DOCTOR OF PHILOSOPHY

"Simple steps" : a general practice based physical activity intervention for pregnant women

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'Simple Steps'

A general practice based physical activity intervention for pregnant women.

Presented to QUB for the degree of MPhil, School of Medicine, Dentistry and Biomedical Science.

Dr Madeline Brennan
MB BCH BAO, MRCGP
DMH, DRCOG

28th April 2015
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Declaration

I hereby declare that:

1) This thesis is not one for which a degree has been or will be conferred by any other university or institution;

2) This thesis is not one for which a degree has already been conferred by this university;

3) The work of this thesis is my own and that, where material submitted by me for another degree or work undertaken by me as part of a research group has been incorporated into the thesis, the extent of the work thus incorporated has been clearly indicated

4) The composition of this thesis is my own work.

Dr Madeline Brennan
Dedications

I would like to dedicate this thesis to the memory of my beloved grandfather Ken who was always so proud of my achievements and sadly passed away during the course of this work in November 2014.
Acknowledgements

I would like to thank all the individuals and agencies who have helped me achieve this Masters.

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To my husband Eamon and my parents, Francis and Gwen, for continuing to support my endeavours as without their love and encouragement this opportunity would not have been possible.
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<td>WHO</td>
<td>World Health Organisation</td>
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<td>NICE</td>
<td>National Institute of Clinical Excellence</td>
</tr>
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<td>GPPAQ</td>
<td>General Practice Physical Activity Questionnaire</td>
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<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>QOF</td>
<td>Quality Outcomes Framework</td>
</tr>
<tr>
<td>GPs</td>
<td>General Practitioners</td>
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<td>CMACE</td>
<td>Centre for Maternal and Child Enquiries</td>
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<td>RCOG</td>
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<td>CEMACH</td>
<td>Confidential Enquiries into Maternal and Child Health</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>GWG</td>
<td>Gestational Weight Gain</td>
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<td>PIH</td>
<td>Pregnancy-Induced Hypertension</td>
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<td>GDM</td>
<td>Gestational Diabetes Mellitus</td>
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<td>VTE</td>
<td>Venous Thromboembolism</td>
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<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>MET</td>
<td>Metabolic Equivalent of Task</td>
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<td>DINE</td>
<td>Dietary Instrument for Nutrition Education</td>
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PPAQ  Pregnancy Physical Activity Questionnaire

PA    Physical Activity

MVPA  Moderate to Vigorous Physical Activity

ORECNI Office for Research Ethics Committees Northern Ireland

HP    Health Professional

QUB  Queen's University Belfast
Chapter 1: Literature Review

1.1 The problem of obesity

Obesity is rising globally and has major healthcare implications with respect to cost, morbidity and mortality. According to the World Health Organisation (WHO), worldwide obesity has nearly doubled since 1980 with more than 1.4 billion adults aged 20 years and older being recorded as overweight (World Health Organisation. 2014). The Foresight report in 2008 reported that by 2050, 60% of men and 50% of women in the United Kingdom could be clinically obese and, without action, the costs of overweight and obesity will rise to £50 billion per annum (Foresight report. 2008). (Government Office for Science: Foresight Report: Tackling Obesities: one year review October 2007-November 2008. 2008)(3) In Northern Ireland the Statistics and Research Agency carried out a health survey in 2012-2013 and of the adult respondents 25% were obese, with a further 37% classified as overweight (Northern Ireland Statistics and Research Agency 2014). However, despite these alarming figures, 73% of respondents felt that they could do something to make their own life healthier and of these 57% believed one way to make this change was to become more physically active. This is positive in that people are acknowledging the importance of exercise with respect to a healthy lifestyle and that there is potential for change.

In 2006 the National Institute for Clinical Excellence (NICE) published guidelines with respect to obesity and these recommended that primary care should ensure that preventing and managing obesity is a priority at both strategic and implementation levels (National Institute of Health and Care Excellence. 2006). Currently, there are
various public health initiatives which are trying to tackle this ever growing problem. In the primary care setting more emphasis is being placed on primary prevention and the promotion of physical activity. The year 2013 saw the introduction of the General Practice Physical Activity Questionnaire (GPPAQ) into the National Health Service (NHS) Quality Outcomes Framework (QOF) in England, allowing payment to general practitioners (GPs) for completion of physical activity questionnaires with their patients, with delivery of brief exercise interventions where appropriate. This initiative has not yet been introduced in other parts of the UK.

1.2 Obesity in pregnancy
As is true for the general population, the prevalence of maternal obesity in pregnancy is also rising. Percentages quoted in the Centre for Maternal and Child Enquiries (CMACE) and the Royal College of Obstetricians and Gynaecologists (RCOG) Joint Guidelines for the management of women with obesity in pregnancy show a rise in the prevalence of the problem, from 9-10% in the early 1990s to 16-19% in the 2000s (J Modder March 2010). The graph (Figure 1) below illustrates the rising trend of maternal obesity in pregnancy and is taken from a study that collated data from 619323 births in England 1989-2007(Heslehurst, Ells et al. 2007).
A recent retrospective study in Northern Ireland calculated the prevalence of overweight and obesity among women booking for antenatal care was 27.8% and 16.8% respectively (Scott-Pillai, Spence et al. 2013).

The adverse outcomes of being overweight or obese during pregnancy are also well documented. The Confidential Enquiries into Maternal and Child Health (CEMACH) issued their 7th report for the years 2003-2005 (Confidential Enquiry into Maternal And Child Health. 2007). This document reported that of the women that died, more than half were either overweight or obese. Higher levels of obesity were reported for those women who died as a result of venous thromboembolism, maternal sepsis and cardiac disease than those who died from other causes, thus linking obesity with an increased risk of these morbidities. The report also specifically mentioned the role of the GP: it recommended that GPs should record
body mass index (BMI) during pregnancy and counsel women who are obese with respect to weight loss or healthy eating.

1.3 Complications associated with obesity in pregnancy

As well as increasing the risk of mortality, obesity in pregnancy is associated with various other complications. A study published in 2001 retrospectively evaluated 287,213 singleton pregnancies in London with respect to maternal obesity and pregnancy outcome (Sebire, Jolly et al. 2001). The study included data on more than 80% of deliveries from 1989 to 1997. The incidence of various adverse outcomes in women with a normal BMI was compared with those in women with a BMI>25. An increased incidence of gestational diabetes mellitus, pre-eclampsia, induction of labour, emergency caesarean delivery, genital and urinary tract infection, wound infection, birth weight above 90th centile and intrauterine death was found in the women with higher BMIs. These findings persisted following a logistic regression analysis which took into account potential confounding factors such as age, parity and pre-existing hypertension. This clearly highlighted that there are increased risks for both mother and child associated with an elevated BMI during pregnancy; however, the impact of gestational weight gain (GWG) and adverse events was not independently evaluated in this study.

More recently, the Centre for Maternal and Child Enquiries (CMACE) carried out a cohort study encompassing 5068 women with maternal obesity; defined as BMI≥35, who gave birth in the UK in March and April of 2009 (Centre for Maternal and Child Enquiries. 2010). This complemented the cohort study discussed above although it focused on higher BMIs (BMI>35). A higher incidence of type 2 diabetes
pre-eclampsia (p<0.0001) and severe pre-eclampsia (p=0.007) was found in women with a BMI>35 in comparison to women of normal BMI<25. Higher rates of induction of labour, post-partum haemorrhage, caesarean section, stillbirth, large for gestational age babies and neonatal admissions were also reported.

Among the cohort of women with a BMI>35, 38% had at least one co-morbidity diagnosed prior to and/or during pregnancy with the most frequently reported conditions being pregnancy-induced hypertension (PIH) and gestational diabetes mellitus (GDM). Comparative rates of pregnancy induced hypertension were 9% for women with a BMI>35 and 1.9% in the general population; for gestational diabetes, the prevalence was 7.8% for women with a BMI>35, compared to 2.5% in the general population. As BMI increased the prevalence of both PIH and GDM also increased with each incremental increase in BMI category (BMI 35-39.9, BMI 40-49.9 and BMI>50) (Centre for Maternal and Child Enquiries. 2010). This trend of increased risk with increasing BMI category was also echoed by a recent review paper in 2013 evaluating the impact of BMI on maternal and neonatal outcomes in Northern Ireland (Scott-Pillai, Spence et al. 2013).

A pre-pregnancy BMI of >25 is considered a major risk factor for gestational diabetes mellitus (GDM) as is excessive GWG (Ruchat, Mottola 2013, Morisset, St-Yves et al. 2010, Hedderson, Gunderson et al. 2010). Obese women are four times more likely to develop GDM than lean women and severely obese women are nine times more likely (Huda, Brodie et al. 2010). It is also well documented that developing GDM in pregnancy predisposes these women to an increased risk of
developing type 2 diabetes mellitus in the future and because of this women who have had GDM should have an annual glucose tolerance test performed.

The role of lifestyle interventions in improving glycaemic control and delaying the onset of type 2 diabetes mellitus in the general population is widely accepted. However, the role of physical activity and lifestyle interventions in decreasing the risk of GDM is unclear. A review in 2013 looked at the role of physical activity in the prevention and management of GDM (Ruchat, Mottola 2013). In the eight papers included that specifically looked at sole physical activity interventions, only three demonstrated an improvement in glucose tolerance and insulin sensitivity. These three randomised controlled trials (RCTs) had small numbers (83, 50, and 40) and although statistically significant differences with respect to glucose tolerance and insulin sensitivity were demonstrated, this did not translate into an overall reduced incidence of developing GDM.

As well as GDM, obesity is also a risk factor for venous thromboembolism and for arterial thrombosis (Royal College of Obstetricians and Gynaecologists. 2009). A hospital based case-control study in Oslo found that a high BMI had a multiplicative effect on the risk of both antepartum and postnatal venous thromboembolism (Jacobsen, Skjeldestad et al. 2008). Venous thromboembolism (VTE) can have significant impact on maternal morbidity and mortality. Another case-control study showed that obesity was associated with an increased risk of VTE during pregnancy and the puerperium and in particular noted that obesity conveyed a higher risk for pulmonary embolism compared to deep venous thrombosis (Larsen, Sorensen et al. 2007).
As well as immediate consequences of maternal obesity in pregnancy there are also some far-reaching sequelae. A recent cohort study in Scotland highlighted the long term consequences of this problem: it showed that maternal obesity in pregnancy is associated with an increased risk of premature death in adult offspring (Reynolds, Allan et al. 2013). Maternal obesity has also been linked to higher rates of obesity in children born to women with raised BMIs and to a tendency for the children born to obese mothers to develop the “metabolic syndrome” (Ornoy 2011).

The evidence from the aforementioned studies clearly highlights the increased risks to both maternal and foetal health as a result of maternal obesity in pregnancy. The evidence would suggest that this risk is higher with increasing BMI category.

1.4 Predictors of obesity in pregnancy

A review article published in the International Journal of Obesity evaluated existing evidence surrounding pre-pregnancy and pregnancy predictors of obesity (Melzer, Schutz 2010). The review concluded that women with larger gestational weight gains and higher pre-pregnancy BMIs tend to retain this additional body weight post-natally, contributing to the overall rise in obesity levels in the general population. This conclusion was drawn from evidence from three retrospective cohort studies; 1423 women from the Stockholm pregnancy and weight development study, a cohort of 405 women from Brazil and a cohort of 371 women from Canada. The review identified pregnancy related factors that the evidence suggest predict the development of obesity in later life and these include GWG, pre-pregnancy nutritional status, age, parity and race. GWG was also shown to be the strongest predictor for sustained weight retention at one year post-partum and can also be an
indicator of obesity up to 15 years after pregnancy. The conclusion highlighted a need for health promotion, specifically dietary and physical advice before, during and after pregnancy.

1.5 Current guidance for weight management in pregnancy

In the midst of the above research and reports highlighting the dangers of obesity in pregnancy, the USA Institute of Medicine (IOM) in 2009 produced a report re-examining their guidelines from 1990 regarding appropriate weight gain during pregnancy (Institute of Medicine. 2009). This has provided a guide for clinicians to apply in practice when providing clinical care and advice and gives guidance for weight gain ranges depending on BMI as shown in Table 1 below.

<table>
<thead>
<tr>
<th>Pre-pregnancy BMI</th>
<th>Total weight gain (lbs)</th>
<th>Rates of weight gain 2\textsuperscript{nd} &amp; 3\textsuperscript{rd} Trimester (mean range lbs/week)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight &lt;18.5</td>
<td>28-40</td>
<td>1 (1-1.3)</td>
</tr>
<tr>
<td>Normal weight 18.5-24.9</td>
<td>25-35</td>
<td>1 (0.8-1)</td>
</tr>
<tr>
<td>Overweight 25.0-29.9</td>
<td>15-25</td>
<td>0.6 (0.5-0.7)</td>
</tr>
<tr>
<td>Obese &gt;/30.0</td>
<td>11-20</td>
<td>0.5 (0.4-0.6)</td>
</tr>
</tbody>
</table>

Shortly after, in 2010, NICE produced guidelines regarding weight management before, during and after pregnancy. NICE, unlike the IOM, did not provide guidance for appropriate gestational weight gain during pregnancy due to lack of supporting evidence.
A review of these guidelines was published in November 2013: it again concluded that there was not enough UK based evidence in this area and highlighted that this is an area of urgent research need (National Institute for Health and Care Excellence 2013). Acknowledging the USA guidance, their conclusion was that the observational data utilised to create the IOM guidelines were not further validated with evidence from large scale trials and that the evidence would not be transferrable to the different ethnic population of the UK.

The NICE guidelines highlighted a need for research to evaluate the most effective ways of helping women to manage their weight during pregnancy (National Institute for Health and Care Excellence 2013). They identified two particular gaps in the evidence. First, that few evaluations of weight management interventions include adequate and validated measures of diet and physical activity - they often rely on self-reporting. Second, that few studies of weight management before, during and after pregnancy include interventions that are evaluated using process and qualitative data to determine which components are effective.

NICE have published guidance on the recommended amount of exercise for women who are pregnant and the RCOG have echoed these recommendations (National Institute for Health and Care Excellence 2010). Currently both sets of guidance suggest at least 30 minutes per day of moderate intensity exercise should be undertaken but if the woman has previously been sedentary or inactive then this should be reduced to three 15 minute sessions per week and gradually increased to a target of 30 minutes per day. No specific guidance is given for what exercise advice should be given to those women who are overweight or obese.
1.6. Existing reviews evaluating interventions to avoid gestational weight gain

A Pubmed search was carried out using the keywords 'physical activity', 'gestational weight gain' and 'pregnancy'. This revealed that there have been numerous review papers evaluating physical activity interventions in pregnancy and their effect on GWG and maternal and foetal health. Women with differing BMI categories have been included and often the interventions are complex, varied and often incorporate combined dietary and behavioural counselling components which can make a synthesis of their conclusions difficult. An overview of the review papers is illustrated in Table 2 but will also be discussed in detail hereafter.
Table 2: Overview of existing review papers evaluating physical activity interventions in pregnancy.

<table>
<thead>
<tr>
<th>Paper</th>
<th>Number of studies (participants)</th>
<th>Inclusion criteria</th>
<th>Duration of intervention (weeks)</th>
<th>Primary Outcome</th>
<th>Secondary outcomes</th>
<th>BMI of participants at recruitment</th>
<th>Stage of pregnancy at recruitment</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA &amp; GWG: a meta-analysis of intervention trials. Streuling et al. 2010.</td>
<td>12 (n=906)</td>
<td>PA only</td>
<td>10-32</td>
<td>GWG</td>
<td>N/A</td>
<td>Normal BMI plus one trial with average BMI 35.1</td>
<td>1st &amp; 2nd trimester</td>
<td>Lower average GWG in intervention groups compared to controls (SMD 0.61kg).</td>
</tr>
<tr>
<td>Antenatal exercise to improve outcomes in overweight or obese women: A systematic review. Sui et al. 2012.</td>
<td>7 (n=300)</td>
<td>PA</td>
<td>4-26</td>
<td>GWG (although 1ary outcome of some trials was use of insulin, HR, BP)</td>
<td>Multiple obstetric &amp; neonatal outcomes.</td>
<td>Overweight or obese (BMI&gt;25)</td>
<td>1st, 2nd &amp; 3rd trimester</td>
<td>For overweight and obese pregnant women provision of supervised antenatal exercise interventions are beneficial in limiting GWG (SMD 0.36kg). Effect on maternal and infant outcomes unclear.</td>
</tr>
<tr>
<td>Interventions to reduce or prevent obesity in pregnant women: a systematic review. Thangaratinam et al, 2012.</td>
<td>34 (n=5481)</td>
<td>Diet alone, PA alone or combined diet &amp; PA.</td>
<td>Not documented.</td>
<td>GWG</td>
<td>Obstetric – antenatal and intrapartum and post-natal outcomes. Neonatal – morbidity and mortality</td>
<td>BMI&gt;18.5</td>
<td>Not documented.</td>
<td>Overall reduction in GWG in intervention group compared with control group (SMD 0.97kg). Greatest reduction noted in diet alone group compared with control (SMD 3.36kg).</td>
</tr>
<tr>
<td>Lifestyle interventions for overweight and obese pregnant women to improve pregnancy outcome: a systematic review and meta-analysis. Oteng-Ntim et al, 2012.</td>
<td>10 (n=1228)</td>
<td>Diet alone, PA alone or combined diet &amp; PA.</td>
<td>Not documented.</td>
<td>GWG</td>
<td>GDM, caesarean section, baby birth weight.</td>
<td>Overweight or obese (BMI&gt;25)</td>
<td>1st &amp; 2nd trimester and some not documented</td>
<td>Combined antenatal lifestyle interventions were associated with a reduction in GWG compared with control (SMD 2.21kg) but note studies overall not of high quality.</td>
</tr>
<tr>
<td>The effects of PA &amp; PA plus dietary interventions on body weight in overweight or obese women who are pregnant or in post-partum: a systematic review and meta-analysis of RCT’s. Choi et al, 2013.</td>
<td>7 (n=1330)</td>
<td>PA versus PA and diet</td>
<td>Not documented.</td>
<td>GWG (also post-partum weight loss but not included here)</td>
<td>N/A</td>
<td>Overweight or obese (BMI&gt;25)</td>
<td>1st &amp; 2nd trimester</td>
<td>Statistically significant lower GWG with supervised physical activity and dietary combined interventions compared with control (SMD 0.91kg).</td>
</tr>
</tbody>
</table>

GWG: Gestational Weight Gain  PA: Physical Activity SMD: Standard Mean Difference.
1.6.1 Streuling et al (2010)

In 2010 Streuling et al evaluated 12 trials to examine whether sole physical activity interventions in pregnancy might help aid control of gestational weight gain (Streuling, Beyerlein et al. 2011). A good range of databases was searched for relevant papers and the trials included were randomised controlled trials (RCTs) involving healthy women with a sole physical activity intervention (no dietary intervention included). Gestational weight gain had to have been specified in the trial inclusion criteria to allow for inclusion in the review. The methodological quality was assessed using Cochrane’s handbook and CONSORT criteria.

Of the 12 trials, none were UK based and a third were conducted in the USA. There were no specific BMI categories listed in the inclusion or exclusion criteria, however, the average booking BMI in 11 of the 12 trials was within normal weight range (18.5-24.9) with only one RCT reporting an average BMI in the obese range (average BMI of 35.1). There was wide variation in the type and duration of the physical activity intervention ranging from walking to water aerobics and in three trials the total number of participants was small with less than or equal to 20 participants. The trial interventions were delivered during the second trimester of pregnancy and, in order to control for the effects of different modes of the physical activity interventions, each intervention was converted to MET (Metabolic Equivalent of Task) units for the purpose of outcome assessment and analysis.
For seven trials, gestational weight change was lower in the intervention group but the opposite was true for the other five trials. However, when the results were amalgamated and a meta-analysis conducted, the intervention groups gained 0.61kg less than their controls. There was low heterogeneity noted between the groups ($I^2=25\%$), indicating little variation between the trials analysed. The overall effect was considered significant. GWG was the only outcome evaluated so it is impossible to infer from this review whether this statistically significant weight reduction translated into reduced incidence of maternal or foetal adverse outcomes.

