FEASIBILITY AND ACCEPTABILITY OF A BRIEF ROUTINE WEIGHT MANAGEMENT INTERVENTION FOR POSTNATAL WOMEN EMBEDDED WITHIN THE NATIONAL CHILD IMMUNISATION PROGRAMME

By

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A thesis submitted to the University of Birmingham for the degree of DOCTOR OF PHILOSOPHY

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September 2019

ABSTRACT

The prevalence of obesity in the UK is high. Postnatal weight gain and/or retention can increase the likelihood of women developing obesity.

This thesis aimed to review existing literature on effective lifestyle interventions to inform the development of a trial to test a behavioural postnatal weight management intervention delivered within routine primary care consultations. The research also aimed to explore participants' experiences of the intervention.

A review of systematic reviews of randomised controlled trials (RCT) identified evidence supporting the use of postnatal behavioural weight management interventions, however the intensity of many of these interventions reduced their acceptability.

A feasibility cluster RCT with a nested qualitative study was developed to investigate the feasibility and acceptability of a brief behavioural weight management intervention delivered in primary care within routine practice nurse consultations. The findings demonstrated that it was feasible for nurses to deliver the intervention, but recruitment of postnatal women was low and adherence to the intervention varied. Semi-structured interviews showed that postnatal women found it acceptable to be weighed by practice nurses at child immunisation appointments. Nurses indicated that primary care settings were suitable locations for postnatal weight management but raised some concerns (immunisation safety and prolonging time restricted appointments by providing weight management advice).

In conclusion, a brief weight management intervention embedded within child immunisation appointments appeared feasible to deliver although, the low recruitment rate may suggest the intervention is not acceptable to postnatal women.

DEDICATION

To my granny, Jessie Ferguson who encouraged me to “love learning which is the food of the mind”.

ACKNOWLEDGEMENTS

I will always be eternally grateful to Professor Amanda Daley and Dr Helen Parretti for taking a chance on me. Thank you to you both and Professor Sheila Greenfield for sharing your time, expertise, unfailing guidance and support. Each one of you motivated me to keep pushing myself to do better.

Thank you to all the mothers who participated in the study, who warmly welcomed me into your homes and shared your experiences of motherhood with me. I am also grateful to the nurses and general practices for participating.

Roman, all the overtime and sacrifices you have made have been fundamental to the completion of this thesis. Thank you from the bottom of my heart. I owe you that top- shelf road bike you have had your eye on!

Mummy and Daddy, thank you for all the opportunities you gave me that have enriched my life. To my sister Lynne, I am very thankful for your constant support and reminders that with God, nothing is impossible.

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STATEMENT OF CONTRIBUTIONS

The introduction and literature review presented in Chapter 1 are the work of Janice Ferguson (J.A.F), with guidance and feedback from my supervisors, Professor Amanda J. Daley (A.J.D), Dr Helen M. Parretti (H.M.P) and Professor Sheila M. Greenfield (S.M.G).

The idea for the systematic review presented in Chapter 2 was conceived by A.J.D. The search strategy was designed by J.A.F with support from A.J.D and H.M.P. J.A.F performed the database searches and reviewed the search results (titles and abstracts) to determine suitability for inclusion. A.J.D and H.M.P each independently checked half of the retrieved search results and consensus for inclusion was equally determined by J.A.F, A.J.D and H.M.P. Double data extraction was then performed, J.A.F extracted data from all retrieved articles with A.J.D and H.M.P extracting data from half of the retrieved articles. Analysis for the mega meta-analysis was jointly performed by J.A.F and H.M.P. With guidance and feedback from A.J.D and H.M.P, the first draft of the published article that makes up most of Chapter 2 was written by J.A.F. It was published by Obesity Reviews in April 2019 ("Behavioural weight management interventions for postnatal women: a systematic review of reviews of randomised controlled trials" Obesity Reviews. 2019; 20: 829– 841. https://doi.org/10.1111/obr.12834).

The feasibility cluster randomised controlled trial presented in Chapter 3 was conceived by, A.J.D and H.M.P. J.A.F with support and feedback from A.J.D and H.M.P developed and wrote the protocol for the feasibility cluster randomised controlled trial. In addition, J.A.F under guidance from A.J.D and H.M.P completed all the required submission forms to obtain ethical approval, and identified validated questionnaires to include in the study participant

questionnaires. J.A.F along with either A.J.D or H.M.P attended GP practices for meetings as well as to deliver training sessions to practice nurses. J.A.F was responsible for preparing questionnaire packs, arranging baseline and follow-up appointments, as well as all data collection. Janice Gunnell (J.G) and H.M.P performed weight change and questionnaire data checks. Data analysis was performed by J.A.F under guidance from A.J.D. and H.M.P.

Under the guidance and support of S.M.G, J.A.F designed the qualitative study described in Chapter 4, in addition to the nurse and participant interview topic guides. Similarly, the nested qualitative study protocol was written by J.A.F with feedback and support from S.M.G. The qualitative study was co-ordinated by J.A.F and all interviews were conducted by J.A.F. J.A.F transcribed the first audio-recorded interview and the professional services of the Transcription Company UK was sought to transcribe the remaining interviews.

The discussion presented in Chapter 5 was also the work of J.A.F, with guidance from my supervisors A.J.D, H.M.P and S.M.G.

LIST OF ABBREVIATIONS

BF: Breast Feeding

BISS: Body Image States Scale

BMI: Body Mass Index

BWCH: Birmingham Women's and Children's Hospital

CCG: Clinical Commissioning Group

CCT: Clinical Controlled Trial

CI: Confidence Interval

CRF: Case Report Form

CRN: Clinical Research Network

EPDS: Edinburgh Postnatal Depression Score

GDM: Gestational Diabetes Mellitus

GDP: Gross Domestic Product

GP: General Practitioner

GWG: Gestational Weight Gain

HSE: Health Survey England

IMD: Index of Multiple Deprivation

INT: Intervention

IOM: Institute of Medicine

ISRCTN: International Standard Randomised Controlled Trial Number

Kg/m²: Kilograms per Metre Squared

MD: Mean Difference

MET: Metabolic Equivalent Task

MET-h/wk: Metabolic Equivalent Task in hours per week

MINS: Minutes

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

NIHR: National Institute for Health Research

OECD: Organisation for Economic Cooperation and Development

PA: Physical Activity

PHE: Public Health England

PIMMS: Postnatal weight management during IMMunisations Study

PPAQ: Pregnancy (and Postnatal) Physical Activity Questionnaire

PPTM: Postnatal/Postpartum

PPWR: Postnatal/ Postpartum Weight Retention

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: International Prospective Register of Systematic Reviews

RCOG: Royal College of Obstetrics and Gynaecology

RCT: Randomised Controlled Trial

SD: Standard Deviation

UC: Usual Care

UK: United Kingdom

UN: United Nations

WHO: World Health Organisation

WMD: Weighted Mean Difference

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CHAPTER 1

INTRODUCTION, BACKGROUND AND LITERATURE REVIEW

In the last decade, the number of people in the United Kingdom (UK) who have overweight or obesity has been increasing steadily (1-3). Overweight and obesity rates have recently plateaued, but remain high. Pregnancy and the postnatal period are key times when women can be vulnerable to rapid weight gain and/or weight retention with research showing that excessive gestational weight gain and postnatal weight retention can contribute to many short and long-term outcomes that can affect the mother and her child (4-6). These include inter-pregnancy obesity and obesity in later life (7, 8). It is well recognised that the National Health Service (NHS) is currently under strain and that the management of chronic health conditions related to obesity contribute to that pressure.

Many diet and exercise interventions have been tested on postnatal women. Some of these interventions have been effective, but would be too resource intensive and/or expensive to provide to every woman giving birth in the UK annually, who would benefit from them. Additionally, many of the intervention studies in this field have reported low adherence and retention rates (9, 10). Nevertheless, the existence of these studies shows that women are interested in weight management during the postnatal period.

Self-monitoring strategies have been the focus of many behavioural weight management interventions that have been successful for people, including women with overweight and obesity (11-14). Regular self-weighing is one such self-monitoring behaviour with proven potential for successful weight loss and weight loss maintenance particularly when used in

conjunction with a lifestyle based intervention (14, 15). Accountability has been shown in both business and weight management interventions to help keep individuals engaged and focused on achieving set goals. When people are aware their goals are being monitored, they may strive to achieve these set goals, in this instance, weight loss.

This thesis describes the rationale behind the design of a pragmatic brief weight management intervention for postnatal women and evaluates the feasibility and acceptability of the intervention. This introductory chapter will provide an outline to the structure of the thesis and then provide an overview of the literature. The literature review provides a summary of the available evidence on the causes and prevalence of obesity and, treatments available for adults, focusing primarily on behavioural interventions underpinned by the self-regulation theory and delivered within primary care settings. This introductory chapter will conclude with a description of the context in which the proposed intervention will be delivered and the rationale for the research.

The research proposal was conceptualised and developed by a research team lead by Professor Amanda Daley and Dr Helen Parretti. The University of Birmingham and the National Institute for Health Research (NIHR) School for Primary Care Research provided grants that funded this studentship.

Chapter 2 presents a systematic review of systematic reviews of behavioural weight management interventions for postnatal women. Five online databases were searched to identify systematic reviews of randomised controlled trials (RCTs) that had assessed the effectiveness of diet and/or physical activity interventions for postnatal weight management

delivered in any context or setting from immediately after childbirth, to two to three years after giving birth.

Chapter 3 examines whether a postnatal weight management intervention that promotes self-management and includes external accountability during routine child immunisation appointments, is feasible. Chapter 4 reports on the experiences of women who participated and nurses who delivered the intervention in Chapter 3. This chapter considers the acceptability of the intervention in more depth.

Chapter 5 concludes the research and contains a discussion of the overall findings compared to similar research. In addition, this chapter discusses research areas that would benefit from further exploration, as well as the health service and policy implications.

1.1 Background and literature review

1.1.1 Overweight and obesity

Multiple, complex factors influence the development of excess weight gain. Overweight and obesity are a consequence of a prolonged exposure to an imbalance of energy. This is caused by the consumption of food and drink in excess of what the body uses for physical activity and metabolism, resulting in the excess accumulation of body fat (16, 17). The associations between obesity and health have been well established. The health consequences of obesity can have a significant impact on the duration and quality of life of the individuals affected (18-20). Potential health complications include; coronary heart disease, type II diabetes, non-alcoholic fatty liver disease, hypertension, osteoarthritis, some types of cancer, poor mental health and reduced body image (18, 21-27).

Body mass index (BMI) is a metric frequently used as an indirect measure or estimation of adiposity in the general population (Table 1). It is calculated by dividing an individual's weight in kilograms by the square of their height in metres.

Table 1: World Health Organisation Classification of adult BMI status

Nutritional status	WHO classification
Underweight	<18.5
Healthy weight	18.5-24.9
Overweight	≥25.0
Pre-obese	25.0-29.9
Obese	≥30.0
Obese class 1	30.0-34.9
Obese class 2	35.0-39.9
Obese class 3	≥40

The World Health Organisation (WHO) defines a BMI ≥ 25 kg/m² as overweight and a BMI ≥ 30 kg/m² as with obesity (28). However, the National Institute for Health and Care Excellence (NICE) recommend the use of lower BMI cut-off points for people from other ethnic groups including Black African and Asian ethnic groups (29). It has been found that mortality rates are lowest amongst those within a BMI range of 22.5-25.0 kg/m² (18) and that remaining within this BMI range may protect against the development of some obesity-related cancers in adults (30). In 2009, a collaborative analyses of 57 prospective studies identified a general trend of increased overall mortality of approximately 30% that was associated with every 5 kg/m² increase in BMI (hazard ratio per 5 kg/m² 1·29 [95% CI 1·27–1·32]) (18).

1.1.1.1 Prevalence of obesity

Obesity is now considered a worldwide epidemic (31) and WHO estimates that the health conditions attributed to obesity are responsible for killing more people globally than undernutrition (32). Around a century ago the prevalence of obesity started to gain

momentum and since the early nineties has rapidly increased, almost doubling in 10 years (33, 34). In 2015, the Global Burden for Disease Obesity Collaboration estimated that almost 603.7 million people globally were living with obesity, which equated to a global prevalence of 12% (35). In 2016, WHO reported similar global rates of obesity and estimated that almost 40% of the world's adult population were living with overweight (36).

Since 2006, the prevalence of overweight and obesity in many high-income countries have remained stable, but is still relatively high compared to less economically developed countries (2, 3). In 2015, approximately two thirds of England's adult population were classed as having either overweight or obesity (1, 37). NHS Digital estimated that in 2017, 29% of adults in England were with obesity, an increase of 3% in one year (38). Similarly, between 2014 and 2015, 65% of Australia's adult population were classed as overweight or living with obesity (39), and between 2015 and 2016, it was estimated that 39.8% of the total USA adult population were living with obesity (40).

1.1.1.2 Factors contributing to obesity

Despite obesity being preventable, it remains a major global health issue with a complex and multi-factorial aetiology (41-43). Although variations can be expected at an individual level, there are several indications that can predict the general presence of obesity. One key instigator of the global "obesity epidemic" has been linked to the process of urbanisation, the course of which can create "obesogenic" environments (44-46). It has been suggested that obesogenic environments are created by an amalgamation of societal, environmental and psychosocial factors that can influence behavioural and biological responses associated with higher rates of obesity (47, 48). There is growing evidence suggesting that weight loss

and weight loss maintenance may be more difficult for people living in obesogenic environments (49). The United Nations (UN) Population Division estimated that in 2018, 55% of the world's population lived in urban areas, and predicted that this figure will increase to 68% by 2050 (50). A study using data from over 200 countries found a statistically significant association between obesity, physical inactivity, sugar consumption and urbanisation (45). Technological advances associated with urbanisation have reduced the physical burden of many daily activities resulting in more sedentary jobs (51-53). Industrial improvements have also produced energy dense, processed food that is readily available and affordable, traits more evident in built up areas.

Research has also suggested other social correlates that can increase a person's likelihood of having overweight and obesity. Studies have detected higher levels of obesity in groups with lower education levels and/ or incomes, as well as those living in more deprived areas (54). A study that included Health Survey England (HSE) data for approximately 26,000 adults reported consistency in the socio-economic gradient between both income and education, and morbid obesity (55). Similarly, a study using health survey data from 11 Organisation for Economic Cooperation and Development (OECD) countries, including England, found that despite the existence of some inconsistencies by gender and between some countries, obesity and overweight were directly related to lower levels of education and income (56).

Studies based mainly in the United States have reported that overweight and/or obesity affects some ethnic groups more than others, namely African and Latin Americans (57, 58). There is emerging evidence indicating that ethnicity may also be differentially associated with obesity in the UK. A 2018 Public Health England (PHE) report identified that levels of

overweight and obesity varied between adults in England by ethnicity; Black and White British ethnic groups were most affected at 69% and 62% respectively, both above the national average of 61% (59). Whereas the same report estimated that Chinese and Asian ethnicities were below the national average at 32% and 56% respectively (59). Recent studies have identified and suggested that some people may be genetically predisposed to higher levels of adiposity (60, 61) and that "obesogenic" environments may activate these polygenes resulting in their phenotypic expression (62, 63). Nevertheless, research is not yet able to explain fully the genetic variability of obesity by ethnicity (64).

Disparities across gender for having overweight and obesity also exist, and in general, more women than men are affected with the exception of some within country and regional differences (65). In the UK, the prevalence of overweight and obesity appears to increase with age for both genders, but the age group with the highest rate varies by gender. In 2018, overweight and obesity was highest (78%) in adult males between 45 and 74 years, and amongst adult females (73%) between the age of 64-74 years (38).

1.1.1.3 Consequences of obesity

The consequences of obesity can place substantial strain on an individual's health and, their economic productivity (66), and impact families, and the NHS (17, 66, 67). PHE reported that between 2014- 2015, it cost the NHS approximately £6.1 billion to treat health conditions linked to having overweight and obesity (37). NHS hospitals in England admitted 711,000 patients with a health condition associated either directly or indirectly with obesity during the 2017/18 period, a 15% increase since 2016/17 (38, 68). Many people with obesity also experience criticism, discrimination and stigmatization from various sources that can also

impact on mental health and well-being (69, 70). It has been estimated that by 2050, it will cost the NHS roughly £9.7 billion and wider society almost £50 billion a year to treat and manage health conditions related to having overweight and obesity (37).

