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An mHealth Walking Intervention for Pregnant Women with Obesity

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Abstract

Introduction: Adverse maternal and infant health outcomes are associated with a rise in obesity and excessive gestational weight gain, which may be modified with physical activity in pregnancy. Using mobile health technology has the potential to reach widely at a low cost, to deliver physical activity interventions founded upon behaviour change theory to support women with gestational weight gain management.

Aim: To establish the feasibility, practicality and acceptability of a walking-based intervention for women who are pregnant and obese. Specific objectives were to; conduct a systematic literature review; develop and test the feasibility, of a walking intervention for women who are pregnant and obese using mobile health technology; qualitatively evaluate participants' and health professionals' views on the intervention design; design a protocol for a definitive RCT intervention.

Methods: A systematic review was conducted investigating the components and effectiveness of walking interventions for women who are pregnant and obese. Following this, feasibility randomised controlled trial, of a physical activity intervention to women who are pregnant and obese, delivered via Facebook, was implemented. It was developed using the Capability, Opportunity, Motivation-Behaviour model as per National Institute of Health and Care Excellence guidelines, to deliver self-monitoring, goal-setting and 'information about health consequences' behaviour change techniques. Semi-structured interviews with participants and health professionals assessed the acceptability of the intervention. Primary outcome measures were feasibility of recruitment, attrition, and trial procedures. Secondary outcomes were: engagement in Facebook group, physical activity, gestational weight gain, maternal and infant outcomes.

Results: The systematic review identified two eligible studies, both underpowered but showing a trend in improved maternal outcomes. For the feasibility trial, 40 women were recruited. Retention rate was 85% in the intervention and 75% in the control group. Participants were compliant to wearing Fitbit (intervention arm 32/35 days and the control 28/35 days). In the intervention arm, 20/20 participants joined the Facebook group. The level of engagement varied, with some active and some 'lurking' participants. The interviews revealed that participants found it practical and convenient to access health information via a closed Facebook group.

Conclusion: Recruitment and adherence rates and Facebook participation, suggest that the study is feasible and acceptable. Findings from the feasibility study informed the final protocol of a large size randomised controlled trial, to test the effectiveness of a mobile health-based walking intervention.

Candidate Statement

I wish to acknowledge the help and contribution I have received throughout my PhD studies.

I received help with my systematic review, from Deborah Harrop (Information Scientist), acting as a second reviewer, in relation to literature searching, data extraction, collection and analysis. Statistical advice was received from Karen Kilner, a statistician within the Faculty.

The rest of the PhD work was conducted by me. I decided on the intervention components and method of delivery and presented the design to a Patient and Public Involvement (PPI) group for the purpose of refinement. Thereafter, I obtained all NHS ethical and national and local governance approvals. I was responsible for all recruitment and data collection, including interviewing of participants and health care professionals. I conducted all quantitative and qualitative data analysis. Throughout, I was advised and guided by my supervisors.

Acknowledgements

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Abbreviations

ACOG	American College of Obstetricians and Gynaecologists
AMSTAR	A Measurement Tool to Assess Systematic Reviews
APEASE	Acceptability, Practicality, Effectiveness Criteria
BCT	Behaviour Change Technique
BCW	Behaviour Change Wheel
BMI	Body Mass Index
COM-B	Capability, Opportunity, Motivation-Behaviour
CONSORT	Consolidated Standards of Reporting Trials
FB	Facebook
FFQ	Food Frequency Questionnaire
FM	Facebook Messenger
GCP	Good Clinical Practice
GRADE and Evaluation	Grading of Recommendations Assessment, Development
HP	Health Care Professional
HTA	Health Technology Assessment
IOM	Institute of Medicine
IPD	Individual Person Data
IT	Information Technology
LGA	Large for Gestational Age
mHealth	Mobile Health
MET	Metabolic Equivalent
MRC	Medical Research Council
MVPA	Moderate Vigorous Physical Activity
NHS	National Health Service
NICE	National Institute for Health and Care Excellence

OSG	Online Social Group
PEQ	Process Evaluation Questionnaire
PHIAC	Public Health Interventions Advisory Committee
PIS	Patient Information Sheet
PPAQ	Physical Activity in Pregnancy Questionnaire
PPI	Patient and Public Involvement
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised Controlled Trial
SM	Social Media
SCBU	Special Care Baby Unit
WHO	World Health Organisation

Glossary

American Institute of Medicine (IOM) Guidelines on Weight Management in Pregnancy: Guidance that specifies target ranges for weight gain during pregnancy and guidelines for proper measurement (1990 and revised 2009)

Antenatal/prenatal: the period before the birth.

Body Mass Index: A key index for relating a person's body weight to their height. The body mass index (BMI) is a person's weight in kilograms (kg) divided by their height in meters (m) squared (kg/m²).

Cadence: Cadence is the rate at which a person walks, expressed in steps per minute. The average cadence is 100 - 115 steps/min.

Facebook: A social networking website that allows registered users to create profiles, send messages, and upload photos and videos.

Gestational Diabetes Mellitus (GDM): Carbohydrate intolerance of varying severity which is diagnosed in pregnancy and may or may not resolve after pregnancy.

Gestational Weight Gain (GWG): Amount of weight gained between conception and just before the birth of the infant.

Information Technology: Information technology (IT) is the use of computers to store, retrieve, transmit, and manipulate data, or information.

Low birth weight: A baby weighing less than 2500 grams at birth.

Macrosomia: An infant weighing over 4000 grams at birth

MET: One MET is defined as energy expenditure of 1 kcal/kg/hour. It is roughly equivalent to the energy cost of sitting quietly.

Mobile Health Technology (mHealth Technology): Mobile health is a general term for the use of mobile phones and other wireless technology in medical care. The most common application of mHealth is the use of mobile phones and communication devices to educate consumers about preventive health care services.

Physical activity (PA): Any force exerted by skeletal muscle that results in energy expenditure above resting level. It includes the full range of human movement and can encompass everything from competitive sport to the general activities involved in daily living (such as housework).

Pregnancy Physical Activity Questionnaire (**PPAQ**): A widely used tool for the assessment and measurement of PA levels amongst pregnant women.

RR: Relative Risk is defined as ratio of the probability of an outcome in an exposed group to the probability of an outcome in an unexposed group.

Chapter 1. Introduction

Over half of maternal mortality in the UK is associated with excess body mass and obesity during pregnancy with little or no support in gestational weight management to prevent associated obstetric risks (1). Whilst previous studies (2),(3) have shown that physical activity (PA) can be beneficial during pregnancy, at present, to our knowledge, there is very limited capacity to refer overweight and obese pregnant women to PA classes such as aqua classes or a gym within the National Health Service. Such services where present, vary considerably between providers and there is a very limited understanding of what sort of intervention is acceptable to women and also what is feasible within the UK's National Health Service (4). Any intervention should have a theoretical grounding to maximise effectivity (5). Modern technology and social media (SM), in particular Facebook may be a favourable medium for delivering an intervention to the current young adult female population (6). This PhD project will aim to inform the suitability of a full-scale randomised PA intervention in early pregnancy and its potential benefits to maternal and infant health.

The aim of the first part of this PhD work is to examine the effectiveness of previous walking interventions on gestational weight gain (GWG), and antenatal outcomes in pregnant, obese women by means of a systematic review. The second stage of this PhD work is to systematically develop and test a feasibility study of the intervention design, based on previous findings in the literature, and theoretical underpinnings, and to test novel mobile health (mHealth) technology as delivery tools. The third part of this PhD work is to explore the feasibility and practicality of the intervention, by means of a qualitative process evaluation with participants and health professionals. Based on the feasibility study and the process evaluation findings, the fourth stage, is the development of a protocol of a fully powered randomised controlled trial.

Structure of the thesis

This research investigates the feasibility of a PA intervention in pregnant women with a raised body mass index (BMI). It explores the practicality of implementing a PA intervention within the National Health Services (NHS). Given the potential benefits of promoting PA in this group of women,the possible barriers and

facilitators to intervention implementation are explored with participants and health professionals (HPs).

Chapter 2 seeks to set the context to this project. It will begin by explaining the pressing public health issue that is maternal obesity and the associated risks. It will then review the literature surrounding obesity related pregnancy complications and the potential role of PA as a modifiable risk factor. Evidence surrounding PA during pregnancy, current national guidelines and interventions studies aiming to increase PA are presented. The views, attitudes and opinions of women in relation to PA in pregnancy are explored. It presents the evidence base for a theoretically underpinned intervention development and the selection of the COM-B model to systematically select behaviour change techniques in the intervention design. The chapter also reviews the evidence-base for a remote intervention delivery method using mHealth technology and SM in particular. The chapter ends with a presentation of my overall rationale for the PhD study.

Chapter 3 sets out the aim and objectives of the PhD thesis.

Chapter 4 presents the set of guidelines that were produced by the Medical Research Council (MRC) on the development of complex interventions, which were followed. It explores the epistemological stance, and the methodological and philosophical underpinnings of the research that have formed the study design. It presents the rationale behind the choice of a pragmatism paradigm and the choice of methodology.

Chapter 5 is a systematic review of the state of current evidence on the effects of walking interventions on GWG in women who are pregnant and obese. It presents the systematic review protocol, including search strategy, inclusion criteria as well as main findings. It concludes with a summary of how the findings from the systematic review have informed the development of the intervention.

Chapter 6 describes the development of a theory-based intervention and systematic selection of behaviour change techniques using Behaviour Change Theory and the 'Capability, Opportunity, Motivation'-Behaviour model (COM-B model). It presents a step-by-step application of the behaviour change wheel, which allowed for a systematic selection of behaviour change techniques.

Chapter 7 describes the protocol of the feasibility randomised controlled trial. It outlines the design, methods, data collection and analysis that formed the feasibility RCT protocol.

Chapter 8 presents quantitative findings related to the feasibility and acceptability of conducting the trial. This includes information on recruitment rate to determine the suitability of eligibility criteria, the effectiveness of the recruitment strategy, attrition and adherence data. Quantitative analysis of Facebook engagement is presented, followed by a qualitative analysis of Facebook content. In the last section of the chapter, changes in secondary outcomes such as PA (steps), gestational weight gain and other measures are explored, comparing the intervention and control groups.

Chapter 9 presents findings of a thematic analysis of semi-structured interviews with study participants and health professionals. During the interviews, views and perceptions of the intervention in terms of acceptability and feasibility are explored.

Chapter 10 presents a summary of findings of the thesis. It provides a discussion of both quantitative and qualitative evaluation of the feasibility RCT. It also presents an evaluation of the methodology and study procedures, suggestions for improvement and recommendations for a future large RCT.

Chapter 11 presents a summary of the unique contribution to knowledge, as well as provide a reflection on my PhD journey and recommendations for research and practice beyond protocol development.

2. Background & Literature Review

2.1 Introduction

There are two parts to this chapter. The first part will seek to set the context to this project. It will begin by explaining the pressing public health issue that is maternal obesity, excessive gestational weight gain (GWG) and the associated risks. It will describe GWG guidelines, physical activity (PA) guidelines during pregnancy and patterns of PA levels during pregnancy. The second part of this chapter will provide a literature review and summarise the findings of previous research relevant to this study. It will critically analyse systematic reviews of PA interventions in pregnancy, barriers to PA in pregnancy and barriers that health professionals (HPs) face when delivering PA and lifestyle advice to women who are pregnant and obese. It will seek to analyse the evidence base for a theoretically underpinned intervention development and the selection of the Capability, Opportunity and Motivation-Behaviour model to systematically select behaviour change techniques (BCTs) in the intervention design. It will also review the effectiveness of social media (SM) and information technology (IT) interventions. The chapter will conclude with an exploration of the potential of a remotely delivered PA intervention using mobile health (mHealth) technology.

2.2 Contextual Background

The Centre for Maternal and Child Enquiries (CMACE) report in 2010 found that over half of maternal mortality is associated with overweight and obesity during pregnancy in the UK (1). The report found that entering pregnancy in an obese state, as well as gaining an excessive amount of weight during pregnancy causes obesity-associated co-morbidities (6). For instance, women who enter pregnancy in an obese state and experience excessive GWG are more likely to experience a change in metabolism, which reduces insulin sensitivity (7),(8). These metabolic changes are possible leading causes of gestational diabetes mellitus (GDM), preeclampsia and macrosomia, leading to an increased risk of Caesarean section (C-section) (7). A rise in these complications poses a great challenge to obstetric care (5).

The focus of this thesis therefore is to develop an intervention that reduces the risks associated with obesity and excessive weight gain in this at-risk population.

2.2.1 Definition and Prevalence of Maternal Obesity in the UK

The World Health Organisation (WHO) has classified obesity in three BMI classes; Class 1 moderate (30-34.99), Class II, severe (35-39.9) and Class III very severe (≥40). In the UK, obesity rates among women of reproductive age have increased steadily (10).There are no official national statistics for maternal obesity in the UK, however a national study from 2010 which examined 619 323 births from 1989 to 2007 of a nationally representative sample found that steadily increasing obesity rates result in 20% of women entering pregnancy in an obese state (11). This thesis will include women from all three obesity BMI classes. The definitions of these are summarised in Table 1 (9).

From: *WHO Obesity: Preventing and Managing the Global Epidemic Report of a WHO Consultation (WHO Technical Report Series 894, 2000* (12)*.*

Table 1. World Health Organisation Overweight and Obesity Classification

Classification	BMI (kg/m²)
Underweight	<18.5
Normal Range	18.5-24.9
Overweight	≥25
Pre-obese	25-29.9
Obese Class I	30-34.9
Obese Class II	35-39.9
Obese Class III	≥40

2.2.2 Gestational Weight Gain Guidelines

In the UK, there are no national guidelines on recommended GWG (13) for any BMI categories, due to a lack of robust country specific evidence on safety and positive clinical outcomes. Currently, the only guidance on GWG is by the Institute of Medicine (IOM) in the United States, which recommends that women who are obese gain no more than 5–9 kilograms during pregnancy (14) (see Table 2). The guidelines are based on observational evidence only which suggest that women with GWG within IOM ranges are more likely to have better maternal and infant outcomes (14). As there is no statistical evidence, for these findings, they are not implemented in the UK (16). Therefore, more research is needed on this topic as a lack of GWG guidelines poses a challenge to GWG management and support.

From: Weight Gain During Pregnancy- *Re-examining the Guidelines.*
Rasmussen et al., (2009). (14)

Table 2. Recommended Weight Gain during Pregnancy

Pre-pregnancy BMI	Total weight gain at term	Rate of weight gain in second and third trimester, mean (range)
Underweight, <18.5 kg/m^2	12.5–18 kg	0.51 kg/wk
Normal weight, 18.5–24.9 kg/m^2	11.5–16 kg	0.42 kg/wk
Overweight, 25.0–29.9 kg/m^2	7–11.5 kg	0.28 kg/wk
Obese, ≥30.0 kg/m^2	5–9 kg	0.22 kg/wk

2.2.3 Excessive Weight Gain according to IOM Guidelines

Studies that measured the prevalence of excessive GWG (according to the American IOM guidelines) found that that more than 40% of women gained excessively (8). They also found that whilst all BMI categories gain excessive weight (8), (17), women who are obese have a high prevalence of excessive GWG (45-63%) (18). For this reason, this research is aiming to develop a strategy to support women who are already obese with GWG management. Figure 1 is showing the percentage of excessive GWG among all BMI groups.

Figure 1. Prevalence of Excessive GWG and Pre-pregnancy BMI (USA-based)

From: Obesity, pregnancy outcomes and Caesarean section: a structured review of the combined literature. by Pignon et al., 2013 (5).

Figure: Proportion (Inadequate / Adequate / Excessive) by prepregnancy body mass index (percentage of total sample).
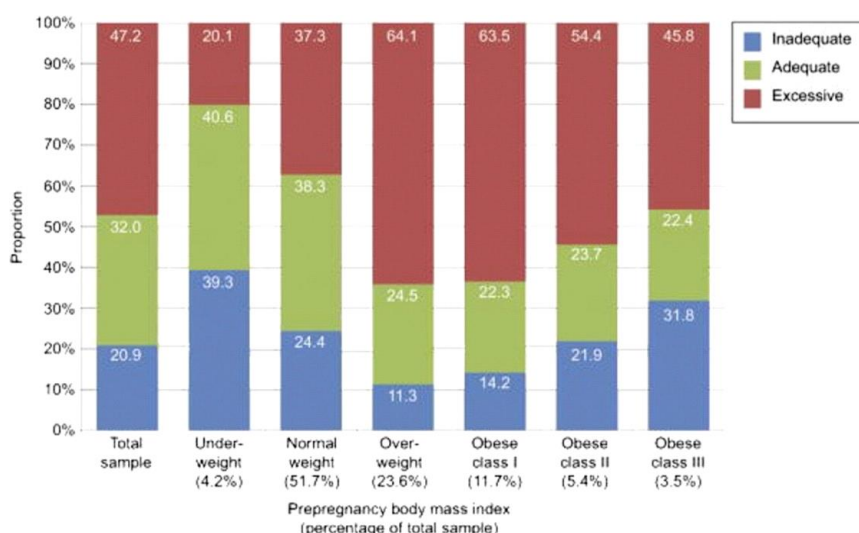
2.2.4 Modifiable Factors to Control GWG

GWG can be controlled by a combination of energy intake (diet) and energy expenditure (physical activity). Dietary interventions focus on controlling energy intake by limiting intake of some macro nutrients (for instance reducing the amount of carbohydrates or fat). Physical activity interventions focus on increasing structured exercise, PA or both. The important distinction between structured exercise and PA is that structured exercise is defined as planned, structured, and repetitive, with the final or intermediate objective being the improvement or maintenance of physical fitness. In contrast, PA includes any voluntary movement produced by skeletal muscles that results in energy expenditure and encompasses a range of recreational, occupational, and household activities (19). The focus of this research is on PA in order to determine the practicality and effectiveness of a PA intervention to modify excessive GWG. The rationale for this choice is provided in the following sections.

2.2.5 Guidelines & Recommendations for PA in Pregnancy

National Institute for Health and Care Excellence (NICE) guidelines (20) advise all women, particularly women who are obese, to be physically active during pregnancy. In 2017, a Physical Activity and Pregnancy Study, commissioned by the UK Chief Medical Officers produced an infographic for health professionals (HPs) to use with the public with a summary of amount, intensity and duration of PA that women in pregnancy should do.

*From: Department of Health Physical Activity in Pregnancy Infographic, 2017.
(21)*

Figure 2 infographic was based on evidence from the systematic review of reviews of randomised controlled trials of physical activity and pregnancy (22). The same review also examined the association between PA and birth outcomes. It found that there were four outcomes with positive effects: 1. Reduction in hypertensive disorders; 2. Improved cardiorespiratory fitness; 3. Lower GWG; 4. Reduction in risk of gestational diabetes. Based on these findings The Royal College of Obstetricians and Gynaecologists (RCOG) (23) UK guidelines recommend 150 minutes of moderate PA per week for pregnant women (24). Similarly, the American College of Obstetricians and Gynaecologists guidelines recommend that pregnant women do 30 minutes or more of moderate exercise a day, in the absence of medical or obstetric complications, on most days of the week (25).

2.2.6 Why Focus on Physical Activity as a Modifiable Factor

The focus of this research on PA solely is to investigate whether maintaining PA throughout pregnancy can on its own have a positive effect on pregnancy outcomes and whether a PA intervention is feasible to implement in the current care pathway. Despite recommendations from the Royal College of Obstetricians and Gynaecologists (RCOG) (30), studies, including the one that is shown in Figure 3 have found that objectively measured PA decreases throughout pregnancy, in particular in the third trimester and more so in women who are obese (31). The graph also shows that women who are obese are less active/ more sedentary at any time point throughout pregnancy, compared to the normal weight group (32). Because it is known that PA levels decrease throughout pregnancy, it is important to explore whether changing this modifiable factor alone can have a positive impact on pregnancy outcomes. This research has therefore been focused on establishing the effectiveness and practicality of PA interventions during pregnancy as well as developing a PA intervention that will address the barriers to PA in pregnancy.

From: Physical activity during pregnancy in normal-weight and obese women: Compliance using pedometer assessment, Renault et al., 2011 p. 432 (32).

Figure 3. PA during Pregnancy in normal and raised BMI categories
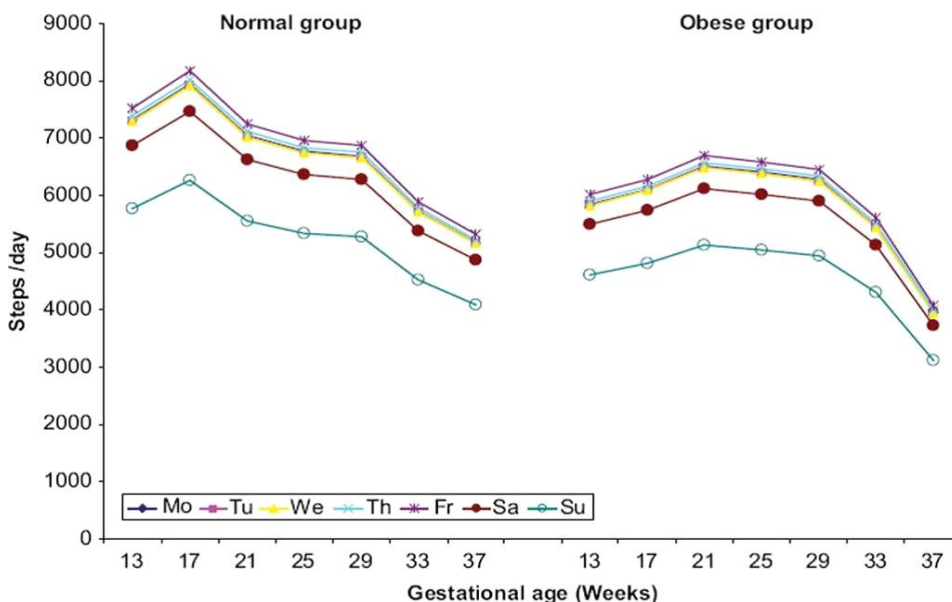
2.2.7 Information Technology Platform as Method of Intervention Delivery

Digital IT platforms (e.g. social media) have a potential to reach widely at a low cost. There is currently a gap in understanding whether remotely delivered PA

interventions during pregnancy are feasible and acceptable to pregnant women who are obese. As resources within the health services are limited, any intervention, if proven effective, would be an additional cost to the health services.

2.2.8 Cost of Maternal Obesity on National Health Services

Despite the RCOG guidelines and the ever-increasing evidence, at present, there is little or no support in gestational weight management to prevent associated obstetric risks within the National Health Services (NHS). In the UK, obesity costs the NHS around £4 billion a year and the economy a further £16 billion in indirect costs (10). Women who are obese place an increasing strain on the NHS when compared with healthy weight counterparts (26). Maternal obesity related complications in pregnancy cost the NHS 37% more per pregnancy (7). Detailed calculations of costs associated with health service use throughout pregnancy and 2 months after the birth, showed that women who are obese utilise an additional £1,200 of NHS resources per pregnancy (26) and additional subsequent healthcare costs associated with infants born to obese mothers (27). In addition, women who are obese are more likely to retain weight gained during pregnancy (28). Apart from having a much higher risk of entering a subsequent pregnancy with a raised BMI, these women are at higher risk of developing type 2 diabetes, high blood pressure, and cardiovascular disease later in life (29). This poses even greater risk factors for chronic diseases throughout life and is a great burden on the health services. Therefore, reducing excessive GWG in pregnancy could lead to fewer complications and reduced costs. However, the current care pathway for women with a raised BMI is becoming more medicalised and prepares for the complications rather than implementing preventative measures. This thesis will aim to develop an intervention and test the feasibility of its implementation within the National Health Services. This research will also test its acceptability by women who are pregnant and obese, and health professionals within the National Health Services.

It will consider a remote intervention delivery method in order to reduce the burden on health professionals (HPs). It will also review the use and effectiveness of social media such as Facebook in all populations (33), (34).

In order to inform the development of a PA intervention, the following section will review the literature of effectiveness of lifestyle interventions to lower excessive

GWG and associated risks. It will aim to explore and identify the evidence of active ingredients in combined diet and PA interventions as well as PA-only interventions. This will inform the development and implementation of a theoretically underpinned feasibility randomised controlled trial (RCT). This ultimately will inform future strategies to reduce short and long- term weight related risks for mothers and their offspring. The following section is a literature review of the evidence in order to inform the development of this thesis.

2.3 Literature Review

2.3.1 Search Strategy

The aim of this literature review was to answer key questions that would inform the development of this thesis. The review examines the effectiveness of PA as a modifiable factor that could reduce the risks associated with maternal obesity and excessive GWG. The review also explores the PA recommendations as well as facilitators and barriers to PA in pregnancy. Following the exploration of PA, the review explores the effectiveness of remotely delivered PA interventions that use information technology (IT) and social media (SM). Lastly, the review explores the most common and effective behaviour change techniques (BCTs) in PA interventions.

The review will attempt to answer the following questions:

1. How much PA is required in pregnancy to have an effect?
2. How much PA should pregnant women who are obese do?

3. What are the barriers and facilitators to PA during pregnancy?

4. What is the effect of sedentary behaviour during pregnancy?

5. What is the clinical care pathway for pregnant women who are obese and what are the barriers to care provision?

6. Are remotely delivered interventions using IT and social media effective?

7. Are theoretically underpinned interventions more effective?

8. What are the most common behaviour change techniques in PA interventions?

Whilst not a formal systematic review, the search adopted a structured, explicit method in order to include all available sources of information, modes of research and types of literature. Searches were carried out on the databases: Ovid MEDLINE, EMBASE, and CINAHL and Cochrane database of systematic reviews. Also, The National Institute for Health Care Excellence (NICE), Department of Health and Royal College of Obstetricians and Gynaecologists (RCOG) websites were searched quarterly to monitor the publication of new guidelines

The main search terms were:

Pregnancy AND obesity,

Pregnancy AND physical activity,

Physical activity AND activity measurement,

Pregnancy complications AND obesity

Midwives OR midwifery AND physical activity

Midwives AND obesity

Physical Activity AND Pregnancy AND Barriers

Physical Activity Interventions AND behaviour change AND obesity

Physical Activity Interventions AND Information Technology

Physical Activity Interventions AND Social Media

2.3.2 Inclusion/Exclusion criteria

The inclusion criteria were broad so as to include all possible sources of information regarding PA. Mainly systematic reviews of randomised controlled trials (RCT's) were considered. In addition, the reference lists of included papers and key relevant literature reviews identified during the search process were also examined for additional relevant studies. Also, non-randomised comparative studies, and observational studies were included. Participants were restricted to pregnant women who are overweight and/or obese as it was of particular interest to explore the benefits of PA in this population. There was no restriction on the type of PA measurement methods (objective or subjective). There was also no restriction on the type of outcomes, country of origin, or type of health care provider/professional so as to identify and include all relevant studies carried out in different health care settings. The searches that explored remotely delivered interventions that used social media were not restricted to any particular disease.

2.3.3 Quantity and quality of the identified literature

Two hundred references that were identified were diverse in nature and were categorised according to quality of the study, based on sample size, methods, analyses, reported outcomes. Several hundred references were identified as meeting the inclusion criteria. The quality of the retrieved literature varied enormously, as did the types of reported studies. These included studies reporting small case series to large population based cohort studies. Common weaknesses included small sample size, inappropriate timing of PA measurement and/or population characteristics. A formal quality assessment of included studies was not performed. However, the sample size, case definitions, methods, analyses reported outcomes, and interpretations of findings of each study was considered. References that were not relevant to the thesis were excluded.

2.4 Effectiveness of Combined Dietary & PA Interventions on GWG

Farpour -Lambert et al (2018) reviewed and ranked systematic reviews of interventions employing either combined or individual PA and/or dietary strategies to manage GWG (7). The authors quality assessed the reviews according to the Validation of Revised Assessment of Multiple Systematic

Reviews for Grading of Clinical Relevance (AMSTAR) ranking. This instrument contains 11 questions with a maximum score of 44 points (8).

The Thangaratinam et al., (2012) review of combined diet and PA interventions scored highest (Grade A, 42 out of 44), (9). The other reviews ranked lower due to not adequately describing excluded studies and statistical tests, and for not providing a clinical consensus statement. The Streuling et al, (2011) review of PA-only interventions scored highest (Grade C, 33/44), (10). For this reason, only these 2 reviews will be considered for evidence. A summary of their findings is presented in Table 3. The findings in the context of this thesis are discussed in the following section.

Table 3. Characteristics of the Systematic Reviews of Diet & PA Interventions

Combined Diet & Physical Activity Reviews					
Systematic reviews	R-AMSTAR score	RCTs (n)	BMI Participants (n)	Type of intervention	GWG (kg) 95% CI
Thangaratinam et al. (2012)	A 41/44	31	Any BMI 3,140	Combined Balanced diet: proteins (15–20%), fat (max. 30%), carbohydrates (50–55%) with low glycaemic index; Light to moderate intensity PA (resistance training, weight-bearing exercises, walking)	Combined -1.4kg (0.85-1.89) Diet-Only -3.8kg (2.45-5.2) PA-only -0.7kg (−1.2 −0.25)
Physical Activity Interventions Reviews					
Streuling et al. (2011)	C 33/44	12 RCTs	Any BMI	Physical Activity Only Light-moderate intensity supervised PA; 3 days/week; aerobic and/or resistance	GWG −0.61 kg (−1.17 −0.06)

2.4.1 Findings of Combined (Diet & PA) Intervention Review

The review by Thangaratinam et al., (2012) included 14 studies that involved PA -only interventions, 10 involved a diet-only interventions whilst 7 contained a mixed dietary and PA intervention (9). In terms of inclusion criteria, the antenatal dietary interventions typically focused on eating a balanced diet (focusing on protein, fat and carbohydrates intake) and/or energy targets. Antenatal PA

interventions generally consisted of 20–70 min of exercise per day at light to moderate intensity, 2–5 days per week. The majority of PA interventions were supervised (n=14), for instance aerobic and/or resistance training, whereas 6 included unsupervised PA interventions such as counselling, education and feedback on weight gain.

The review found that combined interventions were effective at reducing GWG (-1.4kg). Interestingly, a subgroup analysis of diet-only and BMI category showed significantly different findings. Diet-only interventions were mainly described as eating a balanced diet consisting of carbohydrates, proteins and fat, and maintenance, food diary keeping, and low glycaemic load. They had greater effects in reducing GWG in women from all BMI classes (-3.8kg) Most significantly to our research is that the greatest effect of dietary intervention compared to standard care (-7.73 kg) was measured in women with BMI$\geq$25kg/m² (Thangaratinam et al., 2012). Studies in dietary interventions in women who were overweight or obese also showed that they significantly reduced the risk of pre-eclampsia (RR 0.6), GDM (RR, 0.39), and gestational hypertension (RR, 0.30). These findings suggest a strong correlation between dietary interventions and lowered GWG and risk of adverse outcomes in pregnancy.

Combined interventions were not as effective at reducing GWG as diet-only interventions (1.4kg vs. 3.8kg) even though no differences in the types of dietary interventions were reported between the combined versus diet-only types. Several possible explanations may be an increase in muscle mass or increased dietary intake to compensate energy expenditure during exercise. However, the review did not report on differences in lean muscle mass or calorie intake. More likely, the lower effective is due to the way in which the mixed interventions are delivered. In mixed approaches the individual components might not be delivered to the same standard. Also, in a multi-component intervention, participants may have struggled with compliance. Dietary interventions may be simpler to deliver in contrast with physical activity in pregnancy

A subgroup analysis of PA-only interventions in the review included aerobic sessions, light intensity resistance training and weight bearing exercises. Some

of the interventions in the mixed approach also included counselling sessions, and education concerning the potential benefit of PA.

The review found that they were least effective at reducing GWG (-0.7kg). PA only interventions had a significant effect on birth- weight only (but no other pregnancy outcomes). The reason may be the level of complexity involved in the implementation of structured PA interventions, which is different than, for instance implementing dietary interventions. Whilst dietary interventions involve modifications to already in-place behaviour, PA interventions usually imply implementation of a new behaviour (exercise). However, previous studies have shown that starting a new behaviour is harder than modifying a current one (11). An exploration of effectiveness of PA-only interventions will be explored in greater depth in the following section.

2.3.4 Effectiveness of Physical Activity-only Interventions on GWG
Four reviews of PA-only interventions were identified in the Farpour-Lambert review. Streuling et al's., (2011) review had the highest rating (33/44, Moderate, Grade C), (10). A meta-analysis of PA interventions found that women in the exercise intervention group gained significantly less weight during pregnancy (-0.61kg), a finding which is similar to the one by Thangaratinam et al., (-0.7kg). However, the Streuling et al., (2012) review also aimed to measure the dose-effect of PA interventions as well as do a more in-depth analysis to compare the types of interventions.

Interventions included varied by type, intensity (2-5 times per week), and duration (20-70 minutes). In terms of results, there were inconsistencies across individual studies. Seven trials reported significantly lower GWG in the intervention group and 5 trials reported that women in the exercise groups did not gain significantly less weight than their counterparts in the control groups. These were mainly education and knowledge-sharing interventions, which suggest that these types of PA interventions are less successful. Unfortunately, the review did not present GWG results for the 5 trials-only, which reported a significant difference. The review's main limitation is therefore that it combines a large variation of types of PA interventions (including unsupervised PA intervention such as education-only versus aerobic and swimming lessons).

Streuling et al., (2011), also tried to estimate metabolic energy equivalents spent in each intervention and compared them to reported GWG. Women in the intervention groups exercised on average 3 times per week, for between 20 minutes to 1 hour. Based on the described exercise activities in the papers, estimates were made of the intended dose of Metabolic Equivalent (METs) for each intervention, reaching a range of 8630–17920. It found no correlation between mean GWG and metabolic energy equivalents (METs) in the intervention and found no dose-dependent effect of exercise on GWG. It is important to note that these MET values are only estimated values of the dose by the reviewer. The review notes that most interventions do not measure/ report changes in PA levels. Difficulties in attending regularly scheduled program sessions were reported, leaving it unclear how the compliance rates impacted the dose received. It may be that poor compliance, is the biggest limitation to better outcomes of PA only interventions. The reasons for poor compliance are underreported and need to be explored.

How these findings inform our research

Variation in PA Intervention Quality and Design

The differences between RCTs included in the reviews are mainly due to a large variation in search and inclusion criteria as well as in differences in intervention design due to varying type of intervention and mode of delivery. For instance, search terminology varied in description of PA such as leisure-time, fitness, walking or swimming as well as decision to include trials with high risk of bias, allocation concealment, small sample size or attrition bias. Variations in the previously mentioned inclusion criteria standards is the reason Streuling et al., (2011) review rated lower in quality than the review by Thangaratinam et al., (2012).

Thangaratinam et al., (2012) reviews found that poor reporting and inadequate description of design make it difficult to identify the active ingredients of PA interventions. It is therefore difficult to fully understand why diet-only interventions are more effective than diet and PA-combined interventions.

Based on the evidence presented, unsupervised PA interventions may have not been effective in promoting behaviour change. Supervised PA interventions seem to be most effective, however they rely on regular attendance, to which there are many barriers such as poor compliance with interventions by participants (39), (40). A Health & Social Care Survey from 2016 found that only 4% of women meet the recommendations for PA, when measured by accelerometer (42). Therefore, for most women, adoption of this new behaviour requires far more change, motivation and planning. Barriers include limitations to time, equipment, access to facilities and both the fear of and actual consequences of PA which may add to the discomfort of pregnancy symptoms such as breathlessness, and mild muscle soreness (43). These barriers may explain why PA interventions during pregnancy do not always produce a statistically significant result, but do generate high attrition rates (10-35%).

This is particularly informative for our research as it demonstrates that although PA interventions show some effectiveness in lowering GWG, more needs to be done to explore what makes PA interventions less effective. It is unclear whether it is the type of PA, compliance, intensity, duration or method of delivery that are resulting in suboptimal results. Currently, there is a lack of robust PA interventions that are systematically designed, evaluated and reported, which is something that this research thesis will aim to address. Our research is aiming to inform whether a remotely delivered PA intervention may be an effective alternative because it addresses some of the above-listed barriers. The aim is to develop an intervention that will allow women to be more active throughout the day and in their own time and place.

Variation in Participant Characteristics
Streuling et al., (2011) combined women of all BMI categories in the analysis. The Institute of Medicine GWG guidelines (12) differ between normal, overweight and obese populations, and this should encourage researchers to report the BMI of their participants. From previous research we know that attendance and participation in PA interventions differs between women of different BMI

categories (44). The meta-analysis in the Streuling et al., (2011) review makes it difficult to compare the differences in acceptability and effectiveness of the intervention between BMI categories.

Variation in Measuring Tools for PA

The results so far, in the individual systematic reviews, have been of insufficient quality to enable recommendations for clinical practice (Streuling et al., 2011, Thangaratinam et al., 2012) especially as the reviews do not present data on retention rate, or compliance. The individual RCTs included in the Streuling et al., (2011) review also did not provide a measure of dose-effect. Many of the interventions have not taken into consideration whether or not the participants in the included studies engaged and complied with the intervention or whether a behaviour change was achieved. Supervised interventions relied heavily on regular attendance. From previous research, we know that a lack of time makes fitting in structured sessions difficult (13). It is impossible to say if a specific intervention is, or is not, effective if there is no evidence that the intervention, or desired behaviour change, has actually been carried out. PA has frequently been measured by self-report which, as previously discussed, is prone to bias and possible overestimation by individuals. These factors make it difficult to compare PA interventions and may therefore produce contradicting results. Alternatively, PA may not have been measured at all thereby making it impossible to show efficacy of the intervention.

Whilst Streuling et al's., (2011) review did not find a dose-response relationship between PA and GWG, several individual RCTs have aimed to measure how much PA during pregnancy is effective. The following section will discuss these findings.

2.3.5 How much PA during pregnancy is effective?

In terms of findings from individual trials, two RCTs (Zavorsky et al., (2011) and Ruchat et al., (2017) determined that increasing PA energy expenditure to a minimum of 16 metabolic equivalent task (MET) hours up to preferably 28 MET hours per week reduces the risk of GDM and hypertensive disorders of pregnancy (i.e. gestational hypertension and pre-eclampsia) (25). To achieve

28 MET hours per week, one could walk at 3.2 km per hour for 11.2 hours per week (2.5 METs, light intensity), or exercise on a stationary bicycle for 4.7 hours per week (~6-7 METs, vigorous intensity). The study found that the more vigorous the exercise, the less total time of exercise is required per week, resulting in ≥60% reduction in total exercise time compared with light intensity exercise (see Table 4).

From: Compendium of Physical Activities: an update of activity codes and MET intensities by Ainsworth et al., (2000) (45).

Table 4. Physical Activity Energy Expenditure

Intensity	MET value	Description*	example
Sedentary	≤1	Resting, no PA effort	Sitting watching TV
Light	1-2.9	Little effort, no change to heart rate	Slow walking, Light housework, Cooking, Ironing
Moderate	3-5.9	Requires moderate effort, accelerates heart rate, still able to hold a conversation	Brisk walking, Cycling for pleasure, Aqua aerobics Active play with children
Vigorous	≥6	Requires a large amount of effort, causes rapid breathing, sweating and substantially increases heart rate	Jogging/running, Heavy lifting, Climbing, Fast swimming or cycling, Shovelling heavy loads

An RCT by Ruchat et al., (2015) investigated the effect of exercise intensity and duration on capillary glucose responses in pregnant women at low and high risk for gestational diabetes. Participants in the study took part in walking sessions three to four times a week, gradually increasing in duration from 25 to 40 minutes. It found that the best decline in glucose concentrations occurred during 25 minutes walking sessions at vigorous intensity for women at high risk of GDM or for 35-40 minutes sessions at low intensity for women at low risk of GDM (46). Similarly, Zavorsky et al., (2011) found that the relative risk (RR) of GDM changed according to total PA. It found that the more vigorous the exercise, the less total time of exercise is required for it to have an effect. The study findings

are illustrated with this example; 3 METs × 1.6 hours per day × 6 days per week = 28.8 MET hours per week; or one can exercise for less time at a higher intensity to achieve the same expenditure (e.g. 5 METs × 0.95 hours per day × 6 days per week = 28.5 MET hours per week (47). This is informative for our research as it indicates that the risk of GDM can be reduced by means of daily walking. As walking is the preferred mode of PA for women, it may be that it may be effective when implemented as part of an intervention (see Figure 4).

From: Exercise guidelines in pregnancy: New perspectives. Sports Medicine. Zavorsky et al., (2011) p. 350 (47).

Figure 4. Relative Risk of GDM and METs Correlation
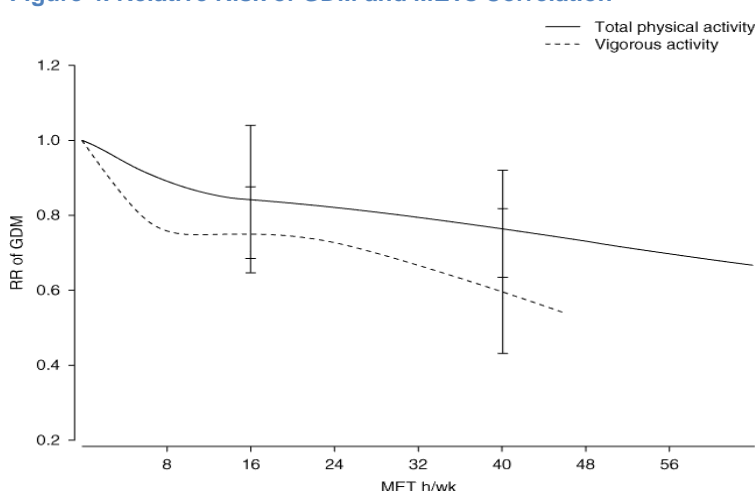
2.3.6 Conclusive Findings to Inform this Thesis

In terms of the effectiveness of PA on pregnancy outcomes, individual trials have been able to show an effect. In terms of systematic reviews of the evidence, structured exercise was the most common type of activity. There is, however variation in its effectiveness. Results from systematic reviews have found a trend of improved outcomes for GWG, GDM, C-section and macrosomia. What is clear is that structured exercise interventions have a high attrition rate and very few interventions have explored whether increasing habitual levels PA may be a solution. This is something that our research will aim to address.

Our research will aim to address the present gap in evidence base. It will aim to systematically design and develop an intervention that addresses the barriers to PA in pregnancy. It will aim to develop PA interventions that are delivered remotely, in order to make it more feasible and acceptable by addressing barriers such as time constraints child care, and cost. Based on the findings from the

reviews, future research should focus on finding the optimal dose (type, frequency, intensity, duration and mode of delivery) as well as the level of supervision in interventions that aim to reduce GWG. Future research should reflect on how to achieve sustainability and long term behaviour change whilst maintaining the cost-effectiveness. Interventions should be feasible in terms of incorporation into clinical settings. This is something that our research will address as well as aim to develop strategies to improve the adherence and compliance to PA interventions.

Better reporting of PA interventions and PA levels will be necessary to draw conclusions about dose-effect as well as effectiveness of PA on maternal and infant outcomes. This issue bridges over with the studies which have attempted to measure the effects of sedentary behaviour during pregnancy. A lack of reporting of dose-effect makes it difficult to estimate what defines 'sedentary behaviour' during pregnancy. The following section will summarise the existing evidence on what we know about sedentary behaviour during pregnancy.

2.4 The Effect of Sedentary Behaviour during Pregnancy

Sedentary behaviour is defined as staying close to the basal metabolic rate, without increasing energy expenditure (48). Activities such as sitting or lying that utilise low amounts of energy are classed as sedentary activity (48). The definition of sedentary behaviour in adults has been changing in the last decade because there is still ongoing research on what quantity and intensity of energy expenditure are needed to lower adverse health risks due to sedentary behaviour. A measure for sedentary behaviour was defined in 2004 by Tudor-Locke and Bassett (49), who introduced the concept of a step index for healthy adults: 1)< 5,000 steps/day ('sedentary'); 2) 5,000-7,499 steps/day ('low active'); 3) 7,500-9,999 steps/day ('somewhat active'); 4) ≥10,000-12,499 steps/day ('active'); and 5) ≥12,500 steps/day ('highly active'). The step index was updated in 2008 as part of an updated review of "How many steps/day are enough?" (50). The following year, the 'sedentary' level (i.e., < 5,000 steps/day) was split into two categories: < 2,500 steps/day ('basal activity') and 2,500-4,999 steps/day ('limited activity') (51). Defining sedentary behaviour in steps for all adults as less than

5000 steps a day may not be the most accurate method for measuring energy expenditure. However, the unit is simple and practical, especially as it can be easily measured by a pedometer. For that reason studies have focused on measuring daily steps count and its association with weight loss and other health outcomes. However it is important to note that by Tudor-Locke and Bassett's categorisation, women who are pregnant may barely qualify as somewhat active (see Figure 3).

A systematic review of sedentary behaviour in pregnancy, which included 26 RCTs, found that pregnant women spent more than 50% of their time in sedentary behaviours and that sedentary behaviours were significantly higher among women who gave birth to macrosomic infants (52). Sedentary behaviour was also shown to be associated with GWG, hypertensive disorders, and birthweight. The main shortcoming of the review is that the definition of time spent in sedentary behaviours varied as did the method of assessment. Studies that used accelerometers defined activities with less than 100 step counts per minute as sedentary behaviours, while activities expending 1.5 metabolic equivalents or less were used for combined heart-rate and activity monitors. Two of the included studies that used a pedometer to measure PA levels defined the term "sedentary" as doing less than 5000 daily steps. Meanwhile, non-objective tools of measuring PA levels, such as Physical Activity in Pregnancy Questionnaire (PPAQ) focused mostly on measuring the amount of television viewing and sitting time.

The included studies had high heterogeneity and high variability in reporting and method of measuring behaviour, and although the review concludes that lowering sedentary time could lower adverse outcomes in pregnancy (48), it remains questionable whether such a conclusion is truly valid.

The review suggests that sedentary behaviour may have a negative impact on pregnancy outcomes. It further demonstrates that the number of daily steps that are required to bring a positive change is unclear. This evidence is informing the development of this thesis as it indicates that any amount of increase of daily steps in our intervention may have a positive impact on pregnancy outcomes.

2.5 How to Measure PA during Pregnancy

Poor quality of PA data in RCTs has been a serious limitation in analysing effectiveness of PA on health outcomes. With the development of new technology

and validated and more user-friendly tools, measuring PA has become easier. PA can be objectively measured using an accelerometer or a pedometer, which are affordable, easy to use, and accurately assess walking, which is the most common activity. The outcome measurements are usually in steps and/or distance walked. Their limitation is that they are not as useful for measuring running, cycling or swimming activities for example (53). In the types of studies which have been reviewed for this project, PA interventions during pregnancy use both objective and subjective ways to assess activity. The guidelines for PA in pregnancy recommend approximately 30 minutes of PA daily or 10,000 steps (14).

It is important to emphasise that the current recommendations on PA are only an estimate (50),(55). Reviews which have examined the effectiveness of pedometers and step counts suggest that PA interventions which employed a step goal have had the greatest impact on increasing physical activity (56), (57). Recent studies in the general population have examined how much of an increase in steps per day is required to achieve an effect on weight and various health outcomes. Bravata et al., (2007) found that an increase of 2500 steps per day is associated with modest weight loss, and improvements in blood pressure (55). Based on the approximation, above, an extra 2,500 steps would imply that 10 minutes of extra exercise per day would result in modest weight loss. A study by Tudor-Locke et al., (2011) has systematically evaluated dose-response effects of different steps/day goals. It found that approximately 7,000-8,000 steps/day is a reasonable threshold of free-living physical activity (50). Free-living physical activity is defined as "the level of activity that the patients, within their physical limitations, at their own pace, and in their own environment, typically perform" *(p. 73)* (58). These findings suggest that an intervention with goal setting and step targets may be an effective and feasible way to increase PA levels during pregnancy. Therefore, this is something that this research will aim to inform.

Using Activity Trackers to Monitor Physical Activity
Activity trackers can provide valuable, objective information on PA patterns and changes in a person's activity behaviour. The accuracy and functions of activity trackers varies. A systematic review summarised the evidence for validity and

reliability of popular consumer-wearable activity trackers and their ability to estimate steps, distance, and PA and energy expenditure (53). It found that when using step counting or accelerometer steps, the correlation with tracker-assessed steps was high for Fitbit (Pearson or intra-class correlation coefficients (CC) > =0.80). It found that walking- and running-based Fitbit trials indicated consistently high inter-device reliability for steps (Pearson and intra-class CC 0.76-1.00), distance (intra-class CC 0.90-0.99), and energy expenditure (Pearson and intra-class CC 0.71-0.97). When wearing two Fitbits while sleeping, consistency between the devices was high.

Fitbit Charge activity tracker is a particular model that previous validation studies have shown to be accurate in measuring activity in patients with limited physical abilities or the elderly population, who may be walking slower and therefore may be most suitable to use with women who are pregnant and obese (53).

The Fitbit activity tracker also allows for remote monitoring of activity if it is synced with a smart phone that is frequently in close proximity to the person who is wearing the Fitbit. All PA data can be monitored and recorded for download from an individual's Fitbit account on a daily basis for a period of one month at a time, provided that the Fitbit the individual is wearing is regularly synced to their Fitbit phone application. For this reason this would be an ideal method to remotely and accurately monitor a PA intervention based on walking. The cost of a Fitbit Charge model is approximately £100.

Figure 5. Fitbit Charge

2.6 Subjective Ways of measuring PA Levels in Pregnancy

Physical activity questionnaires have the potential to capture the target population's relevant lifestyle activities that may not be identified by objective assessments. The questionnaires are completed by individuals and therefore represent self-reported levels of PA. The most commonly used validated

questionnaire in pregnancy is the Physical Activity in Pregnancy Questionnaire (PPAQ). It is comprised of 36 questions that can be scored and added up to measure low, moderate, and vigorous levels of PA. PPAQ scores are measured in estimated average metabolic equivalent (MET-hr/wk). One MET is defined as 1 kcal/kg/hour and is roughly equivalent to the energy cost of sitting quietly. A MET is also defined as oxygen uptake in ml/kg/min with one MET equal to the oxygen cost of sitting quietly, equivalent to 3.5 ml/kg/min (59). Physical activity logs can be burdensome for participants to complete. Self-reports are usually validated by comparing them to objective measures of physical activity such as accelerometers and heart rate monitors. For instance, a systematic review that analysed the accuracy of self-reported versus objectively measured PA, by using Pearson's correlation analysis, found that correlations between the two were generally low-to-moderate and ranged from -0.71 to 0.96. It also found that the correlation varied depending on the type and level of PA and the gender of participants (60). What this means for research is that it may be more reliable to objectively measure PA levels, in order to collect more accurate PA data, in particular to answer the question of dose-effect of PA during pregnancy. Our proposed research will explore both aspects, in order to ascertain the best method of collecting this data.

2.7 Barriers to Physical Activity in Women who are Pregnant and Obese

Despite recommendations that women remain physically active throughout pregnancy, there are still strong indications that the impact of this on women's behaviour is limited (61). The challenges of PA promotion and behaviour change are multifaceted. Below is presented a summary of some of the challenges that women face to remain physically active throughout pregnancy.

Numerous studies, (62), (63), (64) including one with over 1500 participants (43), using a variety of qualitative methods, have identified various barriers to PA with similar themes consistently reoccurring. These are listed in Table 5 below.

From: Perceived barriers to physical activity among pregnant women, Evenson et al., 2009 (43).

Table 5. Perceived Barriers to Physical Activity among Pregnant Women

Perceived lack of opportunity – time

Cost
Child care problems and social conflicts
Concerns about or actual pain,
Lack of energy/ too tired,
Concerns about risk to foetal health
Lack of understanding regarding potential benefits.
Lack of consistent information

Another common theme was identified in a small UK based study by Furness et al*.,* (2011), which found that stigma of discussing obesity and a lack of social support for PA (65) is a barrier as well. Barriers which have been identified are primarily associated with structured exercise and sports rather than PA in general. These are discussed further in a meta-analysis by Sui et al., (2013), (66). The summary of the findings is in the Table 6.

From: Exercise in Obese Pregnant Women: Positive Impacts and Current Perceptions, Sui et al., 2013 (66)*.*

Table 6. Summary of Enablers and Barriers to Physical Activity in Pregnancy

Study	Design	Number of Participants	Findings
Thornton et al (23) US	Interviews	10 pregnant and postpartum and 8 family members	Enablers: partner's advice and support, cultural norms, health professional's advice, friends' support and companionship, and access to child care.
Duncombe et al (24) Australia	Questionnaire	158	Enablers: feeling of fitness, tone, and strength; relieving stress; enjoyment; having a regular routine.

			Barriers: tiredness, lack of time, dislike of exercise, and concern about safety.
Evenson et al (25) US	Short telephone interview	1535	Barriers: pregnancy complications and other health problems, personal reasons, social and cognitive reasons, and environmental factors.
Pereira et al (26) US	Questionnaire	1442	Barriers: work commitment, pregnancy complications, and feelings of depression.
Symons Downs and Hausenblas (27) US	Questionnaire	74	Enablers: feeling that exercise improves mood, increases stamina, staying fit, feeling that weight is under control, and influence from family.

In summary, the barriers to PA in pregnancy are multi-faceted. These barriers need consideration and addressing for any future intervention to be effective. The findings suggest that increasing women's knowledge and perception of PA in pregnancy is an important factor. This can be addressed by sharing information about the health benefits of PA, as well as addressing women's beliefs and concerns about potential risks of PA in pregnancy. However, additional more practical solutions are also necessary to help women address the barriers of time and lack of child care, to enable them to plan PA into their day-to-day life.

2.8 Walking in Pregnancy

Walking is the most frequently occurring type of PA during pregnancy due to its flexibility in intensity and higher accessibility (67). A self-reported questionnaire-based study of 853 women found all categories of activity decreased during pregnancy except walking, which increased by the third trimester as women found it to be beneficial (67). Despite the acceptability of walking during pregnancy its effect on improving pregnancy outcomes has not been

systematically assessed (68); at present there are no published systematic reviews of effectiveness of walking interventions.

Structured exercise interventions are often complex and include attendance at classes, can be time consuming, costly, difficult to implement into daily life (35), and would be a strain on public health resources if NHS-funded. An Australian study from 2013 which looked at the patterns of walking in women during pregnancy found that walking declined during pregnancy. However, it also found that the level of walking returned to pre-pregnancy levels in the postpartum. The study found that walking was the most common activity undertaken for women across the lifespan and that the decline during pregnancy can be avoided if women are given sufficient advice from HPs. The study suggests that encouraging continuous walking could be a way to maintain PA levels in pregnancy (69). Therefore, evidence suggests that developing interventions to promote PA should target changes in habitual activities. Walking, as the preferred activity of pregnant women, low cost and readily available, demands further investigation. A systematic review of the effectiveness of walking interventions in the overweight and obese pregnant population has been undertaken as part of this PhD. The findings from the review are in Chapter 5.

2.9 A review of the Clinical Care Pathway, Provision and Support for Pregnant Women with a BMI $\geq 30 \text{kg/m}^2$ in the UK

In England, the number of women requiring a more advanced level of antenatal care due to obesity has more than doubled over the last two decades (70). However, most management includes diagnostic and clinical intervention, for instance additional screening for diabetes and anaesthetic reviews. The special pathway for women who are obese in the UK is mostly including women with a BMI of 40kg/m² and above and mainly includes clinical management and precautionary measures based on risks that are known to rise as a result of raised BMI and to avoid obstetric complications. To our knowledge, there is no additional support for women with a BMI range from 30-40kg/m² to manage their GWG throughout the pathway (61).

Women with a raised BMI are placed in separate care pathways due to the higher risk of complications. However, the content of these pathways varies across the UK. The local pathway has been verified and is summarised in table 7. The pathway guidelines are mainly medicalised management of women from 8 weeks gestation to 6 weeks post-partum. Women who are diagnosed with GDM following a GTT attend a one-off GDM clinic where they are told about how to monitor their GDM and are provided with some dietary advice.

Source: Jessop Maternity Unit, Royal Hallamshire Teaching Hospitals, Sheffield, November 2017

Table 7. Summary of Care Pathways for women with BMI ≥30kg/m².

	BMI 30-34	BMI 35-39	BMI 40 or more
Lead professional	Midwife (if no other risk factors)	Obstetrician	Obstetrician
8-12 weeks	Routine booking investigations Advise Vit D daily throughout pregnancy (Adcal D3 one tablet daily) Advise 5mg Folic acid until 14 weeks Thromboprophylaxis risk assessment	Routine booking investigations Obstetric review and risk assessment Advise Vit D daily throughout pregnancy Advise 5mg Folic acid until 14 weeks Written referral to anaesthetist Thromboprophylaxis risk assessment Document plan for ongoing antenatal care and provisional plan for delivery Recommend hospital birth	Book into raised BMI clinic Consultant review and risk assessment Advise 5mg Folic acid daily until 14 weeks Advise Vit D 10mcg daily throughout pregnancy Written referral to anaesthetist Thromboprophylaxis risk assessment Document plan for ongoing antenatal care and provisional plan for delivery Recommend hospital birth
20-22 week	Fetal anomaly ultrasound	Fetal anomaly ultrasound	Fetal anomaly ultrasound 75g GTT
24-26 weeks	75g GTT	75g GTT	
28 weeks			Repeat GTT if previous GTT normal
36 weeks		Recommend hospital birth	Fetal biometry U/S growth &liquor Review response to Anaesthetic referral Measure for TEDS Manual handling risk assessment Labour management plan
40 weeks			Fetal biometry U/S growth &liquor

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	BMI 30-34	BMI 35-39	BMI 40 or more
			Review labour management plan
40-41 weeks	See CMW if no other complications	ANC appointment Review labour management plan	
Intrapartum **Refer to raised BMI guideline**	Midwife led if no other risk factors Active 3rdstage	Continuous electronic fetal monitoring IV access, FBC G&S Oral fluids only, consider IV fluids Active 3rdstage	Continuous electronic fetal monitoring IV access, FBC G&S Oral fluids only, consider IV fluids Ranitidine 150mgs 6 hrly Active 3rdstage
Postpartum **Refer to BMI guideline and Thromboprophylaxis guideline**	Dietetic advice	Thromboprophylaxis 6 weeks	Antibiotic cover for 5 days after a caesarean delivery Thromboprophylaxis 6 weeks

This information is highly relevant to the context to this research, which is exploring whether the highly medicalised management of women with a raised BMI throughout the current health pathway can be complemented with a lifestyle intervention. Answering the question of whether such an intervention is acceptable to women and HPs may reduce the need for some of the medical interventions, if such intervention was successful and was proven feasible.

An Evaluation of the Maternal Obesity Care Pathway in the UK

A multidisciplinary steering group in a large NHS Trust in the Northeast of England consisting of healthcare professionals (including midwives, obstetricians, dietitians, anaesthetists, diabetes clinicians and nurse specialists), and academic and primary care partners (including representatives from specialist weight management services, health improvement services and commissioners) aimed to examine maternal obesity care pathways. An *Evaluation of the Implementation of Maternal Obesity Pathways of Care* report was produced in 2015 with the group's findings of the women's experiences (BMI≥40kg/m²) of being on the pathways, healthcare professionals' experiences of delivering the pathways as well as pathway compliance. It was a mixed methods study with data integration using a convergence coding matrix methods to search for agreement and disagreement between studies. The common theme identified between the maternity service users and HPs was the overall

usefulness of the care pathways. Women and HPs expressed a need for *more consistent messages from HPs* as well as the importance and the effect of *terminology on women's response to weight-related discussions.* Also, the clinical management (rather than public health management) aspects of the pathways were viewed positively with good compliance. However, the prevention (public health management) components were predominantly non-compliant, and *both populations agreed that increased antenatal and postnatal weight management support was needed* (71)*.*

The study found two topics where the views of maternity service users and HPs differed; namely *communication of weight and risk*, and *women's engagement with weight management during pregnancy.* HPs identified the sensitivity and stigma of obesity to be a barrier to weight-related communication. In contrast to the perspectives of HPs, the majority of women viewed the communication approach from HPs to be *positive and sensitive*. For these women, it was the *lack of adequate risk communication, which* was most likely to cause an emotive response, rather than issues of sensitivity, whilst HPs felt they were *providing adequate explanations to women about obesity-related risk.* This is an important finding as HPs' primary concern is on *how/if to communicate*, whereas women felt that there *needed to be a higher level of communication (*more explicit and clear communication about weight and associated risks*) (*71)*.* NICE guidelines recommend that all women with a raised BMI are given detailed and practical advice about their diet and PA (16). The guidelines recommend that women are provided with practical and tailored information, including advice on how to increase intake of fruit and vegetables (for instance by using Healthy Start vouchers). This finding indicates that in many instances, NICE guidelines are not implemented. This is something that this research will aim to address, by exploring a novel mode of communication and information delivery, using social media.

2.10 Additional Barriers to Care Provision to Women who are Pregnant and Obese

Multiple reviews have investigated barriers that HPs face when providing lifestyle advice to women who are pregnant and obese (61). A systematic review that examined the barriers to communication on PA and diet identified ten studies

from the UK, six from the United States, four from Australia, two each from Japan and Canada, and one from Finland. It found that they are primarily relating to communicating with women about their weight, healthcare professionals lack of knowledge, a belief that there would be negative consequences of intervening and resource barriers (72). A recent qualitative study interviewed 41 midwives on the challenges of providing PA guidance to women who are pregnant and obese. The study was specifically focusing on facilitators and barriers in counselling. The main themes were *"Counselling as a challenge"; "Counselling as walking the thin ice" and "Counselling as an opportunity"*. There was a general feeling that midwives had to adjust their counselling depending on each woman's situation. In summary, it is perceived by midwives as a 'complex and ambiguous' task, and a fine balancing act with a high risk of being 'rejected' by the pregnant women if 'a line was crossed'. Midwives also reported that their own body shape might be a barrier, if they were not the 'best example'. The study concludes that midwives might benefit from further training to improve opportunities for support and motivation for PA in pregnant women (73). It is within the scope of this research to explore HPs views on barriers to information provision to this group of women.

2.11 Interventions to address HPs Barriers to Care Provision to Pregnant Obese Population

Despite the extensive research and knowledge about barriers that HPs experience in the UK, very few support mechanisms have been implemented to support HPs in this area. Hestlehurst et al., (2014) conducted an extensive search of databases to identify the effectiveness of interventions in changing HPs practice relating to maternal obesity. The review also aimed to examine the most effective behaviour change techniques in these interventions and compare their mode of delivery.   The main findings were that all maternal obesity-focused interventions were targeting pregnant women rather than HPs. The systematic review identified only one ongoing study that targeted HPs (61). This evidence base shows that there is a lack in interventions that have focused on supporting HPs and that more needs to be done to involve HPs in any early stages of development, design and implementation of weight management interventions.

Summary
The first part of this chapter has discussed maternal obesity, GWG and associated adverse outcomes, modifiable factors (diet and PA),

recommendations, current pathways and lastly barriers to delivering lifestyle advice to obese pregnant women. The following section will discuss intervention development approaches, the importance of theoretical intervention development, methodology and using social media as a mode of delivery.