1.6.2 Sui et al (2012)

Whereas Streuling et al evaluated the effects of a physical activity intervention on gestational weight gain in pregnant women regardless of BMI, in 2012 Sui et al (Sui, Grivell et al. 2012) (Sui, Grivell et al. 2012)(26) published a review paper that evaluated the evidence surrounding antenatal exercise interventions which specifically targeted pregnant women who were overweight or obese. Again a wide range of databases was searched and the inclusion and exclusion criteria clearly defined. In contrast to Steuling et al, a quasi-randomised controlled trial was included and, in addition to sole physical activity interventions, the review also included trials which delivered combined lifestyle, exercise and other physical activity interventions. Excluded studies were clearly described and appropriate reasons for this were documented.
Similarly to the previous review gestational weight gain was used as the primary outcome measure and various other pregnancy-related secondary outcomes were also evaluated. During the statistical analysis if there was substantial heterogeneity found i.e. $I^2 > 50\%$, then subsequent repeat analysis was performed using a random-effects model to allow for the possibility of different effect sizes between the included studies. In total seven trials were reviewed which included 276 women from the years 2004-2011. Three of the trials included were also used in Streuling's meta-analysis; one trial used a dual exercise and dietary intervention and the other three trials differed in the type of exercise/physical activity e.g. walking, cycling, stretching and strengthening exercises. Losses to follow up ranged from 2.4%-22% which could have had implications for the overall results.

Overall, five trials of 216 women had outcome data for GWG and analysis of these data concluded that those women who were overweight and obese and took part in a supervised exercise intervention had lower GWG compared to those who did not. The standard mean difference between the two groups was -0.36 which was statistically significant but of note was quite a small difference. However, as already mentioned, it is difficult to determine which type of intervention or which intervention component worked best and loss to follow-up in these studies was substantial, which could affect the reliability of the results and validity of the conclusions. It is also worth mentioning that when GWG among just solely overweight women who took part in an exercise intervention were compared to those who did not, there was no statistically significant mean difference (mean difference -0.12, $P=0.85$, 95% CI -0.51, 0.26).
1.6.3 Thangaratinam et al (2012)

A systematic review by Thangaratinam et al 2012 was published as part of a Health Technology Assessment, and evaluated evidence on both dietary and lifestyle interventions on either reducing weight or preventing weight gain during pregnancy (Thangaratinam, Rogozinska et al. 2012). Thus, this review was more comprehensive than the two reviews discussed above. The interventions included in the review incorporated dietary, physical activity and/or behavioural counselling. The studies included women with a BMI >18.5, thus including women with normal, overweight and obese BMIs. This review included 88 papers; 40 randomised and 16 non-randomised controlled studies and 26 cohort and 6 case-control studies. The review looked at multiple outcomes which included maternal GWG and foetal weight as the primary outcomes but also looked at obstetric outcomes and foetal and neonatal morbidity and mortality.

In relation to the effect of interventions on maternal GWG, a meta-analysis of 30 of the randomised studies concluded that there is moderate evidence to suggest that combined dietary and physical activity interventions in pregnancy are effective in reducing maternal weight gain compared with control group (mean difference 1.42kg) but the mean difference was greater when dietary intervention alone were compared with control groups (mean difference of 3.36kg). Of note however, only half of the randomised trials addressed the issue of an incomplete final data set which not only could affect the validity of the conclusions from the review but also reflects poorly on the acceptability of the interventions.
1.6.4 Oteng-Ntim (2012)

Also in 2012 Oteng-Ntim et al conducted a review of lifestyle interventions in overweight and obese pregnant women with a focus on the effect on maternal and perinatal outcomes (Oteng-Ntim, Varma et al. 2012). The authors felt that their evaluation differed from previous reviews in that they widened their literature search to include non-English published trials and carried out separate meta-analyses for RCTs and non-RCTs with respect to different clinical outcomes. An example search strategy was clearly documented. Three of the papers selected for analysis in this review had been included in the aforementioned reviews by Streuling et al and Sui et al but the rest were not. Thirteen RCTs and six non-randomised trials were included in the review. The interventions reviewed varied in type and combination and involved women of differing gestations and BMI. With respect to the quality of the 13 RCTs, intention to treat was not reported in nine trials and incomplete outcome data were reported in ten trials. Selection bias was noted in seven trials.

Ten of the 13 RCTs specifically looked at gestational weight gain and a statistically significant difference of 2.21kg was found between intervention and control groups, with the greater loss in intervention groups. Forest plot analysis comparing lifestyle advice with standard care favoured the intervention group but heterogeneity was high (92%). In the meta-analysis of the five non-RCTs, a gestational weight gain difference of -0.42kg was calculated but this was not statistically significant. The studies overall were not of high quality and the authors’ conclusions recommended a need for a well-designed large scale prospective trial to fully assess the effectiveness of an antenatal lifestyle intervention in obese pregnant women.
Another review paper (Choi et al, 2013) drew conclusions from 11 randomised controlled trials evaluating physical activity (PA) and dietary interventions in pregnant (seven trials) and post-partum women (four trials) from the most recent decade (Choi, Fukuoka et al. 2013). It looked at the effect of sole physical activity interventions compared to those that incorporated both physical activity and diet and found that the latter were more successful in reducing gestational weight gain. Although, Choi et al’s results were statistically significant, the actual reduction in gestational weight gain was small, with women who received either PA alone or PA plus diet, gained 0.91kg less than the women in the control group.

Further sub-group analysis showed that when studies of supervised PA (instead of both supervised and unsupervised) plus diet were compared with control a statistically significant difference was found with a higher mean difference in GWG (1.17kg P=0.017). This would suggest a greater effect if the PA intervention is supervised. However, when supervised PA interventions alone were compared with controls a statistically significant mean difference was not observed (1.74kg, P=0.077).

The overall conclusion by Choi et al was that research regarding interventions to manage GWG was at an early stage and there is a need for further research. It was acknowledged that the results of the study should take into consideration that the reviewed interventions were heterogeneous and qualities varied with small sample
sizes. Note was also made of a potential publication bias as only papers published in two languages were reviewed and no attempt was made to contact authors of non-published studies. Acknowledgement was made to the conclusions drawn by Streuling et al (2011) and Sui et al (2012) but Oteng-Ntim et al’s review (2012) was published after their analysis period and therefore their conclusions were not alluded to in the discussion.

1.6.6 Summary of review literature

In summary, Streuling et al (2011) and Sui et al (2012) looked at physical activity as the sole intervention. Streuling’s women had normal BMIs in all studies apart from one paper that had an average BMI of 35.1 and the overall conclusion was that there was a lower average GWG in the physical activity intervention groups compared to the controls. Sui et al (2012) looked specifically at sole physical activity interventions in overweight or obese women and also concluded that it was beneficial in limiting GWG.

Thangaratinam et al (2012) compared diet alone, physical activity alone or combined diet and physical activity interventions and found an overall reduction in GWG in all the intervention groups but the greatest reduction was seen in the diet alone intervention group. Oteng-Nitim et al (2012) looked at combined dietary and physical activity and lifestyle interventions in overweight and obese women with a BMI>25 and concluded that these were associated with a reduction in GWG.
et al (2013) evaluated physical activity alone and physical activity combined with dietary interventions in women who were overweight or obese and found statistically significant lower GWG in those who took part in the combined intervention.

In addition to the reviews discussed above, a Cochrane review published in 2012 evaluated the evidence surrounding interventions for preventing excessive weight gain during pregnancy (Muktabhant, Lumbiganon et al. 2012). It included 28 studies, evaluating a total of 3976 women. The interventions were very varied, so that a pooled analysis was difficult and limited. Thus the conclusion was that there was insufficient evidence to recommend methods of preventing excess weight gain during pregnancy.

Since the publication of the above reviews there has been one large RCT conducted in Australia called the ‘LIMIT’ trial. It evaluated antenatal lifestyle advice for women who are overweight or obese and was recently published in the British Medical Journal (Dodd, Turnbull et al. 2014). This was a multi-centred RCT of 2,180 pregnant women with a BMI $\geq 25$. The primary outcome measure was large for gestational age babies with secondary outcomes looking at morbidity and mortality for mother and baby. Combined dietary and lifestyle advice was given and GWG was measured. No difference was found in mean GWG between different study groups. Of note, the actual physical activity component was the research assistant encouraging women to increase their amount of walking and incidental activity and to self-monitor this in a work book. Crude data were not obtained with regards to type, duration and frequency of the physical activity.
Overall the existing literature would suggest that physical activity interventions are likely to be associated with a reduction in gestational weight gain but it is unclear whether this should be done in combination with dietary interventions and details regarding effective components of interventions have not been identified. Differences exist in the characteristics of the various physical activity interventions with respect to frequency, duration and intensity, which make interpretation difficult. Statistically significant differences have been found with respect to reductions in GWG but the clinical implications in terms of maternal and foetal outcomes and overall levels of obesity are unclear. This highlights that there is a need for further research in this area. The vast majority of these studies have also been carried out in secondary care which only a small number recruiting from general practice.

1.7 Patterns and determinants of physical activity in pregnancy

Gaston and Cramp analysed patterns and determinants of exercise during pregnancy over a period of 13 years (Gaston, Cramp 2011). Twenty-five studies were included in the review, although none of these studies were RCTs. Key findings were, not surprisingly, that pregnant women were less active than their non-pregnant counterparts and that pregnancy in itself led to a reduced level of physical activity. Four factors were associated with higher levels of physical activity during pregnancy and these were higher education and income, primigravida status, white ethnicity and higher levels of pre-natal physical activity. Studies included in the review relied on self-reported outcomes and did not utilise an objective measure of physical activity such as an accelerometer which could be considered to be a weakness in the
evaluation. However, the need for care providers to promote physical activity in this group of patients was highlighted.

1.8 Measurement of physical activity

Self-report assessments of physical activity are often relied upon to determine if physical activity based interventions have led to increased physical activity levels, however, there are various different types of questionnaires from which to choose from. Each questionnaire is structured differently and records different aspects of the physical activity undertaken by individuals.

A systematic review by Evenson et al (2012) was carried out to identify self-reported physical activity assessments with evidence of validity or reliability among pregnant women (Evenson, Chasan-Taber et al. 2012). From the 12 studies reviewed they recommended that the most valid and reliable of the questionnaires and diaries were those that included information on dose of activity, to include frequency, duration and intensity and also to include information on the mode of the physical activity. The Pregnancy Physical Activity Questionnaire (PPAQ) takes into account mode, frequency, duration and intensity of physical activity (Chasan-Taber, Schmidt et al. 2004). This review highlighted other physical activity questionnaires that reported evidence for reliability, namely the Modified Kaiser Physical Activity Survey, Modified International Physical Activity Questionnaire and the Third Pregnancy Infection and Nutrition Study (PIN3) Physical Activity Questionnaire.
1.9 Physical Activity behaviour change

The review papers previously discussed have highlighted the differences between studies evaluating the effectiveness of physical activity interventions in pregnancy with respect to type of physical activity intervention and whether or not these are sole interventions or in combination with dietary and other lifestyle components. One other important aspect is the way in which the intervention is delivered, that is the behavioural change technique used.

Brown et al (2012) systematically reviewed five papers which specifically used goal setting strategies in order to prevent excessive gestational weight gain during pregnancy (Brown, Sinclair et al. 2012). All trials included a one-to-one diet and lifestyle counselling intervention and compared this with standard antenatal care. Gestational weight gain was a primary outcome. Retention rates of participants varied from 62% to 82%. Overall, it was concluded that, interventions that were based upon individualised goal-setting may be more effective for women who are overweight or obese. However, there was disparity in how the goals were set and supported, which limits what conclusions can be drawn.

Currie et al (2013) conducted a review of behavioural change interventions incorporated within physical activity interventions for pregnant women (Currie, Sinclair et al. 2013). The research aim was to review the content of physical activity interventions specifically looking at the type of behavioural change technique used. Key findings were that lifestyle interventions were most effective when behaviour
control techniques such as personalised goal setting and planning with feedback were used. Interventions delivered face-to-face were also found to be more effective. The paper also recommended the use of objective measures of physical activity due to possible discrepancies and bias with self-reporting.

With regards to behavioural control techniques, in 2003 The American College of Sports Medicine published an article regarding integrating exercise into antenatal care. They have recommended the ‘Five A’s’ behavioural approach as an appropriate method to adopt when delivering a physical activity intervention (Joy, Mottola et al. 2013). This is a very simple framework for delivering interventions.

1.9 Qualitative evaluations of physical activity interventions during pregnancy

Qualitative analysis has also been carried out in this research area. A qualitative paper by Duncombe et al (2009) explored women’s beliefs regarding the safety of exercise during pregnancy (Duncombe, Wertheim et al. 2009). One theme that emerged from the interviews was that of safety concerns regarding exercise during pregnancy. This is an important factor to be taken into consideration as this is a potential barrier that could prevent engagement with a physical activity intervention.

Campbell et al (2011) evaluated both quantitative and qualitative data with respect to behavioural interventions for weight management in pregnancy (Campbell, Johnson
et al. 2011). Eight qualitative studies incorporating surveys, interviews and questionnaires as tools for identifying barriers, were subjected to thematic analysis. Three themes from the collective data were depicted and included contradictory messages, pregnancy as a transition of time and change, and a perceived lack of control in pregnancy. These themes along with safety concerns regarding exercise in pregnancy are potential barriers to the design and implementation of an acceptable and effective intervention.

1.10 Safety of exercise in pregnancy

As mentioned above, one of the issues raised by the qualitative research was of safety concerns regarding exercise in pregnancy. Wang et al (1998) reviewed the evidence with respect to the safety of physical activity in pregnancy. They summarised some key points to guide what advice can be safely given (Wang, Apgar 1998). It was recommended that vigorous physical activity should be avoided especially in the third trimester. This is in keeping with the current NICE physical activity recommendations for pregnancy. NICE concluded that there was no strong evidence of any adverse outcomes associated with exercise in pregnancy (National Institute for Health and Care Excellence 2010). Other general advice recommended by Wang et al included advising the pregnant woman to avoid exercise that could increase the risk of abdominal trauma, falls or excessive joint stress.
1.11 Psychosocial factors in obesity/health behaviour change

Pregnancy is a time of change both physically and emotionally. Traditionally women are advised to rest and increase their calorie intake, for example ‘eat for two’. In years gone by women were weighed routinely during their pregnancy but this is now not part of standard antenatal care. Thus weight is something that is not routinely addressed in antenatal care. The lack of information given to women with respect to GWG and risk of obesity in pregnancy combined with conflicting socially accepted beliefs surrounding diet and exercise during pregnancy makes it challenging to address and initiate health behaviour change. Other factors such as access to facilities for exercising, educational needs with regards to healthy eating and other home circumstances or social stressors are all psychosocial factors which can influence health behaviour change during pregnancy.

A review paper published in the International Society for the Study of Obesity by Skouteris et al concluded that more emphasis needs to be placed on addressing psychosocial factors when trying to modify behaviours such as increasing physical activity (Skouteris, Hartley-Clark et al. 2010). They proposed a strategy which was able to target behavioural change in relation to eating and physical activity as well as addressing psychological factors such as body image and the woman’s motivation and confidence in making behavioural changes. This train of thought echoes some of the themes already discussed in relation to other reviews. Baird et al (2009) highlighted the importance of incorporating an educational component to any intervention aimed at changing specific health behaviour (Baird, Cooper et al. 2009). Both Shouteris et al (2010) and Baird et al (2009) relayed the importance of
psychosocial factors such as family and peer support as integral components of an effective physical activity intervention in pregnancy. Choi et al (2013) also discussed potential barriers to physical activity interventions: these included lack of information, inconsistent information and negative beliefs (Choi, Fukuoka et al. 2013).

Midwives provide a pivotal role in the delivery of antenatal care and Wilcox et al interviewed 15 midwives in Australia in order to explore their views in relation to interventions aimed at tackling gestational weight gain (Willcox, Campbell et al. 2012). Themes that emerged included the idea of gestational weight gain as of low priority as well as reluctance to discuss weight given the perceived potential negative impact that this may have. GWG was considered to lack importance given that it was no longer routine to weigh women during their pregnancy and some reported discussion of the risk of Listeria infection and of vitamin supplementation to carry more importance than weight gain. Lack of GWG guidelines and views that excess GWG was not significant also reduced the importance given to GWG in pregnancy by the midwives. Time constraints and the feeling that so many other issues had to be addressed in the antenatal appointments were cited. Another theme was the possible psychological impact that addressing GWG may have, with fears that the women would become preoccupied with their weight and possibly restrict their calorie intake, with potential harmful consequences for the mother and baby.
1.12 Conclusion

In conclusion, there have been multiple systematic reviews and meta-analyses which have evaluated numerous trials testing differing physical activity interventions in pregnant women. Overall, the effect of physical activity interventions has been associated with a reduction in GWG. However, whether this is best delivered as a sole intervention or in combination with dietary and/or lifestyle counselling, is unclear. Review papers have included trials with numerous different types of physical activity in interventions, and often these are in combination with dietary interventions. This makes pooled analysis difficult and also causes problems in identifying the components of the intervention that correlate with a reduction in GWG.

The way in which an intervention should be delivered to women is also not fully understood with evidence suggesting that 1:1 counselling, individualised goal setting and ‘5A’s’ behavioural counselling techniques may be beneficial methods. Issues have been raised regarding the best means of obtaining data collection for the measurement of outcomes of physical activity interventions and it has been concluded that self-reporting questionnaires which detail mode, frequency, duration and intensity are best and better if completed alongside an objective measure of physical activity. Thematic analyses in qualitative studies have also highlighted numerous barriers to delivering an effective intervention to avoid excess weight gain in pregnancy.
The NICE guidelines for weight management before, during and after pregnancy have identified gaps in current evidence for an optimal approach to avoiding excessive gestational weight gain in pregnancy (National Institute for Health and Care Excellence 2010). These gaps include a lack of robust data regarding physical activity interventions in pregnancy that use adequate and validated measures of physical activity.

Furthermore, pregnancy management in the UK is increasingly being delivered within the setting of primary care, rather than secondary care and primary care practitioners are recommended to promote physical activity for all sections of the population. However, most previous research relating to physical activity interventions among pregnant women has been conducted with participants recruited from secondary care settings. There is, therefore, scant evidence of the potential effectiveness of interventions which are set in the context of primary care, to promote physical activity amongst pregnant women,

Thus, this project aims to test the feasibility of delivering a sole physical activity intervention in pregnancy, based in primary care, to help manage GWG.

Primary research question:

Is it feasible to deliver and test the effectiveness of an intervention, based in primary care, to promote physical activity among pregnant women?
Secondary research questions:

1. Are the outcome measures of questionnaire, pedometer and accelerometer data feasible for use for pregnant women?
2. Is a pedometer-based physical activity intervention, with goal-setting and feedback, acceptable to pregnant women?
3. What are the perceived barriers to physical activity for pregnant women?
4. Are the rates of response, recruitment and engagement with the intervention sufficient to support the development of a large scale randomised controlled trial?
Chapter 2: Feasibility study of a general practice based physical activity intervention in pregnant women

2.1 Background Rationale

As highlighted in the preceding literature review (Chapter 1) there is a clear evidence gap regarding the best method of helping women to manage their gestational weight gain and increase their physical activity levels in pregnancy. Also, little research has been conducted in relation to promoting physical activity in pregnancy in the primary care setting and so this study was planned to be conducted in the GP environment in order to add to current available knowledge.

The 2010 NICE weight management guidelines for pregnancy stated that few evaluations of the effectiveness of weight management interventions have included adequate and validated measures of diet and physical activity and that they often relied on self-reporting. For this reason validated means of assessing physical activity both objectively and through the means of self-reporting via a questionnaire were chosen for this study. The guidelines also pointed out that few studies of weight management before, during and after pregnancy included interventions that were evaluated using process and qualitative data to determine which components were effective. For this reason feedback questionnaires at the end of the study have been included in the current study protocol, in order to obtain qualitative feedback regarding the physical activity intervention.
The Cochrane Collaboration, in their review of existing literature reporting the effectiveness of interventions to prevent excessive gestational weight gain, highlighted significant methodological limitations of included studies and small observed effect sizes. They recommended that more high-quality randomised controlled trials with adequate sample sizes are required to evaluate the effectiveness of potential interventions. The aim of this current project is to determine the feasibility of delivering a simple, reproducible physical activity intervention in primary care, to help manage gestational weight gain and increase physical activity levels during pregnancy and also to determine the feasibility of testing its effectiveness in a randomised controlled trial.

2.2 Aims and objectives of this study

The aim of this research is to test the feasibility of delivering a simple and reproducible physical activity intervention in primary care that will help reduce gestational weight gain and increase physical activity levels during pregnancy. The full research protocol is detailed in Appendix 1.

Primary research question:

Is it feasible to deliver and test the effectiveness of an intervention, based in primary care, to promote physical activity among pregnant women?

