and results in an improved cadence. Therefore, step count which has readily been reported (Crizer et al. 2017) as a parameter for enhancing recovery, may not be the best motivator to enhance their limitations in walking. Meanwhile, studies reported that an ability to walk even a short distance outdoors can be meaningful for successful and independent living at home among the THR group as well as enhancing their physical function. The accumulation of these findings offered an answer to objective 1 of this study and provided a platform to consider outdoor walking distance as a parameter for subsequent experimental research, that aimed to design and test an intervention of outdoor walk for enhancing individuals' daily activity and recovery using an activity monitor following THR surgery.

The first experimental study aimed to identify, and then evaluate the accuracy and precision of the most suitable commercial activity monitors for THR populations. With consideration that the most common demographics of the individual undergoing THR surgery is 60 years old and above, an exhaustive systematic screening based on MARS and guidelines for the elderly found three smartphone apps (Pacer, Accupedo and StepsApp) and a Fitbit Charge 4 (FC4) to be the most suitable activity monitors. Following these findings, a study was designed to evaluate the validity and reliability of the selected activity monitors in older adults. However, the Covid-19 pandemic struck, universities closed their campus, and all research studies were suspended expect for studies related to Covid-19. In the absence of an opportunity to conduct research with human participants, in particular older adults. Therefore, a decision was made to carry out a single-participant study with myself as a participant. Studies were designed in different environments, and conditions, to have an understanding of the accuracy and precision related to selected activity monitors. Data suggested that when it comes to the accuracy of activity monitors, the error might be exponential rather than linear as distance increases. At slow speed, the accuracy and precision of all activity monitors are questionable in indoor and outdoor settings. However, the FC4 was the most precise activity monitor with the lowest error estimation.

The second experimental study was the first step to providing an answer to the third objective of this study and involved examining the feasibility of an outdoor walk intervention using the FC4 in a mixed-methods study design. The objectives of this feasibility study included 1) Investigating the feasibility and acceptability of the personalised outdoor walking intervention with distance as a goal measured with GPS (purposeful walk) using FC4 activity monitor in individuals over the age of 60 years old,

between 3 months and 6 months post-THR surgery. 2) Exploring the barriers and facilitators to implementing the intervention. 3) Assessing the feasibility and acceptability of different outcome measures. The findings suggested that the purposeful walking intervention was accepted by all participants. Furthermore, the PROMS selected were all relevant to this cohort, but the HOOS questionnaire provided the most comprehensive and relevant set of subjective outcomes. Additionally, gait analysis was well received by all participants and provided the best insight into the effects of the intervention on selected gait parameters. Lastly, participants provided feedback which resulted in the amendment of the activity diary to make it simpler to use in any future study.

The aim of the final study was to determine the effect of the personalised purposeful walking intervention to increase daily walking activity using the FC4 activity monitor. This mixed methods, randomised pilot trial, compared the intervention against a control group who reported their daily steps as opposed to a daily distance outdoor walk. Findings suggested that the participants in the purposeful intervention group had higher activity levels after THR, compared to participants who were in the control group. The Cohen's effect size were larger for the changes in the data for gait, HOOS, and PIADS in the intervention group in contrast to the control group. However, to provide tangible evidence to support the achievement of the third objective, further research with a larger sample size is required.

9.4 Impact of findings

9.4.1 Purposeful walking

The main and novel finding of this research is that a personalised purposeful outdoor daily walk can encourage individuals to become more active while improving their gait, and quality of life by using a wearable activity monitor. This is important as the focus of current studies has been merely on monitoring or enhancing the amount of walking using the step count parameter despite the lack of a positive effect on the level of daily activity even 12 months post surgery (Bandholm et al. 2018).

Meanwhile, there is currently a lack of attention given to a personalised plan in the post-operative period (Wade 2009; Dekker et al. 2020). The findings of this study in the PPI discussions and the pilot study provide evidence to suggest that THR individuals greatly desire a personalised plan and are likely to over-achieve their target when they have a personalised goal in their rehabilitation process.

When it comes to the THR cohort, the evidence of distance-based interventions was limited, in particular when it comes to outdoor walking. This has been neglected despite there being positive evidence regarding the effect of outdoor walking in reducing cardiovascular disease (Morris et al. 2017) and improving gait in older adults (Troosters et al. 1999; Camarri et al. 2006). This study provided further evidence using objective data from the activity monitor and subjective data from the interviews, activity diaries, and the PIADS questionnaire to support the preference of an individual to participate in an outdoor walking routine of daily activity.

Overall, the biggest impact of this study is the introduction of a form of daily activity that is accessible, simple, and adaptable. This is significant as currently an optimal rehabilitation pathway post-THR has not been defined (Bandholm and Kehlet 2012) and an outdoor purposeful daily walk monitored using an activity monitor can help to facilitate and deliver support to finding an optimal programme.

9.4.2 Wearable activity monitor

Further evidence from our feasibility and pilot study suggests that individuals undergoing THR surgery are interested and receptive of wearable technologies and in particular enjoy the outdoor elements where sensors such as GPS technology are used to track their daily outdoor activities (Bahadori et al. 2019a; Bahadori et al. 2020c; Robinson et al. 2021; Babaei et al. 2022; Kurtz et al. 2022). This is significant in the overall well-being of individuals, as current evidence suggests that the majority of THR patients feel socially isolated even 12 months post their surgery (Bandholm et al. 2018).

A recognised technical problem with the activity monitors is their diminishing accuracy in step counting associated with decreased walking speed (Ehrler et al. 2016) which is often a gait characteristic associated with people after THR operation (Cichy et al. 2008). Although, this is a significant limitation, the studies carried out in Chapter 6, in particular the sample size, the findings and study designs were the first to provide insight into the accuracy and precision of activity monitors suitable for older adults at various walking speeds and different settings. Furthermore, findings provided an argument for use of commercial activity monitors in personalised plans, as precision error percentage were lower across all activity monitors in contrast to their accuracy percentage error. The FC4 activity monitor utilised in this study was very well received by all participants in the

feasibility and final studies with majority expressing their desire to purchase their own device following the effects it had on their life, particularly in the intervention group participants. Findings suggested that a wearable activity monitor could aid in optimisation of daily physical activity but that it is not a universal panacea. It does however, provide an opportunity for individuals to, 'help themselves', as they desired in the PPI discussion (Chapter 3).

Overall, the commercial wearable activity monitor facilitated daily activity and made it possible to set a realistic and achievable goal when it came to doing daily walking activity. Targeting and reaching the daily distance goal were experienced as a spur to walk more than usual. The participants described that they would park their car further away or take the dog out for an extra walk in the evening if they saw that they were some distance short of reaching the goal.

9.4.3 Adherence

Good compliance is an important part of a well-delivered rehabilitation intervention and is greatly influenced by participants' characteristics (Reychav et al. 2019). The outcome of any intervention is dependent upon whether its users comply with the given programme, and one of the significant challenges in THR rehabilitation is adherence to rehabilitation goals post-surgery (Martin et al. 2005). While, a simple daily exercise, such as walking, has the potential to transform how recovery is managed, successful implementation can only be achieved once widespread adoption has occurred. Furthermore, HCPs could be hesitant to offer such programme if they suspect a new regime cannot be implemented with suitable and acceptable technologies (Paramonczyk 2005). The findings from the PPI described in Chapter 3 provided

promising findings that THR individuals are keen to walk and are willing to use a wearable device to monitor their daily activity. Furthermore, all HCPs agreed that walking is a simple yet very effective mode of activity and that the use of an activity monitor could provide much needed objective information when it comes to making informed decisions related to the level of disability in THR populations. In addition, the screening and review carried out in Chapter 6 was the first of its kind to evaluate and analyse the most suitable activity monitor with an objective to further enhance the chance of adherence to the use of intervention and daily exercises in THR individuals.

Furthermore, in the feasibility study described in Chapter 7, all participants completed the study and adhered to the purposeful walk intervention using the FC4 activity monitor, with results suggesting a weekly increase of 10% to individuals' baseline walking distance is achievable, with all participants adherent to the use of FC4 and reporting a maximum purposeful walking distance of more than 40% from their baseline amount. Participants reported favourable responses when asked about their experience of the purposeful and use of the activity monitor and said they would consider purchasing one and continuing with daily purposeful walks. However, this study was conducted in a small group of older THR participants and over a duration of five weeks only, so to be able to provide a concrete answer to adherence a larger population and longer period could be important. Furthermore, the high adherence rate observed here may in part be related to the weekly correspondence with the researcher. Therefore, to replicate this level of adherence in clinical practice, it is possible that dedicated staff are required, thereby increasing therapy costs. Importantly, however, despite concerns over older adults' difficulty to use new technologies (Barnard et al. 2013), all of the participants were able to use the device independently at home, with no adverse events or device deficiencies reported. In many cases, participants reported using other features of the FC4 such as monitoring their sleeping quality. Studies have shown that less than 15% of older adults regularly participate in daily exercise (Merom et al. 2012), with barriers to participate including fear or risk of injury, fear of heart attack, low selfconfidence, and lack of knowledge or resources (Burton et al. 2017). Adherence may be even lower in older adults undergoing THR surgery due to fear of falling, pain, or biomechanical changes to their joints (Latham and Liu 2010). As discussed further in the Chapter 8 pilot study, the PIADS questionnaire suggested that the use of an activity monitor had a positive psychological impact on all participants, however, the effect was much superior when it was combined with purposeful intervention. The findings provide light into tackling the current issue surrounding 20% of individuals undergoing THR where they feel socially isolated following their surgery (Smith 2017). Furthermore, it indicates a potential advantage over resistance training where pain, lack of personalised programme, risk of injury, lack of knowledge, or logistic barriers may affect participation.

9.4.4 Gait

The literature reveals that the step length and a walking speed of those undergoing THR do not reach those of the general population, even at 12 months post-surgery (Beaulieu et al. 2010). These gait deficits have been suggested as a possible reason for more than 25% of these individuals not returning to their normal level of physical activity in which they participated pre-surgery (Harding et al. 2014). The gait analysis carried out in this study (Chapter 5) agreed with the current literature, but it provided a more associated insight into the overall objective of the study as it was carried out using an instrumented

self-paced treadmill, which is the closest methodology for mimicking a natural walk. The protocol for the gait analysis was also deemed feasible and acceptable by the THR population as explained in Chapter 7 and it provided an objective assessment of the effect of the intervention in Chapter 8. Despite the small sample size, the gait parameters showed improvement for both the control and intervention groups in the pilot study (Chapter 8). This was expected as participants recover from their surgery having a gradual improvement regardless of their individualised rehabilitation programmes. However, the magnitude of improvement was higher for the walking speed, step length, and cadence across all participants that completed the intervention compared to the control group. The large Cohen's effect size also indicated that a purposeful walking intervention could be a more effective stimulus than step count in improving selected gait spatiotemporal parameters post-THR surgery.