2.12 Using Social Media to Deliver Behaviour Change Interventions

Social media (SM) is part of the Information technology (IT) which includes the use of any computers, storage, networking and other physical devices to create process and exchange all forms of electronic data (81). This review will explore social media (SM) as an intervention delivery tool. These medium tools are growing in popularity and have the potential to reach widely. In table 8, the most popular SM platforms, the number of users and characteristics are summarised. It shows that Facebook is by far the number one preferred SM platform. Facebook is a popular social media platform used by between 82-89% of women ages 18-49 (86). A recent publication by Facebook revealed that US adult users spend, on average, 40 minutes a day on Facebook (87), (88).

From: Adapting Behavioural Interventions for Social Media Delivery, Pagoto et al., (2016) (89).

Table 8. Characteristics of existing online social media platforms.

Platform	Year founded	Number of users	Medium of posts	Private message (yes/no)	Privacy functions (yes/no)	Chat function (yes/no)
Facebook	**2004**	**1.44 billion**	**Text, video, images**	**Yes**	**Yes**	**Yes**
Twitter	2006	302 million	Text, video, images	Yes	Yes	No
Pinterest	2010	72.8 million	Text, video, images	Yes	Yes (private pin boards)	No
Snapchat	2011	100 million	Video, images	Yes	No	Yes
LinkedIn	2002	364 million	Text, images	Yes	Yes	Yes
Instagram	2010	300 million	Video (<15 sec),	Yes	No,	No

2.13 Effectiveness of PA Interventions Delivered via Facebook

A review which specifically investigated PA interventions delivered via Facebook by Ferrer et al., (2017) identified 8 eligible studies (95). All identified interventions utilised behaviour modification strategies. The most common strategies included self-monitoring, goal setting, and social support. In terms of changes in PA levels, 87.5% of the Facebook interventions reported some type of significant PA behaviour change.

Studies which used Facebook managed to retain a high proportion of participants (77-96% of users). Participants' feedback complemented the creation of a friendly competitive environment with 'entertainment' as a key motivator. The engagement among participants varied greatly across studies, but it could not be differentiated whether this was due to intervention design, content, or SM platform. Facebook was found to be a very convenient method of increasing participant communication and has the potential to create a social support network to help participants achieve PA targets. However, in the limited published evidence base, SM interventions varied in length of time, and how health outcomes were measured. The main findings from the review are that the usage of SM to bring about health behaviour change is still in its early stages of development and research is needed to understand what encourages engagement and retention (90).

One of the studies in the review, by Cavallo et al., (2012) (94), also aimed to measure how the varying level of social support within the intervention affects PA. The study compared changes in perceived social support for PA between the control arm which received education-only via a website and the intervention arm which received education via website as well as enrolment in a Facebook support group. They found that the intervention participants' self-perceived social support increased at first, however over time there were no differences in perceived social support between the groups. The review concluded that to test the effectiveness of Facebook-delivered physical activity interventions *more diverse samples and theory-based content with assessment of mediators of behaviour change, objective measures of PA and longer follow-up period were necessary*. Based on these findings, more needs to be done to investigate how use of SM and

Facebook in health intervention delivery can be better optimised. Whilst the method of delivery to target PA seems promising there are large variations in the length of delivery as well as content of the interventions, which makes it difficult to draw any definitive conclusions regarding the 'active ingredients'. The common factor in these studies is method of delivery and the fact that they are targeting the same outcome. Outside of these parameters, it is difficult to draw any commonalities in terms of behaviour change techniques or underpinning theoretical basis. These findings suggest that it may be a feasible mode of delivery for PA interventions that has not yet been tested on a pregnant population in the UK, something which this research will explore further.

Summary of Findings of Facebook-delivered PA Interventions

The most commonly used SM in intervention design is Facebook, followed by health-specific internet sites and then Twitter (89). A meta-analysis of 8 interventions delivered via Facebook, found a positive effect on behaviour change, however due to the multiple intervention components, the effect could not be solely attributed to the method of delivery (95). Furthermore, there are substantial variations in the effect size of interventions that use Facebook. It is therefore unclear whether these interventions are useful for all health behaviours and all populations. The large variation in the target population and the target behaviour in the above-mentioned studies lead to belief that studies that are more robust are needed to draw definitive conclusions. In addition, studies have varied in the length of duration. Whilst some only followed participants for a period of 3 weeks, others spanned over 6 months. A sustained behavioural change is necessary for it to have an impact on health outcomes. Therefore, more research is needed to conclude whether short-term behaviour change, which is presented in these studies, can be achieved in long-term.

This PhD is testing the feasibility of Facebook as a delivery tool for a PA intervention during pregnancy. The application of the tool and how it is being used is explained in chapter 6 and chapter 7 of this thesis.

2.14 The Importance of Theory in Health Interventions

It is widely recognised that theory can inform interventions, from identifying theoretical constructs to targeting and identifying mechanisms underlying particular behaviour change techniques (BCTs). To empirically measure the

differences in effect size between theory based versus non-theory based interventions, Michie et al*., (2010) conducted a systematic review of studies utilising the internet specifically, to promote behaviour change. The overall finding was that interventions utilising theory have larger effects on behaviour than those that do not (74). Up to date, published literature demonstrates mixed approaches to both intervention development and reporting of intervention techniques. A review of PA interventions during pregnancy found that, despite the Medical Research Council (MRC) and National Institute for Health and Care Excellence (NICE) recommendations which advocate a theoretical underpinning of intervention content development, (75) only two of the 14 studies used theory to guide the development of their intervention (76).

Social media-delivered interventions also tend to lack a theoretic evidence-base (81). A review by Sawesi et al., (2016) titled; *The Impact of Information Technology on Patient Engagement and Health Behaviour Change: A Systematic Review* aimed to measure engagement and behaviour theories applied as bases for developing these interventions and their impact on health outcomes (81). Social media showed a positive impact on health outcomes (81%, 13 out of 16 studies). Whilst findings suggest that interventions delivered via SM platforms can improve health outcomes; the number of internet-based interventions that described specific behaviour theories and models were few This implies that the interventions were designed without any theoretical frameworks. This could be due to researchers' lack of knowledge of the theories, struggling to define appropriate theories, and absence of good evaluation methods and usability testing, and theories containing overlapping constructs and inconsistent use of terminology. The difficulty in identifying theory-based studies may also be due to shortcomings in the reporting of theoretical underpinnings**.** The review findings show that standardised reporting of intervention components and mechanisms of action is pivotal to allow replication of effective interventions and to learn lessons from those that are less so. This finding further demonstrates the importance of ensuring a theoretical underpinning of any intervention development, including those that are delivered via SM. In our development of an intervention, a careful consideration of relevant theories will be conducted, in order to identify the most appropriate theories that will be used to strengthen our design. Based on the

evidence presented by Michie et al., (2010) and MRC guidelines, the decision to adopt a theoretical underpinning in the development of this project was made (77).

2.15 National Institute for Health and Care Excellence (NICE) Guidelines for Intervention Development

Current NICE guidelines (78) for intervention development strongly recommend using the behaviour change theory model "COM-B" (79). The COM-B model was created as a result of the finding that there was no easy way to standardise and evaluate the mechanisms of action in behaviour change interventions. Michie et al., (2010) (84) aimed to address the gap in the standard approach which led to the creation of the COM-B model.

This model is based on the subject having the Capability, Opportunity and Motivation for behavioural change. The terms are used in a broad sense with the model suggesting that limitations to just one of these facets would significantly hinder the desired behaviour change. All require consideration during intervention development. The theory is grounded upon a synthesis of 19 behaviour change frameworks identified in a systematic literature review and combined to form a model for guidance and supporting intervention design. Individually, none of the reviewed frameworks covered a full range of intervention functions, or facilitated a systematic development of intervention design. The COM-B tool allows for a systematic selection of behaviour change techniques (BCTs), which are active ingredients within an intervention believed to create behaviour change. In the context of this thesis, this is valuable information that will help to inform the development of the intervention, in particular during the selection of BCTs. The step-by-step application of the COM-B model for the purpose of developing the health intervention that has formed this PhD thesis is explained in detail in chapter 6.

2.8 Summary and Study Rationale

The evidence presented in this chapter demonstrates why it is pivotal that women are supported in managing GWG. The evidence presented also shows that modifiable factors such as diet and PA in pregnancy have the potential to reduce the risks associated with raised maternal BMI and excessive GWG (62). It is

important to develop effective and acceptable PA interventions, which can be implemented within the health care pathway, as evidence shows that levels of PA decrease throughout pregnancy despite RCOG's PA recommendations (31),(30). Interventions which have looked at the effects of PA and GDM status in women who are obese specifically have shown most effect (99). This effect is important as PA has the potential to improve glycaemic control and insulin resistance. However, the evidence remains inconclusive for all other pregnancy and antenatal outcomes. There are several issues that have been identified in the review of the evidence. The fact that interventions vary in length, intensity, type of measure and method of delivery makes it difficult to draw conclusions about their effectiveness, which is further proof that more robust interventions and a more streamlined reporting of measures is needed (100),(101). Furthermore, the barriers to PA in pregnancy, which are reported, are often not addressed within the intervention design (102). For instance, although walking is a low-cost, popular type of PA that could potentially tackle the issue of low PA levels in pregnancy, very few interventions have focused on this type of PA (103). This is despite the fact that increasing the number of 'daily steps' and reducing sedentary behaviour is recommended in the national guidelines and walking also seems to be an acceptable method to increase PA levels in women who are pregnant and obese.

The national guidelines recommend that HPs who are part of the care pathway advise women to adopt a healthy lifestyle, in terms of diet and PA. However, field studies show that HPs face barriers to address this topic with women. Despite the evidence which shows the barriers faced by HPs such as lack of knowledge, confidence and opportunity, there is a lack of focus on HPs role within the intervention design in delivering national guidelines. To our knowledge, there is no national care pathway that is focused in preventative measures. Rather, most pathways are focused on clinical management to avoid or manage complications that arise in women who are pregnant and obese (104).

Thirdly, there is a limited use of theory in the intervention design despite the evidence that theoretical underpinnings and specific behaviour change techniques have been more effective at increasing levels of PA in the general population as well as in the pregnant population. For instance, the reviews have found that giving information about health consequences, goal setting and self-

monitoring techniques are most prevalent in interventions that have shown effectiveness. Based on this data and the evidence that theoretically underpinned interventions are more effective, more systematically developed interventions with theoretically underpinned components are needed.

Lastly, the use of Social Media such as Facebook has been tested in other populations, and has shown some effectiveness (33), (34). SM usage is becoming very common and the access to smartphones and technology gadgets is part of everyday life. SM has the potential to reach widely, at a low cost and its use should be further explored in delivery of affordable interventions within the health services.

Chapter 3 outlines aims and objectives of this thesis. It gives a detailed description of the objectives and links them to the chapter in which they are discussed.

Chapter 3. Aim & Objectives

3.1 Introduction

The literature review demonstrates a clear knowledge gap regarding the effectiveness of walking in reducing adverse pregnancy and antenatal health outcomes in the overweight and obese population. There is also very limited research of the acceptability, feasibility and effectiveness of social media (SM)-delivered interventions within the UK's NHS for these women. Using internet technology and a SM platform like Facebook may be a favourable medium for delivering an intervention to a young adult female population. This PhD project aims to inform the suitability of a full-scale randomised walking intervention in early pregnancy delivered via Facebook and its potential benefits to maternal and infant health.

Thus the research question arrived at was:

Would a walking intervention aiming to reduce adverse pregnancy and birth outcomes in obese women, using social media as mode of delivery, be feasible, practical and acceptable?

3.2 Aim

To develop and test the feasibility and acceptability of the mobile health intervention, measurement and trial procedures for a randomised controlled trial of a Facebook-based walking intervention in a sample of obese pregnant women.

3.3 Objectives

•To review the rationale behind the choice of methodology and methods used in this thesis (see chapter 4).

•To systematically examine the state of current evidence on the effects of walking interventions in women who are pregnant and obese in relation to GWG and pregnancy and antenatal outcomes (see chapter 5).

•To develop a theory-based intervention and systematic selection of behaviour change techniques using Behaviour Change Theory and the 'Capability, Opportunity, Motivation'-Behaviour model (COM-B model) (see chapter 6).

•To design a feasibility randomised controlled trial (RCT) of the intervention versus usual care in the obese pregnant population, to assess likely rates of participant eligibility, consent, receipt of intervention and retention for collection of outcome data (see chapter 7).

•To examine the acceptability and feasibility of the study procedures, mode of delivery, data collection tools and questionnaires proposed for a future definitive trial. It will evaluate Facebook group use (adherence and engagement with the website) by the participants (see chapter 8).

 •To undertake a process evaluation by means of interviews with study participants and health professionals.

•To explore health professionals' and participants' views and perceptions of the intervention in terms of acceptability, feasibility and usability, using the COM-B framework (see chapter 9)

•To discuss the findings from both quantitative and qualitative evaluation of the feasibility RCT (see chapter 10).

• To summarise the unique contribution to knowledge, as well as provide a reflection on my PhD journey and recommendations for research and practice beyond protocol development (see chapter 11).

• To write a protocol for a full-size RCT protocol based on the findings and estimates of the key parameters for a future definitive trial (see Appendix K)

3.4 Design
The first study in this PhD was a systematic literature review to inform intervention development of a feasibility trial study. The second part was a systematic

intervention development that used the COM-B model to ensure a theoretical underpinning. Once a complete design was developed for the feasibility RCT and the study was implemented, a quantitative outcome measures analysis was performed on the feasibility RCT outcomes. A qualitative intervention evaluation in the form of semi-structured interviews with participants from both randomised groups was completed with participants and health professionals to better understand the feasibility study outcomes. The semi-structured interviews informed in greater depth the results from the initial quantitative phase. A protocol for a full size RCT was developed (see figure 6).

3.5 Summary of PhD Process

Figure 6. PhD Project Design

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          ┌─────────────────────────────┐
          │   Systematic Literature     │
          │          Review             │
          └─────────────────────────────┘
                        │
                        ▼
   ┌──────────────────────────────────────────────┐
   │     Intervention Development Involving:       │
   │ 1. Behaviour Change Theory (Capability,       │
   │    Opportunity, Motivation Model the COM-B    │
   │ 2. Patient & Public Involvement (Reproductive │
   │    Health Advisory Panel, Maternal Health     │
   │    users)                                     │
   └──────────────────────────────────────────────┘
                        │
                        ▼
   ┌──────────────────────────────────────────────┐
   │          Feasibility RCT Assessment          │
   └──────────────────────────────────────────────┘
                        │
                        ▼
   ┌──────────────────────────────────────────────┐
   │              Process Evaluation              │
   │        Semi Structured Interviews with       │
   │        a) Participants                       │
   │        b) Health Professionals               │
   └──────────────────────────────────────────────┘
                               │
                               └──────►  ┌──────────────┐
                                         │ Protocol RCT │
                                         └──────────────┘
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This chapter has presented the aim and objectives of this thesis. The following chapter describes the methodology that is used in this thesis. It describes intervention development guidelines which were implemented. It then explores the methodological approach and links it to the philosophical underpinnings. It concludes with a presentation of ethical considerations in research, and in particular focuses on ethical challenges when conducting internet-mediated research.

Chapter 4. Methodology

4.1 Introduction

The main objective of this thesis was to develop and implement a feasibility randomised controlled trial (RCT) of a complex intervention. This chapter begins by explaining the set of guidelines that were produced by the Medical Research Council (MRC) on the development of complex interventions. The chapter then explores the epistemological stance, and the methodological and philosophical underpinnings of the research that have formed the study design. It further gives a detailed account of why a mixed methods approach was selected as the most appropriate methodology to answer the research question.

4.2 Medical Research Council Guidelines to Intervention Development

The MRC (15) developed specific guidelines to support the choice of appropriate methods and to encourage researchers to strive for a good standard in the planning, conduct and reporting of their research . The first step in the MRC guidelines for feasibility study planning is for the researcher to undertake a systematic development phase, starting first with a detailed review of available evidence. Following the review of evidence the guidelines recommend a phased testing approach in the form of a feasibility study to assess recruitment, retention and attrition rates (16). Following the feasibility studies, the guidelines recommend a thorough evaluation of effectiveness and only then implementation and long-term follow up (see Figure 7). This thesis relates to the first two steps in the MRC guidelines, namely the development and testing of the procedures. The guidelines specifically emphasise the importance of incorporating qualitative methods to evaluate and interpret feasibility study findings. Using a mixed methods approach is recommended because it can better identify why and how interventions are or are not effective (17).

4.3 Feasibility & Testing Procedures

Feasibility studies are defined as pieces of work done before the main study to test important parameters needed to design the main study (18). The difference between a feasibility and a pilot study is that pilot studies are a smaller version of the main study to test whether all components of an intervention can work together. A pilot study therefore includes an assessment of the primary outcome. Feasibility studies, conversely, do not evaluate the outcome of interest. Instead,

the purpose of a feasibility study is to estimate parameters that are needed in the design of the main study (18).

Examples of such parameters include:

● Willingness of participants to be randomised

● Willingness of clinicians to recruit participants

● Number of eligible patients; carers or other appropriate participants

● Follow-up rates, response rates to questionnaires, adherence/compliance rates,

● Time needed to collect and analyse data.

If a feasibility study is not undertaken prior to a full size RCT it is at significant risk of failing with its original aims and objectives; for instance not being able to recruit participants or deliver the intervention and trial procedures as intended (19). Feasibility studies do not have the usual power calculation that randomised controlled trials have. Instead the recommendations are that the sample size should be adequate to estimate recruitment rates, willingness of participants to be randomised and number of eligible patients. The primary outcomes in feasibility studies are follow-up rates, response rates to questionnaires and adherence/compliance rates (18). The importance of feasibility testing is outlined in the MRC framework which describes the various stages of intervention development (see Figure 7). The framework also recommends incorporating quantitative and qualitative methods within a feasibility study, known as mixed-methods design. The mixed-methods approach within a feasibility study has been found to better inform the future full size trial design (16). Evidence suggests that a mixed methods design strengthens the depth and breadth of understanding of research findings (20). Creswell et al., (2007) list four types of research situations that can benefit from mixed methods research. These are:

1. If concepts are not well clarified enough to implement a quantitative design, a qualitative analysis can be employed.

2. Instances where findings from the quantitative approach can be better understood with a second source of data.

3. When neither the qualitative nor the quantitative approach alone are adequate to understand the concept, which is being studied.

4. The last situation is when the qualitative data can help and support the interpretation of the quantitative findings (21).

Therefore, the approach in this research was based on the MRC guidelines which recommend that the feasibility of an RCT is measured using a mixed-methods approach. This approach was deemed most appropriate to answer the research question: *Would a walking intervention be feasible, practical and acceptable?* The mixed-methods approach is associated with an epistemological stance that proposes that the best method is the one that addresses the aims of objectives of the particular research project. This approach adopts an ontological stance which is the pragmatism paradigm. The methods, methodology, theoretical perspective and then pragmatism paradigm, will be discussed in the following section 4.4.

From: Developing and Evaluating Complex Interventions-New Guidance, Craig et al., (2013), p. 5 (15)*.*

Figure 7. MRC Framework
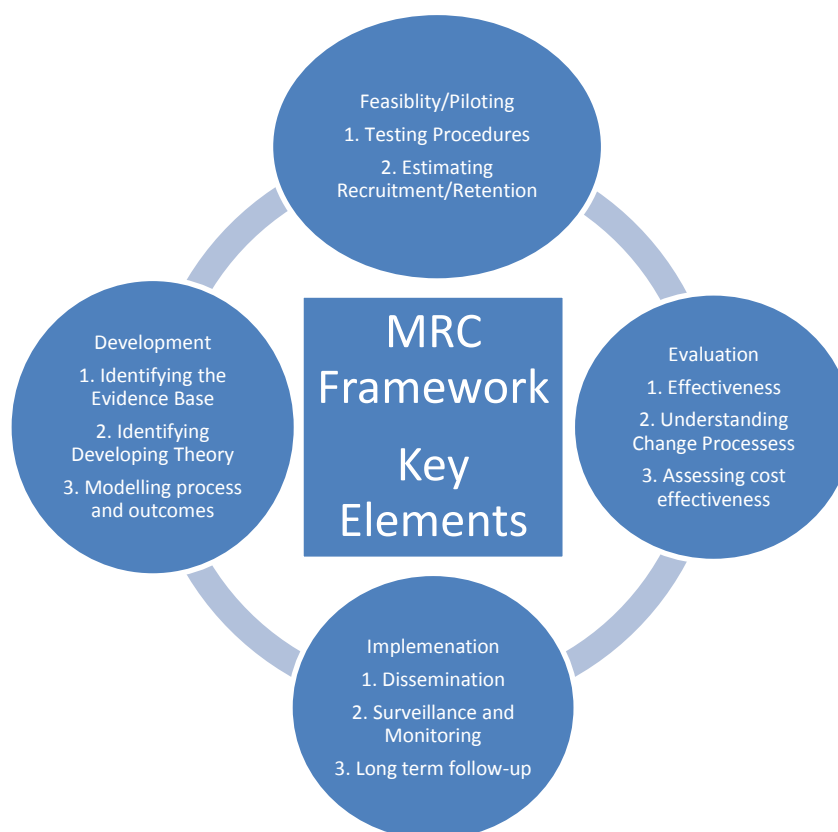
4.4 Research Paradigms

A research paradigm is "the set of common beliefs and agreements shared between scientists about how problems should be understood and addressed" (22). There are five major paradigms; positivism, constructivism, pragmatism, subjectivism and critical (22). According to Guba & Lincoln (1990), research

paradigms can be characterised through their ontology, epistemology, methodology, and, methods. Table 9 gives a detailed overview of the paradigms.

Table 9 adopted from Crotty, M., 1998. Foundations of social research: Meaning and Perspective in the Research Process. p.256.

Table 9. Research Paradigms

Paradigm	Ontology *What is reality*	Epistemology *How can I know reality*	Theoretical Perspective *Which approach do you use to know something?*	Methodology *How do you go about finding it out?*	Method *What techniques do you use to find out?*
Positivism	There is a single reality or truth.	Reality can be measured; hence the focus is on valid tools.	Positivism Post-positivism	Experimental research, survey research	Quantitative Sampling Statistical Analysis
Constructivism	There is no single reality or truth.	Reality needs to be interpreted	Interpretivism	Ethnography Grounded Theory Phenomenology	Qualitative Interviews Narrative
Pragmatism	Reality is constantly renegotiated, debated.	The best method is one that solves problems.	Research through design	Mixed methods Design-based	Combination of the above
Subjectivism	Reality is what we perceive it to be	All knowledge is purely a matter of perspective	Postmodernism Structuralism Post-structuralism	Discourse Theory Archaeology Deconstruction	Auto-ethnography
Critical	Realities are social constructed entities that are under constant internal influence	Reality and knowledge is both socially constructed and influenced by power relations from within society.	Marxism Queer Theory Feminism	Critical Discourse analysis, critical ethnography action research	Ideological Review Civil action open- ended interviews observations

4.5 Philosophical Underpinnings of Paradigms

The first three paradigms in Table 9 (Positivism, Constructivism, and Pragmatism) are most relevant to this research due to the nature of the research question. Only these will therefore be discussed in detail. A positivist paradigm is based on the assumption that behaviour can be explained and measured by objective facts, (observable phenomena), for instance numbers (23) and uses a quantitative method to find the truth. A Constructivism paradigm is based on the belief that one needs to understand subjective views and meanings to interpret

and make sense of data. It uses a qualitative method to find the truth. These two paradigms are often presented as two opposing views. The philosophical underpinnings of each paradigm lead on to define the theoretical perspective, the methodology and the methods used.

However, in reality, the researchers' relationship to the research process is rarely purely subjective or objective and they often work 'interchangeably'. Within Pragmatism, (the third paradigm in Table 9), reality is constantly renegotiated, debated, interpreted, and this allows for any methodological approach as long as it addresses the issue (24). It advocates the use of mixed methods in research and in that way "sidesteps the contentious issues of choosing between two opposing viewpoints of 'objective truth' vs. 'singular reality' (25). Therefore the researcher who uses the pragmatic approach has an *intersubjective* relationship to research process (see Table 10).

4.5.1 Choosing a Paradigm

Choosing a paradigm, based on the ontology and epistemology can be a top down approach or a bottom up approach. In this research, the choice of paradigm was guided by the research question: *Would a walking intervention be feasible, practical and acceptable?*

The choice of methods was based on the MRC guidelines which recommend that the feasibility of an RCT is measured using a mixed-methods approach. The mixed-methods approach is associated with a methodology and an epistemological stance that believes that the best method is 'the one that solves problems' i.e. a pragmatism paradigm (26). In exploratory research, such as implementation and testing of an intervention design the PhD researcher believed that neither of the two extreme approaches used in Positivist and Constructivist paradigms (objective versus subjective) would serve the purpose of answering the questions of feasibility and acceptability of the research design. Instead, a pragmatism-based set of beliefs allowed us to meet the research aims.

The Pragmatic approach is a mixed approach that seeks to "move back and forth between induction and deduction" , using the *abductive* reasoning (27), (28).

When using an inductive approach, no hypotheses can be found at the beginning of the research but instead the researcher begins with detailed observations to

then move onto forming ideas and generalisations that generate theory (see Figure 8).

Conversely, a deductive approach means exploring a known theory and testing if that theory is valid (see Figure 9).

An abductive approach allows for both quantitative and qualitative methods to be valuable depending on the type of research question under investigation. The central assumption is that some questions can be better explored through a combination of mixed methods. As explained by Wheeldon et al., (2010), (p. 117): *Abductive reasoning can be understood as a process that values both deductive and inductive approaches but relies principally on the expertise, experience, and intuition of researchers* (29).

In general, the inductive approach is associated with the qualitative approach and deductive approach is associated with the quantitative approach (see Table 10). Pragmatism rejects the notion of choosing between two opposing viewpoints and strives to integrate quantitative and qualitative research strategies (21),(30) even though they are different in their philosophical underpinnings and their approach to finding the truth (see Table 11).

From: Competing Paradigms in Qualitative Research, Guba&Lincoln et al., 1994 (22).

Quantitative Approach	Qualitative Approach
Emulates natural sciences, reality is objective and therefore it is possible to uncover the truth.	Developed in response to the study of people, reality is subjective; there is no objective truth to uncover.
Deductive, and breaks phenomena down into independent and dependent variables.	*Inductive*, and sees phenomena as holistic and interdependent systems.
Large data sets, numerical analysis and generalisations about large groups.	Small data sets, explaining and/or interpreting, in depth insights into small groups.

Morgan et al., (2007) explains the differences in the inductive, deductive and mixed approaches (27), based on their connection *to theory and data* (see Table 11). Qualitative research emphasises an inductive approach which is subjective. On the other hand a quantitative approach is deductive and objective. In mixed research, however an abductive approach is assumed which requires the researcher to adopt an *intersubjective* stance. He summarises the three approaches in the following way;

- Inductive-subjective-contextual approach is emphasised in qualitative research.
- A deductive-objective-generalising approach is emphasised in quantitative research.
- An abductive-intersubjective-transferability is emphasised in mixed research.

Table 11. A Pragmatic Alternative to Key Issues in Research Methodology

From: Pragmatism as a Paradigm for Social Research, Morgan et al., (2014) (27).

	Positivism	Constructivism	Pragmatism
Connection of Theory & Data	Deduction	Induction	Abduction
Relationship to Research Process	Objectivity	Subjectivity	Intersubjectivity

Inference from Data	Generality	Context	Transferability
Approach	Quantitative	Qualitative	Mixed

4.5.2 Choosing between Mixed Methods Designs

Within mixed-methods, there are four major types of designs. They are: Triangulation, Embedded, Explanatory and Exploratory design (20). According to Creswell (2003), the following should be considered in the choice of mixed-methods approach: i) Goals and aims of each part of the study; ii) Methods of data collection such as what type of data and when it will be collected and; iii) Whether data is collected simultaneously (concurrent designs) or in different stages of the project (sequential designs) as well as how it will be integrated.

Table 12 summarises the four major designs and their corresponding timing, weighting, and mixing decisions.

Table 12. The Major Mixed-Methods Design Types

Design Type	Variants	Timing	Weighting	Mixing	Notation
Triangulation	Convergence Data transformation Validating quantitative data Multilevel	Concurrent: quantitative and qualitative at same time	Usually Equal	Merge the data during the interpretation or analysis	QUAN + QUAL
Embedded	Embedded experimental Embedded correlational	Concurrent or Sequential	Unequal	Embed one type of data within a larger design using the other type of data	QUAN(qual) or QUAL(quan)
Explanatory	Follow-up explanations Participant selection	Sequential: Quantitative followed by qualitative	Usually Quantitative	Connect the data between the two phases	QUAN qual
Exploratory	Instrument development Taxonomy development	Sequential: Qualitative followed by quantitative	Usually Qualitative	Connect the data between the two phases	QUAL quan

A mixed-methods sequential explanatory approach was chosen in this research. The rationale for this approach is that the quantitative data will be gathered to provide a general understanding of the research problem and that qualitative methods can be used to refine and explain those statistical results by exploring participants' views in more depth (32).

The purpose is to use the qualitative results to further explain and interpret the findings from the quantitative phase. In practise, this approach means collecting and analysing first quantitative and then qualitative data in two stages within one study (25). This is particularly useful when undertaking a feasibility trial because multiple method process evaluations allow a study to be examined in greater depth. In this instance, quantitative outcome results gained from the feasibility study will be further illuminated by the findings of semi-structured interviews with study participants, and health professionals.

Findings from both stages of the research will then be considered in the interpretation phase for the purpose of designing a definite future RCT protocol. A pragmatism approach, with its ontological and epistemological stance will allow renegotiation and interpretation of reality in light of its usefulness, whilst incorporating both subjective and objective views.

4.6 The Role of Theory and Behaviour Change Techniques

The MRC framework recommends identification of relevant theories to underpin the development process of complex interventions (15). The motivation to use theory is that it can be used to understand what works and why i.e. to explain the mechanism of action (33). The National Institute of Clinical Excellence (NICE) has produced a set of guidelines for intervention development, which recommend the use of behaviour change theory (BCT). Specifically they recommend the use of the COM-B framework and the Behaviour Change Wheel (BCW) approach to intervention development. The BCW framework is a process that guides the systematic selection of intervention functions and techniques. These are all linked to theories of behaviour change. As per NICE guidelines, the BCW will be used in the development of the intervention design. The selected behaviour change techniques that are implemented in the design will be linked to theory which is important to explain the process of behaviour change (34) and the likely mechanism of action. The BCT and the intervention development process are explained in detail in chapter 6.

4.7 Design

The PhD project design commenced with a systematic literature review to inform the research question. Thereafter, an experimental RCT design was developed and implemented using a mixed-methods approach of sequential nature. The development process was theoretically underpinned as per NICE guidelines using the COM-B model. The development process is described in detail in chapter 6.

4.7.1 Maternal Services Patient and Public Involvement Group

Patient and Public Involvement in research design has been recognised to be important as their participation in research studies. Patients and health service users can help to make sure that the right research is done and in the right way (35). For this reason, a Maternal Health user Patient and Public Involvement (PPI) group was involved in tailoring the design of the study protocol. In this study, the purpose of involving a maternity services users PPI group was to ensure that the intervention design was grounded in an in-depth understanding of the psychosocial context of the people who will use the intervention (36). The approach is particularly useful because it can highlight the issues relating to feasibility and engagement with the intervention. In this instance, the feedback from the PPI group was used to amend the protocol design, and the patient information sheet, to make it more sensitive to the needs of women.

Following this phase, the study was implemented and all PA, GWG, pregnancy and antenatal quantitative data was collected and analysed. Following the quantitative phase, a process evaluation by means of semi-structured interviews with participants from both randomised groups and health professionals was completed to gain better understanding.

4.7.2 CONSORT Guidelines

The CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement was produced with the aim of improving the reporting of parallel-randomised controlled trials (37), (38). CONSORT guidelines have since been developed to address the increase in web-based/mobile interventions due to the recent changes in intervention developments. As part of the new guidelines a CONSORT EHEALTH checklist has been created (39). This study will follow the E-HEALTH checklist to ensure better-quality reporting (39).

4.7.3 Data Protection Act

The Data Protection Act (1988) was passed to ensure that anyone handling personal information should be under legal obligations to protect that information under the Data Protection Act 1998 (40). It regulates the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. Anyone who processes personal data must comply with eight principles, which make sure that personal data are:

- fairly and lawfully processed;
- processed for limited purposes;
- adequate, relevant and not excessive;
- accurate and up to date;
- not kept for longer than is necessary;
- processed in line with your rights;
- secure; and
- not transferred to other countries without adequate protection

4.7.4 Good Clinical Practice

Good Clinical Practice (GCP) is an international set of ethical guidelines, which are followed to ensure that the rights, safety and wellbeing of research participants are protected (41),(42). I completed Good Clinical Practice training in 2015, prior to commencement of this study. Quality control was maintained through adherence to study protocol, and principles of Good Clinical Practice guidelines (International Conference on Harmonisation, 1996) (41). Caldicott Principles were adhered to, to ensure proper handling of patient information data. The guidelines instruct researchers to ensure full confidentiality for participants and safe storage and password protected access to all confidential data (43). Data were handled in accordance with the Caldecott Principles (44). A summary of the particular ethical considerations of this study are presented in the following discussion.

4.8 Ethical Considerations in Research

Ethical guidelines have been developed in medical research to create a system of moral principles and to address conflicts of interest, which may exist between different parties. The four main underlying principles are autonomy, non-

maleficence, beneficence, and justice. 'Ensuring participants' right to autonomy in research' means providing them with sufficient information and time to understand the information. Beneficence is instructing medical researchers to prioritise the well-being of patients. Non-maleficence is instructing researchers to 'do no harm' by ensuring caution and careful decision-making as well as proper training. The principle of justice is instructing a fair and equitable distribution of benefits among participants (45).

4.8.1 Ethical Approval

The study protocol was submitted to the Ethics committee of NHS North of Scotland Research Ethics Committee for approval. In addition to the ethics approval, an approval was obtained from the Health Research Authority (HRA), as well as a local governance approval from the Sheffield Teaching Hospitals.

4.8.2 Informed Consent

Pregnancy can be a stressful time where a woman may feel more vulnerable to any undue pressure (46) and even more at the time of the first hospital appointment and the first scan (47). For this reason, it was important to be considerate of these circumstances when approaching the participants. Particular care was taken to provide clear verbal information at the time of approach. The researcher explained all study details including the purpose of the research, the length of time of the study and the right to confidentiality. The researcher also explained that participation was entirely voluntary and that they could decline to take part at any stage of the study. Also, it was important to explain that a refusal to take part would not have any consequences on participants' usual care. It was also important to provide clear written information that participants could read at home. An information pack was provided, which included a Patient Information Sheet (PIS) (see Appendix A) that had been approved by an NHS Ethical committee and which included detailed information about the study, including: that data would be confidential and anonymised; the right of the participants to withdraw at any point; and that declining to take part would not affect usual care. These documents were reviewed by the Reproductive Health Patient and Public Involvement in Research panel (PPI panel) prior to being approved by the NHS Ethics committee. PPI panel's comments and suggestions were addressed to

provide a suitable information pack. The information pack also included instructions on how to adjust privacy settings on Facebook, should they decide to take part in the study. Participants were given at least 24 hours to consider whether they wanted to take part in the study. Information about confidentiality and internet-mediated research that was provided is explained in the section below.

4.8.3 Confidentiality

The following measures were taken to protect participants' confidentiality: All participants were assigned an ID number which any data relating to them was identified by, and their names and contact details were kept separately in a locked filing cabinet. All study files, data and transcripts were kept in a secure locked filing cabinet with restricted access. All electronic data relating to the studies were only accessible to the researcher and were stored on a password protected PC. Participants were informed that all data in the published material would be anonymised. All participants who took part in semi-structured interviews were recorded. The interviews were transcribed. The transcripts were kept on a password-protected computer. All confidentiality-related concerns were outlined in detail in a data management plan, which was approved by Sheffield Hallam University Ethical Committee and the NHS Ethical Committees. The data management plan is attached in Appendix B.

4.8.4 Confidentiality and Internet-Mediated Research

The research protocol used an internet-based medium i.e. a Facebook group (FB group), which was created for the purpose of intervention delivery. The FB group had stringent privacy settings: The group was made both 'private' and 'secret'. To ensure anonymity the FB group was 'secret' (no non-members could find the group using the FB or Google search engines or know of its existence because it did not appear).The group was also private in that only the moderator could invite and accept members into the group. Only the moderator (PhD researcher) had access to the log in and password to this closed group. No one outside the intervention had access to the group. All data that was collected from the FB group were anonymised prior to analysis. We used the Sheffield Hallam University Social Media Guidance (see Appendix C) and the guidance provided by the British Psychological Society (48) to ensure best conduct.

To protect participants and ensure confidentiality a handout with privacy settings instructions was included in all information packs to ensure that all participants checked their privacy settings and that they knew how to do so. The document with privacy settings instructions was also attached to the FB group wall, for all participants, in case they lost the paper handout. This information was also communicated to them verbally at the time of consent. Participants were also made aware that their name would be visible to other participants who joined the group; but they were also given instructions on how to adjust their FB settings so that their FB profile (photos, wall and friends list) were not visible to other group members. All participants were told about the FB component of the study prior to consent.

All participants were made aware of the level of anonymity on FB and signed a consent form to say that they understood that their name would be seen by other members of the closed FB group. Also, all participants were asked to sign a consent form that asked them to agree not to discuss with non-members what was discussed in the group, and also not to discuss other members' names outside the group. The participants were told that they could leave the group and delete their own comments on the FB group page if they wish to do so. The participants were informed that their comments may be used as research data.

4.9 Summary

This chapter has sought to justify the reasoning and choices behind the methodology of this thesis. It has listed the processes that took place before reaching the final thesis design, including the aspects of research related to ethical conduct, confidentiality, patient involvement and good clinical practice. The following chapters will present my systematic review, the feasibility RCT development process, feasibility RCT design, findings and a process evaluation of the feasibility RCT followed by a full size RCT Protocol design. The last two chapters in this thesis are a Discussion (Chapter 10) on the findings, followed by a Conclusion (Chapter 11) that is examining in greater depth the overall contribution to knowledge, self-reflection and future implications of this work.

Chapter 5. Systematic Review of Effects of Walking on Pregnancy and Birth Outcomes in Pregnant Overweight Women

5.1 Introduction

This chapter presents the process and findings of the systematic review, into the effect of walking interventions in pregnant and overweight women, on gestational weight gain (GWG), pregnancy and birth outcomes. This review will add to current literature by focusing on the effects of walking on pregnancy and birth outcomes in overweight and obese women.

Obesity and excessive gestational weight gain (GWG) increase the risk of complications such as preterm delivery, gestational diabetes mellitus (GDM), pre-eclampsia, prolonged labour and medically-indicated caesarean deliveries (49). Excessive GWG can be particularly concerning for overweight and obese women due to their already increased risk for adverse pregnancy outcomes (50). Excessive GWG is obese pregnant women is associated with significant neonatal adverse outcomes, such as large for gestational age (LGA), macrosomia (birth weight>4000g), low Apgar score and neonatal admission to a special care baby unit (SCBU) (51).

There is moderate evidence that increasing PA can lower GWG and the adverse risks in pregnancy (9). In the UK, the Royal College of Obstetricians and Gynaecologists (RCOG) recommend that pregnant women undertake 30 minutes of moderate PA daily, provided that they are healthy and are considered to have a low risk pregnancy (52). Several studies have shown that walking is a convenient mode of moderate-intensity exercise and it has been reported as one of the most frequently performed activities during pregnancy. A self-reported questionnaire-based study which included 853 women, found that all categories of activity decreased during pregnancy, except walking which increased by the third trimester (53).

A number of systematic reviews have examined PA and exercise interventions during pregnancy. Their findings have given an important insight to the effect of exercise on GWG and pregnancy outcomes, uptake, acceptability and compliance (54),(55). However, they have also demonstrated the lack of walking interventions to determine the relationship between step counts and activity

intensity and pregnancy outcomes despite walking being the most common activity practiced among pregnant women.

Elliot-Sale et al's (2015) review found that aerobic and resistance based exercise interventions were mainly performed during pregnancy, whilst walking interventions were primarily undertaken during the postpartum period. The review also found that the aerobic exercise interventions had a lower adherence rate (63%) versus walking interventions (83%) (54). Russo et al's review that looked at the effectiveness of PA on GDM found that eight of the 10 studies utilised group exercise models, most of which seemed to represent a high burden for the participants. The adherence rates were as low as 16%, whereas loss to follow-up averaged at 33% (2). Both reviews' findings suggest that the practicality and acceptability of group versus individual based PA interventions are in need of further in-depth evaluation.

A review by Choi et al., (2016) found that effective interventions included individualised targets based on each participant's capabilities. It emphasised the importance of addressing the shortcomings of the group-exercise interventions, such as burdensome time commitment and high cost to both participants and providers (55).

After multiple searches of several databases it was established that there are no systematic reviews that have examined exclusively the effects of walking on pregnancy and birth outcomes in women who are overweight and obese. Because walking is the most commonly reported type of PA in pregnancy and can be easily incorporated into a daily routine, it was important to establish whether it is effective in lowering GWG and adverse risks in obese, pregnant women. To the best of the authors' knowledge there are no systematic reviews that have evaluated the effectiveness of walking interventions on pregnancy and birth outcomes before.

5.1.2 Aims and Objectives
The aim was to examine randomised controlled trials which report the effects of

walking on gestational weight gain (GWG) and maternal and infant outcomes, in pregnant women who are overweight or obese.

5.2 Method

The Cochrane handbook for systematic reviews for interventions was used to follow specified guidelines recommended when doing a systematic review(56). The systematic review is reported according to the PRISMA statement checklist (57). The protocol for this systematic review was published on Prospero (International prospective register for systematic reviews) on 12/10/2016. The registration number is CRD42016049251.

5.2.1 Types of Studies

To be eligible for inclusion in the review, a study must have been a completed or ongoing randomised controlled trial, published in the English language. The searches were done from November 2016 to January 2017. No publication date limits were applied.

5.2.2 Types of Participants

The focus of the research was on overweight and obese pregnant population. Therefore, the participants needed to be pregnant at any gestational period, of any age and with a BMI ≥25kg/m². Studies that had a mixed BMI population and did not stratify outcomes according to BMI categories were excluded.

5.2.3 Types of Interventions

The aim was to examine the effectiveness of walking interventions during pregnancy. For this reason, a study must have reported walking as the intervention, measured by either a pedometer and/or the Physical Activity in Pregnancy Questionnaire (PPAQ). Interventions which reported walking as one component of a mixed approach, e.g. diet and walking or walking and aerobic exercise, were excluded.

5.2.4 Comparison Arms

Any study that lacked a control group defined as 'receiving standard care' and/or receiving any other intervention or involvement in any other type of physical activity was excluded.

5.2.5 Types of Outcome Measures

The primary outcome of interest was gestational weight gain. The secondary outcomes of interest were: gestational diabetes mellitus, hypertension, preeclampsia, blood pressure, caesarean section, spontaneous vaginal birth, instrumental birth, induction of labour, gestational age at birth, preterm birth, macrosomia, large for gestational age, small for gestational age, placenta weight, neonatal admission to special care baby unit (SCBU), APGAR Score <7 at 5 min after birth, change in level of physical activity (objectively measured and/or self-reported), and maternal back pain.

5.3 Search methods for identification of studies

5.3.1 Electronic databases

The bibliographic databases that were searched are: ASSIA (via ProQuest), CINAHL Complete (via EBSCO), Cochrane Central Register of Controlled Trials (CENTRAL) (via Wiley), Maternity and Infant Health (via Ovid), MEDLINE (via EBSCO), SPORTDiscus (via EBSCO), Web of Science (via Thomson Reuters). In addition, the clinical trials registers as follows were searched: the International Clinical Trials Registry Platform (World Health Organisation), UK Clinical Trials Gateway (NHS, National Institute for Health Research). Author, citation and reference searches were undertaken on all studies included in this review. The databases were searched in December 2016. The clinical trials registers and the author, citation and reference searches were undertaken in April 2017.

An initial limited search of MEDLINE (via EBSCO) and Web of Science (via Thomson Reuters) was undertaken, followed by an analysis of the text words contained in the title and abstract, and, in the case of MEDLINE, of the index terms used to describe the relevant articles. A second search using all identified keywords and index terms was then undertaken across all included information sources. The search syntax and, where available, the index terms were adapted for use on each information source.

5.3.2 Search Strategy

The search comprised four facets: (1) terms relating to pregnancy, and (2) terms to describe overweight or obesity, and (3) terms to describe walking and (4) terms

to describe randomised controlled trials (as detailed by the Scottish Intercollegiate Guidelines Network [22]). English language search filters were applied where available. A copy of the full list of search terms as written up for MEDLINE (via EBSCO) is included below. The searches have been written up for MEDLINE using the EBSCO interface and are detailed below.

Explanation of search terms used: ti = title field; ab = abstract field; tx = all searchable fields; / = MeSH; exp. = explode MeSH; asterisk = denotes any character; "" = phrase search; N3 = adjacency within three words.

The terms relating to RCTs were taken from a validated search string produced by the Scottish Intercollegiate Guidelines Network [22]. In addition to their terms, "quasi*" or "non-randomised controlled trials as a topic/" or "non randomised controlled trial*" or "non randomised controlled trial*" were added

(see Appendix J for Search Terms). Grey literature was searched for relevant papers.

5.4 Data Collection

5.4.1 Study Selection

All papers were independently double screened for relevancy by two reviewers (PhD researcher and Information Scientist). In the first instance all papers were screened for relevancy using the title and abstract. The full-text of all remaining papers was then screened. The eligibility of a paper was determined using the previously outlined criteria (see table 13). Studies had to report all the criteria in Table 13 to be included. Studies did not have to report GWG if they reported any other pregnancy and antenatal outcomes.

Table 13. Study Selection Criteria

Inclusion Criteria	
Population	Pregnant women with a BMI ≥25kg/m²
Interventions	Walking interventions Only (Complex Interventions and Interventions including other forms of PA were excluded)
Comparator	Usual/Standard Care
Outcome	GWG, Pregnancy & Antenatal Outcomes

Study Design	Randomised Controlled Trial (including feasibility and pilot studies)

Any disagreement between reviewers as to the inclusion or exclusion of a paper was resolved through discussion with a third reviewer. The first author of a paper was contacted for further information if it was not possible to determine the eligibility of a study based on the published information or where relevant outcomes were not reported. Authors of two publications were contacted and were received a response from both, stating that they did not have the relevant data.

5.4.2 Reference Checking
All eligible studies' references were searched for additional publications.

5.4.3 Data Extraction
Data from included studies were extracted by one reviewer using the Cochrane data extraction sheet and checked by a second reviewer. Any disagreements were resolved through discussion.

5.4.4 Quality Assessment
The quality of each included study was determined by one reviewer using the criteria outlined in the Cochrane tool for assessing risk of bias (56). A second reviewer checked the assessments. The quality of a study was determined based on the following domains; sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other potential sources of bias. For each study, a domain was classified as having a "low risk of bias", "high risk of bias" or an "unclear risk of bias" in accordance with the Cochrane criteria for judging risk of bias (56).

5.5 Data Synthesis
Due to insufficient data and variation in reporting between studies, the outcomes were synthesised and reported narratively.

5.5.1 Results

The database and clinical trials searches identified 992 unique papers. After screening for relevancy by title and abstract, the full-text of 23 papers was read and 2 eligible papers were identified. Author, citation and references searches using the two included papers yielded no additional eligible papers for inclusion in the review. The literature review search and screening process is summarised in Figure 10.

Figure 10. Flow diagram of Study Selection

From : The Prisma Statement for Reporting Systematic Reviews and Meta-Analyses, Liberati et al., (2009) (57).

Identification	Papers identified through database searching (n = 1441)	Papers identified through clinical trials searches (n = 68)

Papers after duplicates removed (n = 992)

Papers screened by title and abstract (n = 992) → Papers excluded (n = 975)

Papers screened by full-text (n = 17) → Full-text articles excluded, with reasons (n = 15)

Intervention not walking (n = 5); ineligible study design, e.g. not RCT (n = 4); population not relevant to review/not stratified (n = 5); clinical trial registry - full study included in review (n =1); clinical trial registry - no data

Studies included in this review (n = 2)

Table 14. List of Excluded Studies and Reason for Exclusion

Title, Author of Excluded Study	Reason for Exclusion
Bo, S., Rosato, R., Ciccone, G., Canil, S., Gambino, R., Poala, C. B.,Menato, G. (2014). Simple lifestyle recommendations and the outcomes of gestational diabetes. A 2x2 factorial randomized trial.	GDM patients. Outcome is fasting glucose, 4 groups with different interventions. No Control
Byrne, N. M., Groves, A. M., McIntyre, H. D., & Callaway, L. K. (2011). Changes in resting and walking energy expenditure and walking speed during pregnancy in obese women.	No intervention. Measuring energy expenditure at walking speed
Chasan-Taber, L., Silveira, M., Marcus, B. H., Braun, B., Stanek, E., & Markenson, G. (2011). Feasibility and efficacy of a physical activity intervention among pregnant women: The behaviours affecting baby and you (BABY) study.	Health and wellness arm and giving out advice and information brochures. Two interventions, unclear what PA type it is.
Dodd, J. M. (2014). Dietary and lifestyle advice for pregnant women who are overweight or obese: The LIMIT randomized trial.	Behaviour Change complex intervention. No walking
Harrison, C. L., Lombard, C. B., & Teede, H. J. (2014). Limiting postpartum weight retention through early antenatal intervention: The HeLP-her randomised controlled trial.	behaviour change lifestyle sessions. No PA
Harrison, C. L., Lombard, C. B., Strauss, B. J., & Teede, H. J. (2013). Optimizing healthy gestational weight gain in women at high risk of gestational diabetes: A randomized controlled trial.	4-session lifestyle program. unclear what entails, and whether it includes walking.
Hawkins, M., Chasan-Taber, L., Marcus, B., Stanek, E., Braun, B., Ciccolo, J., & Markenson, G. (2014). Impact of an exercise intervention on physical activity during pregnancy: The behaviours affecting baby and you study.	Comparing exercise arm with health and wellness arm.
Hayes, L., Bell, R., Robson, S., & Poston, L. (2014). Association between physical activity in obese pregnant women and pregnancy outcomes: The UPBEAT pilot study.	No intervention
Mottola, M. F., Giroux, I., Gratton, R., Hammond, J., Hanley, A., Harris, S., Sopper, M. M. (2010). Nutrition and exercise prevent excess weight gain in overweight pregnant women.	Intervention focus on diet. Complex intervention, exercise component not implemented/not described.
Phelan, S., Phipps, M. G., Abrams, B., Darroch, F., Schaffner, A., & Wing, R. R. (2011). Randomized trial of a behavioural intervention to prevent excessive gestational weight gain: The fit for delivery study.	Complex Intervention Including Diet, advice giving and all forms of physical activity
Poston, L., Briley, A. L., Barr, S., Bell, R., Croker, H., Coxon, K., Sandall, J. (2013). Developing a complex intervention for diet and activity behaviour change in obese pregnant women (the UPBEAT trial); assessment of behavioural change and process evaluation in a pilot randomised controlled trial.	Complex intervention, dietary advice, advice in general, some physical activity, unclear at what time period.
Renault, K. M., Carlsen, E. M., Norgaard, K., Nilas, L., Pryds, O., Secher, N. J., Halldorsson, T. I. (2015). Intake of sweets, snacks and soft drinks predicts weight gain in obese pregnant women: Detailed analysis of the results of a randomised controlled trial.	Dietary Intervention- only. No walking intervention was implemented.
Renault, K. M., NÃ¸rgaard, K., Nilas, L., Carlsen, E. M., Cortes, D., Pryds, O., & Secher, N. J. (2014). The treatment of obese pregnant women (TOP) study: A randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women.	All types of physical activity, measured by pedometer

Shirazian, T., Monteith, S., Friedman, F., & Rebarber, A. (2010). Lifestyle modification program decreases pregnancy weight gain in obese women.	Complex lifestyle intervention, unclear what type of physical activity
Zarezadeh, T., & Nemati, N. (2016). The effect of exercise on childbirth in primiparous women: A clinical trial study.	Included all BMI categories. Reported on the length of labour in minutes as only outcome. Did not measure the level of PA.

5.5.2 Description of Included Studies

Table 15. Characteristics of included studies

Author, publication year, location of study	Participant characteristics	Intervention	Control	Primary outcomes
Kong et al., 2014, USA (58)	BMI ≥25kg/m² ≈11 weeks -36 weeks gestation	Walking on treadmill 30 min/day	Standard Care(routine appointments)	GWG, physical activity (steps), pregnancy and birth outcomes
Stutzman et al., 2010, Canada (59)	BMI≥30kg/m²	Walking 3 km daily	Standard Care (routine appointments)	BMI, systolic blood pressure, diastolic blood pressure

The literature searches identified two eligible studies; Kong et al., (58) and Stutzman et al., (59). Both studies measured the effect of walking on pregnancy and birth outcomes in overweight and obese women, and steps were measured with a pedometer. The study participants were women of any parity with a BMI higher than 25kg/m². The Kong et al., study included a total of 37 participants at 11-14 weeks gestation. The intervention consisted of walking on a treadmill for a total of 150 minutes per week (30 minutes per day) until 36 weeks of gestation. Primary outcomes were change in the amount of walking (measured in steps) and GWG. Secondary outcomes were twelve other pregnancy and birth outcomes, such as mode of delivery, birth weight and Apgar score. The Stutzman et al., (2010) study included a total of 22 participants out of which 12 were overweight at 11-14 weeks gestation and the intervention consisted of walking for 3.0 km per day for 5 days per week until 36 weeks of gestation. The data for the overweight and obese participants were presented separately from the data for other participants both for the intervention and the control group. Primary outcome data were change in BMI and systolic and diastolic blood pressure (BP) (see table 15).

5.5.3 Quality Assessments

Study quality has been summarised in Table 16. Both studies adopted the method of randomisation in their studies; however both studies were underpowered and they included a very small sample size, with varying level of risk of bias. Kong et al., was of a higher quality using a computerised sequence generation and opaque sealed envelopes; reducing selection bias and had a low attrition rate. Stutzman et al's randomisation was methodologically of a poor quality as the random sequence generation was carried out using a coin toss, and so introducing potential selection bias. Considering that it is difficult to blind participants and care providers in this type of interventional study, both RCTs adopted a no blind study design.

Table 16. Study Quality

Author, publication year	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding	Incomplete outcome data (attrition bias)	Selective outcome reporting/others
Kong et al., 2014	Computer-based random number generator	Low risk	-	Low risk	Low
Stutzman et al., 2010	Coin toss	High Risk	-	Low Risk	Low

5.6 Primary Outcome Analysis

Due to insufficient data and variation in reporting between studies, the outcomes were synthesised and reported narratively.

5.7 Summary of findings

Available data for the pre-identified expected outcome measures (described above) were limited and only a few of the outcomes of interest were reported in the included studies. The Kong et al., (2014) study reported on physical activity (steps, cadence), GWG (in kilograms), birth weight, gestational length, macrosomia, Apgar score, preterm delivery rates, caesarean delivery, preeclampsia, maternal hypertension and GDM. The reported steps were 8135±1950 for the intervention group and 7392±2100 for the control group, a difference which was not statistically significant. There were no statistically significant differences in GWG $(p=0.86)$, N=37 or pregnancy complications between the intervention and control arms. Due to the small sample size no statistically significant differences between the groups are expected, however a

favourable trend in the birthweight outcome is encouraging. The Stutzman et al., (2010) study, reported BMI, SBP and DBP outcomes for a total of 12 participants. It did not report physical activity outcomes even though all participants were asked to keep a log of their activities. It also did not report the reason for omitting to report physical activity outcomes. Participants' pre and post BMI showed no statistical difference between the intervention and control group. The study reported a positive trend in changes in physiological markers such as systolic blood pressure (SBP) and diastolic blood pressure (DBP) in the intervention group. The overweight women in the control group showed a trend of increased average resting DBP, whereas the intervention group showed a reduction in DBP. An attempt to contact the authors to obtain GWG data for this study, which would have made it comparable to the Kong et al.,(2017) study, were unsuccessful (see table 17).

Table 17. Reported maternal and neonatal outcomes

Kong et al., 2014 (n=37)	Intervention (n=18)	Control (n=19)
GWG (Δ in kg)	11.3±7.2	11.27±7.4
Birth weight(g)	3650±475	3774±491
Apgar score at 5 min	8.75±0.67	8.5±1.46
Preeclampsia	1	0
C-section	5	9
Maternal hypertension	0	0
Gestational diabetes	1	1
Macrosomia (p=0.335)	5	6
Stutzman et al., 2010 (n=12)	**Intervention (n=6)**	**Control (n=6)**
BMI (Δ kg/m²)	4.85±8	4.86±11.5
SBP arm (Δ mmHG)	-2±15	10±15
DBP arm (Δ mmHG)	3±12.3	8±12.3

Δ=delta/change

5.8 Discussion

To the best of the authors' knowledge this is the first systematic review which has aimed to examine the impact of walking in pregnancy as a stand-alone intervention on GWG and pregnancy outcomes. Two eligible studies were identified. Due to the heterogeneity between the study designs and the differences in the types of outcomes reported, the results were analysed narratively. The primary outcome of interest was GWG. Kong et al., (2014) reported GWG in kilograms, without any significant difference between the intervention and the control groups. Stutzman et al., (2010) reported BMI measurements with no significant differences between the intervention and control group. Due to their small sample size, the studies were not statistically powered to detect a difference in the outcomes. Therefore, their findings only showed trends in outcome. This is the main limitation of both studies. For this reason, all findings are only an indication of trends in direction and magnitude of the treatment effects.

In terms of secondary outcomes, the Kong et al., (2014) pilot study showed a non-significant trend for women in the intervention group to have more favourable pregnancy and birth outcomes, such as birth weight and macrosomia, as compared to the control group; however the study was underpowered and therefore no conclusion about statistical significance can be made. The pilot study was successful in that the intervention group did more walking (measured in steps and cadence). The study had a good attrition rate (20%), which indicates the acceptability of a walking intervention in the overweight, pregnant population.

Stutzman et al., (2010) reported on only one outcome of interest, namely BP. It showed that despite the relatively small number of participants, a low-intensity walking program did have a positive effect on maternal BP. As previous studies have shown that a raised BP in pregnancy is associated with preeclampsia (60), low birth weight (61) and spontaneous preterm birth (62); a focus on these outcomes in future larger trials is required.

The literature review showed only 2 studies that met our inclusion criteria, however, during the process of the review we found studies that, while not meeting our criteria, were relevant, in that they examined effectiveness of walking in pregnancy and these are discussed below.

Among the excluded papers was an adequately powered RCT by Ruchat et al.,(2017) (63) that examined the effectiveness of various intensities of walking on GDM. This study was not eligible for inclusion in the review because it did not stratify participants based on their BMI.

However, it is important to mention that the study showed that capillary glucose responses to exercise were strongly influenced by an interaction between GDM risk, exercise duration and exercise intensity. The study recommendations are that women who follow a modified GDM meal plan should walk for a 25 minutes long session at vigorous intensity or for 35–40 min/session at low intensity if they are at risk for GDM and for at least 25 minutes at either low or vigorous intensity if they are at low risk for GDM.

Whilst previous systematic reviews have conducted an analysis that combined all types of PA in pregnancy, none have analysed the effectiveness of walking either in combination with other types of PA or as a stand-alone intervention, despite walking being the preferred choice of PA among pregnant women [19]. Being an easily accessible low-cost type of PA, walking could play a significant role. The lack of statistically significant differences in the included studies could be due to their small sample sizes. The compliance and low attrition in addition to some evidence of positive trend are encouraging and could inform the development of future larger trials in this area. The two studies demonstrate that a walking intervention in early pregnancy is feasible, in terms of compliance by the overweight and obese pregnant women. For this reason, this review concludes that a large walking intervention, with a robust design and better reporting of outcomes would significantly add to the body of knowledge of what is effective for this population.

5.8.1 Strengths and Limitations

This review was completed in accordance with the PRISMA statement for reporting systematic reviews and meta-analyses. Publication and selection bias sought to be minimised through the inclusion of searches of clinical trials registers and the use of two reviewers who each followed a-priori eligibility criteria and used validated quality appraisal and data extraction tools. Despite these measures, this systematic review has several limitations. Most notable is it having

identified only two eligible studies of which a meta-analysis was not possible due to outcome reporting limitations. Adding to the limitation is the overall small sample size in the studies and the quality and reporting of outcomes, which has limited the generalisability of the results. Even so, given the popularity of walking in pregnancy, it is a significant finding that only two trials could be identified. This finding highlights the need for a focus on walking interventions and for the further development of larger well designed trials.

5.9 Conclusion

This systematic review concludes that the effect of walking on pregnancy and antenatal outcomes in the overweight population has not been sufficiently evaluated. Further adequately powered trials and consistent reporting of outcomes are needed to assess the impact and acceptability of a walking program in the pregnant, overweight population. The findings lead to the conclusion that a walking intervention during pregnancy may have a positive effect, but preliminary research to test the feasibility of interacting components is required, to increase the chances of this being implemented successfully. The compliance and attrition rates in both studies suggest that walking may be an acceptable form of PA during pregnancy. Individually, Stutzman et al., (2010) study informed us that walking may be effective in lowering BP in women who are pregnant and overweight. The study by Kong et al., (2014) informed us that women found the intervention acceptable; however they were mainly encouraged to walk on a treadmill (and were provided with one). This type of intervention would not be feasible to be provided within the NHS, and therefore this alternative would not be considered for our design.

In terms of reporting, the review demonstrates a need to develop a harmonised core outcome set for future reporting of clinical trials in this area, to maximise the meaningful interpretation of published data. This is particularly relevant for how weight gain is reported where in some instances studies report on weight gain in kilograms; change in body mass index or as percentage of those who gain within recommended IOM guidelines.

This chapter has systematically searched the evidence of effectiveness of walking during pregnancy in order to inform the development of the intervention.

The following chapter (chapter 6), describes the step-by-step development of the intervention using the behaviour change wheel tool. It describes the identification of the behaviour (walking), identification of 'what needs to change', selection of intervention functions, application of acceptability/feasibility-criteria, followed by a selection of behaviour change techniques and how they are linked to theories of behaviour change.

Chapter 6. Development process of the 'Walking in Pregnancy' Intervention delivered with mHealth Technology

6.1 Introduction

In 2014, The National Institute for Health and Care Excellence (NICE 2014) published guidance for behaviour change and health intervention development (64). The guidance provides help to tackle a range of behaviours including alcohol misuse, poor eating patterns, lack of physical activity, and smoking. The guidance includes the Behaviour Change Wheel (BCW) (65) which, when used in intervention design, has resulted in better outcomes (15). At the centre of the BCW is the 'Capability, Opportunity, and Motivation in Behaviour (COM-B) wheel model (66). Although some reviews have found no evidence of benefit to a theory based approach (67) in health intervention development, other evidence shows that interventions that use a theory-based approach are more effective. Michie et al., (2010), conducted a systematic review of studies utilising the internet to promote behaviour change. The overall finding was that interventions utilising theory have larger effects on behaviour than those that do not (68). Therefore it is widely recognised that theory can inform and also explain why an intervention is effective or not (69). This chapter will map out the BCW application step-by-step approach, setting out the rationale behind the intervention design and the methodology.