1.2 National response to the obesity crisis

NICE has developed several recommended care pathways to prevent and manage the prevalence of overweight and obesity in the UK. These pathways are designed to help the general population not only to lose weight, but to be healthier by encouraging more physical activity and better dietary choices (71). NICE also recommend that healthcare professionals within primary care setting initiate conversations and weight management strategies with patients with obesity (72). Healthcare professionals are advised to assess their patients' weight, provide an opportunity for them to be weighed as well as offer guidance, support and/or a referral for additional help with weight management (72).

1.3 Women and weight

Historically women have experienced societal pressure to meet ideal beauty standards (73, 74). The ideology of slenderness equating to beauty in western society has spanned almost a century and the stigma and shame experienced by those who do not attain this social standard has been well documented (75-78). Furthermore, a study in 2016 identified an association between higher levels of attractiveness for women with a BMI that was lower than would be considered "healthy" (79). Festinger argues that the quest of humans to belong to a cohort is innate and thereby activates self-evaluation, which can only take place when comparisons are made between oneself and others (80). This is known as the social comparison theory. Social media platforms have created an environment whereby

individuals are subjected to a multitude of body images of other people, thereby providing a constant source of material to compare themselves to others (consciously or subconsciously). In 2015, a report by Pew Research Centre stated that 68% of all American women use social media (81) and in February 2019, a UK-based blogger reported that approximately 67% of the UK's entire population used social media (82). Social media therefore continually exposes people to images of other attractive and/or slender people. Research has identified an association between social media use and lower moods and body dissatisfaction particularly amongst young women due to continually comparing themselves to the images they see (83, 84).

It has also been suggested that adult females are more likely to be told by their general practitioners (GP) that they have overweight or obesity and be advised to lose weight more frequently than male patients who are overweight or with obesity (85). This disparity in advice from GPs may explain why women are more likely to receive treatment or a referral for obesity in primary care (86, 87), particularly since men tend to present less frequently than women with health problems (88-90).

1.3.1 Prevalence of obesity in women of reproductive age

A pooled analysis of global BMI trends estimated that the average BMI for women increased by 0.59 kg/m² (0.49–0.70 kg) each decade between 1975 and 2014, which is equivalent to the global population becoming, on average 1.5 kg heavier every 10 years (91). Consequently, the number of women globally with a BMI ≥25 kg/m² increased between 1980 and 2013 from 29.8% (29.3-30.2%) to 38.0% (37.5-38.5%) (92).

In 2016, government statistics estimated that just over 25% of women across England between the ages of 25 and 44 years were considered to have obesity and approximately 30% were living with overweight (93). Emerging evidence suggests that women living in more deprived areas of the UK are also more likely to experience overweight and obesity (55, 56).

One possible explanation for an increase in the prevalence of overweight and obesity amongst women between the ages of 25 and 44 years is that this time period coincides with the childbearing age of women. During a healthy pregnancy, all women, irrespective of pre-pregnancy weight will gain weight and lay down adipose tissue (4, 9, 94-96). The Institute of Medicine (IOM) in the United States issued guidance for pregnant women on weight gain that adjusts for pre-pregnancy BMI (97). Despite this guidance, many women continue to gain more weight than the IOM recommends during pregnancy (97-99). One explanation for excessive weight gain during pregnancy is the traditional ideology of “eating for two” (5, 100), a common reason given by some pregnant women to eat more than is necessarily required (5, 101), which can lead to excessive gestational weight gain. Excessive gestational weight gain increases the likelihood of postnatal weight retention (PPWR) (102). PPWR may then play a role in the long-term development of obesity for many women (5, 97, 103), particularly if women continue to have further pregnancies and are therefore susceptible to additional weight retention after each successive pregnancy. Additionally, the western social pressures placed on women to remain slim may be relaxed during pregnancy (104).

In 2010, a European Perinatal Health Report estimated that over 10% of pregnant women in most European countries have obesity (105). This report also stated that the percentage of

women having obesity varied between European countries, and is as high as 48.4% in Scotland, 35% in Norway and 27% in France (105). It is estimated that around 777,400 births take place in the UK annually, and that 65% of these births will be to women who are overweight or with obesity (106). A UK-based longitudinal study found that the number of women experiencing maternal obesity at an early stage of pregnancy had increased over a 15-year period and that this was more common amongst women who experienced higher levels of socio-economic deprivation (107).

The negative health outcomes to mother, baby and any successive pregnancies associated with maternal overweight and obesity have been well documented (6, 105, 108-110). Many of the health risks are interrelated and include the development of gestational diabetes, pre-eclampsia and gestational hypertension for the mother. There may also be perinatal complications for the baby such as macrosomia, newborn hypoglycaemia, jaundice, shoulder dystocia, asphyxiation and stillbirth (96, 111, 112). Furthermore, evidence shows that children most at risk of childhood obesity are those born to mothers with obesity prior to conception (113); gestational diabetes (114, 115) and/or large for gestational age (116, 117). Evidence also suggests that children with obesity may be more likely to have obesity as adults (118, 119). Between 2011 and 2013, approximately 50% of the women who died during pregnancy in the UK had complications associated with having overweight or obesity (120).

In 2018, the Royal College of Obstetrics and Gynaecology (RCOG) acknowledged that more women were conceiving whilst having overweight or obesity and updated their guidelines for the care of women with obesity. The RCOG guidelines now encourage general

practitioners and nurses to weigh women during routine appointments and discuss weight management, prior to conception (121).

1.3.2 Postnatal weight retention

During the first six weeks following delivery, many women lose some of the weight gained during pregnancy, but almost three quarters will fail to lose all of the pregnancy related weight or regain weight lost in the immediate postnatal period (7, 95, 122). RCTs have consistently shown that women, irrespective of their pre-pregnancy weight, will on average retain 1-5.5 kg of their pregnancy weight at six to twelve weeks postnatal (7, 108, 122-125). A mixture of reviews and cohort studies have estimated that, in general, women retain approximately 0.5-3 kg postnatally and that about 15-25% of women will retain 5 kg or more during the postnatal period (123, 124, 126-128). A UK-based prospective cohort study involving 2,559 postnatal women noted that by six months postnatal, about 73% had still retained some of the weight they had gained during pregnancy (an average of 3.5 kg ± 6.2 kg) (122). In addition, studies suggest that women experiencing overweight and obesity during pregnancy are more likely to retain or gain additional weight during the first one to two years following childbirth (7, 129). It has been proposed that the amount of weight retained postnatally is directly proportional to the amount of weight gained during pregnancy (126). Findings from a systematic review involving 17 studies determined that postnatal weight retention was more attributable to excessive gestational weight gain rather than pre-pregnancy BMI (130). Another more recent systematic review of 11 cohort studies, which included data from almost one million women (from the USA, Scotland, Sweden and Belgium), examined the association between changes in maternal weight between

pregnancies and adverse pregnancy outcomes (131). Meta-analysis, in this review reported that an increase in BMI (by one unit or more) placed the mother almost at a 60% increased risk (95% CI 1.48 to 1.96) of gestational diabetes in the next pregnancy. When maternal BMI increased by more than three BMI units between pregnancies, the odds of developing gestational diabetes more than doubled (adjusted OR 2.28, 95% CI 1.97 to 2.63). This review also found that a moderate increase in BMI (*i.e*. 2 units or more) increased the likelihood of a caesarean section by approximately 16% (adjusted OR 1.16, 95% CI 1.06 to 1.26) (131).

A range of evidence reports an association between a mother's mood and postnatal weight retention (132-135). Low mood or elevated depressive symptoms, irrespective of whether or not they have been clinically diagnosed, can impact negatively on the bonding between a mother and her infant (132, 133). Ertel and colleagues observed that this relationship was more notable in women with obesity prior to pregnancy (134). Poor bonding can cause long-term damage to the infant including developmental delays, both mentally and emotionally (135).

Parenthood may necessitate a shift in priorities. Some qualitative evidence suggests that women prioritise the care of their infant over their own personal needs (136), and often tend to be responsible for the majority of childcare duties during the first year after childbirth (137, 138). During the early postnatal period, there can be multiple demands and challenges associated with looking after a baby that have to be managed alongside adjustments to daily routines, changes in relationships with family and friends and, recovering from childbirth, as well as the physical and emotional effects of recent pregnancy (136, 139). The postnatal period can also be an emotionally delicate and demanding time for

new mothers and weight retention and/or poor body image may be factors in the development of postnatal anxiety and depression (140, 141). The stress of adjusting to a new role as a mother, in addition to parenting concerns can be both physically and mentally exhausting, particularly for first-time mothers (142). A systematic review of four studies identified a positive association between sleeping for five hours or less and PPWR (143). If women initiate poor health behaviours during the early postnatal period, they may become established as part of the new routine with their baby, making these routines more difficult to change (144, 145). It can be presumed that the accumulation of all, or a selection of these postnatal maternal experiences may further reduce the likelihood of women engaging in physical activity or healthy eating during the early postnatal period. In addition, postnatal weight retention that continues beyond the first year following childbirth may be a precursor for further weight retention leading to obesity in the future (5, 146-148).

1.4 Weight management interventions

The burden of obesity prevalence, as well as the healthcare costs of treating overweight and obesity-related health conditions have triggered a wealth of research into weight management interventions. Current evidence has shown that for adults with obesity, a moderate reduction (approximately 5-10%) in total body weight can help reduce the likelihood of the development of type II diabetes as well as cardiovascular disease (149-151). As the obesity epidemic has increased, so have the number of studies that have been designed to test a broad variety of weight loss interventions, namely lifestyle (diet and physical activity), pharmacological and surgical (152).

The provision of weight loss medication that either supresses appetite or that minimises food absorption has been advocated by some for long-term weight loss and maintenance (153). Currently, there is only one drug (Orlistat) approved for use in the UK. However, some evidence implies that the use of this drug may not be entirely safe as it can cause adverse side effects or additional health complications including gastro-intestinal complications (154, 155).

Bariatric surgery has been proven effective for weight loss and long-term weight maintenance (156, 157). However, in the UK it is currently only offered to people with morbid obesity and/or with multiple co-morbidities who have previously attempted several lifestyle weight management interventions (72, 93).

Very low-calorie diets consist of no more than 800 calories a day require professional supervision (72) have also been tested. Despite growing research on the effectiveness of very low-calorie diets (158-162), NICE do not currently recommend them as there is concern about their safety as well as the long-term sustainability of weight loss (163).

1.4.1 Lifestyle weight management interventions

A broad spectrum of lifestyle interventions have also been developed and tested for the management of obesity. These lifestyle interventions commonly include making changes to diet and/or physical activity. They may also use various cognitive and behavioural techniques for additional assistance and include goal setting, increasing motivation, self-regulation (164, 165), weight loss and weight loss maintenance (165, 166), and changing one's beliefs and expectations. Cognitive and behavioural techniques may help improve adherence and long-term weight maintenance (167). A systematic review of weight loss interventions for adults

affected by overweight and obesity concluded that a combination of a low-calorie diet and physical activity were more effective for weight loss in this population compared to diet only interventions (168). Furthermore, this systematic review also suggested that resistance exercise was more effective for reducing total body and body fat mass, whilst retaining fat-free muscle mass (168).

Several systematic reviews have demonstrated the effectiveness of commercial weight loss programmes (169, 170). The group setting of these programmes is preferred by many as it instils group support which can facilitate behaviour change (171). In 2006, both NICE and the Department of Health recommended that primary care clinicians identify people affected by overweight and obesity and offer assistance with weight management (172, 173). NICE also advocated the use of commercial weight management programmes that had proven to be effective (172). At this time, weight management programmes such as Slimming World and Weight Watchers offered 12-week courses at subsidised rates to local primary care organisations across England to which GPs could refer patients as appropriate. Despite the evidence for clinical effectiveness and cost-effectiveness of commercial weight loss programmes, this approach has not been continued in the long-term for many Clinical Commissioning Groups (CCGs) (174, 175). However, NICE guidance still recommends those with obesity or those most at risk of developing type II diabetes should be referred by their GP to locally available commercial weight loss programmes (163). Weekly attendance to these programmes may not be suitable for all patients with overweight and obesity due to the cost of attendance as well as the high level of commitment required to attend weekly group meetings (176).

1.5 Postnatal weight management interventions

Research has shown that irrespective of age or race, women in the postnatal period would prefer to weigh less and are interested in implementing strategies to lose weight and would like help to do so (104, 177, 178). During pregnancy and soon after, women may be more open to receive support and advice, therefore this could be an ideal time to encourage the development of healthy lifestyle habits (179). Weight management interventions may not only help a new mother lose the weight gained during pregnancy, but have the potential to create a healthier environment for the entire family (180, 181).

Postnatal weight management interventions are important but there are no clinical guidelines in the UK for weight management during pregnancy. Developing and testing postnatal interventions is also important given that lifestyle and medical interventions administered during pregnancy have only had modest success to date in preventing excessive weight gain during pregnancy (182, 183).

A range of different lifestyle interventions designed to promote postnatal weight loss have been developed and tested. The core of many of the most effective postnatal lifestyle interventions has been one of, or a combination of diet restriction or physical activity (184-187). However, the combinations and types of diet and/or exercise elements, as well as any additional components that comprise the interventions have been varied, leading to inconsistent results from postnatal weight management studies. In order to evaluate the effectiveness of diet and/or physical activity interventions for postnatal weight management, multiple systematic reviews have been conducted (184, 188, 189). Chapter 2 will describe the findings from a systematic review of systematic reviews of postnatal weight

management lifestyle interventions in detail. Overall, evidence from relevant systematic reviews has shown that interventions containing a combination of diet and physical activity or diet only, may be more effective than exercise only interventions (184, 188). However, the findings from many of these studies should be interpreted with caution as many studies recruited small samples of postnatal women, many of whom were white and middle-class (190-192). In addition, many of the tested interventions were very intensive lifestyle based programmes; were tailored to each individual woman and were frequently delivered by skilled health professionals (184, 186, 193). Despite evidence suggesting that some of these interventions were effective, the NHS lacks the resources (both financial and personnel) to scale-up these intensive interventions and ensure they can be provided to every postnatal woman in the UK who would benefit from them. Furthermore, the acceptability of some of postnatal weight management interventions could also be questioned given the reported high drop-out rates, poor adherence and/ or poor attendance (9, 10, 194). Attempts have been made to conduct studies that might be more appealing to a broader range of ethnicities and economic backgrounds, but they have also reported poor adherence and high drop-out rates (195). These studies, in addition to similar studies contained within several systematic reviews, have highlighted the need for more high quality RCTs that examine more effective weight management interventions, designed to be suitable specifically for new mothers (182).

One possible concept that may avoid the resources needed to implement intensive postnatal lifestyle-based weight management interventions, is the provision of brief interventions that encourage self-management and self-regulation. Evidence suggests that brief interventions

and interventions that encourage self-regulation for the treatment of overweight and obesity can be effective (196). For example, a prospective RCT tested a brief intervention for the treatment of obesity in primary care and determined that it was possible and acceptable to patients for their GP to raise the topic of weight and refer them to a weight management programme (196).

1.6 Theoretical basis of self-regulation in weight management interventions

Social cognitive theories have been applied to behaviour change interventions designed to facilitate weight management for many years (197). One such theory is the self-regulation theory, which can broadly be defined as the subconscious actions an individual uses to regulate or control their behaviour in response to their external environment (198). This theory suggests that specific behavioural changes can occur by increasing self-awareness through the process of regular self-observation, self-monitoring and self-evaluation (199). Health behaviours are affected by the personal intentions and goals set in order to achieve these desired intentions (200).

1.6.1 Self-monitoring and weight management

Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours with the goal of increasing self-awareness. The awareness fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change. Strong evidence supports the role of self-monitoring as an effective strategy in the health behaviour change process, particularly for weight loss in the general population (165, 201). A review by Michie and colleagues of effective behavioural techniques for healthy eating, physical activity and reduction of alcohol consumption,

concluded that self-monitoring was effective alone, but when combined with other techniques, the effect size nearly doubled (202). Self-monitoring, specifically regular self-weighing, has been proven to be a vital and effective component of behavioural change interventions for weight loss (203). Self-weighing is a task that is relatively simple to perform and may therefore be more sustainable. A couple of systematic reviews have noted that weight loss studies in the general population that implement regular self-weighing have been linked with successful weight loss (14, 199).

A systematic review of RCTs to examine the effectiveness of self-weighing as a strategy for weight loss was conducted and made some valuable conclusions (14). This review included a study which examined self-weighing as a single strategy and was found to be ineffective (-0.5 kg [95% CI, -1.3 to 0.3]). However, studies which added self-weighing or self-regulation techniques to weight loss programmes resulted in a significant difference of -1.7 kg (95% CI, -2.6 to -0.8). Multi-component interventions including self-weighing compared to no or minimal controls, also resulted in mean differences of -3.7 kg (95% CI, -4.6 to -2.9) (14).