9.5 Recommendation for clinical application

The findings from this research suggest that it is feasible to apply a purposeful walking intervention, using a commercial activity monitor, targeted at improving daily activity and spatio-temporal gait parameters in the older THR population. These findings are promising for individuals following THR surgery, who feel their recovery is not in line with their personal ambitions of becoming more active, and generally getting their "normal life back." The intervention described in Chapters 7 and 8 may benefit an individual who wishes to "do more" and take control of their daily activity in order to achieve their level of walking activity prior to undergoing THR surgery. However, further research is required with a larger sample size to confirm this. The participants in the feasibility and the pilot trial were at least 3 months and at most 6 months post their

surgery, this period was selected as the time when individuals are released from their perspective surgical pathway care and in many cases will not be seeing their HCPs anymore and hence a decrease in their trajectory of recovery is observed (Withers et al. 2017b). Therefore, it is important to acknowledge that such intervention may not be ideal in the early recovery period when an individual may suffer from a lack of walking confidence, muscle atrophy, and falling. The idea of purposeful walk intervention using a commercial activity monitor is not suggested as a replacement for rehabilitation exercises post-THR, but as a complement to it. A 10% increase in weekly purposeful walks is deemed reasonable and provides a subtle motivator to increase daily activity and self-monitoring. Table 30 details the purposeful walking intervention using the commercial activity monitor investigated in this research, and includes potential indications for use, exclusion criteria, and practical consideration, and can be used to inform the clinical application of this intervention.

Table 30. Recommendations for clinical application of purposeful intervention using a commercial activity monitor.

	Clinical application of purposeful intervention using commercial activity monitor - Recommendations
Indications	After hip replacement Consider application to hip osteoarthritis individuals awaiting hip replacement Consider application to other orthopaedic populations (knee osteoarthritis, knee replacement, hip fracture). Consider application to older adults
Exclusions	Systematic disease affecting walking ability (chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), chronic kidney disease (CKD), Parkinson's Disease, cerebral palsy, multiple sclerosis etc.)
Commercial activity monitor	Wearable. GPS functionality. Easy to operate (large buttons, bright screen, large font/sign). Easy to clean. Real-time feedback.
Adherence	Utilise a built-in sensor to track and monitor daily distance using GPS and subsequent walking information such as a map of the walk. Built-in weekly progress report functionality.
Training schedule	Personalised purposeful walk (outdoor, daily). Duration: five weeks. Week one: participant's post-surgical walking distances measured. A target distance is to be calculated to increase the weekly
Fidelity	walking distance by 10% and be divided by seven to calculate a daily distance for that week. Users should be supplied with clear instructions on how to operate the wearable activity monitor, and contact details, so they can ask questions regarding the use of the wearable. A communication platform is to be designed through the features such as 'community' in the relevant wearable brand application so participants can simply share daily walking activities.
	A daily activity diary should be considered so participants can keep a record of the reasons why they could perform their daily activities.
Practical consideration	If the participant did not meet their target, the daily distance goal they were assigned the previous week to remain in place. Ensure participants know how to charge the wearable activity monitor.

Provide the user with a suitable size of the band that fits their wrist comfortably.

The smartphone should be compatible with the selected wearable activity monitor.

9.6 Recommendation for future research

An overall arching limitation of all studies carried out in this research is mainly inherent to the study methodology, there was no formal power calculation and therefore the sample size in each group was too small for meaningful statistical analysis. This is either due to restrictions of COVID-19 pandemic or restrictions upon recruiting through the NHS. A study with the correct sample size, utilising the settings and conditions explained in Chapter 6 could provide a very thorough answer to the level of accuracy and precision of the activity monitor in an older or THR population. Similarly, both the feasibility study and the pilot studies did not include the required sample size of participants, however, an effect size calculation carried out in the pilot study provided reasoning that a similar study with 24 participants could provide a statistically viable answer to the effect of the intervention in this population. In addition to increasing the sample size, a longer intervention period is also recommended to further evaluate the adherence level as well as the fact that a follow-up period of five weeks may be too short to assess any significant changes in our study outcomes as other studies have shown improvement in physical activity with a longer follow-up time (de Groot et al. 2008; Brandes et al. 2011). The outcome measures chosen for the pilot study (Chapter 8) were streamlined from an earlier feasibility study (Chapter 7) and were utilised given their reliability and previous utilisation in studies related to the THR population. However, an alternative type of gait analysis which is marker-less and portable should be considered if data is to be collected in a hospital setting. While, the reliability of marker-less gait systems for measuring kinematic and kinetic parameters is still questionable, the spatio-temporal parameters are deemed reliable (Moro et al. 2022).

The activity monitor used in this study, FC4, was selected following an exhaustive screening of available devices, including both wearables and smartphone Apps (Chapter 6). However, given the fast pace which surrounds the development and release of commercial activity monitors, a new iteration of this device, Fitbit Charge 5, is now available on the market with a promise of more durability and accuracy in daily use.

9.7 Unanswered questions

While the findings here provide an answer that a purposeful walk monitored via a commercial activity monitor can be used as a method to increase daily activity and function post-THR surgery, the long-term effect of such intervention is yet to be determined. The findings from this study provide insight into the level of purposeful walking activity that is feasible to achieve at 6-month post-THR surgery, however, this research also found that the magnitude of daily walking vary significantly amongst this population. Thus, the research findings could not be used as evidence to suggest the prescription of an amount that should be suggested to all of these individuals. This may also highlight the importance of a personalised plan and how the current procedure in which the same post-surgical rehabilitation exercise is suggested to all may not be the best method and may be the reason for the lack of adherence to rehabilitation programmes post-surgery.

Additionally, the validity and reliability of the commercial activity monitors remain unanswered. In order for this technology to be utilised for informing HCPs decision makings, bigger studies with a population of different ages and walking speeds are

necessary. The findings provide new insight into the most suitable activity monitors, however, given the fast pace development in this area, a standardised protocol should be considered and be utilised in all studies to have an understanding of the level of inaccuracy in the commercial activity monitor used prior to its application in clinical trials.

9.8 Limitations

9.8.1 Data collection

The systematic review included in Chapter 2 was limited by the heterogeneous nature of the included studies. Nonetheless, the systematic review was designed to provide a broad understanding of the current evidence-base; rather than to come to a specific conclusions. The PPI findings were not reported according to any qualitative methodology, this is because by nature, the PPI is not a research study and findings are to be treated as information.

The gait analysis data reported in Chapter 5, was a secondary analysis of data collected as part of a bigger study, and not specifically designed as part of this PhD, it was also affected by the COVID-19 restriction and had to be postponed, causing no data beyond 6 months post-surgery. In addition, the various studies carried out in Chapter 6, were single-participant studies due to the pandemic, with the only participant of the studies being myself.

9.8.2 Participants

The study described in Chapter 6, suffered from COVID restrictions enforced on research and recruiting participants and did not include enough participants to perform statistical analysis. Despite being a clinical population, studies described in Chapters 7 and 8 were below a minimum number of participants required for carrying out feasibility related statistical analysis and efficacy respectively.

9.9 Strength

9.9.1 Study design

The qualitative and quantitative mixed method strategy used throughout this research provides guidance and also the confidence to the conclusion drawn in this thesis. To integrate a new regime into the daily rehabilitation programme post-THR surgery, both quantitative and qualitative approaches are needed to create scientific objectivity and justification for their use (McCusker and Gunaydin 2015). Therefore, from the beginning of this research, the THR population's opinions were sought and utilised to inform every decision-making while objective data were also gathered to justify and where possible demonstrate the significance of the findings. The feasibility and pilot studies included qualitative elements such as activity diary and interviews to allow participants to give their feedback on the commercial activity monitor and the intervention. Gathering participants' perceptions on a proposed intervention is paramount to ensure it is truly feasible and is important to ensure future interventions are informed by the opinion of its intended user.

9.9.2 Data collection

A strength of this research is the outcome measures used to determine the feasibility and efficacy of the intervention. GRAIL is a reliable and objective method of assessing individuals' gait, and the reliability of the GRAIL system and its protocol for assessing individuals' spatio-temporal gait parameters has previously been proven (Al-Amri et al. 2017; Bahadori et al. 2019b). All outcome measures selected for this research have been used previously in THR populations, which has enabled the findings to be compared to other THR studies and allowed a true insight into participants' daily activity and function post-surgery. Furthermore, the addition of the PIADS questionnaire, for the final study (Chapter 8) added value to better understanding of the psychological impact of the intervention of using the commercial activity monitor (Jutai et al. 2002).

The inclusion of qualitative elements throughout this research also provided valuable information on informing and evaluating different aspects of this research. Despite the small sample size in the feasibility study, the interviews provided substantial insight into the selection of suitable outcome measures, amendments to the activity diary, and the feasibility of the intervention. The use of an activity diary has previously been used in other research and was suggested as a motivator and its utilisation in this research was welcomed by the participants and they suggested that it was a great way to self-manage their daily activity.

9.10 Chapter summary

This chapter has discussed the research conducted in relation to the existing evidencebase and current practice. In addition, it has provided a recommendation for future clinical practice, future research endeavours and concluded by highlighting the collective strength and limitations of the research conducted. While some of the studies were affected by the COVID-19 pandemic, it was successful in designing a novel intervention for increasing individual levels of daily activity after THR surgery. Through quantitative and qualitative research methodology, this research was novel due to its findings on the effect of a purposeful walk in contrast to daily step count and its subsequent effect on functional performance at 3 to 6 months post-surgery.

"Don't wish it was easier, wish you were better. Don't wish for less problems, wish for more skills. Don't wish for less challenge, wish for more wisdom."

Jim Rohn

Chapter 10 – Conclusion

Generally, individuals recover well from THR surgery, however, some do not return to physical activity, work, or leisure activities (Dore-Smith and Killingback 2018) and therefore there are still significant rehabilitation challenges in this population (Bandholm et al. 2018). Furthermore, the expectations of people regarding their level of daily activity following THR surgery have increased and where those expectations are unmet, they can be a source of dissatisfaction (Scott et al. 2012; Harding et al. 2015). Evidence also demonstrates that only a small subset of individuals reach the level of daily activity recommended by the WHO guidelines by 6 months following THR surgery (Harding et al. 2014). Other studies looked at a longer period and found that this deficit even remains at 12 months post-surgery (Crizer et al. 2017; Withers et al. 2017b; Holl et al. 2018).

In most cases, following surgery, individuals are discharged home with exercise advice in the form of a patient information leaflet and told to progress independently until their 6-week follow-up (NICE 2020). These information leaflets often contain advice on recovery from surgery and exercise prescription, designed in the form of a 'one size fits all' basis, and rarely set goals and offer advice on progressing daily activity (Wainwright and Burgess 2018). Preliminary work has found that these exercises are often ineffective at increasing muscle strength, individuals' function, quality of life, or level of daily activity, even at 12 months post-surgery (Smith 2017; Withers et al. 2017b).

There are currently no recommendations for the optimal amount of walking that should be recommended after THR surgery, and therefore innovations are required to address the deficit currently seen in the daily activity level post-THR surgery.