6.2 Choosing Behavioural Theories in Interventions

Behaviour theories attempt to explain behaviour change. Whilst there are many behaviour change theories that have been developed over decades, there is little guidance on how to choose and apply an appropriate theory (70) to strengthen intervention design. Michie et al., (2010) have argued extensively that intervention design requires a theoretical approach to identify the most effective behaviour change techniques. A meta-analysis of physical activity and dietary interventions identified that Social Cognitive Theory was one of the most widely used theories (5). However, the choice seemed mostly based on personal preference, rather than a systematic selection process (71). To standardise the process and create a streamlined approach to theory-based intervention development, COM-B model was developed (see Figure 12). At the hub of the theory is the BCW, which is a framework or a tool that provides a systematic method for understanding behaviour and linking this understanding to techniques

known to change behaviour. It is grounded upon a synthesis of 19 behaviour change frameworks identified in a systematic literature review and combined to create a scientific approach to designing effective interventions (70).

6.3 Behaviour Change Wheel

At the hub of the BCW is the Capability, Opportunity and Motivation for behaviour model (COM-B model), which can be seen as the sources of behaviour (See Figure 12). The terms *Capability, Opportunity and Motivation* are used in a broad sense with the model suggesting that limitations to just one of these facets would significantly hinder the desired behaviour change. Therefore, all three facets require consideration during intervention development (70). The facets branch out into *Intervention functions,* (the red part of the wheel). The theory is that any strategy for behavioural change can be classified under one of these headings. *Intervention functions* branch out further into the policy categories (the grey area of the wheel). Whilst the BC Wheel provides a way to systematically identify and select intervention functions, the framework also recognises that not all functions may be acceptable, practical and cost-effective. For this reason the framework also suggests that options are considered using Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, and Equity criteria (APEASE Criteria). This process is explained in more detail (see Figure 13).

Figure 11. COM-B Model

From: An Introduction to the Behaviour Change Wheel, Michie, 2012 (65).
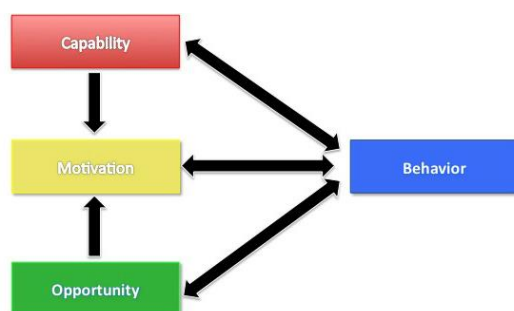
Figure 12. Behaviour Change Wheel

From: An Introduction to the Behaviour Change Wheel, Michie et al., (2012) (66).
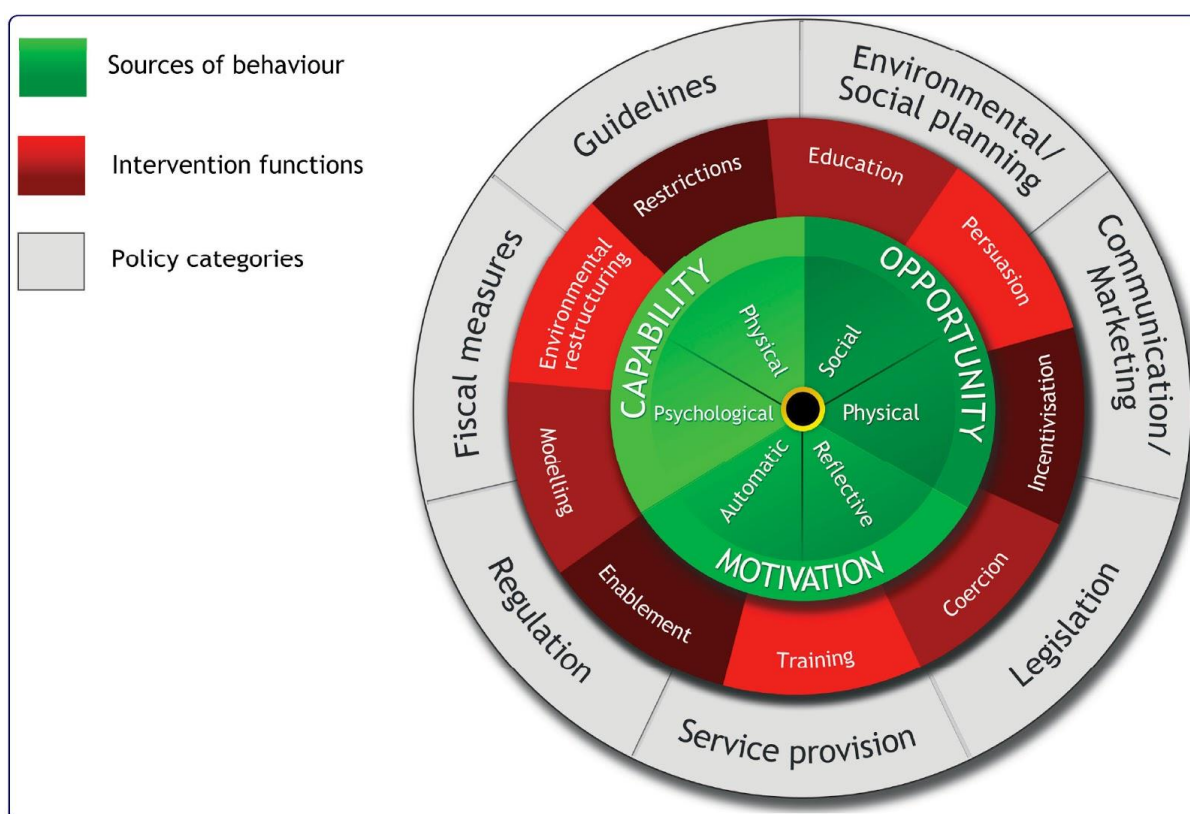
6.3.1 Using the Behaviour Change Wheel

The systematic approach to using the BCW framework is summarised in Figure 2. The steps can be explained as follows: 1. Identify the behaviour; 2. Identify what needs to change (using the COM-B part); 3. Select relevant intervention functions; 4. Apply APEASE (Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, and Equity) criteria to the selected intervention functions; 5. Select appropriate behaviour change

techniques that are linked to the functions (70). The process is summarised in Figure 13.

Figure 13. The process of applying BCW model.
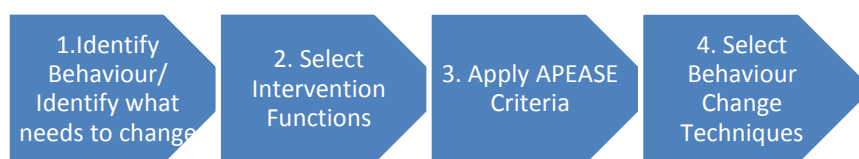
6.3.2 Applying the COM-B Model to the 'Walking in Pregnancy' Intervention Development

The next section will outline the BCW step-by-step development process of the Walking in Pregnancy feasibility study. A systematic approach was used to apply the COM-B model in intervention design, as closely as possible.

Step 1. Defining the problem in behavioural terms and specifying the target behaviour

In this study, the defining problem is lack of physical activity during pregnancy. Based on the findings from earlier literature on PA interventions in pregnancy, the purpose of this intervention is to increase walking, both indoors and outdoors. The detailed justification and underpinning of walking as the preferred type of PA has been explained in Chapter 2 of this thesis. In Table 18, the target behaviour is further specified to explain frequency and social set up for the (group or individual) proposed activity.

Table 18. Behaviour and Frequency

Target Behaviour	Walking/Increasing step count
Who needs to perform the behaviour	Pregnant, obese women
What do they need to do differently to achieve the desired change	Increase walking
When do they need to do it	Daily, every day, any time of day
Where do they need to do it	Indoors/outdoors
How often do they need to do it	30 minutes daily (every day, RCOG Guidelines, 2010) (30 minutes daily) (52)
With whom do they need to do it	Individual/group

Step 2: Selecting COM-B components that need to change:

The relevance of the intervention and need for change were assessed based on previous knowledge about barriers to practicing the behaviour from published literature and earlier studies which were covered in Chapter 1. The relevant COM-B components that will be included following the systematic approach are; ***psychological capability, social opportunity, reflective motivation and automatic motivation***. Psychological capability was selected because the literature review identified that there is insufficient knowledge about the importance of PA in pregnancy, as well as a high perception of risk (72). In addition, previous reviews identified the effectiveness and importance of self-monitoring technique in behaviour change (73). Social opportunity was identified as highly important because of self-reported perceived lack of social support to PA during pregnancy, especially among the overweight population (74). Reflective motivation was highlighted as important due to reported lack of confidence and a lack of understanding of the negative impact of sedentary behaviour (75). The **highlighted columns** in Table 19 are COM-B components that are targeted as part of the intervention.

Table 19. COM-B Components that will be targeted as part of the intervention

COM-B model component	What needs to happen?	Relevance (is there a need for change)
Physical capability	- Have the capability to be able to walk	No need to change as study inclusion criteria only includes participants who can physically walk and who have no other complications that put them at risk for walking. Potential physiological obstacles such as tiredness, sickness and carrying excess weight, have been considered. These will be explored as part of the feasibility study.
Psychological capability	- Be capable of understanding the importance of physical activity in pregnancy - Be able to remember to walk - Be able to self-monitor amount of walking - Be aware of a need to improve the level of physical activity	Needs addressing as women do not have sufficient knowledge about importance and positive effect of PA. Women's perception of risk of PA in pregnancy needs to be addressed The relevance of remembering and self-monitoring needs addressing as it is an important component of behaviour change.
Physical opportunity		Not needed to change as walking can be done anywhere.

COM-B model component	What needs to happen?	Relevance (is there a need for change)
Social opportunity	- Be/feel supported by others to be active during pregnancy	Change needed as women do not always see other pregnant, obese women walking and being active.
Reflective motivation	- Perceive benefits of walking during pregnancy - Perceive few/no concerns about risks of walking during pregnancy - Understand the health consequences of low physical activity in pregnancy - Feel confident about physical activity during pregnancy -	Change needed as literature shows that a barrier to PA in pregnancy is perception of risk. Literature shows that women are not aware of negative consequences of being sedentary in pregnancy. Confidence has been shown to be one of the barriers to behaviour change.
Automatic motivation	- have a habit for walking	This is something that can be addressed overtime, if asking participants to form a habit by executing behaviour at a certain time every day.
Behavioural Diagnosis of the relevant COM-B components:	For the walking to happen *psychological capability, social opportunity, reflective motivation and automatic motivation* need to change to achieve behaviour change.	

Step 3: Identifying Intervention Functions

The 9 intervention functions that are presented in red in the wheel are: Restrictions; Education; Persuasion; Incentivisation; Coercion; Training; Enablement; Modelling; and Environmental Restructuring. To use the BCW one needs a good understanding of intervention functions and their meanings to appropriately select relevant functions (see Table 20).

Table 20. Intervention Functions

From: Behaviour Change Wheel - A Guide to Designing Intervention, p. 111 (70)*.*

Intervention Functions	
Education	Increasing Knowledge or Understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to limit set boundaries around behaviour

Environmental restructuring	Changing physical or social opportunities
Modelling	Providing an example for people to imitate or aspire to
Enablement	Increasing capability or opportunity other than by other intervention functions

6.3.3 Selecting Relevant Intervention Functions based on APEASE Criteria

The selection of intervention function was done based on knowledge about what specifically needs to happen/change and the application of the APEASE assessment criteria in the context of walking in pregnancy. Applying the APEASE criteria allows for assessment of the practicality, effectiveness and acceptability of the functions. Once the APEASE criterion has been applied, and the relevant intervention functions have been identified, a step-by-step guide allows for selection of behaviour change techniques (BCTs). The assessment is presented in Table 21.

6.3.4 Linking Intervention Functions to Behaviour Change Techniques (BCTs)

Each Intervention Function is linked to techniques in the taxonomy of BCTs (34). **Column 1** in Table 21 below lists the identified COM-B components that have been identified as needing to change. **Column 2** in the table is listing the corresponding intervention functions that were identified. In **Column 3,** the APEASE criterion has been applied, answering the question 'Does the intervention function meet all or most of the APEASE criteria? For instance, Modelling and Restrictions are two functions that have not been selected. Modelling has not been selected to avoid creation of a 'naming and shaming' situation. Pregnant women are known to do their best to be healthy during pregnancy to protect their baby from harm (47). Modelling may bring about feelings of guilt and negative feelings, which are likely to have a negative impact on women psychologically and may impact their behaviour negatively. The Modelling function would therefore not be practical and effective for this population and this behaviour. **Column 4** is listing behaviour change techniques that were identified from the taxonomy of BCTs (34). Also, functions were linked to BCTs in a paper by Michie et al. (68) The outlined link in the paper suggested most appropriate techniques to the functions and changes that one aimed to target (76).

BCTs that were selected for inclusion are: goal setting, self-monitoring, information about health consequences, credible source, prompts/cues, problem-solving, feedback, social support, social reward, graded tasks, habit formation. This process is summarised in Table 21.

Table 21. Process of Linking COM-B components to BCTs

Column 1	Column 2	Column 3	Column 4
COM-B component	Intervention Function	APEASE criteria	Proposed BC Techniques
Capability (Psychological)	Education	Yes	Goal setting (behaviour)
			Self-monitoring
			Information about health consequences
			Prompts/cues Problem-solving
			Feedback
Opportunity (Social)	Enablement	**Enablement-Yes** Modelling- No. Not practical to deliver modelling for reasons to avoid a 'naming and shaming' situation.	Social Support
	Modelling		Social reward
	Restriction	Restriction- No. Not practical as there are no options to restrict in this context.	Graded tasks
	Environmental restructuring	**Environmental Restructuring**: Changing the online social environment (creating an online group with all participants that are will try to walk more which will bring about change in social opportunity)	
Motivation (Reflective)	Incentivisation,	**Incentivisation- Yes Education- Yes**	Social Reward
	Education, Persuasion, Coercion	Coercion-No.Not practical with punishment or cost implementation.	Information about health consequences
		Persuasion- Yes	Credible Source

Motivation (Automatic)	Persuasion	**Persuasion -No**	
	Coercion	Coercion- No	
	Incentivisation	Training- No-not needed	Social Reward
	Training	Incentivisation- Yes	

6.3.5 Selecting effective BCTs in PA interventions in Pregnancy

During the BC Techniques selection process, some techniques from the taxonomy were included, whilst others were left out. This decision was based on previous knowledge from the literature. For instance, two reviews in particular, evaluated the content of interventions and mapped the BC Techniques that were used. A review by Currie et al., (2013) that focused on the content of PA interventions for pregnant women identified that the most effective interventions incorporated a range of behaviour change techniques including goal setting and planning, shaping knowledge and comparison of outcomes. A paper by Soltani et al., (2016) showed that goal setting and feedback and monitoring were the most commonly used techniques too (77). Also, two large-scale systematic reviews using the taxonomy and conducting meta-regression showed that interventions prompting participants to self-monitor their behaviour were more effective in achieving behaviour change (78), (68). Perhaps counter-intuitively, Michie et al., (2008) demonstrated that interventions focusing on fewer techniques were generally more successful at changing behaviour than those incorporating many techniques (79). However, what has also been shown is that theoretically-linked techniques work well together. For instance, grouped BCTs that combined self-monitoring with other self-regulatory BCTs (eg. action planning and goal-setting) were effective (68). Whilst the importance of a systematic selection of BC Techniques in intervention design has been proven it is important to include all existing evidence before making the final decision.

6.4 Linking BC Techniques to existing Behaviour Change Theories

All BC Techniques are grounded in behaviour change theories. Although there is an overlap of constructs across theories, each technique within the taxonomy of BC Techniques is theory-linked. This link is important because theories explain

the mechanisms of action of the BC Techniques, which allows for evaluation of interventions and a better understanding of why and how they work. Within this study, selected BC Techniques are linked to various theoretical constructs to identify mechanisms underlying particular behaviour change techniques and then discuss their effectiveness (79). In this study, the selected techniques were s**elf-monitoring** and **goal settings**, **feedback**, **prompts/cues** and **graded tasks,** all of which stem from Control Theory (80).

6.4.1 Control Theory

Control theory explores the regulation of human behaviour. It proposes that behaviour is regulated by a '*negative feedback loop, in which a person's perception of their current state is compared against a goal state',* (p.83) (81)*.* According to this theory, human behaviour is a closed loop of control that will continuously correct itself to minimise the gap between 'a person's current behaviours and the ideal standard of comparison' (see Figure 14). This is why the goal setting and self-monitoring techniques should work in theory. A goal-setting technique is twice as effective (Michie et al., 2013) if combined with behaviour change techniques theoretically predicted to act synergistically; like self-monitoring which will also be used in this intervention. To strengthen the evidence base, a systematic review examined the link between effective interventions and behaviour change theories. It found that techniques associated with Control Theory were effective (78). Also, a study by Prestwich et al., (2016) found that incorporating control-theory based techniques like self-monitoring, goal-setting and feedback, lead to significant short-term improvements in objectively assessed physical activity (82).

Figure 14. Control Theory: Negative Feedback Loop
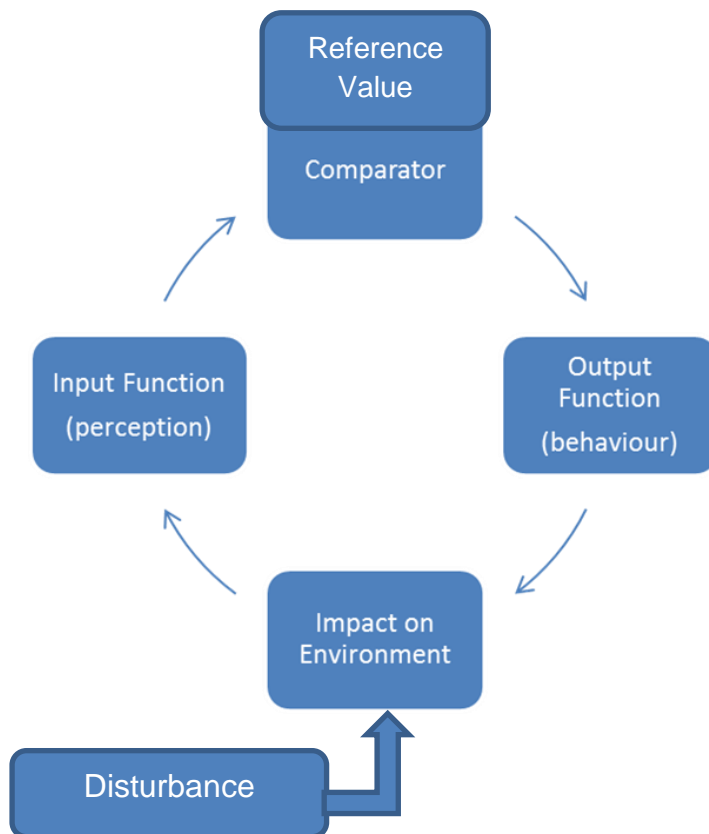
Source: Carver & Scheier (1982) Control Theory (80)

6.4.2 Social Cognitive Theory

Results of a previous systematic review (78) identified that the most commonly incorporated BC Techniques for diet and physical activity behaviour change interventions were related to Social Cognitive Theory. The central idea in Social Cognitive Theory is that behaviour, the environment and personal factors all interact to produce behaviour. Self-efficacy is the central construct in SCT because 'perceived self-efficacy' influences directly our choices of actions, outcome expectations and perseverance and therefore has most influence on behaviour (71). BCTs such as *Information about health consequences, perceived social support and problem-solving* (addressing barriers) are nested in Social Cognitive Theory. Self-efficacy is achieved within the walking intervention by means of allocating individualised goal-setting. *The relationship between goal setting and self-efficacy is reciprocal: goal setting helps to grow self-efficacy, while increased self-efficacy improves the quality of later goals* from Academic self-efficacy: from educational theory to instructional practice. *Perspectives on Medical Education*, pages 76–85 (83). A more recent meta-analysis identified that Social Cognitive Theory is one of the most widely used theories for developing PA and dietary interventions (84) because it explains the mechanism

of behaviour change techniques that have been effectively used in PA interventions.

6.5 Selecting a Mode of delivery for a Walking Intervention

Step 4:

The last step in the application of BCW is a systematic selection of methods of delivery in an intervention. The BC Theory recommends that an APEASE criterion is applied during the selection process; i.e. the questions of *acceptability, practicality effectiveness and cost* are applied. Table 22 lists all modes of delivery options and the 'x' marked modes are the ones that show which modes of delivery have been selected. The selected 'x' marked modes of delivery met the acceptability and practicality criterion. The rationale for the selection of these particular modes of delivery is explained below.

During the development process, we found that using the internet and digital media has the capacity to reach widely and is low-cost. There are also indications from previous studies of smoking cessation which showed that using internet and digital media is acceptable to participants (85). The physical activity smart tracker will be used to self-monitor individually assigned step goals. Parts of the intervention will be individually tailored (self-monitoring, goal setting) via Facebook Messenger whilst other parts (information about health consequences, prompts, cues) will be delivered to the group via Facebook. Although the majority of the mode of delivery tools were determined during the literature review process, the APEASE criteria and BCW model was used to confirm the appropriateness of this choice.

Table 22. Selecting Modes of Intervention Delivery

Mode of Delivery		APEASE Criteria	Explanation
Face to Face	Individual	**Yes**	Both Individual and Group delivery approach was taken. (Individualised PA targets via FB Messenger vs. FB Wall Messages).
	Group	**Yes**	

Distance	Population Level	Broadcast Newspaper		
	Phone	**Digital Media**	**Yes**	
	Internet x	Leaflet		
	Individual Level	**Mobile Phone App**	**Yes**	Practical as already existent and part of the activity-tracker installation package
	Individually accessed internet program	Phone Helpline Mobile Phone Text		

6.5.1 Intervention Delivery using Modern Technology and Social media

Facebook is a popular social media platform used by between 82-89% of women aged 18-49 years (86). There is limited published evidence regarding how effectively interventions can be delivered across social media. A recent systematic review by Maher et al., (2014) found engagement among participants varied greatly across studies, but could not differentiate whether this was due to intervention design, content, or social media platform. However, studies which used Facebook managed to retain a high proportion of participants (77-96% of users) (87). It is a very convenient method of increasing participant communication and has the potential to create a social support network to help participants achieve PA targets. However, more research is required to establish the effectiveness of Facebook in delivering behavioural change (88), (89).

6.5.2 'Walking in Pregnancy' Facebook Group

Intervention arm participants were invited to join a private Facebook group. The purpose of the group was to communicate each participant's goal setting, and to post messages about the benefits of PA in pregnancy and the health benefits of staying healthy in pregnancy. The idea was that sharing of information about health consequences on Facebook will create an awareness of the benefits of physical activity during pregnancy and address concerns about the risks. This idea is based on evidence of effects of information sharing techniques and PA interventions which have incorporated this technique previously (34),(77). Also, social reward and the feeling of social support and encouragement may be prompted by the ability to interact with other pregnant women in a closed Facebook forum (34). Lastly, a generic 'Guide to Walking in Pregnancy' was shared with all participants on Facebook. The guide provided guidance and

suggestions on how and when the participants can walk. The Facebook Group was moderated by the student researcher with the support of the expert research team.

6.5.3 Fitbit Charge Activity Tracker

Fitbit is a type of pedometer that is used to objectively measure the amount of physical activity (measured in number of steps). Fitbit Charge is a wirelessly connected tracker. All Fitbit Charge data statistics are uploaded and saved wirelessly on a smartphone or computer. It tracks daily steps taken, distance travelled, calories burned and it can also track sleep time and quality. The Fitbit Charge allows individualised goal setting, step targets and self-monitoring. An indicator light on the Fitbit wristband can be set to remind users how close they are to reaching activity goals.

6.6 Conclusion

The mode of delivery for this intervention is incorporating technology and social media tools. The behaviour change techniques of self-monitoring, goal setting, social support graded tasks and knowledge shaping were delivered via Fitbit and Facebook. Fitbit and Facebook enable a study design that is low-cost and allows remote implementation, delivery and data collection. These were delivered in the following way:

The participants received a Fitbit pedometer which allowed them to monitor the number of daily steps, (self-monitoring). Once a physical activity baseline was established for each individual they received their individualised goal for each week of the intervention.

This chapter has demonstrated how the BCW was applied in order to select BCTs for the intervention. The following chapter presents the design and methods of a Walking in Pregnancy feasibility RCT. It maps aims and objectives, setting, recruitment, consent and randomisation procedures. It describes the intervention delivery method, FB content, data collection methods and data analysis. It concludes with information about obtained ethical and governance approvals and outcomes of a Patient and Public Involvement Group (PPI group) that were incorporated in the final protocol design.

Chapter 7. Feasibility RCT Design and Methods

This chapter outlines the design, methods, data collection and analysis that formed the feasibility RCT protocol. This preliminary study was done to test the feasibility of incorporating social media and tracking devices in a health behaviour change intervention design, which are relatively new and unexplored in this population. For this reason, it was particularly important to test their acceptability and practicality in real life. All data were collected with the aim of answering one question: 'Is this protocol feasible and will it work?' Feasibility studies are done before a main study to answer this question and to estimate important parameters that are needed to design the main study. The recommended feasibility study sample size is '*one which, is adequate to calculate the recruitment, attrition and adherence rate's (p. 8),* (90). Because feasibility studies are conducted to descriptively assess the feasibility and validity of the RCT plan and not to test the hypotheses of the main RCT they are not expected to have the large sample sizes that are needed to adequately power statistical null hypothesis testing. Therefore, the outcomes of feasibility trials are measured with descriptive statistics and qualitative analysis (91), (92), which is why a power calculation was not appropriate for this feasibility study design. All data were analysed as per recommendations for feasibility trials using descriptive analysis. The purpose of feasibility studies is explained in more detail in Chapter 4 Methodology.

7.1 Aims and Objectives

Aim
To explore the feasibility of a trial testing a walking intervention delivered via Facebook for pregnant women with a BMI≥30kg/m².

Objectives
1. Establish recruitment rates to determine:
a. Effectiveness of recruitment strategy
b. Feasibility of eligibility criteria
c. Time needed to recruit target sample size
d. feasibility of recruiting a representative sample

2. Determine acceptability of walking intervention schedule through:

a. Attrition

b. Adherence to individual step target

c. Process evaluation responses

d. Qualitative Interviews

3. Describe and quantify issues or untoward consequences (particularly in regards to Facebook and Fitbit as mode of delivery tools)

4. Ascertain suitability of research methods for use in future RCT, to include:

a. Block randomisation

b. Usual care control group

c. Facebook participation

d. Compliance to wearing Fitbit

e. Acceptability/burden of proposed outcome measures (questionnaire response rate and completion)

f. Practicality of proposed outcome measures collection

g. Proposed outcome measures

5. Assess questionnaire responses (PPAQ, Process Evaluation Questionnaire, and MyFood24)

7.2 Design

This was a feasibility mixed methods approach comprising both quantitative (a small scale randomised controlled trial) and qualitative (process evaluation) components.

7.2.1. Setting

Participants were screened and recruited from a single site, antenatal clinic at Jessop Wing, Sheffield Teaching Hospitals. Jessop wing has approximately 8000 births per year. The estimated rate of obesity in Yorkshire and Humber is approximately 27% (93).

The Usual Care Pathway for Women who are Pregnant and Obese

The Usual Care Pathway for women who are pregnant and obese at Hallamshire Teaching Hospitals, Sheffield is divided into three BMI categories namely; Category 1. BMI 30-34, Category 2 BMI 35-39, Category 3. BMI 40 and over based on the definition by the WHO (94). Those women who are classed as category 1 come under midwife-led care unless additional risk factors are identified. Women classed as category 2 and 3 come under obstetrician-led care. However, category 3 women (BMI 40 and over) have overall more tests, (repeated glucose tolerance test, assessments by anaesthetists, foetal biometry U/S growth scan, manual handling assessments and a labour management plan) in preparation for birth. Also, all women with a BMI of 30kg/m² should be made aware of the risks associated with obesity in pregnancy and be given healthy eating and lifestyle advice according to the Jessop Wing Maternity Services Clinical Practice Guidelines.

7.2.2 Screening, Recruitment and Consent

The recruitment took place in regular hospital booking clinics which were part of the standard health care path at 11-13 weeks' gestation. BMI measurements are routinely done in the booking clinic which is when potentially eligible participants were screened by the midwife. Following the booking appointment, eligible participants with a BMI of 30kg/m² and over who had no known complications were invited to the study by the PhD researcher (myself). A second screening was done at this point to check that the potential participant met all the inclusion criteria (owning a smartphone or PC and Facebook user). Women, who met all the inclusion criteria and verbally agreed to take part, were offered full information about the study. They were then consented either on the same day or given 24 hours to consider taking part in the study.

7.2.3 Inclusion Criteria

Women classed as obese (BMI >30kg/m²) who were in early pregnancy (11-14 weeks gestation) without any known complications such as diabetes, epilepsy, and any condition that makes them a high risk of miscarriage, were eligible to take part in the study. Eligible women were identified following the routine BMI measurement, which is done by a midwife in the hospital booking appointment.

To be eligible, participants were also required to have access to the internet, either on a desktop computer, laptop or a mobile phone. They also had to be a Facebook user or willing to sign up to Facebook.

7.2.4 Exclusion Criteria
Patients were excluded if:

- Their BMI was less than 30kg/m²
- They were found to have a complicated pregnancy with high risk of miscarriage. This assessment was made by a team of health professionals who were part of patients' usual care and confirmed by the Obstetrics &Gynaecology consultant who was also the advisor on this trial.
- They could not walk due to disability/injury
- There were no limitations with regards to ethnicity; however being able to communicate in English was a requirement due to the nature of the study and lack of funding availabilities for providing interpreters.
- They did not use Facebook
- They did not have a smartphone/ PC to sync the Fitbit

7.2.5 Quantitative Component: Randomised Controlled Trial
After obtaining informed consent, women were randomised to either receive a five week Facebook and walking intervention or usual care.

7.2.6 Randomisation
Participants were randomised to either usual care (control arm) or the intervention arm on a 1:1 allocation. Allocation procedures were done following a generated sequence in blocks of 4 which were generated with support from a statistician based at Sheffield Hallam University. Concealment of allocation was ensured by using opaque brown envelopes. Due to the nature of the study, blinding of the researcher and participants was not practical at any stage of the study. Following randomisation, all women were given a Fitbit with app installation on their phone or were given instructions on how to install it on their computer. Those

participants that were randomised to the intervention were added to the closed, secret Facebook group.

Internet Access and Set Up

To set up the Fitbit app on participants' phone and recruit them to the Facebook group, it was necessary to have access to a wireless internet connection. For this reason, a mobile data device was set up, which participants could connect to, and access to mobile data on their phones. The mobile data device was password protected. The password and access to the mobile data device was only given out when a participant joined the study.

7.2.7 Intervention Arm

Participants in the intervention arm were provided with Fitbit and enrolled in a private, secret Facebook group. The group was made both 'private' and 'secret'. To ensure anonymity the Facebook group was 'secret' (no non-members could find the group using the FB or Google search engines or know of its existence because it did not appear). The group was also 'private' in that one could only join the group by invitation from the moderator who was the only acting administrator of the group. Only the moderator had the password access, the ability to invite and accept members and manage the group wall comments and messages. At the first contact, women were given a Fitbit and were asked to go about their activities 'as usual' during the first week (baseline week). At the end of the first week, a baseline measure of steps was established for each individual participant. Based on each participant's individual baseline measure, a 20% step increase was calculated. For the following 4 weeks, each participant was given a precise number of steps that was their weekly step target. The 20% increase is derived from previous studies in women who are pregnant and obese which have shown that the average step count ranges from 3000 to 4000 steps daily (95). This would mean that each participant will target a daily step increase of 500-1000 steps which equates to 5-10 minutes of extra walking. This is in order to reach the recommended level of physical activity of 30 minutes per day (ACOG, 2015). Those participants who already achieved 10,000 steps or 30 minutes per day would not be asked to do more than that. Table 24 demonstrates the procedure timeline for both arms.

7.2.8 Control Arm

Participants in the control group were also given a Fitbit pedometer to wear for 5 weeks in total. However, these women were manually blinded to the Fitbit step counting function by covering their Fitbit band with tape covering the screen for the entire duration of the study. For the purpose of data collection, Fitbits were synced with each participant's phone, however they were asked not to open the app on their phone to check their step counts. This was to allow measurement of their steps while minimising the effect of the Fitbit as a source of motivation and information on step-count. Participants reported, during the interviews, that they had not opened the application on their phone to check steps. Taking part in the control arm did not influence participants' usual care.

All participants in the control and intervention groups were asked to complete the same baseline and follow-up questionnaires.

7.2.9 Estimation of Potentially Eligible Women at the Recruitment Site

There are 7000 births annually at Hallamshire Hospital and 30% of the mothers are obese (96). Therefore we expected that 2100 eligible women would attend the Jessop wing for regular scans and consultations per year. This equates to roughly 175 eligible participants per month. There may also be exclusions based on the above mentioned criteria. The recruitment rate for women who are pregnant and obese for research purposes was estimated to be around 15% (97). Considering the possibility of a slow start over summer, weekends and the fact that recruitment was done by one researcher, a total of 6 months was planned to recruit targeted number of participants.

7.2.10 Sample Size and Duration

We aimed to recruit a sample of 40 pregnant women who are obese (20 women in each arm). A formal power calculation was not required for this feasibility study, as effectiveness was not the primary outcome to be evaluated (NIHR Research Design Services). In the published literature, the suggested sample size for a feasibility trial ranges from 12 to 50 participants in total, including intervention and control studies (98). The study sample size of 40 was based on an estimation of the numbers of participants that could be recruited from the trial centre over six months. The duration of the trial was for 5 weeks in total. The duration and the

sample size allowed us to meet the objectives of a feasibility study as well as being able to fit it in a practical timeframe for the PhD project.

7.2.11 Features of the Facebook group

Table 23 outlines the features of the posts and interactions within the Facebook group that were derived by applying the COM-B model. The underlying rationale for the components of the walking intervention was discussed in chapter 6, 'Theory-based intervention development'. Specific details of the five-week walking intervention received by participants are provided in Table 24.

Table 23. Facebook group Features and Associated BCTs with Examples

Facebook Features	Characteristics of the Facebook Posts	Behaviour Change Technique (Michie et al. 2011) (34)
Wall Posting	(Post from babycentre.co.uk on Benefits of Walking in Pregnancy	Information about Health Consequences
Wall Posting : *How to overcome tiredness in pregnancy with PA, Does Exercise cause Miscarriage (Tommys)*	Addressing known barriers (perception of risk of PA and Fatigue in Pregnancy)	Problem-Solving
Wall Posting, Commenting, 'Like' Button,	Addressing the group with open-ended questions to encourage interaction	Social Reward
Wall Posting	Positive quotes, encouragement	Vicarious experience & Social reward
Wall Posting: *Please remember to wear your Fitbit today*	Reminders	Prompts/Cues
Wall posting when someone has met their weekly target: Well done for completing your target		Social Reward
20% Step Increase		Goal Setting, Goal Review, Graded Tasks
---	----	*Self-Monitoring delivered via Fitbit*

Table 24. Procedures Timeline

Group	Week 1 (baseline)	Week 2	Week 3	Week 4	Week 5	Post Intervention Evaluation
Intervention	Collecting baseline data: Demographic Variables SE Q PPAQ MyFood24 Providing and advising on: Fitbit Facebook	Facebook Fitbit 20% Increase	Facebook Fitbit 20% Increase	Facebook Fitbit 20% Increase	Facebook Fitbit 20% Increase	SE Q PPAQ MyFood24 Qualitative Assessment (Semi-structured Interviews)
Control	Collecting baseline data: Demographic Variables SE Q PPAQ MyFood24 Providing: Fitbit* *(Blinded)	Fitbit (blinded)	Fitbit (blinded)	Fitbit (blinded)	Fitbit (blinded)	SE Q PPAQ MyFood24 Qualitative Assessment (Semi-structured Interviews)

7.3 Data collection: Feasibility

The overall feasibility of the study was planned to be measured by collecting data on recruitment, acceptability and feasibility of research methods and feasibility of outcome measure collection. Data collection time points are summarised in Tables 24 and 25.

7.3.1 Feasibility of Recruitment

The following data was collected to evaluate the efficacy of the recruitment strategy and plan the number of sites and duration of the recruitment period needed for an RCT:

- Percentage of women with a BMI of 30kg/m² who accepted to take part in the study after they were approached.
- The number of days to recruit the proposed sample size
- Demographics to estimate if the sample is representative of broader population. The population demographics were compared to the Socio-

demographic characteristics data published by the Centre for Maternal and Child Enquiries on Maternal Obesity in UK, (2010) (96).

7.3.2 Data Collection: Acceptability

The acceptability of the intervention was measured through the analysis of adherence and attrition rates along the study process, and through participants' responses in the semi-structured interviews. Adherence to wearing Fitbit and adherence to walking (step counts) was measured. This data were collected from each participant's individual Fitbit website synced with the participant's phone, which then uploaded all PA information to the website. Also, engagement in Facebook group was measured. This information was collected from the Facebook group. Both quantitative and qualitative analysis was done to establish the level of engagement. This information was a primary outcome to understand whether the intervention could be implemented as planned. Semi-structured interviews were conducted to gain insight into participants' views on the acceptability of the intervention. Participants were specifically asked to share their experiences of the intervention, duration, frequency, mode of delivery, and the Facebook group.

7.4   Feasibility of Research Methods

7.4.1 Blinding of the Control Group to the Fitbit tracker

Efforts were made to blind the participants in the control group to the Fitbit counts by putting a plaster over the Fitbit screen. It was important to assess whether the blinding of the control group to the Fitbit count was sufficient in the control group. Insufficient blinding could potentially lead to contamination and a treatment effect in the control group. Contamination was assessed by counting how many Fitbits still had tape over the screen and also by asking participants at follow-up whether they were checking their steps during the study. This was recorded to evaluate whether knowing the step counts among the control participants had any effect on outcomes for that group.

7.4.2 Acceptability/Burden of Outcome Measure Questionnaires

Adherence to and completeness of questionnaires was calculated, to assess outcome measure acceptability/burden.

Table 25. Data Collection Time points

Outcome Measure	Baseline	Follow-Up
Demographic Variables	√	
Rates of Recruitment, adherence, retention, attrition and completion of outcome measures	√	√
GWG	√	√
Physical Activity (Fitbit pedometer)	√	√
MyFood24 (24hour food recall)	√	√
Process Evaluation Questionnaire	√	√
PPAQ (Physical Activity in Pregnancy Questionnaire)	√	√
Gestational Diabetes Mellitus status		√
Mode of Delivery		√
Birth Weight		√
APGAR Score		√
Gestational Age at delivery		√
Admission Days		√
Facebook Activity (intervention only)	√	√

7.5 Data Collection - Outcome Measures

7.5.1 Demographic Variables

Age, occupational status, gestational age, ethnicity and parity were recorded at the initial meeting with all the participants, following their consent.

7.5.2 Anthropometric Measures

BMI measurements at baseline were collected from maternal records. These were calculated by a midwife at booking appointment. At follow-up, participants' weight was measured using the same scales that were used in the booking clinics. The follow-up weighing was done by the researcher.

7.5.3 Diet

Because the GWG is one of the primary outcomes investigated in the study it is important that both diet and physical activity are monitored to assess any changes that may occur in either as a result of the intervention or other factors (99). MyFood24 is a validated online-based questionnaire which comprises of questions relating to all food and drinks intake during a 24-hour period. The

internet-based questionnaire automatically calculates the total calorie intake, as well as a breakdown of total macro and micro nutrients in both calories and grams. Participants completed the questionnaire at baseline and follow up. (100). The 24 hour food diary prompts the participant to describe all food and drink consumed within the last 24 hour period. The total amount of calories and major and minor nutrients are automatically calculated, based on each participant's entry. The participant could enter whether this was a typical daily intake for them. The primary focus of this data collection was to measure how many diaries were returned and their quality.

7.5.4 Questionnaires (PPAQ, PE Q)
The primary aim was to measure the acceptability and burden of outcome measure questionnaires. For this reason, adherence to and completeness of questionnaires was calculated, to assess outcome measure acceptability/burden. Participants were also asked to give feedback on the questionnaires.

In addition to MyFood24, two other questionnaires were used namely; Physical Activity in Pregnancy Questionnaire (PPAQ) and Process Evaluation Questionnaire (PE Q). The PPAQ questionnaire comprises of 32 questions relating to duration and intensity of various activities. The scale of measure of activity is 0-3 hours per day. The PE Q questionnaire comprises of 10 questions relating to self-efficacy, and positive and negative feelings towards walking. The scale of measure is 0-7.

PE Q
The process evaluation tool measured constructs which were hypothesised to be mechanisms of action of the intervention. The tool was modified to explicitly include views on walking. There were several questions which asked the participants to 'rate on a scale' from 0-7. The question scores, measured the following; 1. Intention 2. Confidence 3. Positive beliefs about walking 4.Negative beliefs about walking. The questionnaire was administered at baseline and at follow-up to see if there was a measurable change in before-and-after scores. Self-efficacy was a relevant outcome for this study due to the importance of finding out the impact of the intervention on participants' self-perceived self-efficacy and positive and negative beliefs about walking. The complete PE Q questionnaire is in Appendix D.

Physical Activity in Pregnancy Questionnaire (PPAQ)

PPAQ is a validated questionnaire that measures physical activity levels in pregnant women. Intra-class correlation coefficients used to measure reproducibility of the PPAQ were 0.78 for total activity, 0.82 for moderate activity, 0.81 for vigorous activity, and ranged from 0.83 for sports/exercise to 0.93 for occupational activity. Spearman correlations between the PPAQ and three published cut points used to classify actigraph data ranged from 0.08 to 0.43 for total activity, 0.25 to 0.34 for vigorous activity, 0.20 to 0.49 for moderate activity, and -0.08 to 0.22 for light-intensity activity. Correlations were higher for sports/exercise and occupational activities as compared to household/ caregiving activities (101).

The questionnaire comprises of 32 questions that are grouped in categories of activities (household, occupational etc.). An estimated average metabolic equivalent (MET-hr/wk) is calculated by multiplying the duration of each listed activity by the categorical intensity of the activity (102). The participants were asked to complete a Physical Activity in Pregnancy Questionnaire (PPAQ) at baseline and follow-up. The complete PPAQ is in Appendix E.

7.5.5 Physical Activity

Fitbit Charge pedometers were worn by participants during the study to assess levels of physical activity. Participants were given the choice of which wrist to wear the Fitbit on, however they were asked to wear it on the same wrist throughout the study. Each Fitbit had a number allocated to it which could be linked to the participant. All participants were asked to sync their Fitbit with their phone or computer. The Fitbits were given to the participants at baseline appointment and asked to be returned at the end of the study. All participants were asked to wear the Fitbit during waking hours for 5 weeks (35 days) in total. The Fitbit Charge is a small watch that records steps. Fitbit pedometers are relatively new in research but have been found to be an accurate tool to examine activity patterns (103).

7.5.6 Facebook Engagement Data

Facebook group data of participants' comments and interactions were both quantitatively and qualitatively analysed. Firstly, Facebook usage and engagement data was monitored to assess frequency and timing of usage for each participant. FB activity and engagement data included 'Seen by percentages "likes," comments, and posts to the FB group page as well as average number of messages to the moderator via the Facebook messenger (FM). The time that the FB moderator spent on moderating the FB group and FM responses was recorded for the purpose process evaluation. The characteristics of those that chose not to participate were recorded. Participants' quotes were recorded and qualitatively analysed, to identify the themes and topics that were most occurring.

7.5.7. Process Evaluation Data

During the process evaluation (semi-structured interviews with participants) we explored participants' views on acceptability and practicality of using Facebook, including motivators and barriers for engagement and how it can be improved. We also conducted semi-structured interviews with health professionals (HPs), in order to assess their views on the implementation of the intervention design within the NHS.

7.5.8 Data Handling

All Fitbit data (steps) were downloaded from the Fitbit website and exported into an Excel spreadsheet. The data were then transferred into SPSS. All quantitative data from the questionnaires were entered into SPSS. Calorie intake data from MyFood24 was extracted into an Excel spreadsheet and was then transferred into an SPSS file. Qualitative data from Facebook was entered into a word document for analysis. All qualitative data from the semi-structured interviews with both participants and HPs was recorded and transcribed verbatim with participants' consent (a detailed description of interview methods and findings is presented in chapter 9 of this thesis). All transcripts were imported into Quirkos (version 1.4.1, 2017) software for analysis.

7.6 Data Analysis

7.6.1 Eligibility, Recruitment, Retention Rates
Participant recruitment and retention rates were presented using a CONSORT diagram. (37) Recruitment was calculated as the number of participants who agreed to take part in the study divided by the number of eligible participants who were approached. Retention was calculated as the number of participants remaining at the last data collection point and follow-up divided by the number of participants recruited at the beginning of the study. These figures will be used to determine how many participants need to be recruited to retain sufficient numbers in the large RCT.

7.6.2 Descriptive Analysis
All data handling and analyses were performed using SPSS 2.0 software.

Descriptive statistics were used to analyse demographics details. The Mann Whitney U test was performed to check the differences between the groups and to assess the randomisation method. The U-test is a non-parametric test. In contrast to the t-test, it does not compare mean scores but median scores of two samples. Thus, it is much more robust against outliers (104). It is an appropriate test to use in a small sample or to compare groups when the dependent variable is not normally distributed and at least of ordinal scale.

7.6.3 PPAQ, PE Q
To measure trends and impact of the intervention change scores, differences between the two groups in the amount of change from baseline to follow-up were calculated. Change scores were normally distributed. Therefore it was appropriate to use means, standard deviation and T-tests to analyse the data. As this study was not statistically powered, this was an exploratory analysis.

7.6.4 Steps
Steps data (number of steps per day) was collected. Descriptive statistical analysis was performed to calculate weekly means of steps. The means were plotted on a graph to analyse trends and possible interactions. Once the steps data were plotted, an interaction was observed, which suggested

appropriateness of further analysis. Therefore a standard ANCOVA analysis with Week 1 as covariate was performed with each participant as its own control.

7.7 Ethics

Ethical approval was obtained from Sheffield Hallam University on May 17th 2016. NHS Ethical Approval was obtained from North of Scotland REC on June 17th 2016 by the North of Scotland Research Ethics Committee. The NHS REC approval number is REC 16/NS/0061 (see Appendix F). An approval from the Health Research Authority was obtained on 25th July 2016. An honorary research contract with Sheffield Teaching Hospitals and a Research Passport were obtained in July 2016.

7.7.1 Ethical Consideration for Internet-mediated Research

To minimise risks that are involved in conducting internet-mediated research, all the potential risks were considered in detail during the development of this intervention. The ethical considerations are listed in detail in chapter 4 of this thesis. In particular, there were considerable ethical considerations related to ensuring confidentiality and integrity of participants that were randomised to the closed Facebook group. Therefore, to protect participants, the Facebook group was made private and secret to ensure that the contents could not be seen by non-members and so that the content could not be shared by members to non-members.

7.7.2 Patient and Public Involvement (PPI) Reproductive Health Advisory Panel

During the developmental stage process and prior to submitting the protocol for SHU Ethics, NHS Ethics and HRA Approval, the study design and procedures were reviewed by members of the Patient & Public Involvement (PPI) Reproductive Health Panel group which comprised of maternity service users and providers. The PPI panel feedback was incorporated into the intervention design (see table 26). For instance, the PPI panel's concerns about keeping the Facebook account secure, and the importance of giving instructions about how to set privacy settings on Facebook was taken into account. The PPI panel recommended that participants are asked to consent to not sharing names and contents from the closed Facebook group. Also, once the NHS Ethics application

was submitted, feedback and recommendations were obtained from the Ethics committee which were to inform all participants about how to set their privacy settings on Facebook and to remind them to ensure that they are activated throughout the study. All feedback that was received from the PPI group on the intervention design is in Appendix G.

Table 26. PPI Feedback and Actions

Reproductive Health Panel Suggestions	Action (yes/no)
The panel were concerned that the Facebook account might not be secure. Recommended: • use of a secure log in and password to access the account • Consent form and Patient Information documents to have a confidentiality clause that advised the participants of the importance of guarding the personal information (including the names) of their fellow participants. • patient information sheet should advise the participants to always do their utmost to keep the Facebook account secure, for example close the account after use, only to use the Facebook account if they are sure that it cannot be seen or read by other non-participants. • The panel recommended that section 7 of the consent form is changed to reflect the understanding of the consequences of a breach of confidentiality. • They suggested following wording: I understand that my name will be seen by other people on the Facebook Group ……	Participants already have their Facebook log in and password. It was explained that researcher invites individuals to join and gives out permission. It was explained that the group is private and does not come up in a search engine. The advice was followed. A clause was added in the PIS and the Consent form which advised participants to do their utmost to keep their Facebook account secure and not to share the information of other participants outside the group. A document with instructions on how to ensure that Facebook privacy settings are switched on was handed out to each participant in the information pack. This information was also pinned to the Facebook group wall, for easy access.
Recruitment would be a problem, a women's weight can be a sensitive subject. The panel felt that pregnancy could be a motivator for women to address her mobility and lifestyle habits. It was noted that some women might take offence to being broached for this study. • Awareness when recruiting. Careful phrasing. • Check for eating disorder	Panel's advice was followed. Researcher was sensitive during recruitment and conscious of appropriate phrasing when explaining the study to potential participants This advice could not be followed as researcher could not check for any previous eating disorders.
The panel advised that the "wiplady" gmail address is changed to "wap" "Walking and Pregnancy" as it could cause problems when logging into a PC.	The advice was followed and wip (**w**alking**in**p**regnancy) was not used to shorten the name of the study.

• Add disclaimer that clearly lists, when to stop activity and what symptoms to look for that would need advice on when further consultation should be sought or if the participant should stop activity.	This advice was followed and the information about symptoms was added to the PIS.
• Make it clear that the participants would be lent not given the Fitbit devices and would be expected to return them at the end of the study.	This advice was followed and participants were told that Fitbit was lent to them and would have to be returned at the end of the study.
The panel felt that the addition of a short, user friendly, instruction sheet for syncing the Fitbit device with a smart phone or PC would be helpful.	Participants were given instructions on how to sync but also the researcher assisted them with this at the time of recruitment.
• Fitbit retrieval. Suggestion to give participants different options to return the device. • Stamp or micro-tag each device with logo property of Sheffield Hallam University/ID number	This advice was followed, however the device was not micro-tagged but a small sticker with a number on it was attached to the device, which was also participant's ID number.

7.7.3 Withdrawal of Participants

Participants were free to withdraw from the study at any time. If a participant expressed a desire to stop the intervention they were asked to stay in the study for data collection purposes (to collect pregnancy and birth outcomes from patient records), even if they withdrew from the intervention. If they chose to withdraw from the study completely they were asked if they were willing to give a reason for their withdrawal. However, they were informed of their right to withdraw without stating the reason. Consent was sought to use the data that had been collected up to the point of withdrawal.

7.7.4 Confidentiality

Only a member of the woman's existing clinical care team (who did not need written consent) had access to participants' medical records to be able to check whether they met the inclusion criteria.

Participants that were consented into the study were asked for permission to look at medical records related to their pregnancy health outcomes. The study data collection forms contained the study ID number assigned to the participant. These were kept in secure storage. All interviews with participants and health professionals were recorded and transcribed by an approved external company that applied all confidentiality procedures and ensured that all data transfer was encrypted.

7.7.5 Summary

The intervention delivery was done through social media; a closed, secret Facebook group was created for the purpose of the research study. Only the moderator had access to the log in and password to this closed group. Data that was collected from the closed Facebook group was anonymised prior to data analysis. All ethics guidelines for internet-mediated research, by Sheffield Hallam University ethical committee, were followed, to minimise risk of adverse events.

This chapter has presented the design and time line of the Walking in Pregnancy feasibility study. The following chapter 8 presents all quantitative findings related to the feasibility RCT. It includes information on recruitment, retention and compliance rates. It also includes data on objectively and subjectively measured PA levels, dietary intake, self-efficacy scores. It also presents a quantitative as well as a qualitative analysis of FB engagement. The last paragraph of the chapter is a discussion and a critical analysis of findings that are compared to previous findings in the existing literature.

Chapter 8. Findings from the Feasibility Study RCT 'Walking in Pregnancy'

A physical activity (PA) walking intervention was implemented to test the feasibility and acceptability of an intervention in early pregnancy and to inform the design of a large RCT. Forty participants, with a BMI ≥30kg/m², at 11-14 weeks gestation were recruited and randomised to either an intervention or control group. The intervention was delivered via a Facebook (FB) group. Participants were communicated with via FB and were asked to gradually increase daily PA levels (steps). The control group participants were not asked to make any changes and received usual care. The feasibility trial was conducted to answer the overarching research question of whether a walking intervention delivered by means of mHealth technology, is feasible, practical and acceptable.

The quantitative findings related to the feasibility and acceptability of conducting the trial will be presented in this chapter. This includes information on recruitment to determine the suitability of eligibility criteria, the effectiveness of the recruitment strategy and time taken to recruit. Attrition and adherence data will be presented to give an indication of the acceptability of the intervention. Quantitative analysis of Facebook engagement will be presented, followed by a qualitative analysis of Facebook content. This will be followed by an account of the feasibility of aspects of research design. In the last part of the chapter, changes in scores for the outcome measures will be explored over time, comparing the intervention and control groups. Quantitative analysis of primary and secondary outcomes contributed toward the development of a final RCT protocol, which is presented in Appendix K of this thesis.

8.1 Recruitment Rate

Recruitment took place over a three month period from September 2016 to December 2016. During this period, 72 eligible women were invited to join the study, following their hospital booking appointment at approximately 11-14 weeks gestation. Out of the 72 women that were approached, 40 agreed to join the study (Figure 15). Therefore, the estimated uptake rate was approximately 40/72 ≈56%. The recruitment rate was on average 3 women per week.

8.1.1 Reasons for not declining to take part

Thirty-two women in total declined to take part (72 women in total were approached). All women who declined to take part were asked (if willing to do so) to give a reason. All 32 women gave a reason for not wanting to take part. Using content analysis, the three most common reasons that women listed were: 1. Lack of time, 2. Not interested 3. Does not want to be physically active/wear a Fitbit. There were other additional less frequent reasons listed, however none was due to having to use FB. This gave an indication that FB platform is a readily accepted medium for the target population (young adult females). A summary of 'reasons for not taking part' is listed in Table 27.

Table 27. Reasons for declining to take part in the study

• Does not have time (**13 women** gave this as a reason for declining to take part)	• Does not want to know about the project (**10 women** gave this as a reason for declining to take part)
• Open to the idea of taking part. Then, after reading the Patient Information Sheet and commenting on the eligibility criteria 'raised BMI', declined. However, did not say that 'raised BMI' criteria were the reason for declining (**1 woman).**	• Said no to midwife. Laughed when MW told her BMI raised **(1 Woman).** 'I have been approached because I am chubby' Midwife *told her that she is obese as BMI over 30. Woman looked at herself shocked as didn't think that she was that overweight (HP 1 quoted).*
• Husband spoke for the woman. Says she can't wear it with work uniform. Partner very defensive **(1 woman).**	• Lives far **(1 woman).**
• Waited too long for her appointment already and does not want to spend time on reading Patient Information Sheet • **(1 woman).**	• Has a 5month old baby, too busy. **(1 woman).**
• Had complications previously and does not want to take part **(1 woman)**	• Not interested to wear a Fitbit to know how many steps they are doing. Find it intrusive **(1 woman).**
• No memory space on the mobile phone to download Fitbit app. **(1 woman)**	

Figure 15. Recruitment Diagram
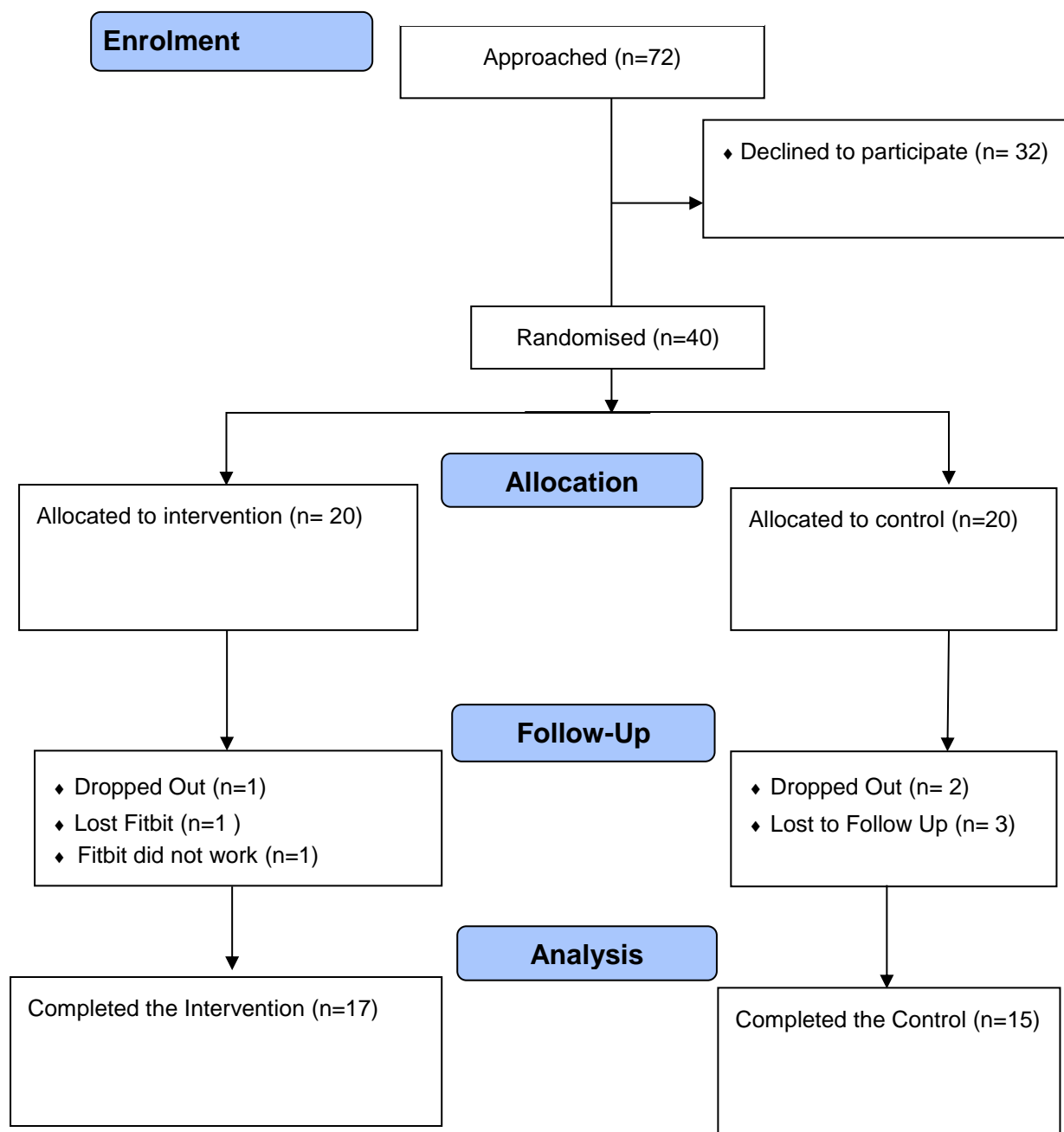
8.1.2 Effectiveness of Exclusion Criteria

Of the 72 eligible women that were invited to take part in the study no women who were deemed clinically eligible based on the initial selection criteria (BMI ≥30kg/m² and low-risk) needed to be excluded because they did not meet other inclusion criteria (requirements of being a Facebook user, access to the internet, mobile phone or PC).

8.1.3 Feasibility of Recruiting a Representative Sample

Forty women were enrolled and randomly assigned, 20 to the walking Facebook intervention and 20 to the control group. The sample as a whole was exclusively White British, and predominantly married or living with partner (85%). The majority were in employment (88%, n=35). The recruited sample is not the typical representation of the Sheffield population where published data from 2017 showed that 51% are black and ethnic minorities (BME), 38% are single and 55% are economically active (105). The mean age of the intervention group was 30 (range 22-41) and the mean age of the control group was slightly younger (27, range 19-38). An independent T-test showed this not to be a significant difference, although the p-value was only p=0.06. Considering the small sample size, this difference in age, may yet have influenced results. There was no upper limit for BMI in the inclusion criteria. The obesity classification according to the World Health Organisation (WHO, 2000) are Obese class I, II and III (See Table 29). The majority of women recruited were Class I, with a higher number of Class I obese in the intervention group (65%) as opposed to the control group that had 40% of Class I obese participants. The control group had a higher percentage of participants that were classified as Class II obese (35%) whilst the intervention group had 20% of Class II obese participants. There were 3 morbidly obese participants (Class III), in the intervention (15%) versus 5 morbidly obese participants (25%) in the control group (see table 28 for detailed demographics data). Descriptive statistics (mean and standard deviation) reflected this difference. Therefore a 34kg/m² mean for the intervention and a 36kg/m² for the control could be observed. The difference was non-significant (p=0.2), however it is a relatively small sample size and by including a wide BMI range of 30-46kg/m² it may have impacted the outcome measures. For the larger trial, we recommend a sub-group analysis of outcomes stratified based on age as well as the WHO obesity classification. (see Table 28 for all the descriptive statistics).

Table 28. Demographics Data

Characteristics	Intervention (n=20)	Control (N=20)	p- value
	Mean (SD)	Mean (SD)	Independent T-Test
Age	30± (5.8)	27±(4.6)	p=0.06
BMI (kg/m²)	34±(4)	36±(4.4)	p=0.2
BMI Range (kg/m²)	30-45	30-46	p= 0.5
Weight (kg)	95±(11)	100±(17.7)	p=0.4
Weight Range (kg)	69-123	73-152	
Gestational Age at baseline	12.5±(0.8)	11.9±(1.3)	
Nulliparous	5	6	
Smoker	1	2	
Employed	18	17	
Marital Status			
Married	13	10	
Co-habiting	6	8	
Single	1	2	

Table 29. Obesity Classification and breakdown of distribution

Classification	BMI (kg/m2)	Intervention	Control
Obese	>30.00	20	20
Obese class I	30.00 -34.99	13	8
Obese class II	35.00-39.99	4	7
Obese class III	>40.00	3	5
(Definition by World Health Organisation, 2000)			

8.2 Acceptability of the 'Walking in Pregnancy' Intervention components

The acceptability of the intervention was assessed by:

- Attrition throughout the intervention

- Adherence to the prescribed number of steps and duration of the trial

- Completion of questionnaire surveys at the baseline and at the end of the study period.

For the purpose of comparing inter-group rates, attrition rates were calculated separately for the intervention and the control group. Overall, the dropout rate in the control group was higher (5/20) where 3 participants dropped out and 2 participants were lost to follow-up. In the intervention group only 1 participant dropped out. In addition to one participant dropping out, one participant lost their Fitbit in the first week and for this reason could not complete all 5 weeks of

walking intervention. The participant was not offered a new Fitbit. One participant's Fitbit did not work, and they did not want a replacement, however they too remained in the Facebook group and completed questionnaires at follow-up and were interviewed as part of the process evaluation. It was confirmed by the researcher that their Fitbit in fact was broken. A replacement for the faulty Fitbit was offered but the participant did not respond to offers to meet up or to be posted the Fitbit. The reason given by the participant was that she worked in the food industry where it is against the rules to wear a wristwatch. Although she had asked for permission from her line manager, she felt that it was frowned upon. Because this participant remained in the study and completed all the other aspects of the study they were not classed as 'withdrawn'. Because the lost Fitbit may have meant that in fact the participant did not want to wear it and was dropping out (although they did ask for a replacement) and the fact that the participant whose Fitbit was broken did not want a replacement, they have been treated in the drop-out rate. As a result, the retention rate in the intervention group was 85%.