A narrative review exploring strategies to improve long-term weight loss maintenance highlighted the importance of regular group contact that provided both support and pressure (167). This review also included multiple studies which demonstrated that initial weight loss and long-term weight loss maintenance were associated with certain physical and cognitive behaviour including regular self-weighing, the employment of self-regulation, motivation and self-efficacy (167).

Self-monitoring has also been proven effective for weight management with postnatal women. A systematic review by Lim and colleagues reported significantly greater weight loss

(-4.61 kg [95% CI, -7.8,-2.15 kg]) for women who participated in postnatal weight management interventions that included self-monitoring compared to those that did not (-1.34 kg [95% CI, -1.66, -1.02 kg]) (188).

1.6.2 External weight monitoring

External support for weight management has been shown to be a key influential factor for successful weight loss, due to the accountability it can foster (204, 205). Furthermore, it has been found that the notion of having to explain one's actions to another individual can alter behaviour and keep people motivated to lose weight (164, 206).

During routine GP appointments, healthcare providers are advised to weigh patients and offer weight management advice if necessary (72). However, this tends to occur at the discretion of the healthcare provider, the guidelines from NICE recommend healthcare professionals use their clinical judgement to determine when to measure a patient's weight (72). Research suggests that healthcare workers may experience embarrassment due to a lack of knowledge (207) and are concerned about offending their patients (208). Nevertheless, a study in which pregnant British women were weighed regularly throughout pregnancy by their healthcare providers expressed positive experiences and were content for it to be a part of routine care (209).

1.7 Primary care settings

Primary care settings serve as a gateway into the NHS, and the general population therefore come into regular contact with these settings. As primary care settings are situated in every community nationwide, they provide suitable vectors through which large-scale, weight

management interventions can be delivered, with the added potential of being able to access hard to reach sub-populations.

A qualitative study has suggested that GPs and nurses are apprehensive about raising the topic of weight with their patients (210). Nevertheless, the provision of more weight management interventions in primary care settings may enable more people to receive treatment as well as making it easier for the subject of weight to be discussed therefore helping to remove some of the stigma associated with overweight and obesity in healthcare settings (211, 212). The use of a brief intervention by health professionals to raise a specific health topic has shown to be ten times more useful for initiating the use of a behaviour change programme compared to leaving the onus exclusively on the patient (213). Furthermore, a substantial amount of evidence exists that has identified the adaptability of nurses to effectively deliver a broad range of health promotion, disease prevention and disease management focused interventions in primary care settings that also report good patient compliance (214). The use of brief interventions involving healthcare professionals signposting patients presenting in primary care to seek weight management support shows some promise. A study that involved healthcare professionals signposting patients with obesity to a weight management intervention was able to recruit 83% of patients with obesity who presented in primary care (196).

1.8 National Child Immunisation Programme

WHO recommends that all children worldwide receive immunisations for measles, mumps, rubella, polio, diphtheria, pertussis and Haemophilus influenzae type B (215). The UK offers additional immunisations to prevent meningitis, rotavirus, pneumococcal infections and

hepatitis B (216). These immunisations are provided by general practices nationwide and generally administered by practice nurses. During their first year, babies receive sets of immunisations at eight weeks old, 12 weeks old, 16 weeks old and at one year old. In 2017, 93.1% of children had received all three doses of the five-in-one (this is now a six-in-one) immunisation by their first birthday, a marginal decline of 0.03% from 2016 (216).

Each child is provided with a personal child health record book, or red book, in which health related information, including immunisations are recorded. Parents are encouraged to bring this with them to each medical appointment they attend for their child.

1.9 Rationale for this research

The UK's relatively high but stable rates of women of childbearing age having overweight and obesity suggest that PPWR may be an issue that affects many women after childbirth in the UK. Multiple studies have been designed and tested a wide range of lifestyle interventions intended to reduce PPWR. Nevertheless, none of these studies have been able to provide an intervention that is not only acceptable to postnatal women, but is also cost-effective and with the capabilities to be delivered on a large scale to all postnatal women with minimal structural changes to the NHS. Participation in postnatal weight management studies suggests that women are interested in postnatal weight management, but the low levels of adherence and high attrition rates suggest that many of the interventions that have been tested may not be suitable for postnatal women. By merging routine child immunisation appointments with a brief intervention designed to provide mothers with external accountability, may alleviate the poor levels of attendance and adherence rates that have frequently been reported in previous studies with this unique cohort. Positive

behaviour changes have been associated with the use of self-management techniques in relation to weight loss both in the general population and postnatal women, especially when they are used in conjunction with other behaviour modification techniques.

CHAPTER 2

REVIEW OF SYSTEMATIC REVIEWS

2.1 Chapter overview

This chapter contains the following published paper: Ferguson J.A, Daley A.J and Parretti H.M. Behavioural weight management interventions for postnatal women: A systematic review of systematic reviews of randomized controlled trials. Obesity Reviews (2019) 20 (6): 829-841. The chapter descriptively and analytically (with the aid of a mega meta-analysis) reports the findings from a systematic review of systematic reviews of RCTs examining the effectiveness of behavioural lifestyle interventions for weight loss in postnatal women. This chapter aimed to review the existing literature on effective behavioural lifestyle interventions to inform the development of the trial presented in Chapter 3.

With feedback and assistance from A.J.D and H.M.P, J.A.F developed and wrote the protocol for the review of systematic reviews, designed the data extraction forms and conducted the database searches. J.A.F, A.J.D and H.M.P contributed to writing the published article, however, J.A.F included additional information for this chapter.

2.2 Introduction

Obesity is a key contributor to many chronic comorbidities including type 2 diabetes, cardiovascular disease (217), stroke, and a number of types of cancers such as colorectal and breast cancer (217-219). These conditions can be life threatening, detrimental to quality of life, and expensive to treat.

The obesity epidemic is affecting all populations, including women of reproductive age. Recent national surveys reported that approximately 66%, 56%, and 58% of women in the United States of America, Australia, and England, respectively, either have overweight (BMI between 25 and 30 kg/m^2) or obesity (BMI over 30 kg/m^2) (39, 220, 221). This means that most women already have overweight when they become pregnant. A period of notable weight gain for many women occurs during and after pregnancy (95, 222). Studies have reported that among women who have a healthy BMI prior to pregnancy, 30% have overweight one year after giving birth (223, 224). Of women who have overweight prior to conception, 44% have obesity one year after giving birth, while 97% of women with obesity prior to pregnancy remain so at one year postnatally. On average, women gain about 14 to 15 kg during pregnancy, and at one year after birth, 5 to 9 kg is retained (95, 225). Some women are able to return to their pre-pregnancy weight after childbirth, but the amount of weight women retain postnatally varies considerably, and many women never lose all of the weight gained during pregnancy (146-148, 225, 226).

The weight gained, and then retained after pregnancy, tends to be centrally located on the body, which is an independent risk factor for the development of cardiometabolic diseases such as diabetes and coronary artery disease (4, 227). Additionally, women are at risk of gaining more weight during each successive pregnancy, increasing their likelihood of complications during any future pregnancies, as well as developing obesity in later life (147, 228, 229). Evidence also shows an association between postnatal weight and poor mental health, which may adversely affect the behaviour and the family as a whole (140, 230, 231). This highlights the need for low cost and acceptable interventions to be designed and tested

to help women successfully lose and manage their weight after giving birth. It is not clear which behavioural intervention approaches might be most successful in helping women lose weight, although in non-pregnant population strategies such as goal setting, self-monitoring of weight, calorie counting, attending a commercial weight loss programme, support from a dietician, and physical activity have evidence of effectiveness (175, 196).

2.3 Objective

Many studies using a variety of methodological designs have tested a range of weight loss interventions during the postnatal period (223, 232). Many of these studies have since been included in systematic reviews of interventions for postnatal weight management. The purpose of this systematic review is to both descriptively and statistically (using a mega meta-analysis) summarise the findings of systematic reviews of RCTs that have examined the effectiveness of behavioural lifestyle interventions for weight loss in postnatal women.

The aim was to determine whether lifestyle interventions have been successful in helping women lose weight and if data allow, to further identify which types of interventions have been successful. When several systematic reviews have performed a meta-analysis, a mega meta-analysis is useful because it provides a comprehensive statistical summary of all the evidence. A mega meta-analysis is also useful when previous systematic reviews have not been able to perform meta-analysis or subgroup analyses because of a lack of trials. The results of this systematic review of systematic reviews will help to provide direction and context for the design of future weight management interventions for postnatal women and may contribute to the evidence base for the development of clinical guidelines.

2.4 Methods

The protocol for this systematic review of systematic reviews was registered in 2017 in the International Prospective Register of Systematic Reviews (PROSPERO), trial registration number CRD42017072475.

2.4.1 Information sources, search strategy, and eligibility criteria for systematic reviews

A comprehensive systematic search of the literature was conducted using the following databases: MEDLINE (PubMed), Embase, CINAHL Plus, The Cochrane Library, and Scopus. The search terms used included postnatal, obesity, BMI, diet therapy, physical activity therapy, body weight, systematic reviews, meta-analyses, and derivatives of these search terms. A sample search strategy is shown in Appendix 1. Databases were searched from January 2000 to January 2018. This date restriction was applied as it coincided with the introduction of better reporting standards for research, particularly for RCTs and systematic reviews. The criteria for the inclusion and exclusion of systematic reviews are shown in Table 2. In summary, to be eligible for inclusion, systematic reviews had to include RCTs and/or quasi-RCTs that had assessed the effectiveness of behavioural lifestyle weight management interventions, namely, diet and physical activity interventions or a combination of these, in any format, context, and setting, and against any comparator. A wide range of definitions are typically used when referring to the postnatal period, but for the purpose of this systematic review of systematic reviews, the postnatal period is defined as used by the authors of the included systematic reviews, which typically starts immediately after childbirth and lasts until 2 to 3 years after giving birth.

Table 2: Inclusion and exclusion criteria for selection of systematic reviews

Selection Criteria	Inclusion Criteria	Exclusion Criteria
Study type	• Systematic reviews that included a summary of evidence from RCTs and/or quasi-RCTs	• Systematic reviews comprised of non-RCT studies (other study designs) • Not published in English • Animal studies • Economic studies
Population	• Adult postnatal women	
Intervention	• Lifestyle (dietary, physical activity, or behavioural) intervention compared to usual care or another intervention to help manage weight after childbirth • Any setting • Group based or individual intervention	• Surgery • Medications
Main outcome	• Weight related data at baseline and follow-up • Postnatal weight loss	

2.4.2 Screening and data extraction

The titles and abstracts of potentially eligible systematic reviews were screened by two independent researchers (J.A.F., H.M.P., or A.J.D.). When insufficient information was available from the title or abstract, full-text articles were retrieved and considered for inclusion. The full-text articles of potentially eligible systematic reviews were further screened for eligibility by two independent reviewers (J.A.F. and either H.M.P. or A.J.D.) with any disagreements discussed with a third reviewer until consensus reached. Two reviewers independently extracted data from the eligible systematic reviews (J.A.F. and either H.M.P. or A.J.D.), and any disagreements were discussed with a third reviewer until consensus

reached. Data extracted for the systematic reviews included author and year of publication, dates of literature search for studies included in the review, participant inclusion criteria, intervention and comparator inclusion criteria, description of studies included in the review, results of any meta-analyses performed, main conclusions of review, and any additional comments.

2.4.3 Quality assessment of systematic reviews

The AMSTAR tool (233) was used to assess the quality of the included systematic reviews. This was performed independently by two reviewers (J.A.F., H.M.P or A.J.D.), and any disagreements were discussed with a third reviewer until consensus reached. A third reviewer was consulted on two occasions to discuss the scoring of some points on the AMSTAR tool.

2.4.4 Mega meta-analysis

The aim was to statistically summarize weight change data reported in the original RCTs within the included systematic reviews.

For inclusion in the mega meta-analysis, RCTs within the included systematic reviews had to have reported data on body weight in a format that would allow statistical synthesis to be performed. Inclusion criteria for the mega meta-analysis was different from the eligibility criteria for the systematic reviews as RCTs that only reported comparisons between two types of diet and/or two physical activity interventions were excluded. Trials that had recruited women antenatally, but then offered an intervention postnatally, or which tested interventions that took place both antenatally and postnatally were eligible for inclusion in the mega meta-analysis as long as a postnatal weight had been reported at baseline as well

as at follow-up (baseline weight used in mega meta-analysis was first reported postnatal weight). Studies that were included in previous systematic reviews that were not RCTs were excluded from the mega meta-analysis. In addition, interventions shorter than 3 weeks were excluded as these are unlikely to have any longer-term impact on weight.

Data were extracted by two independent reviewers (J. A.F. and H.M.P.) with any disagreements referred to a third reviewer (A.J.D.). Review Manager version 5.3 (234) was used to statistically summarize data from RCTs across all included systematic reviews. Data regarding weight change were summarized using mean difference in weight in kilograms. If this was presented using other metrics, a conversion calculation into kilograms was performed. When trials within reviews only published baseline and follow-up weight data, a weight change calculator (235) was used to calculate the weight change and the associated standard deviations.

Some heterogeneity was expected due to the variability in the type of interventions tested in RCTs; therefore, a random effects model was used in the mega meta-analyses. The I^2 value was calculated as a measure of heterogeneity (236, 237). Subgroup analyses were performed to compare the type of lifestyle intervention (diet only, physical activity only, or diet and physical activity), intervention duration (3-12 weeks or greater than 12 weeks), and length of follow-up (less than or equal to 12 weeks, 13 weeks-6 months, and greater than 6 months). The cut-off of 12 weeks was chosen for intervention duration as research has shown that this is a common timeframe used to determine the short-term effects of a behaviour change intervention (238, 239). The effect of lifestyle interventions in women with or without a history of gestational diabetes mellitus (GDM) was also assessed.

A funnel plot was conducted to investigate the possibility of publication bias according to sample size.

2.5 Results

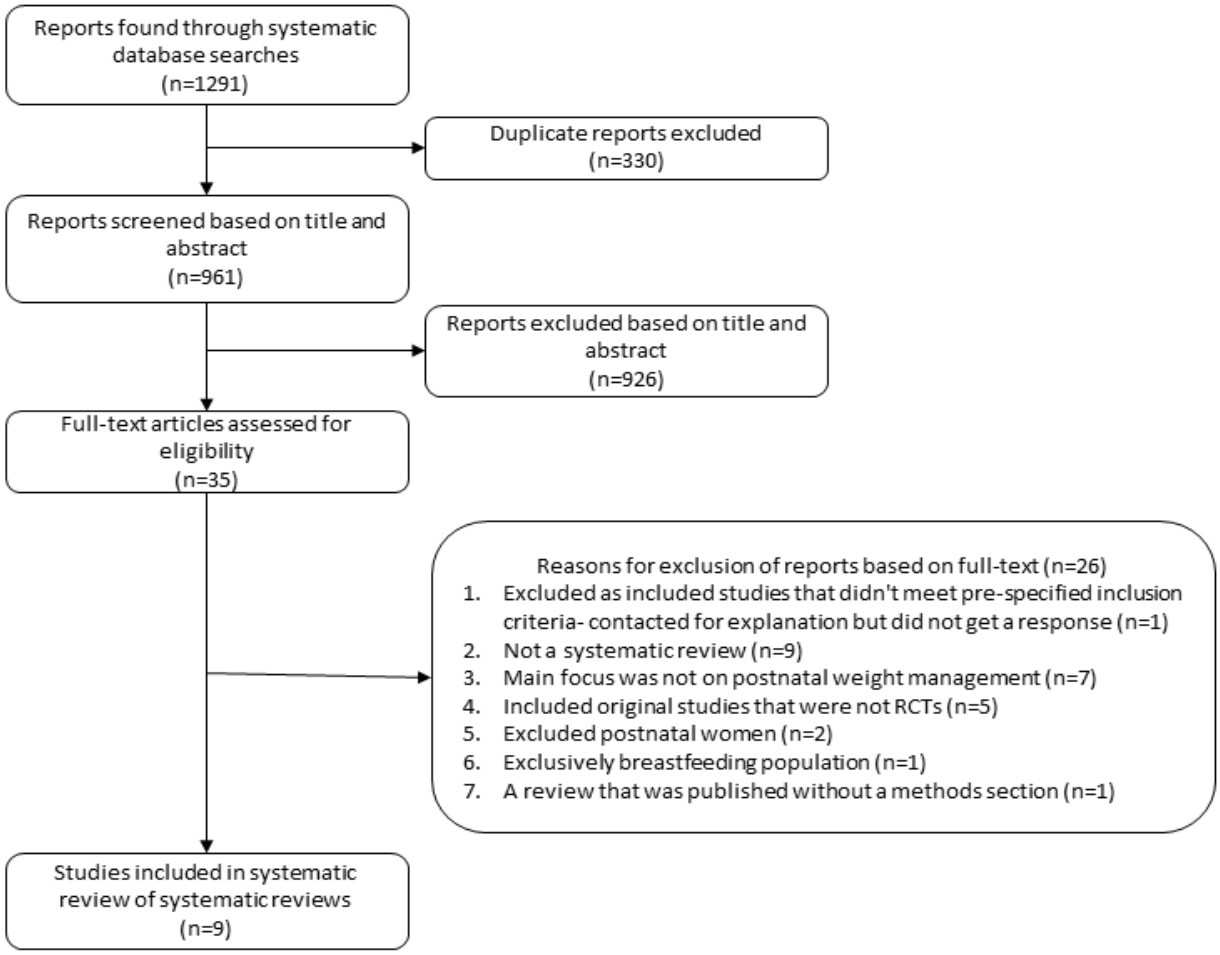
The searches identified 1,291 potentially eligible articles. After the removal of duplicates and screening, nine systematic reviews of RCTs were eligible for inclusion in the systematic review of reviews (see PRISMA flow diagram in Figure 1). Further details of the full papers excluded and reasons for their exclusion are summarized in Appendix 2.