The commercially available activity monitoring wearables have the potential to engage individuals as advocates in their personalised care, as well as offer healthcare providers objective assessments of their patients' daily activity patterns. However, the systematic review conducted in Chapter 2 indicated that research in this area is limited, and where utilised, the parameter to enhance daily activity was step count. A PPI study was then organised (Chapter 3), and included both groups of THR patients (before and after surgery) and HCPs (physiotherapists and surgeons) to better understand the reasons why individuals undergo surgery and how commercial activity monitor are perceived by this THR population and HCPs. The findings highlighted the need for new innovation where, personalised plans are desired and concluded that walking freely, i.e. long outdoor walks without pain, is one of the main reasons that people undergo THR surgery, and therefore should be recognised and monitored as a factor in a positive longterm outcome. These findings prompted a more in-depth look at walking before and after THR surgery through the most reliable system for mimicking natural walking, through gait analysis. The GRAIL system gait analysis of the group of THR individuals using a self-paced treadmill found that at the perioperative stage, the spatio-temporal gait of THR individuals is significantly different from that of the healthy control group. Meanwhile, walking speed and step length remained statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence improved at the 6 weeks stage. This was explained by the fact that despite gradual improvement from pre surgery to up to 6 months post-surgery, the walking speed and step length of the THR group remain statistically significantly different from that of the control group 3 months after surgery. In contrast, the cadence is improved and recovers, when compared to the control group, as early as the 6 weeks stage post-surgery. This

could be interpreted that as the patients rehabilitate, they will naturally gain a better range of movement which increases their capability and results in an improved cadence. Therefore, step count which has readily been reported (Crizer et al. 2017) as a parameter for enhancing long-term activity levels and subsequently returning to walking freely, may not be the best motivator, i.e., more steps does not necessarily mean greater walking distance. Meanwhile, another study (Salpakoski et al. 2014) reported that an ability to walk even a short distance outdoors can be meaningful for successful and independent living at home among the THR group, as well as enhancing their physical function (Simonsick et al. 2005).

This prompted an in-depth look at the most suitable commercial activity monitors for the average age in THR population which is over 60 years old. The selected activity monitors were also evaluated to measure their level of accuracy and precision. Unfortunately, at this point, COVID-19 pandemic hit the world and therefore this evaluation study was mostly carried out as a single-participant study. Nevertheless, the activity monitors were assessed in various conditions and settings. The findings suggested that FC4 in outdoor settings, using a GPS sensor, is the most suitable activity monitor for this research. Thus, with the discovery of walking as an important daily activity, distance as a possibly better motivator, and the FC4 as the most suitable activity monitor for this population a feasibility study was designed. We referred to the outdoor walk that was recorded with a GPS sensor as a 'purposeful walk'.

This feasibility study aimed to determine the feasibility of an intervention where walking distance is used as a parameter to increase daily walking activity using a commercially available activity monitor FC4 in THR patients 3-6 months post-surgery, to explore the

barriers and facilitators to implement the intervention and to assess the appropriateness of different outcome measures, through a series of quantitative and qualitative research methods. The study findings suggested that a 10% increase in individuals' baseline walking distance was acceptable to all participants. Furthermore, although the PROMS (mGES, PASE and HOOS) selected were all relevant to this cohort, future research should only include the HOOS questionnaire, as it provided the most comprehensive and relevant set of subjective outcomes. Gait analysis was well received by all participants and the gait parameters selected provided great insight into the effects of the intervention on walking recovery post-THR surgery. Participants also suggested changes to the layout of the activity diary for easier completion. All findings were then used and outcome measures were streamlined to inform a pilot study to evaluate the efficacy of the purposeful walk intervention compared to a daily step count, using the FC4 activity monitor.

The pilot study was designed as a randmised control trial with a convenience sample size of 12 participants. Six were randomised to the intervention group and 6 were randomised to the control group. In addition to streamlined outcome measures from the earlier feasibility study, a PIADS questionnaire was also included to explore the psychological impact of the FC4 where it is utilised in a different group. This five-week study included personalised daily purposeful walk intervention to be compared against a control group who reported their daily steps as opposed to a daily distance outdoor walk. The study findings suggest that the effect size for all quantitative outcome measures was large. Given the effect size provides insight into the magnitude of the difference between groups, the large effect size observed here may act as an indicator that the findings from this study have practical significance. Therefore, it may be

suggested that a purposeful walking intervention could be a more effective stimulus than step count in improving selected gait spatiotemporal parameters post-THR surgery. This study concluded that overall the purposeful walking intervention was successful in increasing daily walking activity and function in contrast to the control group. However, further studies with larger sample sizes and longer follow-up are needed to assess the evidence on the significance of the effect of the purposeful walk in contrast to step count.

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Appendices

Appendix 1. Mobile Application Rating Scale (MARS)

App Classification

The Classification section is used to collect descriptive and technical information about the app. Please review the app description in iTunes / Google Play to access this information.

App Name:	
Rating this version:	Rating all versions:
Developer:	
N ratings this version:	N ratings all versions:
Version:	Last update:
Cost - basic version:	Cost - upgrade version:
Platform: □□iPhone □□iPad	□□Android
Brief description:	
Focus: what the app targets	□□ Other
(select all that apply) □□ Increase Happiness/Well-being □□ Mindfulness/Meditation/Relaxation □□ Reduce negative emotions □□ Depression □□ Anxiety/Stress □□ Anger □□ Behaviour Change □□ Alcohol /Substance Use □□ Goal Setting □□ Entertainment □□ Relationships □□ Physical health	

Theoretical background/Strategie that apply) Assessment Feedback Information/Ed Monitoring/Tra Goal setting	ducation	□□ CB ⁻ □□ CB ⁻ □□ AC ⁻ □□ Mir □□ Rela □□ Gra	Γ - Behavioural (Γ – Cognitive (th Γ - Acceptance of Indfulness/Meditation Indicated Indicated	ought challenging)
Affiliations:	□□ Commercial	□□ Government	□□NGO	□□ University
Age group (all that apply)		Technical a	spects of app apply)	(all that
□□ Children (under 12) □□ Adolescents (13-17) □□ Young Adults (18-25) □□ Adults		□□ Allows sharing (Facebook, Twitter, etc.) □□ Has an app community □□ Allows password-protection □□ Requires login □□ Sends reminders □□ Needs web access to function		

□□ General

App Quality Ratings

The Rating scale assesses app quality on four dimensions. All items are rated on a 5-point scale from "1.Inadequate" to "5.Excellent". Circle the number that most accurately represents the quality of the app component you are rating. Please use the descriptors provided for each response category.

SECTION A

Engagement – fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience

- 1. Entertainment: Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification)?
 - 1 Dull, not fun or entertaining at all
 - 2 Mostly boring
 - 3 OK, fun enough to entertain user for a brief time (< 5 minutes)
 - 4 Moderately fun and entertaining, would entertain user for some time (5-10 minutes total)
 - 5 Highly entertaining and fun, would stimulate repeat use
- 2. Interest: Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way?
 - 1 Not interesting at all
 - 2 Mostly uninteresting
 - 3 OK, neither interesting nor uninteresting; would engage user for a brief time (< 5 minutes)
 - 4 Moderately interesting; would engage user for some time (5-10 minutes total)
 - 5 Very interesting, would engage user in repeat use
- **3.** Customisation: Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)?
 - 1 Does not allow any customisation or requires setting to be input every time
 - 2 Allows insufficient customisation limiting functions
 - 3 Allows basic customisation to function adequately
 - 4 Allows numerous options for customisation
 - 5 Allows complete tailoring to the individual's characteristics/preferences, retains all settings
- **4.** Interactivity: Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Note: these functions need to be customisable and not overwhelming in order to be perfect.
 - 1 No interactive features and/or no response to user interaction
 - 2 Insufficient interactivity, or feedback, or user input options, limiting functions
 - 3 Basic interactive features to function adequately
 - 4 Offers a variety of interactive features/feedback/user input options
 - 5 Very high level of responsiveness through interactive features/feedback/user input options
- 5. Target group: Is the app content (visual information, language, design) appropriate for

your target audience?

- 1 Completely inappropriate/unclear/confusing
- 2 Mostly inappropriate/unclear/confusing
- 3 Acceptable but not targeted. May be inappropriate/unclear/confusing
- 4 Well-targeted, with negligible issues
- 5 Perfectly targeted, no issues found

A. Engagement mean score =

SECTION B

Functionality – app functioning, easy to learn, navigation, flow logic, and gestural design of app

- **6.** Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?
 - 1 App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)
 - 2 Some functions work, but lagging or contains major technical problems
 - 3 App works overall. Some technical problems need fixing/Slow at times
 - 4 Mostly functional with minor/negligible problems
 - 5 Perfect/timely response; no technical bugs found/contains a 'loading time left' indicator
- **7.** Ease of use: How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?
 - 1 No/limited instructions; menu labels/icons are confusing; complicated
 - 2 Useable after a lot of time/effort
 - 3 Useable after some time/effort
 - 4 Easy to learn how to use the app (or has clear instructions)
 - 5 Able to use app immediately; intuitive; simple
- **8.** Navigation: Is moving between screens logical/accurate/appropriate/ uninterrupted; are all necessary screen links present?
 - 1 Different sections within the app seem logically disconnected and random/confusing/navigation is difficult
 - 2 Usable after a lot of time/effort
 - 3 Usable after some time/effort
 - 4 Easy to use or missing a negligible link
 - 5 Perfectly logical, easy, clear and intuitive screen flow throughout, or offers shortcuts
- **9.** Gestural design: Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens?
 - 1 Completely inconsistent/confusing
 - 2 Often inconsistent/confusing
 - 3 OK with some inconsistencies/confusing elements
 - 4 Mostly consistent/intuitive with negligible problems
 - 5 Perfectly consistent and intuitive

B. Functionality mean score =	
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SECTION C

Aesthetics - graphic design, overall visual appeal, colour scheme, and stylistic consistency

- **10.** Layout: Is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed?
 - 1 Very bad design, cluttered, some options impossible to select/locate/see/read device display not optimised
 - 2 Bad design, random, unclear, some options difficult to select/locate/see/read
 - 3 Satisfactory, few problems with selecting/locating/seeing/reading items or with minor screensize problems
 - 4 Mostly clear, able to select/locate/see/read items
 - 5 Professional, simple, clear, orderly, logically organised, device display optimised. Every design component has a purpose
- **11.** Graphics: How high is the quality/resolution of graphics used for buttons/icons/menus/content?
 - 1 Graphics appear amateur, very poor visual design disproportionate, completely stylistically inconsistent
 - 2 Low quality/low resolution graphics; low quality visual design disproportionate, stylistically inconsistent
 - 3 Moderate quality graphics and visual design (generally consistent in style)
 - 4 High quality/resolution graphics and visual design mostly proportionate, stylistically consistent
 - 5 Very high quality/resolution graphics and visual design proportionate, stylistically consistent throughout
- **12.** Visual appeal: How good does the app look?
 - 1 No visual appeal, unpleasant to look at, poorly designed, clashing/mismatched colours
 - 2 Little visual appeal poorly designed, bad use of colour, visually boring
 - 3 Some visual appeal average, neither pleasant, nor unpleasant
 - 4 High level of visual appeal seamless graphics consistent and professionally designed
 - 5 As above + very attractive, memorable, stands out; use of colour enhances app features/menus

C. Aesthetics	mean score =	
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SECTION D

Information – Contains high quality information (e.g. text, feedback, measures, references) from a credible source. Select N/A if the app component is irrelevant.