8.2.1 Adherence to wearing Fitbit

Descriptive analysis of adherence to wearing the Fitbit pedometer is presented in Table 30. Adherence to wearing Fitbit was measured for participants who completed the study (measured in number of days worn out of a total of 35 days). On average, the intervention group wore the Fitbit for 32.5 days in total compared to 28.8 days in the control group. The number of days was evenly distributed between the groups. An independent t-test did not show a statistically significant difference (p=0.1) between the intervention and the control when comparing the number of days that Fitbit was worn. Participants who lost the Fitbit, whose Fitbit did not work or who dropped out of the study had 7 days or less of Fitbit measurements.

Table 30. Adherence to wearing Fitbit

(Measured as Average number of days out of 35 days in total)

Total Days Fitbit Worn (n=35)		
Group	Mean (days)	(SD) (days)
Intervention (n=17)	32.5	(3.4)
Control (n=15)	28.8	(9.3)
Total	30.7	(7.7)

Difference in compliance was non-significant *(p=0.1)*

Adherence to wearing Fitbit Stratified by BMI

To assess whether there was a relationship between the BMI and the compliance to wearing Fitbit a Pearson's correlation was carried out. There was no significant relationship between compliance to wearing Fitbit (days worn) and BMI (r=0.1, p=0.6). This may be due to small sample size in this trial. This is something that should be explored further in a larger trial (see Figure 16).

Figure 16.Correlation Analysis (Compliance to Fitbit vs. BMI Intervention)
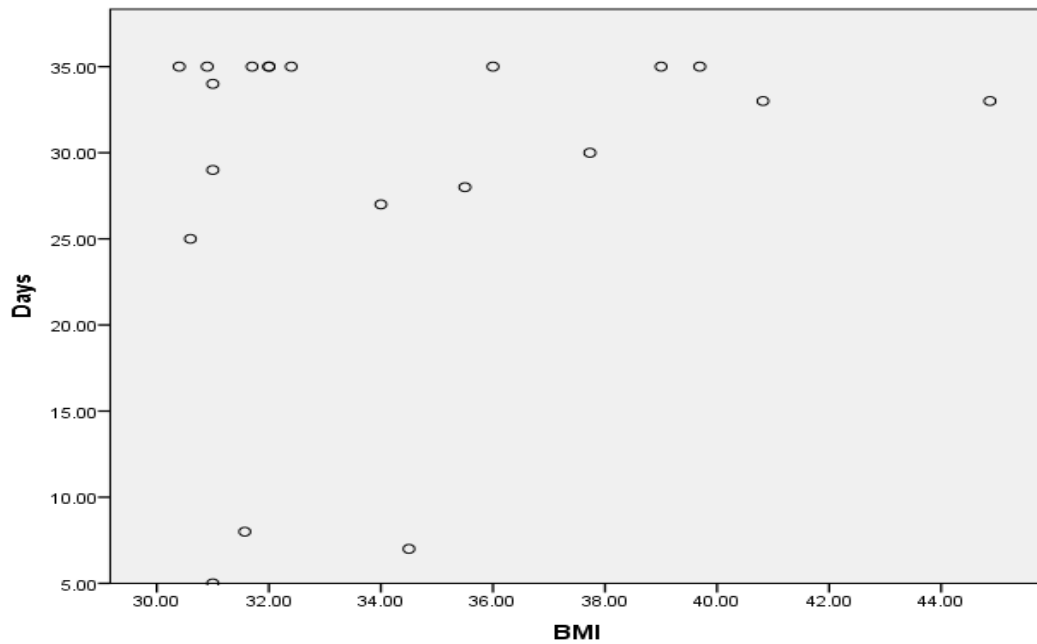
8.2.2 Adherence to Individualised Step Targets

Each participant was given an individual weekly step target which was based on their baseline measure for week 1. In week 2 and 3 half of the participants (≈50%) met their individual step targets. Table 31 shows a summary of how many participants achieved their target or were above their target. The assessment was done strictly, so that even a few steps below the target were classified as 'not meeting the target'. Anyone who met the target and did steps over the target was classified as meeting the target.

Table 31. Adherence to Step Targets

Baseline Week 1	N/A
Week 2	50%
Week 3	50%
Week 4	26%
Week 5	26%

Figure 17, is a presentation of each intervention participant's completed step count and their expected step count in Week 5. The graph is showing that 4 participants achieved steps over their expected target (114%, 104%, 135%, 106%), whilst an additional 5 participants were within 10% of their step target. In Week 5, 9/17 participants were within 10% or above their step target.

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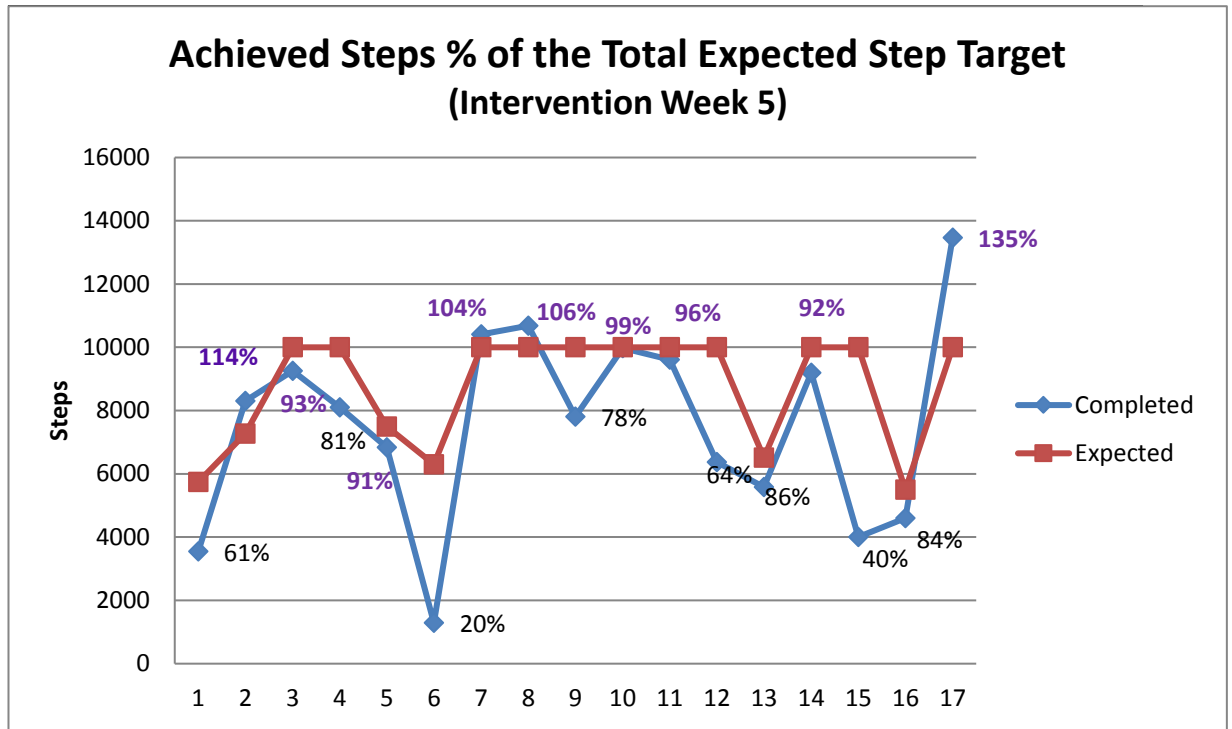
8.2.3 Steps Data Results

The PA data (steps) measurement was collected over a period of 35 days in both the intervention and control group. A descriptive analysis was done to calculate the weekly means and standard deviation for both groups for the purpose of comparison. As this study was not powered it was an exploratory analysis to see whether there is any difference when comparing the two groups. The intervention group had a higher weekly average at each of the 5 time points (Week 1(baseline): 7888vs7108, Week 2: 8359vs6510, Week 3: 7650vs6452, week 4: 7755vs6513 and Week 5: 7625vs6416). The findings plotted in figure 18 show means and confidence intervals.

Figure 18. Weekly Mean Step Count (Mean, CI)

	1	2	3	4	5
Intervention	7888±2592	8359±2292	7650±2586	7755±2031	7625±2661
Control	7108±3001	6510±2710	6452±1832	6513±2076	6416±2253
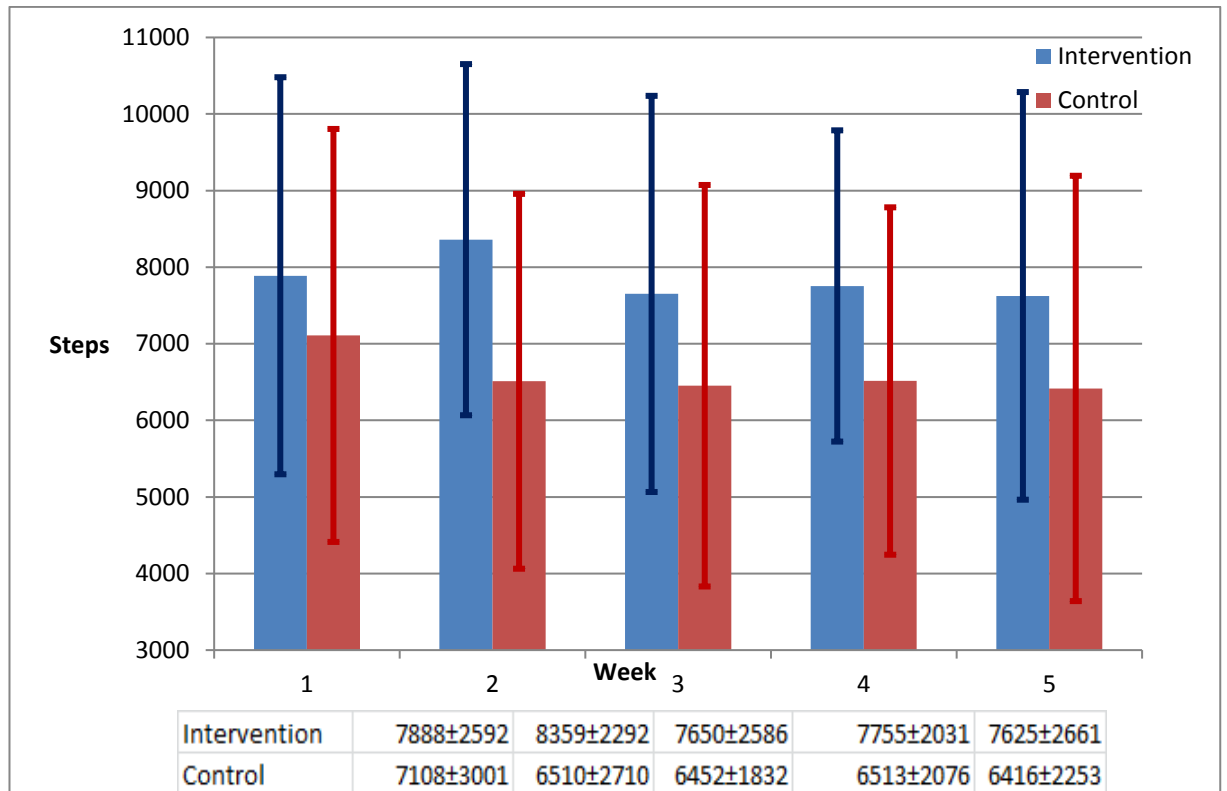
A plot of the steps achieved in the intervention and control groups and the expected target is shown in Figure 19. It shows that the intervention group did on average more steps than the control group at each measuring point (each week). It also shows how far off they were from their step target. The consistency of this pattern suggests that the intervention may have been effective in increasing PA levels in the intervention group.

Figure 19. Steps Change and Difference between Intervention, Control and Expected
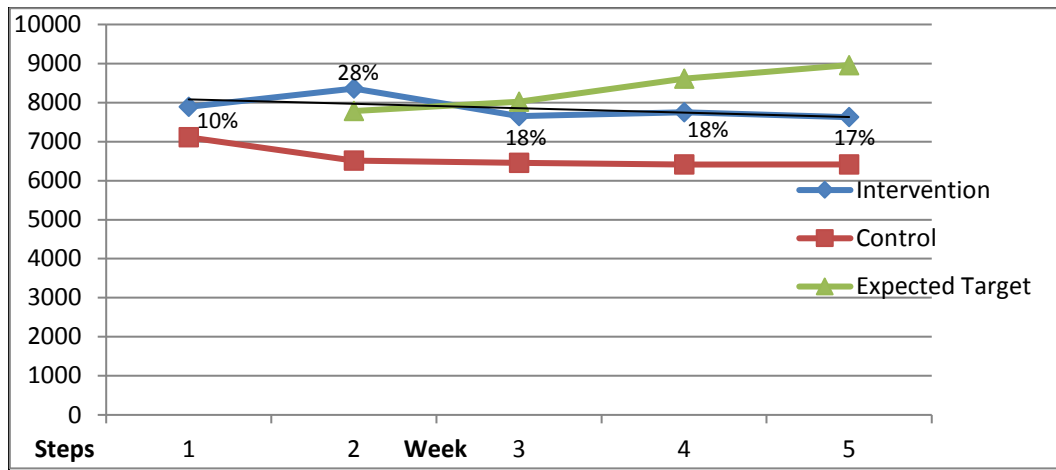
8.2.4 ANCOVA Analysis (Steps Data)

Descriptive analysis in the previous figure showed a difference in steps between intervention and control. An exploratory analysis by means of an ANCOVA with week 1 as covariate to control for baseline differences showed a statistically significant difference at Week 2 8359±2292 vs. 6510±2710 *(p=0.03)* only. In Week 3 7650±2586 vs. 6452±1832 *p=0.2,* Week 4 7755±2031 vs. 6513±2076 *p=0.114*, Week 5 *p=0.2).* (7625±2661 vs 6416±2253 in the Control (*p=0.2*) the difference was not significant. In Figure 20, a Marginal Mean Difference in Steps between the Intervention and the Control. It is showing a significant difference at week 2.

Figure 20. ANCOVA Marginal Mean Difference Analysis (Steps)
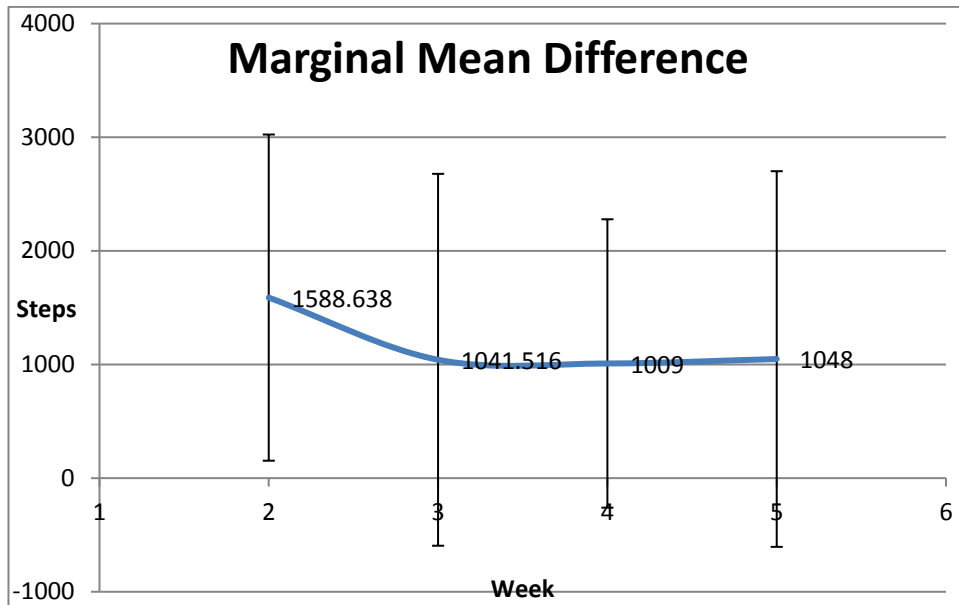
*Marginal Means Difference

Week 2 p=0.03, Week 3 p=0.2, Week 4 p= 0.1, Week 5 p=0.2

8.3 Physical Activity in Pregnancy Questionnaire Data (PPAQ) Completion Rates and Findings

8.3.1 PPAQ Completion Rate

All participants were asked to complete a PPAQ at baseline and follow-up. At baseline (T1), 80% of all participants in the intervention completed their baseline questionnaire compared to 50% of all participants in the control group. Completion rate for the T1 and T2 completion (same person completing the entire questionnaire, at both baseline and follow-up PPAQ questionnaire) was approximately 65% in the intervention and noticeably less (30%) in the control group. Overall, the intervention group participants were more likely to complete the questionnaire. Completion rates for the PPAQ are presented in Table 32.

Table 32. PPAQ Completion Rates (Baseline and Follow-Up)

PPAQ	T 1 (%)	T 2 (%)	(T1& T 2)
Intervention (n=20)	16 (80%)	14 (70%)	12 (60%)
Control (n=20)	10 (50%)	10 (50%)	8 (40%)
Total	26 (65%)	24 (60%)	20 (50%)

8.3.2 PPAQ Results

PPAQ scores are measured in Metabolic Equivalent of Task units (METs). A MET score is reflecting the amount of energy used to do a specific activity. The

definition of MET is that it measures the amount of oxygen consumed at rest (106) .The higher the MET score, the higher is the intensity of exercise. The PPAQ descriptions of the specific activities are designed to provide information about the amount of total, sedentary, moderate and sports & exercise activity, a woman is doing. The figures below show the change in self-reported activity between the groups. They are reporting the total activity, followed by a breakdown of various activity intensities. Participants were given the opportunity to complete the questionnaires when meeting with the researcher or to complete at home in their own time. The majority of the questionnaires that were completed were done during face-to-face meetings. Participants who took the questionnaires home tended not to complete the questionnaires.

Table 33. PPAQ Score Change from Baseline to Follow-Up MET-h/wk

Activity (MET-h-wk	Intervention (Mean, SD)	Control (Mean, SD)	Independent T-test (p-value)
Baseline (Total Activity)	142±68	223±109	
Follow-Up (Total Activity)	191±91	184±118	
Total Activity Change	49± (43)	-39±(34)	p= 0.1
Sedentary Activity Change	-4.7±(5.5)	3±(7)	p=0.1
Moderate Activity Change	28±26	-16±97	p=0.2
Vigorous Activity Change	6±(14)	1.8±(15)	p=0.5

8.3.3 Total Activity (PPAQ)

The total self-reported total activity (METs) scores showed normal distribution. Descriptive analysis using means and standard deviations was done to summarise the outcomes. Women in the intervention group increased their total physical activity on average (49± 43) (p=0.1) largely due to an increase in moderate-intensity activity, whilst it decreased in the control group (-39±34). Women in the intervention group decreased their sedentary activity (-4.7±5.5) (p= 0.06) compared to the control (3±7), (p=0.1) (see Figure 32). This is in line with the objectively measured PA levels with a Fitbit, which showed that women in the

intervention group had higher step count throughout the intervention period (see Table 33).

Error Bars: 95% CI
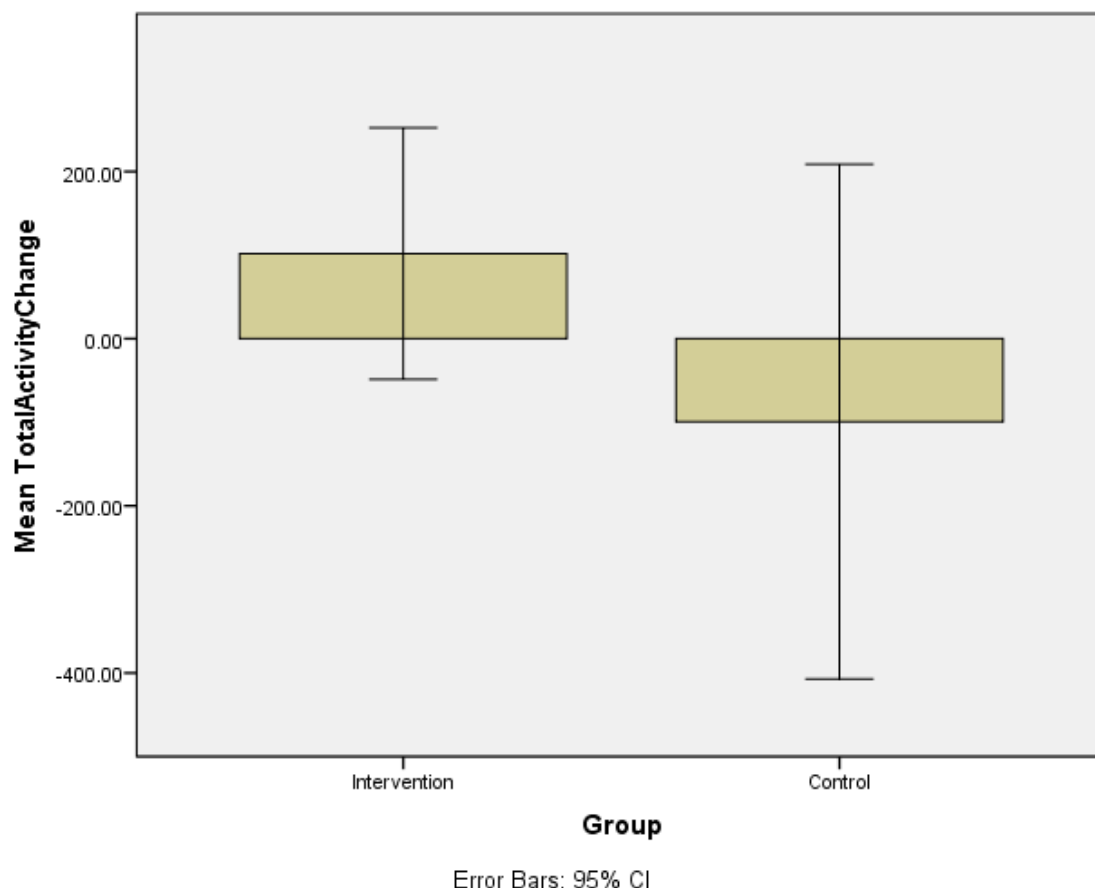
Figure 21 is showing that self-reported Total PA increased in the Intervention group (49± (43) compared to the Control group ((-39± (34).

8.3.4 Correlation PPAQ and Steps

Objectively measured PA (steps) showed a trend that participants in the intervention group walked overall more steps than the participants in the control group throughout the intervention (Week 1: 7888vs7108, Week 2: 8359vs6510, Week 3: 7650vs6452, week 4: 7755vs6513 and Week 5: 7625vs6416). This trend corresponds to the subjectively measured PA (self-reported METs via PPAQ) which showed that participants in the intervention group self-reported an increase in MET scores from baseline to follow-up (+49MET h/week), whereas the control group reported a decrease (-39MET h/week). The majority of the METs increase

in the intervention group was due to an increase in moderate activity (+28±26 MET h/week), which may be attributed to an increase in walking, as walking is classified as low to moderate level of PA. Furthermore, the self-reported PA showed a reduction in sedentary METs in the intervention group (-4.7±5.5 MET h/week), whereas the control group reported being more sedentary (3±7 MET h/week). The self-reported data is open to bias and it may be that the intervention group self-reported an increase because they knew that they were expected to walk more. The higher self-reported scores in the intervention may also be due to the fact that they were aware of their attempts to walk more, and that they therefore perceived that they had walked more. However, the PPAQ findings are in line with the Fitbit data, in terms of showing the same trend of increase of PA in the intervention group. Therefore, due to the low response rates with PPAQ it is recommended that in a future trial only the Fitbit is used to objectively measure PA. Furthermore, it would reduce the burden on the participants as PPAQ is a long questionnaire which is time consuming to complete.

8.4 Process Evaluation Questionnaire (PE Q)

8.4.1 PE Q Completion Rate

The aim of the process evaluation questionnaire was to measure a change in scores from pre-intervention to 5 week follow-up. The responses measured categorical changes in intention, self-efficacy, negative beliefs and positive beliefs in relation to walking. The response rates for the PE Q were higher in the intervention group compared to the control group. The response rate at baseline in the intervention group was highest (90%) whereas only 55% of control group participants completed the questionnaire at baseline. The percentage of participants that completed both baseline and follow-up questionnaire in the intervention group was 55% versus 35% (7 participants) in the control group (see Table 34).

Table 34. PE Q Completion Rates

PE Q	T1 (%)	T2 (%)	T1 & T2
Intervention (n=20)	18 (90%)	13 (65%)	11 (55%)
Control (n=20)	11 (55%)	12 (60%)	7 (35%)
Total	29 (73%)	25 (63%)	18 (45%)

T1= Baseline, T2= Follow-Up, T1,T2= Percentage of participants who completed the questionnaire at both baseline and follow-up.

8.4.2 PE Q Results

Table 35. PE Q Scores (Before and After, Mean, SD)

	Intervention (Before and After, Mean, SD)	Control (Before and After, Mean, SD)
Intention	5.3±1.3 - 5.8±0.9	4.9±2 - 5.2±1.3
Negative Belief	4.1±1-4±1.6	4.2±1.2 - 4.3-±1.1
Positive Belief	6.6±0.4 - 6.7 ±0.5	5.5±2.4 - 5.6±1.8
Self-Efficacy	2±1 - 2.7±0.7	2.8±0.8 - 2.6±0.9

Raw scores data of Intention, Negative belief; Positive Belief and Self-Efficacy from the PE Q questionnaire are presented in table 34. A change in scores is summarised in table 35.

Self-Efficacy

Self-efficacy was measured using the PE Q. The scores showed an increase in mean self-efficacy score change from baseline to follow-up assessment at the end of the study in the intervention group (0.7±1.2) whilst the control group had a mean of -0.2 ±1. The difference in scores was not statistically significant (p=0.4), (see Table 36).

Intention (to walk)

There was an overall trend for the intervention group to have higher change in intention scores to walk (0.5±1.3) in the intervention versus (0.3±1.6) in the control group, p=0.8 when comparing the baseline scores to follow-up scores at the end of the study (see Table 36).

Negative Belief

Negative beliefs lowered in the intervention group (-0.1±2), whilst the negative belief score showed an increase in the control group (0.1±0.9). This change was not statistically significant (p=0.5) (See table 36).

Positive Belief

The positive beliefs scores decreased slightly in the intervention group (0.1±0.2) compared to the control group, which showed a slight increase (0.1±2). The change was not statistically significant (p=0.5).

Table 36. PE Q Scores Change (Baseline to Follow-Up)

Process Evaluation	Intervention (Mean, SD)	Control (Mean, SD)	Independent T-test
Self-Efficacy	0.7± (1.2)	-0.2± (1)	p=0.4
Intention (to walk)	0.5± (1.3)	0.3± (1.6)	p=0.8
Negative Belief	-0.1± (2)	0.1± (0.9)	p=0.5
Positive Belief	0.1± (0.2)	0.1± (2)	p=0.5

8.5 MyFood24 Data

8.5.1 MyFood24 Completion Rate

Once a participant was added to the online database, a link to the MyFood24 online questionnaire was automatically generated and sent out to the participant. All participants were asked to complete the questionnaire twice; at baseline and at follow up assessment at completion of the intervention. The response rate at baseline was highest with a 75% completion in the intervention group (n=15) and a 45% completion rate (n=9) in the control group. The paired questionnaire completion rate (same person completing baseline and follow-up questionnaire) was low in both groups. Only 25% of the intervention participants completed both baseline and follow-up and 10% in the control group (see table 37).

Table 37. MyFood24 Completion Rate

MyFood24	MyFood24 T1	MyFood24 T2	T1 &T2 *
Intervention (20)	15 (75%)	10 (50%)	7 (35%)
Control (20)	9 (40%)	3 (15%)	2 (10%)
Total (40)	24 (60%)	13 (32%)	9 (22%)

* Participants that completed both T1 and T2 questionnaires.

Figure 22. Participants' Individual Calorie Intake at Baseline

Figure 22. Participants' Individual Calorie Intake at Baseline
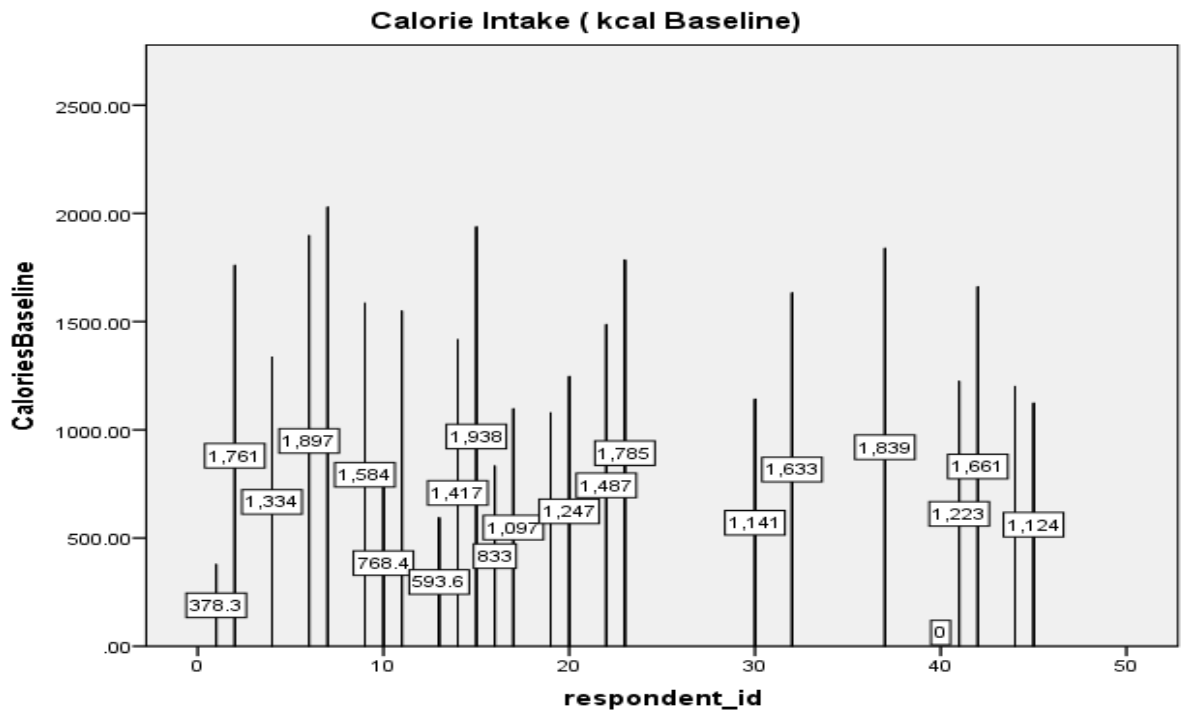
The self-reported calorie intake for each participant is presented in Figure 22. The calorie intake data ranged from 378 to 2100 calories at baseline measurement.

8.5.2 MyFood24 Calorie Analysis

At baseline the mean calorie intake for all 24 participants who completed the diary was 1358±437. Only 9 participants had completed the follow-up diary (7 from the intervention group and 2 from the control group). The mean calorie intake at follow-up was 2002±188 for all participants. Although there is uncertainty around the credibility of the baseline readings, an exploratory analysis of the before and after is showing a 50% increase in calorie intake, that is self-reported. A paired T-test of the baseline and follow-up scores showed a statistically significant difference (p=0.03) for both intervention and control participants. The difference between the baseline and follow-up in the intervention group showed a mean difference of 700 calories. Although the difference was not statistically significant (p=0.1), the difference is still notable. A paired sample T-test was done for 9 participants who completed both baseline and follow-up questionnaire. There was a significant difference in the self-reported intake at baseline and follow-up (see Table 38 for summary).

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Table 38. Calorie Intake (Baseline and Follow Up)

	Calorie Intake (Baseline Mean, SD)	Calorie Intake (Follow-Up, Mean, SD)	Paired Samples-T-test
Intervention	1382±444(n=15)	1934±811 (n=7)	p=0.1 (for 7 Participants that completed both baseline and follow-up)
Control	1318±448 (n=9)	2274±188 (n=2)	p=.04 (paired T-Test for 2 participants)
Intervention & Control Groups Combined	1358±437 (n=24)	2002±732 (9)	Paired Samples T-Test p= 0.03*

Figure 23. Calorie Intake (Baseline and Follow Up)
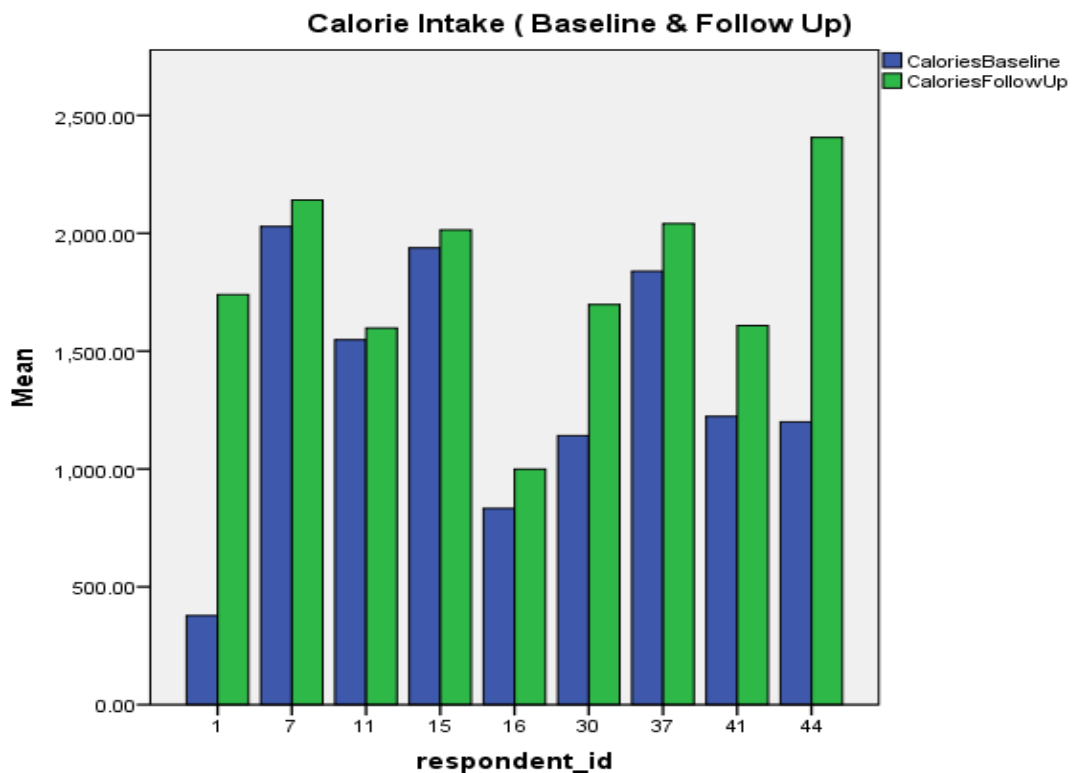
Figure 23 is showing each participant's self-reported calorie intake at baseline (blue bar) and follow-up (green bar).   From the figure we can see at baseline most of participants reported a much lower calorie intake and that all participants reported a higher intake the second time that they completed it. This may be explained by the fact that at baseline more participants experienced morning sickness (as was reported by them during interviews at follow-up). However, it may also be that the participants misreported their intake by not completing the

questionnaire thoroughly or that they deliberately underreported their dietary intake. Underreporting of calorie intake in the obese population has been reported previously in other studies (107) and will be discussed further in chapter 10 of this thesis.

8.6 Gestational Weight Gain Data

Participants' weight at baseline was collected from their hospital notes. All women are routinely weighed at their first hospital booking appointment at 11-14 weeks gestation. At follow-up appointment (after 5 weeks of participation in the study) all women were invited to be weighted. The mean GWG in the intervention group was 2.1kg±6 with a range of 0.25kg-4.25kg. In the control group the mean GWG was 3kg±1.7 with a range of 1-6.6kg.

8.7 Pregnancy & Birth Outcome Data

Pregnancy and birth outcome data were collected from participants' hospital notes, following delivery. Data on mode of delivery, Apgar score, birth weight, admission rate, and gestational diabetes status, was collected (see table 39).

Table 39. Pregnancy and Birth Outcomes compared to National Averages

	Intervention (n=20)	Control* (N=19)	Both Arms (n=39)	National Average[3] (Obese BMI Classes)
Mode of Delivery*				
Spontaneous	4	5	9 (23%)	68.8%
Induced	6	7	13 (33%)	20.2%
C-Section	10	7	17 (43%)	37%*[1]
Gestational Age	39±1	39±2	39±2	-
Premature Birth	2	1	7%	5.3%
Apgar Score (5 min)	9±1	9±0		
Apgar Score (1 min)	8	9		
Birth Weight (g) BMI Obese Class I,II (n=31)	3684±556 (n=18)	3234±908 (n=13)	3530±776	3515 ± 594
	Intervention (n=20)	**Control* (N=19)**	**Both Arms (n=39)**	**National Average[3] (Obese BMI Classes)**
Birth Weight (g) BMI Obese Class III (n=8)	3790±240 (n=2)	3592±542 (n=5)	3453±558	3610 ± 626
Admission Days (mother)	3±3	3±3	3±3	
GDM	1	2	7%	8%

* One person moved away at the end of the pregnancy, for which reason birth data could not be obtained.
*[1] National prevalence of C-section for women in the CMACE report includes BMI Class I women in the normal weight category. National prevalence of C-section for 1.BMI 18-34kg/m² is 24% 2. BMI 34.9-39kg/m² is 37% C-section 3.BMI 39kg/m2 and over 40%.
-Proportion unknown for all births in England

8.8 Facebook Findings

8.8.1 Feasibility of using Facebook within the Intervention Analysis

One of the inclusion criteria for the study was that the participant be a Facebook (FB) member or have a willingness to join FB and open a FB account to be able to join the 'Walking in Pregnancy' FB group. We found that all potential

participants whom we approached (72) were already FB members. This was one indication of the common use of FB and its potential as a wide intervention tool.

8.8.2 Facebook Moderation Analysis

The researcher acted as the moderator. Descriptive statistics for Facebook activity were calculated. There were a total of 166 FB postings made by the moderator, twice daily (morning and evening). The moderator spent on average ½ hour in the morning and ½ hour in the evening on postings. In addition, the moderator spent 2 hours weekly on calculating individual step targets for each participant. The Facebook Messenger (FM) was used by the moderator to communicate suggested step targets. Each participant was sent an average of 7 messages (range 5-11) during the 5 weeks via the Facebook Messenger (FM) telling them their next weekly step target. In addition, the moderator spent 1 hour per week in total, responding to FM messages that were sent by participants. There were no adverse events and none of the participants posted any inappropriate comments on FB that needed moderation. A breakdown of posts and examples of posts, made by the moderator, according to topic and function are presented in Table 40.

Table 40. Examples of Moderator's Facebook Posts

Prevalence of BCT on the FB Wall	Examples of Posts that correspond to a BCT	Responsive Post vs. Pre-planned Post
27.5% information about health consequences	6 Benefits of Walking in Pregnancy babycentre.co.uk)	Responsive & Pre-planned
5% feedback	All of you have completed Week 2 of the challenge! Well done!	**Responsive**
15% social support	(identified in previous studies in the literature as lacking during pregnancy) (Welcome to the group (name), Well done everyone for completing your first week, You can do it!, 'What is the hardest thing for achieving the steps in this trimester, comment...then they commented)	Responsive & Pre-planned

15% beliefs about capabilities	(everyone has been doing really well)	Pre-planned
12.5% problem-solving 12.5%	(addressing two main barriers; Perception of risk of PA and Fatigue) (eg.*How to overcome tiredness in pregnancy with PA, Does Exercise cause miscarriage Tommy's website)*	Pre-planned
12.5% prompts and cues 12.5%	(It is a beautiful day in Sheffield. Please remember to wear your Fitbits today)	Pre-planned
12.5% social reward	(Well done (name) for completing your 5 weeks!	Responsive & Pre-planned
Goal Setting, Self- Monitoring } Delivered via FM	Your target for the following week is…	Pre-planned & Responsive

8.8.3 Facebook Group Analysis

A Facebook Group has access to Facebook's own statistics function; however this function is only made available to groups that have at least 250 members. For this reason, information and descriptive statistics had to be done 'manually' in this study. The study moderator recorded Facebook interactions on a daily basis during the intervention including all comments and web links, discussion board posts, and instances where participants pressed the "like" button in response to content.

'Likes' to posts

Participants had the possibility to 'like' moderator's posts as well as other participants' posts. Participants interacted mostly with 'likes' and short comments to others' posts. Each post that was posted by the moderator received between 2-7 'likes'. Each comment that was posted by a participant received a similar number of 'likes' (2-7) on average.

'Seen By' Posts

The 'Seen by' FB feature is only active in closed and private FB groups with less than 250 members. On the FB own administrative page, the 'Seen by' function is explained as '' *If your group has fewer than 250 people, messages and posts will be marked as* **Seen** *after they're read. If your group reaches 250 members or*

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more, you'll no longer see who's seen messages and posts. If people see a group
post or message, it doesn't always mean they had the chance to read it carefully.'

The Facebook administration does clarify that 'seeing' a post does not guarantee that it has been read carefully. However, although the 'Seen by' function does not guarantee that a person has read the post carefully, it gives an indication of how many participants had at least 'glimpsed' at a post, and potentially read the whole post. In particular, there is a high chance that posts that are 'short messages' without additional links to external websites have been 'seen' and 'read'. The Facebook function 'Seen by' that appears below each posting showed the number of participants that had 'seen' a post. The number of 'Seen by' labels was counted for all 166 posts. All posts were seen by at least 50% (half) of all the participants. The majority of the posts were 'seen' on average by 70% of all participants.

In summary, the range of the 'seen by' posts was 60-80% of all the participants (11-15 out of 19 participants). The 'seen by' function also shows how many have 'seen' versus 'not seen' the post. The 'seen by' function also provides a list of names of all those who have seen the post (See Figure 24). For a future trial, it is recommended to use additional analytics to determine how many participants click and view shared links on the Facebook group wall. There are several search engines that provide an opportunity for this, such as Google Analytics. It allows one to understand and analyse referral traffic coming from different social media channels, such as Facebook. It allows one to track any links shared on social media and to know if social media traffic came from a link that was shared in a Facebook post. Using this feature is recommended for any future trial to determine whether participants are accessing from the information that is shared.

Figure 24. Total Posts 'Seen By' participants

How many posts were seen by % of Participants

Mean = 73.9675
Std. Dev. = 11.61961
N = 47
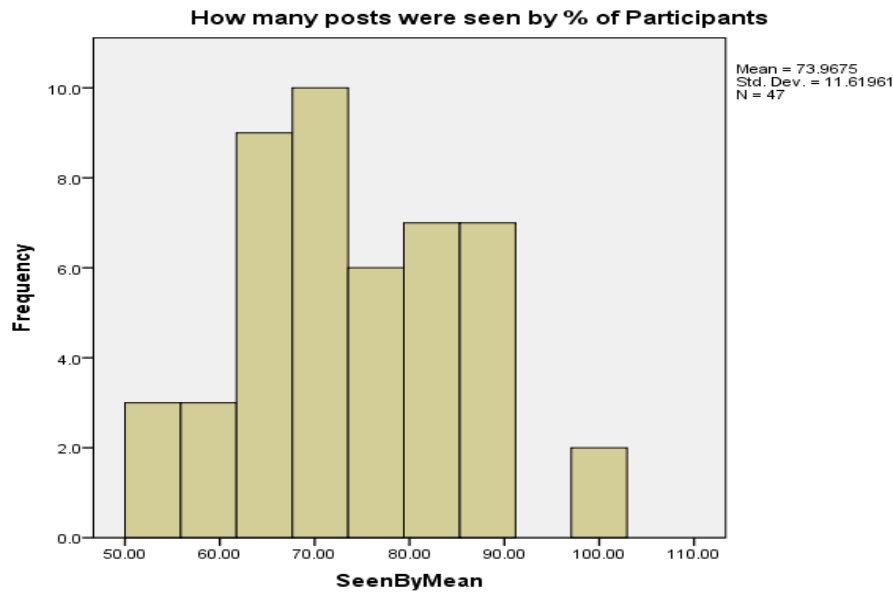
Table 41. Participants' Facebook Engagement

Posts on Group Wall by each participant	Range of 1-7 posts from each participant
FB 'Seen By' per post	60-80% saw each post (11-15 participants)
FB Messenger (Messages from participants to moderator)	14 messages per participant (10-34 messages
FB Group Wall comments (by participants)	52 wall comments

8.8.4 Facebook Interaction Analysis

Due to the low number of participants in the group (n=20) and a relatively short intervention time period, it was challenging to create a sense of 'group' for all participants. Participants joined the FB group as soon as they consented to take part in the study. Because participants were assigned to the intervention when they were recruited, it meant that there were only so many participants in the group at a given time. It also meant that although 20 participants received the intervention, there were at most 13 participants 'active' (doing the intervention) at any one time.

When more participants joined, the group became more 'active'. Also, the fact that participants who completed their 5-week intervention, chose to stay in the FB group meant that for those participants who joined 'later', there were already members and active group participation. However, not all participants that chose

to stay remained active, instead some became 'quiet observers' who would read and occasionally 'like' posts.

FB Wall Postings

All participants were encouraged to post and comment on the group wall, introduce themselves, share their experiences in pregnancy, share photos of their walks, and challenges and experiences. Facebook Wall Posts were analysed thematically. The group wall posting was not as frequent as expected. Each participant posted on average 2 posts during the 5-week period. There was a great variation in number of postings per participant. As will be later explored in the process evaluation in chapter 9, this all depended on each participant's enthusiasm about the group. Participant's wall postings were relatively short and did not mention the PA challenge or the intervention. Instead they were mostly covering topics relating to pregnancy and pregnancy-related challenges.

Facebook Wall Posts Analysis

Facebook wall posts were analysed using content analysis
The themes of posts were; 1.Describing their walks/ how they achieve their steps, 2.Describing challenges during pregnancy 3. Introductions and encouragements of others. Posts and comments varied and very much depended on each individual's personality. Although participants were prompted to discuss their PA achievements, lifestyle, how to stay healthy, and benefits of PA in pregnancy, the post that generated most comments (6) and most lengthy comments was; '*What is the hardest thing that you have experienced in this pregnancy'.* A sample of posts is summarised in Table 42.

Table 42. FB Wall Post Examples

Had a lovely walk up to Graves yesterday, just the 4 hours with a 3 year old. (Participant posted a photo taken during their walk)
Tiredness defiantly! Worse 2nd pregnancy. I do love how these posts suggest sleeping in the day to combat it I worked full time when pregnant with my first, and now I have a toddler to care for!
I do love how these posts suggest sleeping in the day to combat fatigue! I worked full time when pregnant with my first, and now I have a toddler to care for!
This is (name).. This is my fourth pregnancy, my eldest is 18 years middle 16 years and 12 years youngest. Never thought I would ever have another ,thought my days of pregnancy was over and just waiting for the day I was going through the change. I'm 15weeks pregnant and tbh I've had no problems at all, in fact I don't even feel pregnant so was happy to have my scan and see my baby on screen...
Worst thing for me is just waiting around for test results and seeing a car pull up and thinking god is that a midwife. But test results come through the post to is my 2ⁿᵈ pregnancy-the best

thing has been that me and my husband have been able to feel the baby moving earlier but the worst has been the vomiting. Way worse with this baby.
That's soooo cute! (Reaction to a post of a new-born baby in a Christmas jumper)
Hi Ladies Welcome to the Group
Hi. This is my 2nd pregnancy. the best thing has been that me and my husband have been able to feel the baby move earlier, but the worst has been the vomiting. way worse with this baby

8.8.5 FB Messenger

The moderator was also available to be contacted on the FB Messenger. The Messenger allowed private communication between the moderator and the participant. The moderator used this tool to communicate weekly step targets to each participant, as these were not disclosed on the group wall but kept anonymous. Participants, on the other hand, used this tool to ask questions about the intervention, step targets and myfood24 questionnaire. They also used the FB messenger to communicate reasons for not meeting their step targets for example, listing that they were poorly or busy. On average each participant sent 14 messages during the duration of the intervention. The range of number of messages sent was wide, with some participants sending up to 34 messages (nearly one message per day). The access to the Messenger communication channel most likely impacted on the amount interaction and communication the group wall. This finding, that participants are more likely to prefer private communication when possible is something to be considered in future design, in particular when trying to establish a sense of group or team spirit. By having The Messenger as an additional communication channel may result in lower engagement on the Facebook wall with other participants. The Messenger allowed participants to 'avoid' or 'bypass' the group interaction and may be preferred by so called lurkers i.e. participants who do not like to post on social media.

Facebook Messenger (FM) statistics

Participants received an average of 7 messages (SD = 3; range 5-11) via the Facebook messenger to tell them their next weekly step target. Each person received the same feedback via their personal messaging. The FM was used by the moderator to communicate suggested step targets. The number of times each participant messaged the moderator is shown in Figure 25. Participants used the

FM as an alternative 'communication channel' rather than using the group wall. For this reason, fewer messages were being posted on the group wall.
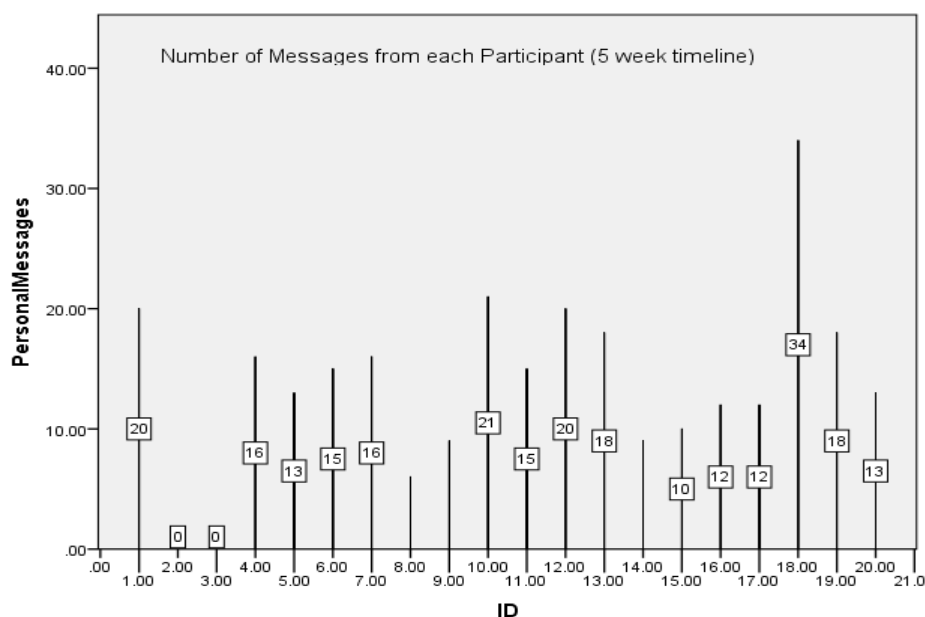
8.8.6 Facebook Wall versus Facebook Messenger Comparison Analysis

The design was to use the FB wall to deliver the BCTs as set out in chapter 6, as well as to use FB Messenger to communicate weekly PA targets to participants. The reason for using the FB Messenger to communicate weekly PA step targets was to avoid ' publicising' on the FB group wall each individual's PA levels. This could be seen as 'naming or shaming', or create unwelcome pressure and competition. However, by allowing that additional communication channel, an alternative intervention component of personalised individual support was created because each participant was given direct access to the moderator/researcher who had met each participant face to face and who was 'leading' the intervention and knew each participant's PA levels. The messages sent via the Messenger were much longer and more detailed than messages posted on the group wall. The reasons for this were explored and are presented in chapter 9 of this thesis. As part of the exploration we learnt several things about allowing the FB Messenger communication channel. Namely, giving the access to direct contact with the researcher and the participants meant that majority of participants relied on this communication channel solely and more so than the group wall. Any study/intervention related questions or thoughts were conveyed via the Messenger first. Reading and responding to those messages

became the most time consuming part of the intervention for the moderator/researcher.

Indirectly, it may have reduced the interaction on the group wall and therefore the group formation/bonding with the other participants. Although the moderator communicated mostly via the FB group wall, the responses received were mainly via the FB Messenger.

The types of messages that were received daily were analysed using content analysis and are summarised in Table 43.

Table 43. Facebook Messenger Topics

1.Reasons for not achieving step targets (sickness, forgot to wear Fitbit, not the 'usual week', work-week, 'home-week' (64 messages)
2. Technical Issues (24 messages)
3. Views on Targets (18 messages)
4. Asking about feedback on how one is doing comparing to the other participants in the group (10 messages)
5. Others

Examples of messages sent via FB Messenger to the researcher on a daily basis are listed in the Table 44.

Table 44. FB Messenger Messages Examples

Reasons for not achieving steps   Hi. I'm so sorry but I completely forgot to wear my fitbit today. I took it off to do some washing up this morning and left it on the side. I hope it doesn't mess things up too much   Hi I have a confession I'm really sorry but we've been sorting our room out for the baby's things and we seem to have lost the wee fit wire I've looked everywhere for it I'm so so sorry I have everything else just tell me what it costs and I'll give you the money next week. I feel terrible I'm so sorry   Hi I'm still having waves of nausea but they seem to be reducing a bit.   Hi, I just wanted to let you know that this 1st week isn't going to be an average look at my activity as I was sent home sick Thursday pm and have been suffering from sickness bug since, as is the whole family! I hope this isn't a problem   Hi just to let you know I left the fit bit at my daughters school yesterday and I've only just got it back so the steps for yesterday and today will be quite low and not an accurate reading.
Technical Issues   Having phone issues. Not sure if my steps will sync as phone currently not working. I'll message you my steps tonight before I go to bed just in case so data not lost

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I've been walking miles it's been registering so I have to put blue tooth on my phone at same time. Few so you can see all the data as well? I'll make sure I update fit bit every day from now
Asking for feedback Is that pretty average for a person just out of interest? No 8000 should be fine. I cover that easily on days I work anyway, other days not so much but gives me more of a push to do more on my days off
Views on Assigned Targets I can do that target for the moment. Work days it's easy to do my daily steps, as I'm sure you've noticed I walk a lot. It's my days off I have to work on still! Work days can be a mix. Depending on how the kids are and what I have to do. I went shopping on my days off this week which I don't always do but we usually try and go for short walks at least. I walk too and from tram on workdays maybe I'm not as lazy as I thought I am. Lol.. managed to hit over 10,000 last week one day... was so busy
Others I have gone through being so sick and not being able to eat or drink my booking in weight wasn't done until the 12 weeks scan, when I first got pregnant I was 132kg so have ended up losing over two stone but will hopefully level out now (what do I do to get you results) Ah so really I don't do anything..lol... Even better as technology isn't my strong point!

8.9 Discussion

8.9.1 Eligibility identification process

Our findings indicate that the timing of recruitment is appropriate and acceptable to participants. This was indicated by the recruitment rate. This study aimed to look at appropriateness of timing and recruitment routes in secondary care, which seemed most appropriate because a scan was done which confirmed a viable pregnancy and a significantly lower risk of miscarriage following that time point (108). In our study, none of our participants miscarried. The fact that women's BMI is measured as part of routine care (which is not always the case in primary care) meant that it was easy to identify eligible women. The researcher found that women were receptive and engaging when they were told about the opportunity to take part in the study. The fact that the researcher was able to build a positive relationship with the staff meant that they engaged and further supported recruitment. In terms of limitations, it was that recruitment was time intensive in that most days were spent in clinics until the set number of participants was recruited. However, as the recruitment was efficient it was the most effective way for this relatively small sample size. In a future trial, additional routes of

recruitment could be added, such as additional sites as well as using adverts in social media and newspapers.

8.9.2 Rates of recruitment

The recruitment target of 40 participants was achieved within a shorter time period (3 months) than was originally allocated for recruitment (6 months). The shorter than calculated recruitment period is an indication that the study was accepted, in terms of timing and design. The recruitment rate was much higher than expected. The researcher's active presence in the antenatal clinics facilitated the successful recruitment, which meant that the recruitment period was halved. A published article on barriers to recruitment of women who are pregnant and obese found that the average recruitment rate to interventions is 14.5%, whereas the recruitment rate to our study was at approximately 50% (97). This could be explained in several ways. Firstly, the dedication from the researcher to recruit the set number of recruits, within the time frame could be a major factor because most days of the week were set out with that sole task as a priority. The fact that the researcher was not part of the usual care pathway theme meant that there were no 'other' topics to be covered with the women apart from discussing the Walking in Pregnancy study. The high numbers of eligible women that were seen in the department within that time period could be a coincidence although it may be that the number of obese women has increased and are higher than previously thought. Longer waiting times due to sheer numbers of patients provided a greater opportunity to speak to women about the study. Lastly, the factor with greatest impact is most likely the simplicity of the study design and the fact that 'women did not feel like they were asked to do much', as well as the popularity of the Fitbit gadget, which was lent out to them. A report by the NHS Health Technology Assessment Programme identified several barriers to participant recruitment. These were; additional demands of the trial, patient preferences, concern caused by uncertainty and concerns about information and consent (109). The report suggests that to improve recruitment, dedicated research staff may be required to support both staff and patients. These barriers were successfully avoided within the recruitment process for this study. In summary, the recruitment of intended sample size was feasible. The findings provide a good indication for approximate uptake, attrition and

compliance which helps to determine an appropriate sample size for a future trial based on these figures.

8.9.3 Retention

Intervention Arm

One person dropped out from the intervention arm. That person was briefly interviewed at the end of the study to find out the reasons why. One participant lost their Fitbit. A decision was made not to offer a new Fitbit because at the time it was not clear how frequently this would happen. In hindsight, this only happened to one participant. In future trials, if a person lost their Fitbit it would be replaced with a new one. One participant's Fitbit did not work, and this was confirmed by the researcher. In a future trial, all devices should be tested for a longer period of time prior to being handed out.

Control Arm

The control group had a higher dropout rate. Two participants (10%) dropped out and three participants were lost to follow-up (15%). The control group was not as compliant to wearing the Fitbit (28 days on average). This finding was as expected, considering they were blinded to their actual step count and therefore were not benefiting from wearing it**.** Despite the lower retention rate in the control arm (75%) the acceptability to be randomised to control is relatively high compared to literature and findings from other studies (110), (35).

Completion rates for each outcome measure showed the PE Q and PPAQ questionnaires had higher completion rates compared to the internet-based MyFood24 questionnaire but overall, completion rates for all three questionnaires were relatively low. This was mainly due to the burden on patients to complete the questionnaires. One of the reasons was that participants who chose to complete the questionnaires at home most often did not complete/return the questionnaires. Majority of the questionnaires that were completed were done during face-to-face meetings. There was a high consistency between Fitbit and PPAQ scores, which indicates that using Fitbit only as a measure of PA may be sufficient.

This may be the reason why the MyFood24 had the lowest completion rate as it could only be completed in participants' homes, but this could also be because it required them to log in to their emails, locate a link to the website and then follow the instructions. There were instances when participants reported that they had not received a link or the link was found in the 'junk mail' folder.

The MyFood 24 dietary questionnaire had a low completion rate and required several prompts. The quality of the completed questionnaires was also questionable with indications of significant underreporting of dietary intakes. Participants reported during interviews that they struggled to answer detailed questions about their dietary intake. For instance if they had made a pie they had to estimate the amount of basic ingredients such as flour, butter milk etc, which they found difficult to do. Other reasons for underreporting may have been that dietary intake is a sensitive topic, especially, for the obese population. It is known from previous studies that there is underreporting of caloric intake and or avoidance of reporting. Also, the food recall was completed in the first trimester when many of the participants suffered from morning sickness. This fitted in with the weight loss that was measured in two participants. The high burden of completing dietary questionnaires is known from previous literature (111). For this reason, the poor outcomes were anticipated. However our findings have given us significant information as to how to improve this data collection in the future, which will be discussed further in chapter 10 of this thesis.

8.9.4 Facebook Findings- comparison with other literature

A review of FB-based PA interventions that included different population found that 7 out of 8 studies reported a change in PA, however only 2 of those showed significantly better PA levels in the intervention versus the control group (88). Similarly, our exploratory analysis showed that the intervention group had higher PA levels throughout, however there was only a significant effect at Week 2. These are only preliminary results, of a feasibility trial, which was not statistically powered, so would need further exploring in a full size RCT. The review of FB interventions recommends a long-term follow up for all interventions, to be able to measure the 'true effect' as well as more diverse samples, which would need to be considered as part of our recruitment strategy.

8.9.5 Facebook Findings from the group wall versus FB Messenger

Following the analysis of the FB group wall and FB Messenger, as well as our findings from the process evaluation which are presented in detail in chapter 9 of this thesis, we suggest that the way that step goals are assigned should be reviewed. One of the main reasons for assigning step goals via the FB Messenger was to avoid publicising individuals' PA levels on the wall however, the participants do mention a lack of competition-factor in the process evaluation in chapter 9. As the majority of participants said that they would prefer to know what 'the others' are doing, it may be more beneficial to present targets on the wall. This would also minimise the use of the FB Messenger or it could mean that it can be altogether eliminated. Eliminating the alternative communication channel (FB Messenger) would leave FB group wall as the only means of communication which may encourage and engage a better discussion on a group level. The support and queries would be posted on the group wall instead of directly to the moderator/researcher and could be addressed by other group members. However, there are ethical elements of this disclosure. Previous studies (112) have shown that competition is not good for everyone, especially those participants who feel they are not doing as well as others. There are however studies which have shown that the competition factor does motivate people to be more physically active, for instance studies which have encouraged teams at work to join in step-counting together, to achieve more steps and win (113). In our population, competition may not have been liked by all members, and may have impacted the willingness to take part altogether. Therefore, it is important to take this into consideration to create an inspiring and supportive group environment that encourages PA and fits all personality-types.

8.9.6 Secondary Outcomes Findings

Physical Activity- Steps

Outcome measures collected throughout the study were appropriate, in that they provided valuable information. The outcome of PA which was collected with the Fitbit focused on step counts and step targets. It allowed us to compare PA between the groups. The difference of 18% (approximately 2000 steps) between the groups at each measure point indicated that the intervention shows promise in increasing and supporting participants to maintain a higher PA level compared to the control group. The difference was significant in Week 2 only (p= 0.03)

however the trial was not powered to detect a significant effect and so we cannot determine effectiveness.

In summary, our intervention showed a trend of consistently higher mean step count compared to the control, over the period of the study. Women in the intervention group had a higher average weekly step count (between 10%-28% more) than the control group for five consecutive weeks. Their step count was highest weeks 2 and 3. Following the initial higher start than the control, they succeeded in maintaining their step count throughout. The limitation of our findings is that the intervention group were not blinded to the step counting and could therefore self-monitor during the baseline week (although they were not given a step target), which is why a difference in steps was observed at baseline week as well. Due to no blinding of the intervention it is unclear whether their steps would have been lower.