2.5.1 Description of included systematic reviews

The characteristics of the nine included systematic reviews are summarized in Table 3 and described below. The reviews were published between 2008 and 2017 and included RCTs with publication dates between 1994 and 2016. The majority of trials in the systematic reviews were conducted in the United States, with the remaining trials conducted in Australia, Canada, Greece, Iran, Japan, Malaysia, Sweden, Taiwan, and Thailand (Table 3 and Appendix 3). All of the included systematic reviews scored as either medium or high quality, except for the review by Kuhlman et al (240), which was also the oldest included systematic review (details of the AMSTAR scoring for each included systematic review are listed in Appendix 4).

Seven of the nine systematic reviews had performed meta-analyses (184-188, 241, 242), while two reported only a narrative synthesis (240, 243). No systematic review included

Figure 1: PRISMA flow chart



exactly the same RCTs. Each systematic review included between two and 33 RCTs, and there was overlap in the RCTs included (Appendix 3). Twenty-two RCTs were included in more than one systematic review. Overall, there were 48 unique RCTs in the nine included systematic reviews. The definition of the postnatal period also varied between systematic reviews. Three defined this as up to 12 months after childbirth (187, 188, 242), one up to 18 months (186), and one up to 24 months (184). The remaining four systematic reviews stated that they included studies with postnatal women but did not define the postnatal period (185, 240, 241, 243).

Table 3: Characteristics of included systematic reviews

Review author & search dates	Study design & inclusion criteria	Participant inclusion criteria	Intervention/ exposure inclusion criteria	Comparator inclusion criteria	AMSTAR score	Studies included in review	Meta-analysis of PPTM weight data	Conclusions and comments
Kuhlmann 2008 (240) 1985-2007	RCTs	Pregnant or PN women No further details reported	Weight management interventions	None specified	Low	3 studies (all RCTs) 2 PN studies 1 Pregnancy study	No	Weight management interventions appear to help PN women manage their weight
Amorim 2013 (184) 1983-2013	RCTs and quasi-randomised RCTs	Women up to 24 months PN With obesity or overweight or excessive weight gain during pregnancy or both Aged ≥18 years and delivered a singleton healthy term infant No restrictions on BF status	Interventions involving diet, PA or both Diet included – advice on weight reduction delivered through groups, telephone or mail, individualised diet counselling prescribed calorie restricted diet PA included any PA counselling to engage in regular PA, structured/ individualised programmes or supervised sessions No restrictions on who delivered the intervention, type, frequency, duration or timing	Comparisons were: Diet vs UC PA vs UC Diet & PA vs UC Diet vs PA Diet & PA vs PA Diet & PA vs Diet	High	14 studies (all RCTs and PN studies) Note: 2 studies recruited during pregnancy	Yes 9 RCTs Results only reported by sub-groups: Diet vs UC 1 RCT MD= -1.7kg (95% CI -2.1, -1.3) PA vs UC 2 RCTs MD= -0.1kg (95% CI -1.9, 1.7) Diet & PA vs UC 7 RCTs MD= -1.9kg (95% CI -3.0, -0.9) Diet & PA vs Diet 1 RCT	Diet alone or Diet & PA interventions appear effective for PN weight loss PA alone interventions appear not to be effective Also included percentage reaching a healthy weight, percentage returning to pre-pregnancy weight as primary outcomes

							MD= 0.3kg (95% CI -0.06, 0.7)	
Choi 2013 (185) 2000-2011	RCTs	Pregnant or PN women with obesity or overweight	Interventions that target increasing PA- both PA alone and PA & diet	None reported	Medium	11 studies (all RCTs) 4 PN studies 7 Pregnancy studies	Yes 4 RCTs WMD= -1.2kg (95% CI -1.9, -0.6) Supervision and type of intervention subgroup analyses conducted	PA and diet interventions appear effective for PN weight loss
Elliott-Sale 2015 (187) 1990-2013	RCTs and quasi-randomised RCTs	Healthy pregnant and PN women (up to 12 months PN) No restrictions on parity Included women with normal weights, overweight or obesity	PA only weight management interventions introduced during or following pregnancy No restrictions on type, frequency, duration, mode, setting or intensity	Usual care or another type of intervention	Medium	5 studies (all RCTs and quasi-RCTs) 2 PN studies 3 Pregnancy studies	Yes 2 RCTs WMD= -1.7kg (95% CI -3.6, 0.1) No subgroup analyses conducted	PA does not appear effective for PN weight loss Limited evidence to suggest that PA can be used to limit gestational weight gain
Nascimento 2014 (186) Inception-2012	RCTs and pilot RCTs	Women up to 18 months PN No restrictions on BMI, BF status, parity or comorbidities	Interventions that provided a supervised PA or PA guidance with a minimum 10-week follow-up No restriction on whether there was a dietary component to the intervention	No intervention, minimal intervention or usual care	Medium	11 studies (all RCTs and PN studies)	Yes 11 RCTs MD= -2.6kg (95% CI -3.7, -1.5) Duration, study quality, supervision, PA goals, type of diet intervention	Lifestyle interventions appear effective for PN weight loss Combined Diet & PA and objective targets are the most effective intervention strategies

							subgroups analyses conducted	
Lim 2015 (188) Inception-2014	RCTs, single-arm interventions, controlled trials and pre-test-post-test studies	Women up to 12 months PN No restrictions on BMI, age or parity	Intervention involving modification of diet, PA or diet & PA	None reported	Medium	46 studies: 33 RCTs 6 Single-arm interventions 7 non-RCTs All PN studies	Yes 17 RCTs MD= -2.6kg (95% CI -3.5, -1.6) Note: A sensitivity analysis led to 4 RCTs with PA or Diet interventions as comparator being excluded Supervision, type duration, individual/ group, technology and setting of interventions subgroup analyses	Diet, PA or Diet & PA interventions appear effective for PN weight loss Self-monitoring significantly more effective than no self-monitoring Diet & PA significantly more effective than PA alone
Guo 2016 (243) 1996-2014	RCTs	PN women previously diagnosed with GDM	Interventions with only behavioural changes and without pharmacological therapy Interventions delivered during the PN period	None reported	Medium	12 studies (all RCTs and PN studies)	No	Lifestyle interventions appear effective in the short-term for weight loss in women with a history of GDM
Lau 2017 (242) Inception-2016	RCTs	Women with obesity and overweight and in the perinatal	Electronic-based lifestyle intervention comprising of at least one component of diet, PA and weight management	Minimal intervention or usual care	High	14 studies (all RCTs) 5 PN studies	Yes 5 RCTs	E-based lifestyle interventions appear effective for PN women with obesity or overweight to lose weight at 1-2

		period (pregnancy to 12 months PN) The RCTs could include antenatal or PN interventions	Delivered through at least one of the following: website, internet, apps, text message, email, computer or video player			7 Pregnancy studies 2 from pregnancy to PN studies	Results only reported by sub-groups: 1-2 months PN MD= -3.6kg (95% CI -6.6, -0.6) 6 months PN MD= -0.9kg (95% CI -3.8, -1.3) 12 months PN MD= -3.3kg (95% CI -8.4, 1.8)	months, but not at 6 or 12 months PN
Sherifali 2017 (241) 1990-2016	RCTs, non-RCTs (CCTs), pre-post studies, historically controlled and pilot studies	Pregnant or PN women ≥18 years	eHealth weight management interventions targeting either GWG or PN weight loss Must have a behavioural component (PA or diet) in the technology Minimum duration of 3 months & no restriction on setting	In-person interventions, other health technology interventions or no intervention (including UC)	Medium	10 studies: 7 RCTs 1 Pilot RCT 2 CCTs 4 PN studies 6 Pregnancy studies	Yes 4 RCTs MD= -2.6kg (95% CI -3.8, -1.3) Pregnancy/PN, energy intake, glycaemic parameters subgroup analyses conducted	Weight management in PN period can be significantly enhanced by use of e-health technologies

Abbreviations: PA= physical activity, PN= postnatal, BMI= Body Mass Index, UC= usual care, BF= breast feeding, WMD= weighted mean difference, MD= mean difference, GWG= gestational weight gain, GDM= gestational diabetes mellitus, RCT= randomised controlled trial, CCT=clinical controlled trial.

Two of the systematic reviews placed no restrictions on the type of postnatal women they included from studies (186, 188). However, three reviews included only women who either have overweight and/or have obesity (184, 185, 242), one systematic review only included women with a history of gestational diabetes (243), and one included only healthy women (187). Two did not report if they placed any restrictions on the type of postnatal women they would include (240, 241).

The scope of the included systematic reviews varied. Five of the reviews included studies that investigated the effectiveness of lifestyle interventions both during pregnancy and the postnatal period (185, 187, 240-242). However, as the review authors performed analyses for these populations separately, they were eligible for inclusion in this review of reviews. Two reviews focused exclusively on e-health technology interventions (241, 242). One review restricted its inclusion criteria to physical activity only interventions (187) while one focused on postnatal lifestyle interventions to prevent type 2 diabetes (243). The remaining five systematic reviews focused on different diet and physical activity modification interventions (184-186, 188, 240) (see Table 3).

2.5.2 Mega meta-analysis of weight data

While there were 48 unique RCTs included in the systematic reviews, 13 did not report weight related data; therefore, only 35 of these were considered potentially eligible for inclusion in the mega meta- analysis. However, two were published in Chinese (244, 245) and therefore excluded. This meant 33 unique trials were eligible for inclusion in the meta-analysis. In addition to the above exclusion, a further 11 RCTs were excluded from the mega meta-analysis, mostly due to a lack of useable reported weight data (other reasons for

exclusion are given in Appendix 5). Two studies (246, 247) that compared either two different diets or two different types of physical activity with no comparator group were excluded from the mega meta-analysis. Including studies with dependent variables like this would either have affected the validity of the results or required a separate meta-analysis (of proportions to be performed) (248, 249).

All the included RCTs reported that they objectively assessed weight, except for the RCT by Youngwanichsetha *et al.* (250), which did not clearly state that weight related data were objectively collected. Therefore the mega meta-analysis included data from 22 unique RCTs and 1,553 postnatal women and demonstrated that overall women randomized to a lifestyle intervention had significantly lower body weight at last follow-up than comparators (mean difference of −1.7 kg [95% CI, −2.3 to −1.1]) (Figure 2).

Most RCTs included in the reviews did not report data by weight status and those that did reported it inconsistently or in a format that could not be used in the mega meta-analysis, therefore a sub-group analysis on the basis of weight status was not possible.

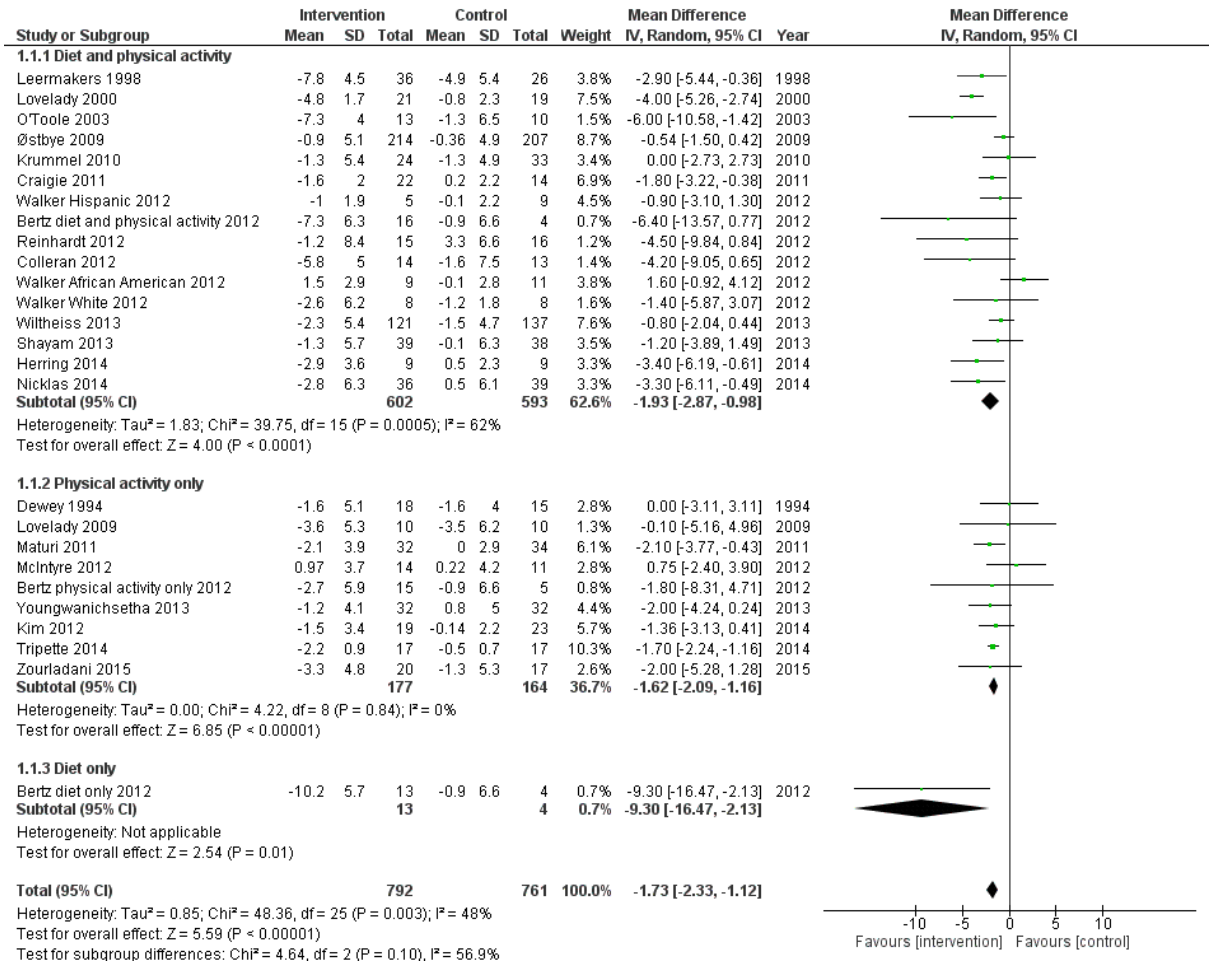
2.5.3 Subgroup analyses

2.5.3.1.1 Intervention type

When analyses were restricted to combined physical activity and diet intervention trials, the mean change in weight was −1.9 kg (95% CI, −2.9 to −1.0; $P < 0.01$; $I^2 = 62\%$; 16 comparisons) relative to comparators (Figure 2). Analysis of physical activity-only interventions resulted in a weight change of −1.6 kg (95% CI, −2.1 to −1.2; $p < 0.01$; 9 comparisons) relative to comparators and no heterogeneity ($I^2 = 0\%$). There was only one study in the diet-only

subgroup analysis (190), and this showed that the dietary intervention significantly reduced postnatal weight (MD = −9.3 kg; 95% CI, −16.5 to −2.1; p = 0.01) relative to comparators.