- 13. Accuracy of app description (in app store): Does app contain what is described?
 - 1 Misleading. App does not contain the described components/functions. Or has no description
 - 2 Inaccurate. App contains very few of the described components/functions
 - 3 OK. App contains some of the described components/functions
 - 4 Accurate. App contains most of the described components/functions
 - 5 Highly accurate description of the app components/functions
- **14.** Goals: Does app have specific, measurable and achievable goals (specified in app store description or within the app itself)?
 - N/A Description does not list goals, or app goals are irrelevant to research goal (e.g. using a game for educational purposes)
 - 1 App has no chance of achieving its stated goals
 - 2 Description lists some goals, but app has very little chance of achieving them
 - 3 OK. App has clear goals, which may be achievable.
 - 4 App has clearly specified goals, which are measurable and achievable
 - 5 App has specific and measurable goals, which are highly likely to be achieved
- **15.** Quality of information: Is app content correct, well written, and relevant to the goal/topic of the app?
 - N/A There is no information within the app
 - 1 Irrelevant/inappropriate/incoherent/incorrect
 - 2 Poor. Barely relevant/appropriate/coherent/may be incorrect
 - 3 Moderately relevant/appropriate/coherent/and appears correct
 - 4 Relevant/appropriate/coherent/correct
 - 5 Highly relevant, appropriate, coherent, and correct
 - **16.** Quantity of information: Is the extent coverage within the scope of the app; and comprehensive but concise?
 - N/A There is no information within the app
 - 1 Minimal or overwhelming
 - 2 Insufficient or possibly overwhelming
 - 3 OK but not comprehensive or concise
 - 4 Offers a broad range of information, has some gaps or unnecessary detail; or has no links to more information and resources
 - 5 Comprehensive and concise; contains links to more information and resources
 - **17.** Visual information: Is visual explanation of concepts through charts/graphs/images/videos, etc.
 - clear, logical, correct?
 - N/A There is no visual information within the app (e.g. it only contains audio, or text)
 - 1 Completely unclear/confusing/wrong or necessary but missing
 - 2 Mostly unclear/confusing/wrong
 - 3 OK but often unclear/confusing/wrong

- 4 Mostly clear/logical/correct with negligible issues
- 5 Perfectly clear/logical/correct
- **18.** Credibility: Does the app come from a legitimate source (specified in app store description or within the app itself)?
 - 1 Source identified but legitimacy/trustworthiness of source is questionable (e.g. commercial business with vested interest)
 - 2 Appears to come from a legitimate source, but it cannot be verified (e.g. has no webpage)
 - 3 Developed by small NGO/institution (hospital/centre, etc.) /specialised commercial business, funding body
 - 4 Developed by government, university or as above but larger in scale
 - Developed using nationally competitive government or research funding (e.g. Australian Research Council, NHMRC)
- **19.** Evidence base: Has the app been trialled/tested; must be verified by evidence (in published scientific literature)?

N/A The app has not been trialled/tested

- 1 The evidence suggests the app does not work
- 2 App has been trialled (e.g., acceptability, usability, satisfaction ratings) and has partially positive outcomes in studies that are not randomised controlled trials (RCTs), or there is little or no contradictory evidence.
- App has been trialled (e.g., acceptability, usability, satisfaction ratings) and has positive outcomes in studies that are not RCTs, and there is no contradictory evidence.
- 4 App has been trialled and outcome tested in 1-2 RCTs indicating positive results
- 5 App has been trialled and outcome tested in \geq 3 high quality RCTs indicating positive results

D. Information mean score =	*
	•

Scoring

App quality scores for	
SECTION	
A: Engagement Mean Score =	
B: Functionality Mean Score =	
C: Aesthetics Mean Score =	
D: Information Mean Score =	
App quality mean Score	

^{*} Exclude questions rated as "N/A" from the mean score calculation.

Appendix 2. Summary of the systematic search for the wearable brands (File attached as a Microsoft Excel spreadsheet.)

Appendix 3. Evaluation of Activity Monitors for Walking Distance? - Bournemouth University research ethics checklist.



Research Ethics Checklist

About Your Checklist	
Ethics ID	37817
Date Created	13/04/2021 14:22:05
Status	Approved
Date Approved	28/04/2021 14:31:52
Risk	Low

Researcher Details	
Name	Shayan Bahadori
Faculty	Faculty of Health & Social Sciences
Status	Postgraduate Research (MRes, MPhil, PhD, DProf, EngD, EdD)
Course	Postgraduate Research - HSS
Have you received funding to support this research project?	No

Project Details	
Title	Evaluation of Activity Monitors for Walking Distance?
Start Date of Project	14/04/2021
End Date of Project	31/05/2021
Proposed Start Date of Data Collection	14/04/2021
Original Supervisor	Ian Swain
Approver	Susan Dewhurst

Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)

Nowadays people, are very interested in activity monitors (AM) (wearables or smartphone apps) as these are the trend in technology for the tracking of daily life activities such as walkin. The aim of this study is to evaluate the validity of four AMs (3 smartphone apps and a Fitbit Charge (FC) wearable) comparing to standardise outdoor track, and to the hand-tally count for measuring steps and distance walked. The study outcomes will provide insight on the reliability, repeatability, and functionality of these AMs.

Filter Question: Does your study involve Human Participants?

Participants Describe the number of participants and specify any inclusion/exclusion criteria to be used 3 healthy participants.

Page 1 of 4 Printed On 30/03/2023 08:55:36

Inclusion criteria

- Safely ambulatory without assistive devices
- Aged from 18 to 90 years old
- Able to walk at least 5 kilometre (km) a day
- Must be able to give written informed consent

Exclusion criteria

- Neurological or musculoskeletal conditions that might make the assessments dangerous
- Cognitive function that prevents participants from understanding study
- Medical conditions that might be jeopardised by exercise

Do your participants include minors (under 16)?	
Are your participants considered adults who are competent to give consent but considered vulnerable?	
Is a Disclosure and Barring Service (DBS) check required for the research activity?	

Please provide details on intended recruitment methods, include copies of any advertisements. A total of 3 healthy volunteers will be recruited through online flyers and posters. Do you need a Gatekeeper to access your participants? No

Data Collection Activity	
Will the research involve questionnaire/online survey? If yes, don't forget to attach a copy of the questionnaire/survey or sample of questions.	No
Will the research involve interviews? If Yes, don't forget to attach a copy of the interview questions or sample of questions	No
Will the research involve a focus group? If yes, don't forget to attach a copy of the focus group questions or sample of questions.	No
Will the research involve the collection of audio recordings?	No
Will your research involve the collection of photographic materials?	No
Will your research involve the collection of video materials/film?	No
Will the study involve discussions of sensitive topics (e.g. sexual activity, drug use, criminal activity)?	No
Will any drugs, placebos or other substances (e.g. food substances, vitamins) be administered to the participants?	No
Will the study involve invasive, intrusive or potential harmful procedures of any kind?	No
Could your research induce psychological stress or anxiety, cause harm or have negative consequences for the participants or researchers (beyond the risks encountered in normal life)?	No
Will your research involve prolonged or repetitive testing?	No
What are the potential adverse consequences for research participants and how will you minimise them?	

Page 2 of 4 Printed On 30/03/2023 08:55:36

Consent

Describe the process that you will be using to obtain valid consent for participation in the research activities. If consent is not to be obtained explain why.

The study will be explained to the participant, who will be given an information sheet which they will be given 24 hours prior to taking part in the study to read through and ask questions on. If the participant is happy to volunteer to take part, and they fulfil the inclusion and exclusion criteria, they will be asked to sign a participant agreement form.

Participants are free to withdraw, without giving a reason, at any point during the study up to the point when the data are processed and become anonymous.

Do your participants include adults who lack/may lack capacity to give consent (at any point in the study)?	No
Will it be necessary for participants to take part in your study without their knowledge and consent?	No

Participant Withdrawal

At what point and how will it be possible for participants to exercise their rights to withdraw from the study?

Participants may withdraw at any time during the assessment period, without needing to give a reason.

If a participant withdraws from the study, what will be done with their data?

If a participant does withdraw without completing all the assessments, the investigator will confirm with the participant that they are happy for their data to be used up to the point of withdrawal. If they are not happy with this, their data will be removed from the study.

Participant Compensation	
Will participants receive financial compensation (or course credits) for their participation?	No
Will financial or other inducements (other than reasonable expenses) be offered to participants?	No

Research Data	
Will identifiable personal information be collected, i.e. at an individualised level in a form that identifies or could enable identification of the participant?	No
Will research outputs include any identifiable personal information i.e. data at an individualised level in a form which identifies or could enable identification of the individual?	No

Storage, Access and Disposal of Research Data

Where will your research data be stored and who will have access during and after the study has finished.

Information with regards to study patients will be kept confidential and managed in accordance with the Data Protection Act. Participants will be anonymized with regard to any future publications relating to the study.

Enrolled participants will be allocated a unique code number that will be used on all research documentation to ensure confidentiality. Only authorized members of the research team will have access to this research data. All research data will be stored securely in adherence with the Data Protection Act 1998 and Trust Confidentiality Policy.

Once your project completes, will your dataset be added to an appropriate research data repository such as BORDaR, BU's Data Repository?

Yes

Dissemination Plans	
How do you intend to report and disseminate the results of the study?	
Peer reviewed journals,Internal Report,Conference presentation	
Will you inform participants of the results?	Yes
If Yes or No, please give details of how you will inform participants or justify if not doing so	
Participants will have an opportunity to see their data at the end of each trial.	
Final Review	
Are there any other ethical considerations relating to your project which have not been covered above?	No
Risk Assessment	
Have you undertaken an appropriate Risk Assessment?	Yes

Attached documents

Participant Agreement Form.docx - attached on 13/04/2021 14:58:59

Participant Information Sheet.docx - attached on 13/04/2021 14:59:06

Protocol.docx - attached on 13/04/2021 14:59:17

Page 4 of 4 Printed On 30/03/2023 08:55:36

Appendix 4. Feasibility study of the purposeful walking intervention - Bournemouth University research ethics checklist.