Studies of the general population have found that reaching a specific number of steps per day in obese adults does result in weight loss. For instance Creasy et al., (2018) found that 10,000 steps per day, with approximately 3,500 steps per day performed as bouted moderate to vigorous PA (MVPA), defined as 10 or more minutes in duration (114), were associated with enhanced weight loss (115). Bravata et al., (2010) found that 2419 ±1394 has a positive effect on health outcomes in the general population (116). Having these concrete and easy to understand measures (steps or minutes) that can be communicated to the public is a useful and effective public health tool.

Physical Activity (duration/intensity)
One of the initial guidelines was that one should acquire 10,000 steps per day to meet the recommended daily PA levels, which are thought to have a positive impact on health outcomes in the general population (117). The limitation of using steps as a measure of PA and pedometers, such as Fitbit, is that they do not measure distance, cadence and duration of activity. For the purpose of the full size trial it is worth considering whether additional measurements should be considered, as more recent studies have suggested that cadence (measured as steps/minute) in conjunction with bout (duration of activity) should be used as a guideline instead (118). In the general population Slaght et al., (2017) defined

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moderate PA, as ≥100 steps per minute in healthy, normal weight adults (118). In pregnancy moderate PA has been defined as cadence ≥80 steps per minute, with slight variation between trimesters (119).

Measuring Duration and Cadence

The challenge with administering targets like cadence and bout is that at present there is no way for participants to self-monitor their cadence. At present, to measure intensity participants would have to wear an accelerometer, which is usually strapped to the leg or the waist and is not very practical, especially in the pregnant population. For this reason, RCTs which measured PA in obese pregnant women by means of an accelerometer; recorded PA only 7 days at a time, once per trimester (120). There has been some technological developments, in that the duration in minutes can now be recorded with a Fitbit Charge HR wristband by means of the 'active minutes' function but only when they are performed at a certain intensity ≥100 steps/minute, which is more than moderate intensity in the pregnant population.

Whilst it is a limitation in this study that cadence and duration was not measured, the simplicity of the design and the fact that steps can be achieved at any time during and/or in-between habitual daily activities that women already do, is its strength. Changing the goal setting to duration and certain cadence would be difficult for several reasons. Firstly, at present, there is no readily available device that can measure cadence to inform a user that they are walking too slowly. Therefore, implementing a cadence of ≥80 steps/ minute would not be possible. In terms of duration, to achieve bouts of ≥10 minutes would require participants to do more planned and structured walking, and would make it more of an exercise planning rather than an intervention to increase PA in general, through habitual activities. At present, there is not enough evidence to quantify the frequency, length, bout, duration, or intensity of walking which is required to have an effect on pregnancy outcomes. We know that increasing PA levels overall has positive impact on health outcomes and asking participants to increase daily steps is doing exactly that- making them more active.

Cadence (≥80 steps per minute) and bout (≥ 10 minutes duration) is an alternative way to set PA targets. However because there are no user-friendly measuring

devices to administer and collect this data because it is still not known exactly what duration in combination with cadence of walking is required to reduce the risk of adverse pregnancy outcomes, we propose that step targets should be used in a future larger trial. Because an increase of habitual PA is the aim with our intervention, 10,000 steps is a sufficient target, as acquiring these steps throughout the day in varying levels of intensity and bouts is more feasible to implement.

PPAQ Scores

PPAQ scores at baseline in the intervention versus control group were 142 MET-h hours/ week versus 223 MET- hours/weeks respectively. This level of self-reported PA is in line with findings from the *Physical Activity Patterns during Pregnancy in a Diverse Population of Women* study by Schmidt et al., (2006) which found that total energy expenditure (MET-hours/day) was 33MET/day in the first trimester (233 MET-hours/week) (121). The self-reported MET score was also in line with findings by McParlin et al., (2010) which included a sample of women from North of England, which reported a weekly MET-hours/week of 185 MET-hours/week (122). The study objectively measured PA during pregnancy in obese and overweight women. Their findings agree with what has been proposed in our design. Namely, they found that it is possible for overweight and obese women to achieve the recommended 30 minutes of moderate activity throughout pregnancy. More importantly, they found that recreational activities appear to contribute little to overall habitual activity levels in this group of women. Because of their findings, they propose that future studies should use measurement methods which capture overall habitual PA, (eg. use Fitbit). They also suggest that interventions to promote PA in pregnancy should support changes in habitual activities at work and home, and in particular walking. Furthermore, the study identified the fact that those women who were active in early pregnancy significantly reduced their PA in late pregnancy and that further investigation is needed to identify methods to encourage maintenance of PA throughout pregnancy (122). Total activity was higher in the intervention group with increase in moderate intensity activity (28±26) and lowered sedentary activity (-4.7±5.5) being the major contributors to this difference. Using PPAQ was useful in that it provided an insight into the PA levels of low, moderate and vigorous activity. The

PPAQ scores showed a similar trend to the Fitbit steps trend. The recommendation for a large trial is to use a shortened version of a PPAQ, to lower the burden on participants or to not use a PA questionnaire at all.

Correlation BMI and Compliance

The correlation between BMI and compliance to wearing Fitbit was examined as previous studies suggest that women with a higher BMI may be less motivated or unwilling to take part in PA interventions (123). Our findings showed a non-significant weak evidence of a positive relationship between BMI and Compliance to wearing Fitbit (r= 0.11, p=0.6). This finding does not support the hypothesis that the higher the BMI, the lower is compliance to intervention and willingness to be monitored.

Pearson's correlation analysis between BMI and Steps showed non-significant evidence of a negative moderate, relationship (r=-0.4, p=0.1). This finding does support our previous hypothesis that participants with lower BMI will be more active. The correlation may have been more evident with a larger sample size. It may be that patients with higher BMI self-selected themselves out of the study by declining to take part. However, we did not have permission to collect BMI data on participants who declined to take part.

8.9.7 Suitability of Methodology for a Large RCT Intervention

1. Mobile Technology

Using mobile technology was feasible in our group of participants. Most participants already knew about the functions of the activity tracker technology and all participants (40/40) had a compatible device (a smartphone) to which they could sync the activity tracker. It is not clear whether their previous knowledge and usage of these types of devices was their motivation to take part as they might have felt more confident due to previous experience. Adherence to wearing the Fitbit was high in both intervention and control group, which could be explained by the popularity and a spike in usage among the general population. Activity tracker devices are popular yet still relatively pricey. For this reason, it seemed that all participants were happy to borrow and own one for the duration of the study free of charge. The general perception seemed to be that they were

getting this 'fancy tool' and they all expressed excitement as well as a worry about losing the device and whether it would have to be replaced.

The main limitation in using the Fitbit to objectively measure PA levels was the limitations of the 'blinding' in the control group. Having to manually put sticky tape over the screen on the device meant that the device was no longer as aesthetically appealing to wear. It was also inconvenient because the switch on button is on the side of the screen and care had to be taken to not cover it, so that the device would stay switched on. It also meant that participants did not know when the Fitbit had switched off because they did not see the pre-warnings of low battery charge unless they checked their phones. Prior to conducting a future trial, it is important to explore alternative, more effective ways, to blind participants to step readings on the wristwatch (rather than covering with sticky tape) and to the PA readings on the Fitbit mobile phone application. The mobile phone Fitbit application should be deactivated on participants' phones so that they cannot open it and check the step counts.

Further recommendations for a future RCT, is that both groups should be blinded during the baseline week to establish the baseline step count. The fact that the intervention participants were not blinded during the baseline week may have impacted their baseline measure. This may explain why a difference in the baseline measure between the groups was observed, as the intervention participants may have monitored their steps. However, despite the fact that the baseline measure in the intervention group may have been affected by no blinding, the fact that their step counts are consistently higher throughout the intervention compared to the control group is indicating that the intervention may have had an effect.

2. Digital media (Facebook)

All women that joined the study (40) had been using FB prior to joining the study. All participants in the intervention (20 out of 20) accepted group moderator's invitation to join the private 'Walking in Pregnancy' group. Because the enrolment was rolling, each participant started and completed their 5-week intervention period at different times. After completing their intervention period, the majority of participants chose to remain in the FB group. This indicated that they found some

benefit and enjoyment to be part of the group. However, the rolling recruitment was also a limitation because although participants chose to stay in the group, many became passive observers.

Due to the nature of the feasibility study and the time limitations of the PhD programmes, the period during which participants were expected to contribute was relatively short, which was a challenge when trying to establish a group community. The changing group dynamics could have also been perceived as a disturbance and a source of uncertainty among participants, which was a potential obstacle to group participation. For the larger trial, the intervention period will be longer and for this reason, this shortcoming will be avoided. This is discussed in more detail in Chapter 9 'Process Evaluation' as well as in Appendix K 'The RCT Protocol'.

3. Limitations of the FB Messenger

The Messenger was used to assign individual step targets, which were purposefully not displayed on the group wall. At the onset of the study the primary purpose of the Messenger was solely that. However, we found that making that by private communication channel available to participants, it became utilised by participants to discuss anything study-related with the moderator. The Messenger access became a 'behind the wall' channel of communication. This is one of the shortcomings of the study because it meant that there was less communication on the group wall about topics which were study-related.

Additional shortcomings are the fact that there were no expectations given about the number of posts that each participant should make. As a result, many participants took an 'observer' role and did not actively participate, and this limited the ability of the intervention to deliver social support as intended. When participants were asked by the moderator to introduce themselves and to welcome the newcomers to the group, only some of the members did so. If from the start, all participants were told that their partaking and commenting was a requirement to take part in the study, they may have been more active. However, this was not made a prerequisite, due to the concerns that it might be off-putting for some to take part in a FB study in which they had to be actively participating

as opposed to being observers if they so preferred. The ways to promote participants' communication should be explored further. A study published by Syred et al., (2014), examined this particular topic; how to engage and maintain conversation in Facebook groups that are promoting healthy behaviour (124). It found that the moderator needs to develop a strategy, which should reflect two facets of moderation for online health promotion interventions: 1. *unengaged and professional oversight to provide a safe space for discussion and to maintain information quality, and* 2. *A more engaged and interactive presence designed to maintain interest that generates new material for discussion and is responsive to user requests* to share content that will hold the interest of participants, and that is responsive to participants' needs. More about how to encourage engagement and social support and practical suggestions will be presented in Chapter 10 'Discussion of this thesis'.

4. Limitations of the Myfood24 online tool

The conclusion of our findings is that there are several potential limitations with using the Myfood24 online tool. The self-reported calorie intake at baseline is very low and not as expected from a population that is obese or morbidly obese. At follow-up there was an increase in self-reported calorie intake (2002±188) by all participants. The mean calorie intake at follow-up is more reflective of a realistic calorie intake and is much closer to the recommended calorie intake in pregnancy, which is 1904kcal in the first 6 months of pregnancy and an additional 200 kcal in the last trimester (125). Barr et al., (2011) measured dietary intake of 100 pregnant, obese women in the UK, using a 24-hour questionnaire on two occasions. Similarly to our findings, participants reported a mean intake of 1789±589kcal (125).

The first reason for low calorie intake reported is underreporting due to omissions in the food diary or underestimation of portion size. The risk of underreporting by the overweight population has been documented in previous studies(107). One other factor that could give skewed readings is the 'observer effect'. The observer effect is what is described as occurring when individuals modify an aspect of their behaviour in response to their awareness of being observed (126). Participants with very low caloric intakes were asked about this at follow up. These participants reported severe morning sickness in early pregnancy. One

participant who reported only 379 calorie intake over a 24 hour period, had lost weight at follow up and also reported that this was not a 'typical day' but rather a day when she was feeling very nauseous. GWG for this participant was negative i.e. the participant weighed 6 kg less at follow-up weighing.

Also, MyFood24 was validated against the interview-based 24-dietary recall and biomarkers from urine samples. The validation study found that dietary intake was lower when reported via the online-based MyFood24, which also may add to the low reporting of dietary intake in our population (127). MyFood24 provided slightly lower estimates compared to the interviewer-administered tool (total energy intake 1791kcal versus 2030kcal in the interview-based recall, fat intake 68g versus 77g and carbohydrate 198g versus 224g in the interview-based recall. The fact that the validation study included participants of all BMI categories may mean that these differences would be even more prominent in a raised BMI population where underreporting is more prevalent.

Additionally, a review of dietary intake tools during pregnancy confirmed our finding of the high intra-rater variability which is common in the pregnant population. For instance, the caloric intake in our population ranged from 350-2100 calories. The review and other trials have found that pregnancy is a time of high instability in dietary intake due to eating disorders such as hyperemesis but also deliberate underreporting (128). Therefore, variation in reporting is to be expected with any measurement tool. Also, the fact that participants' dietary intake baseline differed so much from participants' dietary intake at follow-up also raises the question of how representative a one off- measure is of one's diet. It also indicates that multiple 24-hour recalls would need to be completed throughout pregnancy, to get a more accurate idea of average calorie intake. Considering the additional burden that this would place on participants, a 24-hour food recall may not be the best option to use in this population.

In terms of choosing a dietary intake measuring tool, a review of dietary tools during pregnancy (111) found that short-term food diaries were most commonly used to assess dietary intake in trials (23/39, 59%), followed by food frequency questionnaires (FFQ) (12/39, 31%) and 24 hour recalls (8/39, 20%),(129). The

review found that the studies included did not provide details on the rationale for choosing various dietary tools in pregnancy, that *dietary intake tools have limitations* which lead to mis or under-reporting which is more likely in female and obese participants and due to participants being more likely to change their dietary habits which reduces the diaries' *ability to capture habitual intake.* Importantly, the review found that food diaries over a long time (more than three days) lead to higher dropout rate thus increasing the risk of bias. This is in line with our findings that fewer participants completed the dietary recall (MyFood24) a second time. Therefore, increasing the number of any dietary recalls may not be a way to ensure more accurate reporting.

What seems to be evident is that a more user-friendly and easy to complete dietary intake questionnaire is needed. Although it may be that changing to a different dietary assessment tool may produce similar obstacles as were experienced in our study, it seems that exploring other alternatives is the best option. We found that completion rates of questionnaires are affected by how easy and accessible they are. Therefore, questionnaires which can be accessed easily without requiring elaborate instructions are preferred. Whilst MyFood24 is a useful tool in terms of immediate analysis that it provides, it had a very low return rate and a complexity which may have added to the prevalence of underreporting. Because time constraint is an important factor to consider in trial settings (130), and because return rate for questionnaires was highest for those that were done face-to-face it is recommended that a food frequency questionnaire is used.

5. Outcome Measures- Gestational Weight Gain
Gestational weight gain (GWG) data was collected for the purpose of testing the feasibility of weighing as well as for the purpose of comparison. Whilst participants did not always seem keen to be weighed, this outcome is an important indicator of the effectiveness of the intervention. Because collecting GWG data is pivotal it is important to consider whether weighing and frequency of weighing may put off women from taking part or dropping out of the study. The fact that women did not seem keen is in contrast to previous findings of Daley et al.'s (2015) feasibility study which examined women's perceptions of being

weighted as part of an intervention to control GWG. The study found that regular weighing and setting weight gain limits was feasible and acceptable addition to routine antenatal care. In the study, women themselves reported that they liked being weighed because it *helped them avoid gaining too much weight* and *be vigilant about their eating* (131). Therefore, the findings by Daley et al., (2015) suggest that women might find weighing beneficial and may not perceive it as uncomfortable as was perceived by the researcher in our study.

Whilst, in our study, the researcher perceived that the women were not always keen to be weighed, women's perceptions about being weighed as part of our feasibility study were not explored within the process evaluation. It is therefore only possible to speculate on possible reasons for that impression. Women's reactions to being asked to be weighed within our study may be due to other barriers such as time constraints, or the inconvenience of having to walk to a different part of the ward to be weighed because the scales were located in a separate room with other measuring equipment. It may also be due to the fact that women are not used to being weighted routinely during pregnancy and are therefore less accepting of it. However, Daley et al., (2015) and Brownfoot et al., (2015) both found that women felt positive about being weighed. In fact, 73% of women reported that they did not feel anxious about being weighed (132). Although this figure indicates that approximately 27% of women do feel anxious about being weighed, the majority of women do not have a problem with it. It may be a benefit to advise women who are identified as anxious about weighing about the benefits of weighing and how it can benefit their and their baby's health.

6. Other limitations

The intervention was online-based. All participants met the moderator during the recruitment phase; however, they did not meet any of the participants face-to-face prior to the intervention. This may have been a limiting factor to establishing a sense of community and 'trust' for the group. Having one -face-to-face meeting may overcome challenges with engaging participants in the FB group, where users may not be comfortable interacting with strangers (133). Following completion, a process evaluation of the intervention was carried out in the form of semi-structured interviews with participants and health professionals. Specific

questions relating to the intervention outcomes were qualitatively evaluated to gain better insight into reasons why.

In terms of the recruited sample, the lack of ethnic diversity is a shortcoming and may limit the generalisability of the findings. Popular social media such as Facebook is likely to be ideal for reaching the pregnant, population; however, future research is necessary to explore usability in mixed ethnic background groups. In addition, from our findings it was clear that some participants engaged more than others did in the group. This suggests that maybe there are types of individuals who would be more likely to benefit from intervention content through FB, than others would.

Summary of the Chapter

Forty participants with a BMI of ≥30kg/m² were recruited and randomised to the intervention (a closed, private Facebook group that encouraged walking) and a control (standard care pathway and a blinded activity tracker) at 11-14 weeks gestation. The primary outcomes were the feasibility, recruitment, retention and compliance rates. Secondary outcomes were step count, physical activity (PA) in pregnancy scores (PPAQ), process evaluation questionnaire, GWG and pregnancy and antenatal outcomes. The feasibility study confirmed the appropriateness of the recruitment strategy. A key finding of the feasibility trial was the effectiveness of the recruitment method and timing.

In our recruitment procedure, women who expressed an interest in taking part were given an information sheet and up to 24 hours to decide if they wanted to take part. The majority of the women who declined to take part (13/30) did so without allowing an opportunity to be told about the study by the researcher (reasons for declining to take part are listed in Findings Chapter 8).

The recruitment rate also confirmed that our inclusion criterion was feasible (BMI, Facebook user or willing to use Facebook, owning a smartphone). This corresponds to others' findings that women's usage of social media and the acceptability of using mobile technology is high (134), (135), (136).

The primary aim of the feasibility study was to assess the feasibility and acceptability of the trial procedures. In the published literature by MRC guidelines (137), the recommended sample size for a feasibility trial ranges from 12 to 50 participants, including intervention and control arms. Our sample size was sufficient in giving an indication of the feasibility outcomes such as recruitment, retention and compliance rates. Table 45 is summarising findings of the feasibility of the study to inform development of a large RCT.

Table 45. Findings of the Assessment of the Feasibility for a Full Size RCT

Review of Methodology	Findings	Evidence
1. Did the feasibility/pilot study allow a sample size calculation for the main trial?	Measure of recruitment and retention rates identified. Sample size calculation for main trial can be calculated.	One site was sufficient to recruit all 40 participants. Recruitment completed within 10 weeks. Average recruitment rate of 1-2 participants per day. Drop-out rate in control 25% vs. 15% in the intervention.
2. What factors influenced eligibility and what proportion of those approached was eligible?	Ineligibility was due to BMI being too low or women already being diabetic prior to pregnancy.	Only eligible women were approached, as the BMI criteria and complications-factors were checked as part of the routine appointment, prior to the researcher approaching the women.
3. Was recruitment successful?	Recruitment was successful. Allocated time for recruitment was 6 months. The recruitment target was reached after 2.5 months.	Out of 72 women approached, 40 agreed to take part in the study, ≈55%.
5. Were participants successfully randomised and did randomisation yield equality in groups (allocation concealment and randomisation process)?	Participants were randomised successfully. Demographic and baseline assessments were fairly equal between the groups. There was a slightly higher BMI average in the control group participants. Allocation concealment was achieved.	**Allocation concealment** was achieved using opaque brown envelopes. **Randomisation process** was done by a statistician who generated a randomisation sequence. For the large trial an automated computerised system will be used for the randomisation process.

6. Were blinding procedures adequate?	Due to the nature of the trial, blinding of the participants was not feasible. Blinding of researcher who delivered the study procedures was not feasible due to the nature of the study. Researcher who did data analysis was not blinded.	
7. Did participants adhere to the intervention?	Participants were compliant with wearing Fitbit and to accessing Facebook group.	All 20 participants joined the Facebook group. Not all participants posted on the wall; however they had not received instructions that they had to post on the wall. Instead many participants only read posts and wrote on the FB Messenger. 16/20 participants remained in the group, post intervention.
8. Was the intervention acceptable to the participants?	The intervention was acceptable to the participants and was perceived as 'low-demand' on their time.	**Rate of recruitment** is an indicator that the design and study procedures were perceived as practical to take part in. **Compliance** with wearing Fitbit was high (32/35) vs 28/35 which indicates acceptability of the Fitbit as a measuring tool. **Retention rate** was 80% (85% in Intervention versus 75% in control) indicates acceptability of the study procedures.
10. Were outcome assessments completed?	Physical Activity (remote data collection) was completed and feasible as long as participants wore the Fitbit. Facebook data could be collected. Study questionnaires had lower completion rates (MyFood24, PPAQ, PE Q)	Days Worn Fitbit (32/35 vs. 28/35 in the control) Outcome assessments were completed. Questionnaires should be administered in clinics rather than allowing participants to complete them at a later point/at

			home to ensure higher completion rates.
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This chapter has presented our findings from the feasibility study. The findings from the feasibility study suggest that FB may be both feasible and acceptable for supporting a healthier lifestyle during pregnancy. To gain a better understanding, in-depth exploration was undertaken during interviews with participants, the findings of which are presented in the following Chapter 9.

Chapter 9. Evaluation of the Intervention Process

9.1 Introduction

A qualitative process evaluation of health interventions has been identified as an important contributor to a better understanding of randomised controlled trials design and implementation (138). Several authors have identified the reasons for qualitatively reviewing randomised controlled trials, the most important of which are to improve the science of testing approaches and to strengthen the evidence-base for using a randomised study design (139), (140). Further benefits are that qualitative analysis of complex randomised trials can give a better understanding of the measured outcomes and health conditions that are being studied (17). In 2015 the Medical Research Council published a guidance document on how to evaluate and report complex interventions. The purpose of the guidance was to encourage researchers to use a mixed methods approach to examine the mechanism of impact, implementation and outcomes. The recommendations are that process evaluations ought to adopt qualitative methods to better assess the intervention (15). This chapter will present qualitative findings from the process evaluation of delivery.

9.2 Aims & Objectives

The aim was to evaluate the design and implementation of a Facebook-based, PA intervention.

The objectives were to:

1. Investigate participants' views on acceptability and feasibility of the intervention components.

2. Investigate their overall experience of taking part in the Walking in Pregnancy intervention and their views on PA in pregnancy.

3. Investigate health professionals' views on using Facebook to deliver PA advice intervention components.

4. Investigate health professionals' views and wider experiences of providing care, specifically linked to PA, and explore the practicality of implementing an intervention within existing maternity services.

9.3 Interviews with Participants Design

Semi-structured interviews were carried out face-to-face with participants in the same week that they completed the 5-week intervention period on the maternity ward. Two interviews were carried out over the phone. They were carried out by

the PhD researcher. The interviews lasted between 20-40 minutes. There were 10 open-ended questions exploring experiences of and views on prescription of step targets, Facebook as an intervention delivery platform, timing of the intervention and motivators and barriers to physical activity. The interview guide was piloted on members of the general population prior to the interviews with participants. As a result, some questions were rephrased in order to make them clearer and easier to understand for participants. A couple of additional questions were added in order to get answers about specific part of the intervention. For instance; 'What specifically did you like about the intervention?', 'What did you dislike about the intervention?' The participants were asked general questions about the intervention, for instance; *'How was your experience in taking part in the study? What was your experience of taking part in the Walking in Pregnancy Facebook group?* They were also asked more general questions about experiences of PA in pregnancy. For instance; *Did you receive advice about PA in pregnancy from HPs, Are you planning to stay physically active during pregnancy? What would you like to be supported with in pregnancy/is there any kind of support that you are missing?* Also questions about how this intervention could be improved and in particular what they liked/disliked about it were asked. The interview guide is attached in Appendix H.

Inclusion Criteria
All study participants were eligible to take part in the interviews. The majority of the intervention arm participants (16/20) accepted the invitation to participate in the interviews, compared to 6 out of 20 participants in the control arm. Participants' characteristics are presented in table 47. Participants' reasons for declining to take part in the interviews were not recorded.

Exclusion Criteria
There was no exclusion criterion for taking part in the interview process. All participants, from both intervention and control arms, including those that dropped out, were invited to give feedback on the study process. Two participants who dropped out accepted the invitation to participate in the interviews.

Identification, Consent and Data Collection
All participants were told at the start of the study that there would be an 'evaluation process' at the end and that they could choose whether or not to participate. At the follow-up appointment (5 weeks and at the time of completion

of intervention) participants were asked if they would be willing to take part in a semi-structured interview. Each participant that agreed to take part in the interview process was re-consented for the process evaluation interviews part of the study. They were given a patient information sheet (PIS), which stated that all interviews would be recorded and transcribed. They were also told that all the data would be anonymised and stored safely. After reading the PIS they were given a consent form to sign, if they decided to take part in this phase of the research study.

9.4 Interviews with Health Professionals

A convenience sample of nine HPs, known to be involved in providing care to women who are pregnant and obese were sampled from the antenatal ward. Out of the nine HPs that were approached, eight were recruited to take part in the study. HPs that were approached were of different seniority and grade. This was done to increase variation and to identify important shared patterns that cut across all levels of seniority and grade (see table 46). Four of the HPs were aware of the study and had been helping with identifying eligible participants. Four HPs were senior midwives, and one was a junior midwife. One matron was included and one obstetrics consultant whose responsibility is to look after the morbidly obese clinic (women with a BMI ≥40kg/m2) (see Table 46). All HPs were given an information sheet and 24 hours to decide whether they wanted to take part in the study. If they agreed to take part, HPs were consented prior to and on the day of the interview. HPs were provided with a PIS which informed them of the aim of the study, that it would be recorded and that all data would be anonymised. All HPs that agreed to take part in the study signed a consent form.

Design

Semi-structured interviews were conducted with health professionals (HPs). The interviews lasted between 30-60 minutes. Although HPs were familiar with the study, a presentation of the summary of intervention components was done prior to the interviews, to ensure that HPs were familiar with all aspects of the proposed programme. As part of the interview, specific questions of feasibility and acceptability of using Facebook as part of the care pathway were asked, for instance; *what do you think about the proposed programme? What might be the*

benefits/limitations of the intervention design that was implemented? What influence do you think the intervention will have on your everyday work?
HPs were also asked more open-ended questions about care provision related to lifestyle and physical activity. For instance; What *do you think are the main issues in encouraging pregnant women to engage in physical activity? What is the current practice/ current recommendations regarding PA in pregnancy?* The questions for the semi-structured interviews are attached in Appendix I.

9.5 Data Analysis

All interviews with participants and HPs were recorded and transcribed by an approved external company that applied all confidentiality procedures and ensured that all data transfer was encrypted. All transcripts were imported to Quirkos software (version 1.4.1 2017) where they were thematically analysed. Thematic analysis using a descriptive approach was used to analyse the findings because it allowed for recording of patterns across the data which was important to understand and explain participants' experience of PA (141). It means that the descriptive analysis of the qualitative data sought to elaborate, enhance illustrate and clarify the results from the first part (the quantitative approach). Using a descriptive approach fitted in with the overall purpose of conducting a mixed-methods sequential explanatory design (28). The *explanatory* mixed-methods design is explained in detail in Chapter 4 of this thesis (Methodology).

In thematic analysis, an inductive approach allows for themes to emerge from the data. In this analysis, a purely inductive approach was primarily used in data analysis because it allowed for generation of 'new' theme development to be directed by the content of the data. Using the inductive approach meant that the researcher was free to code the data, find patterns of themes using the 6 steps, which have been summarised in Figure 26. These are familiarisation with data, coding, searching for themes among codes, and reviewing and naming themes to produce the final analysis (141).

Figure 26. Thematic Analysis

From: Using Thematic Analysis in Psychology, Braun et al., (2006) (141).
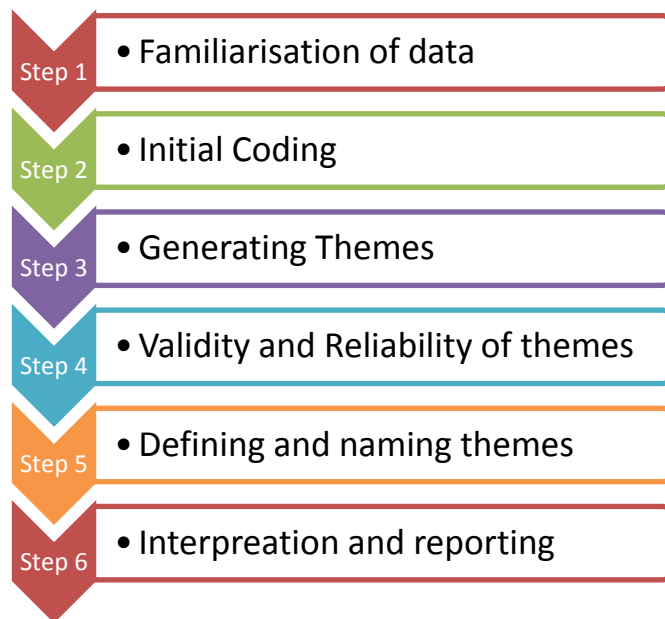
The first step in the analysis was familiarisation of data, which involved reading through transcripts and listening to the recordings to 'get to know' the data. The second step involved the identification of reoccurring data that generated initial codes. The third and fourth step involved searching for and reviewing the themes. Once the themes had been reviewed they were defined to illuminate their meaning. The phases were not linear but followed a back and forth process, to achieve an in-depth analysis of the data (see Figure 27).

To ensure that the reviewing was transparent it was done with another researcher who reviewed the codes and themes. The researcher and I then discussed emerging patterns in the data sets to detect and validate the common thread and prominent thematic codes. During the coding process, data were reduced into small chunks of meaning. The use of a second researcher allowed the initial large number of emerging thematic codes to be reviewed. Once the data was coded, themes were searched for to identify patterns that captured something significant and interesting about the data and the research question. Some codes clearly fitted together and formed a theme, whilst others were more 'overlapping'. The codes that were overlapping were highlighted and reviewed in-depth to identify their meaning and their 'theme essence'. The codes were grouped into main themes with subsequent sub-themes. The initial naming of themes was reviewed to reach the theme essence, by refining and defining. Once the themes were

agreed between the researchers and defined, they were linked to the research question and written up to produce the final write-up of the findings.

9.6 Findings from Interviews with Participants

Table 46. Interview Participants' Characteristics

Intervention Arm Participants	Number of Participants Approached: 20	Number of Participants Interviewed16	**Characteristics:** 1 drop out (drop out from the study but participated in the interviews) , 1 whose Fitbit did not work, 14 had mixed levels of involvement and compliance
Age (years)	**BMI (kg/m²)**	**Participant Number**	
33	45	11	
24	39	2	
22	30	36	
32	31	28	
27	32	19	
34	35	17	
32	42	7	
29	30	5	
25	32	9	
36	34	10	
31	34	30	
24	31	23	
26	34	25	
25	31	14	
23	36	29	
24	32	20	
Control Arm Participants	Approached: 6	Interviewed 6	**Characteristics:** 1 drop out, 1 did not complete questionnaires, 4 mixed compliance
Age (years)	**BMI (kg/m²)**	**Participant Number**	
31	36	41	
28	31	33	
26	39	36	
27	36	39	
24	38	15	
25	32	6	
Health Professionals	8	8	**Characteristics:** 1 community midwife 3 GDM midwives 1 senior midwife 1 junior midwife 1 matron 1 midwife/ward manager *Age and weight data of HPs was not recorded.

The codes were grouped into main themes with subsequent sub-themes. The initial naming of themes was reviewed to reach the theme essence, by refining and defining. There were 4 themes and 10 subthemes in total that were identified.

The findings are presented in the order of main theme/sub-themes (see Figure 27).

Figure 27. Summary of Themes and Sub-themes from Interviews with Study Participants

Theme 1 Information Provision	Theme 2 The Role of the Moderator	Theme 3 Types of Engagement	Theme 4 Striving to Achieve Goals
Ease of Access	Feeling Watched	Sharing Experiences	Perceptions versus Reality
Trusting the Source	Feeling Supported	Competition	Failure versus Achievement Feelings
Learning New Things			Barriers to Achieving Goals
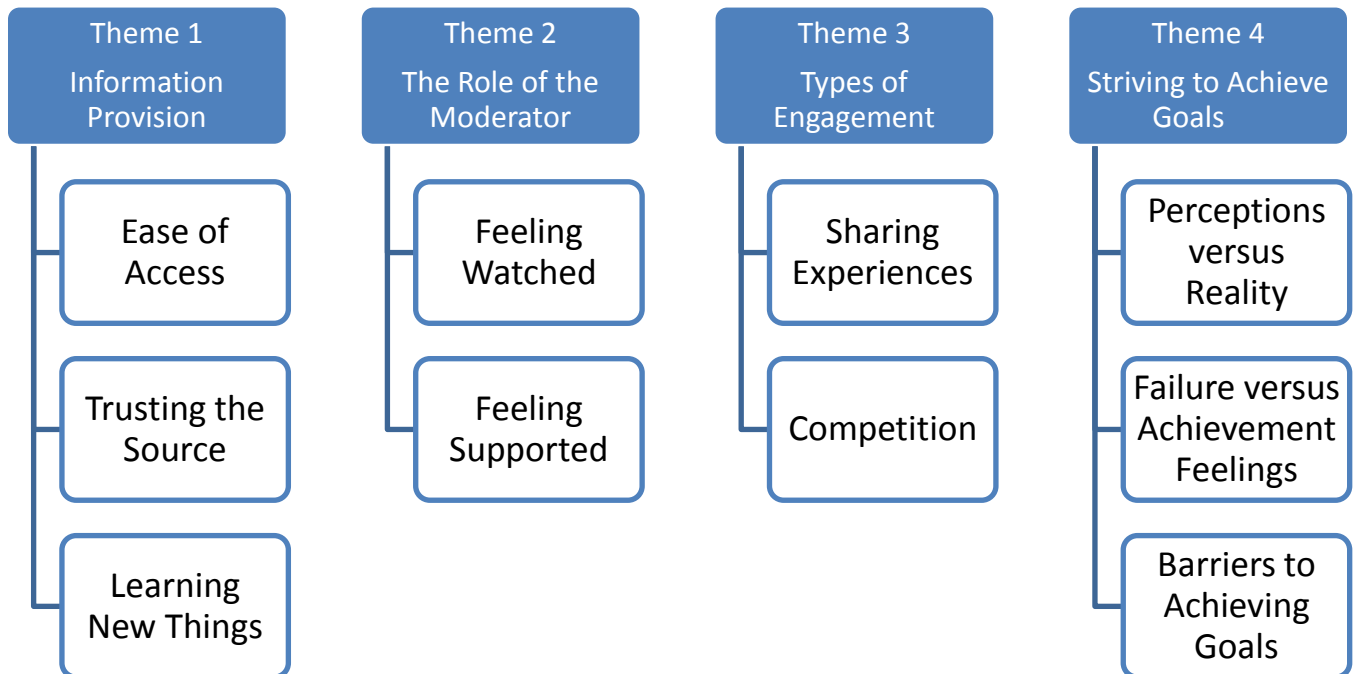
Theme 1. Information Provision

All participants discussed using a closed Facebook group as a communication channel. Participants spoke about having access to a reliable information source. The fact that information was provided directly to participants using the medium of Facebook was mentioned as a positive element of the intervention by participants. There are two sub-themes within this theme, described below. Firstly, this acts as facilitated access to information, and secondly, the information was perceived as coming from a reliable source.

a. Ease of access to information

Information was given using Facebook, which was already a familiar medium to participants.

> *Facebook page was quite good because you post a lot of things.* (Participant 11, Age 33, BMI 45kg/m²)

> *I was quite happy that the information was on there.* (Participant 2, Age 24, BMI 39kg/m²)

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It appeared that participants were accessing Facebook via their phones, which would alert them to new posts.

I got the information on Facebook. It was quite a good medium because my phone would buzz at me and see that there was a post from the group.
(Participant 36, Age 32, BMI 42kg/m²)

This was seen as an easy way to access information about the benefits on PA during pregnancy. This may imply that without the information being presented to them via Facebook, the participants would not have searched for this information themselves, and so the use of Facebook as a medium for channelling information can be seen as adding something new to the participant's experience. Not only was the information easily accessible, but the audio alerts prompted participants to read the messages.

People have their phones all the time now, usually people respond don't they pretty quickly.
(Participant 41, Age 31, BMI 36kg/m²)

b. Trusting the source
Participants described how, if they were to search for health related information, the internet would be their first choice. However, they recognised that information on the internet was varied in quality, and often contradictory.

And then you start asking questions, and then you start Googling, and then you start getting yourself into a panic because you're reading far too much into things that don't need to be there. So I think if there was something that just gave you the basics that would be helpful, for me it would. I don't know about anybody else but yeah, especially when you're a first time mum just the basics of what to expect.
(Participant 19, Age 27, BMI 32kg/m²)

However, they trusted that the information they received through the intervention was reliable, and so would prioritise that over other information.

c. Learning New Things

The majority of the participants said that they enjoyed reading posts that were shared by the moderator.

It was quite nice actually to get the different pieces of information and the different exercises that you can do and what not to do and things to avoid so I found it quite helpful.
(Participant 17, Age 34, BMI 35kg/m²)

They talked about how they had very little knowledge about the recommendations around and benefits of PA in pregnancy, and were reassured by the information they received.

I hadn't realised beforehand that exercise was absolutely OK and that actually I could have still kept jogging in pregnancy. You just think that that kind of pressure is going to impact on the baby but having read all the information you know that that's not the case.
(Participant 36, Age 32, BMI 42kg/m²)

This theme demonstrates the need for basic health information and basic messages about what is acceptable during pregnancy. These messages still need to be more widespread for people to benefit. Information and knowledge is empowering and would enable women to make better informed decisions about their lifestyle.

The ability to channel information to participants in this way, and the trust that the participants have in the information, suggests that using Facebook in this way is an effective way of getting these messages across to people. This subtheme suggests a lack of knowledge about to the benefits of exercise. This further demonstrates the lack of knowledge and information about benefits of exercise during pregnancy.

Theme 2. The role of the Moderator

Participants spoke about the psychological impact of feeling that there was someone there for them. They described that the constant presence of someone who was watching or measuring their PA as feeling the expectation from someone to be active and do well in pregnancy. One element of this was about

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how being monitored was motivating them to thrive to achieve their targets and the second element was about how having someone regularly present and sharing useful knowledge was supporting.

a. Feeling watched

Participants described feeling fear of failure to meet expectations and disappoint not just themselves but someone else:

It felt like someone was always there, watching and on the days when I did not achieve my steps I felt disappointed.
(Participant 11, Age 33, BMI 45kg/m²)

Because I knew you were monitoring. So then you make sure that you push yourself a little bit later on and think no I've got to get out and do something, which I wouldn't have done before. So I think it certainly helped on that front.
(Participant 2, Age 24, BMI 39kg/m²)

This attitude can be seen in other health environments, for instance people might attend diet groups to help them to lose weight, rather than dieting alone, as it is motivating to be weighed and monitored by someone else.

b. Feeling supported

In other comments, participants described elements of the interactions which involved knowing someone was there

I think it was nice that you posted stuff on to say keep going, yeah that was quite nice. It's encouraging.
(Participant 2, Age 24, BMI 39kg/m²)

If I did have any issues I could have put it on the wall.
(Participant 36, Age 32, BMI 42kg/m²)

The two sub-themes (Feeling Watched and Feeling Supported) are both relating to having a real human on the other end of the computer. Both themes describe interacting with an actual person, rather than just receiving generic, pre-prepared internet information.

Theme 3. Types of Engagement

Facebook engagement varied greatly between participants. Whilst some were actively posting comments, others took the role of 'quiet observers'. Their profiles were still registered as having 'seen' the posts and they would use the 'like' button, which notified us that they were engaging in the group, however they were not directly interacting with the other group members. This could be due to time constraints but it could also be due to the fact that personality has an impact on how people interact with health interventions.

a. Sharing experiences

The reasons for the minimal participation of the 'quiet observers' were further explored during the interviews. The participants who were less active on FB were asked about their reasons for not posting often or commenting. Their explanations seem to suggest that limited interaction may have been indicative of their wider feelings towards the pregnancy, for example one participant elaborated:

I don't like that idea of comparing and I don't want to be one of those people that compares their pregnancy and compares their symptoms, what their feelings are. I liked the fact that I was part of a group, but I think it's a personal journey, for me anyway.
(Participant 5, Age 29, BMI 30kg/m²)

It could also be indicative of their feelings towards sharing information in general. Certainly, the comments suggested that those who contributed less did not have a negative view regarding this aspect of the intervention.

I don't really think I did post much to be honest. I just read what you put because it was the information I needed. I didn't feel that I needed to comment. I think I 'liked' a few pages.
(Participant 5, Age 29, BMI 30kg/m²)

I think it is nice to have that group. I generally tend to go on net mums or baby sitters but it is nice to have that group and reference of stuff to go and

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have a look at and to see how people are feeling. I don't post there but it is nice to read.

(Participant 30, Age 31, BMI 34kg/m²)

Whilst some participants did not like the idea of comparing experiences, others described that this is what they were seeking. They explained how they wanted more interaction and engagement from other participants. They expressed a greater need for support and interaction and made suggestions as to how the peer-support and interaction on Facebook can be stimulated

Just finding out about how other people's pregnancies are getting on is interesting when you are pregnant.

(Participant 23, Age 24, BMI 31kg/m²)

I would have preferred more interaction and involvement from other participants. If other people had posted more I would have posted more.

(Participant Age 31, BMI 36kg/m²)

We can see from the comments that participants have very differing views on how much involvement they wanted with other participants.

The impact of personality was further evident in the way that some chose to interact within the group. Whilst some participants were happy to interact and be active within a Facebook group with members whom they had not met, others spoke about how the lack of a first meeting was an obstacle to them feeling comfortable to interact freely within the group, suggesting that one in-person meeting would create a more dynamic online group. This was communicated in the following way:

I think that a face-to-face meeting at the start of the intervention would have made it easier to interact with the group on FB.

(Participant 36, Age 32, BMI 42kg/m²)

I think maybe because you haven't got a face to the name, maybe, so I think if we'd have kind of met in a group and they'd got it as a group, maybe, we might have kind of shared a bit more through the Facebook page .

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(Participant 41, Age 31, BMI 36kg/m²)

This sub-theme illustrates that people have different perceptions and ideas about interacting with strangers on the internet. Whilst some continued to be active throughout the study, others chose not to interact as much because they had not met the members in-person. This finding should be taken into account in intervention design to accommodate people's differences. Interventions need to be flexible enough to account for that – this worked well as for the people who wanted to be less actively involved, they were still able to participate (by reading and 'liking' posts), and those who wanted more participation had that option as well.

b. Competition

Participants were not encouraged to share their individual step targets and achievements to avoid 'naming and shaming' if a participant did not meet their target. This meant that participants did not know what the others were doing in terms of steps. While this worked fine for some, it was reported as a weakness in design by others because competition was mentioned as a trigger and motivator to do more. Some participants felt that knowing what the other participants are achieving (in terms of steps) was the missing component in the study:

Maybe if there was more interaction in terms of how many steps you'd done that day or if it was a bit more like well I've done 9,000 I need to get to 10,000 and what's everybody doing.
(Participant 11, Age 33, BMI 45kg/m²)

There was times I was thinking well I'm doing about 10,000 at times and then some days I've only got 8,000 and things like that and you think well is anybody else doing like 15,000 or?

(Participant 2, Age 24, BMI 39kg/m²)

Maybe if there was more interaction in terms of how many steps you had done… I'm a bit more competitive, if I knew that somebody had done more then I'd have found that motivating.

(Participant 15, Age 24, BMI 38kg/m²)

Others reported that they felt as though they were competing with themselves.

I'm just quite competitive so I had to achieve my steps even if it meant at the end of the day looking at my Fitbit and thinking I've still got 1000 steps at the end of the day and just marching around the house.

(Participant 11, Age 33, BMI 45kg/m²)

You know, like I said, I mean every person's different but to me it was my challenge and I don't want to compare. You get into competition with yourself.

(Participant 19, Age 27, BMI 32kg/m²)

The sub-theme of Competition further illustrates how personality has an impact on how people respond to interventions. Whilst some participants mentioned that a motivator would have been to 'compete' with the other participants and that it would have helped them to achieve more steps, others were pleased that they could keep their achievements as a part of their personal journey.

Theme 4. Striving to Achieve Goals

a. Perceptions versus Reality

Participants spoke about how they developed an awareness of their level of activity as a result of step monitoring and step target 'prescription'.

It definitely made me consider my activity a lot more. I could have been a lot better at it. It was quite interesting how many steps I actually do some days.
(Participant 23, Age 24, BMI 31kg/m²)

In this way, we can see that the intervention helped them to align their perceptions with reality.

It was quiet enlightening to see how much I walk and then on the days that I don't go to work, for example how much I don't walk.
(Participant 19, Age 27, BMI 32kg/m²)

It's made me think. Because I thought like being in my profession that I did loads of steps. But actually that was the least amount of steps that I did when I was at work.

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(Participant 5 Age 29, BMI 30kg/m²)

This sub-theme demonstrates a potential gap between perceptions versus reality in terms of people's health behaviour. It shows that self-monitoring and step counting and can help to align a person's perception with reality, potentially motivating them.

It does make you more aware of how active you are.
(Participant 11, Age 33, BMI 45kg/m²)

This entire theme illustrates the importance of awareness in changing health behaviour. When people have accurate information about their own health habits, they develop an awareness that their behaviour is not matching their goals expectations - which provides information for behavioural regulation.

b. Failure versus Achievement feelings

Participants spoke about the advantages of goal setting and how that was a motivation to do more to reach their step target:

It was encouraging because if I saw that I were just below the target I'd make the effort to walk a bit more.

(Participant 19, Age 27, BMI 32kg/m²)

Goal setting had two effects; it motivated participants to be more active.

I think it makes you competitive with yourself. So you think OK I've done 5,000 steps, I'll do 7,000 steps. It does, it increases your, you get into a little competition with yourself.

(Participant 20, Age 24, BMI 32kg/m²)

However it also created a feeling of disappointment on the days that the step targets were not achieved:

I did feel not necessarily guilty but a bit disappointed on the days that I didn't make my target.

(Participant 11, Age 33, BMI 45kg/m²)

This finding illustrates that goal setting does motivate people, however it is important that the targets are individualised and 'reasonable' and provide a gradual increase, to minimise disappointment, which can be demotivating.

c. Barriers to achieving goals

Because the majority of study participants were employed they spoke about the difference between days when they were at work and the days that they were at home. Depending on the type of occupation some found it more challenging to meet step targets when they were at work whilst others struggled more during the days when they were off work.

Some participants were able to make changes to their working day, through increased awareness.

I work in a job where I am sat at a desk all day. Obviously I can do bits in the morning, lunch and bits at the end of the day. So I drove less and walked further in and out of work but it was a challenge.

(Participant 17, Age 34, BMI 35kg/m²)

They spoke about how they made plans and adjustments to their daily routine, to fit in 'more walking'. However, the participants who were not in employment also reported challenges with meeting step targets and were also looking for ways to increase this as a result of the intervention. This finding is suggesting that participants would benefit from the action planning technique to be incorporated into the intervention. This technique allows participants to plan when and where they will do something, which means it is more likely that they will do it.

Pretty hard (to meet the step target) because I don't really leave the house usually. I just walk my kids to school and that's it but now I'm trying to go out to places just so that I knew that I'd get more steps on it.

(Participant 9, Age 25, BMI 32kg/m²)

When I was at home I had to make more of an effort and we used to go out and have an actual walk somewhere. I didn't just want to stand in the living room and march on the spot really; I didn't feel that was kind of the idea behind it.

(Participant 2, Age 24, BMI 39kg/m²)

This theme describes the types of challenges people face in achieving the target steps, and also shows that with increased awareness, people may make more effort to make changes to their lifestyle, which links back to the 'perception versus reality' theme.

Summary of Findings

Participants liked receiving information about healthy lifestyle during pregnancy via the Facebook channel. They also liked having goals and receiving feedback on their progress because they experienced motivational support and attention as they felt a 'constant presence' of someone being there for them. Whilst the 'constant presence' was appreciated there was also a feeling of disappointing someone if they did not manage to achieve their set targets. Participants' personality seemed to play a role in how they responded to having individualised goals. Whilst some participants liked having set targets and competed with themselves, others wished that there was more competition and sharing of goals among all participants, which they felt would motivate them more.

9.7 Findings from Thematic Analysis of Interviews with Health Professionals

Eight midwives were interviewed to find out their views on the current health care pathway for obese pregnant women, prescription of PA, digital media in intervention design and remote activity trackers. From the interviews, 4 themes and 10 sub-themes were identified, following the thematic analysis (see Figure 28).

Theme 1.
Barriers within the Health System
- Knowledge
- Provision of Services and Resources
- Priorities

Theme 2.
Personal Factors
- Self Image

Theme 3.
Barriers within the Patient
- Knowledge
- Sensitivity of the Topic
- Motivation
- Socio-economic Factors

Theme 4.
Overcoming Barriers with mHealth Technology
- Reaching more Patients
- Concerns about the Unknown
- Whose Job is it?
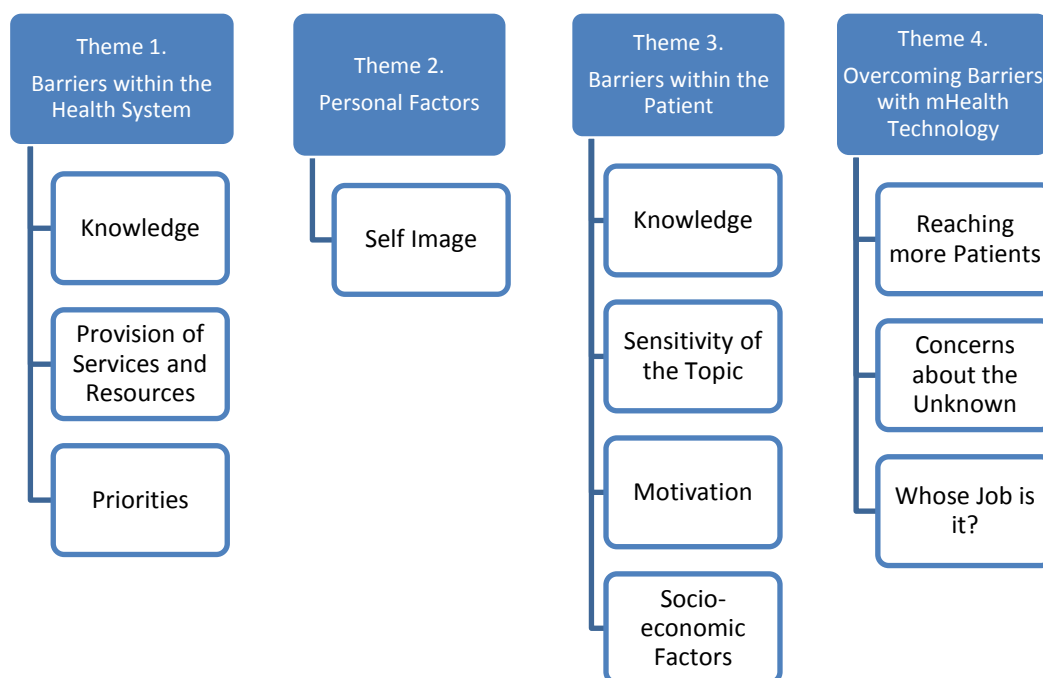
Theme 1. Barriers within the Health System to Lifestyle Support

HPs spoke about barriers to communicating lifestyle issues. The three subthemes relate to HPs own knowledge and training in providing advice and guidance on lifestyle issues, and secondly, the provision of health care and priorities within the health care services.

a. Knowledge

HPs spoke about the lack of training in what advice to give about diet and PA. They spoke about how whilst the prevalence of obesity has increased; there has not been any training about how to address this health problem with patients. They also spoke about a lack of training in how to approach the subject of PA and diet, which they know is a sensitive subject, especially for women who are obese.

We all need the same education as we are meant to be giving if we are meant to be giving information to the women we need it ourselves to give it. We are not sure about diet. We are willing to have (information) about it but it's not there. I don't think it's in midwives training (the diet and exercise).
(HP 3)

But we don't even talk about it (diet and healthy lifestyle) between ourselves. It's not a subject that, what do we eat is not necessarily a subject. We all have different knowledge. We do talk about it sometimes because you have your lunch. So some of the girls would have a different

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lunch and that's really interesting , you know , and other girls are asking well what are you eating, you know, and it's quinoa or whatever they call that and things like that.
(HP 4)

b. Provision of Services and Resources

HPs spoke about the changes that have happened during their career and how previously there were more resources and time to advise others about diet and PA during pregnancy.

We don't give them any information. We used to have information about diet but we don't have that and even at the BMI clinic (BMI over 40) they don't use that information anymore.
(HP 1)

They mentioned that previously more community-based services were in place and available to the pregnant women, which they could refer them to. They spoke about how now there is very little point in advising on PA and diet because they do not have anything to offer to their patients. Whilst previously they could follow the discussion up with a referral to see a dietitian or to aqua aerobics lessons, there is simply nothing for them now.

We just say your BMI is 35; therefore you need glucose tolerance test because you might be more likely to get diabetes. And others will say your BMI is above 30, do you realise that is obese category.
(HP 6)

We don't have any handouts. We have nothing to show. Nothing about diet or PA nothing at all to show
(HP 3)

They used to have a dietician here in antenatal clinic which is not there anymore.
(HP 4)

We used to send women to aqua aerobics and yoga classes but that is all gone now.
(HP 1)

From this theme it becomes clearer that HPs perceive that patients not only need to be told they are obese, they also need to be told something they can do about

it. HPs comments suggest that they do not feel that they can give advice because there is a responsibility to not just talk or give advice but to suggest a solution. Therefore, if they tell the patient something negative about their health, for instance that they are overweight, that they also need to suggest a solution. The midwives spoke positively about their involvement in the Walking in Pregnancy study, as it gave them something to offer.

Anything we can give them would be much better. It was great while we were recruiting (for this study) because you could say to them about walking. ..But they still need a goal and someone to encourage them.
(HP 1)

If there was something we could actually sign post to. ..Like join Slimming World but it is expensive and we don't provide anything. But even if it is just something like having a Fitbit and having a Facebook page, that would be helpful.
(HP 5)

c. Prioritising limited clinical time
The HPs recognised that there was a lack of support for women, whilst there is a great need to do more. They were careful about expressing their views on 'what they thought was needed' because they recognised that they themselves were overstretched and lacked manpower and resources to do more.

I think as well the worry is you are opening rightly or wrongly up a really long discussion with someone in an appointment that is 15 minutes long and you have got to get through the whole booking.
(HP 6)

Health professionals spoke about their lack of influence on which health concerns are covered during the booking sessions. As an example, they mentioned that on their 'to do' list they have 'procedures for disposal of placenta' which is far less relevant than diet and lifestyle.

We give loads and loads of paperwork and none of them are about physical activity. We give advice about disposal of placenta which is not even anywhere near the delivery because they may miscarry before they reach that point but we don't give anything about activities or physical activities.
(HP 4)

There was a general impression that HPs felt powerless as they are not active decision makers in what information is prioritised. There was a reoccurring theme of 'time pressure' and overburden in numbers of patients and topics that have to be addressed during the hospital booking appointments. What came across is that a lot of the 'compulsory' topics that are addressed during the appointments are viewed as 'outdated', ' wrongly prioritised', or 'irrelevant'.

I would put the screening for Downs Syndrome lower on the priority list than tackling obesity because I think obesity is far more frequent and causing a lot more damage than something like screening for Down's syndrome.

(HP 5)

It's like the smoking cessation. They brought in this carbon monoxide screening for everybody, which still infuriates me. I still find that a pointless waste of time.

(HP 2)

The midwives recognised that discussing weight and PA was important, but felt it was difficult to fit it in with everything else they were required to cover.

I think there's that many other things to do during these booking appointments…it's getting ridiculous with the amount of stuff that you've got to do … although I think it would be a good idea (to give advice about PA and healthier lifestyle)
(HP 6)

There is a strong message in this theme that HPs do not feel able to prioritise providing lifestyle advice to their patients, due to the requirements to follow guidelines and other compulsory procedures. This indicates that obesity, lifestyle support and PA in particular, has not been prioritised and given the attention it deserves. Furthermore, this suggests that reviewing the priorities with HPs of all levels might improve practice and care provision for patients.

Theme 2. Personal Factors

a. Self-image

This sub-theme illustrates that obesity is a complex issue. HPs spoke about their self-perceived health/weight status. HPs that had raised BMI saw it as an obstacle to giving advice as they were not 'the right person' to give out such information. Similarly, HPs who perceived themselves as normal weight saw it as an obstacle to advise women with raised BMI because they did not understand the challenges of weight management. Whilst it is a clinical issue, it also has personal and social implications, which is why HPs hesitate to discuss it with the patients.

The midwives spoke about the difficulties of discussing this topic in relation to their own BMI status. The overweight midwives did not think that they were in the right position to give advice whereas the normal weight midwives avoided the topic altogether because they did not want to come across as 'judgemental'.

I think as I look at me because I am thin and so I can't you know. I don't know what it is like to be overweight and try to lose weight.
(HP 4)

If you are bigger yourself you feel weird asking somebody else to think about their weight because they know, you know that they're looking at you being bigger.
(HP 7)

HPs must often give advice on issues that they have not experienced themselves, and the fact that this particular issue causes such self-reflection further illustrates that obesity is not simply perceived as a clinical issue.

Midwives described speaking about PA and diet as particularly sensitive due to the stigma linked to being overweight and obese. Therefore, these findings indicate that a midwife's self-image has an impact on advice giving.

Theme 3. Barriers within the patient from HP's perspectives

In addition to problems identified within the system, and within HPs themselves, they spoke about issues within the patients that were barriers to discussing PA in pregnancy.

a. Knowledge

HPs described their concerns about the general lack of knowledge and awareness about healthy lifestyle among their patients. HPs perceptions are that women are unaware of the risks associated with being overweight and obese. For this reason, they described their patients as not particularly concerned about the fact that they are overweight:

I think part of it is because people don't really understand what being overweight is about, what repercussions on their health it does actually have. It's a bit like smoking in pregnancy; people have small babies that they sometimes perceive that's a benefit.
(HP 7)

They also spoke about how bringing about awareness of the risks of overweight and obesity is not enough because the problem, according to them is that the women do not have sufficient knowledge to make the right healthy choices. They spoke about specific circumstances when they discovered the low level of knowledge, in particular among overweight women whom they had to give dietary advice because they had developed GDM, for instance, a lack of knowledge on how to read food labels.

I think the diabetic clinic is the first time someone has told them how to read a food label. Some of these things are complicated. It's no good saying 20g of sugar is too much because how much is normal.
(HP 1)

This theme points to a need for health knowledge to be more accessible, to empower the population to make informed decisions, in particular when it comes to dietary habits. It suggests that more could be done to create and facilitate access to reliable sources of information which could in turn support the public to make informed, healthier lifestyle choices.

b. Motivation

HPs described their patients as lacking motivation to lose weight and lead a healthier lifestyle. They spoke about previous interventions and how there was a low uptake when patients were offered appointments with a dietitian on site.

I find it difficult because of a lot of them aren't motivated. And we actually don't provide very much for them.
(HP 5)

There was, at the very beginning of the raised BMI clinic a dietician that came. I think the take-up; she was in a room on her own. Even then they didn't stop to see her, quite a number of them.
(HP 6)

There was a study and people did recruit to it but what they were being asked to do was exceptionally arduous. There was blood testing involved. There were regular visits up here. When you've sat in a clinic and had a scan and you've been here for two-and-a-half hours already, to then say now we're going to go through the research side with you, there's no wonder some people just think you can forget it, I'm not interested.
(HP 7)

HPs perception of their patients was that they lacked motivation, time and interest to improve their health even when there were resources to support them.

c. Sensitivity of the Topic

HPs described how doing the routine BMI measurement at the first hospital booking appointment is a challenge to do for women with high BMI. HPs perceived that patients do not like their weight to be read out loud or talked about during the consultation.

HPs spoke about the importance of communicating weight-related issues in privacy.

What I like to do is sometimes bring them in without their partners. I like to do their weight and measurements without their partners in there, because then they're sometimes a bit more free to talk about it; whereas some ladies will get on the scales and say don't read it out, I don't want to know what I am, I don't want him to know what I am.
 (HP 6)

HPs described that the challenges with communicating weight-related issue were 'real' because they have experienced that women have avoided the topic when they were told that they had a raised BMI. This was particularly noticed as a barrier to having an open conversation about diet and physical activity.

Uncomfortable (to talk about weight). Really, really difficult because, just because maybe she will ask more if I say that your BMI is 40. It's very

difficult, very sensitive thing to mention and the woman herself her face changes completely as we start talking about the weight.
(HP 3)

The finding which is demonstrated in this theme is the necessity of HPs being aware of wider issues and the sensitivity of personal issues, and obesity in particular. HPs are aware that patients might not want sensitive issues to be mentioned even in front of their closest family members e.g. their partner.

I've noticed that ladies will say don't read my weight out while he (the partner) is in the room, And then it's very difficult if they have got a raised BMI to say your BMI's a little bit raised,.....or they'll say don't shout it out, write it down. I've had to have the support worker come and write it down because they don't want their husbands to know what it is.
(HP 4)

The observations which HPs described in this theme are suggesting a high level of sensitivity that is linked to being overweight or obese. This finding should be taken into consideration in future interventions that are providing education and training to HPs in how they talk about weight and weight-related health problems and whether this topic should be addressed during consultations without the woman's partner in the room.

HPs described the 'risks' of bringing up sensitive issues such as weight and raised BMI- associated risks in pregnancy.

A lot of women will take offence actually that you're telling them that they are overweight.
(HP 5)

HPs emphasised the need to normalise talking about weight and weight-associated risks. They made suggestions about how the barriers to communicating sensitive issues can be addressed. Often, they mentioned how previously smoking was a difficult topic but has now been normalised and is therefore easer to discuss.

If we approach it with everybody, so that it becomes the norm. Instead of that a woman feels like she is being picked on because of her weight, it needs to become normal, like screening for alcohol and cigarettes, just 'general advice' for all pregnant women.
(HP 7)

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I think it needs to become more embedded (talking about PA) now and they just accept it this is what we are doing. So if we ask them about PA, what do you do 'oh I walk for the bus ' for example.
(HP 4)

c. Socio-economic factors

HPs spoke about the barriers that they have identified when promoting healthy diet and physical activity, which are different depending on the socio-economic status of their patients.

But I would say a lot of our ladies they do try and eat healthy. I've worked in in two very different areas, quite an affluent area and then an area that's quite poor, and obviously there's a massive difference in what people can afford.
(HP 6)

They recognised that the 'healthier lifestyle' is more costly and therefore cannot be afforded by those patients from low-income groups.