Figure 2: Mean difference in weight change (kg), intervention type subgroup analysis

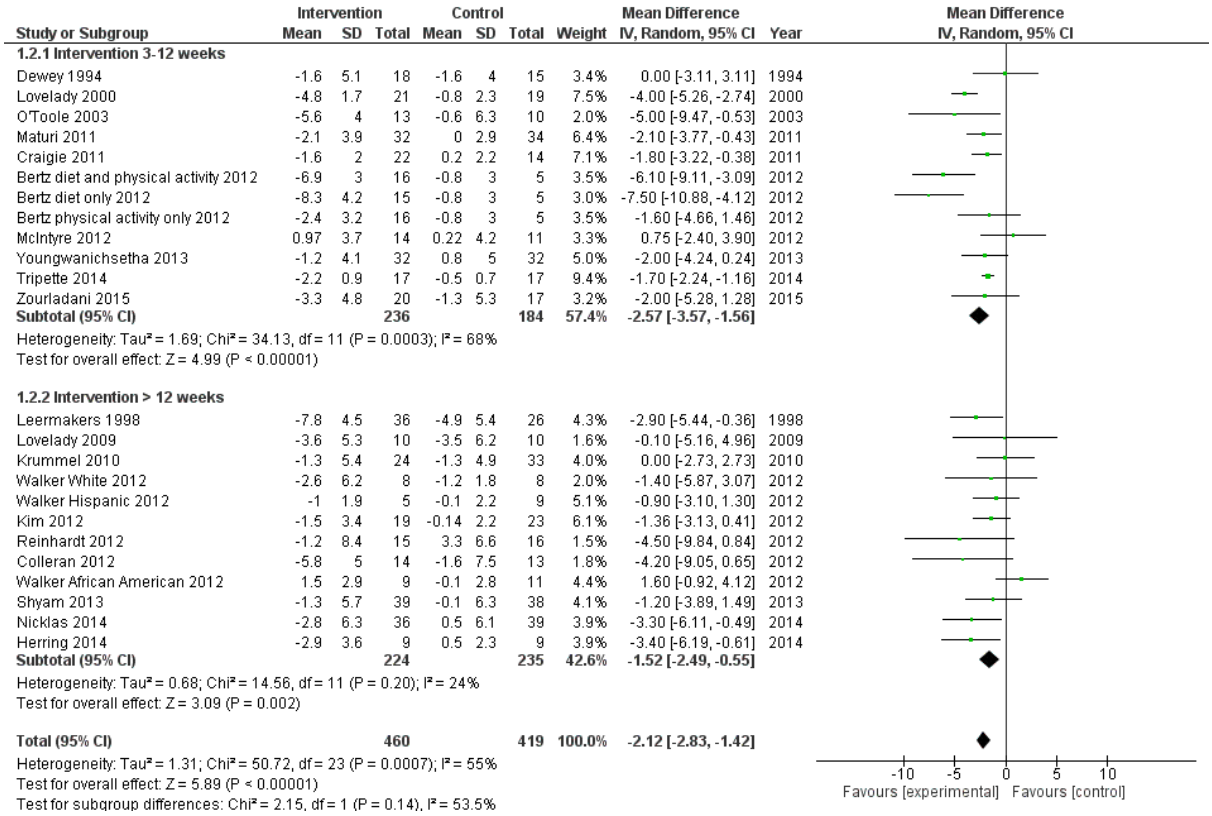


Please note that this analysis was based on last follow-up weights recorded in the trials.

2.5.3.1.2 Intervention duration

The mean weight change for participants who received interventions of between three- and 12-weeks duration was −2.6 kg lower than the comparator group (95% CI, −3.6 to −1.6; p< 0.01; I^2 = 68%; 12 comparisons) (Figure 3). In the analysis where only trials greater than 12 weeks duration were included, participants who received an intervention were 1.5 kg lighter than comparators at follow-up (95% CI, −2.5 to −0.6; p = 0.002; I^2 = 24%; 12 comparisons).

Figure 3: Mean difference in weight change (kg), intervention duration subgroup analysis

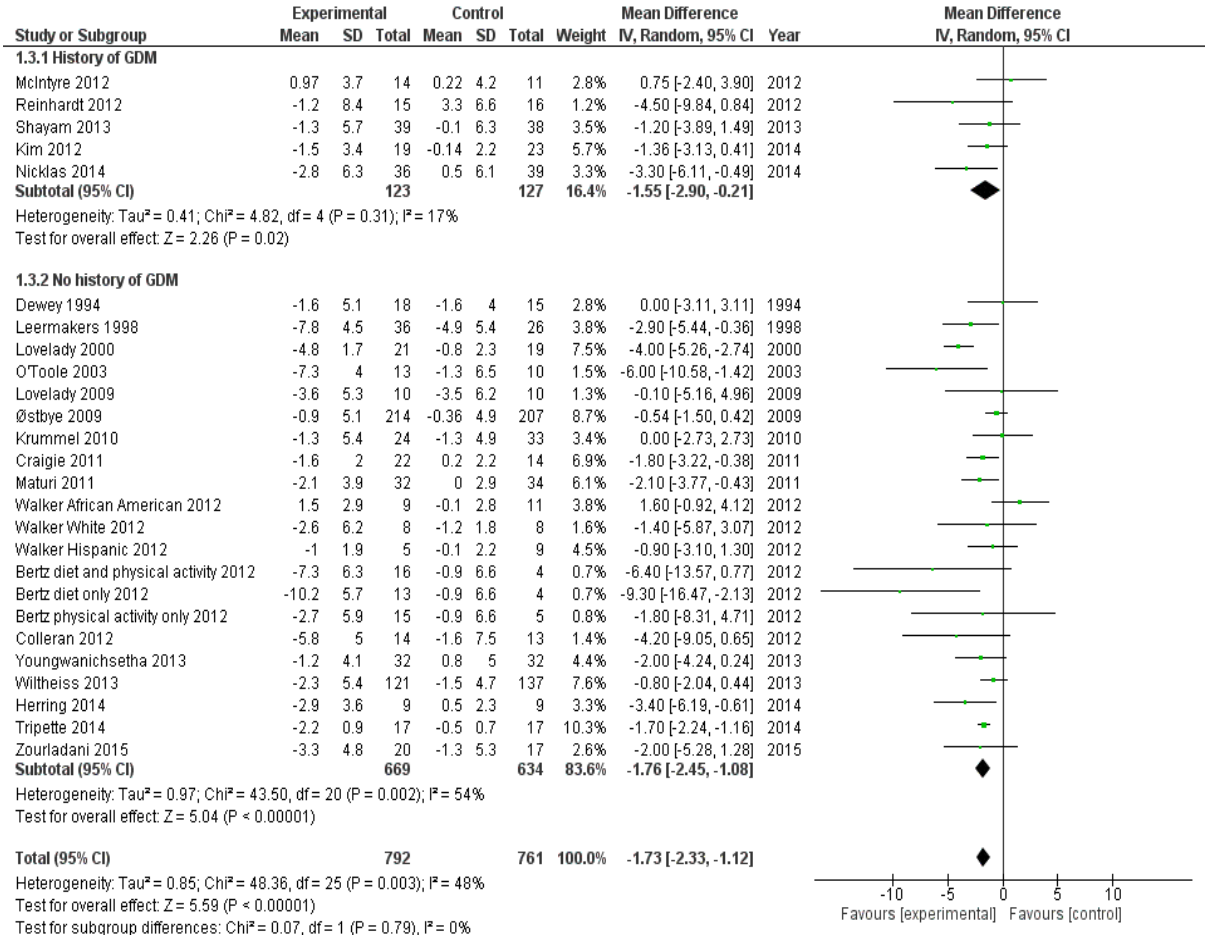


Please note that this analysis was based on end of intervention weights recorded in the trials and two trials (25, 65) were excluded (as no end of intervention data were reported). Therefore, the figures in this forest plot differ to those shown in Figures 2, 4 and 5.

2.5.3.1.3 History of GDM

When analysis was restricted to trials that had included only women without a history of GDM, the intervention group lost 1.8 kg more than comparators at follow-up (95% CI, −2.5 to −1.1; p< 0.01 and I^2 = 54%; 21 comparisons) (Figure 4). When the analyses were repeated for women with a history of GDM, participants who received an intervention were 1.6 kg lighter than comparators at follow-up (95% CI, −2.9 to −0.2; p = 0.02; I^2 = 17%; 5 comparisons).

Figure 4: Mean difference in weight change (kg), GDM subgroup analysis

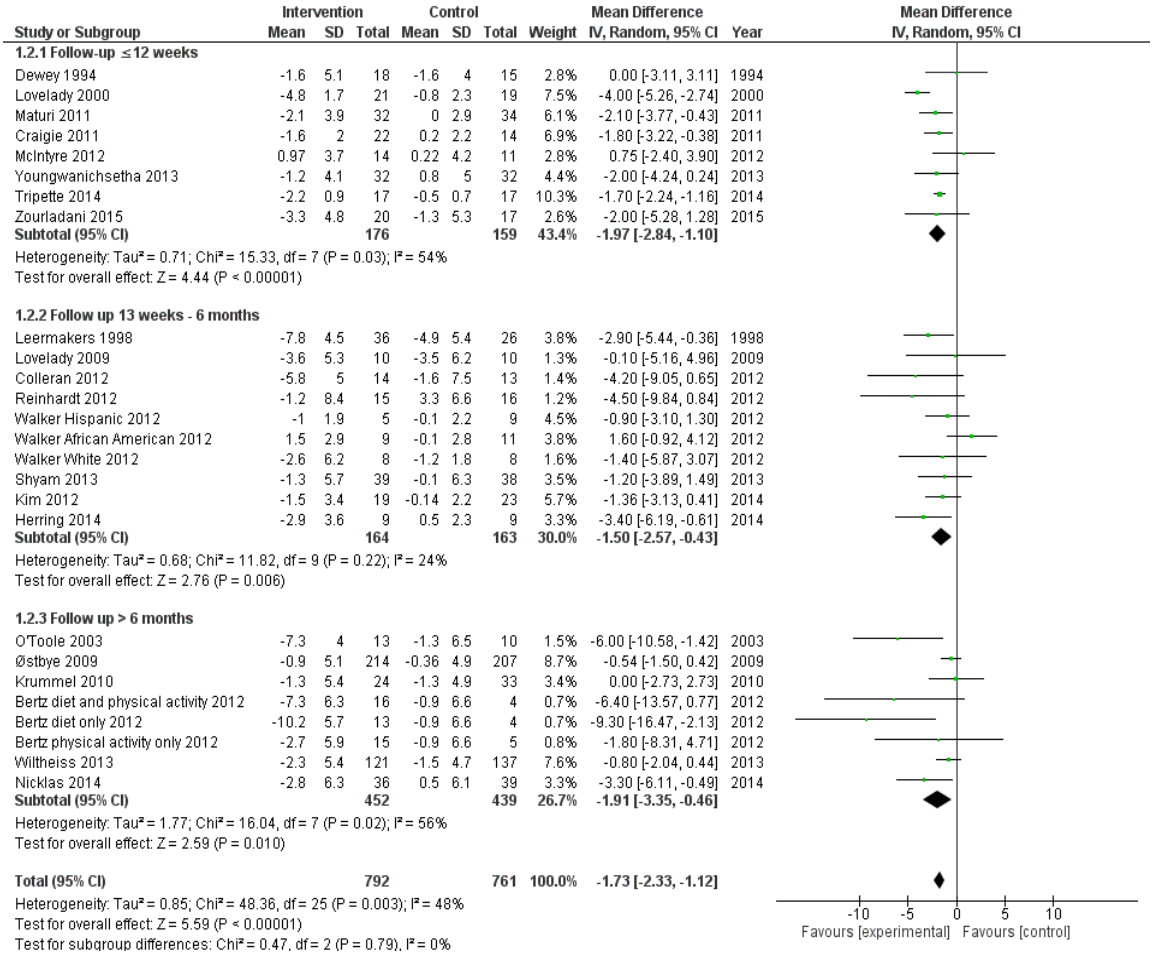


Please note that this analysis was based on last follow-up weights recorded in the trials.

2.5.3.1.4 Length of follow-up

The mean weight change for participants at follow-up 12 weeks or less was −2.0 kg lower than the comparator group (95% CI, −2.8 to −1.1; p< 0.01; I^2 = 54%; eight comparisons) (Figure 5). At follow-up between 13 weeks and 6 months, participants who received an intervention were 1.5 kg lighter than comparators at follow-up (95% CI, −2.6 to −0.4; p = 0.006; I^2 = 24%; 10 comparisons), while at more than 6 months follow-up, participants who received an intervention were 1.9 kg lighter than comparators at follow-up (95% CI, −3.4 to −0.5; p = 0.01; I^2 = 56%; eight comparisons).

Figure 5: Mean difference in weight change (kg), length of follow-up subgroup analysis



Please note that this analysis was based on last follow-up weights recorded in the trials.

The funnel plot (Appendix 6) displayed some asymmetry, suggesting the possibility of some bias, due to a lack of published studies with larger sample sizes.

2.6 Discussion

This systematic review of systematic reviews of RCTs has comprehensively and systematically synthesized both descriptive and statistical evidence of the effects of lifestyle interventions for postnatal weight management for the first time. Nine systematic reviews that had included RCTs were eligible for inclusion in this review of reviews. Overall, these reviews concluded that lifestyle interventions were effective in reducing weight in postnatal

women. Based on the current available evidence, pooled results in the mega meta-analysis also showed that lifestyle interventions significantly reduced weight in postnatal women by −1.7 kg (95% CI, −2.3 to −1.1) relative to comparators at follow-up. Interventions that involved both diet and physical activity interventions, physical activity alone, and dietary interventions alone were all effective, relative to comparators, although there was only one trial in the diet-only analysis. In women with a history of GDM, postnatal weight was −1.6 kg (95% CI, −2.9 to −0.2) lower than comparators, and lifestyle interventions appeared as effective in women with and without a history of GDM (1.6 kg versus 1.8 kg, respectively). Interventions of shorter duration (3–12 weeks) appeared to be more effective in reducing postnatal weight than longer interventions, although this may be the result of recidivism where it becomes harder to lose and maintain weight over time in longer interventions and which therefore have longer follow-up assessments. The AMSTAR scores for the systematic reviews increased in line with the year of publication and coincided with the transition of QUORUM (251) to PRISMA (252) and requirements from journals for better reporting of trials and systematic reviews (253).

2.6.1 Comparison with the literature

Despite some variation in the inclusion and exclusion criteria adopted by the nine included systematic reviews, all reviews reported that lifestyle interventions reduced postnatal weight. This is consistent with the findings of reviews involving other adult populations (254). The mega meta-analysis showed that lifestyle interventions to date have been moderately effective in helping women lose about 1.7 kg of weight in the postnatal period, but weight loss does not have be large to be important for health. This reduction in weight is

similar to that reported by several of the meta-analyses reported in the included systematic reviews, demonstrating consistency of results (184, 185, 187). Clinical guidance from NICE in England suggests that weight loss of approximately 2 kg is clinically important for health (71) and can contribute towards an effective reduction in the risk of cardiovascular disease and type II diabetes mellitus (150). Modelling has also shown that even if a small amount of weight is lost, this weight loss remains cost effective if the weight regained occurs on a lower weight trajectory (255). Furthermore, as the relationship between obesity and mortality is linear, even small amounts of weight loss may be clinically important (149, 150, 256).

It is important to set the results of this study in context with other types of weight loss interventions that postnatal women may choose to use. Evidence suggests that commercial weight loss programmes are an effective intervention for weight loss, and people attending these types of programmes will lose on average about 5 kg (175), which is substantially higher than our pooled estimate here (−1.7 kg).

Three trials in the mega meta-analysis reported weight loss (relative to comparators) of the same magnitude or greater than reported for commercial weight loss programmes (190, 257, 258), but these trials all involved very intensive and expensive interventions that would be difficult for health care services to fund for the large number of women who need to lose weight after having a baby. The study by O'Toole *et al.* (257) involved an individually structured diet and physical activity intervention delivered by a dietician and a physiologist. Participants were asked to record their daily food consumption in a food diary and attended weekly group sessions for the first 12 weeks, then once every 2 weeks for 2 months and then once a month until 1 year postnatal. The other two trials with weight loss greater than 4.5 kg

in the mega meta-analysis (190, 258) also involved intensive and/or lengthy interventions involving behaviour modification counselling, motivational interviewing, or specialized dietetic support, none of which can be easily implemented at a population or community health level. Additionally, all three of the trials reporting effects greater than 4.5 kg randomized very small numbers of participants (ranged from 23 to 57 participants) (190, 257, 258), and their estimates may therefore be susceptible to bias.