Research Ethics Checklist

About Your Checklist	
Ethics ID	42236
Date Created	11/02/2022 13:53:41
Status	Reviewed
Risk	Low

Researcher Details	
Name	Shayan Bahadori
Faculty	Faculty of Health & Social Sciences
Status	Postgraduate Research (MRes, MPhil, PhD, DProf, EngD, EdD)
Course	Postgraduate Research - HSS
Have you received funding to support this research project?	No

Project Details		
Title	A Feasibility Study to Evaluate a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor in Individuals Post Total Hip Replacement Surgery.	
Start Date of Project	01/03/2022	
End Date of Project	01/05/2022	
Proposed Start Date of Data Collection	07/03/2022	
Original Supervisor	lan Swain	

Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)

Participants who had undergone total hip replacement surgery within the post-operative period of 3 to 6 months will be recruited from the local community. Those eligible to take part in the study will be invited to attend a baseline assessment (before the start of intervention) at the Orthopaedic Research Institute, Bournemouth University. Data will be collected on gait, and activities of daily living. The Gait Realtime Analysis Interactive Laboratory (GRAIL, Motekforce Link, Amsterdam, the Netherlands) system will be used to carry out the gait analysis. Only spatio-temporal data (walking speed, cadence and step length) will be recorded for analysis. Activity of daily living will be measured using a series of Patient Reported Outcome Measures questionnaires (the Hip Disability and Osteoarthritis Outcome Score (HOOS), the Physical Activity Scale for the Elderly (PASE), and the modified Gait Efficacy Scale (mGES)). During this visit, participants will be given a FC4 activity monitor and instructed how to operate it. Participants will wear their FC4 activity monitor for 5 weeks. In the first week participants will wear their FC4 activity monitor in order for us to understand the patients post-surgical walking amounts. In week two a target distance will be calculated to increase weekly walking distance by 10% and will be divided to calculate a daily distance for that week. In weeks thereafter, if individuals meet their target, a new step target is calculated to increase walking distance by 10% from the previous target. If individual did not meet their target, the daily distance goal they were assigned on previous week remains in place. Participants will be invited to attend a final assessment at 5 weeks from their baseline appointment, where their baseline measures will be repeated. Depending on their availability, participants will also be invited to attend a focus group where they will be able to openly express their thoughts on the use of the FC4 activity monitor, compliance, practicality, and feasibility of the intervention. This a small feasibility trial with convenient sample size that aims to evaluate the usability, adherence and acceptability of the purposeful walking intervention in order to decide whether a full-scale effectiveness trial is warranted. The outcome measures will be analysed through descriptive statistics.

Page 1 of 7 Printed On 10/03/2022 15:54:36

Filter Question: Does your study involve Human Participants?

Participants

Describe the number of participants and specify any inclusion/exclusion criteria to be used

Five adults who have had THR surgery at least 3 months and at most 6 months post-surgery, due to symptomatic hip osteoarthritis will be recruited.

Eligibility

Inclusion

Participants meeting all the following inclusion criteria will be considered for participation within the study:

- Male and female, aged 60 years and over;
- 3 to 6 months post unilateral total hip replacement surgery for osteoarthritis;
- · Capable of giving informed consent;
- Can provide verbal confirmation that they have been signed off by their surgeon;
- · Capable of completing the activity diary independently;
- · Have access to smartphone or computer;
- Able to complete the trial protocol.

2.3.1 Exclusion

Participants will be excluded if they meet any of the following criteria:

- Unable to provide informed consent (insufficient English, cognitive disorder such as dementia, psychiatric illness);
- Unable to complete follow-up (insufficient English, lives overseas, unable to return easily);
- Not physically able to use Grail gait lab;
- Systematic disease affecting walking ability (chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), chronic kidney disease (CKD), parkinson's, cerebral palsy, multiple sclerosis);
- Requiring revision hip replacement;
- Previous hip replacement (resurfacing or THR) on the contralateral side;
- Known metastatic tumour involving the hip;
- Not physically able to climb stairs or walk 40m;
- Unable to complete study follow up.

Do your participants include minors (under 16)?	No
Are your participants considered adults who are competent to give consent but considered vulnerable?	No
Is a Disclosure and Barring Service (DBS) check required for the research activity?	No

Recruitment

Please provide details on intended recruitment methods, include copies of any advertisements.

Five adults who have had THR surgery at least 3 months and at most 6 months post-surgery, due to symptomatic hip osteoarthritis will be recruited using marketing tools such as posters and Twitter posts (Figure 1), shared on the University channels, at local leisure centres, University of Third Age (U3A), community of older adults and physiotherapy centres. Those interested in the study will be asked to contact the lead researcher (SB) for more information. Once an individual has expressed an interest in taking part, the lead researcher (SB) will email the individual a copy of the participant information sheet (PIS). To comply with Good Clinical Practice (GCP) guidelines, SB will ensure that the participant has sufficient time (48 hours) to consider their participation within the study. Interested participant will then be contacted via a telephone call for initial screening to ensure they meet the pre-determined eligibility criteria (section 2.3). Each

Page 2 of 7 Printed On 10/03/2022 15:54:36

participant will be advised that they are under no obligation to take part and can withdraw at any time without providing a reason. If the participant decides to proceed with the study, they will be asked to complete an informed consent form at their baseline assessment. The original signed consent form will be kept in the Study Site File and participants will be provided with a copy.

Twitter handles are @ShayBahadori and @BU Orthopaedic.

need a Gatekeeper to access your participants?	
--	--

Will the research involve questionnaire/online survey? If yes, don't forget to attach a copy of the questionnaire/survey or sample of questions. How do you intend to distribute the questionnaire? face to face Will the research involve interviews? If Yes, don't forget to attach a copy of the interview questions or sample of questions Will the research involve a focus group? If yes, don't forget to attach a copy of the focus group questions or sample of questions. Please provide details e.g. where will the focus group take place. Will you be leading the focus group or someone else?

To qualitatively explore the feasibility of the intervention, a focus group will be held at Bournemouth University, ORI.

Subject 1: Activity Monitor

What was it like to wear the activity monitor?

What was it like to use the activity monitor?

Did the activity monitor encourage you to do a daily walk (achieved your daily goals)? (Remember to ask 'How' if they didn't expand on it)

What were your thoughts on the use of activity monitors prior to study?

Would you consider buying an activity monitor? Could you please explain why.

Subject 2: Purposeful walking:

How did you feel about going for your outdoor walks?

Did you find your goals manageable? Could you please explain

Did you find your daily distance goals helpful with increasing your daily activity? Could you please explain

Subject 3: Time (testing/intervention)

How did you feel about the amount of time you spent with us on baseline day and follow up day testing?

How did you feel about being part of a study that involves you for 5 weeks?

What did you think about the layout of the activity diary?

How did you feel about completing the daily activity diary?

How did you feel about the questions asked on the daily activity diary?

Subject 4: Explore

Were there any challenges that you would like to share in regard to doing your daily outdoor walking?

Page 3 of 7 Printed On 10/03/2022 15:54:36

Were there any positive experiences that you would like to share in regard to doing your daily outdoor walking?	
Will the research involve the collection of audio materials?	Yes
Will your research involve the collection of photographic materials?	No
Will your research involve the collection of video materials/film?	No
Will any audio recordings (or non-anonymised transcript), photographs, video recordings or film be used in any outputs or otherwise made publicly available?	No
Will the study involve discussions of sensitive topics (e.g. sexual activity, drug use, criminal activity)?	No
Will any drugs, placebos or other substances (e.g. food substances, vitamins) be administered to the participants?	No
Will the study involve invasive, intrusive or potential harmful procedures of any kind?	No
Could your research induce psychological stress or anxiety, cause harm or have negative consequences for the participants or researchers (beyond the risks encountered in normal life)?	No
Will your research involve prolonged or repetitive testing?	No

Consent

Describe the process that you will be using to obtain valid consent for participation in the research activities. If consent is not to be obtained explain why.

Once an individual has expressed an interest in taking part, they will be screened via a telephone call to ensure they meet the predetermined eligibility criteria and have no Covid-19 symptoms. Participants will then be invited to attend an assessment at the Orthopaedic Research Institute, Bournemouth University, where they will have their informed consent taken. Following informed consent, data will be collected on gait, and activities of daily living. Figure 2 outlines the study flow. Participants will be invited to attend a final assessment at 5 weeks from their baseline appointment where their baseline measures will be repeated. In addition, participants will also be asked to keep a diary of their daily walking activities and the intensity of their walk based on Borg Scale. After the intervention period is complete, participant will be invited to attend a focus group in which they will be able to openly express their thoughts on the use of the activity monitor, their compliance, practicality and the usefulness of the intervention.

Do your participants include adults who lack/may lack capacity to give consent (at any point in the study)?	No	
Will it be necessary for participants to take part in your study without their knowledge and consent?	No	

Participant Withdrawal

At what point and how will it be possible for participants to exercise their rights to withdraw from the study?

Yes, you can stop participating in study activities at any time and without giving a reason. However, as regards to information we have already collected before this point, your rights to access, change or move that information are limited. This is because we need to manage your information in specific ways in order for the research to be reliable and accurate. Further explanation about this is in the Personal Information section below.

If a participant withdraws from the study, what will be done with their data?

As per BU statement:

After you decide to withdraw from the study, we will not collect any further information from or about you.

As regards to information we have already collected before this point, participants right to access, change or move that information are limited. This is because we need to manage their information in specific ways in order for the research to be reliable and accurate.

Page 4 of 7 Printed On 10/03/2022 15:54:36

Further explanation about this is in the Personal Information section of PIS document.

Participant Compensation	
Will participants receive financial compensation (or course credits) for their participation?	No
Will financial or other inducements (other than reasonable expenses) be offered to participants?	No

will participants receive illiancial compensation (or course credits) for their participation?	INO
Will financial or other inducements (other than reasonable expenses) be offered to participants?	No
Research Data	
Will identifiable personal information be collected, i.e. at an individualised level in a form that identifies or could enable identification of the participant?	Yes
Please give details of the types of information to be collected, e.g. personal characteristics, education, work role, experiences	opinions or
Height, weight, and email address. All participants entered onto the database will be assigned a participant ID number, allo protection of the participant's identity	wing for
Will the personal data collected include any special category data, or any information about actual or alleged criminal activity or criminal convictions which are not already in the public domain?	No
Will the information be anonymised/de-identified at any stage during the study?	Yes
Will research outputs include any identifiable personal information i.e. data at an individualised level in a form which identifies or could enable identification of the individual?	No

Storage, Access and Disposal of Resear	rch Data
During the study, what data relating to the participants will be stored and where?	Daily walking distance, gait, the activity of daily living, height, weight, and email address. Data will be collected on an electronic case report form (eCRF), using a secure, web-based portal (Actipath). Data will be stored in this database. All participants entered onto the database will be assigned a participant ID number, allowing for protection of the participant's identity. Information with regards to study participants will be kept confidential and managed in accordance with data protection legislation, the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) and Research Ethics Committee.
How long will the data relating to participants be stored?	All research data will be stored securely in adherence with the BU Data Protection Act Policy and the EU General Data Protection Regulations (GDPR). All data relating to this study will be kept for 5 years on a BU password protected secure network. All data will be anonymised.
During the study, who will have access to the data relating to participants?	The database is restricted, user authentication is required to input or view research data and the amount of data that can be viewed by a user will be determined by their role, as defined in the data management plan and the delegation log. Any data entered to the database is managed with an audit trail that will record the username of all those entering and /or changing data in this study.
After the study has finished, what data relating to participants will be stored and	aily walking distance, gait, the activity of daily living, height, weight, and email address. Data will be collected on an electronic case report form (eCRF), using a secure, web-

Page 5 of 7 Printed On 10/03/2022 15:54:36

where? Please indicate whether data will be retained in identifiable form.	based portal (Actipath). Data will be stored in this database. All participants entered onto the database will be assigned a participant ID number, allowing for protection of the participant's identity. Information with regards to study participants will be kept confidential and managed in accordance with data protection legislation, the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) and Research Ethics Committee
	Please find attached documents for further information.
After the study has finished, how long will data relating to participants be stored?	All research data will be stored securely in adherence with the BU Data Protection Act Policy and the EU General Data Protection Regulations (GDPR). All data relating to this study will be kept for 5 years on a BU password-protected secure network. All data will be anonymised.
After the study has finished, who will have access to the data relating to participants?	Only authorised members of the research team will have access to this research data.
Will any identifiable participant data be transferred outside of the European Economic Area (EEA)?	No
How and when will the data relating to participants be deleted/destroyed?	All data relating to this study will be kept for 5 years on a BU password protected secure network and destroyed in according with data ethics standard procedure.
Once your project completes, will any anonymised research data be stored on BU's Online Research Data Repository "BORDaR"?	Yes

How do you intend to report and disseminate the results of the study?