Going to the gym can be expensive, and I think a lot of people are more worried about going to a gym.
(HP 7)

Going to a gym is quite a difficult one because I think a lot of ladies who are overweight have a poor diet because they don't have the money to buy fresh fruit and vegetables.
(HP 2)

As well as observations of socio-economic differences in relation to healthy lifestyle, there is a perception by the HPs that a healthy lifestyle is more costly, and this, as well as other issues around discussing obesity, may be dissuading HPs from broaching the issue with women. However, the Walking in Pregnancy intervention was designed to be easily accepted by women from all walks of life. This theme supports the importance of this.

Theme 4. Using mHealth technology as part of clinical pathway to delivery health information

a. Reaching More Patients

I think that's great (Facebook) for people who are pregnant in that age group of technology being everything now. Everyone lives life on their phone. They don't read paper. And you might meet more friends and be motivated.
(HP 7)

I think it's brilliant having it on Facebook. I think that it's something that many women would go into that and get a lot of help from that and support.
(HP 4)

HPs discussed the importance of health intervention designers being aware of their target population and the acceptability of tools which are made part of the design. HPs perceptions of the potential acceptability of Facebook as a medium are supported by the evidence from the women themselves.

b. Concerns about the 'Unknown'

HPs had positive views of using Facebook and were aware that the majority of the patient group use mobile phone and social media. They talked about how convinced they were that this would be acceptable to the patient.

Because they recognised the risks in using social media to deliver health information they reflected on barriers like for instance, safety. They admitted to being unfamiliar with restrictions around using such a tool due to ethical issues and seemed therefore unsure about being part of it.

I think it's like all things that when you develop something that goes online, somebody's got to be responsible for checking it's updated, it's not being abused, it's got the right information on.
(HP 1)

It would have to be monitored. There was, was it the NHS website you could register your due date and they used to send on weekly updates about what size the baby was… but then people miscarrying weren't able to get themselves off the website very easily. How easy is it to get yourself off the Facebook group?
(HP 4)

HPs concerns about the safety of online communication demonstrate a need for clear and up to date information, for this to be seen as an acceptable care pathway. To have a good uptake of this new method of delivery, HPs will require training and evidence-based information that this new method is advantageous and does not pose any confidentiality risks.

c. Who's Job is it?

HPs feedback about monitoring PA during pregnancy and delivering advice via Facebook were mixed. Whilst there was acknowledgement by HPs that there is a lack of support for obese pregnant patients, the views were that this gap/lack should be addressed 'elsewhere' and 'by someone else'.

Community midwives should pick it up, it should be done in the community.
(HP 1)

It doesn't have to be a midwife who is managing the Facebook group. It can be someone who is knowledgeable.
(HP 3)

The main reason given was the time and resource limits. The feeling of being overworked and overstretched, as well as the feeling that they could not possibly take on or do more than they are already doing, came across in all interviews.

If someone was employed alongside to do that then that would be amazing but I think as midwives in a booking clinic, I don't think you've got that even that extra 10,15, 20 minutes to be able to get through that with them.
(HP 6)

I think probably if this became part and parcel of standard care, I think the problem is the midwife having the time to discuss to a patient what you need to do.
(HP 7)

HPs who are part of the care pathway do have some responsibility to provide information and support on healthier lifestyles, but due to limited resources and constant feeling of time pressures implementation of additional steps in the care pathway are perceived as a challenge. This should be taken into account in the

early planning phase of procedures within a future larger trial, with special consideration of the practicalities of implementation.

Summary of Findings

HPs discussed barriers to discussing healthy lifestyle with obese pregnant women. These included systemic barriers, and personal factors relating to both the HP and the patient. One significant barrier is lack of time due to which health care services have to strictly prioritise the most pressing issues. As a result, addressing healthy diet and physical activity has been pushed down on the list of priorities within the health care pathway to the women who are pregnant and obese. HPs did recognise that using technology does have the potential to deliver advice and support widely at a low cost and could address the time restraint. Their concerns were regarding the potential risks relating to confidentiality of using this new method of delivery and about how to moderate the group effectively.

9.8 Discussion

The qualitative evaluation both supports and expands upon the other aspects of the study, resulting in several additional findings. All participants spoke about the positive aspects of being part of the FB group, however, what came across is that the experience and utilisation of the group differed between participants. They described how they 'made it work for them'. Some described benefits of reading articles/information posted by the moderator whilst others used it to access information as well as to interact with and build relationships with other participants and to find out about their experiences. The participants appreciated having the group to access for their varying levels of need. Our findings are similar to other studies of FB interventions. For instance, a study which aimed to improve PA and health in breast cancer survivors, showed that overall participants felt positively about being part of a FB community of people in a similar situation, and felt that their overall experience improved as a result of the FB group (142). However, the mentioned study was a single-group study and all participants were their own control. For this reason, no comparison could be made participants who did not receive any intervention. In our study, when asked about the negative aspects of being part of a FB group during pregnancy, the participants had no negative feedback apart from some who wished for more interaction between group members.

Engagement

Engagement with Facebook was described as mostly positive, with an emphasis on easy access to information and encouragement. We found that the subtheme of level of interaction with other participants had two opposing views, 'not enough engagement and interaction among group participants' versus 'sufficient amount of interaction among group participants as it was delivered within the feasibility study'. This was explored further with participants. During the interviews, the less active participants explained how they would read all the posts and comments which were made by other group members; however, they themselves would not partake in the discussions. On the other hand, we found that participants who posted and commented on the group wall also expected and wished the other members to do the same. For that reason, there was a mild sense of frustration that others' engagement levels were not enough.

This is similar to findings from a previous review by Smailhodzic et al., (2016) of the effect of the use of social media on patients for any health-related reason. The review included all illnesses such as cancer, fibromyalgia, organ transplant patients and others. It found that some patients only use social media to read about others' stories, without actively contributing themselves, so called "lurkers". The review found that this behaviour was linked to anxiety (143). This was explained by the 'lurkers' or the more quiet participants as their way of getting information but keeping to themselves as they do not like to 'compare' their symptoms and worries with other people. Other studies in the review reported that reading about others' stories and experiences lowered anxiety in some people. In particular, Erfani et al., (2013) study demonstrates the same findings that cancer patients found a great sense of comfort and support in reading others' posts and comments in a FB group for cancer survivors (144).

Step Targets

A lot of the focus during the interviews was relating to the experiences of having step targets. Participants spoke about the awareness of their levels of activity but also about the awareness it brought of 'not having done enough' or not 'reached the target'. The fact that participants spoke about developing a new awareness is indicating that the self-monitoring technique (145) was a method that may have impacted their behaviour (PA), once they became aware of their objectively

measured PA levels. This awareness was brought about as participants had to self-monitor their PA levels, which is the mechanism of action of self-monitoring technique. There were particular discussions about challenges of meeting targets whilst being in part-time employment, which meant that the challenges differed on workdays from home-days. It was clear that it became even more challenging for those in full-time employment due to the lack of opportunity. This finding is similar to other studies which show that working conditions do not accommodate and encourage PA during working hours despite evidence which suggests benefits to all (146),(147).

Meeting Face to Face

Some participants suggested that their experience of partaking in the intervention would improve if there was a face-to-face meeting at the very beginning. This need was only expressed by some participants and mainly those that wanted more engagement and interaction from other participants. This finding is similar to a study by Gruver et al., (2016), which piloted a FB group for mothers with babies aimed at preventing obesity in children. Prior to the pilot, an interview with maternity service users was conducted which found that *even one in-person event for the group would assuage their concerns about not knowing the other participants*. Based on this finding, the pilot peer group began with a face-to-face event where 3 out of 8 participants attended. Following this introductory event it was found that participants who attended the in-person event had similar rates of participation compared to those who did not attend (median of 23 posts/comments for all participants over the course of the intervention in both groups) (135). It is worth exploring whether existing antenatal classes, could be a venue for a face-to-face meeting within this intervention. It is recommended that the schedule of existing classes is reviewed to explore whether their timings could be timed with study processes of a future large RCT.

Competition

A re-occurring theme among some participants was the desire to know what the other participants were doing (in terms of steps) and how that compared to their own step count. Whilst some studies have explored the important components of a remote PA intervention and found that competition is important to motivate participants, these results were found in younger populations, for instance university students of all BMI groups (112). The same study found that although

participants appreciated being able to compete with their friends, by ranking and earning awards, they were less willing to share their PA accomplishments through social media unless they were positive. For this reason, it is not certain that the 'competition factor' would only have positive effects on our obese participants, as its effect seems to vary (148).

One of our findings is that goal setting and targets do work but from previous literature we know that they have to be reasonable and provide a gradual increase, to minimise disappointment, which can be demotivating. Because past experience is an important factor that can strengthen a person's self-efficacy. For it to be strengthened, it is important that the tasks are moderate so that people have the 'mastery experience' which strengthens their self- belief in their capability to perform tasks and in this case steps (149).

Challenges by HPs

Our findings from the interviews with HPs were consistent with other findings which show that there is a mismatch between the information that the midwives provide and the guidelines on what information should be provided to support a healthy weight gain in women (150),(151). We identified the challenges that HPs face, in providing advice about PA and lifestyle to women who are pregnant and obese, which are similar to what has previously been identified in other studies, but which have so far failed to be addressed. For instance the issue of lack of sufficient training, stigma linked to giving advice about GWG to obese women as well as lack of priority for the issue was identified in our study as well as a study by Warren et al., (2017) *Eat well keep active; qualitative findings from a feasibility and acceptability study of a brief midwife-led intervention to facilitate healthful dietary and physical activity behaviours in pregnant women* (152). Despite the increase in need and urgency of this public health issue, mainly due to a steep rise in the number of women of childbearing age that enter the pregnancy in an obese state (49), no additional programs have been put in place to better equip midwives for this challenge. As a result, there is still a mismatch between what the evidence-base tells us, and what midwives actually do in practice (153).

Furthermore, there was a mismatch in what was reported by women in our and other studies and what HPs perceive to be true. HPs perception of their patients was that they lacked motivation and interest to improve their health. However, this description did not match up with our feasibility and process evaluation findings. Participants were willing and motivated to receive information and strived to become more active. HPs feedback may be based on their experience of previous interventions, which had been unsuccessful. In the interviews, HPs spoke about several interventions where patients had been asked to see a dietician several times throughout pregnancy. HPs attributed the lack of success of the previous interventions to a lack of motivation in women. Instead, it may be that previous interventions did not provide the right kind of support and have therefore been unsuccessful in recruiting and retaining participants. Their views may be due to stigma, which has been reported in previous studies. For instance, Mulherin et al., (2013) measured maternal service providers weight stigmatising attitudes. It found that maternity care providers perceived obese women as having poorer self-management behaviours, and reported less positive attitudes towards caring for obese pregnant women (154). Also, other literature has reported of midwives' cynicism toward obese, pregnant women (155). The study found that caring for obese women, particularly during the intrapartum period was viewed negatively, and attributed to the challenges of providing care for this high risk group. Although in this particular case the negative views were because such patients put more pressure on HPs due to higher risk of complications (and are therefore more difficult and demanding to treat) the fact that their complications are due to something preventable (i.e. overweight and obesity), HPs view the patient negatively because the patient is responsible or 'to be blamed' because they got themselves into this unhealthy state. Whilst we cannot ascertain why HPs perceive obese women as unmotivated to adopt a healthier lifestyle, our findings suggest that this misconception may be an additional barrier to lifestyle advice provision.

Care provision to women who are obese
Similar to our findings from interviews with HPs previous studies have shown that there is not much provided in addition to the special clinical care that obese women need. A study by Kerrigan et al., (2015) found that care of obese women is more medicalised and focused on the associated risks rather than early

interventionist and preventative measures. However, the study also found that whilst there is awareness amongst HPs to try to support normal management of birth in obese women more concrete guidelines and mechanisms in place are necessary to improve the care of this group of women (155). Our findings also demonstrated a gap between what we know and the guidelines, and the actual care provision.

As part of our feasibility study the FB group was moderated by the researcher and not by a HP who was in charge of providing care to the participants. Therefore, HPs were limited in how much they could reflect on the challenges and benefits of moderating a closed, private FB group for women who are pregnant and obese. Whilst our findings showed that HPs identified the major challenges as time constraint, and potential risk to confidentiality other literature has identified HPs experiences of using SM as bringing about more equal communication, harmonious relationship and the negative aspects of suboptimal interaction and also some loss of privacy. The moderator's (researcher's) experience of moderating the FB group was similar to what was found in other literature. The SM enabled a more direct and equal level communication with the participants. The participants were more readily available and respondent to instructions and there was a perceived notion of having access to participants and a sense of 'knowing where you have them'. However, this was also a time burden because it was a mutual expectation, which meant that participants had expectations from the group moderator. Whilst the moderator did not feel a sense of loss of privacy because the intervention was run from an independent FB account which was set up solely for the purpose of running the intervention, there was a feeling that the participants had a constant access to the moderator. For this reason, for the larger trial, specific times should be set out to address questions on the FB wall from participants and at least two moderators to moderate the group are recommended.

9.9 Summary of Points

Participants reported that partaking in the Facebook group activity did not add much more to their busy schedule and that they liked the ease and simplicity of

FB communication. It is known from previous research that overburdening participants leads to lower uptake and retention rates (156). For this reason, this is an important finding; the fact that participants felt that it was manageable and not overburdening implies that the design is feasible and acceptable to participants.

Furthermore, our findings are consistent with findings from other studies which suggest that women with high BMI would benefit from additional information and support about weight management during pregnancy. Our findings are also consistent with other studies which show that midwives face many challenges when trying to address GWG with women.

Table 47. Summary of Suggested Improvements made by Study Participants

Problems	Suggestions for Improvement
Participants did not know the other group members	Face-To-Face meeting at the start for instance in antenatal classes or Structured introductions to enable participants to get to know each other online
Some did not engage in posts and comments	Emphasise more at the start that it would be good if everyone participated. However recognise that even so-called lurking benefits lurkers and therefore not set a requirement for how often participants should post. Previously we know that engagement is about quality not just quantity.
Competition factor would have been motivating/Wanting to know what the others are doing	Make sharing of steps optional for those who would like to do so. Competition is not a trigger/motivator for all. Some benefit whilst others may find it off-putting.

This chapter has presented qualitative findings based on semi-structured interviews with participants and health professionals. The next chapter is a discussion of key findings, consistency of findings, evaluation of techniques and methodology. It is also a discussion of the suitability of the design for a future trial.

Chapter 10. Discussion

10.1 Introduction

Randomised Controlled Trials (RCTs) are a significant investment of time and resources and therefore demand a strong evidence base for their undertaking. The overall aim of the PhD was to systematically develop and implement a feasibility trial whose findings would determine the suitability for a large size RCT. The case for this RCT has been discussed in previous chapters in this thesis. The gap in effective methods to manage gestational weight gain (GWG) was discussed in Chapters 2 and Chapter 5. In Chapters 4 and 6 the evidence behind the choice of methodology and the systematic development of the feasibility study design was presented. Chapter 7 described the protocol and study procedures, following the development of the feasibility design. The purpose of the feasibility study was to highlight potential practicality and management issues of the trial and to improve and better inform the design of a large RCT. Findings from the feasibility study that have informed the practicality and feasibility of the design were presented in Chapter 8. The feasibility trial methods helped to test the appropriateness of the measurement and delivery tools used. In particular, the aim was to describe and quantify issues or untoward consequences, (in particular with regards to Facebook as a mode of delivery tool). This process is particularly important to confirm that the RCT procedures will answer questions of genuine importance to clinicians and researchers. In this chapter the findings from the feasibility trial (Chapter 8) and from the process evaluation (Chapter 9) will be discussed in relation to the consistency of findings, strengths and limitations, evaluation of behaviour change techniques (BCTs) mechanism of action, methodology and lastly recommendations for future research. Based on these, a large trial RCT protocol will be designed and presented in Appendix K.

Outline of the Discussion Chapter 10

1. Summary of Key Findings (Systematic Review, Feasibility RCT, Process Evaluation)
2. Consistency of Findings
3. Evaluation of BCTs using the APEASE Criteria
4. Evaluation and Recommendations of Methodology and Future Trial Procedures
5. Review of Potential Primary Outcome for a Future Trial
6. Summary of Recommendations

10.2 Summary of Key Findings
10.2.1 Systematic Review
The systematic review aimed to examine the literature about the effectiveness of walking on pregnancy and antenatal outcomes in the overweight and obese population. Due to the focus of the review question, only two pilot studies with a limited scope and sample size were identified. One of the included studies showed a trend in reduced blood pressure (BP) and the other study showed a trend in lowered rate of c- section in the intervention group. Due to the fact that both studies were underpowered, the main finding is that there is no conclusive evidence to show effectiveness of walking in the pregnant, obese population (157), (158). In conclusion more research is needed to determine the effectiveness of walking on gestational weight gain (GWG) and antenatal outcomes in obese women.

10.2.2 Feasibility RCT
The feasibility RCT delivered a 5-week long Facebook-mediated walking intervention to a sample of women who are pregnant and obese. It was developed using the COM-B model, to deliver a range of BCTs including: self-monitoring, goal-setting and 'information about health consequences' BCTs. Forty participants with a BMI of ≥30kg/m² were recruited and randomised to the intervention (a closed, private Facebook group that encouraged walking) and a control (standard care pathway and a blinded activity tracker) at 11-14 weeks gestation. The primary outcomes were the feasibility, recruitment, retention and compliance rates. Secondary outcomes were step count, physical activity (PA) in pregnancy scores (PPAQ), process evaluation questionnaire, GWG and pregnancy and antenatal outcomes. The feasibility study confirmed the appropriateness of the recruitment strategy. A key finding of the feasibility trial

was the effectiveness of the recruitment method and timing. The recruitment target of 40 women was achieved by the single researcher who attended the hospital booking clinics. Routinely, women have a first scan at 11-14 weeks gestation. For most women, this is a positive experience when they see their baby on the ultrasound for the first time (47). However, there are women whose scans may show complications which, is why they were not approached until their post-scan routine appointment, immediately after the scan. During this appointment, the midwife confirms a healthy pregnancy and then routinely measures the BMI. Following this confirmation, eligible women with a raised BMI were approached by the researcher. This ensured that all women who were approached had an eligible BMI to take part. In addition, the fact that they received an indication of a healthy pregnancy via the scan put a lot of women in a positive mood, which likely helped the recruitment procedure.

Compared to other studies, the timing of our intervention was slightly earlier than other trials of similar design. For instance, the UPBEAT lifestyle intervention pilot delivered to pregnant, obese women started at ≈20 weeks gestation (159). The outcome measures in the trial were similar; measuring diet, PA and GDM status at 28 weeks gestation. Similarly, the LIMIT Trial (160), included women from 10 up to 20 weeks gestation. This was a large trial which included 2500 participants and the intervention lasted throughout the length of pregnancy. Previous findings indicate that the earlier the intervention is started, the more likely it is to have an effect on pregnancy and birth outcomes (161). For this reason, we recommend that recruitment for the large trial is done in the same time period (11-14 weeks gestation).

In our recruitment procedure, women who expressed an interest in taking part were given an information sheet and up to 24 hours to decide if they wanted to take part. Once they agreed to take part, they were consented and randomised. The strategy for identifying eligible participants seemed appropriate and most women who had time to speak to the researcher were willing to take part. The majority of the women who declined to take part (13/30) did so without allowing an opportunity to be told about the study by the researcher. As a result, the majority of women who declined to take part did so without knowing what the study was about or its design (reasons for declining to take part are listed in

Findings Chapter 8). We can conclude from this that it was the concept of being involved in any study or intervention that formed their decision, rather than anything specific about the design of this particular study.

Recruitment Rate

Previous studies have found that the recruitment rate for the pregnant population, if done by an external researcher, is approximately 14.5% (97). Our recruitment rate of 55% was therefore comparatively high. As a result, the allocated time for recruitment was reduced from 6 to 2.5 months. This is suggestive of the acceptability of the study design among participants. Recruitment rates in previously published studies in these populations vary from 14-60% (162). That this study was at the top end of this range suggests that the recruitment process was effective. The recruitment rate also confirmed that our inclusion criterion was feasible (BMI, Facebook user or willing to use Facebook, owning a smartphone). This corresponds to others' findings that Facebook usage and prevalence of smartphones is high. Previous studies have reported Facebook usage to be between 90-95% in our target population (86). It also confirms women's usage of social media and the acceptability of using mobile technology (134), (135), (136).

Facebook is used widely and is easily accessed on a mobile phone frequently throughout the day. Using Facebook as the delivery tool meant that participants had access to the intervention via an already familiar channel as all participants who were recruited already had a Facebook account. Because participants were not asked to access anything they were unfamiliar with, the intervention was not perceived as a burden. This has been a low-cost and low labour way to reach widely and to deliver the intervention. The fact that participants were responsive and responded to every single message delivered via Facebook Messenger and that 60-80% of the moderator's posts were marked as 'seen by' on the wall is an indication that the majority of messages and posts were received as intended. Previous studies have examined barriers to engagement in interventions delivered via social media (SM) (163) such as lack of time and anonymity. However, in contrast, these barriers were not identified during our process evaluation. We did, identify two types of participants, posters (participants who post a lot) and lurkers (participants who read but do not post or comment online). Lurkers preferred reading others' comments whilst not posting. These personality

types have been reported in other studies, which found that despite their varying engagement in online social groups (OSGs), both lurkers and posters benefit from taking part in OSGs (164). Suggestions on how to cater for both types of participants are listed in *Elements of Intervention-Social Support and Engagement* in this chapter.

Sample Size in our Feasibility Trial

The primary aim of the feasibility study was to assess the feasibility and acceptability of the trial procedures. In the published literature by MRC guidelines (137), the recommended sample size for a feasibility trial ranges from 12 to 50 participants, including intervention and control studies. Our sample size was sufficient in giving an indication of the feasibility outcomes such as recruitment, retention and compliance rates. It is comparable in size to that of previous walking feasibility/pilot studies. For instance, a walking intervention (165) included a sample size of 40 in a pilot RCT, to test effectiveness of walking in pregnancy outcomes. Ruchat et al., (2012) included 46 participants, with the primary aim of testing the effect of walking on GDM status (63). Redman et al., (2017) used a sample size of 54 women, to measure the proportion of women who gained weight within the IOM guidelines with their mHealth delivered lifestyle intervention (166). Similarly an American lifestyle intervention, delivered via Facebook included 66 participants, expecting a 30% drop out rate (167). On the other hand, a feasibility study which tested the deliverability of text-messaging interventions included only 14 participants in total (168).

10.2.3 Process Evaluation Interviews

Facebook Component- Receiving Information

The feedback by participants on the Facebook component of the intervention was very positive. During the analysis, 'facilitated access' and 'reliable source' themes emerged. Participants said that they *'read all the posts'* and that they found it useful to have a reliable source of information about PA in pregnancy. Participants gave feedback about how useful it was to read new information about PA in pregnancy, which is supported by our quantitative findings ('seen by' Facebook function which has been explained in Findings chapter 8), which showed that posts had been seen by 60-80% of all participants.

Knowledge expansion emerged as a main theme in our interviews with participants. Within that main theme, the subtheme '*Practical Support/Someone Knowledgeable*' and '*Experience that someone was constantly present'* reflected women's appreciation of receiving the advice and support and reported that it was nice that 'someone was always there' who could answer questions and give advice. Similarly, a large qualitative study in the UK, which specifically examined what advice and information is provided to pregnant women found that only 25.4% (1 in 4) of women, felt that they receive weight gain and lifestyle advice that they need (1).

HPs views and Feedback during the Process Evaluation

Health professionals (HPs) spoke about challenges they face in delivering advice to pregnant, obese women about healthy lifestyle. When asked specifically about their views on the feasibility RCT design they were supportive of it in principle. However, the focus of their feedback was on the barriers to implementation such as lack of time, gap in knowledge and sensitivity of the topic. Also, HPs reported women's lack of motivation as a barrier to care provision, which contradicted our own findings based on the recruitment, compliance rate and findings from the interviews with participants. We found that women seem willing to receive information and are motivated to adopt a healthier lifestyle and to be more physically active. Instead it may be that HPs misconception or cynicism towards the obese, pregnant women that is a barrier to care provision. Similar findings have been reported in previous studies, where HPs talked about how they perceived a lack of motivation and willingness to adopt a healthier behaviour among pregnant, obese women (169).

In addition, HPs did not view it as part of their job to deliver dietary and PA advice to pregnant, obese women. In the subtheme '*Who's job is it'*, HPs feedback was that the intervention was acceptable providing there was another dedicated person who could take on the responsibility to deliver it. HPs that were interviewed as part of our study, considered it their primary task to provide clinical management and that someone else (for instance community midwives) should provide lifestyle advice. Previous studies (155) found that at present, the care

provided to obese women lacks preventative measures like giving lifestyle advice and instead focuses on medicalised management to avoid adverse outcomes.

Whilst HPs recognised the practicality of delivering information remotely via the internet, the concerns were mainly around its integration with the current practice and a concern that any additional element would require more of their time (which they already perceived as not enough). The fact that presently there is no allocated time within HPs role, for preventative strategies, is a barrier to the implementation of any intervention. This is especially pertinent when the clinics are overflowing and each HP is incredibly pushed for time to deliver the care they already do. The barrier of time is in line with previous evidence by Hestlehurst et al., (2007), which examined the challenges that HPs face in providing care to the obese pregnant women and found that time pressure, gap in knowledge and sensitivity of the topic were subjects that must be addressed to improve care provision (170), (171). This may be why a study by Brown et al., (2012), found that only 25% of women receive adequate information about diet and PA in pregnancy, irrespective of their BMI range (1). The present study adds new insights as it gives us some indication as to why HPs are not approaching the topic with pregnant women.

Feasibility RCT Summary of Findings
Each finding has been reviewed in light of evidence which has informed the development and the final design for the large RCT. A summary of these findings on the feasibility of methodology, in terms of recruitment, eligibility criteria, allocation concealment and blinding were summarised in Table 50 in this chapter.

10.3 Consistency of Findings
Findings from the feasibility RCT and the process evaluation in terms of acceptability of the design were consistent. The majority of the intervention participants remained in the Facebook group after completing the intervention which corresponds to their feedback that they 'liked' and 'found it useful and

interesting' to get the information via Facebook. Our findings that some participants were more active than others on the Facebook wall, corresponded with the findings from the evaluation, where the active participants fed back that they would have liked more input from everyone in the group. On the other hand, participants who only read the Facebook posts but did not contribute to the interactions spoke about how that suited them the best and that they did not have a particular need to be more engaged. Previous studies, have reported that the level of engagement may directly impact on the effectiveness of the intervention (172). Engagement with the intervention can enhance social support, self-efficacy, and in turn behaviour change. However findings by Yardley et al., (2016) also indicate that it is not only the quantity but also the quality of engagement that determines effectiveness (172). The definition of meaningful engagement, measures of engagement and social support and how it can be improved are discussed below in the later section of this chapter titled *Elements of Intervention and Mechanisms of Action- Social Support.*

10.4 Evaluation of BCTs' Selection Process, Mechanisms of Action and Recommendations

10.4.1 Evidence-based design

This study was strengthened by the systematic intervention development. We followed the NICE guidelines and used the COM-B model to select the techniques that are relevant to our target population and underpinning theories which explain the mechanisms of action. Whilst the systematic approach is advocated by NICE guidelines and others (173), several arguments against a systematised behaviour change science have also been published. For instance, Ogden et al., (2016) argues in "All Models are Wrong but some are Useful" that *existing variability in persons and interactions is neglected by this aim to systemise behaviour change science* (and its application in intervention development), and that *existing and valuable variability in theories is diminished to the detriment of both the effectiveness of behaviour change science and its potential to progress (p84)* (174).

Whilst Ogden et al., (2016) makes a valid point; we found that our approach allowed us to apply behaviour change science systematically but also gave a degree of 'choice and reflection'. For instance, whilst applying the *Acceptability, Practicality and Effectiveness criteria* (APEASE criteria) allowed a systematic selection of intervention elements, choices still had to be made regarding which techniques to prioritise. This decision-making was based on the evidence from previous PA interventions that aimed to control GWG (77). The selection was also based on previously identified gaps that women themselves reported that they were lacking during pregnancy that are known to enhance self-efficacy (152). For instance, goal setting and self-monitoring techniques were identified as effective in PA interventions (175), whilst lack of social support for PA in pregnancy was identified as an important element (169). Some of the findings indicate that, whilst the decision to incorporate this BCT was right in retrospect, the challenge of delivering this BCT may have been unappreciated. For instance, within our design we aimed to deliver social support via the Facebook group which was partly successful.

On reflection, the use of the COM-B model and the systematic approach was beneficial and there was still a degree of choice to make the systematised approach apply to our target population. The feasibility, acceptability and the effectiveness of the selected BCTs and their mechanism of action will be discussed in the following section.

10.4.2 Assessing the Effectiveness of BCTs in an Intervention

There are several methods to assess the effectiveness of BCTs within an intervention. A recent systematic review by Michie et al., (2018), identified the following methods; experimental manipulation of BCTs, observational studies comparing outcomes in the presence or absence of BCTs, meta-analyses of BCT comparisons, meta-regressions evaluating effect sizes with and without specific BCTs, reviews of BCTs found in effective interventions, and meta-classification and regression trees (176).

The primary focus of the feasibility study was to evaluate the deliverability (method of delivery of BCTs) and the acceptability (how participants accepted

and responded to the techniques). Therefore, the evaluation of the effectiveness of BCTs on behaviour within the Walking in Pregnancy Feasibility trial will be examined based on the feasibility and acceptability of the intervention as well as the effect size on the outcomes measured, in line with the APEASE Criteria which was explained in detail in Chapter 6 of this thesis.

10.4.3 Elements of the Intervention and Mechanisms of Action

When characterising the potentially active ingredients of a behaviour change intervention, a distinction can be made between the "content" of interventions (their putative active components) and the way in which they are delivered. Content can be characterised in terms of BCTs [3–7], defined as the smallest identifiable components that in themselves have the potential to change behaviour (p.4), (177).

To understand how and why interventions work, it is important to explain BCT's mechanism of action, how we believe they may affect behaviour change and then evaluate their effectiveness by means of measuring a change in the behaviour of interest. This understanding of processes is what allows the development of more effective interventions (177). Figure 29 is a model which shows where the gap and the questions lie in relation to the BCTs and the actual behaviour change. This section will explain each BCT, its mechanism of action and assess it according to the APEASE Criteria. It will thereafter link the findings to the existing literature and evidence base.

Figure 29. BCTs lead to behaviour change through a variety of mechanisms of action

From : From Theory-Inspired to Theory-based Interventions: A Protocol for Developing and Testing a Methodology for Linking Behaviour Change Techniques to Mechanism of Action, Michie et al., (2016) (177).

Mechanism(s) of Action

Behaviour Change Technique (BCT) → ? → Behaviour Change
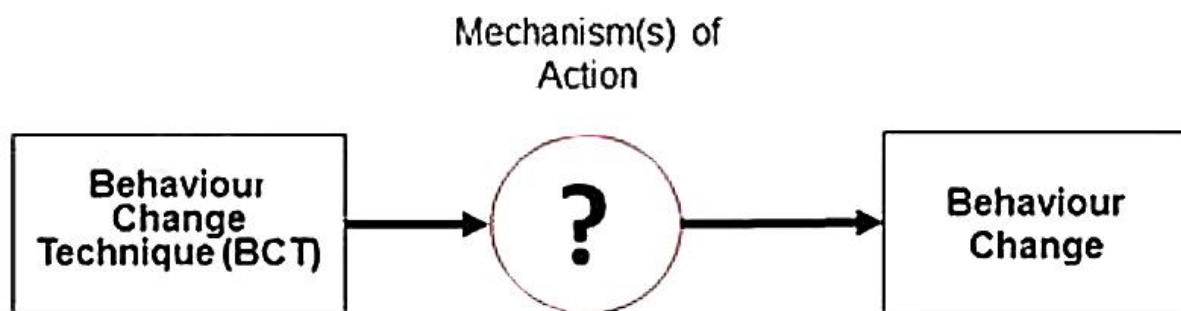
Summary of BCTs and Mechanisms of Action used in this feasibility trial

Table 48. BCTs and Mechanisms of Action

Behaviour Change Technique	Mechanism of Action
Goal Setting (behaviour) and Review behaviour goal	Goal setting allows a person to have something concrete to strive for and it allows for a sense of achievement when these are met, which can in turn enhance self-efficacy.
Graded Task	By setting easy-to-perform tasks and making them gradually more difficult, but achievable, until behaviour is performed, enhances self-efficacy and encourages positive behaviour change.
Self-Monitoring of behaviour	Allowing the individual to self-monitor forces a person to think about every occurrence of a behaviour
Feedback on Behaviour	Feedback and Monitoring motivates participants, to give positive feedback when they achieved their target, which in turn raises the feeling of self-efficacy and motivation. The additional mechanism of action of feedback is that the 'monitoring;' of participants has also the ability to further motivate behaviour change.
Information about Health Consequences	Providing information about why and how a behaviour is beneficial can contribute to behaviour change due to a deeper understanding.
Credible source	Having access to a Credible source creates a trust that what one is doing is 'right' and encourages the behaviour change
Social Support (unspecified)	Providing encouragement and counselling directed at the behaviour enhances a feeling of being supported, which can in turn change behaviour.
Prompts/Cues	Receiving stimulus prompts and cues behaviour

10.4.4 *Goal Setting, Review of Goals and Graded Tasks* Mechanism of Action and Effectiveness

Goal Setting, Review of Goals and Graded Tasks techniques have similar mechanism of action i.e. enhancing self-efficacy. The Goal setting technique is within the 'Goals and Planning cluster' of the BCTs taxonomy (178). Its mechanism of action is that it allows a person to have concrete goals to strive for and it allows for a sense of achievement when these are met, which can in turn enhance self-efficacy (179). The positive increase in self-efficacy is expected to have a positive effect on the individual's behaviour as a result (71). 'Graded tasks' is a technique which is part of the 'Repetition and Substitution' cluster of BCTs. The mechanism of action of the BCT is to set easy-to-perform tasks, making them gradually more difficult, but achievable, until behaviour is performed. This also increases self-efficacy (73).

Goal setting, review of goals and graded tasks BCTs were implemented in the following way in our study: During the baseline week all participants in our study were asked to wear a Fitbit while going about their normal tasks, to establish a baseline measure which allowed for an individualised weekly step target to be determined. A step target was calculated for each individual, which was a weekly addition of 20% of their baseline steps. Each week, participants were asked to increase their daily steps by that same amount that had been calculated for them in the first week.

Participants' achievement of the step goals varied. In the first two weeks 50% (half of all participants, 10/20) achieved their step targets. In the second two weeks only 25% achieved their step targets. The participants who did not reach the step count still strived to achieve more steps than in previous weeks, which could be noted in their overall step count when weeks were compared. This was also confirmed by the participants themselves via the Facebook Messenger, who stated that they were striving to achieve steps but that something had prevented them from reaching the target (examples of messages from the Messenger are in Findings Chapter 8). In that way, the goal setting technique was feasible and effective in that it gave participants something to strive toward and as a result they did more steps. Similar findings have been presented in the most recent review of PA interventions aimed to investigate behaviour change and

maintenance in healthy inactive adults (180).The quantitative analysis of goal setting and step targets showed that participants increased the mean number of steps they were doing, whilst an analysis of individuals' change in steps showed that some were better at achieving those goals than others (180).

Graded Tasks

In our study, an increase of 20% of the baseline measure was used as a goal. The 20% increase is derived from previous studies in women who are pregnant and obese which have shown that the average step count ranges from 3000 to 4000 steps daily (95), which would mean an increase of 500-1000 steps which equates to 5-10 minutes of extra walking. This target is to reach the recommended level of PA in pregnancy of 30 minutes per day (52). The graded task technique was effective in that participants strived to increase their daily step count and in that although participants did not always meet their target, all participants were maintaining their level of steps and the activity patterns did not show a drop in step counts (see chapter 8 Findings).

Because the baseline measure may have been higher due to the so-called Hawthorne effect (126) it may not have reflected participants' habitual level of activity. The Hawthorne effect is defined as the alternation of behaviour by the subjects of a study due to their awareness of being observed (126). This effect may also be due to the initial enthusiasm and novelty of taking part in the intervention which has been shown to wear off over time, in other studies (181). More importantly, the fact that the intervention group was not blinded in the first week to their step counts meant that they could self-monitor their steps, which also may have affected their step count. Therefore, the researcher made sure to ask each participant to confirm that they felt the target was achievable and if they had not achieved it, participants had the choice of keeping the target from the previous week instead of aiming for an even higher target.

For those participants who struggled to achieve their target, the graded task technique meant that at times they felt that they were not always following the planned progress and it also resulted in a disappointment. If a participant failed to achieve their weekly target, they were asked if they wanted to still go ahead

with an increase for the following week or keep the old target. Participants' choice most often was to have the increase even if the previous week's target was not achieved, because they did not want to 'fall behind' with the plan. They continued with their new target throughout the 5-week intervention even though they had in the previous week not achieved the exact step target. Our findings conclude that it is important that the graded task is as personalised and as tailored for each individual as possible. A graded task technique will be most effective only if the new task is reasonable and achieved, which gives a sense of accomplishment (149).

We suggest that for the large RCT the gradual increase is 10% of the baseline measure. A gradual increase of 10% was also used in a pilot study in inactive pregnant women (182), which measured an increase in PA over a period of 12 weeks. The large RCT will take place throughout the pregnancy, which will allow more time for a gradual increase and adjustment to the change. Graded task technique was one of only two techniques which was found to have a negative effect on self-efficacy (when the task being too hard/ not achievable), in a review by Olander et al., (2013) which identified effective BCTs in PA interventions for the obese population (183).

The fact that the graded task may have been set too high for participants may have impacted on the quantitative results. Therefore, although participants did not always meet their target, they did increase their overall step count, which may be a better measure of effectiveness of the intervention than measuring how many reached their step target. In previous PA interventions, participants have been encouraged to set their own step targets, which has been shown to be an effective and acceptable goal setting method (184). There are positive aspects of having participants set their own goals; it would give the participants more autonomy and control of their own progress and it would lower the workload and time burden on those delivering the intervention.

The results, (chapter 8, table 30) showed a reduction in adherence to step count goals (25% of participants met their step goals) in the last two weeks. However, graph 18, in the same chapter, shows that more than half of participants were within 90% of their step target goals. Therefore, while a lower number of

participants met their exact step target, the majority were within the 80-90% of their target. This indicates that intervention participants were successful in maintaining and/or increasing their daily steps. In terms of implementing this intervention throughout the duration of pregnancy, it is unclear how the compliance to the step targets will change. It may be that women would struggle to achieve these targets later during pregnancy. It is equally possible that they form habitual behaviours that help propel them onwards. However, based on previous studies, we know that PA levels decrease, especially in the third trimester (185). What we have proposed is to reduce the gradient of increase from 20% to 15% increase per week, in order to ensure that the increase in targets is more gradual. However, even maintaining daily steps (participants were doing an average of 7-8000 steps per day) may be beneficial as we know that currently a high proportion of women are sedentary in the third trimester, which is detrimental to their health (186). It is still unclear what the recommendation of PA of 150min per week is equivalent to (in terms of daily steps) during pregnancy or what number of steps constitutes a meaningful and clinically significant difference.

10.4.5 Effectiveness of *Review of Goals* and *Graded task*

From previous studies we know that achieving goals promotes improved self-efficacy. However, as only some of the participants achieved goals and the goal achievements varied over the period of four weeks it is unclear whether the goal setting, review of goals and graded tasks techniques affected the mild trend of improved self-efficacy scores. BCTs social support and, self-monitoring may also have had an effect on self-efficacy (183). Based on the fact that our feasibility study was not powered to detect an actual difference and also the fact that other BCTs impact self-efficacy, it is not possible to have a more definite answer regarding the impact of goal setting on self-efficacy.

If we further draw on the qualitative findings from the participants' feedback we know that they appreciated having the step targets because it *motivated them to compete with themselves and strive to achieve those* (as reported in the interviews). Also our finding that the intention (to walk) improved could indicate that having goals did improve participants' intention (to walk) and therefore may have had a positive effect. However, some participants spoke about having

feelings of disappointment on the days that they did not reach their target, which may have affected the self-efficacy scores negatively. This feeling of disappointment was also fed back during the evaluation where participants spoke about challenges and lack of opportunity to walk more and be more active due to work commitments. Previous literature has discussed the importance of setting reasonable goals, which participants can achieve and which could have a positive effect on their self-efficacy and behaviour change (149). Previous studies also found that some personalities, might find it de-motivating and off-putting when they cannot achieve their goals (187). Therefore, more can be done within the intervention to address barriers to PA that are due to work commitments for instance.

10.4.6 Recommendations for a future trial

In a future trial, both intervention and control group participants should be blinded to step counts during the baseline week, to establish an accurate baseline measure on which consequent step targets can be calculated. It is also recommended, that if a future trial is taking place throughout the pregnancy, there can be a lower gradient in increase of steps. Therefore, it is suggested that an increase of 10% is implemented rather than an increase of 20%, to allow for a more gradual increase and more time to adjust for all women. Some studies have suggested that allowing women to set their own goal and not impose a specific increase is more effective at improving self-efficacy. However, for logistical reasons, it is recommended that for the larger trial, a 10% increase is suggested to women. They can then choose to accept this or suggest a different target, if they do not find this increase appropriate.

10.4.7 Effectiveness of *Feedback on Behaviour* and *Self-Monitoring of Behaviour* BCTs

The aim of the Feedback on Behaviour technique was to motivate participants, to give positive feedback when they achieved their target which in turn raises the feeling of self-efficacy and motivation. The additional mechanism of action of feedback is that the monitoring of participants also shows them whether or not they have met their goal. The Self-monitoring technique is within the 'Feedback and Monitoring' cluster in the BCTs taxonomy (178).

In the 'Walking in Pregnancy' intervention, all intervention participants were informed of their weekly average step counts and their new step target. Self-monitoring within the intervention was done by means of a Fitbit activity tracker. It allowed the intervention participants to see their daily steps on the wrist-worn activity watch. The self-monitoring technique allowed the participant to have an overview of their progress over time, which is its main mechanism of action.

Both techniques were feasible and their function was achieved in the sense that getting feedback throughout the study was perceived as 'being constantly watched' (as self-reported during semi-structured interviews). From other commercial weight loss programs, it is known that simple monitoring by 'the other' is effective in for example weight loss support (188). This intervention feature received a positive response from the majority of participants. Participants received feedback on their steps both via the Facebook Messenger (privately) as well as on the Facebook wall (where other group members could see it). It is difficult to measure the effectiveness of feedback on behaviour technique within this feasibility study, because the difference also happened at baseline. This initial difference may have been due to the fact that intervention participants were not blinded to pedometer readings during the baseline week. However, the fact that the PA levels are consistently higher in the intervention group throughout the study, is suggesting that the techniques may have been effective.

Self-Monitoring
Participants' feedback on self-monitoring was positive. They appeared to value having information about their progress and how active they actually are. Participants appeared to be always aware of whether or not they were achieving their steps, as they would send messages to the moderator wanting to explain if they had not managed to reach their targets. This suggests that asking participants to self-monitor is a reasonable and acceptable technique. During the interviews, participants also spoke about how self-monitoring had brought about a greater awareness of their PA levels. Many expressed a surprise at how few steps they were doing during some days.

The evidence of the effectiveness of self-monitoring has also been shown in other reviews. A meta-regression by Michie et al., (2009), which looked at effectiveness of BCTs in PA and dietary interventions, showed that the technique of prompt self-monitoring of behaviour explained the greatest amount of between-study heterogeneity (13%) (68). The importance of incorporating this BCT was further demonstrated in a subgroup analysis that showed that self-monitoring in combination with other techniques were significantly more effective (pooled effect size 0.42, 95% CI 0.30 to 0.54; n=10,572) than those interventions that did not include self-monitoring (pooled effect size 0.26, 95% CI 0.21 to 0.30; n=34,) (68). Furthermore, interventions which combined self-monitoring and goal-setting techniques were significantly more effective than interventions which only included self-monitoring and no other technique (pooled effect sizes for healthy eating: 0.54 versus 0.24; physical activity: 0.38 vs. 0.27; all interventions: 0.42 vs. 0.26). A review by Currie et al., (2013) specifically examined trials that aimed to reduce the decline of PA in pregnant women, found that implementing techniques such as goals and planning, and comparison of outcomes can reduce the decline of PA in pregnancy (175).

An additional review by Soltani et al., (2016) focused on interventions that aimed to control GWG found that successful interventions included BCTs from the 'monitoring and feedback' taxonomy cluster, including self-monitoring (77).
Most importantly, a review by Samdal et al., from (2017) found that the BCTs goal setting together with self-monitoring of behaviour were the only techniques that were associated with positive intervention effects at both short and long term (148). This is particularly relevant for the future trial, which will be done for 6 months (starting at approximately 12 weeks- 36 weeks).

The compliance to wearing a Fitbit is consistent with the feedback received during process evaluation where participants spoke about how they found it useful to know how many steps they had done and how that gave them an indication of where they were at in achieving their goals. This is very much in line with previous findings of the importance of self-monitoring in behaviour change. A study which investigated the effectiveness of electronic trackers found that continuous self-monitoring from wearable technology with real-time feedback is very effective in particular in combination with group-support (189).

However, a more critical evaluation of self-monitoring found that it has mixed effectiveness and depends on participants' personality (190). The study identified that the effectiveness of self-monitoring is linked with how individuals integrated the process of self-monitoring and that the self- monitoring has to be individualised, for instance by individualised graded tasks and by action planning to make sure that participants adhere to it (190).

In conclusion, this technique was accepted and feasible for delivery within the intervention design. Our findings are in line with findings of other studies which demonstrate that this technique should be incorporated in the large size trial. Self-regulatory behaviour change techniques are linked to control theory (80). Control theory describes how behaviour change may occur when goal setting, monitoring of behaviour, receiving feedback and reviewing relevant goals in the light of feedback techniques are implemented. An indication of this in our study is that being able to see the steps on the Fitbit improved participants' adherence to the intervention. The control group was blinded to their steps counts, by covering the screen on their Fitbit which displayed their steps. The control group being blinded to their step count and therefore unable to self-monitor may have been the reason for lower adherence (28 vs. 33 /35 days).

10.4.8 *Information about Health Consequences* and *Credible Source* BCTs

The Information about Health Consequences technique is within the Natural Consequences cluster (178). Its mechanism of action is based on the idea that once people understand why they are instructed to perform certain behaviour and how that behaviour benefits their health, they are more likely to do it. The Credible Source technique reinforces behaviour because we trust that the new behaviour does benefit and has the potential to produce better outcomes. These techniques are effective at increasing motivation. However, they are most effective at producing behaviour change when used in combination with *Goal Setting and Planning* cluster and the *Feedback and Monitoring* cluster. In combination with these, they are able to produce long-term behaviour change (191), (148).

Delivering the *Information about Health Consequences* technique via Facebook was feasible. Feedback from participants during the interviews was reflected in the *Facilitated access* subtheme, where women described that they got all the

messages and found it easy to stay updated as *their phone would buzz at them when there was a new post on the group wall*. The majority of the participants accessed the intervention group on their phone. The finding from previous research, that we are always in close proximity to our phones and frequently log into communication channels throughout the day (192), was confirmed in our intervention. Participants were responsive to the moderator and to all messages sent via FB Messenger.

We did not test the effectiveness of this BCT objectively; whether the information that they received via Facebook improved their understanding and knowledge about PA but only whether it improved their intention and positive and negative beliefs about walking. However, participants did self-report that their knowledge improved which was described in chapter 9 *Knowledge Expansion* theme. From the Process Evaluation (PE) questionnaire, we measured a trend in slightly improved Intention (to walk) in the intervention group; however it is unclear whether Knowledge Expansion enhanced motivation.

Other studies, such as the large Australian study LIMIT, which was delivered face-to-face, included 2212 pregnant women, was able to show behaviour change due to knowledge expansion-only. The findings from the trial which provided lifestyle advice to overweight women, was that it resulted in higher intake of fruit and vegetables and improved activity levels (160). As information-provision was the only BCT in the LIMIT trial, all behaviour change was attributed to it.

For our future trial, recommendations are that rather than testing participants' knowledge, their beliefs about the topic of PA and exercise in pregnancy should be explored. For instance, they could be asked about whether they agree or disagree with certain statements. An example could be; 'Is *it safe to exercise in pregnancy*'. It is recommended that a suitable, relevant questionnaire is developed and included in the main trial.

Whilst previous research has shown that pregnant women do want to receive more advice around healthy lifestyle and that, Arden et al., (2014) study found that women find it difficult to hear about risks of obesity to the baby and HPs

found it difficult to discuss too. As a result, the advice that is provided on how to manage GWG is not always clear (193). Interestingly, the study found that due to a lack of advice from HPs, women seek information for themselves from potentially un-regulated sources. This finding reinforces the need for facilitated access to a Credible Source technique, which was found to be valued and liked when provided as part of this feasibility trial (1). This is why it may be informative to test how participants' behaviour changes, to understand if their knowledge has changed.

10.4.9 Prompts/Cues

The Prompts and Cues technique is part of the 'Associations' BCTs cluster. These techniques are believed to motivate behaviour change by introducing stimulus with the purpose of prompting or cueing the behaviour. Participants received prompts on Facebook which were directed at the group and private messages via Facebook messages to monitor their steps and achieve their step targets. Delivering the prompts/cues BCT was feasible and acceptable to study participants. All participants responded on the Facebook Messenger when being told their weekly step target. On the group wall, participants responded with 'likes' and comments as well as photos of their behaviour. 'Prompts and cues' seemed to be effective in that they encouraged participants to increase and/or maintain their steps by taking regular walks. In terms of the effectiveness, it appears that this technique worked and was acceptable to participants as they responded to the prompts on the Facebook Messenger as well as being keen to explain the reasons for not meeting their targets. This technique has been found to be effective in a systematic review by Olander et al.*, (2013) that aimed to identify the effective techniques in changing obese individuals' PA self-efficacy and behaviour (183). The review found that the largest effects on PA came from interventions that used 'teach to use prompts/cues', 'prompt practice' and 'prompt rewards contingent on effort or progress towards behaviour'. Interestingly, the two BCTs, which had an effect on both PA and self-efficacy scores were 'prompt self-monitoring of behavioural outcome' and 'plan social support/social change'. This review further illustrates the importance of incorporating prompts/cues.

10.4.10 Social Support

The Social Support (unspecified) technique is delivered by 'Advising on, or providing social support *(e.g. from friends, relatives, colleagues,' buddies' or staff)* or praise or reward for performance of the behaviour' (34)*,* including encouragement and counselling directed at the behaviour. The mechanism of action through which social support might change behaviour is that it may influence an individual's enhancement of self-efficacy. Findings by Bandura et al., (2004) showed that individuals who receive social support, such as *emotional encouragement, affirmation, help and boosting mood,* are likely to hold stronger self-efficacy beliefs, which in turn may affect behaviour and health-related outcomes (194).

The role of Social support during pregnancy has been highlighted in previous studies which found that social support is strongly related to coping, improved quality of life, and reduced levels of psychological distress (195). On the other hand, a lack of social support (74) has been identified as a barrier to adopting a healthy lifestyle during pregnancy. We sought to deliver a social support BCT via the closed, private Facebook group, which is a relatively new method in health research. The research on how social media and online support groups (OSGs) such as our FB group can enhance engagement and social support is still ongoing. Below is an assessment of our findings on the deliverability of the social support technique via FB, challenges and improvement suggestions.

Our Findings

We measured engagement in our FB group objectively, with already available tools (i.e. frequency of likes, comments posts). Whilst the majority of the posts were marked as 'seen' (by participants) and in the interviews participants reported that they had read all the posts, the frequency of 'likes', and comments and posts varied among participants. During the five-week period frequency of commenting averaged from 2-7 comments per participant, which by our measure indicated low engagement in some participants. Coulson et al., (2010) have shown that there is a strong link between participation, engagement and increased communication in online support groups (OSGs) and that they all have a positive impact on enhancing social support and in turn self-efficacy (196). It is therefore

important to assess why some participants engaged less, to be able to make suggestions for improvement in a future trial.

Figure 30. Social Support and *Proposed* Mechanism of Action

(As proposed by the researcher based on the Findings from this PhD study)

Engagement	Social Support	Self-Efficacy	Behaviour Change
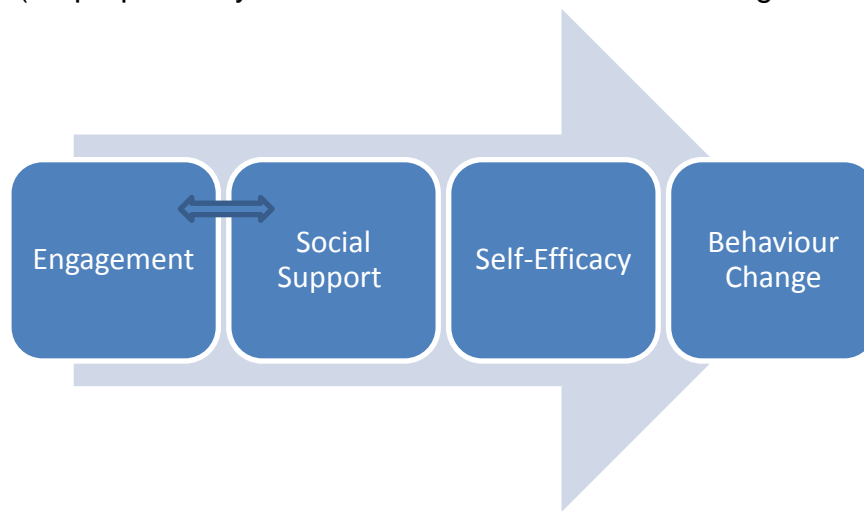
10.5 What Makes People Engage

Coulson et al., (2010), explored engagement in OSGs. It identified that factors that are experienced as disadvantages become barriers to engagement. The study involved 300 participants who all had polycystic fibrosis and as a result found it difficult to conceive. The study listed possible disadvantages to engagement in OSGs (see Table 49). Out of the fourteen disadvantages, only three were reported in our study (as shown in bold in table 49). These were; social comparison, lack of physical proximity and not receiving a reply. In our study, some participants reported that it was their own personal journey and that they did not want to engage in social comparison. These participants were the so-called lurkers (participants who only read all the posts but do not comment or post). The posters (participants who post and comment a lot and who rely on others doing the same) on the other hand wanted a lot of interaction, comparison and some also reported a lack of face-to-face meeting as a barrier (i.e. lack of physical proximity/physical interaction). Participants who were posting frequently reported the barrier *Not receiving a reply.* Whilst polycystic fibrosis is a different condition than pregnancy and obesity which is our interest, it is close enough to be relevant to our study. The study suggests that if the advantages can outweigh the disadvantages (so called barriers), the engagement in OSGs will increase (196).

Table 49. Identified Disadvantages of taking part in a SM support group

From: Coulson et al., (2010): 'They all supported me but I felt like I suddenly didn't belong anymore' (196).

Reading about negative experiences
Reading about other people's pregnancies
Inaccurate information
It is addictive
Unhelpful replies
Volume of messages
Cliquishness
Technical issues related to the site
Hostile behaviour
Social comparison
Lack of physical proximity
Judgemental replies
Lack of privacy
Not receiving a reply

10.6 How to Increase Engagement in a future RCT

To enhance engagement, the intervention has to cater for both types of participants although others' findings suggest that lurkers still benefit from the intervention and that they are motivated by the group, by the activity of posters, and by reading others' posts. The lurkers just don't feel like they need to participate. For instance, a study by Erfani et al., (2016) discovered that participants who read about others' situation experience a sense of comfort because it lowers their own anxiety (142). To cater for both types of participants it is important that the posters are identified by the researcher early on in the study, to keep them motivated and to create a group dynamic. In some studies this has been encouraged by incentivisation, including monetary compensation, social reward by praise and positive feedback when they do engage (197). The last mentioned method has been proven to be successful in other interventions that used OSGs (198). Additional techniques which have been mentioned by Coulson et al., (2010) are fostering of four aspects of empowering processes, namely; enabling members to exchange useful information, enabling members to exchange social support, and allowing them to find positive meaning in living with

the health condition and to help others. These suggestions should be incorporated in a future study.

Practical suggestions for strategies to encourage engagement

Participants who are randomised to the intervention will be asked to participate in the Facebook group more actively and will be given specific instructions and ideas about what information they can share as suggested by previous studies (199). For instance, all participants, will be asked to introduce themselves on the wall when they join the study, a suggested frequency of posts (e.g. once a week) about how they feel about their experience of the PA intervention, achieving/not achieving their targets and to post any questions, post suggestions for good places to walk, share ideas on how they achieve their steps, share photos of their walks, directly on the wall to everybody. Whilst placing this request to all participants may be off putting for 'lurkers' on the OSGs, other studies have shown (144), that some who are less active on OSGs may need more encouragement to participate. For instance, some participants may feel shy or inadequate or feel like their contribution does not matter, in which case they should be motivated and told that their contribution is valued and that it matters. Most often lurkers are not shy. Instead, studies have shown that those who post less or those who are less content with OSGs tend to be more educated and therefore get more bored or are more sceptical of the accuracy of others' comments and information (200). Studies have also shown that younger participants tend to engage more and comment and post more, whilst older participants are more likely to be lurkers (200). However, this study involved a wider age range (with no upper age limit). As our target is the pregnant population, this finding is not as relevant as our participants will be within the smaller range of 18-44 years, which is considered as relatively young.

In our study the posts that were most commented on were posts about pregnancy in general. Participants also joined in conversations about how they found taking part in the study. Based on the findings that general topics as well as intervention-specific topics engage the women, it is recommended that a variation of posted topics is incorporated in a future trial by the moderator.

In addition, participants will be asked to comment and post on the FB wall 1-2 times a week (201). Those participants that are at the time of randomisation

reporting that they are very active Facebook users will be asked to take a lead in getting the group going. These participants might be incentivised to do so by more praise or encouragement. An additional important element is to have time to foster these processes, which in our feasibility study was limited (5 weeks with rolling enrollment and participants completing at different times). For the large trial, there will be more time to foster these processes which would allow creation of relationships in OSGs which may make it more effective (202).

Participants' Suggestions to enhance Social Support by Face-to-Face meetings
Encouraging interaction and participation to enhance a sense of social support within a newly established group was a challenge due to participants' varying needs. Some participants suggested that they would have liked at least one face-to-face meeting. This could be addressed by having a so-called blended design, using elements of both face-to-face and internet-based interventions. Including both the integrated and the sequential use of both treatment formats may support their study participation in the Facebook group. However, there is no evidence that a face-to-face meeting would catalyse the Facebook group engagement.

On the contrary, a study by Udde-Kraan et al., (2008) found that OSGs of three different conditions (breast cancer, arthritis and fibromyalgia), were able to offer support in the same way that face-to-face help can, including enhancing *social support, empathy, experiential knowledge, reduced isolation and the opportunity to share personal experiences* (203). Perhaps, in our study, some participants did not feel this support because the group numbers were small and the engagement period was relatively short, but a larger group with longer participation may provide ample interaction for their needs, remotely. Based on this evidence that OSGs can provide same social support as face-to-face meetings it is not recommended that such meetings are made compulsory in a future trial. In particular as this would significantly change the remote intervention delivery-design and may increase cost of delivery.

10.7 Self-Efficacy Measure
Self-efficacy is defined as 'the belief in one's capabilities to organise and execute the courses of action required to produce given attainments' (194). Evidence from previous reviews (149) has shown that enhancing self-efficacy is an effective

means of increasing PA. Multiple BCTs were implemented to enhance self-efficacy.

All participants completed a PE Questionnaire which assessed self-efficacy as well as intention to walk and positive vs. negative feelings towards PA. The self-efficacy scores in the intervention group showed a non-significant trend (0.6±1.2) versus 0.2±1 of improvement although the number of participants does not allow a statistical comparison. Similarly to other studies, we cannot draw definite conclusions about which BCTs or which combinations of BCTs had greatest effect on self-efficacy scores in our intervention. Our findings of a trend of improved self-efficacy are most in line with the meta-analysis by Prestwich et al., (2014). The finding was that out of 26 BCTs that were incorporated in various interventions, those that incorporated self-monitoring, feedback, prompts or planned for social support increased self-efficacy (204). However, several other reviews by Williams et al., (2011) and Dombrowski et al., (2012) have all reported mixed findings (73), (78).

In summary, based on the evaluation of the acceptability and deliverability of the BCTs and their potential effect on self-efficacy we conclude that all BCTs included should be incorporated in the large RCT, with addition of suggested improvements to the method of delivery.

10.8 Evaluation, Shortcomings and Recommendations to Methodology and Trial Procedures

We found that most of the procedures and outcome data collection methods are feasible and acceptable to collect as part of the main trial, with some modifications which will be discussed below.

10.8.1 Trial Procedure and Recommendations for the large RCT

The remote mode of delivery meant that there were few obligatory face-to-face appointments. Also, because all necessary face-to-face appointments were made to coincide with routine hospital appointments there were no additional visits or meetings to attend. For these reasons, the overall feedback by participants was very positive regarding the ease and low burden of taking part in the study. This is important and consistent with current literature which

recommend less burdensome approaches in intervention delivery, as they are better perceived and result in lower drop out rates (156). The suggestion is that the same planning should be done for the main RCT, to assimilate as many study procedures as possible with the routine appointments. In this way, the participants would spend additional time with the researcher during routine appointment, which would vary depending on the participant and how long they took to complete the questionnaires.

10.8.2 Inclusion Criteria and Eligibility

The findings from the feasibility trial have confirmed that the pre-estimated percentage of eligible women is correct and therefore a recruitment rate of 4 participants per week can be assumed to remain the same. The refusal rates for participation were approximately 44% and the reasons for those have been presented in Chapter 8 in detail. The most common reason given for not taking part was lack of time. None of the participants' refusals were linked to the design of the study or the timing of the recruitment. There were no refusals for randomisation, which indicates the feasibility and acceptability of randomisation to either intervention or control group design. The dropout rate in the control group was slightly higher, which is expected due to less engagement and perceived benefit for participants. One participant in the control group expressed a desire to be part of the intervention group because she said that taking part in the intervention would really benefit her as she is trying to be healthy during pregnancy and not gain excessive weight. This finding that study participants are more keen to take part in the intervention is a common finding from previous trials where the control participants perceive that they are 'not getting anything' out of taking part in the study (205). Also, one control participant who dropped out reported that she already had an activity tracker, which she preferred to the one provided in our study and for that reason she dropped out of the study because she did not see any benefit in 'just wearing' our activity tracker.

There was not one instance where a person who was approached could not take part as result of the eligibility criterion of needing to be a Facebook user or being willing to join Facebook as well as have a mobile phone. This is a significant finding, which indicates that the inclusion criteria were feasible and not too

restrictive to our target population. This is very much in line with national data which showed that Facebook usage in women ages 18-44 is high (90-95%) (86).

One of the things which we did not get to explore within our feasibility study is whether this type of intervention design would be suitable for women from diverse demographic backgrounds. Our sample consisted predominantly of women from a white background even though our inclusion criterion was open to women of all backgrounds. It is important to consider this in any future trial design that the acceptability of this study design and method of intervention delivery may differ as it has not been tested in all demographics group. In a future trial, this may impact the retention and compliance rates.