Taken together, this raises the question of whether it might be more useful to refer or encourage postnatal women, who wish to lose weight, to a commercial weight loss programme since this may be more effective and provision is already in place for women to attend such programmes, both during and after pregnancy. Some even promote their programme as being suitable for all, including pregnant and breastfeeding women (259) or from 6 weeks after childbirth (260). Furthermore, a recent trial in the UK (196) found that referral of adult patients with obesity to commercial weight management programmes by GPs during routine consultations can be an effective weight loss intervention. Nevertheless, postnatal women are a unique subgroup of the population with many challenges and barriers that may impact their ability to consistently attend commercial weight loss programmes, for example, availability of childcare, child feeding, and sleeping patterns. Future research should address this question.

Research evidence has been inconsistent on the preference of postnatal women for different types of weight management interventions with some reporting that women prefer to attend group-based sessions (261, 262), while others found that home-based interventions are preferred due to issues such as time constraints, convenience, and childcare

requirements (10, 263). A recent systematic review that compared self-help interventions (such as printed materials, internet, and mobile phone apps) with controls in general populations reported a significant effect favouring the interventions at 6 months follow-up (−1.9 kg [95% CI, −2.9 to −0.8]) (264). Self-help interventions are attractive because they are low cost, varied, flexible, and can be tailored to the specific needs of the individual. Given many postnatal women might find it difficult to attend more formal weight loss programmes and some have expressed a preference for home-based programmes, self-help interventions for postnatal weight loss are worthy of consideration. Particularly as the effect estimate (−1.9 kg [95% CI, −2.9 to −0.8]) in self-help interventions is similar to the result in our mega meta-analysis (−1.7 kg [95% CI, −2.3 to −1.1]), in which the interventions tested, typically, involved professional support and/or more resource intensive interventions than self-help interventions.

This systematic review of systematic reviews was published at a similar time to another review of systematic reviews conducted by Farpour-Lambert and colleagues, which aimed to identify lifestyle interventions during both pregnancy and the postnatal period (265). Key differences between the reviews are that this review focused exclusively on the postnatal period and included nine systematic reviews (184-188, 240-243), one of which was a Cochrane review (184) and met their inclusion criteria. Whereas, the review by Farpour-Lambert *et al.* reported that diet and physical activity interventions can lead to a change in postnatal weight retention in any BMI category by -2.6 to -2.3 kg and for women with overweight and with obesity by -3.6 to -1.2 kg. Their findings suggest marginally better weight loss outcomes compared to the findings from this review of reviews. Additionally,

unlike the review of reviews in this thesis, Farpour-Lambert *et al.* did not perform a mega meta-analysis of data or sub-group analyses to attempt to explore possible differences in the data.

2.6.2 Physical activity and diet-only interventions

These findings show that both physical activity and diet only interventions can be effective in reducing weight in postnatal women. Only one trial that recruited a small sample was eligible for inclusion in the diet-only analysis highlighting the need for more studies on this question in this population of women. The recent scientific report and systematic review by the American Physical Activity Guidelines Committee concluded that there was insufficient evidence to determine whether physical activity is associated with weight loss during postnatal period. The systematic review in this thesis provides an up-to-date summary of the current evidence by concluding physical activity interventions can play a role in reducing weight after childbirth (−1.6 kg), relative to comparator groups (266).

2.6.3 Strengths and limitations

This review has a number of strengths and limitations that need to be considered when interpreting the findings. The review focused only on systematic reviews that had included RCTs so that a summary from high-quality evidence was available. Drawing together these findings in one place has generated a comprehensive evidence-based review of the effectiveness of lifestyle interventions for postnatal women. Data from this systematic review of systematic reviews can be used to guide the development and design of future interventions in this population, as well as future health policy for postnatal women. By performing a mega meta-analysis of previous meta-analyses, a quantitative estimate of the

amount of weight loss that can be obtained from behavioural lifestyle interventions for weight loss in this population of women has been provided. Nevertheless, as the mega meta-analysis only included RCTs that had been included in published systematic reviews, it is possible that more recent, eligible, individual RCTs may have been omitted from analysis.

Although the AMSTAR tool was used to evaluate the overall quality of the included systematic reviews, the individual quality of the 22 studies included in the mega meta-analysis was not assessed. A limitation of some of the trials included in the individual systematic reviews was the broad range in the number of months postnatal women could be to meet the systematic review inclusion criteria. It was therefore not possible to determine the effect of the intervention in relation to the time it was initiated during the postnatal period. Unpublished systematic reviews were excluded and, the grey literature was not searched. It was not possible to include one systematic review (267) due to a lack of clarity regarding the inclusion and exclusion criteria, and the authors did not respond to a request for more information.

Most of the trials within the included systematic reviews were conducted in the United States of America, and most participants were of White ethnicity, so the findings from the systematic reviews, and by implication our findings, may not be generalizable to other ethnic groups. We did not contact study authors of RCTs where there was unusable weight data because most were more than 5 years old. As expected, there was some overlap of trials between the nine included systematic reviews. However, this is a particular advantage of performing a mega meta-analysis since each trial only contributes once to the overall pooled findings. In the overall pooled estimate, there was a moderate level of heterogeneity, which

is likely to be the result of the variation in the types of interventions (268). This heterogeneity was only partially resolved by subgroup analyses.

There were limited data (one small trial) on diet-only interventions, and this remains an important avenue for future research. The most recent RCT included in any systematic review was published in 2015, highlighting the need now for more trials to test the feasibility and effectiveness of novel lifestyle interventions for weight loss in postnatal women. Bias was considered with the aid of a funnel plot (Appendix 6). The asymmetry of the funnel plot suggests the possibility of some bias, due to a lack of published studies with larger sample sizes.

This review did not find any RCTs that had tested an intervention embedded within routine health care appointments, and this might be a pragmatic way to offer support to all postnatal women who wish to lose weight after having a baby. Evaluation of these types of interventions is an important direction for further research. The analysis involving women with a history of GDM only included five small trials; therefore, this result should be interpreted as preliminary.

2.7 Conclusion

This systematic review of systematic reviews and mega meta-analysis of RCTs found that lifestyle interventions are moderately effective in reducing weight after childbirth. Clinical guidance for the care of post-natal women should be updated to reflect the findings of this review and the accompanying mega meta-analysis.

CHAPTER 3

FEASIBILITY CLUSTER RANDOMISED CONTROLLED TRIAL

3.1 Chapter overview

This chapter reports the results of a cluster randomised feasibility cluster trial conducted as part of a mixed methods study to evaluate a brief postnatal weight loss intervention delivered by practice nurses as part of the national child immunisation programme. This chapter will present the quantitative findings, with the qualitative findings described in Chapter 4.

3.2 Background

3.2.1 Obesity

A multitude of interrelated lifestyle, behavioural, social and environmental factors have created "obesogenic" environments, in which many individuals are more susceptible to an energy imbalance that increases the likelihood of obesity (17). This energy imbalance is commonly the result of a reduction in physical activity and an excessive caloric intake and has contributed to global obesity rates tripling since 1975 (36). The obesity epidemic has altered the profile of the UK's population, resulting in a greater proportion of the population now being classed as overweight or with obesity than ever before. A report by the OECD predicts that 35% of England's population will have obesity by 2030 and that England currently has one of the highest levels of obesity in Europe (269). Despite rates of overweight and obesity stabilising in England in recent years, overweight and obesity rates still show no sign of reducing (66, 269).

Obesity contributes to the development of many preventable, non-communicable and chronic diseases (including type II diabetes, cardiovascular disease and some cancers) (270, 271). These chronic diseases may affect quality of life, be expensive to manage or life-threatening (272-274). Based on the UK's historical BMI trends, the cost of treating obesity-related diseases are projected to cost approximately £648 million in 2020, and by 2030 cost an additional £2 billion (269).

3.2.2 Pregnancy and postnatal weight retention

In 2016, HSE estimated that about 30% of women over 16 years were overweight and 27% were with obesity (275), suggesting that many women initiated pregnancy above a healthy weight range (276). In 2017, approximately 762,000 women gave birth in the UK (277). Based on the prevalence of overweight and obesity in women over 16 years old in 2016, this could mean that around 400,000 women with overweight and obesity may potentially conceive a child each year. Pregnancy increases women's susceptibility to excessive weight gain and research has consistently reported a relationship between excessive gestational weight gain (GWG) and PPWR (95, 278).

GWG can be described as the total amount of weight a woman gains from conception to just before childbirth. PPWR can be defined as the difference in a woman's weight pre-pregnancy compared to her weight at any time point after delivery (279). Overall, research suggests that most women will retain some weight after pregnancy but estimations on the amount of weight retained has varied. Some studies have estimated that by one year postnatal, from 13 to 20% of women will retain ≥5 kg (95, 225). Whereas, other studies have

reported that by one year postnatal, approximately 25% of women will retain more than 4 kg of the weight they gained during pregnancy (223). Nevertheless, on average many women will retain between 0.5-3 kg after each pregnancy (108, 124, 125), and that by six weeks postnatal, two thirds of women will weigh more than their pre-pregnancy weight (95). Research has also reported that excessive GWG and PPWR can be key contributors to obesity in later life (280, 281).

Furthermore, when women are unable to return to their pre-pregnancy weight, one key consequence is that subsequent pregnancies are initiated at a heavier weight, thereby increasing the likelihood of pregnancy related complications for both the mother and child (6, 282, 283).

3.2.3 The early postnatal period and further weight gain

During the postnatal period, as new mothers adjust to motherhood, they may make lifestyle and behaviour changes, that could either optimise or impair their weight management, implying that some women may be more susceptible to additional weight gain during the postnatal period (95, 124). The postnatal period is a time where large changes and new challenges may arise for women that can affect, not only a new mother's body, but also her routine and lead to the creation of negative health behaviours. These factors may prevent weight loss and/or encourage additional weight gain during the postnatal period. For instance, after childbirth, many women may put the needs of their infant before their own health and wellbeing (136) meaning that lifestyle choices, such as regular physical activity and structured meal plans may also change after having a baby (136, 139). These lifestyle adjustments and parenting concerns can be time consuming and may lead to significant

fatigue (142), further reducing the likelihood of new mothers engaging in healthy lifestyle behaviours. A number of studies have shown that in general, once negative health behaviours have been established, they are difficult to reverse (144, 145). If left unmanaged, weight retention and/or additional weight gain during the postnatal period can place women on a trajectory of additional weight gain (147). This weight gain ultimately increases the likelihood of developing obesity, and subsequently developing chronic disorders later in life (108, 284, 285), especially since pregnancy-related weight gain and retention tends to occur around the mid-section of the body (227, 228). The distribution of fat across the mid-section of the body has been identified as a risk factor for morbidity and mortality due to the progression of diseases such as diabetes and cardiovascular disease (4, 227).

3.2.4 Current postnatal care

Currently no national guidelines for postnatal weight management exist in the UK. NICE recommends that healthcare professionals involved in weight management offer information and advice on the risks of obesity and discuss suitable weight management behaviour before, during and after pregnancy (286). However, no indication is given about what interventions might be most suitable. Consequently, postnatal care in the UK tends to focus on the physical healing from childbirth, ensuring mothers and families are adjusting to motherhood and, sufficient infant weight gain, but with little focus on maternal weight management (287). The absence of guidance may be due to the lack of consensus and clarity of information relating to both weight loss and the resumption (or initiation) of physical activity after having a baby (288). Consequently, postnatal weight management

recommendations women receive from their healthcare providers can be inconsistent, or non-existent (289).

3.2.5 Previous interventions for postnatal weight management

Research indicates that postnatal women are concerned about their weight and would like assistance with weight management (104, 178). Researchers have developed and tested a variety of postnatal weight management interventions, with some reported as being effective for reducing postnatal weight retention (192, 193, 290, 291). The review of systematic reviews (see Chapter 2) that was conducted as part of this thesis showed that a range of diet and physical activity interventions for postnatal weight management have been tested across a broad range of settings and provided by a variety of skilled healthcare professionals (e.g. dieticians, lifestyle counsellors, exercise physiologists, nurses and psychologists). The interventions were moderately effective (yielding a weight loss difference of approximately 2 kg between intervention and comparator), but with substantial heterogeneity. However, most interventions tended either to be very resource intensive, or required substantial participant input. Furthermore, many of these interventions were not embedded within routine health care contexts or at a population level.

3.3 Theoretical framework and intervention rationale

3.3.1 Self-management and self-monitoring

One type of weight management intervention that can be applied at a national level and potentially offered to all postnatal women, is for health professionals to encourage women to regularly self-monitor their weight during routine healthcare appointments. The potential

efficacy of regular self-weighing has its roots embedded in self-regulation theory (292, 293). This theory suggests that specific behavioural changes can occur by increasing one's self-awareness through the process of regular self-observation, self-monitoring and self-evaluation (199). Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours with the goal of increasing self-awareness. The self-awareness that is fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change.

Evidence from multiple meta-analyses suggest that regular self-monitoring, such as self-weighing is an effective strategy in the health behaviour change process, particularly when used in multi-component weight management interventions (202, 294). A systematic review and meta-analysis of effective weight loss strategies for postnatal women reported that interventions that included regular self-weighing resulted in greater postnatal weight loss (188). Other studies, mainly systematic reviews have reported similar findings in both the general population and postnatal women (14, 15, 199, 295, 296). In addition, a systematic review of RCTs that examined the effectiveness of self-weighing as a strategy for weight loss determined that self-weighing as a stand-alone intervention did not appear effective (14). However, the same systematic review also found that self-weighing appeared to be conducive to weight loss when incorporated into a multi-component intervention and when compared to no or minimal intervention (3.7 kg [95% CI, -4.6 to -2.9 kg]) (14). Similarly a review by Madigan and colleagues have reported that the addition of self-weighing to a weight loss intervention, can lead to participants losing more weight in comparison to weight loss interventions that do not include self-weighing (14). A more recent review of

effective behaviour change techniques, concluded that self-monitoring combined with goal setting was effective for both short and long-term weight loss (295).

3.3.2 Accountability and weight management

Social support, has been shown to be an important aspect for effective, long-term behaviour change, including weight loss (297). Established social networks can offer support, advice, encouragement and accountability, features people who would like to lose weight may seek from external sources (298). Implementing interventions across the NHS whereby patients are monitored or are held 'accountable' to a health professional in a supportive way, may help to keep people focused on their health goals. The use of accountability is a common feature of many commercial weight management programs including Weight Watchers and Slimming World. Bovens stated that two concepts of accountability exist, one is a virtue, the other a mechanism (299). For the purpose of this thesis, accountability will be considered a mechanism and therefore consisting of "an obligation to explain and justify conduct" (p. 951 (299)). Accountability is well known in the realms of business and organisational change management literature, where it has been conducive to keeping individuals engaged and focused, thus ensuring goals are achieved. For example, by setting clear goals and placing the onus of achieving these goals on an individual using an accountability partner, salespeople are committed and motivated to sell more (300, 301).

External accountability, may be an effective strategy to help women lose weight, based on the premise that if people know their weight is being monitored externally, they may be more likely to adhere to their weight loss goals. Research has emerged which implies that couples can positively influence one another's health behaviours (302). Similarly, the

American Society of Training and Development found that when a person makes a commitment to someone, up to 65% achieve their goal (303). This increases to almost 95% with the addition of regular accountability meetings (303). Evidence from systematic reviews infer that multi-faceted weight management interventions which include self-weighing as well as some form of accountability can result in more significant weight loss when compared to weight management interventions which only include self-weighing (14, 304).

3.3.3 Internet-based weight management interventions

In-person commercial weight management interventions are effective (174, 175), but would be expensive to deliver to all the women who give birth annually in the UK and who would benefit from losing weight. In recent years, technology has improved and become more affordable and accessible, and as a result its usage is high, even amongst social and ethnic minority groups (305). The widespread use of technology has led many health promoting researchers to design and conduct studies, (primarily RCTs), to test the use of technologies in health promoting interventions, including weight management (306, 307). As more people become “digitally aware”, digital healthcare resources have the potential to be contained within effective health promoting and/or health management interventions. The UK government has seen potential in both technology and digital services and envisages their use in the near future to provide health services that promote independence and wellbeing (308). Internet-based weight management programmes, especially those with enhanced features (309), have the potential to provide large numbers of individuals who are living with overweight or obesity with an accessible way to lose weight. In 2015, a systematic review and meta-analyses of RCTs were conducted to evaluate the effectiveness of eHealth

interventions for weight loss and/or maintenance in adults having overweight and obesity (310). The meta-analyses showed that eHealth weight loss interventions resulted in modest, but statistically significant weight loss in comparison to minimal or no treatment. The authors also noted that limited evidence existed for the effectiveness of eHealth interventions to be determined. Kozak *et al.* recently evaluated technology-based interventions for weight loss and concluded that web-based interventions have improved over the years and can lead to moderate weight loss in individuals with obesity (311). However, the weight lost tended to be less than 7-10% and that there was limited research available to determine the effect of web-based interventions for weight loss maintenance (311).