Peer reviewed journals

Will you inform participants of the results?

Yes

If Yes or No, please give details of how you will inform participants or justify if not doing so

Participants will have an opportunity to see their data at the end of each assessment day.

Final Review

Are there any other ethical considerations relating to your project which have not been covered above?

No

Risk Assessment

Have you undertaken an appropriate Risk Assessment?

Yes

Attached documents

Poster.ppt - attached on 17/02/2022 15:56:46

Page 6 of 7 Printed On 10/03/2022 15:54:36

Study Protocol.docx - attached on 17/02/2022 15:56:52
PASE Questionnaire.pdf - attached on 17/02/2022 15:56:59
Participant Agreement Form.docx - attached on 17/02/2022 15:58:54
Participant Information Sheet.docx - attached on 17/02/2022 15:59:02
Activity Diary.docx - attached on 17/02/2022 15:59:22
V2Participant Information Sheet.docx - attached on 02/03/2022 14:53:53
V2Participant Agreement Form.docx - attached on 02/03/2022 14:54:43
Responses to comments.docx - attached on 02/03/2022 15:45:05

Page 7 of 7 Printed On 10/03/2022 15:54:36

Appendix 5. Interview Topic Guide – Feasibility study.

Subject 1: Activity Monitor

What was it like to wear the activity monitor?

What was it like to use the activity monitor?

Did the activity monitor encourage you to do a daily walk (achieved your daily goals)? (Remember to ask 'How' if they didn't expand on it)

What were your thoughts on the use of activity monitors prior to study?

Would you consider buying an activity monitor? Could you please explain why.

Subject 2: Purposeful walking:

How did you feel about going for your outdoor walks?

Did you find your goals manageable? Could you please explain

Did you find your daily distance goals helpful with increasing your daily activity? Could you please explain

Subject 3: Time (testing/intervention)

How did you feel about the amount of time you spent with us on baseline day and follow up day testing?

How did you feel about being part of a study that involves you for 5 weeks?

What did you think about the layout of the activity diary?

How did you feel about completing the daily activity diary?

What are your thoughts on the style of questions asked in the activity diary? Could you please explain

Subject 4: Explore

Were there any challenges that you would like to share in regard to doing your daily outdoor walking?

Were there any positive experiences that you would like to share in regard to doing your daily outdoor walking

Appendix 6. Activity diary – Feasibility study.

Activity diary

NAMF		
 	 	

Please use this diary to record your daily activity starting from week 2. We would like you to record the amount of distance you walked in kilometres (Km) as recorded on your activity monitor and how intensely you felt you were exercising on average (Borg Scale). The Borg Scale is provided for you below, please use this as a guide and score yourself out of 10, (e.g. 1/10 representing hardly any exertion and 10/10 representing maximum effort).

Bring your activity diary with you to your follow-up assessment for review by the research team.

RPE Scale	Rate of Perceived Exertion
10	Max Effort Activity Feels almost impossible to keep going. Completely out of breath, unable to talk. Cannot maintain for more than a very short time.
9	Very Hard Activity Very difficult to maintain exercise intensity. Can barely breath and speak only a few words
7-8	Vigorous Activity Borderline uncomfortable. Short of breath, can speak a sentence.
4-6	Moderate Activity Breathing heavily, can hold short conversation. Still somewhat comfortable, but becoming noticeably more challenging.
2-3	Light Activity Feels like you can maintain for hours. Easy to breathe and carry a conversation
1	Very Light Activity Hardly any exertion, but more than sleeping, watching TV, etc

Date (Please write the date for every entry below)	DO NOT WRITE ANYTHING HERE	Daily Walk	•	daily outdoor walk affected by ance an X on the scale to indicate you fatigue, pain, and general bus	our estimate level of	Please use this section to expand on any condition/feelings which may have affected your daily outdoor walk for this day
	Total Distance (Km)		Not at all Not at all	Fatigue Pain	Very much so Very much so	
	Intensity (Borg Scale i.e. 4/10)		Not at all	General Busyness	Very much so	

Total Distance (km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
	Not at all	Fatigue	Very much so
Total Distance (Km)	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so

Total Distance (Km)	Not at all	Fatigue	Very much so	
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	
Total Distance (Km)	Not at all	Fatigue	Very much so	
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	

Total Distance (Km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
	Not at all	Fatigue	Very much so
Total Distance (km)	Not at all	Pain	Very much so
Intensity (Borg Scale	National (1997)	General Busyness	
i.e. 4/10)	Not at all	,	Very much so

Total Distance (Km)	Not at all	Fatigue	Very much so	
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	
			1	
Total Distance (Km)	Not at all	Fatigue	Very much so	
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	

Not at all	Fatigue	Very much so	
Not at all	Pain	Very much so	
Not at all	General Busyness	Very much so	
Not at all	Fatigue	Very much so	
Not at all	Pain	Very much so	
Not at all	General Busyness	Very much so	
	Not at all Not at all Not at all Not at all	Not at all Not at all Pain Not at all General Busyness Fatigue Not at all Not at all Pain Fatigue Rot at all Pain	Not at all Pain Very much so Not at all General Busyness Very much so Very much so

Total Distar	nce (km)	Not at all	Fatigue	Very much so
		Not at all	Pain	Very much so
Intensity (Bo i.e. 4/10)	org Scale	Not at all	General Busyness	Very much so
		Notatell	Fatigue	
Total Distar	nce (Km)	Not at all Not at all	Pain	Very much so Very much so
Intensity (Bo	org Scale	<u> </u>	General Busyness	
i.e. 4/10)		Not at all	General busyness	Very much so

Total Distance (Km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
	 	Fations	1
Total Distance (Km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
	[•

Total Distance (Km)	Not at all	Fatigue	Very much so	
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	
Total Distance (km)	Not at all	Fatigue	Very much so	_
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	

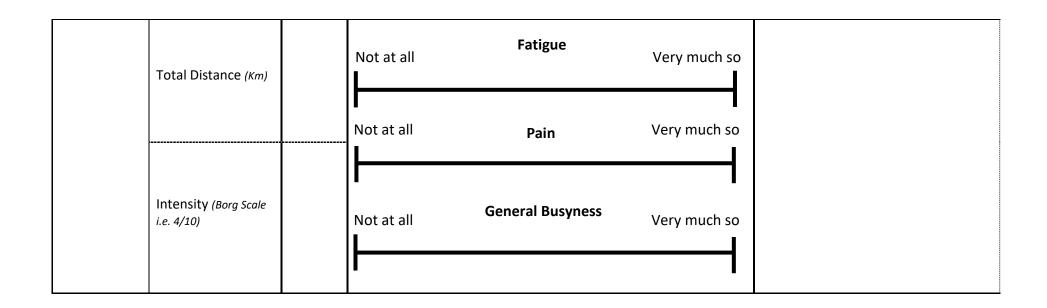
Total Distance (Km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
	Not at all	Fatigue	Very much so
Total Distance (Km)	Not at all	Pain	Very much so
Intensity (Borg Scale		General Busyness	
i.e. 4/10)	Not at all		Very much so

Total Distance (km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
			1
Total Distance (Km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so

 			
os μοπως γο	General Busyness	Ile te toV	Intensity (Borg Scale i.e. 4/10)
Very much so	nis9	lle te toVI	
Very much so	Fatigue	lls ts toN	Total Distance (km)
-			
Very much so	General Busyness	lle te toN	Intensity (Borg Scale i.e. 4/10)
Very much so	nisq	lle te toN	
Very much so	Fatigue	lls ts toN	Total Distance (Km)

Total Distance (Km)	Not at all	Fatigue	Very much so	
	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	
	Not at all	Fatigue	Very much so	
Total Distance (km)	Not at all	Pain	Very much so	
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so	

Total Distance (Km)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so
	l l		I
Total Distance (κm)	Not at all	Fatigue	Very much so
	Not at all	Pain	Very much so
Intensity (Borg Scale i.e. 4/10)	Not at all	General Busyness	Very much so



Appendix 7. Hip dysfunction and Osteoarthritis Outcome Score (HOOS).

HOOS HIP SURVEY

1

Today's date:	//	Date of birth: _	//	
Name:				
INSTRUCTION will help us keep t	rack of how you	•	•	
your usual activitie Answer every que If you are uncerta can.	estion by ticking		ox, only <u>one</u> box fon, please give the	•
Symptoms These questions during the last we		ered thinking of y	our hip symptom	s and difficulties
S1. Do you feel grin	nding, hear clicking Rarely	g or any other type of Sometimes	of noise from your hi	p? Always
S2. Difficulties spre	ading legs wide ar	oart		
None	Mild	Moderate	Severe	Extreme
S3. Difficulties to st	ride out when wal	king		
None	Mild	Moderate	Severe	Extreme
Stiffness The following que during the last we the ease with which	ek in your hip. S	Stiffness is a sens		
S4. How severe is y	our hip joint stiffn	ess after first waken	ing in the morning?	
None	Mild	Moderate	Severe	Extreme
S5. How severe is y	our hip stiffness a	fter sitting, lying or	resting later in the o	lay?
None	Mild	Moderate	Severe	Extreme
Pain				
P1. How often is yo	ur hip painful?			
Never	Monthly	Weekly	Daily	Always
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\				□ og the felleving
What amount of lactivities?	nip pain nave y	ou experiencea tr	ie last week durii	ng the following
P2. Straightening yo				
None	Mild	Moderate	Severe	Extreme

What amount of hip pain have you experienced the **last week** during the following activities?

P3. Bending your hip fu				
None	Mild	Moderate	Severe	Extreme
P4. Walking on a flat su	rface			
None	Mild	Moderate	Severe	Extreme
P5. Going up or down s	tairs			
None None	Mild	Moderate	Severe	Extreme
P6. At night while in be	d			
None	Mild	Moderate	Severe	Extreme
P7. Sitting or lying				
None	Mild	Moderate	Severe	Extreme
P8. Standing upright				
None	Mild	Moderate	Severe	Extreme
P9. Walking on a hard s	urface (asphalt	, concrete, etc.)		
None	Mild	Moderate	Severe	Extreme
P10. Walking on an une	ven surface			
None	Mild	Moderate	Severe	Extreme
o .	ns concern yo after yourself.	For each of the	following activit	ean your ability to move ies please indicate the hip.
A1. Descending stairs None	Mild	Moderate	Severe	Extreme
A2. Ascending stairs None □	Mild □	Moderate □	Severe	Extreme
A2 Diaina for a siu:				
A3. Rising from sitting None	Mild	Moderate	Severe	Extreme
A4. Standing				
None	Mild	Moderate	Severe	Extreme

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

A5. Bending to the	floor/pick up an c	bject		
None	Mild	Moderate	Severe	Extreme
A6. Walking on a fl	at surface			
None	Mild	Moderate	Severe	Extreme
A7. Getting in/out o	of car			
None	Mild	Moderate	Severe	Extreme
A8. Going shopping				
None	Mild	Moderate	Severe	Extreme
A9. Putting on sock				
None	Mild	Moderate	Severe	Extreme
A10. Rising from be				
None	Mild	Moderate	Severe	Extreme
A11. Taking off soc	eks/stockings			
None	Mild	Moderate	Severe	Extreme
		ntaining hip position		.
None	Mild	Moderate	Severe	Extreme
A13. Getting in/out	of bath			
None	Mild	Moderate	Severe	Extreme
A14. Sitting			-	
None	Mild	Moderate	Severe	Extreme
A15. Getting on/off				
None	Mild	Moderate	Severe	Extreme
		s heavy boxes, scrubb		.
None	Mild	Moderate	Severe	Extreme
A17. Light domestic			-	_
None	Mild	Moderate	Severe	Extreme

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your hip.