Secondary research questions:

1. Are the outcome measures of questionnaire, pedometer and accelerometer data feasible for use for pregnant women?
2. Is a pedometer-based physical activity intervention, with goal-setting and feedback, acceptable to pregnant women?

3. What are the perceived barriers to physical activity for pregnant women?

4. Are the rates of response, recruitment and engagement with the intervention sufficient to support the development of a large scale randomised controlled trial?

2.3 Methods

Study Design:

This is a feasibility study based in primary care. A feasibility study was chosen as opposed to a pilot study in order to address the aforementioned research questions in respect of recruitment and engagement with the study and also to determine acceptability of the intervention. The National Institute of Health Research (NIHR) have defined feasibility studies as pieces of research done before a main study in order to answer the question ‘Can this study be done?’ (NIHR). They are useful to determine if recruitment is possible and are clinicians willing to recruit participants. Adherence and compliance rates as well as response and follow-up rates are assessed but not outcome measures. In contrast, pilot studies are a smaller version of the proposed larger scale trial and outcome measures are assessed. For these reasons a feasibility study was appropriate.

Practice Sample:

Four practices from differing socio-economic backgrounds were invited to take part by way of a letter of invitation (Appendix 2a). This was purposeful sampling, based
on location and socio-economic status. Initially two Belfast based practices were invited to take part in the study and agreed to do so in August 2014; Woodbrooke Medical Practice and a split site practice - Springfield Road Surgery and Riverdale Park surgery. Both these surgeries are based in areas of socio-economic deprivation. Hillsborough Medical practice were invited and agreed to take part in September 2014. This practice is situated in Hillsborough just outside Lisburn City and would have quite an affluent patient population. In October 2014 a fourth practice, Elmwood Medical Practice, was also invited to take part. It is a Belfast based practice with patients from socio-economically deprived areas.

A face-to-face meeting took place with the lead GPs in each of the four practices, at which the researcher explained the study, the recruitment process and gained written agreement from the lead GP for each practice to take part. A copy of this consent form is included in Appendix 2b.

Participants:

The GP or midwife conducting the booking visit identified potential participants for the research study in accordance with the inclusion and exclusion criteria specified below;

Inclusion Criteria:

- Aged 18-50 years
- BMI 18.5-39.5
- Singleton pregnancy
- English as first language
• Live within a 30 mile radius of Belfast

Exclusion criteria:

• Pre-existing medical conditions (e.g. diabetes, cardiovascular disease, hypertension, disability that prevents participation in an exercise intervention)
• Currently involved in other research.

Sample size:

Based on a pragmatic decision, for the purposes of feasibility, the aim was to recruit 30 participants. As this was a feasibility study a power calculation was not deemed appropriate to determine the target sample size: the focus of this study was on estimating parameters for either a pilot study or a larger scale randomised controlled trial.

Recruitment:

Recruitment across the five sites took place between August and November of 2014.

At booking for antenatal care, women with a BMI of 18.5-39.5 who met the inclusion criteria were given information about the study and invited by the GP or midwife with whom they were consulting, to consent to be contacted by the researcher. This was a written consent form completed by both the patient and the recruiting health professional (Appendix 2c). These consent forms were collected by the researcher from the various sites and subsequently she made contact via telephone with the potential participants. If the patient agreed to take part the first
visit was planned for when the woman was at approximately 12-13 weeks gestation. Visits between the researcher with participants took place in their respective GP surgeries.

Data collection:

*Study visit 1:*

At the initial visit with participants baseline measurements were taken, namely height and weight (in order to calculate BMI) and blood pressure. A ‘patient details’ form was completed which recorded other baseline data, including postcode, age, parity, occupation status, ethnicity and medical history. Informed written consent was also taken at this stage (Appendix 2d).

A validated basic dietary questionnaire entitled The Dietary Instrument for Nutrition Education (DINE) was used to collect information regarding dietary habits (Appendix 3). The DINE was developed for use in nurse-administered health checks in general practice or worksite programmes (Roe, Strong et al. 1994). The questions allow for a brief assessment of an individual's total fibre, total fat and unsaturated fat within their diet and can be completed in 5-10 minutes. It provides a basis for identifying both good and bad food habits and for offering individually tailored brief dietary counselling. This was completed in accordance with NHS current guidance and current standard practice within the Belfast Trust. In addition to this, participants were also asked about their average number of portions of fruit and vegetables eaten per day.
At the end of the initial visit each participant was asked to wear an accelerometer for one week to obtain a baseline physical activity level. An accelerometer was used in order to obtain an objective measure of physical activity in the participants. An Actigraph accelerometer was chosen, from which data obtained can be uploaded and analysed to calculate steps taken and differing intensities of physical activity. Participants were asked to record in a diary when they were wearing the accelerometer and when it was taken off (Appendix 4).

*Study Visit 2:*

At a second visit between the researcher and participant, planned for the end of the week of their accelerometer data collection, the participants were randomly allocated to either the control or the intervention arm of the study. This randomisation process, which used block randomisation and concealed envelopes, was carried out by a second researcher, who was not involved with delivering the intervention or the data collection. It was carried out in blocks of four and the allocation was given to the primary researcher in a sealed envelope prior to the second visit with the research participant. At this second visit, accelerometer information was collected by the researcher and a baseline Pregnancy Physical Activity Questionnaire (PPAQ) was completed by the participant (Appendix 5). The PPAQ is a 34 item questionnaire developed for use in pregnancy to give information not only on total physical activity but also on levels of physical activity at different intensities. At this visit, after completion of gathering accelerometer and questionnaire data, the envelopes were opened to determine to which arm of the trial the participant was allocated.
The Intervention:

Those participants who were allocated to the intervention group were given a ‘Fitbit’ pedometer (Fitbit zip, fitbit.inc, 2012) to wear for 12 weeks, during waking hours, with removal during water-based activity. This monitor is worn on the hip and records step counts and has Bluetooth technology allowing the users to upload their data onto a computer based programme to track their activity. The participants were asked to record their daily step count in a step count diary (Appendix 6). One-to-one tailored physical activity brief intervention advice was given to those placed into the intervention group based on the 5A’s approach (Ask, Advise, Assess, Assist and Arrange) (Sim, Wain et al. 2009). This is outlined below.

(1) ASK

Participants were asked about the type and duration of physical activity that they currently undertook, during a typical week. Questions were based on the Pregnancy Physical Activity Questionnaire.

(2) ADVISE

Participants were advised (informed) that healthy adults, including women who are pregnant, should aim to undertake 150 minutes of moderate intensity physical activity weekly, in bouts of 10 minutes or more. This activity is best spread across the week, rather than being undertaken all at once and people who did not currently do as much activity as this were advised to build up their activity gradually, beginning with 15 minutes three times per week and gradually building upon this.
(3) ASSESS

The researcher assessed their average levels of daily activity and discussed these with the participant. Participants were asked to assess their own level of physical activity in relation to the recommendations and consider their readiness and ability to maintain or increase their PA levels. They assessed their own step count at the end of each week and the researcher advised that a proposed increase should not be greater than 10% (in daily step count) during any week.

(4) ASSIST

The researcher discussed local facilities and opportunities for walking with the participant to help them to plan how to achieve regular activity, exploring their preferred approach to this, in terms of location, possible group activities and other social support for physical activity which may be available within the local community. Participants were shown how to wear a pedometer and record step counts.

(5) ARRANGE

Plans for follow-up text messages from the researcher were made with the participant. Participants were asked to record their daily step count activity in a diary using the Fitbit pedometer. The text messages served as a reminder to fill in the diary and also were an opportunity for the participants to speak with the researcher to help resolve any problems experienced or to obtain further guidance. Face-to-face reviews were arranged to take place after 12 weeks.
Contact was maintained with participants via telephone and text messaging to a ‘PayAsYouGo’ mobile telephone specific to the project and held by the primary researcher. The reminder text messages were sent initially weekly for four weeks and then fortnightly for the next eight weeks.

**Study Visit 3:**

Both the intervention and the control group received their usual antenatal care. Both groups were followed up after 12 weeks which approximated to 28 weeks gestation. Pedometers were collected at this visit from the intervention group and an accelerometer was given to all participants, to be worn for one week, to allow a repeat objective measurement of their physical activity.

**Study Visit 4:**

After this week the accelerometer was collected and a second PPAQ was completed by all women alongside a study feedback questionnaire (see Appendix 7a and 7b). The questionnaires included questions about the acceptability of wearing and recording data relating to the accelerometer and pedometer and about the acceptability of questionnaires used in the study. Participants were also asked if they would like to receive advice from a health professional about physical activity in a future pregnancy.

The flow chart overleaf summarises this phase of the study.
Visit 1
(Week 1)

Visit 2
(Week 2)

Visit 3
(Weeks 14-15)

Visit 4
(Weeks 15-16)

12-13 weeks gestation:
- Discuss project, explain randomisation
- Baseline measurements (height/weight/BP)
- Patient details form
- Allocate study ID
- DINE
- Accelerometer given for 1 week

13-14 weeks gestation:
- Collect accelerometer
- Baseline PPAQ
- Randomly allocated to group

Intervention Group
- Brief physical activity advice (5A's)
- Pedometer and diary given

Control Group
- Usual antenatal care

Weeks 3/4/5/6/8/10/12/14 – text message sent
- Usual antenatal care continued

Intervention Group
- Collect pedometer & data
- Give accelerometer

Control Group
- Give accelerometer

Both groups
- Collect accelerometer
- Repeat weight and blood pressure
- Second PPAQ
- Feedback questionnaires

13-14 weeks gestation:
- Collect accelerometer
- Baseline PPAQ
- Randomly allocated to group

Intervention Group
- Brief physical activity advice (5A's)
- Pedometer and diary given

Control Group
- Usual antenatal care

Weeks 3/4/5/6/8/10/12/14 – text message sent
- Usual antenatal care continued

Intervention Group
- Collect pedometer & data
- Give accelerometer

Control Group
- Give accelerometer

Both groups
- Collect accelerometer
- Repeat weight and blood pressure
- Second PPAQ
- Feedback questionnaires
Data Analysis:

All the dietary questionnaires were analysed and scores were calculated using the corresponding DINE scoring sheet. These scores were then classified as low medium or high intake as per the pre-defined ranges in the scoring sheet (Roe, Strong et al. 1994).

Accelerometer data were analysed using Actilife computer software (version 6.11.6, Actigraph LLC, USA). A valid dataset was defined as having at least four valid days of data. A valid day was defined as having at least ten hours of wear time. Non-wear time was defined as a run of zero counts lasting more than 60 minutes (Cain KL ). In order to obtain total minutes of moderate to vigorous physical activity (MVPA) per day, the data were reintegrated in 60 second epochs before Triano cut off points were applied (Troiano, Berrigan et al. 2008). These settings were chosen so that the data would be comparable with a similar analysis of physical activity in pregnant women in the United States (Loprinzi, Fitzgerald et al. 2013).

The responses to the written PPAQ were analysed to calculate total activity expenditure and total moderate-to-vigorous intensity activity so that this data could be evaluated in conjunction with the accelerometer data. These values were calculated according to the guidance of the questionnaire’s authors. Each question asked about a specific physical activity and had a corresponding MET value. Time spent in this activity and intensity were also taken into account and questions with similar intensities of exercise were summated (Chasan-Taber, Schmidt et al. 2004).
Accelerometer data was entered onto SPSS in order to facilitate analysis using the ActiLife software. Paper records were used to manually tally up scores for the PPAQs.

2.4 Ethical considerations

Ethical approval for this study was obtained through ORECNI in June 2014, (IRAS project ID 145009). A copy of the approval letter is included in the appendices (Appendix 2e). Written informed consent to participate in the study was obtained from both the participating patients and the recruiting GP practices (Appendices 2b, 2c and 2d).

With regards to the ethical principle of autonomy, all participation in this study by both the practices and the pregnant women was voluntary. This is highlighted in the consent forms and all participants were advised that they were free to withdraw at any stage for any reason without incurring any disadvantage to their usual care. In the event of the development of any medical or psychological issues that would prevent ongoing participation in the study, for example miscarriage, a distress protocol was devised (Appendix 2f).

Participating practices were reimbursed £150 in recognition of their time and willingness to participate in recruitment. The research participants did not receive any financial incentive for taking part. In terms of non-maleficence and safety considerations, exercise in pregnancy is not known to be harmful to the unborn child.
and thus no adverse outcomes were to be expected. However, patients were informed that they were free to withdraw from the study at any point and if any medical scenarios arose which could prevent ongoing participation in the trial, recruits could contact the primary researcher directly. Contact details were also included in a letter sent to the patient’s GP and a copy of this letter was filed in their antenatal clinic notes so that other health professionals could contact the researcher if so required. At the end of the study a patient questionnaire was completed to gain feedback on the intervention and again aid reporting of any adverse effects or safety aspects. As the researcher met participants individually on a one-to-one basis, a lone worker policy was created in order to reduce the risk of harm to the primary researcher (Appendix 2g).

In terms of confidentiality, the researcher had access to patients’ personal data during the study and these data were analysed in the Department of General Practice at Queen’s University, Belfast. The storage of the research data will be retained in a secure locked filing cabinet and password protected computer in QUB Department of General Practice for three years. In the event of the participant disclosing information that would warrant concern for her or the unborn child’s safety a disclosure protocol was developed (Appendix 2h).

2.5 Quality Assurance

The research study progress was reviewed regularly by the Research Governance Office of the Queen's University, Belfast and the research supervised by Professor
Cuppes who is head of the Department of General Practice at the University. Regular meetings with all of the study supervisors ensured that progress took place in accordance with the planned protocol and has been reviewed bi-annually by the University’s Postgraduate Research Committee.

2.6 Modification to initial protocol

Unfortunately recruitment rates fell short of what was projected. The original research protocol had asked that the research participants complete a questionnaire at the end of the study in order to gain information about the acceptability of the various components of the intervention. In order to add to this qualitative assessment ethical approval was sought and granted (Appendix 2i) to interview some potentially eligible pregnant women and the health professionals who had agreed to be involved in recruitment to ascertain their views about physical activity and participation in a study of physical activity during pregnancy. This would take the form of brief semi-structured interviews and is detailed in the next chapter.
Chapter 3: Pregnant women’s and health professional’s views on physical activity in pregnancy.

The second phase of the study took the form of semi-structured interviews with both pregnant women and GPs and midwives who were involved in recruitment to the initial phase of the study. This phase was developed because it was considered necessary to explore reasons for poor uptake to the feasibility study. A qualitative approach to explore perceptions of physical activity in pregnancy was considered to be the best way to achieve this.

3.1 Aims and objectives of this study

The aim of this aspect of the study was to explore views on physical activity in pregnancy and to help identify possible facilitators and barriers both to increasing physical activity and participating in physical activity research in pregnancy.

3.2 Methods

Study Design:

Semi-structured interview templates were developed in response to poor uptake and adherence to the first phase of the study. The questions were chosen to examine reasons why pregnant women were reluctant to take part in physical activity research
during their pregnancy and also to explore possible facilitators to increasing physical activity levels in pregnancy to aid further research in this area.

Practice Sample:

Purposeful sampling was used and one practice was selected where recruitment had some success and a second practice in which recruitment was unsuccessful (Woodbrooke Medical Practice and a split site practice - Springfield Road Surgery and Riverdale Park surgery, respectively). As mentioned previously, both these Belfast based practices are located in socio-economically deprived areas.

Participants:

Pregnant woman who were booked for review at their antenatal clinic appointment in general practice were eligible to be invited to participate in a short semi-structured interview. Woman who were already recruited into the initial phase of the study or who did not have English as their first language were excluded from this phase of the study.

Sample size:

Six routine antenatal clinics in two practices were identified as being suitable for the researcher to attend, due to time-table constraints in other aspects of her work. Women who were booked for these clinics and not known to meet any exclusion criteria were invited to take part. The sample size was pragmatic: 33 women were identified as attendees at these clinics and this number was considered to include
women with a range of different relevant background characteristics. Five GPs and one midwife were involved in recruitment to the initial phase of the study in these two practices and all six were invited to take part.

Recruitment:

Women due to attend one of six routine antenatal clinic appointment with midwives in Woodbrooke Medical Practice, Springfield Road Surgery and Riverdale Park Surgery were sent a letter in advance of their appointment, to inform them about the study and that the researcher would be present in their practice on the day of their appointment, to invite them to talk briefly with her about their thoughts on physical activity in pregnancy. Women were directed to the researcher after their appointment with the midwife was completed, if they were agreeable to take part. A written consent form was completed at the time of the interview (Appendix 2j).

In Woodbrooke Medical Practice the GPs were the point of contact for approaching pregnant women about the ‘Simple Steps’ research study. These GPs were personally invited by the researcher to take part in semi-structured interviews at a mutually convenient time and place. The midwife, who was the contact point for recruitment to the study in the Springfield Road/Riverdale Park Practices, was also personally invited to take part in an interview with the same format.

Data collection:
Six questions regarding views on physical activity in pregnancy were asked to both the women and the Healthcare Professionals (HPs) alongside the GPPAQ (General
Practice Physical Activity Questionnaire) (National Institute for Health and Care Excellence (NICE) 2013) (see Appendix 8). The GPPAQ is a brief screening questionnaire, used to assess individuals’ levels of physical activity and consisting of four questions which give a score that correlates to either being active, moderately active, moderately inactive or inactive.

The pregnant women met with the researcher after their appointment with the midwife and completed semi-structured interviews in a clinic room at their practice. The questions asked about their views on physical activity in pregnancy and potential facilitators and barriers to women increasing their physical activity and taking part in physical activity research in pregnancy (Appendix 9a). Each interview took approximately ten minutes to complete and participant responses were hand-written by the researcher at the time. There are some methodological weakness associated with hand-writing response as they are necessarily selective with the potential for researcher bias and inaccuracies. However, due to practical reasons, such as trying to encourage participation given prior poor engagement with phase 1 of the study, that young children are commonly present at these appointments which could interfere with audio-recording and also due to a limited time frame to conduct and analyse the semi-structured interviews, hand-recording of the responses was chosen.

The HPs completed an adapted form of the semi-structured interview which asked them about their views on physical activity in pregnancy and also what they felt were facilitators and barriers to their patients increasing their physical activity and taking part in physical activity research in pregnancy (Appendix 9b). These interviews
lasted 10-15 minutes and participant responses were documented by the researcher. A written consent form was completed at the time of the interview (Appendix 2k).

Prompts were used during the interview process if the interviewee failed to give a response to the question or answered very briefly. These prompts are printed on the semi-structured interview documents (Appendices 9a and 9b) and were based upon responses given by women who had declined to take part in the feasibility study and on current literature.

All the data from the semi-structured interviews were transcribed by the researcher, anonymised and stored on a password protected computer.

**Data analysis:**

The Framework Method of analysis is commonly used to analyse qualitative data in health research, particularly data derived from semi-structured interviews (Gale, Heath et al. 2013). This was chosen as the method for analysis, aiming to identify common themes within the interviewees’ responses and to allow different views from the two separate groups to emerge.

The Framework Method is an appropriate analytical method as it can allow themes to emerge from both deductive and inductive approaches. The questions for the semi-structured interviews were compiled in order to address four key themes via deductive processes;

1. Physical activity and pregnancy
2. Facilitators to increasing physical activity in pregnancy

3. Barriers to increasing physical activity in pregnancy

4. Barriers to engaging in research in physical activity in pregnancy

An inductive process was also used during the analysis of the data in order to identify possible new themes and further sub-themes.

The analytical process involved four stages (adapted from seven stages outline in (Gale, Heath et al. 2013);

1. Transcription; all hand written responses from the semi-structured interviews were transcribed onto a Microsoft word document.

2. Familiarization; datum were read and re-read in order for the researcher to become familiar with the data content to aid the inductive process of theme development.

3. Coding; codes were highlighted throughout the dataset with similar values and feelings highlighted in the same colour.

4. Charting of data into a framework matrix; Highlighter pens and ‘post-its’ were used to label codes in the data and codes were then grouped together and charted onto a framework matrix. The aim of this was to compare responses between the two cohorts interviewed to establish common threads in the four different categories. From this sub-themes were developed under the four pre-determined areas. An excerpt of this is shown in the table below;
### Themes:

<table>
<thead>
<tr>
<th>Interviewees:</th>
<th>Facilitators to</th>
<th>Barriers to</th>
<th>Barriers to engaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA &amp; Pregnancy</td>
<td>increasing PA</td>
<td>increasing PA</td>
<td>in research</td>
</tr>
</tbody>
</table>

#### Women
- Nausea
- Tiredness

#### HCPs
- Important
- Time

All raw data were reviewed by a second researcher so that these themes were verified and validated. The data were reviewed independently; then a meeting was arranged at which both researchers discussed the analysis. Some differences in their labelling and coding were discussed and agreement was reached regarding categorisation of data within sub-themes.