New mothers actively seek information from a range of sources on the welfare of their baby and for themselves (312, 313). A recent survey of new mothers found that irrespective of age or socio-economic status, 90.5% of new mothers used the internet as a valued source of information and that the fourth most searched topic online for these mothers was weight loss (314). A recent systematic review concluded that internet-based weight management interventions for postnatal mothers appeared to be beneficial, but that more research would be vital to determine if they are also effective (241).

With smartphone usage amongst mobile phone users in the UK being approximately 83% (315), the use of an online weight management intervention may be more accessible to a wider range of postnatal women and address health inequalities, which is an important ambition of the NHS (316).

3.3.4 Timing of the intervention

Pregnancy and the postnatal period are seen by some researchers as “teachable moments” when new, healthier routines and lifestyles can be incorporated because of the change in routine that a new baby can create (262). As the potential for postnatal weight gain can occur soon after delivery, the initiation of an intervention soon after women deliver their baby is worth considering. It is vital to address weight management not only before pregnancy, but in between pregnancies to help minimise the risk of weight gain with each successive pregnancy (317). A 15-year follow-up study on the effects of pregnancy found that women who returned to their pre-pregnancy weight before one year postnatal were less likely to be overweight later in life (147). This study also reported that postnatal weight retention can affect all women, not just those who were living with overweight before pregnancy (147). Weight loss during the first few weeks postnatally tends to be greatest due to factors such as a reduction in fluid retention and uterus size as the body attempts to return to its pre-pregnancy state (318). This initial weight loss may serve as a useful tool to motivate and encourage women to remain focused on weight loss during the early postnatal period. This is important because, in the UK, after the six-week postnatal check, mothers receive no further routine appointments for their health if there are no concerns.

3.3.5 National Child Immunisation Programme

Child immunisation appointments are offered as part of routine care for babies in the UK. During the first year of life, a child receives their first set of immunisations eight weeks after birth, then at 12 and 16 weeks, with further immunisations at 12 months (319). PHE reported that attendance at these immunisation appointments is high, with a coverage rate

of approximately 94.4% (320). The child immunisation programme is routinely delivered in primary care, typically by practice nurses and GPs.

Integrating an intervention into pre-existing health contacts, such as child immunisations could be an ideal setting to deliver a weight management intervention to postnatal women because of these high attendance rates and because no additional healthcare appointments would be required. Given that the national child immunisation programme routinely schedules vaccinations for babies across the UK four times during their first year, this means that mothers have regular contact with their practice nurse or general practice during this period. By combining child immunisation appointments with a brief weight management intervention for new mothers, it is hypothesised that mothers will be able to attend a single appointment in which the health of their baby, as well as their own health, is considered. Embedding an intervention within the national child immunisation programme would also make it readily available to every woman who gives birth in the UK, thus tackling health inequalities within the population (177, 223). If such an intervention was proven to be feasible (and later effective), it could then be implemented nationwide relatively quickly by the NHS with minimal cost. By embedding a weight management intervention into routine primary care, it may help alleviate the concerns healthcare professionals experience when trying to raise the sensitive issue of weight (321), since it would help to normalise the process. Embedding weight management interventions within routine primary care may also reduce the potential for feelings of perceived stigma (322, 323), as it would be offered to all postnatal women.

3.3.6 Justification for a feasibility trial

The short and long-term negative effects of postnatal weight retention for both the mother and child have been well documented (98, 324). Considerable research has been conducted in an attempt to determine the most effective weight management interventions for postnatal women. However, many of these studies have either been relatively small, or tested the effectiveness of interventions that were very intensive, expensive, delivered by weight management specialists and/or not embedded into routine healthcare contacts. Although some weight management interventions have been shown to be effective, the financial implications required to ensure that these interventions are made readily available to every postnatal woman impedes their implementation on a national level. Additionally, the design of some postnatal weight management interventions has been too rigid, (for example, the set structure in relation to attendance to elements of the intervention) for some postnatal women. The rigidity of some interventions has been reported to be a barrier to adherence (136, 139). Nevertheless, postnatal women continue to show interest in weight loss intervention studies that are offered during the postnatal period and acknowledge the importance of consistent attention to diet and physical activity in weight management (139) and are receptive to weight management interventions (177, 325). Thus, indicating that there is a need to make such interventions available to every postnatal woman wishing to lose weight after having a baby.

Given the high rates of overweight and obesity in the general population, the steady birth rate and, the lack of guidelines in the UK for acceptable weight gain during pregnancy, it is important to test and appraise the effectiveness of postnatal weight loss interventions. This

is vital as the UK's health and social care resources are already under substantial financial pressure and if the number of women who are overweight or with obesity continues to increase, the associated health conditions may become an even greater burden.

Women in the UK are not routinely weighed during pregnancy or in the postnatal period and research has shown that if healthcare professionals do not habitually discuss weight and weight related issues, then women do not tend to view their weight as a cause for concern (98, 207). The postnatal period has been identified as a potentially suitable time point to raise the topic of a healthy lifestyle, specifically in relation to postnatal weight retention, weight management and the prevention of additional weight gain.

NICE have expressed that gaps in research and the existence of poor quality evidence have restricted the development of clinical guidance on suitable and effective postnatal weight management interventions (286) that can be scaled up and rolled out nationally. It is therefore necessary to find effective pragmatic interventions that could be readily available to all women. Systematic reviews on postnatal weight management interventions have shown that very few interventions have been conducted in primary care settings or in a way that they can be delivered on a population level to all postnatal women needing to lose weight after having a baby.

This trial was designed to assess the feasibility and acceptability of an intervention delivered within child immunisation appointments that encourages regular self-weighing and recording of weight, supplemented with the use of an internet-based weight management programme and external accountability from practice nurses.

3.4 Purpose, objectives and research questions

Using a mixed methods approach involving a feasibility cluster RCT and nested qualitative study (semi-structured interviews), the aim of this study was to determine the feasibility and acceptability of a postnatal weight management intervention embedded within the national child immunisation programme. Bowen *et al.* suggest that there are eight main areas a feasibility study can address; acceptability; demand; implementation; practicality; adaptation; integration; expansion and limited efficacy testing (326).

This intervention was developed after reviewing the relevant literature (see Chapters 2 and 3). Findings from previous work suggested that women were receptive to postnatal weight management interventions but factors including childcare responsibilities, interventions that required substantial engagement from participants prevented participation and/or adherence. This intervention was designed to be embedded within the national child immunisation programme, a novel approach to postnatal weight management interventions. As this research was testing a new approach to weight management it was appropriate to first assess the feasibility of this type of intervention. It was also considered important to establish whether the intervention would work as it was being delivered during pre-existing NHS immunisation appointments. Preliminary feasibility studies frequently precede full-scale studies as they help determine whether it is worthwhile testing the efficacy and effectiveness of an intervention (326). Feasibility studies are designed to establish if the efficacy of an intervention is worth pursuing. This is advantageous due to the financial implications associated with full-scale studies. Feasibility studies are used to assess the practicality of key methodological components in the design of an intervention prior to

conducting a main trial including; the recruitment process, time scales, acceptability of the intervention, the data collection process and attrition rates (327).

The objectives of this study were to determine:

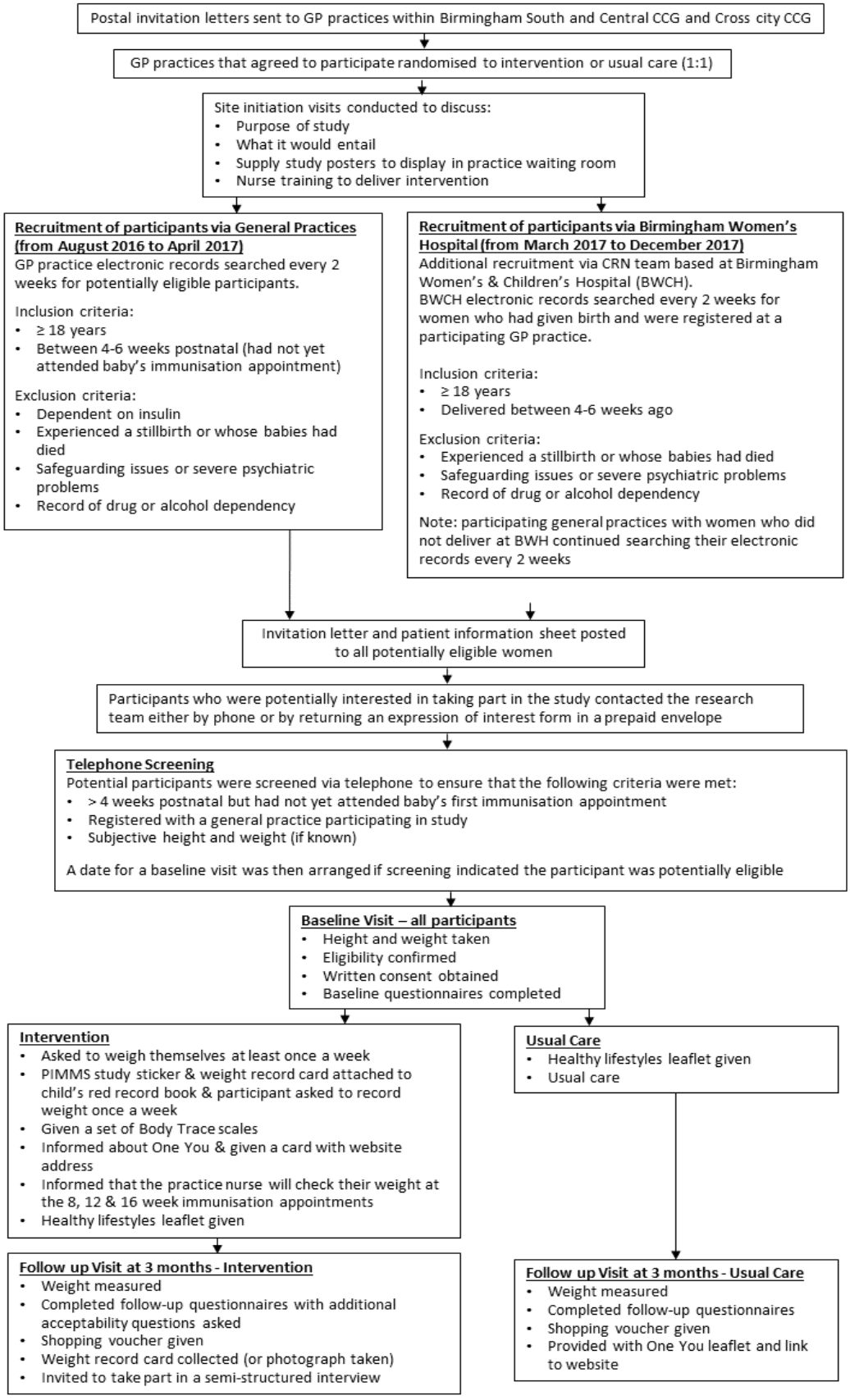
- the acceptability and feasibility of delivering a weight management intervention to postnatal women within the child immunisation programme as determined by the recruitment rate and levels of adherence to the intervention;
- explore the views of women and practices nurses about the feasibility and acceptability of the intervention in terms of perceived appropriateness and satisfaction with the intervention (see Chapter 4);
- if it is practical for practice nurses to deliver the PIMMS intervention during child immunisation appointments.

3.5 Methods

3.6 Design overview

The **P**ostnatal weight management during **IMM**unisations **S**tudy (PIMMS), was a pragmatic, feasibility cluster RCT with a nested qualitative study that aimed to determine the feasibility and acceptability of a brief weight management intervention for postnatal women that was embedded within the national child immunisation programme in primary care. Appendix 7 shows the trial protocol and an overview of the feasibility cluster RCT is provided in Figure 6 below.

Figure 6: Study flowchart



3.7 Ethical approval

Favourable ethical opinion was obtained from the West Midlands Black Country Ethics Committee on the 17th February 2016 (Ref: 15/WM/0445) and the Health Research Authority on the 20th June 2016 (UK Integrated Research Application System (IRAS) ID: 186569).

3.8 Recruitment and randomisation of general practices

J.A.F searched Birmingham South, Central and Cross City Clinical Commissioning groups (CCGs) lists of GP practices and compiled a list of the first 29 practices with a list size of more than 6,000 registered patients. These 29 practices were invited to participate in this feasibility cluster RCT between April 2016 and June 2016. The assumption was that larger practices would potentially have greater numbers of postnatal women who could be invited to participate. Practices served as clusters and they were randomised to either offer the intervention or continue providing usual care during child immunisation appointments.

Simultaneous randomisation was used, whereby the sampling frame and randomisation of the general practice clusters occurred prior to participants being invited to take part in this study. The randomisation sequence was produced using SPSS software (version 22; SPSS, Inc., Chicago, IL) and performed by an independent statistician from the University of Birmingham with a 1:1 allocation using random block sizes of two and four. An independent researcher performed the concealment of group allocations using sealed opaque, sequentially numbered envelopes that were opened by the same member of the research team after an expression of interest was received from a practice. The PIMMS research team were not involved in the concealment of allocation of practices.

Site initiation visits were arranged with the recruited practices during which the purpose of the study was detailed, along with what the study would involve for the practice.

3.9 Recruitment of postnatal participants

Several approaches were used to identify and invite potentially eligible postnatal women to participate as detailed below.

3.9.1 Recruitment of participants via general practices

Initially, participants were identified by general practices searching their electronic patient records every two weeks to identify women who had given birth in the previous four weeks or who were scheduled to attend a six-week postnatal check. Practices were asked to remove any women from their lists who were:

1) in contact with social services;

2) experiencing a serious mental health problem;

3) their baby had died;

4) dependent on insulin;

5) had already attended their baby's first immunisation appointment;

6) mothers whom the practice felt it was inappropriate to invite.

Pre-prepared study invitation packs containing an invitation letter (with the appropriate practice letter head) (Appendix 8), a patient information sheet (Appendix 9), expression of interest form (Appendix 10) and a freepost envelope were mailed to potential participants by the practices. The invitation letter provided a brief overview of the study and asked women to contact the research team directly either by telephone or by using the enclosed reply slip and freepost envelope, if they were interested in participating. Interested

participants were also asked to respond within seven days of receiving the invitation letter. This time frame was set as there was only a short window within which a baseline appointment could be arranged, *i.e*. between approximately four weeks (when the invitation letter was received) and 8 weeks postnatally (time of first immunisation).

3.9.2 Recruitment of participants via Birmingham Women's and Children's Hospital

Initial recruitment rates were low, and it was thought that this was due to several reasons. Firstly, some general practices needed frequent reminders to send out invitation packs regularly and secondly, participants responded after they had already attended their baby's first immunisation appointment. From March 2017, the main recruitment method was changed to a centralised system whereby, the Clinical Research Network (CRN) West Midlands at Birmingham Women's and Children's Hospital (BWCH) performed the searches for potential participants. The nature of the records at BWCH meant that it was not possible for the CRN team to screen for all of the GP surgery exclusion criteria, instead they were asked to remove any women from their list who met any of the following:

1) in contact with social services;

2) experiencing a serious mental health problem;

3) their baby had died.

Some of the recruited general practices were not geographically close to BWCH. Therefore, women registered at these practices were likely to deliver their baby at other local hospitals. Where this was the case, practices continued to send the study invitation letters as these women/births would not be recorded at BWCH.

3.9.3 Recruitment of participants via poster

Participating practices were asked to display posters advertising the study in their reception and waiting areas. The posters provided a brief overview of the study and the contact details for the research team (Appendix 11). Participants recruited via poster could participate in the study after a GP at their practice had confirmed they were eligible.

3.10 Eligibility criteria

3.10.1 Inclusion criteria

- Women who had given birth in the last four weeks and had not yet attend the first immunisation visit for their baby;
- aged 18 years or more;
- BMI of 25 kg/m² or more (23 kg/m² if Asian) (328, 329).

3.10.2 Exclusion criteria

- Women who had had a stillbirth or whose babies had died;
- dependent on insulin;
- dependent on drugs or alcohol;
- women with safeguarding issues;
- women experiencing severe psychiatric problems;
- GP considered not suitable to participate in the study.

3.11 Expressions of interest from postnatal women

Women interested in participating in the study contacted the research team at the university. A researcher (J.A.F/H.M.P) conducted a screening telephone call, during which

the study was explained to potential participants and any questions were answered. A telephone screening form (Appendix 12) was used to provisionally ensure that women met the initial inclusion criteria as detailed above. If women met the initial inclusion criteria, a date and time for a home visit was arranged to confirm eligibility and, for baseline data to be collected.