SP1. Squatting				
None	Mild	Moderate	Severe	Extreme
SP2. Running				
None	Mild	Moderate	Severe	Extreme
SP3. Twisting/pivo				
None	Mild	Moderate	Severe	Extreme
SP4. Walking on u	neven surface			
None	Mild	Moderate	Severe	Extreme
Quality of Life				
Q1. How often are	you aware of you	r hip problem?		
Never	Monthly	Weekly	Daily	Constantly
Q2. Have you mod	lified your life styl	e to avoid activities p	otentially damagin	g to your hip?
Not at all	Mildly	Moderately	Severely	Totally
Q3. How much are	e you troubled with	lack of confidence in	n your hip?	
Not at all	Mildly	Moderately	Severely	Extremely
Q4. In general, how	w much difficulty	do you have with you	r hip?	
None	Mild	Moderate	Severe	Extreme
П	П	П	П	П

Thank you very much for completing all the questions in this questionnaire.

Appendix 8. The Modified Gait Efficacy Scale (mGES).

Appendix.

The Modified Gait Efficacy Scale (mGES)

1. How much confidence do you have that you would be able to safely walk on a level surface such as a hardwood floor?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

2. How much confidence do you have that you would be able to safely walk on grass?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

3. How much confidence do you have that you would be able to safely walk over an obstacle in your path?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

4. How much confidence do you have that you would be able to safely step down from a curb?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

5. How much confidence do you have that you would be able to safely step up onto a curb?

	1	2	3	4	5	6	7	8	9	10
ſ										

No Confidence Complete Confidence

6. How much confidence do you have that you would be able to safely walk up stairs if you are holding on to a railing?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

7. How much confidence do you have that you would be able to safely walk down stairs if you are holding on to a railing?

	1	2	3	4	5	6	7	8	9	10
ſ										

No Confidence Complete Confidence

8. How much confidence do you have that you would be able to safely walk up stairs if you are NOT holding on to a railing?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

(Continued)

The Modified Gait Efficacy Scale

Appendix.

Continued

9. How much confidence do you have that you would be able to safely walk down stairs if you are NOT holding on to a railing?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

10. How much confidence do you have that you would be able to safely walk a long distance such as ½ mile?

1	2	3	4	5	6	7	8	9	10

No Confidence Complete Confidence

Appendix 9. Randomised pilot trial of the purposeful walking intervention - Bournemouth University research ethics checklist.



Research Ethics Checklist

About Your Checklist	
Ethics ID	45499
Date Created	27/07/2022 15:18:07
Status	Approved
Date Approved	10/08/2022 06:10:24
Risk	Low

Researcher Details	
Name	Shayan Bahadori
Faculty	Faculty of Health & Social Sciences
Status	Postgraduate Research (MRes, MPhil, PhD, DProf, EngD, EdD)
Course	Postgraduate Research - HSS
Have you received funding to support this research project?	No

Project Details	
Title	Can a Purposeful Walk Intervention with a Distance Goal using a Commercially Available Activity Monitor Improve Individuals' Health Outcome Post Total Hip Replacement Surgery
Start Date of Project	08/08/2022
End Date of Project	30/09/2022
Proposed Start Date of Data Collection	15/08/2022
Original Supervisor	Ian Swain
Approver	Samuel Hills

Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)

Participants who have undergone total hip replacement surgery within the post-operative period of 3 to 6 months will be recruited from the local community. Those eligible to take part in the study will be invited to attend a baseline assessment (before the start of intervention) at the Orthopaedic Research Institute, Bournemouth University. Data will be collected on gait, hip related subjective outcome measures (Hip Disability and Osteoarthritis Outcome Score (HOOS) questionnaire), and the effects of the Fitbit Charger 4 (FC4) activity monitor as an assistive device on functional independence, well-being, and quality of life (Psychosocial Impact of Assistive Devices Scale (PIADS) questionnaire). During this visit, participants will be randomised (1:1) either to the *Intervention* or *Control* group. Participants will be given an FC4 activity monitor and instructed on how to operate it. Participants wear their FC4 activity monitor for 5 weeks. During these 5 weeks, participants in the intervention group will be given a personalised outdoor walking daily distance goal. Participants in the control group will not be given any weekly distance target and will be asked to report their daily number of steps and will be advised with a set paragraph outlined as "during the next 5 weeks, walk as much as you feel able. Any amount of walking is better than none. But please listen to your body and walk to a distance and pace level that you feel comfortable." Participants will be invited to attend a final assessment 5 weeks from their baseline appointment, where the baseline measures will be repeated. Participants will be given an activity diary to record their daily walking activity. They will be asked to record the distance walked in kilometers (km) or number

Page 1 of 6 Printed On 30/03/2023 09:13:57

of steps taken, depending on the group they are randomised to, as reported on their activity monitor after each outdoor walk.

Filter Question: Does your study involve Human Participants?

Participants

Describe the number of participants and specify any inclusion/exclusion criteria to be used

Twelve adults who have had THR surgery due to symptomatic hip osteoarthritis and are at least 3 months and at most 6 months post-surgery will be recruited.

Inclusion

Participants meeting all the following inclusion criteria will be considered for participation within the study:

- Male and female, aged 60 years and over;
- 3 to 6 months post unilateral total hip replacement surgery for osteoarthritis;
- Can provide verbal confirmation that they have been discharged from their surgical care;
- · Capable of independent walking;
- Capable of completing the activity diary independently;
- Have access to smartphone or computer;
- Willing to complete the trial protocol.

Exclusion

Participants will be excluded if they meet any of the following criteria:

- · Unable to provide informed consent;
- Unable to complete follow-up (insufficient English, lives overseas, unable to return easily);
- Not physically able to use Grail gait lab;
- Systematic disease affecting walking ability (chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), chronic kidney disease (CKD), parkinson's, cerebral palsy, multiple sclerosis);
- Requiring revision hip replacement;
- Previous hip replacement (resurfacing or THR) on the contralateral side;
- Known metastatic tumour involving the hip.

Do your participants include minors (under 16)?	No
Are your participants considered adults who are competent to give consent but considered vulnerable?	No
Is a Disclosure and Barring Service (DBS) check required for the research activity?	No

Recruitment

Please provide details on intended recruitment methods, include copies of any advertisements.

Twelve adults who have had THR surgery due to symptomatic hip osteoarthritis and are at least 3 months and at most 6 months post-surgery, will be recruited using publicising tools such as posters and Twitter posts (Figure 1), shared on the University channels (Bournemouth University research blogs, the Public Involvement in Education and Research (PIER) group), at local leisure centres, University of Third Age (U3A), community of older adults and physiotherapy centres. Those interested in the study will be asked to contact the lead researcher (SB) for more information. Once an individual has expressed an interest in taking part, the lead researcher will email the individual a copy of the participant information sheet (PIS). To comply with Good Clinical Practice (GCP) guidelines, SB will ensure that the participant has sufficient time (48 hours) to consider their participation within the study. Interested participant will then be contacted via a telephone call for initial screening to ensure they meet the pre-determined eligibility criteria (section 2.3). Each participant will be advised that they are under no obligation to take part and can withdraw at any time without providing a reason. If the participant decides to proceed with the study, they will be asked to complete an informed consent form at their baseline assessment. The original signed consent form will be kept in the Study Site File and participants will be provided with a copy.

No

Data Collection Activity	
Will the research involve questionnaire/online survey? If yes, don't forget to attach a copy of the questionnaire/survey or sample of questions.	Yes
How do you intend to distribute the questionnaire?	
face to face	
Will the research involve interviews? If Yes, don't forget to attach a copy of the interview questions or sample of questions	No
Will the research involve a focus group? If yes, don't forget to attach a copy of the focus group questions or sample of questions.	No
Will the research involve the collection of audio recordings?	No
Will your research involve the collection of photographic materials?	No
Will your research involve the collection of video materials/film?	No
Will the study involve discussions of sensitive topics (e.g. sexual activity, drug use, criminal activity)?	No
Will any drugs, placebos or other substances (e.g. food substances, vitamins) be administered to the participants?	No
Will the study involve invasive, intrusive or potential harmful procedures of any kind?	No
Could your research induce psychological stress or anxiety, cause harm or have negative consequences for the participants or researchers (beyond the risks encountered in normal life)?	No
Will your research involve prolonged or repetitive testing?	No
What are the potential adverse consequences for research participants and how will you minimise them?	

Consent

Describe the process that you will be using to obtain valid consent for participation in the research activities. If consent is not to be obtained explain why.

Those interested in the study will be asked to contact the lead researcher (SB) for more information. Once an individual has expressed an interest in taking part, the lead researcher (SB) will email the individual a copy of the participant information sheet (PIS). To comply with Good Clinical Practice (GCP) guidelines, SB will ensure that the participant has sufficient time (48 hours) to consider their participation within the study. Interested participant will then be contacted via a telephone call for initial screening to ensure they meet the pre-determined eligibility criteria. Each participant will be advised that they are under no obligation to take part and can withdraw at any time without providing a reason. If the participant decides to proceed with the study, they will be asked to complete an informed consent form at their baseline assessment. The original signed consent form will be kept in the Study Site File and participants will be provided with a copy.

Do your participants include adults who lack/may lack capacity to give consent (at any point in the study)?	No
Will it be necessary for participants to take part in your study without their knowledge and consent?	No

Participant Withdrawal

At what point and how will it be possible for participants to exercise their rights to withdraw from the study?

Each participant will be advised that they are under no obligation to take part and can withdraw at any time without providing a reason.

If a participant withdraws from the study, what will be done with their data?

As per BU statement:

After they decide to withdraw from the study, we will not collect any further information from or about them. As regards to information we have already collected before this point, participants right to access, change or move that information are limited. This is because we need to manage their information in specific ways in order for the research to be reliable and accurate.

Further explanation about this is in the Personal Information section section of PIS document.