### 3.3 Ethical considerations

Ethical consent for this aspect of the study was obtained through an amendment submission to ORECNI in December 2014. A copy of the approval letter is included in the appendices (Appendix 2i). Written informed consent to participate in the semi-structured interviews was obtained from both the patients and the recruiting GPs and midwives (Appendices 2j and 2k).
With regards to the ethical principle of autonomy, all participation in this study by both the GPs, midwives and the pregnant women was voluntary. This was highlighted in the consent forms.

No financial incentives were given for participation. In terms of non-maleficence and safety considerations, no harm was expected to arise from participating in interviews. If the pregnant woman had experienced any distress during their appointment with the midwife they were under no pressure to stay and take part in the interviews as the researcher was located in a separate room within the general practice’s premises.

In terms of confidentiality, no identifiable patient data were recorded on the semi-structured interview booklet and patients were advised during the process of obtaining consent that their responses would be anonymised and they would not be identifiable in any documentation relating to the study.

The researcher had access to patients’ responses and these were analysed in the Department of General Practice at Queen’s University, Belfast. The storage of the research data will be retained in a secure locked filing cabinet and password protected computer in QUB Department of General Practice for three years.
Chapter 4: Results - Feasibility Study

4.1 Recruitment

Four practices were invited to take part in recruitment. Table 4.2 below details recruitment figures and uptake. Due to organisation changes within two practices, no participants were recruited and no data on eligible participants were obtained in these practices. In practice 3, there was a change in the pathway for new antenatal clinic referrals in that the patients could directly refer themselves to the midwives who conducted the booking appointment in secondary care and for which the researcher did not have research governance approval. In Practice 4, there were some difficulties that may have inhibited recruitment; not all GP partners were present at the meeting with the researcher, the consent form was to be attached to a leaflet that is usually given out to newly pregnant women so recruitment was reliant on this leaflet being given and one GP in this practice did not see newly pregnant women but instead directly referred them to the hospital antenatal clinic.

Table 4.1 Recruitment figures

<table>
<thead>
<tr>
<th>Practice</th>
<th>Recruitment period</th>
<th>Eligible for participation</th>
<th>Consented to contact n (%)</th>
<th>Successfully recruited n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21.07.14-28.11.14</td>
<td>45</td>
<td>25 (56%)</td>
<td>6 (24%)</td>
</tr>
<tr>
<td>2</td>
<td>28.08.14-28.11.14</td>
<td>23</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>3</td>
<td>06.10.14-28.11.14</td>
<td>Unknown</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>14.09.14-28.11.14</td>
<td>Unknown</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
The graph below (Graph 1) shows the projected recruitment timeline versus the actual recruitment figures. As can be seen the period of recruitment was extended and in between times there was contact made with the recruiting practices at different intervals to determine if anything could be done to improve recruitment.

Graph 1: Recruitment graph

Twenty eight women consented to be contacted by the primary researcher about the study. The pie chart overleaf (Fig 4.1) shows the outcomes of these contacts: of those who were not recruited, seven declined to participate, three did not attend arranged appointments with the researcher and eight could not be contacted. Four were not eligible as they were too early of a gestation when the recruitment period ended. There were at least four attempts at contact made and voicemails left where possible.
4.2 Baseline characteristics of participants

At their initial visit (visit 1) a baseline characteristics questionnaire was completed for all 6 participants. This questionnaire included questions about age, parity, occupation, among other details and the results are summarised in the table below (Table 4.2).

Table 4.2 Characteristics of participants of feasibility study

<table>
<thead>
<tr>
<th>PARTICIPANT IDENTITY NUMBER</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>30</td>
<td>35</td>
<td>20</td>
<td>24</td>
<td>27</td>
<td>25</td>
</tr>
<tr>
<td>Postcode</td>
<td>BT17</td>
<td>BT17</td>
<td>BT17</td>
<td>BT17</td>
<td>BT17</td>
<td>BT17</td>
</tr>
<tr>
<td>Medical Conditions</td>
<td>None</td>
<td>Arthritis</td>
<td>None</td>
<td>Asthma</td>
<td>Meniere's</td>
<td>Hypothyroid/PCOS</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>White</td>
<td>White</td>
<td>White</td>
<td>White</td>
<td>White</td>
<td>White</td>
</tr>
<tr>
<td>Parity</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Occupation</td>
<td>Nurse</td>
<td>Clerical</td>
<td>Clerical</td>
<td>Clerical</td>
<td>Clerical</td>
<td>Unemployed</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>67.6</td>
<td>64.2</td>
<td>49.4</td>
<td>62.4</td>
<td>55.2</td>
<td>96.0</td>
</tr>
<tr>
<td>BMI</td>
<td>26</td>
<td>22</td>
<td>20</td>
<td>24</td>
<td>21</td>
<td>34</td>
</tr>
<tr>
<td>Blood pressure*</td>
<td>113/65</td>
<td>99/64</td>
<td>96/58</td>
<td>118/74</td>
<td>100/68</td>
<td>139/82</td>
</tr>
<tr>
<td>Gestation**</td>
<td>13</td>
<td>12+5</td>
<td>15+5</td>
<td>12+2</td>
<td>13</td>
<td>16+1</td>
</tr>
</tbody>
</table>

* mmHg ** weeks
4.3 Diet Questionnaire  Six participants completed the Dietary Instrument for Nutrition Education (DINE). Scores for the answers to the questions were totalled and results for each of the three sub-categories of dietary fibre intake, total fat intake and unsaturated fat intake are shown in the table below (Table 4.3).

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>DF (Dietary Fibre)</th>
<th>TF (Total Fat)</th>
<th>UF (Unsaturated Fat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>26</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>36</td>
<td>43</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>33</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>31</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>5</td>
<td>42</td>
<td>34</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>49</td>
<td>22</td>
<td>5</td>
</tr>
</tbody>
</table>

Dietary fibre:

A low dietary fibre intake is defined as <20g per day according to DINE, medium intake equivalent to 30-40g per day and high fibre intake equivalent to >30g per day. NHS guidelines would recommend at least 18g per day (NHS 2015)(NHS 2015, NHS 2015)(52,52). Half of the participants reported a medium fibre intake, one third reported high fibre intake and the remaining participant reported eating a low fibre diet.
Total Fat:

A low fat score is equivalent to 83g/day, a medium fat score to 84-122g per day and a high fat score to >122g per day. NHS guidelines state total fat intake should be approximately 70g/day (NHS 2014). Half of the women had low intakes of total fat in the diet whereas two women had medium intakes and one had a high intake.

Unsaturated Fat:

Half of the participants reported low and half reported medium unsaturated fat intake. There are no current NHS recommendations regarding recommended intakes of unsaturated fats.

In addition to the DINE questionnaire, each participant was also asked to report the average number of fruit and vegetable portions which they consumed daily. The results are shown below (Table 4.4). Only two participants met current guidelines that at least 5 portions of fruit or vegetables should be eaten daily (NHS choices 2013).
4.4 Accelerometer data

All six participants were given an accelerometer to wear for one week at the beginning of the study to obtain baseline data. They were also asked to complete diaries to keep a record of when they were wearing the monitor (Appendix 4). Only two participants completed the accelerometer diary fully at baseline.

Comparable data were obtained from four out of six participants at baseline and also a second dataset was obtained from only one participant at the end of the study. Participant three, who subsequently dropped out after visit 1, had no valid baseline wear time data when the accelerometer was analysed. Participant six took the accelerometer off so often during the day that there was not enough baseline wear time to analyse the data. The baseline accelerometer data are shown in the table below (Table 4.5).
Table 4.5 Baseline accelerometer data for participants 1, 2, 4, and 5

<table>
<thead>
<tr>
<th>Physical Activity Variables</th>
<th>Participant</th>
<th>Sedentary (minutes/day)</th>
<th>Light intensity (minutes/day)</th>
<th>Moderate-vigorous (minutes/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>494.8</td>
<td>301.75</td>
<td>14.25</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>377.8</td>
<td>295</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>512.3</td>
<td>201.3</td>
<td>14.1</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>543.4</td>
<td>181</td>
<td>31.4</td>
</tr>
</tbody>
</table>

Those women who achieved higher values than these comparable averages are highlighted in blue.

Only one participant wore the accelerometer for a second time at the 12 week follow-up appointment. These results are shown in the table below (Table 4.6).

Table 4.6: Accelerometer data for participant 4 at baseline and follow-up.

<table>
<thead>
<tr>
<th>Physical Activity Variables</th>
<th>Participant</th>
<th>Sedentary (minutes/day)</th>
<th>Light intensity (minutes/day)</th>
<th>Moderate-vigorous (minutes/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 (1)</td>
<td>512.3</td>
<td>201.3</td>
<td>14.1</td>
</tr>
<tr>
<td></td>
<td>4 (2)</td>
<td>543.4</td>
<td>222.4</td>
<td>8.1</td>
</tr>
<tr>
<td>Percentage change from baseline</td>
<td></td>
<td>+6%</td>
<td>+10%</td>
<td>-42.5%</td>
</tr>
</tbody>
</table>

The amount of time spent in sedentary and light intensity activities increased between the two measurements and as expected the amount of time spent in
moderate-to-vigorous activity decreased. At the first data collection the participant was 12 weeks pregnant and at the second data collection point she was 28 weeks pregnant.

4.5 Pregnancy Physical Activity Questionnaires (PPAQ)

Five out of six participants completed the PPAQ at baseline. Only one participant completed the follow-up PPAQ. The PPAQ allows for calculation of average weekly energy expenditure in METs per hour per week. Current US government guidance recommends total weekly physical activity in the range of 500 to 1,000 MET-minutes and this level of activity provides substantial health benefits for adults (Office of disease prevention and health promotion. 2015). The table below (Table 4.7) shows the results from the PPAQ’s in terms of average weekly energy expenditure MET/hour/week and has been calculated for moderate-to-vigorous physical activity and total activity.

Table 4.7: PPAQ results

<table>
<thead>
<tr>
<th>Participant</th>
<th>Moderate-to-vigorous physical activity (MET-h week⁻¹)</th>
<th>Total activity (MET-h week⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>135.2</td>
<td>421.5</td>
</tr>
<tr>
<td>2</td>
<td>193.7</td>
<td>453.1</td>
</tr>
<tr>
<td>4 (1)</td>
<td>28</td>
<td>186.2</td>
</tr>
<tr>
<td>4 (2)</td>
<td>0</td>
<td>204.9</td>
</tr>
<tr>
<td>5</td>
<td>98.2*</td>
<td>330.6</td>
</tr>
<tr>
<td>6</td>
<td>75.4*</td>
<td>194.2</td>
</tr>
</tbody>
</table>

Of note none of the women met the target of 500 to 1,000 MET-minutes.
4.6 Pedometer and step count diary.

Data relating to step counts for two out of three participants in the intervention group were incomplete. One participant dropped her pedometer down the toilet and the other put hers through the washing machine. Summary data for the one participant who completed the 12 weeks are shown in the table below (Table 4.8) with percentage change from previous week in average weekly step count calculated and shown in brackets. Overall there was a difference in step count of -20% from week one to week twelve.

Table 4.8: Step count diary results for Participant 1

<table>
<thead>
<tr>
<th>Week</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
<th>Average for week</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14345</td>
<td>11063</td>
<td>8007</td>
<td>10987</td>
<td>6001</td>
<td>12678</td>
<td>5784</td>
<td>9,980</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9064</td>
<td>13206</td>
<td>11345</td>
<td>7654</td>
<td>5275</td>
<td>14567</td>
<td>8954</td>
<td>10,009</td>
<td>+0.3</td>
</tr>
<tr>
<td>3</td>
<td>13751</td>
<td>10031</td>
<td>9876</td>
<td>4009</td>
<td>11311</td>
<td>5745</td>
<td>6641</td>
<td>8,766</td>
<td>-12</td>
</tr>
<tr>
<td>4</td>
<td>6754</td>
<td>7012</td>
<td>15003</td>
<td>11522</td>
<td>9876</td>
<td>4958</td>
<td>10137</td>
<td>9,323</td>
<td>+6</td>
</tr>
<tr>
<td>5</td>
<td>13115</td>
<td>12748</td>
<td>5699</td>
<td>9043</td>
<td>8271</td>
<td>10996</td>
<td>6341</td>
<td>9,459</td>
<td>+1</td>
</tr>
<tr>
<td>6</td>
<td>9211</td>
<td>11456</td>
<td>3451</td>
<td>14975</td>
<td>13842</td>
<td>6114</td>
<td>7822</td>
<td>9,553</td>
<td>+1</td>
</tr>
<tr>
<td>7</td>
<td>2714</td>
<td>13879</td>
<td>12941</td>
<td>15014</td>
<td>5672</td>
<td>7811</td>
<td>6789</td>
<td>9,260</td>
<td>-3</td>
</tr>
<tr>
<td>8</td>
<td>9247</td>
<td>3992</td>
<td>11041</td>
<td>10981</td>
<td>5016</td>
<td>6721</td>
<td>10543</td>
<td>8,220</td>
<td>-11</td>
</tr>
<tr>
<td>9</td>
<td>11017</td>
<td>6241</td>
<td>7004</td>
<td>9923</td>
<td>11947</td>
<td>4756</td>
<td>5175</td>
<td>8,009</td>
<td>-2</td>
</tr>
<tr>
<td>10</td>
<td>2394</td>
<td>5717</td>
<td>8345</td>
<td>13121</td>
<td>12671</td>
<td>6821</td>
<td>13981</td>
<td>9,007</td>
<td>-12</td>
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<td>11</td>
<td>14732</td>
<td>5167</td>
<td>9214</td>
<td>3217</td>
<td>11008</td>
<td>6216</td>
<td>6104</td>
<td>7,951</td>
<td>-12</td>
</tr>
<tr>
<td>12</td>
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<td>9813</td>
<td>8321</td>
<td>3045</td>
<td>5877</td>
<td>11124</td>
<td>7,941</td>
<td>0</td>
</tr>
</tbody>
</table>
4.7 Drop outs

Six participants were successfully recruited to the study. All six attended the first visit and completed a baseline questionnaire detailing patient characteristics and basic dietary information. Two participants dropped out before the second visit; one of these participants provided completed accelerometer and PPAQ data. One participant went on holiday and did not respond to any attempts to make contact for follow up. Another participant dropped out to due illness within the family. At the second visit the four participants were randomly allocated, with three falling into the intervention group and one into the control group. The participant in the control group attended the final visit (visit 4), completing a second data collection of accelerometer data and feedback questionnaires. Two from the intervention group dropped out and one completed the 12 week pedometer and step count diary intervention. The reasons for the two later stage drop outs were flare up of psoriatic arthritis and antenatal complications, specifically placenta praevia and gestational diabetes mellitus. It was not possible to collect a final data collection of accelerometer and PPAQ from the participant who completed the 12 week step count diary as she went into early labour. A flow chart overleaf (Figure 4.4) shows the flow of participants and their engagement through the study.
Figure 4.4 Flow of participants throughout the study.

68 Eligible

26 consented

6 recruited

4 randomised

Intervention group n=3

Control group n=1

2 dropped out

1 completed intervention

1 completed control

89 phone-calls
4 DNAs

2 dropped out
4.8 Feedback questionnaires

Only one participant completed the patient satisfaction questionnaire and the results are shown below.

Table 4.9 Feedback questionnaire from participant 4

<table>
<thead>
<tr>
<th>Question:</th>
<th>Response:</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found the accelerometer easy to wear</td>
<td>Agree</td>
<td>Easier first time but a bit uncomfortable the second time as belly got bigger.</td>
</tr>
<tr>
<td>The PPAQ was too detailed:</td>
<td>Strongly disagree</td>
<td></td>
</tr>
<tr>
<td>In a future pregnancy I would like to receive advice from my GP/midwife regarding PA in pregnancy</td>
<td>Strongly agree.</td>
<td></td>
</tr>
</tbody>
</table>
5.1 Participants

Five GPs and one midwife from two recruiting practices were invited to take part in semi-structured interviews to explore their views on physical activity in pregnancy. These included all those responsible for recruitment in Practices 1 and 2 and all agreed to take part. Six consecutive ante-natal clinics were chosen across the two same two practices. 33 women from these ante-natal clinics were invited and 15 (45%) took part in the semi-structured interviews.

5.2 Physical Activity levels of participants

A brief assessment of personal levels of physical activity was obtained from each participant in the semi-structured interviews, based on responses to General Practice Physical Activity Questionnaire (GPPAQ). The results are illustrated in this bar chart below (Fig 5.1) with number of participants on the y-axis. Each individual’s responses were matched to one of four categories of physical activity: inactive, moderately inactive, moderately active or active; within each category the numbers of HPs (GP/midwife) and of pregnant women are shown in red and blue respectively.
Overall, the HPs reported higher levels of activity with the majority (5/6) categorised as being active or moderately active, compared with the majority of the women (9/15) being categorised as inactive.

5.3 Thematic analysis

The semi-structured interviews were designed to explore health professionals’ and pregnant women’s views of facilitators and barriers to engaging in physical activity during pregnancy and of engaging in research in physical activity whilst pregnant. Using a framework approach, analysis of the combined 21 interviews identified data which supported four main themes:

1. Physical activity and pregnancy
2. Facilitators to increasing physical activity in pregnancy
3. Barriers to increasing physical activity in pregnancy
4. Barriers to engaging in research in physical activity in pregnancy

Each of these themes (see Figure 5.2) will be discussed below. Selected quotes from the interviews are shown to support the themes identified and are anonymised, identifying each participant only by number and status (pregnant woman (PW) or healthcare professional (HP)). A sample interview transcript is included in Appendix 10.

At the outset of the interviews, individuals were asked about their understanding of the term physical activity. The World Health Organisation (WHO) defines physical
activity as any bodily movement that requires energy expenditure (World Health Organisation. 2015). Exercise, however, by its true definition is a subset of physical activity that is planned, structured and repetitive and has a final or an intermediate objective: the improvement or maintenance of physical fitness (Caspersen, 1985). The majority of women interviewed equated physical activity with exercise and gave examples such as walking, gym, swimming and sports. Only two of the 15 who were interviewed recognised that activities within the home, such as ‘cleaning’, could represent physical activity. The health professionals interviewed tended to elaborate a little more in their explanation of the term physical activity and used descriptive phrases; only one of the 5 interviewees mentioned basic activities of daily living and considered that their role was to encourage people to take part in physical activities additional to these.

‘Exercise includes anything that increases your basal metabolic rate’ HP4

‘Generally speaking any form of locomtion’ HP5

‘Any type of activity that increases your heart rate’ HP2

5.3.1 Physical activity and pregnancy

<table>
<thead>
<tr>
<th>PA &amp; Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Recognition of a need for advice</td>
</tr>
<tr>
<td>• Responsibility for giving advice</td>
</tr>
<tr>
<td>• Importance of physical activity</td>
</tr>
<tr>
<td>• Source of advice</td>
</tr>
</tbody>
</table>
Recognition of a need for advice:

There was a general consensus among the women that there was a need for advice about physical activity during pregnancy. Whilst most participants stated that they were not concerned about physical activity causing harm in pregnancy, several reported that they were ‘unsure’ about how much physical activity was safe or how often they should take it. One woman however reported that she had stopped going to the gym because she was afraid that it might harm her pregnancy. Another stated that although she did not believe physical activity was harmful, she had stopped going to the gym and ‘switched to walking’ when she found out she was pregnant. The women interviewed were very open to the prospect of receiving advice from their healthcare professional and some expected to receive it.

‘I would feel alright about it (GP or midwife talking to patient about PA)......there is a need for advice’ PW7

‘Yes there is a need for advice - to date I haven’t received any physical activity advice or information. I got some off the internet by researching it myself’ PW9

‘It would be reassuring to have some guidance’ PW12

One of the HPs recognised that there was a ‘myth’ that physical activity can cause harm in pregnancy and that there was a need to dispel that myth. However, that HP also admitted that they were unsure regarding current recommendations regarding physical activity advice in pregnancy. When asked specifically about PA recommendations for pregnant women, all stated that they were unsure but assumed they were the same recommendations as for the general population. There appeared
to be a need to update HPs in general about current recommendations since the HPs interviewed reported giving variable detail regarding the frequency of physical activity which they recommended, from twice to five times weekly.