10.8.3 Time Frame

The feasibility study was run for a period of 5 weeks. The studies which have been done so far, using the internet for the purpose of intervention delivery have varied in time range from 5 weeks to 12 months. An American pilot study that delivered a lifestyle intervention via Facebook to African-American pregnant women was delivered throughout the length of the pregnancy (167). The study had a relatively high retention rate (80-85%), however all participants received monetary compensation for each completed assessment. Whilst our study lasted for a period of 5 weeks, 80% of women chose to remain in the Facebook group after the study had finished. That the majority of participants chose to stay is a strong indication that they were willing to engage for a period longer than 5 weeks. It also further confirms the previous finding that they enjoyed and/or saw a benefit in taking part in the group it seems that a longer period may be acceptable. The primary aim of this study was to test the feasibility of study procedures. Therefore, the recommendation is that a pilot study should be conducted for a longer duration, for instance throughout pregnancy, prior to a large RCT.

Time scales of previous Facebook-delivered PA interventions, which did not specifically include the pregnant population, were analysed in a systematic review by Ferrer et al., (2017). A total of 8 interventions were identified, which ranged from 5 weeks to 12 months. The longer studies had lower retention rates,

which may be attributable in part to the challenges of maintaining a behaviour change, in addition to the already noted impact of longer trials on retention rates (209).

The aim of the large RCT is to deliver a PA intervention throughout the course of pregnancy. Therefore, it is important to assert that participants find it acceptable to take part in the intervention for duration of 6-9 months. Due to the nature of the condition and the fact that previous studies have shown that women are more motivated to adopt a healthier lifestyle during pregnancy (210) we expect that the retention rate will remain high in our target population. For instance a feasibility study which delivered a lifestyle intervention to obese women using text-messaging throughout pregnancy recruited a cohort of 14 women who all successfully completed the study from 14 weeks gestation until delivery (210).

Follow up times are also relevant. There is a distinction between initial behaviour change and behaviour change maintenance, which is harder to achieve (208). Maintenance of behaviour is hypothesised to occur at a minimum of 6 months after initial behaviour change; however, reviews which have examined this have not specified a specific length of time (180). Previous studies have reported that PA levels decrease throughout pregnancy (95). In a future trial, that would be implemented throughout pregnancy it is important to consider the fact that PA levels drop in all BMI categories due to physiological changes (95). For our participants, it is difficult to measure behaviour change long term as their status changes post-pregnancy and different/ additional behaviours are more relevant postnatally. However, long-term behaviour change and improved outcomes are the most desirable. Therefore, it is recommended that participants are followed-up postnatally for a period, in any future trial.

Pregnant women who decide to take part may be more motivated by their condition to remain in the intervention and may be more committed to behaviour change than other population groups. It is desirable that there is a continuous impact and that behaviour change is maintained postnatally which is why it is recommended that participants are followed up for a period postnatally.

Whether the observed positive outcomes of the feasibility trial translate into long term benefits to the mother and child needs to be assessed. Implementation and evaluation of the intervention for the duration of the entire pregnancy is required to ascertain the effectiveness of the intervention. The assessment of the burden of the frequency and intensity of the intervention was tested, within a period of 5 weeks. Based on the findings from the feasibility trial, we consider the level of safety of procedures in the intervention to be adequate. There are, however things which cannot be assessed at this point such as whether a larger sample will cause a loss of a participant-centred, individualised focus. We have also not assessed how a longer duration of the intervention will impact engagement with the intervention. The recommendation is that prior to a large size trial, a pilot study is conducted first, in order to assess how the duration of the intervention will impact engagement.

10.8.4 Retention Rate and Recommendations

Retention rate in the intervention group was 85%, which is a good finding, compared to other feasibility and/or pilot studies conducted in pregnancy. For instance, a walking intervention to test the outcomes on GDM in all BMI ranges had a lower retention rate of 65%. However, that study included more invasive procedures such as blood and peak exercise tests (63). This is in line with other findings, that intrusive and demanding study designs have much higher dropout rates (206). Based on our feasibility study findings we can make some predictions about the retention rate in the large RCT. The simplicity and the ease of the design, that participants perceived that they were not asked to do much, and timing follow-up appointments to coincide with routine appointments could be one explanation for the high retention rate in our study. This feedback was reported during the process evaluation interviews in which participants reported that they found it 'easy to take part'.

Our intervention was conducted over a period of 5 weeks, which is shorter than other feasibility and pilot interventions. For instance, Kong et al., (2014) pilot was conducted throughout the entire length of pregnancy, as well as the Ruchat et al., (2012) study (63). Extending the duration time of the large RCT, throughout the pregnancy, and enlisting larger sample size, may impact engagement, retention, group dynamics and participants' experiences of the intervention (207).

However, the high retention rate in the feasibility RCT and the fact that the majority of participants chose to stay in the FB group after completing the intervention, suggests it may result in a much larger, more dynamic group.

10.8.5 Monitoring of Adherence to Fitbit

It is recommended that the adherence to prescribed individual step targets is monitored every two weeks, to make sure that participants are wearing the Fitbit as well as aiming to reach their target. During the feasibility trial, each participant was monitored once a week, however with a larger sample size, it is feasible to monitor once every two weeks, or increase the time allocated to the researcher as this is a time-consuming task. The burden of more frequent monitoring has to be weighed against potential lowered compliance if participants receive feedback on behaviour less frequently.

Compliance to wearing the Fitbit (intervention 32/35 or 90% of days and control 28/35 or 80% of days) has confirmed the acceptability of using this tool to assess PA and deliver the self-monitoring and goal setting techniques. The high levels of compliance with wearing the Fitbit are similar to previous studies. For instance a study by Chung et al., (2017) showed that compliance in overweight adults was 99% of 60 days in total. The compliance with wearing Fitbit in our population corresponded to the overall high compliance rate in other studies (211).

10.8.6 Participants' Recommendation to Incorporate Competition BCT

Comparison and Sharing of steps and competition among participants were not incorporated in our intervention design. Some participants reported that they had wished to know what the others were doing in terms of steps progress and counts. The technique of social comparison and competition has been implemented in other PA interventions, to motivate behaviour change. Studies of PA interventions delivered via SM have found that those with social comparison features are more effective than those with stand-alone self-monitoring (113). However, the sharing of achievements is not always effective, in particular for those participants who are not successful at achieving their goals. The study by Achen et al., (2015), which delivered a PA intervention via Facebook showed that those participants who did not always meet their targets were less likely to share their goals and in fact avoided doing so (187). In that way, only the successful participants shared

their achievements, which in turn resulted in negative feelings among those that had not been as successful. In this way, sharing of steps and achievements could have a negative effect on the group and the feeling of social support (212). The review of mHealth interventions by Maher et al., (2014) found that whilst they do harness social support by sharing behavioural tracking and promoting encouragement from peers sharing can also have a negative effect (213).

For this reason, and the fact that pregnancy is a sensitive period in which social comparison can bring about negative feelings (195) these techniques were not included in our intervention, as we did not find it appropriate to expose or 'name and shame' participants who had not achieved their steps by putting that information on the group wall. Based on findings from the interviews with participants, it is obvious that there are different personal characteristics within any group and whilst some felt that competition was lacking others were happy to be on the 'intervention journey' and keep it a private experience so that they would not want to share and compare with others. This is similar to what was done in the Munson et al., (2012) study, which found that some benefited whilst others abstained from sharing goals (145).

A suggestion for a large RCT is to make the sharing of goals an option and an alternative that participants can opt out of. The sharing can be encouraged by the moderator but could be done voluntarily by group members themselves, as opposed to the moderator/researcher/HP. In this way, a feeling that the researcher is 'naming and shaming' is avoided, whilst benefiting those participants who are motivated by the competition factor. The challenge here is that only those participants who achieve their targets and reach more steps become the 'sharers'. As demonstrated in other similar studies, participants are less likely to share their steps if they are negative (187).

10.8.7 Limitations of and Recommendations for alternatives to PPAQ

The low return rate and anecdotal feedback indicated that participants found the PPAQ questionnaire to be lengthy. The questionnaire has 36 questions in total, with 4 options for each question. The advantage of the PPAQ is that it generates data on the amount of activity spent in 4 levels of activity intensity, which allows

for analysis of amount of time spent in low, moderate and vigorous activity. Because it is lengthy and therefore less likely to be completed by participants, it is recommended that for the large trial a shorter questionnaire is used to reduce participant burden (156), which is an important factor to consider in intervention design as previously reported by Langler et al., (2014). An alternative tool which has been used in a large trial (160) in women who are pregnant and obese is the Short Questionnaire to Assess Health-enhancing Physical Activity (SQUASH) (214). The questionnaire comprises 11 questions evaluating time spent on different types of physical activity (including commuting, leisure, household and incidental, and work-related activities). The questionnaire has been validated against accelerometer data and has been used during pregnancy (215). It is therefore a good alternative to the PPAQ.

Alternatively, our findings indicate that Fitbit data was in line with findings of the self-reported PPAQ, which suggests that using a questionnaire to measure PA may not be necessary. However, because a SQUASH questionnaire would give information about self-reported sedentary, low, moderate and vigorous activity it is recommended that the short SQUASH questionnaire is used.

10.8.8 Limitations of and Recommendations for alternatives to MyFood24

MyFood24 is an internet-based questionnaire, for which a link was emailed to participants. It had a lower return rate than the questionnaires which were completed during face-to-face meetings. There are several explanations for this occurrence. Firstly, participants were emailed a link to the MyFood24, which required them to look out for and locate in their inbox. This may have been a first barrier to its completion as several participants reported that they had not received the link or that they had found it after searching in their junk mail folder, which is a place that they do not regularly check. Secondly, the link to MyFood24 was sent out automatically, once the researcher had added the participant's email to the MyFood24 database. The shortfall here was that if participants reported that they had not received the link, there was no way for the researcher to verify this. To address the lower return rate, a recommendation which will be passed on to the developer, is that it might yield higher returns if questionnaires were mobile phone friendly or if the MyFood24 could be accessed as a mobile phone application. The advantages of MyFood24 were that it does automatic analysis

and is a low burden on the researcher in terms of analysis. However, due to the low acceptability among participants, it is recommended that simpler dietary intake questionnaires are used, such as a Food Frequency Questionnaire (FFQ) which can be administered during face-to-face appointments.

10.8.9 Measuring Gestational Weight Gain

Several factors may have influenced the accuracy of measuring GWG within the feasibility trial. For instance, the level of clothing, timing (morning, afternoon, exact number of days of gestation), standardisation of scale and the fact that it was done by a HP at baseline and by the researcher at follow-up, may have impacted the accuracy of weighing. In a future trial, it is recommended that the same person is doing all weightings and to use the same equipment.

10.8.10 Appropriateness of Facebook for a large RCT

The acceptability of joining a closed, private Facebook group was confirmed, where all participants who were randomised to the intervention arm did join the group. In the process evaluation, the feedback on the group was positive and all participants liked having an easy access to a source of information and community. This finding is particularly relevant as previous studies have found that women do not receive enough information about healthy lifestyle in pregnancy (1). The finding that women valued the Facebook group and that it gave them a sense of community is particularly valuable as previous evidence showed that fewer available supportive persons during pregnancy is a predictive factor of postpartum depression (216).

Also, a large study which examined the effect of social support on pregnancy outcomes found that a lack of social support had adverse effects on pregnancy outcomes (195). It also found that having a larger social network increases social support during pregnancy and that those psychosocial interventions may be effective in preventing postpartum depression. A Facebook group has the potential to build this network (217), which can further explain the acceptability of women to join our intervention group.

10.8.11 Time Demand to Deliver Intervention and Collect Outcomes

The monitoring of participants' PA levels via the Fitbit website is important but can be time consuming, depending on the frequency and length of intervention. However, maintaining PA during pregnancy could in turn reduce the overall costs to the health services due to less complicated pregnancy and delivery procedures, which is why it is still cost-effective to prescribe and monitor PA.

Whilst face-to-face interventions are costly and time consuming (218), using mHealth technology could lower the cost. Preliminary data suggests that using social media like Facebook allows participants to interact frequently and at their convenience, which facilitates engagement and retention and deliver a high intervention dose—all at low cost. Further, OSGs like Facebook allow for social support, which has been reported as lacking during pregnancy.

For a future trial, it is recommended that to reduce the time constraint barrier the monitoring has to be scheduled and systematic. The recommendation is to investigate whether this monitoring via the Fitbit website can be automated, which would make it less labour-intensive to monitor and assign steps. Also, a pre-set follow-up message should be prepared for those participants who are compliant versus those who need reminders, to ensure that all participants get the same message and same number of messages. It is most important that automated reminders are developed because it would make it feasible for implementation within the health care path in the NHS, if the larger trial is successful.

10.8.12 Researcher and Staff Capacities

From the experience of running the feasibility trial, the researcher estimates that at least two moderators/researchers/HPs are required to conduct a large trial, however this would also depend on the size and number of participants that would be involved. During the feasibility trial, access to the Facebook Messenger proved to be feasible and frequently used communication channel. It is however, an additional labour-intensive component, to provide a direct, private channel to each participant. For this reason it is important to weigh the benefits versus time constraints in using the Messenger in combination with the Facebook wall as a channel of communication. Arguably, if communicating with participants regarding step targets and reminders if their targets have not been achieved is

acceptable to be done via the Facebook wall, the Messenger component can be eliminated.

Time Management Recommendations

Set time has to be allocated each day for posting and moderation on Facebook, and if Facebook Messenger is to be used as a communication channel its use should be limited to serve a set of functions. Based on the feasibility trial experience, allocating one hour to attend to Facebook, twice a day by the moderator, would in that case be sufficient to moderate the group. Also, setting an online meeting, once a week, where participants are informed that the moderator/HP/researcher will be available to answer any questions, is recommended and might be a way to lower the sporadic messaging throughout the week. It will not take away participants' reported experience that 'someone is always there' (which was reported in the process evaluation as a benefit of taking part) but rather enhance it by allowing a set time for communication and questions. A previous study which delivered a lifestyle intervention via Facebook and text messaging included behaviour change sessions, with a health coach calls, which were delivered over the phone. The sessions included 15 to 20 min counseling calls to participants weekly for the first two study weeks and then twice monthly thereafter. This suggests that it may be more effective to include live sessions with a HP who can answer questions (136).

Recommendations for Research Sites

All clinical staff at the recruitment site should be informed of the study in a briefing meeting. This will ensure more understanding and support from the clinical staff. Prior to the feasibility trial, we were told that the staff would be informed by the ward manager and the matron, however this was not the case and many of the clinical staff was unaware of the study and the purpose of the trial. This shows the researchers should minimise any burden/tasks for the hospital staff and the information giving should be done by researchers (with permission), by attending staff meetings and taking opportunities to raise awareness of the project proactively rather than relying on matron/managers/hospital staff. As the trial is introduced into a clinical environment, it is recommended that staff of all levels, including administrative staff is informed. This is particularly useful during the

large trial when participants hand in completed questionnaires to the administrators who are manning the front desk throughout the day. A box with study name should be provided, where they can safely store all completed questionnaires.

10.8.13 Recommendations for Additional Equipment

All participants were given an activity tracker and this is still a feasible option. All activity trackers have to be set up beforehand with a password that is accessible to the study moderator and all participants should sync their activity tracker to their phone at the time of recruitment, to be sure that it is set up and functioning. This requires a good connection to the internet at the time of recruitment. The option for this is to acquire access to the wireless internet network at the hospital and provide temporary passwords. However, this option is highly unlikely due to the restrictions placed on who can access to the hospital wireless network, for security reasons. Alternatively, a dongle can be used at the time of recruitment, which participants can connect to, and set up the activity tracker. It is a small and portable device, smaller than a mobile phone and convenient for use. The device can be topped up with mobile data credit, according to the need.

For the large trial, it is important to consider whether lost or broken activity trackers will be replaced. In the feasibility trial, there were three faulty activity trackers which were replaced. One participant lost their activity tracker at the very start of the intervention and this was not replaced because, at the time, we did not know how frequently this would be happening. However, the recommendation for the large trial is that if a participant is keen to continue, a new activity tracker should be given out. In addition, it is recommended that a PA tracker which can be blinded more effectively is used.

Limitations of measuring PA with Fitbit

It is important to mention that detailed evidence-based guidelines were published by RCOG in June 2017, three months following the completion of our trial. An infographic with evidence-informed messages was produced with more detailed recommendations regarding frequency, intensity and duration of PA that pregnant women should undertake during pregnancy. The duration of recommended PA is 30 minutes per day with the aim to accumulate 150 minutes

per week. The recommendation in terms of intensity is for pregnant women to do *moderate* PA. Moderate PA is defined as *'activity that makes you breathe faster'* (114) which is done in 10 minute bouts. However, the supporting document that was produced with the infographic points out that ' *It is important to highlight to women that 'every activity counts'* and that doing more PA and doing more steps throughout the week is also beneficial. At present, the pedometers measure steps and are not very good at measuring duration and intensity of activity. Assigning step counts is at present the simplest most straight forward way to assign PA.

In light of this new and more detailed recommendation, it may be worth exploring whether PA goal setting should be assigned and measured as duration and intensity in a future RCT. This would however, require piloting to test the feasibility of the recommendations. The specific goal setting of duration and intensity would change the nature of our intervention in that women would have to plan non-stop walking for a length of time , which may be more difficult to fit into their habitual activities or to do for example with small children. Furthermore, moderate intensity and duration can at present not be easily measured, making self-monitoring and monitoring impossible. Lastly, there has been no piloting of this new guideline to test its effectiveness on GWG, maternal and infant outcomes. Based on the current situation, the recommendation is to continue with step counting and targets in a future large trial.

10.9 Ethical Considerations

It is pivotal that Facebook privacy settings instructions are shared in written format in the information pack as well as face-to-face. The researcher should be familiar with privacy settings instructions and be able to assist each participant, if they are struggling to do so, on their own. Management of ethics and ethical conduct in a large trial is crucial, especially when conducting a trial via a social media platform. Any suspected adverse event should be reported and all participants should be referred to the right support team if a problem arises. Within this trial no adverse events occurred.

General Data Protection Regulation

During the write-up of this project, (May 2018), the General Data Protection Regulation (GDRP), was passed, which is a new set of rules aimed to give European Union citizens more control of their personal data. GDPR applies to

any organisation operating within the EU, as well as any organisations outside of the EU. Under the terms of GDPR, organisations such as Facebook and Fitbit, have to ensure that personal data is gathered legally and under strict conditions and those who collect and manage it are obliged to protect it from misuse and exploitation.

10.9.1 Facebook
 As part of the update, Facebook has released a new feature called Access Your Information, a new "secure way" for users to access and delete their posts, reactions, comments, and searches from their timeline or profile. Features like this allow participants of any Facebook groups to delete their activity history on Facebook, if they wished to do so.

10.9.2 Fitbit
The Fitbit Company has published an update to their Information Retention policy in May, 2018. In the update it has changed the way it retains data. For instance, it has made it easier for its users to edit or delete personal data about activities, dietary intake, and sleep. It states that they keep user information as long as the account is in existence. Information, like exercise or activity data, is kept until a user deletes their own data by accessing the account settings on Fitbit's user's personal website.

10.10 Determining the Primary Outcome Measure for the large RCT
Previous trials have discussed what values constitute clinically meaningful differences in this particular target population. Pregnancy is a time when a woman is particularly encouraged to follow a healthy lifestyle. However, unlike in non-pregnant obese individuals, weight loss is not encouraged or recommended, especially as the implications of a weight loss in pregnancy are unknown (219). Instead, the RCOG recommend a healthy weight gain, healthy diet and 30 minutes of physical activity daily. Most small lifestyle RCTs in women who are overweight or obese have primarily focused on limiting GWG, based on the assumption that certain weight gain recommendations will in turn improve outcomes in pregnancy and childbirth. However, GWG as a primary outcome is problematic for two reasons; 1. As there are no specific weight gain guidelines in the UK, it is questionable whether this is a primary outcome of interest and how a meaningful difference would be measured in relation to improved clinical

outcomes. 2. Other PA interventions have reported no or small change in GWG whilst observing a change in other outcomes such as fasting plasma glucose levels, GDM status and LGA (161), (220).

Generally, the sample size for any study depends on: (221)

- Acceptable level of significance
- Power of the study
- Expected effect size
- Underlying event rate in the population
- Standard deviation in the population.
- Drop-out rate

The sample size calculation seeks to ensure enough patients are recruited to detect a difference in the outcome measure of interest at a pre-specified level of significance. Therefore, the appropriateness of some of primary outcomes will be explored systematically to be able to select the primary outcome for the large trial.

10.11 Summary of Recent Large Trials and Their Primary Outcome

Recent major lifestyle intervention trials included following primary outcomes;

Healthy Eating and Lifestyle in Pregnancy (HeLP) Trial
Primary outcome in the HeLP trial was a difference in BMI at 12-months follow-up. We do not expect a weight loss during pregnancy as this is not recommended and we are not intending to continue the intervention during the postpartum period, therefore BMI change is not a recommended primary outcome for the large trial.   The change in BMI was selected in HeLP trial as they were hypothesising a weight loss in the intervention group during post-partum follow-up. The calculation of significant difference in outcome in this trial was based on weight loss in non-pregnant women who are obese, as no reviews had looked at the significant difference in pregnant women (222).

Antenatal lifestyle advice for women who are overweight or obese: LIMIT randomised trial
The primary outcome was the incidence of infants born large for gestational age (birth weight ≥90th centile for gestational age and infant sex). Elevated maternal

blood glucose levels are well recognised as contributing to LGA. For instance, among women with unrecognised maternal GDM, the prevalence of LGA infants is fivefold higher compared to nondiabetic controls. Also, it has been shown that maternal hyperglycaemia 1-hour after a 75 g oral glucose tolerance test (OGTT), even within the recommended ranges, increases LGA. Based on these findings, we think that mean fasting glucose would be a better outcome indicator than the eventual LGA clinical outcome. Data on LGA can be collected as part of the secondary outcomes (223).

Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial

Primary outcome in the UPBEAT trial was the maternal diagnosis of GDM, according to the International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria. The sample size of 1546 women was calculated to provide 80% power to detect a 25% reduction in the incidence of GDM and a 30% reduction in infants large for gestational age.   Secondary outcome was LGA delivery defined as adjusted birth weight >90th centile for gestational age adjusting for maternal height, corrected maternal weight, ethnicity, parity, and sex of baby (159).

To use the GDM status as the primary outcome (as defined by IADPSG criteria), a large sample size would be needed. Due to the large sample size, which is needed to detect a significant difference in GDM status, it is recommended that GDM status is not used as the primary outcome.

Maternal Plasma Glucose and Adverse Pregnancy Outcomes

A large multi-centre study examined whether there is an association between maternal hyperglycaemia and risk of adverse pregnancy outcomes. A total of 25,505 pregnant women from nine countries were included in the analysis. All women had a 75-g oral glucose tolerance test between 24 and 32 weeks of gestation. The study calculated odds ratios for adverse pregnancy outcomes associated with an increase in the fasting plasma glucose level of 6.9 mg per decilitre [0.4 mmol per litre]), an increase in the 1-hour plasma glucose level of 1 SD (30.9 mg per decilitre [1.7 mmol per litre]), and an increase in the 2-hour plasma glucose level of 1 SD (23.5 mg per decilitre [1.3 mmol per litre]). For birth

weight above the 90th percentile, the odds ratios were OR 95% CI [1.38] (1.47 to 1.64), emergency C-section OR (95% CI) [1.46] (1.38 to 1.54); and neonatal hypoglycaemia OR 95% CI [1.08] (0.98 to 1.19). These results indicate strong associations of maternal glucose levels below those diagnostic of diabetes with increased birth weight. The study showed additional effects on secondary outcomes, which were not significant. This is one of the largest trials known to date and it has been used extensively to set a sample size with GDM as a primary outcome based on the significance of a 6.9mm/l difference between two randomised groups (224).

Maternal Fasting Plasma Glucose

In this case, a clinically relevant difference between mean maternal fasting plasma glucose in the intervention group by 6.9 mg/dL at the time of a 75-g oral glucose tolerance test at 24–28 weeks of gestation could be used in our trial to determine the sample size. Women with raised BMI are at increased risk of developing GDM during pregnancy.

Based on this trial, a sample size calculation determined that 23 women were required per group to detect a difference of 6.9 mg/dL in fasting plasma glucose between intervention and control groups for statistical power of 90% at a type I error rate of 0.05. This would require a sample size of 46 women. Assuming a dropout rate of 20% (based on the findings from the feasibility trial), we would need to recruit 56 women in total. Women with gestational diabetes mellitus (GDM) are at increased risk for adverse perinatal and maternal outcomes, including macrosomia, C-section and later diabetes. It is a measureable outcome and therefore suitable as primary outcome for a fully powered trial.

Gestational Weight Gain

GWG has been the primary outcome in many trials. Several studies have shown that a clinically relevant difference in mean GWG between the intervention and control group is 6kg, (225),(226), which had a positive effect on GDM incidence and other pregnancy outcomes. The women in the intervention group successfully limited their energy intake, and restricted the gestational weight gain to 6.6 kg vs a gain of 13.3 kg in the control group (p=0.002, 95% CI: 2.6-10.8 kg). Sample size was calculated based on prior studies (225), (227) using a 6-kg clinically relevant difference in mean weight gain between the exercise and the

control group, from baseline to delivery. According to this, a two-sided independent sample *t*-test with a 5% level of significance, a standard deviation of 10, and a power of 0.90 gave a target study population of 59 in each group. Dropout was estimated at 15%; therefore, we aimed to include 150 women. However, the GWG as a primary outcome remains questionable, as the effects may be different depending on the Obese BMI Class I, II and III. Namely, previous studies have shown that incidence of excessive GWG is different between the BMI classes. Therefore, the sample would have to be stratified based on the BMI category.

Gestational Weight Gain within IOM Guidelines

A large cohort study of 20.950 women, from 2013 compared maternal and neonatal outcomes in obese women according to weight change and obesity class (228).It studied data of women with a singleton pregnancy in the US from 2002-2008. The study found that optimal maternal and neonatal outcomes occur when weight gain is less than current Institute of Medicine recommendations (IOM) for women who are obese.

It measured the risk for adverse outcomes by multiple logistic regression analysis for weight change categories. Weight change was defined as the difference between the self-reported pre-pregnancy weight and delivery weight. Main findings were that weight loss (for women who lost weight, the mean (±SD) weight loss was −4.8±4.5kg, −4.6±4.3kg, and - 5.6±4.2kg for class I, II, and III, respectively) was associated with lowered odds of C- section for class I women nulliparous (OR 95% CI) [0.21] ; and increased small for gestational age infants class I (OR, (95% CI) : [1.8 (1.3-2.1)]; class II OR, (95% CI) [2.2 : (1.5-3.2)]; class III OR (95% CI) [1.7: 1.1-2.6)]. High weight gain was associated with increased large for gestational age infants (class I OR (95% CI), [2.4 (1.9-2.9)]; class II OR, (95% CI), [1.7; 1.3-2.1)]; class III OR (95% CI):[(1.6; 1.3-2.1)]. The probability of adverse outcomes (C-section, postpartum haemorrhage, small for gestational age, large for gestational age, neonatal care unit admission) was reduced when obese women (class I, II, III) reduced the GWG (−4.8±4.5kg, −4.6±4.3kg, and - 5.6±4.2kg respectively) (228).

If the decision is made to follow the IOM guidelines on GWG, we would need to calculate a meaningful difference separately for the three obese BMI categories (class, I, II and III), (as the three groups have been reported as having different proportions of excessive GWG) to determine the appropriate sample size. If we base our calculations on the American study (229), which found that 63.4 % of women of Obese BMI Class I group gain excessive weight (above the 4-9 kg which is recommended and assuming similar prevalence of excessive GWG among Class I obesity women in Britain, who are pregnant). Based on this statistic, if the primary outcome is incidence of women that gain weight within the recommended IOM guidelines (4-9kg), to show a statistically significant difference of 20% between the intervention and the control group (based on RCT by Stanek et al., (2018) *The Effect of an Exercise Intervention on Gestational Weight Gain: The Behaviours Affecting Baby and You (B.A.B.Y.) Study* (230), with a 80% confidence interval, and assuming a 20% drop out rate, 94 participants would be needed in each group giving a total of 188 participants. This estimate only holds true for BMI Obese Class I. The other two classes of obese BMI categories have a different occurrence of excessive GWG. Therefore, a separate calculation has to be done for them.

Preeclampsia

Approximately 8-10% of women develop preeclampsia in pregnancy (60), with half of cases usually suffering from hypertension prior to pregnancy. Pre-eclampsia varies in severity and mild treatment such as alterations to diet, regular blood tests and blood pressure monitoring are recommended, however 75% of the cases resolve on their own post-delivery (231). It is defined as blood pressure more than or equivalent to 140/90 (mmHg) following 20 weeks of pregnancy with proteinuria more prominent than or equivalent to 300 mg for 24 hours, protein/creatinine proportion more than 0.3, or a dipstick test result more than or equivalent to +1. It is caused by: Diabetes, kidney disease, obesity, autoimmune disorders, sickle cell, PCOS, higher age, and deficiency in vitamin E, C, D or magnesium (231), amongst others. It is a complicated condition whose diagnosis and symptoms vary in severity, and a risk group that is more varied than the other previously mentioned pregnancy outcomes, we chose not to use it as a primary outcome for our intervention.

Physical Activity (steps)

The most important benefits of using pedometers as a motivational tool are the immediate feedback they give and the fact that aiming to take a predefined number of steps/day is a clear and understandable goal. In general populations, the most widely recognised step recommendation to improve health is to accumulate 10 000 steps/day (232). Tudor-Locke et al., (2011 has systematically evaluated dose-response effects of different steps/day goals in the general population. It found that approximately 7,000-8,000 steps/day is a reasonable threshold of free-living physical activity (233). Free-living physical activity is defined as "the level of activity that the patients, within their physical limitations, at their own pace, and in their own environment, typically perform (234). However, this guideline may be unrealistic for pregnant women, even though RCOG recommends that pregnant women do 30 minutes of PA or 10,000 steps per day (52). Studies which have aimed to objectively measure PA in pregnancy have found that PA was lower in obese women at all gestational ages (6,482, 7,446, 4,626 steps/day in obese vs. 7,558, 8,865, 6,289 steps/day in normal-weight, p < 0.05-0.11) (95). The mean difference at each measuring point was approximately 1,000- 1,800 steps.

A randomised controlled study involving pregnant women, by Renault et al., (2011), showed that participants in the intervention groups (PA and diet) and PA had a mean of 8838 ± 2878 and 8828 ± 2798 steps/d (n= 91/78); in week 21, 8122 ± 3121 and 8829 ± 2980 steps/day, and in week 37, 6219 ± 2198 and 5972 ± 2133 steps/d throughout pregnancy. GWG less than 5 kg was obtained by 26% in group PA plus diet, 22% in group PA, and 17% of the women in the control group (p = .07). The limitation of this study is that it did not measure the number of steps that the control group did, which limits any interpretation of the dose-effect size of steps (235). At present, no studies have reported the isolated effect of an increase objectively measured PA in steps on GWG and/or pregnancy and birth outcomes.

In the general population, three RCTs meta- analyses, involving the general population showed that an increase of approximately 2000 to 2,500 steps/day

(116),(236),(237) is associated with modest weight loss and improvements in blood pressure. Based on the above mentioned studies, conducted both during pregnancy and the general population, there seemed to be a difference of 1000-2000 steps between the normal weight (who have better pregnancy and health outcomes) and the obese pregnant women. The difference in steps is similar to the studies which have measured effect sizes and health outcomes in the general population. For the larger trial, it seems reasonable to assume that an effect size of 2000 steps is reasonable, based on the findings in the above mentioned studies.

On the basis of aiming to show an improvement of 2000 steps/day, a two-sided independent sample *t*-test with a 5% level of significance, a standard deviation of 3000, and a power of 0.90 (as established through published papers (235); a sample size of 48 participants per arm is required. Taking into consideration a 20% drop out rate, would imply a 116 women in total.

10.12 Proposed Composite Outcome

To determine the association between number of steps and pregnancy and birth outcomes we propose a composite primary outcome including PA (measured as steps) and maternal fasting plasma glucose.

Primary outcome of PA (Steps)

An improvement of 2000 steps/day, a two-sided independent sample *t*-test with a 5% level of significance, a standard deviation of 3000, a power of 0.90 and a 20% drop out rate would require a sample size of 116 women in total.

Maternal fasting plasma glucose

Power calculation determined that 23 women were required per group to detect a difference of 6.9 mg/dL in fasting plasma glucose between groups based on an independent-sample t test for statistical power of 90% at a type I error rate of 0.05 and assuming a dropout rate of 20%, would imply 56 women in total to be recruited.

Because we are proposing to use a composite outcome of steps and mean maternal plasma glucose, the larger sample size of 116 women is recommended.

10.13 Limitations of the Thesis and How they Influenced the Results and Conclusion

Strengths and limitations of my research have been examined throughout this chapter and in previous chapters but a summary of the main issues is provided below.

As this was a feasibility study, the aim was to test the acceptability and design of the study rather than the effectiveness of the intervention. The strength of the current study therefore lay in the amount of data generated on feasibility which has contributed to the design of a large RCT. This includes data on the recruitment strategy, the design of the study, the remote intervention delivery and data collection processes.

This study was also strengthened by the systematic intervention development and theoretical underpinning. The use of mixed-methods produced a more complete picture of the acceptability and feasibility of study procedures than either method could produce if used alone.

Time Frame

The duration of the study was 5 weeks in total. Although the participants did not achieve their exact step target for each week, the majority of the participants achieved 90% or more of their step target in week 5. This led us to conclude that the intervention may be effective in supporting a maintenance and/or increase of PA levels. The qualitative findings confirmed that participants liked to take part in the study and that they found it easy. These findings formed our conclusion that the study design and features were acceptable to women who are pregnant and obese. However, it is unclear whether the goal setting, and graded tasks would be acceptable in a long term intervention (for instance throughout pregnancy). This is one of the main limitations of this study. In order to test the acceptability of study procedures over a longer period of time, it is recommended that a pilot study is conducted prior to a large RCT.

Blinding

One limitation of our findings is that it was difficult to blind participants to the step count readings. All participants had their Fitbit tracker synced to the Fitbit application on their phone, in order to record their step count. Therefore, although best effort was made to blind the control group participants by means of using sticky tape to cover up the display on the Fitbit wristband, they could access their activity reading on the application. Participants were asked not to open the phone application; however it is unclear how many complied.

Blinding at Baseline

A further limitation of our findings is that the intervention group were not blinded to the step counting by means of sticky tape over the Fitbit wristband during the baseline week and could therefore self-monitor (although they were not given a step target), which may be why a difference in steps was observed at baseline week as well. However, an Ancova analysis with baseline week as covariate showed that the intervention group did more steps, with a significant difference in week 2.

Health Professionals' Involvement

Health professionals that were interviewed were all made aware of the study and supported recruitment only. We did not test the feasibility of health professionals delivering the intervention due to limited time and resources. This would have better informed barriers to intervention delivery within the NHS.

Intervention Retention

The study duration of 5 weeks was done to test study procedures. At the end of the 5 the weeks, all participants remained in the Facebook group. This led to the conclusion that participants liked to be part of the group and the intervention, which was also confirmed during interviews with the participants. However, it may also be that some participants stayed in the group by default. This is a limitation as this was not specifically asked or explored during the interviews.

Intervention Access

Participation in the Facebook group intervention was measured by number of 'likes', comments and 'seen by' markings. In the instances where a link to an external article was provided, it was also labelled as 'seen by' if it had been viewed by participants. The 'seen by' function indicated that 60-80% of participants saw all the posts. It did not necessarily mean that the link had been clicked on and read by the participants. Therefore, it is a limitation in that we cannot know how much of the intervention was actually accessed by participants. Following the completion of the study, we learnt that it is possible to monitor the clicks on website links via Facebook, by means of installing and setting up an additional program that can monitor this activity (however even this would not mean the linked article was actually read, or understood).

Demographics

Although the sample was broadly representative of pregnant women with obesity, it was homogenous in terms of ethnic background, thus limiting generalisability to the wider population with obesity. This is a limitation as we do not know how the study would be received by other ethnic groups. Strategic approaches to recruit women who are pregnant to the study from a wider range of ethnicity and demographic characteristics are therefore required.

Sample Size

The sample size was based on previous recommendations for feasibility studies. Half of the participants were randomised to the intervention group (20 participants in total) and to the control group. The limitation of the feasibility study is that we cannot draw any definite conclusion about how a larger sample size in an RCT would impact the Facebook group dynamic and participants' experiences.

In summary, this thesis has demonstrated relatively high recruitment (55%), retention (85%) and compliance (within 90% or higher). However, there are still significant questions about how longer intervention duration, a proper blinding of participants and mixed demographics would impact the feasibility and acceptability of the study. Therefore, these questions would need to be addressed before an RCT could be conducted. Limitations of the feasibility study

and future recommendations have been described in this chapter. A summary of what worked well and what could be improved is in Table 50.

10.14 Summary of What Worked Well and Suggestions for Refinement

The strength of our design is the remote monitoring of objectively measured PA levels (Fitbit), and remote intervention delivery (Facebook). The method had a low burden on both participants and researchers. The limitation of using this method to measure PA levels is that it was difficult to effectively blind the control group participants to the PA readings with just a sticky tape over the wristwatch and having to rely on participants to not open the Fitbit application on the phone to check their steps. A further limitation is that the intervention participants were not blinded during the baseline week. Based on the experience from the feasibility trial, better measures can be implemented to ensure proper blinding in a future trial. An additional strength of the design was in using SM as a communication tool which participants found to be practical and convenient. It meant that participants could access all the information readily on their phones and/or computers. The limitation was that some participants engaged more by means of posting and commenting on the Facebook group wall, whilst others reported that they only read the posts but did not comment or interact much with the other participants. Based on these findings, in a future trial effective methods should be used to increase engagement by all participants. All other suggestions for refinement are summarised in Table 50.

Table 50. Summary of What Worked and Suggestions for Refinement

1. What has Worked Well
BCT Elements
All BCTs were acceptable and deliverable. It is recommended that they are all delivered in a future trial with an addition of two BCTs and a few Suggestions for improvement;   1. Graded tasks to lower gradient of increase of steps (10% increases instead of 20%)   2. Enhancing Engagement and Social Support Technique on FB by   -identifying posters early on in the trial   -Incentivising posters to be more active and involve lurkers   - Setting posting targets for participants, sharing ideas about what kind of posts and shares they can do)/ Setting number of posts to participants

-Post on topics that involved most in the group. For instance, not just PA related but pregnancy-related in general

3. Adding Competition (to achieve steps) optional

4. Measure effectiveness of BCTs both objectively and subjectively using Empowerment Scale Questionnaire, Mechanisms of Action Questionnaire and Knowledge Questionnaire.

Mode of Delivery

Facebook
Facebook group worked well. There were no adverse outcomes and no moderation of inappropriate comments. Recommendations 1. Be aware of Barriers to Engagement 2. Encourage engagement by regular participation and meaningful interaction 3. Continue with the Facebook group until 6 weeks post-delivery (no steps target) 4. Whilst continuing with a closed, private group format the interaction on FB Messenger should be limited. 5. Scheduling FB Messenger time with HPs and participants to 1-2 times every month. 6. Create a detailed schedule and plan posts to correspond to topics and benefits of PA associated with gestational age (e.g. 1-3 months gestation, 3-6 months gestation and 6-9 months gestation). 7. Pin posts that contain generic and important information to ensure easy access to all participants irrespective of when they join the study. 8. Optional Face-to-Face meeting with HPs and participants that coincides with routine OGTT testing.

Fitbit
Remote collection of PA data worked well. Creating Fitbit accounts for participants that were synced with wristband and Fitbit mobile phone application and could be accessed by the researcher worked well. Recommendations for a future trial: *Blinding*- Blind intervention group participants at baseline week as well as the control group participants. Following baseline week un-blind the intervention participants so that they can then monitor their steps throughout the study. Blinding- Use a more effective way for blinding participants to Fitbit Steps data. Explore alternative solutions to using sticky tape (to cover the wristwatch). For instance, deactivate the screen on the Fitbit wristwatch. Deactivate the Fitbit mobile phone application for all participants during baseline week and for control participants only throughout the study. -Explore alternative Fitbits that may measure cadence/intensity of PA and duration.

Data Collection of clinical outcomes- appropriate
Collecting GWG data. Setting collection points to coincide with routine appointments to reduce the burden on participants and researchers

-Considering the last routine appointment as the last time point for GWG data collection 35/36 weeks gestation.
Physical Activity Targets
Creating a step target plan on the last day of Baseline Measure (10%) and ask participants if they can agree and adhere to that. Set a Monitoring Schedule of Steps based on the outcome of Baseline Week for every participant
Measuring Tools
SQUASH questionnaire instead of PPAQ
Food Frequency Questionnaire administered during routine appointments, face-to-face instead of MyFood24, Empowering Processes Scale Self-Efficacy/Knowledge Questionnaire Mechanisms of Action Evaluation Questionnaire

10.15 Conclusion

The practicality of the trial procedures has been discussed in this chapter, with recommendations for the main, large size RCT. Based on the evaluation of all findings in this chapter, a design for a full size RCT is presented in Appendix K. The next chapter (chapter 11) is providing a conclusion with a summary of recommendations, implications for clinical practice and research, as well as reflections of my PhD journey.

Chapter 11. Conclusion

This concluding chapter will aim to summarise the unique contribution to knowledge, as well as provide reflection on my PhD journey. It will also provide recommendations for research and practice beyond protocol development.

11.1 Contribution to Knowledge

This study has shown that a mobile health walking intervention is acceptable to pregnant women with high uptake and retention rates, which may have the potential to positively impact the pregnancies of these high risk women, reducing the risk of morbidity and mortality in these women and their unborn children.

This study has added to research by providing information on the feasibility of a remotely delivered PA intervention, using social media within the NHS and UK. Research is limited to how a remotely delivered mHealth intervention could be implemented within the NHS with the majority of studies being conducted face-to-face. Previous research is lacking with regards to evidence that an mHealth intervention could be incorporated into the current health service and used as a tool to deliver a PA intervention to pregnant women who are obese. This research is especially important during the current changes occurring within the NHS when time and resources are increasingly stretched. Given the lack of available services in the area of maternal obesity, alternative modes of information delivery, with the potential to reduce burden on HPs, their input and time per patient whilst still enabling individual and tailored care, need to be investigated to identify if they can be effective and thus benefit the NHS. This type of intervention has the potential to reduce cost while also maintaining quality and reachability. The aim would be to reach more patients than are possible through current, mainly face to face, practice.

Using data collected from this feasibility study, as outlined in the previous chapter 10 Table 50, the intervention and trial protocol have been refined before conducting a full scale definitive trial to examine the clinical and cost effectiveness of full implementation. It would be only after this development and further trialling that it would be possible to assess whether this intervention was clinically and cost-effective. A remotely delivered PA intervention could advance health care within the NHS in terms of increasing accessibility to limited HP's time. I acknowledge that a social media- based intervention may not be the sole solution

due to the varying ways in which people engage with such interventions. However, I believe there is potential to offer this as an adjunct method for delivering PA and lifestyle advice. The challenge remains of how to integrate a PA intervention into the current pathway to benefit health professionals, patients and the NHS.

11.2 Implications for Future Research

11.2.1 Measuring Engagement in Future Research

Based on our assessment of the deliverability of the social support technique via FB, and the role it plays in increasing engagement, following are recommendations for future research. Our findings have shown that there is a strong link between participation, engagement, communication in online support groups (OSGs), and increased self-perceived social support. Enhanced social support has the ability to increase self-efficacy, which has been found to promote behaviour change (196).

The main challenge, according to Yardley et al., (2016) is to understand the relationship between the engagement with the digital intervention and the desired behaviour change (238). Based on our findings, effective engagement would be one that resulted in a) enhanced social support and improved self-efficacy; b) enhanced self-perceived social support c) behaviour change (e.g. Increased/maintained levels of PA) d) and a significant effect on the primary outcome. Furthermore, sufficient engagement would also be indicated if there was evidence that the access to a reliable digital information source improved knowledge.

There are several lines of thought about how to assess engagement in OSGs. For instance, Hwang et al., (2014) showed that frequency of participation predicted encouragement and support. One of the findings was that participants who used social media tools at least weekly were almost five times as likely to experience encouragement and support compared to those who used the features less frequently [adjusted OR 4.8 (95% CI 1.8-12.8) (201). On the other hand, Yardley et al., (2016) have highlighted that it is not the quantity but also the

quality of the engagement that determines its effectiveness on behaviour outcomes (172). Therefore, it may be that it is more valuable to aim for effective engagement, rather than simply more engagement.

The paper defines effective engagement as an engagement level with the intervention that achieves the intended outcome. Therefore, simply measuring engagement by the number of likes, comments and hours spent on the Facebook group wall may not be the best measure of sufficient or effective engagement. Instead, multiple ways to measure engagement should be used.

Our research confirmed the finding that some participants were happy with all posts as long as they were frequent, whilst others lurked and only participated in discussions on topics that found interesting. Therefore, future interventions should cater for all types of participants (both lurking, less active participants' as well active participants who post frequently). In future research, it is important that the posters are identified by the researcher early on in the study, to keep them motivated and to create a group dynamic by means of social reward by praise and positive feedback when they do engage. Other studies which have looked at 'lurkers' found that lurking in the online support groups may be as effective as reading and posting messages to the groups (203). These findings indicate that for future interventions both quantity and quality of engagement are equally important for effective engagement, social support and in turn improved self-efficacy.

To measure engagement for the future RCT, it is suggested that both objective and subjective measures are used to assess engagement. Engagement can be measured using already available Facebook tool such as 'seen by', 'likes' and comments measurements as well as a separate measuring tool that does not rely on Facebook's own metrics.

For instance, a questionnaire can be used to assess;

-time spent reading the group content

-frequency of log in to Facebook

-frequency of checking the Facebook Group Page

In addition, to address the quality of engagement, a measurement tool which can be adjusted to be appropriate for pregnancy is the Empowering Processes Scale which is measured by a 43-item scale (164), (197). It measures four empowering processes: *receiving useful information, receiving social support, finding positive meaning and helping others.* This would allow for a more meaningful and accurate interpretation of the impact of the Facebook group and the interactions. The downside of this measurement tool is that it is time consuming and places more burdens on participants; however it is valuable information which would allow for further intervention improvement.

11.2.2 Implications for using Facebook in Research in Light of Recent Privacy and Data Protection Revelations

During the write-up of this thesis, it became evident that Facebook may have breached certain regulations linked to privacy and protection of data, by sharing their users' data with a third-party (Cambridge Analytica). Facebook users who installed a 'This is your Digital Life' App on Facebook, handed over their profile to the third-party company. At this point, it is not clear what impact this revelation will have on public's Facebook usage. What has become evident is that further regulations may be put in place on social media platforms such as Facebook, to protect its user's privacy and shared data. We fully recognise the concerns and potential problems that can occur when sharing data in a social media context. Ensuring confidentiality and right to privacy was something that was brought up during the PPI discussions. We addressed these concerns as far as we could, and all the tools that were available to us (which are provided by Facebook on how to protect a user's profile etc.), were provided to our participants. A step-by step manual with instructions on how to set a level of privacy, was pinned on the group wall, as well as shared in a printed format in a folder that was given out to all participants. In the Patient Information Sheet, we explained that once they join our group, the other participants will be able to see their name and only parts of their profile for which they have given permission to. All participants consented to this on the consent form as well as to trying to protect privacy of others by not sharing the group wall contents with anyone outside of the study. It is also important to mention that all participants who joined our group were already using Facebook and were therefore already familiar with our instructions. In conclusion

on this topic, we recognise that whilst the privacy and data protection is a concern, it is very unlikely that the public will stop using social media platforms because of the recent events published in the media. The impact of the scandal on Facebook usage is still unclear; however, we do not expect Facebook usage to fall but instead more regulations and awareness among users on how to protect their integrity and data on social media. Apart from ensuring that they use all the privacy setting tools, they may not share the same amount of information as previously. However, this is something that can only be investigated over time.

11.3 Implications for Clinical Practice

Currently in the UK, women who are pregnant and obese are not offered advice on physical activity. Based on our work, it is likely that women could benefit from specific advice on diet and physical activity for weight gain, and some maternal outcomes. Healthcare professionals should address this topic with women, as very limited advice is currently provided.

Discussions about appropriate diet and physical activity in pregnancy should incorporate specific advice on benefit for gestational weight gain, and the likelihood of preventing gestational diabetes. Mothers should be reassured about the safety of physical activity in pregnancy, by highlighting the benefits and lack of harm. Health professionals should receive more support and training so they are confident in how to deliver advice to women who are pregnant and obese. This may improve women's knowledge about benefits of PA in pregnancy and in turn improve health outcomes.

Reducing excessive GWG in pregnancy could lead to fewer complications during pregnancy and reduced costs. Therefore, implementing preventative measures has the potential to reduce the need for the current care pathway for women with a raised BMI, which is highly medicalised and focuses on complication management. A remote intervention delivery method could reduce the burden on health professionals (HPs). This research has informed that future strategies, such as remote intervention delivery could reduce excessive weight gain, support women and as a result reduce short and long- term weight related risks for mothers and their babies.

11.3.1 Implementation in the NHS

In this study, a PhD researcher implemented the feasibility study design, Fitbit set up and FB group moderation. The role of the moderator could be performed by HPs, lay members and maternity user representatives with appropriate training; this however requires further exploration. HPs feedback was overwhelmingly positive to the intervention design. Our findings from the process evaluation showed that HPs found our intervention to be a good idea. However, the implementation would place an additional demand on the staff and resources within the NHS. The potential resources and staff demand and their implications for service provision was one of the main concerns mentioned during the evaluation.

The taxonomy of implementation outcomes lists the following implementation outcomes, that are separate from clinical outcomes, that need to be considered: acceptability (to stakeholders/providers), adoption (uptake), appropriateness, feasibility, fidelity, implementation costs, penetration and sustainability (239). Implementation of the large trial intervention, assuming there is acceptability, adoption and appropriateness, will depend upon the complexity costs of the particular intervention, the implementation strategy used, and the location of service delivery. The implementation strategy in this case involves remote monitoring and delivery. This will require a trained moderator. The training of staff would involve approximately a three-hour session to provide training on moderation, safety online, and using Facebook. The moderator could be a maternity user representatives with appropriate training that could share already prepared information, to make it more cost-effective and lower the burden on HPs. The development and planning of the content would be done prior to the implementation so that the moderator could solely focus on moderating the group and sharing pre-planned content. The moderator could also be trained to monitor PA levels during pregnancy by checking compliance and PA on the Fitbit website. The monitoring of PA levels could be achieved with the support of participants themselves. Participants could be asked to show their achieved PA levels during the routine appointments. The moderation could be supported

by a grade 5 or 6 health visitor or a midwife, those days of the week when participants are told that a HP will be present to answer any questions.

The intervention design is taking into consideration the demand on time resources. For this reason, all data collection points are coinciding with routine appointments, to minimise the additional time resources that would be required to implement the intervention. Also, the mode of delivery is remote and does not require face-to-face meetings, which further reduces the burden on health service providers. As recruitment and implementation is proposed to be done over several sites, calculations for coordination of all sites and separate costing of resources for each site would have to be considered.

The future full-size trial needs to re-evaluate and consider how the implementation can best be adopted following the large trial, to better assess implementation cost, in the NHS.   A more hands-on experience of the day-to-day running of the intervention is necessary to fully evaluate the processes.

11.4 Implication for Policy

Whilst there were two camps regarding the levels of participation and engagement, where some needed more participation by other participants and some thought it was just enough, the one thing that all participants valued was being able to access information via FB that they knew was coming from a trustworthy source. This was reported as a primary benefit by all participants and there were no negative aspects reported of a) receiving information about benefits of PA in pregnancy or b) receiving the information via FB. Future policy making should consider creating more reliable information channels via social media, such as Facebook, as this is a widely used tool. Women perceived that having access to reliable and trustworthy information via their commonly used communication channel was efficient and valuable.

A study by Bernhart et al., (2004) found that many women seek social support on the web from other pregnant women or mothers, especially during their first pregnancy (240). A review by Sayakhot et al., (2016) confirmed this finding that women look for online social groups for information and social support (241). More specifically, a study which examined the confidence and decision-making

following internet-searching for information related to PA during pregnancy found that women felt more confident and ensured after reading others' experiences (242). Our findings indicate that women liked our FB group because they received information that they were confident was from a reliable and accurate source. What our findings suggest is that there is an unmet need for reliable online-based health information sources and support groups. For this reason, FB's potential to deliver health interventions, and social support, as well as its use in clinical practice, needs to be further explored.

During our interviews, we discovered that women search for reliable pregnancy-related information online, mentioning Netmums forum and Babysitters for example. This is similar to previous findings on the subject. A survey study published in 2011, by the Pew Institute showed that 80% of all adults look on the internet for health information. It found that 19% of health-related queries are pregnancy and childbirth-related (86).

The social networking site Facebook surpassed Google as the most visited site in the United States, according to the Internet analytics firm Experian Hitwise (243). Whilst maternal health provisions in the National Health Service in the UK give out information in the form of leaflets and post, limited information is provided online. For instance, several internet-based NHS sources such as *NHS Choices* and *Start for Life* are available. However, many women may not be aware of their existence. As use of Facebook in our target population is so prevalent (90-95%), it could be used as a platform and a venue to bring attention to NHS and other credible sources and stimulate pregnant women to use them. This is particularly relevant as studies have shown that patients often look beyond just one source for additional information, namely the internet and social media sources.

The most searched topics of interest among pregnant women are fetal development, nutrition in pregnancy, medications in pregnancy, pregnancy complication and antenatal care (244). This clearly demonstrates a need among women to have access to internet-based channels and sources of information. A study by Kofinas et al., (2014) compared giving contraception advice to women via FB versus pamphlets. The study found that those participants that received information via FB had a higher knowledge score (15 compared with 12, p<.001)

as well as higher percentage increase in the Contraceptive Knowledge Inventory score (36% compared with 12%, p<0.001). Also, participant satisfaction with counselling method was significantly higher in the Facebook group (median 10 compared with 6, p<.001) (134). What we found in our study, from all participants but in particular from the more quiet 'lurkers' is that they read and accessed all the information which we provided because they were particularly keen to have the knowledge.

In this study, we found that participants appreciated having what they perceived as 'constant access' to a HP (the FB moderator) especially as they felt that they do not get much time with HPs during face-to-face appointments. This may be one of the reasons that they otherwise seek more pregnancy-related information online. Previous studies have sought to identify reasons for alternative information source-seeking. They found that patients believe that doctors might not know the most recent medical breakthroughs (200) and due to a perception that HPs are not able to meet their emotional and informational needs (245). This finding crosses over with the subtheme of having access to HPs, which is what the participants perceived as a benefit and what they liked about the intervention. Despite the awareness of issues around authenticity and accuracy of information which patients access, HPs' use of social media in clinical care is still limited. Although a few in number, several studies have reported how using social media can in fact tackle the problem of misinformation. A study by Dhar et al., (2017) published data on HPs experiences of running a FB group for liver transplant patients. The group which had 350 members reported that 72% of members reported that the group had a very positive impact on their health and wellbeing. The most commonly reported themes on the group wall were supportive or inspirational content (33%) and the second most common themes were educational posts (19%). Although this was an American study, which operated at one secondary care site only, it showed positive experiences among patients and HPs (246). In future policy making, social media should be noted as an effective and widely reaching channel which can be used to provide accurate information to women who are pregnant.

11.5 Reflections on my PhD Journey

Undertaking this PhD project has been a most valuable learning experience. From the start, I immersed myself in the relevant literature and as a result improved skills such as systematic search techniques, critical analysis and appraisal of evidence. I found it particularly challenging but rewarding to think about intervention development using behaviour change theories as my background is in human biology and epidemiology and not in health psychology. As a researcher I found the science of behaviour change fascinating. I would like to explore this further, especially in intervention development and implementation science.

Reflecting on the process of intervention development, I believe that the decision to involve a Patient and Public Involvement (PPI) Reproductive Health group was pivotal. The details of how the group's feedback impacted on the development is summarised in chapter 8 of this thesis. My personal experience as a researcher was that these meetings better prepared me for the recruitment process because they gave me an idea of how the study might be perceived by my participants. In a future study, I would ensure that I have more PPI engagement in all aspects of the study development, and to consult with throughout the entire content development process.

In terms of recruitment, I became aware from the start that I was an external researcher and that I was not part of participants' usual care. To address this I made a conscious effect to work around HPs workloads and acknowledged the necessity to create and maintain a relationship with the HPs involved in the study. I made sure to maintain a good relationship in order to ensure HPs support of the intervention. I have learnt that creating a good relationship with clinicians that I was working with was vital for the success of the intervention. The most memorable moment was my first day on the maternity ward when I recruited my first participant.

Recruitment and moderation of the FB group was the part of the project that I enjoyed most. I have to acknowledge that my role as researcher may have impacted on the recruitment, retention and adherence of participants as it was me that introduced participants to the study, recruited them and met with them at

each of the data collection time points. Whilst I followed the same format and procedure for each of the participants at each of the time points, it is unavoidable that my personality influenced the recruitment process. Interviews were also conducted by me, with whom participants and health care professionals had met several times. This therefore may have made them more comfortable and relaxed in conversation. I believe this allowed a more honest and open conversation to occur, for example participants felt they were able to critique the FB group which aided the purpose of the interviews.

Data collection was at times challenging. Early on, I had to adjust my data collection methods to improve return rates for questionnaires. I enjoyed collecting and analysing empirical data. In doing so, my organisational skills, organising and managing large data sets, improved. I enjoyed and genuinely appreciated the contrasts that exist in a mixed-methods approach. I appreciated the experience of qualitative interviews with pregnant women and midwives to ascertain their views, attitudes and beliefs about the intervention. These provided a rich source of data which complimented the quantitative data collected in the first part of the trial. Using this methodology added, I believe, tremendously to the project findings.

I have to acknowledge how my role in the research may have impacted my analysis process and interpretation of the study. My background and my previous interests may have impacted on certain focuses within the study, for example being more interested in certain clinical outcomes such as GDM. Having a research background may have affected the way I analysed and interpreted findings. However, throughout the process I made a conscious effort to remain objective in my approach. I was involved in informing HPs about the study, to gain their support with recruitment, which may have influenced their views of the intervention. My particular interests may have impacted my interaction with clinicians and, in particular my choice of questions and what I chose to focus on during the interviews with the midwives. Throughout the process I tried to be as objective and impartial as possible. Overall, I have gained many useful and transferable skills which will be utilised in the future; these include project management skills, time management, and communication skills.

What has motivated me throughout this research is that I feel passionately about improving maternity health services. During my research, I have identified that the provision of support for women who are pregnant and obese is inadequate to help them achieve the best outcome for themselves and their babies. Although I have not personally struggled with obesity during pregnancy, I have used maternity services and experienced a lack of support in other areas. As a woman and a mother I would like to contribute to better experiences of all women and babies.

11.6 Final Conclusion

This feasibility RCT informed the suitability of the protocol design for a future full-size RCT within the National Health Service addressing issues such as effectiveness, time and risk. At the moment, to our knowledge, there is no support in place in the UK for women who are pregnant and obese at first booking appointment. Physical activity is recognised as a key factor in improving pregnancy health outcomes for women with a raised BMI. Therefore, robust and evidence-based interventions are needed in order to support behaviour change in women who are at high risk of complications in pregnancy. Furthermore, interventions that can reach widely at a low cost are needed. This research has ultimately informed future strategies to reduce short and long- term weight related risks for mothers and their offspring. The Walking in Pregnancy feasibility study used a novel approach, evaluating the practicality of using social media, and remote activity trackers to support pregnant women with raised BMI. It has provided evidence on practicalities of intervention delivery to manage maternal obesity within UK's National Health Services. Our findings were that the intervention was acceptable and feasible to participants. This intervention has informed the development of a protocol for a large RCT (see Appendix K). If proven effective, this intervention has the potential to reach widely at a low cost.

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Appendices

Sheffield Hallam University

Participant information sheet

Study title:	Walking in Pregnancy
Lead Investigator	Michaela Senek
Telephone number	07788661390

Study Sponsor: Sheffield Hallam University

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

This study is has been approved by the

Participant name:

You will be given a copy of this information sheet to keep

1. What is the purpose of this study?

The purpose of this study is to find out more about possible benefits of physical activity and walking during pregnancy. Previous studies are not very clear about the full benefits of walking during pregnancy.

2. Why have I been invited?

You have been invited because you are pregnant and your body mass index (BMI: weight/height^2) is ≥30kg/m^2.

3. Do I have to take part?

Your decision to take part in this study is entirely voluntary. You may decide not to participate or you can withdraw from the study at any time. Taking part or deciding to withdraw from this study will not affect the standard care that you receive.

4. What will happen to me if I take part?

You will be approached by Michaela Senek (a Sheffield Hallam University researcher). She will talk you through the project, answer any relevant questions, and if you are happy she will ask you to sign a consent form. She will then allocate you randomly to one of the two groups: to use the Facebook + Fitbit® (a step counting device worn like a wrist watch), or the Fitbit® by
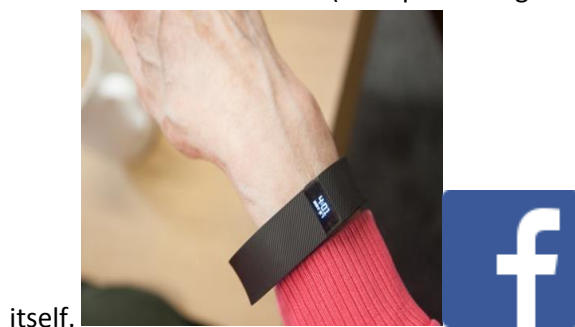
itself.

If you are allocated to the Facebook + Fitbit®(50% chance): You will be given a Fitbit® and invited to the closed Facebook group. You will be shown how to use them. The Fitbit® is worn on your wrist like a watch, and records information such as your step count. The Fitbit® automatically sends your step count to a Fitbit website for which a log in for your Fitbit device has already been created. You will also be given a detailed instruction booklet, and contact details for the research team if there are any problems or if you have any questions at any stage. You will be asked to use the Facebook and Fitbit® throughout. Very soon after receiving the Facebook you will receive messages on what goals you should set etc. A closed Facebook group means that only the administrator and creator of the group (in this case the researcher) can invite and allow members to join the group. This means also that only

members will be able to see the contents of the closed group. The group is also secret which means that even if it is searched by name it will not come up in a search in Facebook search engine either on Facebook or Google. The purpose will be for you to support each other through the Facebook and achieve your walking goals. We ask that you check the Facebook every day and that you engage and comment on our posts. We also ask that you put the Fitbit® on each day when you get up for 5 weeks in total. The study team will continue to be available for questions relating to your health and your condition throughout your time on the study, and you should seek medical advice if you feel unwell. Facebook comments may be used as research data.

If you are allocated to the Fitbit® on its own (50% chance): You will be given a Fitbit® which has been 'blinded'. This means there will be strong black tape over the display so that you will not be able to see your step count. You will be given instructions, and contact details for the research team if there are any problems or if you have any questions at any stage. You will be asked to wear the Fitbit® throughout for 5 weeks. We ask that each day you put the Fitbit® on when you get up. The study team will continue to be available for questions relating to your health and your condition throughout your time on the study, and you should seek medical advice if you feel unwell.