Participant Compensation	
Will participants receive financial compensation (or course credits) for their participation?	No
Will financial or other inducements (other than reasonable expenses) be offered to participants?	No

Research Data	
Will identifiable personal information be collected, i.e. at an individualised level in a form that identifies or could enable identification of the participant?	Yes
Please give details of the types of information to be collected, e.g. personal characteristics, education, work role, opinions or experiences	
Height, weight, and email address. All participants entered onto the database will be assigned a participant ID number, allowing for protection of the participant's identity	
Will the personal data collected include any special category data, or any information about actual or alleged criminal activity or criminal convictions which are not already in the public domain?	No
Will the information be anonymised/de-identified at any stage during the study?	Yes
Will research outputs include any identifiable personal information i.e. data at an individualised level in a form which identifies or could enable identification of the individual?	No

Storage, Access and Disposal of Resear	ch Data
During the study, what data relating to the participants will be stored and where?	Daily walking distance or step count, gait, the activity of daily living, height, weight, and email address. Data will be collected on an electronic case report form (eCRF), using a secure, web-based portal (Actipath). Data will be stored in this database. All participants entered onto the database will be assigned a participant ID number, allowing for protection of the participant's identity. Information with regards to study participants will be kept confidential and managed in accordance with data protection legislation, the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving research/policies-standards-legislation/uk-policy-framework-health-social-care research/) and Research Ethics Committee. Please find attached documents for further information.
How long will the data relating to participants be stored?	All research data will be stored securely in adherence with the BU Data Protection Act Policy and the EU General Data Protection Regulations (GDPR). All data relating to this study will be kept for 5 years on a BU password protected secure network. All data will be anonymised.

Page 4 of 6 Printed On 30/03/2023 09:13:57

During the study, who will have access to the data relating to participants?	The database is restricted, user authentication is required to input or view research data and the amount of data that can be viewed by a user will be determined by their role, as defined in the data management plan and the delegation log. Any data entered to the database is managed with an audit trail that will record the username of all those entering and /or changing data in this study.
After the study has finished, what data	Daily walking distance or step count, gait, the activity of daily living, height, weight, and email address. Data will be collected on an electronic case report form (eCRF), using a secure, webbased portal (Actipath). Data will be stored in this database. All participants entered onto the database will be assigned a participant ID number, allowing for protection of the participant's identity.
relating to participants will be stored and where? Please indicate whether data will be retained in identifiable form.	Information with regards to study participants will be kept confidential and managed in accordance with data protection legislation, the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving research/policies-standards-legislation/uk-policy-framework-health-social-care research/) and Research Ethics Committee
	Please find attached documents for further information.
After the study has finished, how long will data relating to participants be stored?	All research data will be stored securely in adherence with the BU Data Protection Act Policy and the EU General Data Protection Regulations (GDPR). All data relating to this study will be kept for 5 years on a BU password-protected secure network. All data will be anonymised.
After the study has finished, who will have access to the data relating to participants?	Only authorised members of the research team will have access to this research data.
Will any identifiable participant data be transferred outside of the European Economic Area (EEA)?	No
How and when will the data relating to participants be deleted/destroyed?	All data relating to this study will be kept for 5 years on a BU password protected secure network and destroyed in according with data ethics standard procedure.
Once your project completes, will your dataset be added to an appropriate research data repository such as BORDaR, BU's Data Repository?	Yes

Dissemination Plans		
How do you intend to report and disseminate the results of the study?		
Peer reviewed journals,Conference presentation		
Will you inform participants of the results?	No	
If Yes or No, please give details of how you will inform participants or justify if not doing so		
Participants will have an opportunity to see their data at the end of each assessment day.		

Final Review	
Are there any other ethical considerations relating to your project which have not been covered above?	No

Page 5 of 6 Printed On 30/03/2023 09:13:57

Yes

A 11			
Affac	nea	docu	ments

Study Protocol.docx - attached on 04/08/2022 08:57:38

Appendices.docx - attached on 04/08/2022 08:59:20

Activity Diary (control).docx - attached on 04/08/2022 08:59:36

Activity Diary (intervention).docx - attached on 04/08/2022 08:59:42

HOOS Questionnaire.pdf - attached on 04/08/2022 08:59:52

Participant Agreement Form.docx - attached on 04/08/2022 08:59:59

Poster.ppt - attached on 04/08/2022 09:00:40

PIADS Questionnaire.pdf - attached on 04/08/2022 09:01:54

Participant Information Sheet.docx - attached on 09/08/2022 15:27:43

Page 6 of 6 Printed On 30/03/2023 09:13:57

Appendix 10. Consort Checklist – Pilot trial.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	3-4
objectives	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	9
•	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	10
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	10
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

CONSORT 2010 checklist Page 1

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11-13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-17
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist Page 2

Appendix 11. The Psychosocial Impact of Assistive Devices Scale (PIADS).

								mo	onth/day/year
Clier	nt Name:			□ m	ale 🗆	female			
(last name, then first name)									
Diagnosis:				Date	of Birtl	h:		- /da/a	
The	form is being filled out at (choose		1 D hor						
The	form is being filled out by (choose	se one)	1. □ 1101 1 □ the	client v	vithout a	ny heln	2. □ 1	he clien	t with help fro
the o	caregiver (e.g., client showed or to	old care	giver wl	nat answ	ers to gi	ve) 3.	□ the o	aregive	r on behalf of t
clier	nt, without any direction from the	client	4. □ c	ther (de	scribe):				
	word or phrase below describes h								
unusu	ial but it is important that you ans	wer eve	ery one o	of the 26	items.	So, for e	each wor	d or phr	ase, put an "X"
tne ap	ppropriate box to show how you a	re arrec	rtea by u	ising the			 		_ (device nam
	Decreases	-3	-2	-1	0	1	2	3	Increases
1)	competence								
2)	happiness								
3)	independence								
4)	adequacy								
5)	confusion								
6)	efficiency								
7)	self-esteem								
8)	productivity								
9)	security								
10)	frustration								
11)	usefulness								
12)	self-confidence								
13)	expertise								
14)	skillfulness								
15)	well-being								
16)	capability								
17)	quality of life								
18)	performance								
19)	sense of power								
20)	sense of control								
21)	embarrassment								
22)	willingness to take chances								
23)	ability to participate								
24)	eagerness to try new things								
25)	ability to adapt to the								
	activities of daily living								
26)	ability to take advantage of opportunities								
H. Dav	/ & J. Jutai, 1996								

Today's Date:

Psychosocial Impact of Assistive Devices Scale (PIADS)

For more information about PIADS contact: Jeffrey W. Jutai, PhD, University of Ottawa, 613-562-5800 x8218. email: jjutai@uottawa.ca

Appendix 12. Activity diary – Intervention group – Pilot study.

Activity diary (Intervention)

NAMF		
 	 	

Please use this diary to record your daily activity starting from week 2. We would like you to record the amount of distance you walked in kilometres (Km) as recorded on your activity monitor and how intensely you felt you were exercising on average (Borg Scale). The Borg Scale is provided for you below, please use this as a guide and score yourself out of 10, (e.g. 1/10 representing hardly any exertion and 10/10 representing maximum effort).

Bring your activity diary with you to your follow-up assessment for review by the research team.

RPE Scale	Rate of Perceived Exertion
10	Max Effort Activity Feels almost impossible to keep going. Completely out of breath, unable to talk. Cannot maintain for more than a very short time.
9	Very Hard Activity Very difficult to maintain exercise intensity. Can barely breath and speak only a few words
7-8	Vigorous Activity Borderline uncomfortable. Short of breath, can speak a sentence.
4-6	Moderate Activity Breathing heavily, can hold short conversation. Still somewhat comfortable, but becoming noticeably more challenging.
2-3	Light Activity Feels like you can maintain for hours. Easy to breathe and carry a conversation
1	Very Light Activity Hardly any exertion, but more than sleeping, watching TV, etc

Date (Please write the date for every entry below)	DO NOT WRITE ANYTHING HERE	Daily Walk	Please use this section to expand on any condition/feelings which may have affected your daily outdoor walk for this day
	Total Distance (κm)		
	Intensity (Borg Scale i.e. 4/10)		

Total Distance (km)		
Intensity (Borg Scale i.e. 4/10)		
Total Distance (Km)		
Intensity (Borg Scale i.e. 4/10)		

	Total Distance (κm)		
	Intensity (Borg Scale i.e. 4/10)		
	Total Distance (Km)		
	Intensity (Borg Scale i.e. 4/10)		

Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	
Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	

Total Distance (km)	
Intensity (Borg Scale i.e. 4/10)	
Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	

Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	
Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	

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 Intensity (Borg Scale i.e. 4/10)	
Total Distance (km)	
Intensity (Borg Scale i.e. 4/10)	

Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	
Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	

Total Distance (km)		
Intensity (Borg Scale i.e. 4/10)		
Total Distance (κm)		
Intensity (Borg Scale i.e. 4/10)		

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Total Distance (Km)		
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Total Distance (km)		
Intensity (Borg Scale i.e. 4/10)		

Total Distance (Km)	
Intensity (Borg Scale	
i.e. 4/10)	
Total Distance (Km)	
Intensity (Borg Scale	
i.e. 4/10)	

Total Distance (Km)	
Intensity (Borg Scale i.e. 4/10)	

Appendix 13. Activity diary — Control group — Pilot study.

Activity diary (Control)

Please use this diary to record your daily activity starting from week 2. We would like you to record the amount of steps you walked as recorded on your activity monitor and how intensely you felt you were exercising on average (Borg Scale). The Borg Scale is provided for you below, please use this as a guide and score yourself out of 10, (e.g. 1/10 representing hardly any exertion and 10/10 representing maximum effort).

Bring your activity diary with you to your follow-up assessment for review by the research team.

RPE Scale	Rate of Perceived Exertion
10	Max Effort Activity Feels almost impossible to keep going. Completely out of breath, unable to talk. Cannot maintain for more than a very short time.
9	Very Hard Activity Very difficult to maintain exercise intensity. Can barely breath and speak only a few words
7-8	Vigorous Activity Borderline uncomfortable. Short of breath, can speak a sentence.
4-6	Moderate Activity Breathing heavily, can hold short conversation. Still somewhat comfortable, but becoming noticeably more challenging.
2-3	Light Activity Feels like you can maintain for hours. Easy to breathe and carry a conversation
1	Very Light Activity Hardly any exertion, but more than sleeping, watching TV, etc

Date (Please write the date for every entry below)	DO NOT WRITE ANYTHING HERE	Daily Steps	Please use this section to expand on any condition/feelings which may have affected your daily steps for this day
	Total steps		
	Intensity (Borg Scale i.e. 4/10)		

Total steps		
Intensity (Borg Scale i.e. 4/10)		
Total Distance (Km)		
Intensity (Borg Scale i.e. 4/10)		

Total steps		
Intensity (Borg Scale i.e. 4/10)		
Total steps		
Intensity (Borg Scale i.e. 4/10)		

-	Total steps	
	Intensity (Borg Scale i.e. 4/10)	
-	Total steps	
 	Intensity (Borg Scale i.e. 4/10)	

Total steps		
Intensity (Borg Scale i.e. 4/10)		
Total steps		
Intensity (Borg Scale i.e. 4/10)		

Total steps	
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Intensity (Borg Scale i.e. 4/10)		

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Intensity (Borg Scale i.e. 4/10)		

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Intensity (Borg Scale i.e. 4/10)	

Total steps		
Intensity (Borg Scale i.e. 4/10)		
Total steps		
Intensity (Borg Scale i.e. 4/10)		

Total steps	
Intensity (Borg Scale i.e. 4/10)	