Responsibility for giving advice:

Among the health professionals, it was felt that it was mainly the midwives' role to offer physical activity advice but it was also acknowledged that GPs also had a responsibility to ensure that advice relating to this aspect of health was provided for women who are pregnant. The GPs' responses indicated that they would feel comfortable giving advice but time was mentioned as a constraint to delivery of physical activity advice. One HP reported a perception that such advice was given low priority in respect of other necessary aspects of the GP consultation, within the allocated time of 10 minutes. The pregnant women's comments indicated that they perceived that both GPs and midwives should take responsibility for providing this advice.

'Probably should be GPs' role as well as midwives'" HP2

'Midwives' role as time constraints of GP appointment (10 minutes) ' HP4

'Both GPs' and midwives' role but more so the midwives as see these women regularly and can reinforce that advice and have more time. GPs are too busy. Midwives are better placed to deliver it' HP5

'It is the midwives' role to promote exercise as it helps prevent obesity/GDM' HP6

'I expected that they (GP/midwife) would speak to patients about this (physical activity)' PW9
‘It wouldn’t do any harm to receive advice from (GP/Midwife). It would be reassuring to have some guidance’ PW12.

Importance of physical activity:

Five of six health professionals, without any use of prompts, stated that physical activity in pregnancy was ‘important’. This was echoed by the women interviewed although there was a sense that the emphasis on the importance of physical activity needed to be guarded in respect of its amount. Phrases such as ‘not too much’, ‘not too strenuous’, ‘less intense’ and ‘nothing drastic’ were mentioned by women, with an inference that there was a potential for harm rather than benefit if a certain level of physical activity was exceeded. Physical activity was associated with being beneficial with multiple benefits to being physically active in pregnancy described by both pregnant women and health professionals. These benefits included benefits to mum and baby, labour, energy levels, mental health, preventing gestational diabetes, reducing gestational weight gain and improving mood and general well-being.

Source of advice:

Having recognised that they needed advice regarding how they should be physically active during pregnancy, the women interviewed were open to receiving advice from their GP or midwife. Only one woman, who appeared to be confident in respect of her knowledge of the health-related impact of physical activity, deviated from this view. She appeared to consider that her level of physical activity knowledge was high and would have felt ‘patronised’ if her GP or midwife gave her advice. This
highlights the need to consider all patients as individuals and the importance of recognising individuals’ needs and particular circumstances. Comments made by two others also highlighted the need for sensitivity in giving advice – they considered that some women might feel ‘offended’ if they perceived that the Health professional considered them ‘fat’. Other possible sources of advice which women mentioned included written information, such as leaflets or booklets; the internet was used as a source of advice by both the women and HPs.

'It falls down to the woman as they have the information in the books' PW8

'I got some off the internet by researching it myself' PW9

'I found the weight watchers booklet in my bounty pack useful' PW2.

'I usually direct them to PIL on the patient.co.uk website.' HP4.

5.3.2 Facilitators to increasing physical activity in pregnancy

Facilitators to increasing PA

- Health Promotion
- Financial and other incentives
- Peer support

Health promotion:

The health professionals’ interviews collectively mentioned the importance of health education and health promotion to help encourage women to increase their physical
activity levels during pregnancy. They identified a lack of available information about the benefits of physical activity in pregnancy for the general public and pregnant women in particular. Suggestions of approaches which could be used to promote physical activity amongst this group of women included advertising campaigns, written information, and increased attention in the media. Patient education was mentioned in that health professionals should be actively educating women about the benefits of physical activity in pregnancy.

'health promotion e.g. targeted advertising to promote physical activity – to avoid weight gain, highlight benefits to mum and baby' HP1

Many of the pregnant women also felt that if their GP or midwife spoke to them about PA then this in itself would encourage them to increase their PA levels.

'If doctor/MW told me that I needed to I would do it either with or without incentive' PW4

'If GP/MW encouraged me' PW12

Only one woman interviewed had reservations about PA levels being discussed during her appointment with the GP or midwife. This woman appeared to consider that she already had a high level of knowledge regarding the health benefits of physical activity and was following current guidelines in respect of her personal engagement in physical activity. Generic advice rather than personal....I would take offence if my GP/MW asked me to increase my physical activity levels' PW2
HPs recognised a need for a consistent message, some being aware of their inadequate current knowledge regarding guidelines. There was also a perception that health promotion messages needed to address the ‘myths’ specifically and provide information clearly to reassure women regarding the safety of different amounts and types of physical activity.

‘Need to challenge the myths about exercise in pregnancy.’ HP5

Financial and other incentives:

In the wake of the recent study published in the British Medical Journal regarding financial incentives to aid smoking cessation in pregnancy which received widespread media attention, ‘the use of incentives’ was used as a prompt when interviewees were asked about factors that they think would encourage women to increase their physical activity levels during pregnancy (Tappin, Bauld et al. 2015). Financial incentives in the form of money or vouchers, to encourage PA were discussed in interviews but only one HP considered that these may be useful facilitators of this behaviour. One HP was unsure about the benefits of financial incentives and three HPs interviewed were negative about the prospect of incentivising physical activity in pregnancy.

‘Unsure if there is good evidence that incentives and pedometers are cost effective methods’ HP1

‘Regarding incentives, this money could be better spent, women should take responsibility for their own health and this has a better chance of becoming an ongoing change’ HP6
When the pregnant women were asked about financial incentives, there were four positive comments and eight negative comments. This was surprising in that it would have been expected that this would have been considered a positive factor. Specific financial incentives mentioned as potential motivating factors including shopping vouchers and vouchers for a baby store. In respect to the negative views regarding incentives there was a sense that women felt they should be doing physical activity anyway and should not need a financial reward.

'It's not the government's role to give out hand-outs' PW8

'You should be doing it (physical activity) anyway, so no role for incentives' PW9

'I would say no to incentives – a person should want to do it. We are not babies and it sounds stupid' PW12

Other types of non-financial incentives to increase physical activity levels were mentioned. These tended to be linked to personal circumstances and preferences, so that free gym classes and free gym membership to pregnant women were considered by some to be likely facilitators for increasing their participation in physical activity. Other women mentioned provision of practical support such as crèche facilities for women who have other children and would like to exercise. One woman also reported personal experience of the use of a pedometer with positive impact on her physical activity levels, but others considered that pedometers would not be helpful to them.

'Pedometers would be really good as I would maybe want to take more steps' PW8

'Free classes/gym membership with crèche facilities' PW15
Peer support:

The health professionals who were interviewed mentioned group based exercise programmes as something that would encourage women to increase their PA levels during pregnancy and this thought was echoed by some of the pregnant women interviewed. Personal experiences were cited with women having found group settings a positive influence in the past. Peer support by another person accompanying an individual in physical activity was also considered helpful.

'Exercise groups for antenatal mums with possibly government funding to reduce the cost' MW

'I had group personal training before and found group setting beneficial. I think it would be beneficial if there was a group of pregnant women who could get together and do exercise classes specific for them' PW7

'Having someone to go with you (would encourage me to increase my PA levels' PW8

'Pedometer may be useful with competition aspect to compare with others as me, my brother and sister had Fitbit monitors and we logged on and compared step counts' PW9

The importance of social support from family and friends was also reflected by one woman who reported that a major factor in encouraging her to increase the amount of her physical activity was 'My mum's influence'. Also, another woman reported that she needed 'good motivation'. She did not consider that incentives or pedometers would help her but the influence of 'boyfriend, family members and friends' was important.
5.3.3 Barriers to increasing physical activity in pregnancy

Barriers to increasing PA

- Fear of harm
- Physiological barriers

Fear of harm:

Half the women interviewed mentioned fear of harm as a barrier to increasing PA during pregnancy while four specifically mentioned that they were not worried about potential harm. This was linked to their uncertainty regarding the levels of physical activity that were recommended and their feeling of lack of guidance or advice regarding what they should and should not do in pregnancy. When women were asked specifically about what type of harm they were thinking about, the possibility of miscarriage was mentioned.

'Anxiety regarding risk' PW2

'Worried re harm to baby if did too much' PW3

'Fear of harm with intense exercise' PW10

'In early stages I would be worried re harm as first three months critical' PW11

'I would avoid running or going to the gym for fear of harm' PW13

This sentiment was echoed by the HPs interviewed. HPs were aware that there was a belief among pregnant women that exercise and physical activity in pregnancy could
potentially cause harm to their unborn child. It was generally felt that their fears were unsubstantiated by medical evidence with the women’s beliefs being referred to as ‘misconceptions’ and ‘myths’. One HP elaborates on this idea of myths and that there is a need among HPs to address this and help dispel these unfounded myths.

‘Health beliefs that exercise causes harm to the baby’ HP1

‘Fear of harm especially in first trimester’ HP2

‘Misconceptions regarding harm’ HP3

‘Fear based on myths about a risk of miscarriage or causing problems with the baby. Fear is the main element relevant and specific to pregnancy other reasons like time/work more general reasons’ HP5

Physiological barriers:

Women mentioned physiological factors such as tiredness, nausea and pelvic pain as barriers to increasing PA levels in early pregnancy and, in the later stages of pregnancy, the physical change in their body due to the increasing size of the baby made physical activity difficult. Tiredness and nausea were also identified by two HPs as being barriers to physical activity in pregnancy.

‘Tiredness! In the first three months – sickness and tiredness. In the last three months – difficult with bump and tiredness’ PW7

‘With increased gestation the bump gets in the way. Decreased energy levels in later stages of pregnancy. Feeling uncomfortable in general in the last trimester’ PW14

‘SPD (Symphysis Pubis Dysfunction) – hip pain in pregnancy’ PW15

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5.3.4 Barriers to engaging in research in physical activity in pregnancy

**Barriers to engaging in research**

- Time
- Embarrassment
- Reservations about benefit

**Time:**

All of the HPs interviewed mentioned that time would be a likely constraint preventing pregnant women from engaging in research about PA in pregnancy. Four of the pregnant women interviewed mentioned time as a constraint. Competing priorities with work, childcare and other commitments were also cited. Again this would tie in with the time constraint as other commitments would take up their time.

*I would be agreeable but I would have some difficulty maybe making appointments due to other commitments*’ PW13

**Embarrassment:**

When asked about potential barriers for pregnant women engaging in PA research, three HPs mentioned that the women may be embarrassed about their weight or their activity levels and would prefer not to discuss their excess weight or low physical activity with anyone. Many HPs find it challenging to speak to patients about their
physical activity levels and this is usually due to fear of causing offence particularly if the person is overweight. Women and all patients can be sensitive about their weight and during pregnancy and the inevitable gestational weight gain; HPs may not tackle this health promotion opportunity as forcefully as it perhaps needs to be.

'Embarrassed about physical activity levels' HP2

'Embarrassed if they didn't do a lot (physical activity)' HP3

'Embarrassed about their weight' HP6

These sentiments of potential embarrassment were also cited by the pregnant women who were interviewed but in relation to other women and not themselves personally.

'Although some women may be offended "calling me fat" as different shapes and sizes' PW13

'I would be happy enough. Overweight women may take it the wrong way' PW14

Reservations about benefit:

Some of the women interviewed had their reservations about taking part in research during their pregnancy. They mentioned worries about the unknown and what would be expected of them. One very interesting and surprising comment was of a woman mentioning that she would feel like a 'guinea pig'. Other reservations were around getting weighed which as highlighted earlier, may be a source of embarrassment for some women. Interestingly, whilst the women thought that
weighing might cause embarrassment, only one HP did so but other HPs identified that women might be embarrassed about their low levels of physical activity.

'Feeling like a guinea pig' PW3

'Having to get weighed' PW2

'If I heard a 'bad story' about an adverse outcome' PW5

Some HPs considered that women were not motivated to take part in research about physical activity in pregnancy and that this could be attributed to their perceptions of a lack of benefit from doing so, either for themselves or others. One HPs' comment which summarised the attitude of many women to research participation in pregnancy appeared to take cognisance of the physiological changes in pregnancy that were reported by many women to affect their levels of energy adversely and to recognise the competing demands on their time from work and childcare

'Can't be bothered. Feel it may take up too much time and energy.' HP5
Chapter 6: Discussion

6.1 Summary of the main findings

This study in its current format would not be feasible to extend into a large scale RCT due to difficulties with recruitment and engagement. The qualitative aspect of the study yielded some insight into what are potential facilitators to pregnant women increasing their physical activity levels and encourage them to take part in physical activity research. These key areas will be discussed further below.

6.1.1 Recruitment

Recruitment rates to the quantitative aspect of the study were poor. Across two recruiting practices during the four month recruitment period, 68 women were eligible for participation but only 26 (33.3%) of these women consented to be contacted by the primary researcher about participating in a study about PA in pregnancy. Of these 26 only six (23.1%) were successfully recruited to the study which equivocates to only 8.8% of the total eligible participants (6 out of a potential 78).

Recruitment to the second part of the study, the qualitative aspect, was better but still not great. 100% of health professionals invited to take part did so but only 15 out of 33 women (45%) invited to take part in the semi-structured interviews did so.
6.1.2 Participant characteristics

The age range of the participants was from 20 to 35 years and all were of white ethnicity. There was two parous women and four primigavidas enrolled. Four women were of normal BMI, one was overweight (BMI 26) and one obese (BMI 34). Being overweight or obese is also a negative influencing factor on PA (Trost, Owen et al. 2002). Gestation at first visit ranged from 12 weeks to 16 weeks so all women were embarking upon their second trimester of pregnancy. This was considered an appropriate time to intervene as first trimester has just been completed which is the time during pregnancy at which the miscarriage rate is highest. Also, the nausea and tiredness usually settle at this stage which were mentioned in the qualitative findings as potential barriers to increasing PA. The study would be complete before 30 weeks gestation, again avoiding the last few weeks in which the ‘bump’ as mentioned again in the qualitative analysis as a potential barrier to engagement.

6.1.3 Participant socio-demographics

All women recruited were from the BT17 postcode area which is in the most deprived decile of deprivation based on the ranking system of deprivation for Northern Ireland (Northern Ireland Statistics and Research Agency 2010). This measure indicates levels of socio-economic deprivation relative to all other areas of Northern Ireland. This multiple deprivation measure (MDM) takes into account factors such as income, employment, health, education, proximity to services, living environment and crime and disorder. Income and socio-economic status has repeatedly been documented as having a positive association with PA (Trost, Owen
et al. 2002) and so these participants with a potentially low socio-economic status would tend to be less physically active. However, based on occupational status not all of the participants would be classed as economically deprived as one participant was a nurse, four were clerical workers and only one participant was unemployed. Therefore, the socio-economic status of these participants cannot be implied solely from the postcode area in which they live. There is also the possibility that the socio-economically deprived pregnant women in this area opted not to take part in the study.

6.1.4 Physical activity of Phase 1 participants

In order to gauge how physically active the participants were their accelerometer data were compared with values from existing literature and a comparison made. From the baseline accelerometer data from four participants, three of the four women had higher than average minutes spent in sedentary behaviour per day. The participants values were 494.8, 512.3 and 543.4 minutes per day spent in sedentary activity and comparable values in pregnancy is 460.5 minutes per day (Loprinzi, Fitzgerald et al. 2013). Interestingly though, these same women also had higher than the average amount of minutes per day spent in moderate to vigorous intensity activity (14.25, 14.1 and 31.4 minutes per day compared with an average of 11.9 minutes per day (Loprinzi, Fitzgerald et al. 2013)). All women recorded less than the average minutes per day spent in light intensity physical activity. Overall the pregnant women in this study spent more time per day in sedentary and light physical activity than comparable averages but more time engaging in moderate to vigorous physical activity. Numbers were small and so justified conclusions cannot
be drawn but this could possible indicate the effect of actually taking part in a PA intervention in which the participants were aware that their PA levels were being assessed.

Five out of the six participants completed the PPAQ. None of the participants reached the target of 500 to 1,000 MET-minutes which are the recommended physical activity targets per week. This conflicts with the accelerometer data which would indicate that three participants spent a greater amount of time in moderate to vigorous PA than comparable data from a USA based study (Loprinzi, Fitzgerald et al. 2013). Self-reporting relies on recall and perhaps this could have accounted for this discrepancy.

6.1.5 Physical activity of Phase 2 participants

At the beginning of the semi-structured interviews, all HPs and pregnant women were asked to complete a brief GPPAQ to categorise their PA levels as either active, moderately active, moderately inactive or inactive. Five out of six health professionals were categorised as being active or moderately active but of the pregnant women 9/15 (60%) were categorised as inactive. These results for the pregnant women who participated in the interviews indicate that the percentage of women who were inactive in this group was markedly higher than for all women in this age range. As shown below, 16-22% of 19-34 year old women in Northern Ireland in 2012-2013 were classed as being inactive, according to the British Heart
Foundation's Report this year (British Heart Foundation. 2015). This data was obtained through self-reporting.

Error! No text of specified style in document.Table 6.1 Percentage of women achieving PA recommendations based on age.

<table>
<thead>
<tr>
<th>Age range of women:</th>
<th>19-24</th>
<th>25-34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting recommendations</td>
<td>58%</td>
<td>63%</td>
</tr>
<tr>
<td>Some activity</td>
<td>16%</td>
<td>13%</td>
</tr>
<tr>
<td>Low activity</td>
<td>3%</td>
<td>8%</td>
</tr>
<tr>
<td>Very low activity</td>
<td>22%</td>
<td>16%</td>
</tr>
</tbody>
</table>

6.1.6 Adherence to protocol

The dropout rate was also high with two women (33.3%) choosing to drop out of the study after the first visit and three subsequently dropping out due to medical reasons or reasons related to pregnancy. Of these three, one had placenta praevia and GDG, one went into labour before the final visit and one woman had a flare up of psoriatic arthritis and was unable to continue. Overall only one participant completed all stages of the project protocol (16.7%). Generally an acceptable overall drop-out rate for a study is 20% or less but for a study with such a short intervention interval a lower estimate would be more appropriate. If the drop-out rate had have been lower this could have been allowed for in a large scale RCT by including an intention to treat analysis.
Due to the block randomisation process and drop-outs, three women out of the four were allocated to the intervention group and were given pedometers and step count diaries. Only one of these diaries was returned (33.3%), again indicating poor compliance and acceptability of this intervention component. One participant accidently dropped her pedometer into the toilet and then stated she had issues trying to link up the new device to her online account but did not contact the researcher or reply to text messages asking about her progress until after the twelve week intervention period had finished. Another participant accidently put her pedometer 'through the wash', and lost her step count diary and when she did eventually establish contact, had to withdraw from the study for medical reasons (placenta praevia and GDM). One participant did complete the full 12 week diary and stated that she found the pedometer easy to wear and a useful tool. Thus it appears, although based on a small number of recruits and lack of qualitative feedback about the intervention that the pedometer and diary proposed for use were not readily applicable to the study population. Further qualitative study with a greater number of pregnant women is needed to determine how these tools may be modified to encourage women to be attentive to their use or to design alternative methods of support for goal-setting and feedback to help promote physical activity.

6.1.7 Completion of outcome measures

All six women (100%) completed the DINE questionnaire at their initial visit with the researcher. This was a brief questionnaire that ascertained a general overview of an interviewee's diet specifically relating to total fibre, total fat and total unsaturated fat intake. Dietary advice to all participants was given in line with local Trust
guidance which is available in the antenatal handbook given to all women at the time of their booking visit in secondary care.

Compliance with the planned method of data collection by using an accelerometer was, however, poor. All six participants were given an accelerometer to wear for one week at baseline after visit 1 and at follow-up 12 weeks later. Of the initial six women, usable data were only obtained from four women; one participant had no valid wear time when the accelerometer and then subsequently dropped out and another participant took off the accelerometer so often during the day that there was not enough wear time. This highlights that compliance with the accelerometer was not great and one could infer that this was not an acceptable method of obtaining PA data from the participants.

6.1.8 Thematic analysis findings

Overall, some key themes were identified from the semi-structured interviews. What seemed prevalent was the importance that both HPs and pregnant women attributed to physical activity. However, this importance seemed to be overshadowed by many barriers. Barriers for the HPs to promote PA to pregnant women included limited time within consultations and ambivalence towards accepting responsibility for giving the advice as well as a lack of clear knowledge as to what the current recommendations were for PA in pregnancy. For pregnant women key barriers to being physically active included fear of harm and physiological barriers; the former is something which is within the remit of health professionals and governing bodies to tackle and address. Key facilitators to increasing PA identified in this study
include peer support and health promotion. Certainly social support is frequently
cited in the literature as a positive factor in relation to PA. A large review of the
literature with regards to correlates of adult participation in PA highlighted that
social support emerged as a consistently important correlate: every study that
included a measure of social support for PA found a significant positive association
between these variables (Trost, Owen et al. 2002).