All: When you start the study, at the end of 5 weeks, your physical activity capacity will be assessed. This will be done by Michaela Senek. You will also be asked by Michaela Senek to complete some questionnaires which ask about various aspects of your health, activities, and about your experiences with taking part in the study. The smartphone/PC and Fitbits® automatically record information about how they have been used. The research team will look at this information to work out how the technology is being used, whether any parts of it improve health outcomes or if it may be causing difficulties. However this will not be used to spy on you or reprimand you, and we will not have any knowledge of where you have been or what activities you have been doing. The app and Fitbit® do not have cameras and do not audio-record their surroundings.

If you decide to take part in the study, we would also like to collect information about your pregnancy health outcomes from your medical notes. The information that we would look at is your weight, Gestational Diabetes Mellitus, preeclampsia, Mode of Birth, Birthweight, Apgar score and Admission to neonatal special unit status.

TIPS: We recommend that you put on the Fitbit as part of your normal routine, like you might a watch e.g. putting it on when you get up in the morning. If you would like the research team to provide prompts to remember to do this then, please let them know. If you forget to wear the Fitbit® then please write this down so that you can let the research team know.

At the end of your time on the project, we will ask you to take part in an audio-recorded discussion (focus group), for up to one hour, to discuss your experiences of taking part in the study. We are interested in your views on how well this has gone, likes, dislikes and any problems will be explored. The venue for the focus groups will be at Sheffield Hallam University. Focus Group discussions may be transcribed by an external company which follow strict rules of keeping confidentiality.

When the project is finished, you will need to return the Fitbit® to Michaela Senek. If the Fitbit® become lost or damaged then please let Michaela Senek know as soon as possible.

5. Expenses and payments

No payment will be given to you for taking part in the main study. However your travelling expenses for the focus group will be covered.

The Fitbit gadget is owned by Sheffield Hallam University. The Fitbit device will be lent to you for the purpose of this study and you will be expected to return in to the researcher at the end of the study. You will be given several options to choose your preferred location of convenience to return the Fitbits.

6. What are the possible disadvantages of taking part?

We do not anticipate any health risks of taking part in this trial for you or your baby. However, if you experienced any inconvenience or health issues, please do inform the research team and contact your health professionals.

Although there are no significant risks of harm as such, if for some reason you cannot take part in the study due to illness, fatigue or other pregnancy complications you should always stop. This study is not expected to present risks to your pregnancy. If you experience any of the signs listed below you should stop the walking and contact your medical practitioner if you have further concerns or symptoms.

- Painful contractions

- Bleeding

- Amniotic fluid leakage

- Dizziness

- Chest/Calf Pain

7. What are the possible benefits of taking part?

This study aims to explore the acceptability of a walking program during pregnancy. Although some of you may benefit from this study, it is hoped that the results of this study will help to inform a larger study to assess the full effects of walking during pregnancy which will benefit other pregnant women in the future.

8. What if there is a problem or I want to complain?

If you have any queries or questions please contact:

Michaela Senek
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Royal Hallamshire Hospital
Secretary: Dawn Grayson 0114 2268568

If you would rather contact an independent organisation, you can do this through the usual Hallamshire Hospital procedures by contacting Patient Service Team (PST) . The Patient ST can be contacted, Monday to Friday 9am till 5pm, through the following ways:

Telephone: 01142712400.

Email: PST@sth.nhs.uk.

In person: the Patient Partnership Department on B Floor, Royal Hallamshire Hospital

9. Will my taking part in this study be kept confidential?

All reasonable steps will be taken to ensure your confidentiality. A separate rules agreement will be signed by those participants that are allocated to the Closed Facebook group part of the intervention to ensure confidentiality.
The study data collection forms will only contain the study ID number assigned to you. These will be kept in secure storage. The data will also be put into computer packages. This will contain your study ID number and will be deposited in a safe data file on the university computer. Should you wish to take part in the focus group this will be recorded and then

written up word-for-word. The transcript will be kept on a computer. All computers used as part of this study will be password protected.

Written transcripts and data files will have all links to you removed at the end of the study and will then be kept for as long as they might be useful in future research. Identifying details will be taken out of any final report and any publication so people reading these will not be able to identify you.

All study documents relating to the administration of this research, such as the consent form you sign to take part, will be kept in a folder called a site file or project file. This is locked away securely. The folder might be checked by people in authority who want to make sure that researchers are following the correct procedures. These people will not pass on your details to anyone else.

If you are asked to join the Closed Facebook group, the other group members of the closed Facebook group participants will see your name on Facebook. However, the members will not be able to see your Facebook profile contents as long as you have your privacy settings on.

The Walking and Pregnancy Facebook group will be closed and secret. The Facebook group members will only be those that have been recruited to take part in this study. As long as you have your privacy settings on, the group members will not have access to your Facebook profile. You can withdraw from the group by exiting the group on Facebook and letting the researcher know that you no longer wish to take part in the study. You can also delete your comments which you made on the Facebook group page.

When you wear the Fitbit device, a researcher will be able to see online on the Fitbit page how many steps you are taking daily, the total distance walked and an approximate number of calories that you have used to do so. They will not be able to see your location or any other information.

If any issues were raised throughout the study, the researcher will consult with her university research support office to be then discussed with the mangers and relevant health care professionals in the maternity unit to take an appropriate action in accordance with their professional Code of Conduct.

We will inform maternity health care professionals about conducting this research project in this hospital.

10. What will happen to the results of the research study?

The results from this study will be used to inform a future physical activity intervention for pregnant women. The results will be presented locally to the Maternal and Infant Health Research Group, as well as being written up for publication in peer reviewed journals and presented at conferences. Data will be kept for future research.

11. Who is sponsoring the study?

The sponsor of the study has the duty to ensure that it runs properly and that it is insured. This study's sponsor is Sheffield Hallam University.

12. Who has reviewed this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. North of Scotland Research Ethics Committee has reviewed this study.

13. Will I get to know the results of the study?

Yes, the results of the study when published will be available and can be posted out to you, if you wish. If you were interested to know about the results before publication we can provide a summary of the results for you as well. You can obtain these results by contacting Michaela Senek.

14. Further information and contact details

If you have any queries or would like to have more information, please contact:

Michaela Senek
Phd Researcher
Faculty of Health and Wellbeing
Centre for Health and Social Care Research
Sheffield Hallam University
Chestnut Court
Collegiate Crescent
Sheffield
S10 2BP
Telephone: 07788661390
email:m.senek@shu.ac.uk

Hora Soltani
Professor (Director of Studies)
Centre for Health and Social Care Research,
Sheffield Hallam University, Montgomery House,
32 Collegiate Crescent, Collegiate Campus, Sheffield, S10 2BP
Telephone: 0114 225 5444
email: h.soltani@shu.ac.uk

If you have queries/complaints please contact:

Patient Service Team (PST)

The Patient Services Team can be contacted Monday to Friday 9am till 5pm. The team can be contacted in the following ways:

-Telephone on 01142712400

-Via email on PST@sth.nhs.uk

-In person in the Patient Partnership Department on B Floor, Royal Hallamshire Hospital

Appendix B. Data Management Plan

Project Name Walking in Pregnancy (SHU Template)
Principal Investigator / Researcher Michaela Senek
Description Research Question The ultimate question is "what are the effects of
physical activity intervention for obese pregnant women"? This is focused on "Would a walking based intervention during pregnancy be feasible, practical and acceptable by obese pregnant women." Aim The aim of this project is to examine the feasibility of a physical activity (PA) intervention in the form of walking in combination with a closed online-based group forum on pregnancy outcomes in obese pregnant women. Objectives will be to: 1. Develop an intervention consisting of walking and social networking 2. Explore acceptability of the intervention by women 3. Assess recruitment, retention and compliance 4. Explore practicality of collecting relevant outcome data Methods This is a mixed methods feasibility study comprising of a quantitative component including a feasibility randomised control trial and a qualitative component using focus group interviews. Feasibility Study Design Quantitative component A sample of 60 obese pregnant women (30 women in each arm) at 12 weeks gestation will be recruited through Jessop maternity ward. Participants will be allocated in to one of the two groups: control (usual care) or the intervention group. The walking intervention will consist of individualized step targets based on baseline
measurement. The method of supporting the delivery of intervention will be a closed online-based Facebook group forum. This social support will be given to the intervention group only. The study will commence at 20 weeks gestation for a total length of 5 weeks. Inclusion Criteria All women aged 18 years and above with a BMI ≥30kg/m2 with a singleton pregnancy and no other known clinical
complications will be included in the study. Exclusion Criteria: Any participant who is under 18 years of age. Any participant with pelvic girdle pain, pregnancy induced hypertension, or previous history of hypertension. Setting: Obesity Clinic. Jessop ward, Royal Hallamshire Hospital. Facebook Page Content A Facebook group will be created containing general information about the benefits of walking and the intervention target (target steps per day). The intervention is drawing on goal setting (increasing total number of steps per day) and social support that have been identified as behaviour change techniques. The closed Facebook group will give women an opportunity to communicate and network with participants that are at

similar gestational stage. It is anticipated that the social nature of the intervention will enhance women's motivation by offering support and encouragement.

Institution Sheffield Hallam University

Data Collection

What data will you collect or create?

Physical Activity Data (pedometer recordings of daily step counts, Excel format

PPAQ (Pregnancy Physical Activity Questionnaire) Anonymised Facebook Closed Group comments Focus Group discussions data (audio files/transcripts)

Pregnancy Outcomes data (BMI, gestational diabetes mellitus, preeclampsia, APGAR score, Birthweight, Admission to neonatal special unit.

How will the data be collected or created?

Physical Activity data will be collected with a pedometer (participants will be asked to wear a pedometer) Physical Activity data will be collected in Excel spreadsheets with Participant allocated numbers. Facebook Closed group comments will be collected by the moderator and anonymised.

Pregnancy Outcomes data will be accessed from patient notes.

Focus group discussion data will be recorded with a voice recorder and transcribed.

Documentation and metadata

What documentation and metadata will accompany the data?

Methodology and protocol will accompany the data to make it more accessible and understandable to external reserachers so that they can make sense of the data. Everything will be sufficiently labeled for others to understand the data.

Ethics and Legal Compliance

How will you manage any ethical issues?

Information sheets and consent forms will be used to ensure that informed consent is gained that allows for the preservenation and sharing of the anonymised data. No patient identifiable data will be disseminated.

The study data collection forms will only contain the study ID number assigned to

each participant. These will be kept in secure storage. The data will also be put

into computer packages. This will contain the study ID number and will be deposited in a safe data file on the university computer. Should the participants

wish to take part in the focus group this will be recorded and then written up word-for-word. The transcript will be kept on a computer. All computers used as

part of this study will be password protected.

The data will be stored in Research Store Q:\Research drive which is the safe

and secure storage of 'live' research data

How will you manage copyright and Intellectual Property Rights (IPR) issues?

SHU will own the primary data that it collects, but the secondary data (information from participants' patient notes about pregnancy health outcomes) will be owned by Sheffield Teaching Hospitals.

Patients will be told that this information will be collected from their patient notes. They will need to consent for this.

Storage and Backup

How will the data be stored and backed up during the research?

All study documents relating to the administration of this research, such as the consent form will be kept in a folder called a site file or project file. This will be stored in a locked cabinet to meet the requirements of the Data Protection Act. The NHS Code of Confidentiality will be followed.

All primary data will be stored in the Research Store (Q:\Research) drive.

How will you manage access and security?

The study data collection forms will only contain the study ID number assigned to
each participant. These will be kept in secure storage. The data will also be put
into computer packages. This will contain the study ID number and will be deposited in a safe data file on the university computer. Should the participants
wish to take part in the focus group this will be recorded and then written up word-for-word. The transcript will be kept on a computer. All computers used as
part of this study will be password protected.

For the part of the research process that will be happening through social media, there will be a closed, secret Facebook group that is created for the purpose of the research study. Only the moderator will have access to the log in and password to this closed group. Data that is collected from the Closed Facebook group will be anonymised prior to data analysis.

Selection and Preservation

What data are of long-term value and should be retained, shared, and / or
preserved?

Anonymised data will be archived and made available for use in other research.

All data (raw and analysed) will be deposited in the University's Research Data
(SHURDA) before the end of the research project. The data will be retained in the
archive for a period of 10 years since the last time any third party has requested
access to the data. When depositing the data, no further changes to data formatting will be required as all necessary actions will have been conducted as the research progresses.

What is the long-term preservation plan for the dataset?

Some 'raw' data (with appropriate documentation), and the analysed data will be made available to legitimate researchers or practitioners -
Transcription of focus group discussions will not be made available.

Data Sharing

How will you share the data?

A data sharing agreement with re-users of the data will not be required, as the raw anonymized data and the data collection methodologies will be made available on a. Creative Commons with Attribution (CC-BY) or equivalent license. The only exclusion from this raw data to be shared will be the secondary data that is owned by Hallamshire Hospital Trust, audio from the focus groups, given the potential of voice recognition, thus threatening pledges of anonymity of data, which has been given to all contributors to the research. While a robust approach to ensuring consent is received from all respondents in the study to allow raw data to be shared, should some respondents refuse permission, these data will be removed before depositing the data in the SHU Research Data Archive (SHURDA).

Are any restrictions on data sharing required?
Data that contains any participant identifiable information will not be shared.

Responsibility and Resources

Who will be responsible for data management?
First researcher (Phd student) will be responsible for data management. Same person will be responsible for implementing DMP. Director of Studies and Supervisory team will share some responsiblity in data management. Researcher will be responsible for all activities. Consultant and Registrat or site will assist with Patient Identification part of the project
but everything else will be the responsibility of the researcher (Phd student).

What resources will you require to deliver your plan?
No additional resources than the ones that I have now will be required to deliver my plan.

Appendix C. SHU Social Media Guidance in Research

Research Ethics Guidelines for Internet-mediated Research

Internet-mediated research is defined as "any research involving the remote acquisition of data from or about human participants using the internet and its associated technologies" (British Psychological Society, 2013). This may involve a range of methodologies.

Participants may come from a range of countries with different legal systems so care is required (e.g. see guidelines on research with North American participants).

Particular Ethical Issues:

1. The **distinction between public and private spaces**

In face-to -face research studies, participant observation can only occur without specific permission from the individual being observed if it is occurring in a public space, i.e. somewhere where you might expect to be observed. Opinions differ about whether posts to online spaces are public or private.

Legally, the copyright for personal webpages remains with the author or the hosting company. This is also true of other material such as that on social network sites so multiple permissions may be necessary.

Good practice guidelines:

i. If possible seek advice/ permission to access from group moderator or site host. As a minimum be able to demonstrate that attempts have been made.

ii. If there is some uncertainty whether it is a public domain, researchers should consider the nature of the material and whether disclosure would potentially be damaging for participants and if consent is really required, bearing in mind the requirement to protect research participants which is paramount.

iii. **Online questionnaires** are required to supply information about the study before participants undertake it (information sheet equivalent) and how consent is to be obtained. It can be stipulated in anonymous questionnaires that withdrawal is not possible and at the very least, the questionnaire should stipulate that pressing the submit button will be taken as providing informed consent. However, it is considered good practice to include a tick box to obtain informed consent in the questionnaire for participants to complete. Participants need to be told that if they elect to withdraw from the research they simply log off the site and their data will not be kept and that withdrawal after submission is not possible with data collected anonymously.

iv. **Qualitative Studies** using data collected from online sources. While all research participants must be informed about how data will be stored and their anonymity protected this presents particular issues in qualitative studies. For example by using search engines, individuals can take quotes from published journal articles, conference presentations and locate the discussion forum archives they came from and this may make it possible to identify individuals. Researchers need to assess whether this exposes the research participants to additional threats to their privacy or potential harm. Risks must always be weighed against benefits.

v.   Researchers must pay particular attention to the **anonymisation of qualitative data** obtained from online sources. Paraphrasing of verbatim quotes is often recommended for example. This is even more crucial if consent for the use of the data has not been obtained from the individual. While it is unlikely that individuals would ever know that their online posts had been used as research data, should they discover it, they have legal rights under the Data Protection Act if the data can be linked to them personally via search engines for example. They can ask for their personal data to be withdrawn.

vi.   **Issues relating to data quality** due to the lower levels of control that are possible compared to those in face-to-face studies**.** With internet studies, it can be difficult to

be certain who has accessed studies, the conditions under which the data was provided, and how they felt about doing it. Sometimes in experimental manipulations, differences in software or hardware may affect the data collected. Where precision in measurement is required, such as in perceptual studies, care must be taken to assure that appropriate levels of control are possible or the resulting data may be invalid.

vii.   Researchers need to be aware of their **social responsibility** when undertaking research so that they actions as researchers do not negatively impact on others. This may require thinking about the outcomes of the research and any consequences it may have for others. For example, a researcher deciding to join a special interest group without disclosing that they are a researcher may impact negatively on the current group dynamics and once the research is published, it could affect future group membership as the group will no longer be seen as a 'confidential' space. There have been examples of this with eating disorders and other specialist support groups.

Balancing the benefits of the research against the risks is always essential. In studies deemed to have a level of ethical risk such as those on sensitive topics and/or using vulnerable populations, the decision may be that an internet-mediated study is not appropriate.

The Ethics Guidelines for Internet-mediated Research produced by the British Psychological Society (2013) were consulted in producing this guidance. These are available at:
http://www.bps.org.uk/system/files/Public%20files/inf206-guidelines-for-internet-mediated-research.pdf

1. I intend to walk every day during my pregnancy

Definitely do 1 2 3 4 5 6 7 Definitely do not

2. I will make an effort to walk every day during my pregnancy.

Definitely false 1 2 3 4 5 6 7 Definitely true

3. I am confident that I can walk every day during my pregnancy

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

4. For me to walk every day during my pregnancy will be.

Very easy 1 2 3 4 5 6 7 Very difficult

5. Walking every day in pregnancy is healthy for me and my baby

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

6. Walking every day in pregnancy can help me gain the strength and stamina that I need for labour.
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

7. Walking every day in pregnancy might make me more tired.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

8. It is good to spend as much time as possible in pregnancy resting.
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Pregnancy Physical Activity Questionnaire

Instructions:

Please use an ordinary No. 2 pencil. *Fill in the circles completely. The Question will be read by a machine so if you need to change your answer, erase the incorrect mark* ***completely****. If you have comments, please write them on the back of the questionnaire.*

Example: During this trimester, when you are NOT at work, how much time do you usually spend:

E1. **Taking care of an older adult**

If you take care of your

mom for 2 hours each →

day, then your answer

should look like this...

None

Less than 1/2 hour per day

1/2 to almost 1 hour per day

1 to almost 2 hours per day

○
○ 2 to almost 3 hours per
○ day

○ 3 or more hours per
● day
○

It is very important you tell us about yourself honestly. There are no right or wrong answers. We just want to know about the things you are doing during this trimester.

1. Today's Date:

| | | / | | | / | | | | |
Month   Day   Year

2. What was the first day of your last period?

| | | / | | | / | | | | |
Month   Day   Year

○ I don't know

3. When is your baby due?

| | | / | | | / | | | | |
Month   Day   Year

○ I don't know

___

During this trimester, when you are NOT at work, how much time do you usually spend:

4. Preparing meals (cook, set table, wash dishes)

None

Less than 1/2 hour per day

1/2 to almost 1 hour per day

1 to almost 2 hours per day

○
○ 2 to almost 3 hours per day

○ 3 or more hours per day
○
○
○

5. Dressing, bathing, feeding children while you are <u>sitting</u>

None

Less than 1/2 hour per day

1/2 to almost 1 hour per day

1 to almost 2 hours per day

○
○ 2 to almost 3 hours per day

○ 3 or more hours per day
○
○
○

Page 1

During this trimester, when you are NOT at work, how much time do you usually spend:

6. **Dressing, bathing, feeding children while you are standing**

- None
- Less than 1/2 hour per day
- 1/2 to almost 1 hour per day
- 1 to almost 2 hours per day
- 2 to almost 3 hours per day
- 3 or more hours per day

7. **Playing with children while you are sitting or standing**

- None
- Less than 1/2 hour per day
- 1/2 to almost 1 hour per day
- 1 to almost 2 hours per day
- 2 to almost 3 hours per day
- 3 or more hours per day

8. **Playing with children while you are walking or running**

- None
- Less than 1/2 hour per day
- 1/2 to almost 1 hour per day
- 1 to almost 2 hours per day
- 2 to almost 3 hours per day
- 3 or more hours per day

9. **Carrying children**

- None
- Less than 1/2 hour per day
- 1/2 to almost 1 hour per day
- 1 to almost 2 hours per day
- 2 to almost 3 hours per day
- 3 or more hours per day

10. **Taking care of an older adult**

- None
- Less than 1/2 hour per day
- 1/2 to almost 1 hour per day
- 1 to almost 2 hours per day
- 2 to almost 3 hours per day
- 3 or more hours per day

11. **Sitting and using a computer or writing, while not at work**

- None
- Less than 1/2 hour per day
- 1/2 to almost 1 hour per day
- 1 to almost 2 hours per day
- 2 to almost 3 hours per day
- 3 or more hours per day

12. Watching TV or a video

○
○
○ None
○
○ Less than 1/2 hour per
○ day

1/2 to almost 2 hours per
day

○ 2 to almost 4 hours per
○ day

○ 4 to almost 6 hours per
○ day

○
○ 6 or more hours per day

13. Sitting and reading, talking,

or on the phone, while not
○
at work

○ None
○

○ Less than 1/2 hour per
○ day

1/2 to almost 2 hours
per day

○ 2 to almost 4 hours per
○ day

○ 4 to almost 6 hours per
○ day

○
○ 6 or more hours per day

14. Playing with pets

None

Less than 1/2 hour per
day

1/2 to almost 1 hour per
day

○ 1 to almost 2 hours per
○ day

○ 2 to almost 3 hours per
○ day

○ 3 or more hours per day
○

15. Light cleaning (make beds,

laundry, iron, put things

○
away)

○ None
○

○ Less than 1/2 hour per
○ day

1/2 to almost 1 hour per
day

○ 1 to almost 2 hours per
○ day

○ 2 to almost 3 hours per
○ day

○ 3 or more hours per day
○

16. Shopping (for food,

clothes, or other items)

○
○
○ None
○

○ Less than 1/2 hour per
○ day

1/2 to almost 1 hour per
day

○ 1 to almost 2 hours per
○ day

○ 2 to almost 3 hours per
○ day

○ 3 or more hours per day
○

During this trimester, when you are NOT at work, how much time do you usually spend:

17. Heavier cleaning (vacuum, mop, sweep, wash windows)

○ None
○ Less than 1/2 hour per week
○ 1/2 to almost 1 hour per week
○ 1 to almost 2 hours per week
○ 2 to almost 3 hours per week
○ 3 or more hours per week

18. Mowing lawn while on a riding mower

○ None
○ Less than 1/2 hour per week
○ 1/2 to almost 1 hour per week
○ 1 to almost 2 hours per week
○ 2 to almost 3 hours per week
○ 3 or more hours per week

19. Mowing lawn using a walking mower, raking, gardening

○ None
○ Less than 1/2 hour per week
○ 1/2 to almost 1 hour per week
○ 1 to almost 2 hours per week
○ 2 to almost 3 hours per week
○ 3 or more hours per week

Going Places...

During this trimester, how much time do you usually spend:

20. Walking <u>slowly</u> to go places (such as to the bus, work, visiting)

***Not* for fun or exercise**

None
Less than 1/2 hour per day
1/2 to almost 1 hour per day

21. Walking quickly to go places (such as to the bus, work, or school)

***Not* for fun or exercise**

None
Less than 1/2 hour per day
1/2 to almost 1 hour per day

22. Driving or riding in a car or bus

None
Less than 1/2 hour per day
1/2 to almost 1 hour per day

○ 1 to almost 2 hours per day	○ 1 to almost 2 hours per day	○ 1 to almost 2 hours per day
○ 2 to almost 3 hours per day	○ 2 to almost 3 hours per day	○ 2 to almost 3 hours per day
○ 3 or more hours per day	○ 3 or more hours per day	○ 3 or more hours per day

---

For Fun or Exercise...

During this trimester, how much time do you usually spend:

i) **Walking <u>slowly</u> for fun or exercise**	i) **Walking <u>more quickly</u> for fun or exercise**	i) **Walking <u>quickly up hills</u> for fun or exercise**
None	None	None
Less than 1/2 hour per week	Less than 1/2 hour per week	Less than 1/2 hour per week
1/2 to almost 1 hour per week	1/2 to almost 1 hour per week	1/2 to almost 1 hour per week
○ 1 to almost 2 hours per week	1 to almost 2 hours per week	1 to almost 2 hours per week
○ 2 to almost 3 hours per week	○ 2 to almost 3 hours per week	○ 2 to almost 3 hours per week
○ 3 or more hours per week	○ 3 or more hours per week	○ 3 or more hours per week

Page 3

During this trimester, how much time do you usually spend:

26. Jogging

- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

27. Prenatal exercise class

- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

28. Swimming

- ○ None
- ○ Less than 1/2 hour
- ○ 1/2 to almost 1 hour
- ○ 1 to almost 2 hours
- ○ 2 to almost 3 hours
- ○ 3 or more hours per

29. Dancing

- ○ None
- ○ Less than 1/2 hour per week
- ○ 1/2 to almost 1 hour per week
- ○ 1 to almost 2 hours per week
- ○ 2 to almost 3 hours per week
- ○ 3 or more hours per week

Doing other things for fun or exercise? Please tell us what they are.

30. _____
Name of Activity

- None
- Less than 1/2 hour per week
- 1/2 to almost 1 hour per week
- 1 to almost 2 hours per week
- 2 to almost 3 hours per week

31. _____
Name of Activity

- None
- Less than 1/2 hour per week
- 1/2 to almost 1 hour per week
- 1 to almost 2 hours per week
- 2 to almost 3 hours per week

○
○
○

○
○
○
○

During this trimester, how much time do you usually spend:

vi) **Sitting at working or in class**

○ None

○ Less than 1/2 hours per day

○ 1/2 to almost 2 hours per day

○ 2 to almost 4 hours per day

○ 4 to almost 6 hours per day
○ 6 or more hours per day

i) **Standing or slowly walking at work while carrying things (heavier than a 1 gallon milk jug)**

○ None

○ Less than 1/2 hour per day

○ 1/2 to almost 2 hours per day

○ 2 to almost 4 hours per day

○ 4 to almost 6 hours per day
○ 6 or more hours per day

i) **Standing or <u>slowly</u> walking at work <u>not</u> carrying anything**

○ None

○ Less than 1/2 hours per day

○ 1/2 to almost 2 hours per day

○ 2 to almost 4 hours per day

○ 4 to almost 6 hours per day
○ 6 or more hours per day

xi) **Walking <u>quickly</u> at work while <u>carrying</u> things (heavier than a 1 gallon milk jug)**

○ None

○ Less than 1/2 hour per day per day

○ 1/2 to almost 2 hours per day hours per day

○ 2 to almost 4 hours per day per day

○ 4 to almost 6 hours per day per day

○ 6 or more hours per day day

i) **Walking <u>quickly</u> at work <u>not</u> carrying anything**

○ None

○ Less than 1/2 hour

○ 1/2 to almost 2

○ 2 to almost 4 hours

○ 4 to almost 6 hours

○ 6 or more hours per

Thank

Yo

North of Scotland Research Ethics Committee

Summerfield House

2 Eday Road

Aberdeen

AB15 6RE

NHS

Grampian

Telephone: 01224 558458

Facsimile: 01224 558609

Email: nosres@nhs.net

Please note: This is the favourable opinion of the REC only and does not allow

you to start your study at NHS sites in England until you receive HRA Approval

---

17 June 2016
Mrs Michaela Senek
Chestnut Court
Collegiate Crescent Sheffield Hallam University
SHEFFIELD
S10 BP
Dear Mrs Senek

Study title:	**Walking in Pregnancy - a social networking physical activity intervention for pregnant obese women**
REC reference:	**16/NS/0061**
IRAS project ID:	**202040**

Thank you for your letter of 14 June 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Ms Sarah Lorick, nosres@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

<u>Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.</u>

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/NS/0061 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Professor Nigel Webster

Chair

Walking in Pregnancy

The panel had been sent copies of the following before the meeting to read and consider:
- Lay Summary
- Fitbit Gadget video + Facebook content
- Consent Form
- Participant Information Sheet

Michaela gave the panel some context to the study, explaining that the object of this research is to encourage over weight pregnant women to exercise by walking more. To measure the benefits to the women from the outcomes of the feasibility study, using the participants as a focus group that will be monitored to see if they have experienced any lifestyle benefit.

The participants recruited will all have a BMI of 30 plus. Each participant will be interviewed, lent a Fitbit pedometer; this can be linked to a smart phone or PC for the participant to monitor and set goals and targets on. It can also be remotely monitored by the research team; that will also have a set of graphs that show how the individual is progressing by how many steps they have taken, if they have used the stairs or have been hill walking.

The study also promotes the use of a private, closed Facebook group account. This will be a forum where the participants can blog their progress and encourage each other, and interact with the research team.

The panel were concerned that the Facebook account might not be secure. They recommended the use of a secure log in and password to access the account. The panel sought reassurance that the consent form and Patient Information documents held a confidentiality clause that advised the participants of the importance of guarding the personal information (including the names) of their fellow participants who will be using the Facebook account. This information should not be divulged outside of the study. The panel recommended that section 7 of the consent form is changed to reflect the understanding of the consequences of a breach of confidentiality. The patient information sheet should advise the participants to always do their utmost to keep the Facebook account secure, for example close the account after use, only to use the Facebook account if they are sure that it cannot be seen or read by other non-participants. It was established that other studies and initiatives use this forma of interaction, such as the smoking cessation group. The panel felt that these (especially local studies) would be helpful to list for the Ethics application.

The panel were shown the Fitbit device which is like a watch and is warn on the wrist. They were also shown the Facebook page on a laptop.

The program will start when the participant has been seen after their first scan, at approximately thirteen weeks. They will also be given help or instructions on joining the Facebook group at that time, for help and support. The participant members would be able to see each other's names and posted messages. It is hoped that they would gain social support and encourage each other.

It was explained that the programme would last for five weeks, on receipt of the Fitbit device, the first week would be monitoring normal movement behaviour, and the participant would then be given an individualised program that increases their walking capacity to achieve a specific goal or target.

The randomised control group would have a barrier tape on the back of the device; this would prevent them from monitoring how many steps they are taking.
It is unsure if recruitment would be a problem, a women's weight can be a sensitive subject. The panel felt that pregnancy could be a motivator for women to address her mobility and lifestyle habits. It was noted that some women might take offence to being broached for this study.

The panel were informed that the consultant who will be assisting in the recruitment does hold a regular obesity clinic.

Lay Summary

Being Overweight and obese during pregnancy is becoming more common in pregnancy. Approximately 25-30% of women of child bearing age are obese and around 50% are overweight at the time of conception. Women who are either overweight or obese have a much higher risk of adverse pregnancy outcomes. For example they are more likely to develop gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, caesarean section and other complications. Recent research suggests that overweight and obese pregnant women are less active than normal weight women and also that the level of physical activity decreases throughout pregnancy. The evidence also suggests that maintaining a good level of physical activity can reduce the risks of adverse pregnancy outcomes. A large study which looked at the most preferred types of physical activity identified that walking and swimming were the most popular types of physical activity by pregnant women. The current feasibility study will investigate whether a Fitbit Pedometer and a Social networking Site (Facebook) can be used to encourage pregnant, obese women to increase and maintain activity during pregnancy.

The purpose of this study is to find out more about possible benefits of physical activity and walking during pregnancy. Previous studies are not very clear about the full benefits of walking during pregnancy.

We will be working with an Obstetrics & Gynaecology consultant at Jessop Wing, Hallamshire Hospital to help with the recruitment process and provide clinical advice. Participants that consent to take part in the study will be given a Fitbit pedometer and enrolled in a closed Facebook group. Each participant will wear a Fitbit for a week in order to measure their baseline physical activity level. Thereafter, the participants will be asked to gradually increase their physical activity level (they will be given a weekly step target). The Facebook component of the intervention will contain motivational and educational posts and rewarding messages about their progress. The feasibility study will test the recruitment strategy, acceptability of the intervention design, randomisation acceptability, and timing of the intervention. Participants from both the control and the intervention will be purposefully selected to take part in focus group following the intervention in order to give feedback on the study.

Fitbit Gadget video + Facebook content

The panel advised that the "wiplady" gmail address is changed to "wap" "Walking and Pregnancy" as it could cause problems when logging into a PC.

They advised having a disclaimer paragraph, along the lines of a sports therapy disclaimer that clearly hands the responsibility onto the participant if they ignore any warning symptoms during the study.

Consent Form

As previously noted:

The panel recommended that section 7 of the consent form is changed to reflect the understanding of the consequences of a breach of confidentiality. The patient information sheet should advise the participants to always do their utmost to keep the Facebook account secure, for example close the account after use, only to use the Facebook account if they are sure that it cannot be seen or read by other non-participants.

The panel suggested the following wording:

I understand that my name will be seen by other people on the Facebook Group

Participant Information Sheet

The panel felt that this document read very well, they recommended the following:

- Add disclaimer that clearly lists, when to stop activity and what symptoms to look for that would need advice on when further consultation should be sought or if the participant should stop activity.
- Make it clear that the participants would be lent not given the Fitbit devices and would be expected to return them at the end of the study.

The panel asked if it would be advisable to check at the recruitment stage for any eating disorder history

The panel felt that this was a worthwhile study; they hoped that the Ethics application was successful and would be interested and pleased to assist Michaela in taking this study forward.

The panel felt that the addition of a short, user friendly, instruction sheet for syncing the Fitbit device with a smart phone or PC would be helpful.

The Fitbit device costs approximately £70 each, the question was raised on how to retrieve them from the participants at the end of the study.

It was thought that they should be given several options such as:

- A group meeting, get together at the end of the study, where there could be an open feedback discussion on the project, at that point they hand back the device.
- At the second scan they hand the device back to the clinic; that will have instructions on forwarding them on to the research team.
- A one to one interview and feedback opportunity at the end of the study

- A collection point maybe connected with the office for Midwives, where the devices could be collected by the midwife service.

Each device would be stamped or micro-tagged with the property of Hallamshire University and have an individual ID number that can be linked to the participant that it has been issued to. There should be a sign in / out book for the devices so that they can be traced at any stage of the study.

Appendix H. Interview Guide Study Participants

1.1.   Phase Two: Qualitative Interview Guide:

This is the proposed interview guide

First of all, how would you say you have found the experience of taking part in the intervention?

Is there anything you have liked about it?

PROMPTS:

•   Easy to take part/incorporate into daily routine

•   Design

•   Convenience

•   etc

Is there anything you have disliked about it?

PROMPTS:

•   Interference in daily routine

•   Technical issues

•   Remembering to wear

•   Not wanting to be in control group or intervention group

•   etc

In your opinion, did the intervention help you to increase or maintain your physical activity? Why / why not?

In your opinion, do you feel that you would use the intervention components long term if it was available to you?

What are your views on using the Fitbit in combination with Facebook?

PROMPTS:

•   Support

•   Length of support

•   etc

How have you found your involvement in the overall project?

Are any changes needed to the study?

What are your views on the fact that you could be randomly assigned to the Facebook group or not?

Were there any specific tests or questionnaires which you felt were particularly relevant or not relevant?

PROMPTS:

•   Time-consuming

•   Difficult to understand

•   etc

Appendix I. Interview Guide Health Professionals

- **Please tell me:**
    - your experience of the care provided to women with a BMI >30kg/m2
    - What do you think are the main issues in encouraging pregnant women to engage in physical activity?
    - What do you think about the proposed program? What might the benefits/limitations?
    - how do you think that the timing of recruitment is suited
    - What are the disadvantages of having an intervention in early pregnancy for obese pregnant women?
    - How feasible do you think it is to implement an intervention like this?
    - What are the benefits of intervention design
    - What are the limitations of intervention design
    - Should PA be prescribed and monitored

- What do you think about using digital technology eg. Facebook for the purpose of delivering health information

- what is is current practice in terms of current recommendations that are made?

    - Should it be addressed as part of routine care

    - what influence do you think the intervention will have on your everyday work

    - what things do you think will be difficult in the intervention implementation

    - what things will be easy to implement

    - What are the advantages of using Facebook What are the disadvantages of using Facebook

    - What are the advantages of the study design and procedures (Fitbit, Facebook, Online Food Diary)

    - What are the disadvantages of the study design and procedures/improvements/changes suggestions?

    - What are the benefits of having an intervention in early pregnancy (11-14 weeks at first booking) for obese pregnant women?

    - What do you think about having electronic food diaries - will participants complete them? Are there other alternatives that you would suggest?

    - What is lacking in the current pathway for these patients?

    - What should be the prioritized to change?

      What do you think about monitoring PA with something like Fitbit?

- Anything in particular that you have thought of/think of that you would like to share

Appendix J: Search terms for Systematic Review

1. pregnan*.ti,ab

2. matern*. ti,ab

3. gestat*. ti,ab

4. prenatal. ti,ab

5. pre-natal. ti,ab

6. antenatal.ti,ab

7. obstetric*. ti,ab

8. pregnancy/

9. maternal behaviour/

10. obstetrics/

11. or/1-10

12. overweight. ti,ab

13. obes*. ti,ab

14. weight N3 gain*. ti,ab

15. BMI N6 25. ti,ab

16. BMI N6 30. ti,ab

17. BMI N6 40. ti,ab

18. "body mass index" N6 25. ti,ab

19. "body mass index" N6 30. ti,ab

20. "body mass index" N6 40. ti,ab

21. obesity/

22. obesity, morbid/

23. overweight/

24. or/12-23

25. walk*. ti,ab

26. step*. ti,ab

27. pedometer*. ti,ab

28. physical* N3 activ*. ti,ab

29. exercis*. ti,ab

30. walking/

31. exercise/

32. motor activity/

33. or/25-32

34. randomized controlled trials as topic/

35. randomized controlled trial/

36. random allocation/

37. double blind method/

38. single blind method/

39. clinical trial/

40. clinical trial, phase i.pt

41. clinical trial, phase ii.pt

42. clinical trial, phase iii.pt

43. clinical trial, phase iv.pt

44. controlled clinical trial.pt

45. randomized controlled trial.pt

46. multicenter study.pt

47. clinical trial.pt

48. exp. clinical trials as topic/

49. clinical N1 trial*.tx

50. singl* N1 blind*.tx

51. singl* N1 mask*.tx

52. doubl* N1 blind*.tx

53. doubl* N1 mask*.tx

54. treb* N1 blind*.tx

55. treb* N1 mask*.tx

56. trip* N1 blind*.tx

57. trip* N1 mask*.tx

58. placebo*.tx

59. "randomly allocated".tx

60. allocated N2 random*.tx

61. quasi*.tx

62. "randomized controlled trial*". ti,ab

63. "randomised controlled trial*".ti,ab

64. "randomized control trial*". ti,ab

65. "randomised control trial*".ti,ab

66. RCT*.ti,ab

67. "randomized trial*".tx

68. "randomised trial*".tx

69. placebos/

70. nonrandomised.tx

71. nonrandomized.tx

72. "non-randomised controlled trial*".tx

73. "non-randomized controlled trial*".tx

74. non randomized controlled trials as topic/

75. or/34-74

76. case report.tx

77. letter/

78. historical article/

79. or/76-78

80. 75 not 79

81. 11 and 24 and 33 and 80

Intervention Design for a Randomised Controlled Trial

This chapter is a protocol for a large RCT and based on the findings which have been presented in the preceding chapters.

Title: Walking in Pregnancy- An mHealth technology Intervention promoting Physical Activity for Pregnant, Obese women- Study Protocol for a Randomised Controlled Trial

11.1 Introduction

Approximately 20% of women of childbearing age, in the UK, are obese. Obesity (BMI≥ 30kg/m²) and excessive gestational weight gain (GWG) increases the risk of complications in pregnancy, such as raised maternal glucose levels which can cause gestational diabetes mellitus (GDM). Currently, there is very little support for obese women to manage their GWG. There has been limited research to show that physical activity (PA) during pregnancy may improve maternal and infant outcomes. PA interventions have shown an effect in lowering maternal glucose levels (63). For instance, a reduction in maternal fasting glucose from glucose category 5 (5.0–5.2 mmol/L) to glucose category 3 (4.5–4.7 mmol/L) (a 10% reduction in fasting glucose) resulted in a reduction in the rate of neonates born large for gestational age (LGA) from 16.5% to 10.1%. It also lowered the cord blood C-peptide from 17.7% to 8.2%, and the rate of primary C-section from 23.7% to 18.5% (223). Therefore, it is important to conclusively identify whether increasing PA in women who are pregnant and obese would improve health benefits, and if so to characterise the nature of the relationship. Mobile health (mHealth) technology is a new innovative way to deliver PA interventions which needs further exploring in the pregnant obese population. Thus, we developed a remote mHealth technology-led PA intervention for women who are pregnant and obese using the COM-B model and a protocol for a large scale RCT to test it.

11.2 Aim

The study aim is to investigate the health effects of a walking intervention for women who are pregnant and obese to examine the relationship between changes in walking (steps) and maternal fasting glucose.

11.2.1 Objectives

a. Measure Physical Activity Levels (steps)

b. Measure Mean Fasting Glucose (25 weeks gestation)

c. Measure Gestational Weight Gain (from 11-14 weeks to 36 weeks gestation)

d. Quantify Maternal and Infant Outcomes

e. Measure Facebook Engagement

f. Measure Effectiveness of Mechanism of Action

11.3 Methods

Walking in Pregnancy is a two-arm parallel intervention study randomised controlled trial recruiting women with a singleton pregnancy between 11-14 weeks gestation at the first hospital antenatal clinic visit. Eligible women will be randomised to standard obstetric antenatal care or the Walking in Pregnancy-Facebook Intervention.

11.3.1 Setting

Participants will be screened and recruited from multiple sites across South Yorkshire, including Jessop Wing, Sheffield Teaching Hospitals, Rotherham Maternity Ward, The Rotheram NHS Foundation Trust, and Barnsley Maternity Ward, Barnsley Hospital

11.3.2 Recruitment

The recruitment will take place in regular hospital booking clinics which are part of the regular health care path at 11-13 weeks' gestation. BMI measurements are routinely done in the booking clinic which is when 'potentially eligible' participants were screened by the midwife. Following the booking appointment, eligible participants with a BMI of 30kg/m² and over who have no known complications will be invited to the study. A second screening will be done at this point to check that the potential participant meets all the inclusion criteria (owning a smartphone or PC and Facebook user) and has no known complications that will make it unsafe for the woman to take part in physical activity. Women, who meet all the

inclusion criteria and verbally agree to take part, will be offered full information about the study. They will then be consented either on the same day, or given 24 hours to consider taking part in the study.

11.3.3 Inclusion Criteria

Women classed as obese (BMI ≥30kg/m²) who are in early pregnancy (11-14 weeks gestation) without any known complications are eligible to take part in the study. All participants are required to have access to the internet, either on a desktop computer, laptop or a mobile phone. They should also be a Facebook user or willing to sign up to Facebook.

11.3.4 Exclusion Criteria

- BMI less than 30kg/m²
- A complicated pregnancy with high risk of miscarriage.
- Unable to understand written English
- Do not use Facebook
- Not have a smartphone/ PC to sync the Fitbit

11.3.5 Randomisation

Pregnant women meeting the inclusion criteria will be randomly allocated to intervention or control groups at a 1:1 ratio using a computerized random-number generator. Allocations will be concealed from the researcher and contained in sealed opaque envelopes. Due to the nature of the study, blinding of researcher or participants will not be viable.

11.3.6 Primary Outcome

We chose a composite outcome of PA (steps) and mean maternal fasting glucose as the primary outcome measure (9). Studies in the general population have shown approximately 7,000-8,000 steps/day is a reasonable threshold of free-living physical activity (233) and that an increase of approximately 1,500 [35] to 2,500 steps/day (116), (236), (237) is associated with modest weight loss and improvements in blood pressure. Maternal fasting glucose is checked routinely in women who are obese between 24 and 28 weeks, as part of an oral glucose tolerance test (OGTT).

Primary Outcome

a. Physical activity and a mean improvement of 2000 steps/day

b. A reduction in mean maternal fasting plasma glucose in the intervention group by 6.9 mg/dL at the time of a 75-g oral glucose tolerance test at 24–28 weeks of gestation.

Secondary outcomes of interest are:

Maternal: GWG (calculated as the difference between weight measured at the time of recruitment (11-14 weeks gestation) and weight just before delivery (35-36 weeks gestation), GDM, hypertension, preeclampsia, blood pressure, caesarean section, spontaneous vaginal birth, instrumental birth, induction of labour.

Neonatal: birth weight, gestational age at birth, preterm birth, macrosomia, large for gestational age, small for gestational age, placenta weight, neonatal admission to special care baby unit (SCBU), APGAR Score 1and 5 min after birth.

Non-clinical outcome of interest; social empowerment, self-efficacy

11.3.7 Sample Size

Using PA (Steps) as a Primary Outcome to determine Sample Size

A sample size calculation determined that 116 women were required (58 per group) to detect an effect size of 2000 step/day, with a standard deviation of ±3,000 steps/day (235); to ensure 90% statistical power and with a p-value set at <0.05 and taking into consideration a 20% drop out rate.

Maternal Fasting Glucose as a primary outcome to determine Sample size

 A sample size calculation determined that 23 women were required per group to detect a difference of 6.9 mg/dL in fasting plasma glucose between intervention and control groups for statistical power of 90% at a type I error rate of 0.05. This would require a sample size of 46 women. Assuming a dropout rate of 20% (based on the findings from the feasibility trial), we would need to recruit 56 women in total.

The sample size calculation seeks to ensure enough patients are recruited to detect a difference in the outcome measure of interest at a pre-specified level of significance. When using a composite primary outcome, the outcome that requires a larger sample size to detect a statistically relevant difference is used. Therefore, the proposed sample size for the trial is 116 women in total.

11.4 Intervention Arm

11.4.1 Facebook delivered Physical Activity Plan

The walking in pregnancy intervention will be delivered from 11-14 weeks gestation to 36 weeks gestation. Participants in the intervention arm will be enrolled in a Facebook group. A Walking in Pregnancy closed; private group will be created on the social media tool Facebook. A closed, private group on Facebook is a space where only a select group of people can share posts, messages, photos and documents. This type of group ensures more privacy because it does not come up in the Facebook search engines. Only a person who is invited by the group administrator can join the group. In addition, only the group members can see who is in the group, and only those who are members can view and post comments.

Participants in the intervention group will be asked to actively construct plans including potential timings and locations to achieve their steps. For instance, 'park the car further away from work and walk part of the way'. The plan will also include their weekly step target, week-by-week (10% weekly increase of their baseline measure). A Fitbit tracker will be used to deliver 'self-monitoring' techniques. and to objectively measure PA.

11.4.2 Facebook Procedures

Behaviour Change COM-B Model

Based on the previous findings we propose a selection of behaviour change techniques (BCTs), which are summarised in Table 37 below. Amongst others, we identified *self-monitoring, goal-setting, information about health consequences, social support, prompts and cues, and coping planning* as relevant BCTs for our intervention. In addition, previous reviews identified the effectiveness and importance of self-monitoring technique in behaviour change(73). Column 1 in Table 51 summarises the COM-B components that were targeted as part of the intervention.

Behavioural Intervention Elements

Table 51. Behavioural Intervention Elements

COM-B component	Proposed BC Techniques	BC Technique delivery
Capability (psychological)	Goal setting (behaviour)	Participants will receive individualised goals based on a 10% step increase from the baseline week.
	Self-monitoring	Participants will self-monitor using activity tracker.
	Information about health consequences	Participants will receive information via a closed Facebook group.
	Prompts/cues	Participants will receive prompts and problem-solving suggestions via a closed Facebook group.
	Problem-solving	
	Feedback	
	Action Planning	Participants will receive feedback via a closed Facebook group.
	Vicarious Experience	
Opportunity (Social)	Social Support	Participants will receive social support and social reward via a closed Facebook group.
	Social reward	
	Graded tasks	
Motivation(Reflective)	Information about health consequences	Participants will receive information via a closed Facebook group.
	Credible Source	Information shared in the Facebook group will be from credible sources (scientific journal findings, Tommy's, NHS)
	Competition (optional)	
	Monetary Compensation	
Motivation(Automatic)		

11.4.3 Facebook Moderation

Because of the rolling recruitment, participants will be joining the study at different times. To ensure that all participants receive the same information, some information will be repeated through the study, whilst key articles and informational documents that summarise the most relevant information will be

pinned to the group wall instead (a feature making them always readily available to the user). The moderator will signpost to the "pinned" posts to remind participants to read through the articles that contain information that is considered to be pivotal. For instance, the infographic produced by RCOG, (14) about health benefits of PA during pregnancy or an NHS video about benefits of walking during pregnancy. Rolling recruitment also means that participants will be at different gestational stages throughout the study. Posts will be of the following characteristics:

1. **Physical activity**- Posts asking participants to discuss their progress with step targets. How have your step counts been since last week? Up down or same?

2. **Physical activity study, science or news** - For example; *Here is a list of benefits of PA for your health.*

3. **Poll**- For example, *What times of the day are the most challenging for you to achieve any steps*' *What days of the week are the most challenging for you to achieve steps?'.*

4. **Suggestion**- For example, share with the group and help others. How have you planned your day to make sure that you achieve your steps?

Because of the rolling recruitment, participants' gestational age will vary. Health topics and benefits of PA will relate to health benefits for women who are in either 2nd or 3rd trimester (14). Health advice and PA recommendations are very similar in both 2nd and 3rd trimester, therefore majority of the posts will be applicable to all participants. To make posts as relevant as possible to all, each post will incorporate a message that is relevant, irrespective of participant's gestational age. For instance, participants who are entering the 2nd trimester will be expecting to have their OGTT at 25-27 weeks gestation. To these participants, the messages about how PA may lower the risk of gestational diabetes will be shared. However the message will also incorporate information about the importance of maintaining PA to those who are in the 3rd trimester to lower the risk of developing GDM in the 3rd trimester or even if they have been diagnosed with GDM, that PA is a way to regulate blood glucose levels. For instance, a paragraph that summarises findings of benefits of PA during pregnancy from scientific publications will be shared as a post on the Facebook wall. The paragraphs will specifically mention benefits that occur in the three trimesters. Examples of posts are listed in table 52.

Frequency of Posts

The moderator will post twice a day (morning and late afternoon). Posting will be done 5 days a week, which is approximately 22 days per month. The intervention will be conducted over a period of approximately 6 months (from 12 weeks gestation to 36 weeks gestation), which is approximately 132 days. For this reason 264 posts will be prepared. The proportion of same-topic posts will be equally divided, apart from the topic which we found engaged most during the feasibility trial, about encouraging women to share their experiences of being pregnant. This topic motivated the majority of participants to engage with posts, comments and likes in the Facebook group. Because of the rolling recruitment, posts which were shared from the start will be repeated. The most informative posts will be pinned to the group wall.

Table 52. Facebook Moderation Plan

Why (BCTs)	What will be Posted	Sources/ Timing	Examples of Posts
To deliver the ***Information about Health Consequences*** (early pregnancy) ***Reliable Source***	Summary of findings from scientific journals on 1. Effects of PA benefits of PA on GDM, GWG, Preeclampsia, Back pain, Mood, Physical Activity in Pregnancy Infographic by RCOG, 2017 RCOG PA Guidance, 2017 Key Messages psychological wellbeing, GDM, GWG, Back Pain, Preeclampsia	Systematic reviews: Thangaratinam et al., Tobias et al., CMACE Report Renault et al.,	Physical activity lowers your blood glucose level, so regular exercise can be an effective way to manage gestational diabetes. *Exercise is not dangerous for your baby – there is some evidence that active women are less likely to experience problems in later pregnancy and labour.*
Information about Health Consequences	Effects of PA benefits of PA on GWG, Back pain, Mood, Post-partum, Birth Weight, Mode/Length of Delivery	2nd, 3rd trimesters	*Physical activity lowers your blood glucose level, so regular exercise can be an effective way to lower the risk of developing gestational diabetes. If you do get GDM, PA is a way to manage it !*
Information about Health Consequences	A paragraph-long post with facts.	NHS PA in Pregnancy RCOG Guidelines Tommy's Videos	*The more active and fit you are during pregnancy, the easier it will be for you to*

Reliable Source		Articles from Tommy's NHS and other reliable sources on the topic of PA in pregnancy.	*adapt to your changing shape and weight gain. It will also help you to cope with labour and get back into shape after the birth.*
Feedback	Positive comments about achievements	2nd, 3rd trimesters	*Well done for achieving your targets!*
Prompts/Cues	Reminders	2nd, 3rd trimesters	*Please remember to wear your Fitbit today.* *Try to keep active on a daily basis: half an hour of walking each day can be enough, but if you can't manage that, any amount is better than nothing*
Social Reward ***Vicarious Experience***	Praise posts; Wall posting when someone has met their weekly target:	2nd, 3rd trimesters	*Well done for completing your target*
Problem-solving	Problem-Solving	Posts/Photos of Ideas of where to walk (eg. stairs, parking further away, getting of a bus stop earlier/walking to the bus)	*Walk to your nearest grocery store instead of taking the car.* *Do not exhaust yourself. You may need to slow down as your pregnancy progresses. As a general rule, you should be able to hold a conversation as you exercise when pregnant.*
To encourage interaction and ***engagement*** on the wall, to deliver a sense of social support throughout pregnancy.	Polls and Suggestions on pregnancy-related topics that are of interest; Fatigue, Sleep Problems, back pain, preparing for giving birth, other symptoms.	2nd, 3rd trimesters	*If you are pregnant, exercise will strengthen your muscles so that you can carry the extra weight of pregnancy. They'll also make your joints stronger, improve circulation, ease backache, and generally help you feel well.* *A relaxing bedtime routine is a bath before bed. What is your favourite most*

			relaxing bedtime routine for a good night's sleep?
Encouraging engagement	Suggested Topics for Participants of Posts and Information to Share	2nd, 3rd trimesters	*Introduce yourself when you join the group!* *Share ideas of your favourite places to walk* *Share ideas of your favourite time of the day to walk* *Share your best tips on how to get the step count up!* *Share a photo of your walk* *Tell us how you feel after a walk* *What is the most surprising thing about trying to stay physically active during pregnancy?* *Share Your motivational Message; What motivates you to be stay healthy in pregnancy!*

Social Reward

Early on participants who post and engage more frequently will be identified and encouraged to keep up the engagement. These participants will be rewarded (socially) by praise and more interaction with the moderator.

Physical Activity Measure

At the first contact, women will be given a Fitbit and will be asked to go about their activities 'as usual' during the first week (baseline week). During the baseline week, both intervention and control group participants' Fitbit will be blinded by covering their Fitbit band with tape covering the screen and by deactivating the Fitbit mobile phone application. At the end of the first week, a baseline measure of steps will be established for each individual participant. Based on each participant's individual baseline measure, a 10% step increase will be calculated. For the following weeks, each participant will be given a precise number of steps that will be their weekly step target. The 10% increase is derived from previous studies as well as our feasibility trial in women who are pregnant and obese which have shown that the average step count ranges from 3000 to 4000 steps daily (95). This would mean that each participant will target a daily step increase of 300-400 steps each week, which equates to 1-5 minutes of extra walking, to

achieve the recommended target of 30 minutes per day (52). Those participants who already achieved 10,000 steps or 30 minutes per day would not be asked to do more than that. Table 53 demonstrates the procedure timeline for both arms.

Table 53. Data Collection Time Line

Group	Week 11-12 Gestation	Week 11-16 Gestation	Week 26 Gestation	Week 35 Gestation	Post-Delivery
Intervention	Collecting baseline data: Demographic Variables GWG SE Q SQUASH FFQ Mean Fasting Glucose (25w) Providing and advising on: Fitbit Facebook Questionnaires	Facebook Fitbit 10% Increase, until reach 10,000 steps target) Fitbit Steps	GWG SE Q SQUASH FFQ GDM Status	GWG SE Q SQUASH FFQ Fitbit Steps	Maternal Weight Mode of Delivery Birth Weight Apgar Score (1,5 min) LGA SGA Questionnaires
Control	Demographic Variables GWG SE Q SQUASH FFQ Mean Fasting Glucose Questionnaires Fitbit* *(Blinded)	Fitbit (blinded) Fitbit Steps	GWG SE Q SQUASH FFQ Fitbit Steps	GWG SE Q SQUASH FFQ Fitbit Steps	Mode of Delivery Birth Weight Apgar Score (1,5 min) LGA SGA Questionnaires

11.5 Control Arm

Participants in the control group will also be given a Fitbit pedometer to wear throughout pregnancy. For the purpose of data collection, Fitbits will be synced with each participant's phone, however the Fitbit phone application will be disabled to viewing by means of a password so that participants will not be able to check their step counts. This is to allow measurement of their steps while minimising the effect of the Fitbit as a source of motivation and information on

step-count. Taking part in the control arm will not influence participants' usual care.

Usual Care Pathway

The summary of usual care pathways for pregnant overweight women is divided into three BMI categories namely; Category 1. BMI 30-34, Category 2. BMI 35-39, Category 3. BMI 40 and over. Those women who are classed as category 1 come under midwife-led care unless additional risk factors are identified. Women classed as category 2 and 3 come under obstetrician-led care. However, category 3 women (BMI 40 and over) have more tests, (repeated glucose tolerance test, assessments by anaesthetists , foetal biometry U/S growth scan, manual handling assessments and a labour management plan) in preparation for birth. Also, women with a BMI of 30kg/m2 should be made aware of the risks associated with obesity in pregnancy and be given healthy eating and lifestyle advice according to the Jessop Wing Maternity Services Clinical Practice Guidelines.

11.6 Data Collection

11.6.1 Demographic Variables

Age, occupational status, gestational age, ethnicity and parity will be recorded at the initial meeting with all the participants, following their consent.

11.6.2 Physical Activity

Physical activity (steps) data will be collected using the Fitbit pedometer. All Fitbit pedometers will be synced to participants' mobile phone Fitbit app. This will ensure that all steps data is recorded on the Fitbit page. Following the baseline measure, 10% of the average daily step count will be calculated for each participant. All additional data which will be collected throughout the intervention is summarised in Table 53.

SQUASH

SQUASH is a validated PA questionnaire. The questionnaire includes 11 questions relating to the time spent on different types of physical activity. It takes approximately 3–5 min to complete. The categories of activity types listed in SQUASH are commuting activity (including walking to and from work and

bicycling to and from work), leisure time activity (including walking, bicycling, gardening, odd jobs, sports specified by participants), household activity (including light household work and intense (214).

11.6.3 Diet

Participants will be asked to complete a food frequency questionnaire (FFQ). This will be administered during face-to-face appointments. The primary focus of this data is to measure change in caloric intake throughout pregnancy and to assess whether there are associations with changes in levels of physical activity. Because a change in PA may impact the dietary intake in participants and because it has an impact on GWG and other pregnancy and birth outcomes it will be monitored to assess any changes that may occur as a result of the intervention (99).

11.6.4 Effectiveness of Engagement

To be considered adherent to the intervention, women should be active in the Facebook group by means of 'likes', posts, and comments on others' posts. Also, a questionnaire will be administered to test the effectiveness of the BCTs which were implemented. Women will be asked to post and comment, every other day or at least 3 times per week. Engagement will also be measured by responsiveness to step targets and change in behavior (PA levels).

Process Outcomes Questionnaire

The process evaluation tool measures constructs which are hypothesised to be mechanisms of action of the intervention. The tool was modified to explicitly include views on walking. The question scores, when added together measured the following: 1.Intention, 2. Confidence, 3. Positive beliefs about walking, and 4.Negative beliefs about walking. The questionnaire will be administered at baseline and at 20, 26 and 36 weeks follow-up to see if there is a measurable change in before-and-after scores. Self-efficacy is a relevant outcome for this study due to the importance of finding out the impact of the intervention on participants' self-perceived self-efficacy and positive and negative beliefs about walking.

Mechanisms of Action Evaluation Questionnaire

A questionnaire designed to assess the impact of BCTs and their mechanisms of action in general.

Empowering Processes Scale

Udden Kraan et al., (2008) developed a scale with 29 items that describe the empowering processes that take place in the online support groups (203). In each item, the frequency with which certain events happen in the online support group is measured. There are four empowering processes: receiving useful information, receiving social support, finding positive meaning and helping others. Respondents can answer on a 4-point scale that ranges from "seldom or never" (1) to "often" (4). Additional items will be added to reflect specific aspects, for instance attitudes toward PA and walking in pregnancy.

11.6.5 Blinding

Baseline measurements will be done before randomisation. Intervention participants will be added to the closed, private Facebook group, where their identities will be apparent. Therefore later assessments will be done non-blinded due to the nature of the study.

11.7 Data Analysis

Demographic data will be analysed by descriptive analysis to examine differences in demographic variables (age, height, weight, employment, race, marital status, and parity) between the groups. Primary analyses will be carried out and results will be analysed based on the "intention to treat" principal. PA will be measured as difference from baseline to delivery. GWG (kg) will be measured as the difference from baseline (11-14 weeks gestation) to 36 weeks gestation. GWG will be corrected for length of gestation. Although, it is recommended that preconception weight is used and that weight at delivery (adjusted for length of gestation) is used (12), it would be challenging to obtain this data. We would be relying on women's self-reported weight, which is why we do not propose to use the pre-conception measurement. Differences among Obese BMI groups women in the intervention group (Obese-I,II, III category), and the control group (Obese I,II,III BMI category),will be analysed to determine the differences in meeting 2009 IOM GWG recommendations, pregnancy complications, and infant outcomes among the Obese BMI categories, I, II,III). A correlation coefficient

analysis will be conducted to examine the association between baseline BMI and level of PA, and rates of GWG at different time points across pregnancy. Significance will be defined as $P < 0.05$. Correlation analysis will also be conducted to measure the association between level of PA and GDM outcome.

11.8 Ethical Considerations

Ethical approval will be sought from National Health Service Research Ethics Committee. Also, an approval from the Health Research Authority will be obtained as well as a local governance approval from Sheffield Teaching Hospitals. All confidentiality-related concerns will be outlined in detail in a data management plan. The data management plan will ensure that there is a clear strategy for how to secure data sharing and anonymise identifiable, sensitive participant data. Ethical approval will be sought for the data management plan. Also, guidance for data handling and operational arrangements under the EU General Data Protection Regulation (GDPR) will be followed throughout the study.

11.9 Discussion

The purpose of this study is primarily to test the association of maintained PA levels throughout pregnancy and its effect on mean fasting glucose. The risk of gestational diabetes is increased 2-3 fold with obesity (247), which is in turn associated with a number of adverse outcomes during and after pregnancy, such as preeclampsia, complications during delivery and macrosmia (248). Strengths of our study design are a systematic development of the intervention design and the previous testing of implementation and delivery by means of a feasibility RCT. An additional strength is that the design is low-cost. If proven effective it could be recommended for implementation as part of the care pathway for women who are pregnant and obese. A weakness in terms of the study design, is that women in the control group may be motivated to increase their PA levels (creating the observer effect) which could potentially lead to smaller between-group differences (226). Additional possible weakness of our study is that it is proposing a novel approach, using social media and mHealth technology tools. Whilst this approach may be effective in supporting women with GWG the uptake and implementation within the health services needs further exploring. The results from our study will add to the evidence base on whether such programs should

be implemented as part of the regular pregnancy care pathway for this high-risk obstetric group.