6.2 Study findings in relation to study objectives

The research questions outlined at the outset of this project were the following:

1. Is it feasible to deliver an intervention, based in primary care, to promote
   physical activity among pregnant women?
2. Are the outcome measures of questionnaire, pedometer and accelerometer
data feasible for use for pregnant women?
3. What are the perceived barriers to physical activity for pregnant women?
4. Is a pedometer-based physical activity intervention, with goal-setting and
   feedback, acceptable to pregnant women?

In response to the first question, this study in its current format is certainly not
feasible due to the aforementioned difficulties with regards to recruitment, adherence
and compliance. Recruitment in the primary care setting has proven difficult and
factors such as low socio-economic status of the practices and quite markedly lower
activity levels than the general population in this cohort of patients may have
impacted upon uptake into the study.
The questionnaires were completed by all participants without difficulty, thus indicating that it is feasible to use these as outcome measures in a future study. It is difficult to answer this second question with regards to feasibility of the outcome measures of pedometer and accelerometer as only one feedback questionnaire was returned and this participant was in the control group and so did not use the pedometer. However, given the poor engagement of participants with pedometer and accelerometer data collection, it appears that the use of these measures requires further study. A study in the USA in 2009 was conducted to determine the feasibility of pregnant women wearing pedometers (Downs, LeMasurier et al. 2009). Content analysis was used to determine pedometer feasibility. After the women were given information on the pedometer’s history, told how to properly wear and use it, and received assurances from the research team that it was not harmful to the participant or her foetus, 100% of the women agreed to wear the pedometer for the 3-day assessment and 0% had reservations about their participation. These findings illustrate the feasibility and acceptability of using pedometers to assess women’s PA behaviours in pregnancy, however, data was only collected for three days which is a short intervention in comparison to this study.

The semi-structured interviews identified potential barriers to PA for pregnant women providing an answer to question three. Physiological barriers such as tiredness and nausea were mentioned: it is difficult to suggest a counter to these problems but women could be helped to address other barriers such as back pain and pelvic pain and the ‘bump getting in the way’. Physical exercise for lumbar pain and complementary therapy with yoga are known to be effective in managing back pain
in pregnancy (Bhardwaj, Nagandla 2014) and these could potentially be incorporated into an intervention.

Again, with regards to question four, it is difficult to conclude from this study whether or not a pedometer based PA intervention is acceptable to pregnant women as there were such small numbers (three participants in the intervention group). As mentioned previously one participant did complete the full 12 weeks and found the intervention acceptable but the remaining two participants had medical issues as well as technical issues which prevented assessment of the acceptability of the pedometer. Further study is also required to explore how pedometers may be made more attractive for use by pregnant women, or if alternative methods of providing support for goal-setting and feedback may be identified.

6.3 Strengths and weaknesses of the study

One strength of this study was that it was attempted in the primary care setting. With the rapidly changing landscape of the NHS there has been a ‘shift left’ and a lot of secondary care workload has been transferred to the community setting and no doubt this will continue in the future. Current policy plans as set out in the Transforming Your Care document, indicate that more responsibility for healthcare will be devolved to the community and home based sources (Transforming your care. A review of Health and Social Care in Northern Ireland. 2011). There is a push for midwife led care and more shared care in obstetrics and so it was felt that recruiting in the primary care setting would be appropriate.
However, a weakness of the study was its failure to recruit sufficient numbers. Unfortunately, due to increasing pressures in everyday primary care and lack of additional resources for the conduct of the study, as indicated by comments made by the HPs during the semi-structured interviews, time was a major constraint to inviting participation within the first booking visit with a pregnant woman. As HPs reported, there was so much else to cover within this ten minute appointment, health promotion advice was de-prioritised and recruitment to this study was often not mentioned. The issue of improving rates of recruitment may be addressed if added resources allowed a researcher to act as the initial point of contact.

Another strength is that all pregnant women were invited to take part including those with a normal BMI so as to reduce any stigma attached to inviting participation only from women who were overweight or obese. It has to be acknowledged that the study has provided no information about those pregnant women who were asked but declined to consent to contact by the primary researcher. These non-responders may be physically inactive or have some specific reservations about PA in pregnancy. A future study design may include collection of anonymised data regarding all potential participants, in order to allow better generalisability of the findings and to confirm their external validity.

The semi-structured interviews are a real strength to this study and have provided quite a lot of information as to reasons which prevent women from increasing their PA levels during their pregnancy. Levels of participation by those who were invited to take part were good (100% of HPs and 45% of women). However, these
interviews took place in only two settings, both in areas of socio-economic
deprivation and so the results may not be generalisable to the general population of
pregnant women and the HPs involved in providing their care.

The two practices that were involved with recruitment were based in low socio-
economic areas of Belfast although not fully reflected when looking at the
occupational status of the participants. Whilst this may have been a factor in poor
uptake to this study, it is a strength of the examination of its feasibility in that
women from these areas tend to be more physically inactive and so these are the type
of women who would benefit from research to determine how better provision of PA
advice and encouragement may be delivered within primary care.

The 12 week follow up period was planned to span across the second and third
trimester but in a larger scale trial longer term follow up into the post-natal period
would be preferable, as recommended by NICE (National Institute for Health and
Care Excellence 2010), to establish whether or not the intervention was associated
with behaviour change. The small sample in this study has been of value in
demonstrating how medical complications can intervene with outcome
measurements, even in the shorter-term, amongst pregnant women.

6.4 Summary of the main conclusions and comparison with the literature

The literature review in chapter one clearly highlighted that maternal obesity in
pregnancy is a problem and is associated with both antenatal and postnatal
complications for mother and baby. It also showed that there is a research gap in identifying what is the best way in which to address this issue. What this project adds is that a proposed pedometer based PA intervention is not feasible to be delivered to pregnant women recruited in a primary care setting in Belfast. Further work is required to determine how approaches to recruitment, retention and completion of objective measurements of PA may be improved amongst this population sub-group. Qualitative findings suggest that clear advice about PA, given to pregnant women by HPs involved in their care, and provision of social support in PA by others, perhaps within groups, may enhance engagement in such an intervention. There appears to be a need to update HPs in general about current PA recommendations in pregnancy, since the HPs interviewed reported giving variable detail regarding the frequency of physical activity which they recommended, from twice to five times weekly and were unsure about specific recommendations for pregnant women.

As already mentioned recruitment did not meet its expected target with only 8.8% of the total eligible participants successfully recruited (6 out of a potential 78). In the literature reviewed in chapter one, there was no mention of recruitment rates or difficulties but the Cochrane database review did specifically look at incomplete outcome data; of the 27 trials reviewed, 14 had relatively low levels of attrition or had carried out intention-to-treat analysis but seven studies had a high rate of loss to follow-up and in six studies loss of outcome data was unclear (Muktabhant, Lumbiganon et al. 2012).
Difficulties with recruitment in primary care are not unique to this study. This is often the case and there is some literature which explores this issue, including a report of how often UK primary care trials faced recruitment delays (Bower, Wilson et al. 2007). Of the 34 trials reviewed, 29% recruited to timetable, 35% required up to 50% greater time than planned and 35% required over 50% additional recruitment time. Various methods were employed in these studies to increase recruitment rates, such as extending the recruitment period (56%), seeking extra funding (31%), introducing other recruitment methods (18%), increasing the number of sites (44%), recalculating power 21% and finishing with insufficient patients (18%). Certainly for this study both the recruitment period was extended and the number of sites was increased but the final outcome was that the recruitment goal was not achieved. There have also been qualitative research studies carried out in this area to explore barriers and facilitators to recruitment of physicians and practices for primary care health services research (Johnston, Liddy et al. 2010). Facilitators identified included developing a sampling frame, establishing front-office rapport, adapting recruitment strategies, promoting buy-in and interest in the research question, and training a staff recruiter.

In the literature review, a qualitative paper was discussed in which pregnant women possessed safety concerns regarding exercise during pregnancy (Duncombe, Wertheim et al. 2009). This sentiment was certainly echoed in the thematic analysis from the semi-structured interviews which were conducted during this project. A further qualitative paper evaluated data relating to behavioural interventions for weight management during pregnancy and highlighted three main themes: contradictory messages, pregnancy as a transition of time and change and a
perceived lack of control in pregnancy (Campbell, Johnson et al. 2011). The themes from this piece of work would complement the theme of pregnancy as a transition of time and change in that physiological factors were mentioned frequently when the women were asked about barriers to increasing their PA levels. A perceived lack of control was something that did not come through and with respect to contradictory messages the themes from this work would suggest that there is a lack of health promotion messages and reliance on misconceptions about PA causing potential harm in pregnancy. This lack of information complements some of the comments in Choi et al’s review which discussed potential barriers to PA interventions and these included lack of information, inconsistent information and negative beliefs (Choi, Fukuoka et al. 2013).

A qualitative study carried out locally in Northern Ireland among pregnant women at risk of having babies with macrosomia, suggested that they did not link physical activity with any impact on their baby’s size or development (Reid, McNeill et al. 2014). This lack of association of physical activity with the outcome of their pregnancy may suggest that within this culture and society there is no perception of the health value of being physically active. Lack of perceived importance could be a reason for poor recruitment and low level of interest in the study.

Peer support was a key theme that emerged from the thematic analysis, indicating that pregnant women felt that this would be a facilitator to increasing their PA levels during pregnancy. This again is in keeping with previous research findings which relayed the importance of psychosocial factors such as family and peer support as
integral components of an effective PA intervention in pregnancy (Skouteris, Hartley-Clark et al. 2010, Baird, Cooper et al. 2009).

PA was ranked as important by many of those interviewed including HPs. This is in contrast to a qualitative paper in which midwives were asked about their views in relation to interventions aimed at tackling GWG (Willcox, Campbell et al. 2012). GWG was considered to lack importance given that it was no longer routine to weight women during their pregnancy. Other themes that emerged from this paper which would fit in with some of the themes from this study include the perception of a reluctance to discuss weight given the potential negative impact that this may have. This fits in with one of the themes from this study 'embarrassment' in which HPs felt that the pregnant women may be embarrassed about their weight or PA levels and that they are reluctant to talk to patients about this for fear of causing offence. Time constraints were also mentioned in this paper which again was evident in this study.

6.5 Implications for practice and further research

This study has highlighted that there are major difficulties with recruiting research participants from primary care. Potential reasons for this that have already been alluded to in the analysis of the semi-structured interviews and include time constraints, increasing workload and issues surrounding responsibility of delivering PA advice.
On a more positive note, the qualitative information that was obtained from the semi-structured interview has given some useful insights into potential facilitators to increasing PA levels in pregnant women. The idea of peer support was prevalent and this could be further explored and perhaps local services introduced to aid pregnant women to increase their PA levels during their pregnancy. Examples of this could include a potential extension of the ‘Healthwise’ referral scheme in the north of Ireland (Public Health Agency 2010). This is a scheme in which HPs can refer individuals with medical conditions to local leisure centres for free 12 weeks gym membership and individually tailored fitness advice. A variant of this could be introduced for pregnant women so that they felt guided and supported by HPs. Group based classes could also be introduced at trust level under the guidance of physiotherapists and this could also alleviate some of the physiological barriers noted such as back and hip pain which some women mentioned were potential barriers to engaging in PA in pregnancy. Also there may be a need for training of HPs to increase their knowledge of the PA recommendations during pregnancy and how best to advise and assist their patients to increase their PA levels during pregnancy.

Further research would be needed to further explore the ‘myths’ around PA causing harm to the unborn child which were not explored fully in this study. There is certainly a gap for health promotion here, both educating women and the public about the safety and benefits of exercise during pregnancy and also educating HPs about current guidance and that this should be integral to the booking visit at the GP surgery. Also, the role of social media is something which could be explored further. There are various internet websites utilised for pregnancy advice and apps to
track baby’s growth. Perhaps an NHS app with a baseline GPPAQ upon registration and PA prompt when accessing the site or the app could be a means in which to increase this health promotion advice which the women in this study have said they would want to receive. In Choi et al’s review in 2013, they drew attention in their conclusions to a systematic review of the use of text messages and smart phone apps showing potential in improving physical inactivity and these seemed to be well accepted by non-pregnant study participants (Stephens, Allen 2013).

6.6 Personal reflection

I am thankful to all the support and guidance of my research supervisors who helped me with this project and provided kind words of encouragement when recruitment was not going as initially projected. Also to the Health and Social Care Research and Development and the Northern Ireland Medical and Dental Training Agency for funding this post.

From brainstorming ideas about potential projects to sitting in front of a national ethics panel, I have learned a lot about the principles of research. Conducting a literature review has really helped my critical appraisal skills and this is something which I have integrated into my own personal clinical practice whilst working as a GP. It has proved me with both skills and experience in appraising clinical trials and research papers which is integral for any practitioner who is trying to keep up to date in the ever evolving landscape of evidence based medicine.
On reflection on the methodology of this study, I feel that recruitment may have been more fruitful if I had have been able to recruit from antenatal clinics in the secondary care setting. But as a GP I felt that a community based approach may have yielded better results than it did which was disappointing. The PPAQ questionnaire that was used was technically very time consuming to tally up the scores and interpret the results which on reflection I should have tried and tested this out fully prior to selecting this as a method of assessment of physical activity.

The semi-structured interviews yielded some very interesting results and if I had more time this could have been expanded and explored further to delve into misconceptions about PA in pregnancy and sources of these beliefs and opinions. The influence of social media would also have been an interesting area to explore in today’s technological era.

This post has also given me the opportunity to present my research at both local and national conferences and publish my first ever blog. This has given me vital experience and confidence in oral presentations and the opportunity to hear of other exciting work in the medical field.
Appendix 1:

Research protocol
‘Simple Steps’ to a healthier pregnancy

A physical activity intervention in pregnant women

Research protocol

Project summary

-General information

- IRAS Project ID: 145009
- Funding from R&D Office.
- Primary Researcher: Dr Madeline Brennan ST3
- Supervisors: Professor Margaret Cupples QUB, Dr Mark Tully CPH, Dr Valerie Holmes CPH.

Rationale & background information

Gestational weight gain has been highlighted as an independent contributory factor to the global problem of obesity. Women with larger gestational weight gains and higher pre-pregnancy BMIs tend to retain this additional body weight post-natally, contributing to the overall rise in obesity levels in the general population. Obesity is rising globally and has major healthcare implications with respect to cost, morbidity and mortality. As is true for the general population, the prevalence of maternal obesity in pregnancy is also rising. Percentages quoted in the Centre for Maternal and Child Enquiries (CMACE) and the Royal College of Obstetricians and
Gynaecologists (RCOG) Joint Guidelines for the management of women with obesity in pregnancy show a rise in the prevalence of the problem, from 9-10% in the early 1990s to 16-19% in the 2000s. The Confidential Enquiries into Maternal and Child Health (CEMACH) issued their 6th report for the years 2000-2002. This reported that 35% (78) of all women who died were obese which is 50% more than in the general population highlighting the increase mortality risk associated with obesity in pregnancy. As well as increasing risk of mortality, obesity in pregnancy is associated with various other complications such as gestational diabetes mellitus, pre-eclampsia, induction of labour, emergency caesarean delivery, genital and urinary tract infection, wound infection, birth weight above 90th centile and intrauterine death. Current literature has shown that overall a physical activity intervention in pregnancy, either stand alone or in combination with a dietary intervention; is likely to be associated with a reduced gestational weight gain.

However, it has been difficult to determine cipher out what type of physical activity intervention is best to achieve this reduction in gestational weight gain. In 2010, NICE produced guidelines regarding weight management before, during and after pregnancy. These guidelines highlighted a need for research to evaluate the most effective ways of helping women to manage their weight during pregnancy. They identified two gaps in the evidence which are relevant to this project. First, that few weight management interventions include adequate and validated measures of diet and physical activity - they often rely on self-reporting. Second, that few studies of weight management before, during and after pregnancy include interventions that are evaluated using process and qualitative data to determine which components are effective.
Study goals and objectives

The purpose of this research is to test the feasibility of delivering a simple and reproducible physical activity intervention that will help reduce gestational weight gain and increase physical activity levels during their pregnancy.

Methodology

Study Design:

The study is a feasibility study based in primary care.

Inclusion Criteria:

- Aged 18-50
- BMI 18.5-39.5
- Singleton pregnancy
- English as first language
- Live within a 30 mile radius of Belfast

Exclusion criteria:

- Pre-existing medical conditions (e.g. diabetes, cardiovascular disease, hypertension, disability that prevents participation in an exercise intervention)
- Currently involved in other research.
Recruitment:

Recruitment is planned to take place across six GP surgeries in the greater Belfast area. The aim is to recruit 30 patients in total with 15 patients randomly allocated to each arm of the study.

At booking for antenatal care, women with a BMI of 18.5-39.5 will be given information about the study and invited to consent to be contacted by the researcher. Information about those who consent will be given to their GP; only those whom the GP confirms have no contra-indications to taking part in the exercise intervention will be recruited.

The researcher will meet participants again at the end of this one week interval to collect accelerometer information and a questionnaire. A Patient Physical Activity Questionnaire (PPAQ) will be completed. A stratified randomisation process, based on BMI and GP practice, will have been conducted by a second researcher previously and the allocation given to the researcher in an envelope which will be opened at this meeting to reveal the patient’s allocation to intervention or control arm of the study. Those in the intervention group will be given brief intervention physical activity advice, based on the 3A’s approach (Ask, Advise, Assess, Assist and Encourage). A patient will then be given to the intervention group patients and they will be asked to set realistic individual daily step count targets. They will be asked to document their step count on a daily basis with a weekly reminder sent via text message for the first four weeks and then fortnightly thereafter for a total of 12 weeks. The control group will receive usual antenatal care.

The Intervention:

All patients, at the initial meeting, will have their baseline measurements taken, namely height and weight (in order to calculate BMI) and blood pressure. A patient details form will also be completed which will record other baseline data such as postcode, age, parity, occupation status, ethnicity and medical history. A basic
dietary questionnaire entitled DINE will be used to collect information regarding dietary habits and some basic dietary advice will be given according to the NHS current guidance and current standard practice within the Belfast Trust. For any patient who has difficulty with reading, the researcher will offer support by reading the questions aloud and recording their responses. An accelerometer will be given to the patients and they will be asked to wear this for one week to determine a baseline physical activity level. The researcher will also demonstrate to the recruits how to use the pedometers and accelerometers and how to access and record their readings and offer appropriate support as required.

The researcher will meet participants again at the end of this one week interval to collect accelerometer information and a baseline Pregnancy Physical Activity Questionnaire (PPAQ) will be completed. A stratified randomisation process, based on BMI and GP practice, will have been conducted by a second researcher previously and the allocation given to the researcher in an envelope which will be opened at this meeting to reveal the patient’s allocation to intervention or control arm of the study. Those in the intervention group will be given brief intervention physical activity advice, based on the 5A’s approach (Ask, Advise, Assess, Assist and Arrange). A pedometer will then be given to the intervention group patients and they will be asked to set realistic individual daily step count targets. They will be asked to document their step count on a daily basis with a weekly reminder sent via text message for the first four weeks and then fortnightly thereafter for a total of 12 weeks. The control group will receive usual antenatal care.
Both groups will be followed up after 12 weeks which will be approximately 28 weeks gestation. Pedometers will be collected at this visit from the intervention group and an accelerometer given to all patients to be worn for one week. After this week the accelerometer will be collected and a second PPAQ completed alongside a study feedback questionnaire.

Contact will be maintained with patients via telephone and text messaging to a mobile telephone specific to the project and held by the primary researcher.

Safety Considerations

Exercise in pregnancy is not known to be harmful to the unborn child and thus no adverse outcomes are to be expected. However, patients are free to withdraw from the study at any point and if any medical scenarios arise which could prevent ongoing participation in the trial, recruits can contact the primary researcher directly. Contact details will also be included on a letter sent to the patient’s GP and a copy of this letter filed in their antenatal clinic notes so that other health professionals can contact the researcher if so required. At the end of the study a patient questionnaire will be completed to gain feedback on the intervention and again aid reporting of any adverse effects or safety aspects.
Data Management and Statistical Analysis

The researcher will have access to patients' personal data during the study and these data will be analysed in the Department of General Practice at Queen's University, Belfast. The storage of the research data will be retained in a secure locked filing cabinet and password protected computer in QUB Department of General Practice for three years.

Quality Assurance

The research study progress will be reviewed by the Research Governance Office of the Queen's University, Belfast and the research supervised by Professor Cupples who head of the Department of General Practice at the University. Regular meetings with all of the study supervisors will ensure that progress takes place in accordance with the planned protocol and this in turn will be reviewed bi-annually by the University's Postgraduate Research Committee.

Expected Outcomes of the Study

The primary outcome is to assess the feasibility of a delivering a randomised controlled trial of a physical activity intervention, in primary care, during pregnancy, for overweight and obese pregnant women. The determination of feasibility will be based on findings regarding rates of recruitment, engagement (adherence) in intervention and completion of outcome measurements. Secondary outcomes of this study will include measurement of gestational weight gain and physical activity levels during pregnancy and the variations in the measurements will inform the calculation of a sample size calculation for a definitive trial of an intervention which will be refined by feedback from patients who take part in this study.
Dissemination of Results and Publication Policy

Patients and participating practitioners will be offered a written report of the results of the project. It is planned that the results will help guide the development of a larger scale definitive randomised controlled trial of the intervention, following refinement based on participant feedback. The results will be disseminated by means of presentations to local and international conferences and in a paper to be submitted for publication in a peer-reviewed journal.

Duration of the Project

Recruitment is planned to commence in June 2014 with completion planned for January 2015.

Ethics

An application will be submitted via the Integrated Research Application System (IRAS) for ethical approval to the Office of the Research Ethics Committees for Northern Ireland (ORECNI).

Informed Consent Forms

Written informed consent to participate in the study will be obtained from both the patients and the recruiting GP practices.
References


10. Weight management before, during and after pregnancy: NICE public health guidance 27.
Appendix 2:

Ethics Documents
Dear Dr X,

I am Dr Madeline Brennan, a GP Research Registrar, working with Professor Margaret Cupples. We are conducting a study to evaluate the potential effect of a physical activity intervention targeting pregnant women. Others involved in the study are Dr Mark Tully and Dr Valerie Holmes from the Centre of Public Health at Queen’s University, Belfast.

We would like to invite your practice to take part in the study by identifying women, at their antenatal booking visit, who have a BMI between 18.5 and 39.5, and offering them information about it. If they are willing to consider taking part I would be glad to explain the details to them. Those who take part would be randomly allocated...
either to a control group who will receive usual antenatal care or an intervention group who will, in addition, receive a physical activity intervention involving the use of a pedometer. Further details are given in the enclosed practice information sheet.

If you agree, I would like to come and speak to the practice regarding the study and I will happily answer any questions you may have before inviting you to sign a consent form indicating the practice’s agreement to participate. I hope to contact your practice manager within the next 2 weeks to discover your views but am happy to be contacted at any time on the above telephone number or by mobile (07............).

Thank you for taking the time to read this letter.

Yours sincerely,

Dr Madeline Brennan
GP CONSENT FORM

‘Simple Steps’ to a Healthier Pregnancy
A physical activity intervention in pregnant women

Name of Researcher: Dr Madeline Brennan

Please INITIAL all boxes

1) I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.

2) I understand that all data will be treated securely as described by Data Protection and stored appropriately as required by the University.

3) In the event of becoming aware of the patient developing medical or psychological issues that would prevent ongoing participation in the study, such as miscarriage, the practice will inform the primary researcher in order to minimise any potential distress for the patient.
4) I give consent for practice premises to be used if the patient prefers to meet the primary researcher at their GP practice pending room availability and prior arrangement with the practice.

5) The GP partners in the practice, specified below, agree to take part in the above study.

Name and address of Practice

_____________________________  __________________  __________________

Name of GP partner       Date       Signature
Department of General Practice,
1 Dunluce Avenue,
Belfast, BT9 7HR
Tel: 028 9020 4285

‘Simple Steps’ to a Healthier Pregnancy
A physical activity intervention in pregnant women

AGREEMENT TO CONTACT

Name of Researcher: Dr Madeline Brennan

Contact detail: as above or 07818460844

I agree to be contacted by telephone by the above named researcher regarding the above study.

________________________  ______________  ______________
Patient’s Name              Date              Signature

________________________
Telephone number

________________________  ______________  ______________
Name of health professional Date              Signature
taking consent

Practice Name: Woodbrooke Medical Practice
Practice Address: 212 Stewartstown Road,
Belfast, BT17 0FB.
PARTICIPANT CONSENT FORM

'Simple Steps' to a Healthier Pregnancy
A physical activity intervention in pregnant women

Name of Researcher: Dr Madeline Brennan

Please INITIAL all boxes

1) I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.

2) I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3) I understand that all data will be treated securely as described by Data Protection and stored appropriately as required by the University.

4) I give permission for researchers from Queen's University, Belfast to retain any study data about me in the event of my withdrawal from the study.

5) I understand the research is being conducted by a team of researchers at Queen's University, Belfast and that my personal details will be held by them until the study is complete.

6) I understand that I will not be identifiable in any data published in relation to this project.
7) I agree to my GP being informed of my participation in the study.

8) I agree that if in the event that I disclose any information to the primary researcher that warrants concern for my health or that of my unborn child then this information will be disclosed to my General Practitioner and that I will be made aware of this.

8) I agree to take part in the above study.

__________________________  __________________________  __________________________
Name of patient               Date                           Signature

__________________________  __________________________  __________________________
Name of researcher            Date                           Signature
06 July 2014

Professor Margaret Cupples
Queen’s University Belfast
Department of General Practice
4th Floor, Dunluce Health Centre
1 Dunluce Avenue, Belfast
BT8 7HR

Dear Professor Cupples

Study title: A physical activity intervention in pregnant women to aid weight management during pregnancy.
REC reference: 14/NI/1014
IRAS project ID: 145009

Thank you for your letter of 01 July 2014, 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 Vice-Chair, who chaired the meeting on 24 June 2014 when the application was originally reviewed.

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, Kathryn Taylor, RECA@hscni.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 favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the

Providing Support to Health and Social Care
approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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<tr>
<th>Document</th>
<th>Version</th>
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<td>30 May 2014</td>
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**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

**Reporting requirements**

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.
Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service 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/

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/NI/1014 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp Dr Alastair Walker  
Vice-Chair (Chair of the June meeting)  
Email: RECA@hscni.net

Enclosures: “After ethical review – guidance for researchers”

Copy to: Dr Paula Tighe, Queen's University Belfast
Distress Protocol

‘Simple Steps’ to a healthier pregnancy

A physical activity intervention in pregnant women

Participants in the study are free to withdraw at any stage as detailed in the participant consent form.

In the event of the development of any medical or psychological issues that would prevent ongoing participation in the study, for example miscarriage, the measures detailed below are in place in order to minimise any potential distress.

a) Participants can contact the primary researcher directly by telephone, email or letter to withdraw from the study at any time if they so wish.

b) The participant’s General Practitioner/midwife can contact the primary researcher directly if they feel their patient is suffering from any form of distress related to the study.

c) In the unfortunate event of a miscarriage the GP or midwife will contact the primary researcher so that the patient will be withdrawn from the study as to minimise any further distress. This information is incorporated into the GP practice consent letter. To ensure that health professionals involved in the participants care are aware of their participation in the study, a letter will be written to the participant’s practice to inform them that their patient is taking part. It will be recommended to the practices that a screen message would be displayed on the patient’s notes to indicate participation. A copy of this letter confirming participation will be put in the patient’s antenatal notes when they become available.
Lone Worker Policy

‘Simple Steps’ to a healthier pregnancy

A physical activity intervention in pregnant women

1. Background

Participants in this study will be offered a choice of venue at which data collection will occur and interviews conducted, including their GP Practice or their own home. If the GP Practice is used this will be pre-arranged with the relevant practice and will be during normal practice opening hours. Arrangements will be made to ensure that a member of the practice staff is aware of the location and expected duration of the contact. This policy therefore relates to the protection of the researcher when visiting a participant in their own home.

2. Policy aim

This policy aims to ensure that the researcher is confident that –

i) If anything untoward were to happen, the researcher would know how to access assistance and support

ii) If the researcher were unable to access assistance their absence would be noted, their whereabouts traceable and appropriate action taken.

3. Practical Safety

3.1 All home visits will be scheduled in daylight hours and a research supervisor will be aware of the arrangements.

3.2 The researcher’s supervisor will hold details of the participant’s name, address and contact number in a sealed envelope. They will also hold the details of the researcher’s mobile phone number, car registration, make and model. The supervisor will know the expected start and end times of each meeting and arrangements will be made for the researcher to contact their supervisor at the end of each meeting.
3.3 The researcher will carry a mobile phone to all visits.

3.4 The researcher will carry a personal alarm to all visits.

3.5 On arriving at the location the researcher will assess the situation as they approach and not enter the location if they have any doubts about their safety. If the person answering the door gives any cause for concern (e.g. If they are drunk) the researcher will make an excuse not to go in.

3.6 On entering the building the researcher will remain aware of the environment and maintain escape routes.

3.7 As a general practitioner, the researcher has had lone worker training, has had experience in visiting patients in their own homes and experience in diffusing situations where individuals display frustration or agitation.

5. Emergency Procedure

In the event that the researcher’s whereabouts are unknown for more than half an hour – they do not arrive at appointment when expected or they do not contact their supervisor when expected, the supervisor will take the following action (in this order as required)

i) A call is made to the researcher’s mobile phone
ii) A call is made to the participant’s phone number
iii) The police are contacted
iv) The researcher’s next of kin are informed.

6. Supporting researcher when a violent incident occurs

6.1 The university supervisors have a responsibility to support a researcher when they report an incident of violence or abuse. Support should include:
i) post trauma support such as debriefing, counselling or medical attention
ii) ensuring the incident is investigated
iii) supporting the researcher in dealing with the police and during any prosecution that may follow.
Disclosure protocol

'Simple Steps’ to a healthier pregnancy

A physical activity intervention in pregnant women

It is envisaged that the meetings with participants will be focused, specifically discussing physical activity, step-counts and filling in questionnaires. However, in the event of the participant disclosing information that would warrant concern for her or the unborn child’s safety the following measures will be adhered to;

- The primary researcher will contact the participant’s GP.
- The participant will be pre-informed as to what information is due to be shared and why. It will then be up to the GP to take these concerns on board and manage them appropriately.
- Potential circumstances that would warrant this type of disclosure would be illicit drug taking, alcohol abuse, domestic violence and active thoughts of suicide, whereby not disclosing information could lead to serious harm to the participant or their unborn child.

In the event of poor practice in respect of health or social care being disclosed during an interview and where the participant expresses the need for clarification of events:

- The researcher will offer the participant assistance in making an appointment with someone who can help her.

In the event that the participant expresses that she wishes to make a complaint to either the Trust or their GP Practice:

- The participant will be given a leaflet on ‘how to make a complaint’ as per Trust guidelines.
- The participant will be directed to contact the GP Surgery’s Practice Manager so that the relevant in-house complaints procedure can be followed.
14 January 2015

Dr Madeline Brennan
Department of General Practice
Dunluce Health Centre
1 Dunluce Avenue, Belfast
BT8 7HR

Dear Dr Brennan

Study title: A physical activity intervention in pregnant women to aid weight management during pregnancy.

REC reference: 14/NI/1014
Amendment number: Substantial Amendment 1 - 10/12/2014
Amendment date: 16 December 2014
IRAS project ID: 145009

The above amendment was reviewed at the meeting of the Sub-Committee held on 14 January 2015.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

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<thead>
<tr>
<th>Document</th>
<th>Version</th>
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<td>16 December 2014</td>
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<tr>
<td>Research protocol or project proposal</td>
<td>4</td>
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</table>
Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R&D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/NI/1014: Please quote this number on all correspondence

Yours sincerely

pp Dr Catherine Hack
Chair
E-mail: RECA@hscni.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Paula Tighe, Queen's University Belfast
Prof Margaret Cuppies, Queen's University Belfast
PARTICIPANT CONSENT FORM

‘Simple Steps’ to a Healthier Pregnancy
A physical activity intervention in pregnant women

Patient Questionnaire: Women’s views on physical activity in pregnancy

Name of Researcher: Dr Madeline Brennan

Please INITIAL all boxes

1) I confirm that I am happy to answer questions in relation to my views on physical activity in pregnancy. □ □ □

2) I understand that my participation is voluntary. □ □ □

3) I understand that if I do not take part, this will not affect my care in any way. □ □ □

4) I understand that I will not be identifiable in any data published in relation to this project. □ □ □

_________________________________________  ___________________________  ___________________________
Name of patient                        Date                        Signature

_________________________________________  ___________________________  ___________________________
Name of researcher                      Date                        Signature
PARTICIPANT CONSENT FORM

‘Simple Steps’ to a Healthier Pregnancy
A physical activity intervention in pregnant women

Questionnaire: GPs’ and Midwives’ views on physical activity in pregnancy

Name of Researcher: Dr Madeline Brennan
Please INITIAL all boxes

1) I confirm that I am happy to answer questions in relation to my views on physical activity in pregnancy.

2) I understand that my participation is voluntary.

3) I understand that I will not be identifiable in any data published in relation to this project.

Name of GP/Midwife  Date  Signature

Name of researcher  Date  Signature
Re: Simple Steps’ to a Healthier Pregnancy
A physical activity intervention in pregnant women

Date
Dear ____________

Dr Madeline Brennan is conducting a research project with me and within her work at Queen’s University, looking at physical activity levels in pregnant women. As part of this project we would like to know what women think about physical activity in pregnancy.

She will be in the waiting area of the surgery during your next antenatal clinic appointment and, if you agree to give ten minutes of your time to her, she would tell you more about the project and ask you about your thoughts related to physical activity in pregnancy. Any thoughts you would share with her would be entirely confidential and recorded anonymously. Please be assured that you are under no obligation to take part in this project and if you do not wish to do so it will not affect your care in any way.

Many thanks,
Dr Margaret Cupples

Contact Tel: 90602931.
Dear Panel,

REC ref: 14/NI/1014
IRAS project ID: 145009

Title: 'Simple Steps' to a healthier pregnancy - a physical activity intervention in pregnant women.

Unfortunately recruitment for the above project has not gone as well as projected across the four GP surgeries. The aim was for a maximum of 30 participants for this feasibility study but so far only five participants have been recruited, all from Practice 1. In that practice, in which I work, across the recruitment period 21.7.14-31.10.14 there were 34 patients eligible to be invited to take part in the study. Of these, 20 consented to be contacted by the primary researcher (58%); however, only six were recruited, including one participant who has dropped out. It is not known if the 14 women who did not consent to contact were not offered the opportunity to do so or declined.

The original research protocol had asked that the research participants complete a questionnaire at the end of the study in order to gain information about the acceptability of the various components of the intervention. However, it would be helpful to interview some potentially eligible pregnant women and the health professionals who had agreed to be involved in recruitment to ascertain their views about physical activity and participation in a study of physical activity during pregnancy.
It is proposed that a brief semi-structured interview, lasting 10 minutes, would be carried out with patients in Practice 1, with their consent, after attending an antenatal clinic appointment. A letter to inform them about the study will be sent in advance so that they have time to consider whether or not they would be happy to answer some questions about physical activity in pregnancy. This interview will take place after their appointment in order to minimise any disruption or distress. The GPs and midwives at Practice 1, the midwife at Practice 2 and the GPs at both Practices 3 and 4 who had agreed to be involved in recruitment will be interviewed at a time and place convenient to them.

We have included copies of the proposed semi-structured interviews, consent forms and letters of invitation along with the required summary of changes form.

Yours faithfully,

Dr Madeline Brennan. Prof Margaret Cupples
GP Research Registrar. Professor of General Practice
Participant Information Sheet

'Simple Steps' to a Healthier Pregnancy

A physical activity intervention in pregnant women

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this

What is the purpose of the study?

The amount of time that a woman spends being physically active tends to decrease when they are pregnant. It is normal to gain weight during pregnancy but it has been observed that if there is excessive weight gain during pregnancy then there is an increased risk of complications. The purpose of this study is to look at physical activity levels during pregnancy and to see if giving a physical activity intervention can help pregnant women to be more physically active and gain a healthy amount of weight during their pregnancy. The aim of this study is not to ask women to 'over-exercise' but simply to look at their daily step count to see if their physical activity levels could be gradually increased.

Why have I been invited?

If you are pregnant and have had your weight checked at booking you will have been invited to take part in this study of physical activity during pregnancy.

Do I have to take part?

It is up to you to decide. It is important that you read this information leaflet so that you are fully aware of why the research is being done and what exactly is involved. If you agree, you will be asked to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

At your booking visit in general practice you have been asked to consider participation in this study and have been given this information leaflet as well as a
consent form to allow the primary researcher to contact you via telephone. The aim is to recruit 30 patients in total.

**Visit 1:**
The first contact from the researcher will be at 12-13 weeks pregnant at which time you should already have attended the hospital for your hospital booking visit and booking scan.

Visits with the researcher will be planned for a mutually convenient location, either the GP surgery if preferred or your own home.

At this first meeting, following your consent, a few measurements will be taken, namely height, weight and blood pressure, with other information such as age, parity, occupation, ethnicity and medical history. A short diet questionnaire will be used and you will be given some basic dietary advice. An accelerometer (a small device which measures physical activity) will be given to you and you will be asked to wear this for one week. These are small credit card sized devices and easily clip on to your clothes. Following this you will be assigned either into a group that will receive standard antenatal care and advice or a group that in addition to their standard care will be provided with some additional physical activity advice.

**Visit 2:**
The accelerometer will be collected by the researcher at the end of this one week interval and a short Pregnancy Physical Activity Questionnaire (PPAQ) will be completed. At this meeting you will be told which group you have been allocated to. The group receiving standard care will not meet with the researcher again for 12 weeks (see visit 3).

If you are in the group who are to receive the additional physical activity advice you will be given brief 1:1 physical activity advice by the researcher. You will also be given a pedometer to wear every day during waking hours for 12 weeks and will be asked to set targets for daily step counts. You will be asked to record your step count on a daily basis in a diary. A weekly reminder will be sent via text message for the first four weeks and then fortnightly thereafter to help you remember to record your step count. The researcher will also telephone you after one week to check if you have any problems with the pedometer and will be available for you to contact by telephone during the study should you have any queries.

**Visit 3:**
Both groups will be followed up after 12 weeks. Pedometers will be collected from those participants who had been recording their step count and all participants will be asked to wear an accelerometer (small credit card shaped device that clips onto your clothes) for one week, again every day during waking hours.

**Visit 4:**
After one week of wearing an accelerometer the researcher will meet with you to collect this and you will be asked to complete a second questionnaire about your physical activity and a study feedback questionnaire.

**What will happen if I don’t carry on with the study?**

You can decide to withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the
What are the possible disadvantages and risks of taking part?

Time is the main consideration. The project involves four visits and the wearing of a pedometer or accelerometer.

What are the possible benefits of taking part?

The study is designed to provide information about how to help pregnant women adopt a healthy lifestyle and to increase their physical activity levels.

What if there is a problem?

If you have a concern about any aspect of this study you should contact the primary researcher in the first instance. Problems may be addressed by a complaints procedure managed by the University. Contact details for the researcher are provided at the end of this information leaflet.

Will my taking part in this study be kept confidential?

We understand how important confidentiality is to you and your confidentiality will be ensured during and after the study. It may be necessary for the researcher to access your patient notes if further information is required but this will only be done with your consent. All information which is collected about you during the course of the research will be kept strictly confidential and secured in a locked filing cabinet in the Department of General Practice, Queen's University, Belfast. Any information about you will be stored anonymously and will have your name and address removed so that you cannot be identified.

What will happen to my data?

The health information that we obtain from you will have all identifiable data removed and entered onto a study database by the Researcher. The data will be analysed at the end of the study only by the research team. Completed questionnaires and notes will be stored in a locked cabinet and in accordance with research regulations, this information will be stored for 5 years, after which it will be destroyed.

What will happen to the results of the research study?

When the study is completed the results will be presented at scientific meetings and published in health journals. If successful we hope to take the research forward to a larger scale project to help improve antenatal care. You will not be identified in any report or publication which results from this work.
Who is organising and funding the research?

This research project is organised by doctors from the Department of General Practice in Queen's University, Belfast as part of a Masters qualification. This project is supported by funding from the Public Health Agency Research and Development Division. The researchers conducting this study are not receiving any money for taking part.

Who has reviewed the 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. This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (ORECNI).

Further information and contact details

If you would like to discuss any aspect of the study or have any questions about it, then please contact the primary researcher Dr Madeline Brennan on 077****** You may also speak to your general practitioner who will be familiar with the research project.

Thank you for considering taking part in this study. If you agree to take part, you will be given a copy of this information sheet and the signed consent form to keep.
'Simple Steps' to a Healthier Pregnancy

A physical activity intervention in pregnant women

Background

Gestational weight gain has been highlighted as an independent contributory factor to the global problem of obesity. Women with larger gestational weight gains and higher pre-pregnancy BMIs tend to retain this additional body weight post-natally, contributing to the overall rise in obesity levels in the general population. Obesity is rising globally and has major healthcare implications with respect to cost, morbidity and mortality. As is true for the general population, the prevalence of maternal obesity in pregnancy is also rising. As well as increasing risk of mortality, obesity in pregnancy is associated with other complications such as gestational diabetes mellitus, pre-eclampsia, induction of labour, emergency caesarean delivery, genital and urinary tract infection, wound infection, birth weight above 90th centile and intrauterine death. Current literature has shown that overall a physical activity intervention in pregnancy is likely to be associated with a reduced gestational weight gain; however, it has been difficult to cipher out what type of intervention is best to achieve this. In 2010, NICE produced guidelines regarding weight management before, during and after pregnancy and highlighted a need for research to evaluate the most effective ways of helping women to manage their weight during pregnancy. They identified two gaps in the evidence relevant to this project. First, that few weight management interventions include adequate and validated measures of diet and physical activity - they often rely on self-reporting. Second, that few studies of weight management before, during and after pregnancy include interventions that are evaluated using process and qualitative data to determine which components are effective.

About the study?

The study is a feasibility study based in primary care. Recruitment is planned to take place across six GP surgeries in the greater Belfast area. The aim is to recruit 30 patients in total with 15 patients randomly allocated to each arm of the study.

At booking for antenatal care, women with a BMI of 18.5-39.5 will be given information about the study and invited to consent to be contacted by the researcher.
Recruitment is planned to commence June 2014 with first contact with patients at approximately 12-13 weeks gestation. Visits will take place at a mutually convenient location, either the GP surgery if preferred or the patient's own home.

At the initial meeting baseline measurements will be taken, namely height and weight (in order to calculate BMI) and blood pressure. A patient details form will also be completed which will record other baseline data such as postcode, age, parity, occupation status, ethnicity and medical history. A basic dietary questionnaire entitled DINE will be used to collect information regarding dietary habits and some basic dietary advice will be given according to the NHS current guidance and current standard practice within the Belfast Trust. An accelerometer will be given to the patient and they will be asked to wear this for one week to determine a baseline physical activity level.

The researcher will meet participants again at the end of this one week interval to collect accelerometer information and a baseline Pregnancy Physical Activity Questionnaire (PPAQ) will be completed. A stratified randomisation process, based on BMI and GP practice, will have been conducted by a second researcher previously and the allocation given to the researcher in an envelope which will be opened at this meeting, to reveal the patient's allocation to intervention or control arm of the study. Those in the intervention group will be given brief intervention physical activity advice, based on the 5A's approach (Ask, Advise, Assess, Assist and Arrange). A pedometer will then be given to the patients and they will be asked to set realistic individual daily step count targets. They will be asked to document their step count on a daily basis with a weekly reminder sent via text message for the first four weeks and then fortnightly thereafter for a total of 12 weeks. The control group will receive usual antenatal care.

Both groups will be followed up after 12 weeks which will be approximately 28 weeks gestation. Pedometers will be collected at this visit from the intervention group and an accelerometer given to all patients to be worn for one week. After this week the accelerometer will be collected and a second PPAQ completed alongside a study feedback questionnaire.

Contact will be maintained with patients via telephone and text messaging to a mobile telephone specific to the project and held by the primary researcher.

**What do I have to do?**

When booking patients for antenatal care, if the GP confirms that meet the inclusion criteria for the trial, the GP will give the patient an information leaflet about the trial and complete a consent form that will allow the primary researcher to contact the patient via telephone.

**Who is organising and funding the research?**

This research project is organised by doctors from the Department of General Practice in Queen's University, Belfast as part of a Masters qualification. This project is supported by funding from the Public Health Agency Research and Development Division. The researchers conducting this study are not receiving any money for taking part.
Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (ORECNI).

Further information and contact details

If you would like to discuss any aspect of the study or have any questions about it, then please contact the primary researcher Dr Madeline Brennan on 07818460844 or Professor Margaret Cupples at 02890 204252,
Appendix 3:

DINE questionnaire
Thank you for taking part in this study.

Please fill out this questionnaire.

It will take about 20 minutes to complete.

The questionnaire has 3 sections: A, B and C.

Please try to answer ALL the questions in Sections A&B.

**Section A: Your General Information**

1. ID number

2. Age:

3. Postcode:

4. GP Practice:

5: Medical conditions (if any):

6. Current medications:
7. Ethnicity: ________________________________

8. Have you any other children? Yes/No

If yes how many? ________

9. Occupation: ________________________________

---

**Section B: Your Diet**

This section is about the foods that you normally eat. Tick the box after each food which best describes how you usually eat that food.

**For example**, if you usually eat 2 slices of white bread per day you would fill in the box like this:

<table>
<thead>
<tr>
<th>Bread</th>
<th>Never</th>
<th>1 - 2 a day</th>
<th>3 - 4 a day</th>
<th>5 or more a day</th>
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<tbody>
<tr>
<td>White bread</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**N.B. Note** - if you never eat bread, please tick the 'never' box
D1. About how many pieces of bread do you eat on a usual day? Are they usually white, brown, or wholemeal?

(Please tick ✓ one box on each line)

<table>
<thead>
<tr>
<th>Bread</th>
<th>Never</th>
<th>1 - 2 a day</th>
<th>3 - 4 a day</th>
<th>5 or more a day</th>
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<tr>
<td>White bread</td>
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<td>Brown sliced pan/bread</td>
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<td></td>
<td></td>
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<tr>
<td>Wholemeal/soda bread or wholemeal scones</td>
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D2. About how many times a week do you have a bowl of breakfast cereal or porridge? What kind do you have most often?

(Please tick ✓ one box on each line)

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<tr>
<th>Breakfast Cereal</th>
<th>Never</th>
<th>1 - 2 a week</th>
<th>3 - 5 a week</th>
<th>6 or more a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar type: e.g. Frosties or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rice/Corn type: e.g. Corn Flakes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Porridge or Ready Brek or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheat type: e.g. Shredded Wheat or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muesli type: e.g. Alpen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bran type: e.g. All-Bran</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## D3. About how many times a week do you eat a serving of the following foods?

*(Please tick one box on each line)*

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>1 - 2 a week</th>
<th>3 - 5 a week</th>
<th>6 or more a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasta or rice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potatoes: baked, boiled, mashed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peas</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beans (baked, tinned, dried)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or lentils</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other vegetables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(any type, fresh, frozen, tinned)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit (fresh or canned)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## D4. About how many times a week do you eat a serving of the following foods?

*(Please tick one box on each line)*

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>1 - 2 a week</th>
<th>3 - 5 a week</th>
<th>6 or more a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheese (any except cottage)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(include cheese dishes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beefburgers or sausages</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(include low fat)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beef, pork or lamb</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(if vegetarian: nuts)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacon, meat pies, processed meat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
D5. About how many times a week do you eat a serving of the following foods?

(Please tick ✓ one box on each line)

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>1 - 2 a week</th>
<th>3 - 5 a week</th>
<th>6 or more a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chicken or turkey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish (NOT fried)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(include tinned, baked, grilled)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANY fried foods: fried fish, chips</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(include oven/micro), cooked breakfast</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cakes, pies puddings, pastries, ice cream</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biscuits (include butter and crackers), chocolate, crisps (include low fat varieties)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

D6. About how much milk do you yourself use in a day, for drinking or in cereal, tea, or coffee? What kind of milk do you usually use?

(Please tick ✓ one box on each line)

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>About a quarter pint</th>
<th>About a half pint</th>
<th>1 pint or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full cream</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi-skimmed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skimmed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
D7. About how many rounded teaspoons of margarine, butter or other spreads do you usually use in a day, for example on bread, sandwiches, toast, potatoes or vegetables? 

(Please write the number of teaspoons in the boxes)

**Butter or margarine**

(e.g. Flora, sunflower types, Blue Band, Krona, Stork, Dairygold)  

[ ] teaspoons

**Low fat spread**

(e.g. Low-Low, Outline, Golden Olive, Shape, Flora Extra Light, Delight, Benecol, Half Fat Butter, Dairygold light)  

[ ] teaspoons

D8. What sort of fat do you use?

(Please tick one box on each line)

<table>
<thead>
<tr>
<th>Fat Type</th>
<th>On bread and vegetables</th>
<th>For frying</th>
<th>For baking or cooking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butter, dripping, lard, solid cooking fat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hard or soft margarine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyunsaturated or sunflower margarine or low fat spread</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure vegetable oil (e.g. sunflower or olive)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I don’t use fat</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
D9. In an average day, how many portions (one fruit or an average sized serving) of fresh fruit or vegetables would you eat?

(Please tick ☑ one box)

- None □
- 1-3 a day □
- 4 a day □
- 5 or more a day □
Section C: Baseline Measurements

(TO BE COMPLETED BY RESEARCHER)

1. Today’s date: _________________________

2. Height (cm): ________________________

3. Weight (kilos): ________________________


5. Gestation (weeks): _________________________

6. EDD: _________________________

Thank You!

You have now finished the questionnaire.

Thank you for taking the time to answer these questions.
Appendix 4:

Accelerometer diary
'Simple Steps' Study
Monitor Information Sheet

Actigraph Device Number: _____

You are been asked to an activity monitors on your waist for seven days from when the researcher leaves you until they return to collect it from you. For the seven day period please carry on with your normal daily activities.

Description

The monitor is called an accelerometer. This device senses movement during your everyday activities and should be worn at all times throughout the day with the exception of when you shower, bath or swim (as it is not waterproof); and whilst sleeping. The monitor should be reattached as soon as possible when you finish any of the above activities.

When you remove the monitor for whatever reason it is important that you fill in the accelerometer diary (given to you by the researcher). It is asked that you note

1) The reason why you removed the monitor e.g. had a shower, went to bed etc
2) The time you removed the monitor and put it back on e.g. 9.30am

Placement

Please clip the belt around your waist with the clip at the front, with the monitor resting on your right hip (see picture). Please make sure that the monitor is approximately in the centre of the right side of your body.

They can be worn above or below clothes depending on where is found to be the most comfortable. It is also possible to put the belt through trousers belt loops to avoid the risk of it falling off. The monitors do not need to make contact with the skin although if it does, this is not a problem.

If you have any problems or queries please contact:

Dr Madeline Brennan: 07818460844
Email: mbrennan09@qub.ac.uk
Diary for Wearing Activity Monitor

Please write down times monitor was removed and put back on.

<table>
<thead>
<tr>
<th>Day number</th>
<th>Day of week</th>
<th>Monitor wear time</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Time taken off on</td>
<td>Time back on</td>
</tr>
<tr>
<td>Example</td>
<td>MONDAY</td>
<td>8.00am</td>
<td>8.30am</td>
</tr>
<tr>
<td></td>
<td></td>
<td>9.00pm</td>
<td>7.00am</td>
</tr>
</tbody>
</table>

QUB information only: Monitor taken off/collection Date: Time:
Appendix 5:

Pregnancy Physical Activity Questionnaire.
Acknowledgments must be given to Chasan-Taber et al. (2004) Biostatistics & Epidemiology, School of Public Health & Health Sciences, University of Massachusetts, if this questionnaire is used or modified.

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
   - 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: [ ]/ [ ]/ [ ]
2. What was the first day of your last period? [ ]/ [ ]/ [ ] [ ] I don't know
3. When is your baby due? [ ]/ [ ]/ [ ] [ ] 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 sitting
   - 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:

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 1 hour per day
    - 1 to almost 2 hours per day
    - 2 to almost 3 hours per day
    - 3 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 1 hour per day
    - 1 to almost 2 hours per day
    - 2 to almost 4 hours per day
    - 4 to almost 8 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 slowly to go places (such as to the bus, work, visiting)**
   - 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

21. **Walking quickly to go places (such as to the bus, work, or school)**
   - 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

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
   - 2 to almost 3 hours per day
   - 3 or more hours per day

---

**For Fun or Exercise...**

During this trimester, how much time do you usually spend:

23. **Walking slowly for fun or exercise**
   - 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

24. **Walking more quickly for fun or exercise**
   - 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

25. **Walking quickly up hills for fun or exercise**
   - 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
During this trimester, how much time do you usually spend:

<table>
<thead>
<tr>
<th>Activity</th>
<th>None</th>
<th>Less than 1/2 hour per week</th>
<th>1/2 to almost 1 hour per week</th>
<th>1 to almost 2 hours per week</th>
<th>2 to almost 3 hours per week</th>
<th>3 or more hours per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jogging</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Dancing</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

Doing other things for fun or exercise? Please tell us what they are.

<table>
<thead>
<tr>
<th>Name of Activity</th>
<th>None</th>
<th>Less than 1/2 hour per week</th>
<th>1/2 to almost 1 hour per week</th>
<th>1 to almost 2 hours per week</th>
<th>2 to almost 3 hours per week</th>
<th>3 or more hours per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Activity</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

Please fill out the next section if you work for wages, as a volunteer, or if you are a student. If you are a homemaker, out of work, or unable to work, you do not need to complete this last section.

**At Work...**

During this trimester, how much time do you usually spend:

<table>
<thead>
<tr>
<th>Activity</th>
<th>None</th>
<th>Less than 1/2 hours per day</th>
<th>1/2 to almost 2 hours per day</th>
<th>2 to almost 4 hours per day</th>
<th>4 to almost 6 hours per day</th>
<th>6 or more hours per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting at working in class</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Standing or slowly walking at work while carrying things (heavier than a 1 gallon milk jug)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Walking quickly at work while carrying things (heavier than a 1 gallon milk jug)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Walking quickly at work not carrying anything</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

Thank You
Appendix 6:

Step count diary.
### Daily Step-count Record

<table>
<thead>
<tr>
<th>Week/step-count goal</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
<th>Average for week</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3/</td>
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<td></td>
<td></td>
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<tr>
<td>4/</td>
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<td></td>
</tr>
<tr>
<td>5/</td>
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<td></td>
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<tr>
<td>6/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Daily Step-count Record

<table>
<thead>
<tr>
<th>Week/step-count goal</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
<th>Average for week</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8/</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11/</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>12/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 7:

Feedback questionnaires.
This is a survey about your experience of the ‘Simple Steps to Healthier Pregnancy’ Study. Please read the following statements and circle the response that MOST CLOSELY represents your view:

1. I found the accelerometer easy to wear:

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>agree</td>
<td>nor disagree</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:

2. The Pregnancy Physical Activity Questionnaire was too detailed:

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>agree</td>
<td>nor disagree</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:

3. In a future pregnancy I would like to receive advice from my GP or midwife regarding physical activity in pregnancy:

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>agree</td>
<td>nor disagree</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:
'Simple Steps' to a healthier pregnancy

Patient Satisfaction Questionnaire: Intervention Group

This is a survey about your experience of the 'Simple Steps to a Healthier Pregnancy' Study. Please read the following statements and circle the response that MOST CLOSELY represents your view:

I found the accelerometer easy to wear:

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Comments:

I found the pedometer easy to use:

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Comments:

I found having a daily step-count goal a good motivator:

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Comments:
I found writing down my daily step-count a good motivator:

Strongly  Agree  Neither agree  Disagree  Strongly agree
nor disagree  disagree

Comments:

I found the pedometer programme time-consuming:

Strongly  Agree  Neither agree  Disagree  Strongly agree
nor disagree  disagree

Comments:

The pedometer fitted in well around my daily routine:

Strongly  Agree  Neither agree  Disagree  Strongly agree
nor disagree  disagree

Comments:

I remembered to wear the pedometer most of the time during the study:

Strongly  Agree  Neither agree  Disagree  Strongly agree
nor disagree  disagree

Comments:
The Pregnancy Physical Activity Questionnaire was too detailed:

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Comments:

I disliked receiving physical activity advice during pregnancy:

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Comments:

In a future pregnancy I would like to receive advice from my GP or midwife regarding physical activity in pregnancy:

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
</table>

Comments:
If you have any further comments regarding this study and pedometers, we would be grateful for these in the box below:
Appendix 8:

General Practice Physical Activity Questionnaire.
**General Practice Physical Activity Questionnaire**

**Date**

**Name**

1. Please tell us the type and amount of physical activity involved in your work.

<table>
<thead>
<tr>
<th></th>
<th>Physical Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>I am not in employment (e.g. retired, retired for health reasons, unemployed, full-time carer etc.)</td>
</tr>
<tr>
<td>b</td>
<td>I spend most of my time at work sitting (such as in an office)</td>
</tr>
<tr>
<td>c</td>
<td>I spend most of my time at work standing or walking. However, my work does not require much intense physical effort (e.g. shop assistant, hairdresser, security guard, childminder, etc.)</td>
</tr>
<tr>
<td>d</td>
<td>My work involves definite physical effort including handling of heavy objects and use of tools (e.g. plumber, electrician, carpenter, cleaner, hospital nurse, gardener, postal delivery workers etc.)</td>
</tr>
<tr>
<td>e</td>
<td>My work involves vigorous physical activity including handling of very heavy objects (e.g. scaffolder, construction worker, refuse collector, etc.)</td>
</tr>
</tbody>
</table>

2. During the last week, how many hours did you spend on each of the following activities? Please answer whether you are in employment or not.

<table>
<thead>
<tr>
<th></th>
<th>Physical Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Physical exercise such as swimming, jogging, aerobics, football, tennis, gym workout etc.</td>
</tr>
<tr>
<td>b</td>
<td>Cycling, including cycling to work and during leisure time</td>
</tr>
<tr>
<td>c</td>
<td>Walking, including walking to work, shopping, for pleasure etc.</td>
</tr>
<tr>
<td>d</td>
<td>Housework/Childcare</td>
</tr>
<tr>
<td>e</td>
<td>Garden/DIY</td>
</tr>
</tbody>
</table>

3. How would you describe your usual walking pace? Please mark one box only.

- Slow pace (i.e. less than 3 mph)
- Steady average pace
- Fast pace (i.e. over 4 mph)
Appendix 9:

Semi-structured interview questions.
Patient Questionnaire: Women’s views on physical activity in pregnancy

Q1. What do you understand by the term ‘physical activity’?

Q2. What are your thoughts on physical activity in pregnancy?

(prompts: benefit/harmful/how much and how often do you think you should do it)

Q3. How do you feel about your GP or midwife talking to you about physical activity in pregnancy?

(prompts: not needed/useful/need for advice)
Q4. What or who would encourage you to increase the amount of physical activity you do in pregnancy?

(prompts: GP/midwife/written info/pedometers/incentive)

Q5. What would prevent you from increasing your physical activity levels in pregnancy?

(prompts: time/other commitments/work/fear of harm)

Q6. What would prevent you from taking part in a research study about physical activity in pregnancy?
Questionnaire: GPs’ and Midwives’ views on physical activity in pregnancy

Q1. What do you understand by the term ‘physical activity’?

Q2. What are your thoughts on physical activity in pregnancy?

(prompts: benefit/harmful/how much and how often do you think you should do it)

Q3. How do you feel about talking to your patients about physical activity in pregnancy?

(prompts: not needed/useful/GPs’ or midwives’ role to advise)
Q4. What do you think would help encourage women to increase the amount of physical activity they do in pregnancy?

(prompts: GP/midwife/written info/pedometers/incentive)

Q5. What do you think would prevent women from increasing their physical activity levels in pregnancy?

(prompts: time/other commitments/work/fear of harm)

Q6. What do you think would prevent women from taking part in a research study about physical activity in pregnancy?
Appendix 10:

Summary interview transcript.
Appendix 10: Summary interview transcript

Q1. What do you understand by the term physical activity?

PW7: exercise e.g. gym, swimming. Makes you feel better and clears your head.

Q2. What are your thoughts on PA in pregnancy?

PW7: I didn’t do any as too tired to even walk. I think it would be beneficial. Recommendations are same as for everyone else but slow down the bigger you get and take it easy with weights. I have no concerns regarding harm.

Q3. How do you feel about your GP or midwife taking to you about physical activity in pregnancy?

PW7: I would feel alright about it. There is a need for advice.

Q4. What or who would encourage you to increase the amount of physical activity you do in pregnancy?

PW7: Yourself – need to encourage yourself. I had group personal training before and found group setting beneficial. I think it would be beneficial if there was a group of pregnant women could get together and do exercise classes specific for them. I wouldn’t wear a pedometer. Incentive would not be beneficial as if you were going to do it you would do it regardless.
Q5: What would prevent you from increasing your physical activity levels in pregnancy?

PW7: Tiredness! In the first three months – sickness and tiredness. In the last 3 months – difficult with bump and tiredness. Childcare but if I really wanted to exercise I could make arrangements.

Q6: What would prevent you from taking part in a research study about physical activity in pregnancy?

PW7: No barriers.
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