Women who contacted the research team but did not meet the inclusion criteria, were signposted to use the Public Health England website One You for more information about health (https://www.nhs.uk/oneyou/) and thanked for their interest in the study.

3.12 Blinding

The cluster allocation of participants' GP practice was revealed at the baseline home visit, but participants were not informed of the exact purpose of the study, or the specific nature or content of the comparator group until after follow-up data were collected. Double blinding of participant group allocation was not possible due to the nature of this study.

3.13 Intervention

3.13.1 Intervention overview

The intervention consisted of practice nurses encouraging participants to manage their weight through self-monitoring by regularly self-weighing and signposting to using a healthy lifestyles website (https://www.nhs.uk/oneyou/) during child immunisation appointments. Practice nurses also provided a source of external accountability since weight loss was monitored regularly. The intervention was embedded within the first three child

immunisation appointments which take place when babies are eight weeks, 12 weeks and 16 weeks old.

3.13.2 Self-monitoring and weight loss goals

The intervention was designed to be brief and simple to deliver. Participants were provided with a set of Body Trace scales, a user's manual (Appendix 13) and were shown by a researcher how to use the weighing scales. The Body Trace scales were selected as they could objectively record a participants' weight each time they were used and remotely transmit this information to the research team via the Body Trace website. The participants were asked to weigh themselves once a week, ideally on the same day and at around the same time, each time, using the scales provided. In addition, participants were advised that no one else in their household should use the scales. Participants were also asked to record their weight on a weight record card (Appendix 14), to aid with self-monitoring. This weight record card was attached to their child's personal health record book (the red book), which is typically taken to each child immunisation appointment.

As there are currently no clinical guidelines specifically for healthy weight loss in postnatal women, NICE guidelines for weight loss in the adult general population were used. NICE recommends between 0.5 to 1 kg weight loss per week (163). Participants also received an information leaflet at baseline with general healthy lifestyle advice (Appendix 15).

3.13.3 One You (online health promoting website)

Public Health England have made publicly available a healthy lifestyle promoting website called One You (www.nhs.uk/oneyou). One You has a range of information to help people of all ages adopt a healthier lifestyle, and includes a section dedicated to weight loss. It offers a

12-week weight loss plan with food diaries and activity logs which are available to download. The One You website offers visitors the opportunity to sign up to receive regular emails or text messages to keep website users motivated with their healthy lifestyle goals. The One You website also provides healthy recipe ideas and meal plans. It is designed to be very user-friendly and has several apps that can be downloaded and used on a smartphone including an easy meals app and a "couch to 5K" physical activity app. The researcher (J.A.F) provided details of the One You website and the web address to access the online healthy lifestyle programme during baseline visits with intervention participants. Mothers were also advised to register with One You via the website in order to receive tailored health reminders via email or text. Practice nurses were asked to then signpost women to this website within the immunisation appointments.

3.13.4 External accountability

To encourage external accountability, nurses were asked to weigh participants and record this on their weight record card at each immunisation appointment. Additionally, nurses were asked to check adherence to self-weighing (participant completion of the weight record card) and, encourage women to continue or to start self-weighing weekly. It was hoped that if participants were aware that their weight was going to be monitored at each child immunisation appointment, this might encourage participants to manage their weight by demonstrating restraint in their eating and participating in regular physical activity.

3.13.5 Nurse training at practices randomised to deliver the intervention

Face-to-face training was provided to nurses at each intervention practice by the research team. The training provided an overview of the study and described the study procedures.

As the intervention was brief, nurse training took approximately 15-20 minutes. A standard training protocol was followed and, each nurse was provided with a study information leaflet (Appendix 16). A training manual (Appendix 17) was designed and provided to each nurse at the practice. This manual included: a brief summary of the study; information on the adverse health consequences of postnatal weight retention; general information about the One You website; examples of how to signpost participants to the One You website for more information and examples of how to support participants. It also provided nurses with appointment specific instructions on how to weigh and record the participants' weight since these data were used to assess intervention fidelity and delivery.

3.13.6 Usual care group

Postnatal women recruited from usual care practices received all aspects of the national child immunisation programme plus a general healthy lifestyle advice leaflet at baseline (Appendix 15).

3.14 Feasibility Cluster RCT procedures

3.14.1 Baseline appointment

At the baseline home appointment participant eligibility for the study was confirmed, which included an objective height and weight measurement for the calculation of BMI. This data, in addition to other relevant participant information were recorded on a case report form (Appendix 18). Participants confirmed as eligible were then asked to provide written informed consent (Appendix 19), complete the study questionnaire booklets (section below and Appendix 20). All participants were informed that the research team would visit them again in approximately three months for the final follow-up assessment. Participants were

also provided with researcher contact information and details on how to withdraw from the study should they wish to do so.

3.14.2 Follow-up appointment

The three-month follow-up visit was conducted in participants' homes. Participants' weight was measured, and they were asked to complete the follow-up questionnaires (Appendix 21 and 22). The intervention group were asked to complete some additional questions about how weighing themselves weekly made them feel (last page of Appendix 21), including how it might have influenced their mood, and general wellbeing, as well as questions relating to their perceptions on the acceptability of the intervention (see acceptability section below).

Weight record cards were retrieved from the intervention group, who were also invited to participate in semi-structured interviews to discuss their views and experiences of participating in the study. After completing all study procedures, participants in both groups were thanked for their time and offered a £10 shopping voucher.

3.14.3 Study duration

In total, participants were involved in the study for approximately four months. The nurses and the participating general practices remained in the study until every postnatal woman participating in the study that was registered at their general practice had attended their infant's 16-week immunisation appointment.

3.15 Outcome measures

3.15.1 Primary outcomes

The primary outcome was the feasibility and acceptability of the intervention. The recruitment rates for both general practices and participants were calculated to assess the feasibility of the recruitment methods and to allow an estimate of recruitment rate for a subsequent effectiveness trial. Intervention adherence by both practice nurses and participants was measured to assess engagement with the intervention. The feasibility and ease of data collection using the methods and study equipment were also assessed via the quality and completeness of the data collected.

3.15.1.1 Study acceptability

Study acceptability was determined via a number of data sources. The overall interest in the study (response rate); drop-out rates and withdrawal rates served as initial indicators of the general acceptability and interest in weight management for postnatal women. The level of completion of the questionnaire booklets was used to ascertain participant compliance to complete all the questions they were asked.

Upon completion of the study (at follow-up), participants who received the intervention were asked to rate four key elements of the intervention on 10-point Likert scales to help determine if the main elements of the intervention were acceptable. The intervention participants were asked to respond to the following questions:

- Would you recommend this study to a friend?
- Did the intervention help you to manage your weight?
- How appropriate was it for the nurse to weigh you at your child's immunisation visit?

- Did the study make you anxious about your weight?

3.15.1.2 Adherence to self-weighing

Body Trace scales remotely send weight data in real time (via 4G) to a computer server where these data are collated as described earlier and used as an objective source of weigh data. In addition, self-reported weight data from the participant's weight record cards were used as a secondary source of information that was used to determine adherence to weekly self-weighing.

3.15.2 Other outcomes

To explore the potential effect of the lifestyle intervention on postnatal women, additional data relating to their diet, physical activity, body image, mood and objective weight measurements were collected at baseline and at follow-up. These data were collected in the baseline and follow-up questionnaire booklets, which contained the validated measurement tools detailed below.

To measure levels of physical activity and calculate; the total amount of physical activity; sedentary activity; light intensity activity; moderate intensity activity; vigorous intensity activity; household and care activities; occupational activity and activity from sports and exercise for each participant, the questionnaire booklets also included the Pregnancy (and Postnatal) Physical Activity Questionnaire (PPAQ) (330). To preliminary determine whether the intervention affects participants' perceptions of their postnatal bodies, the women's attitudes and perceptions of their postnatal body before and after participating in the study were gauged using the six-item Body Image States Scale (BISS) (331).

A 10-item, self-rating scale, the Edinburgh Postnatal Depression Score (EPDS) (332), was used to identify possible postnatal depression. A score of 1, 2 or 3 for question 10 of the EPDS serves as a potential warning that the mother and/or the children in her care could be at risk of harm and require medical assistance (or a mental health assessment) to be sought. Any participant with a score of less than four for question 10 was advised to see her GP, and their GP was also promptly informed.

A short form, 20-item food frequency questionnaire (333) was used to assess the diet pattern and food frequency of participants however, due to concerns relating to the quality of the data, it has not been included in this thesis.

Data relating to breastfeeding and immunisation uptake rates were also collected (Appendix 18) to ensure that the intervention did not have any adverse effects on these outcomes. No additional data on adverse events were collected. However, in an attempt to determine the emotional impact of regular self-weighing on women during the early postnatal period, intervention participants were asked to state how they felt immediately after they recorded their weight using a Likert scale in the form of emojis (on the weight record card, (Appendix 14) consisting of five options (delighted; happy; alright; disappointed or upset).

3.15.3 Semi-structured interviews

Intervention participants were also invited to take part in semi-structured interviews through which they could further share their views and feelings about the acceptability of the intervention. In addition, nurses who delivered the intervention were also invited to take part in semi-structured interviews to explore their experiences and views on the acceptability and feasibility of delivering the intervention. These semi-structured interviews

with both postnatal women and the nurses who delivered the intervention are discussed in more detail in the qualitative chapter of this thesis (see Chapter 4).

3.16 Sample size justification

A sample size of 80 women would be enough to estimate adherence and questionnaire return rate with a minimum 11% precision, and 95% confidence level. Feasibility studies are not designed to evaluate the outcome of interest, in this case weight loss and as such, formal power calculations are not appropriate and were not performed for this study (327, 334).

3.17 Data analysis

Data were entered into a database created in Microsoft Access and analysed using SPSS software (version 22; SPSS, Inc., Chicago, IL). Descriptive statistics were used to obtain means, standard deviations and percentages to describe the characteristics of the sample of women and assess study feasibility by the completion of trial procedures. The total number of participants included in each analysis was reported in order to account for missing data. Measurements of study feasibility included recruitment source and recruitment rate, rates of intervention compliance and adherence (frequency of self-weighing and nurse weighing during immunisations) and participant retention rates. The retention rate was calculated as the rate of completion of three-month follow-up appointments.

Objective weight data transmitted from the participant weighing scales to the Body Trace website were the primary source of information on participants frequency of self-weighing. When data were unavailable from the Body Trace website, the participant's weight record card was accessed.

In order to determine the acceptability of the intervention, participants rated elements of the intervention on a 10-point Likert scale (see page 75). Participant acceptability of the intervention was considered by a score of six or more, unacceptability was regarded when participants scored five or less on the Likert scale.

Level of completion of the relevant sections of the weight record card was used to determine nurse adherence (feasibility) of delivering the intervention during child immunisation appointments.

Exploratory statistical analyses were also conducted to evaluate the secondary outcomes detailed on pages 76-77. Adjusted for baseline (univariate) analysis were completed to determine any statistical differences in continuous outcome variables between the intervention and usual care groups at follow-up including mean weight change, body image, physical activity and depression scores. Summary information regarding breastfeeding rates and attendance at immunisations were also calculated.

In addition, some continuous variables were converted into categorical variables to allow further provisional comparisons at follow-up to be made between the groups. Unadjusted changes in weight between baseline and follow-up were categorised as either weight gain or weight loss for each participant to enable provisional comparisons in weight change between the groups to be made. Similarly, all available frequency of self-weighing data for the intervention participants was categorised into one of two categories; self-weighed less than 11 times, or self-weighed more than 12 times for the duration of the intervention. The differences between the intervention and control groups, and frequency of self-weighing were compared using the independent chi-square test (cross tabulations).

3.18 Data handling

All data was managed according to both the Data Protection Act (335) and the University of Birmingham's standard operating procedure as well as in accordance with the principles of Good Clinical Practice.

Participant data were stored under a patient ID number and anonymised. Paper files were locked in filing cabinets in a secure building at the University of Birmingham. Electronic data were held on a secure server hosted by the University of Birmingham. Access to the information was limited to the research team and relevant regulatory authorities. Access was restricted to computer held data and was password protected.

3.19 Results

3.20 Study feasibility

3.20.1 Recruitment of general practices

The participant flow diagram below (Figure 7) shows recruitment and follow-up. Twenty-nine general practices were invited to participate in the study between July and September 2016. Fourteen practices (48%) initially responded agreeing to participate.

Two practices (7%) responded stating that they were unable to participate and 13 (45%) did not respond. All fourteen of the practices that expressed an interest were randomised; seven to deliver the intervention and seven to continue to offer usual care only. After randomisation, two practices withdrew from the study, before any participants were recruited. Both practices had been randomised to offer usual care, therefore a total of 12

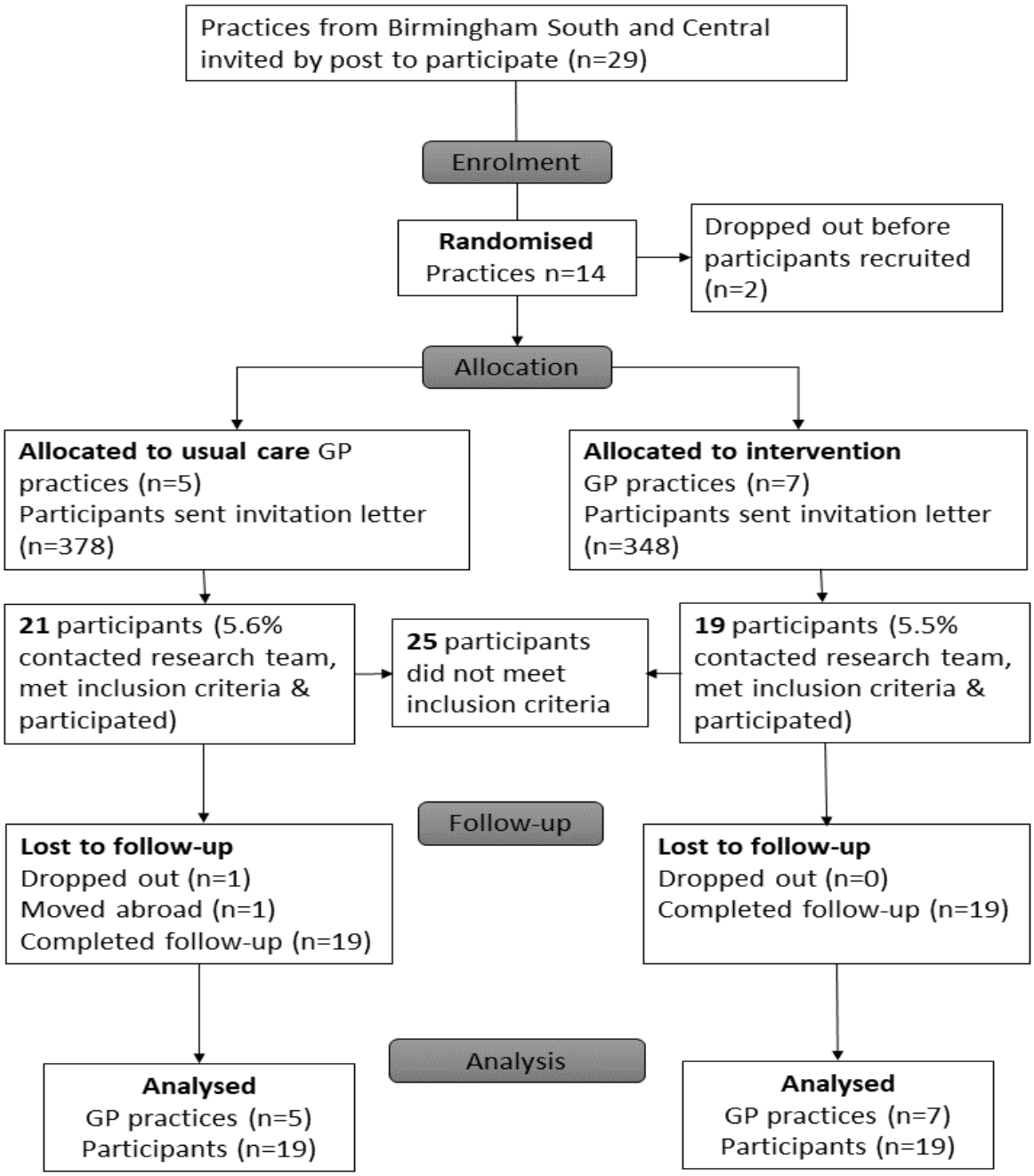
practices participated in the study, seven delivered the intervention and five delivered usual care.

3.20.2 Recruitment of postnatal women

Participant recruitment took place between August 2016 and January 2018 (see Figure 6 for progression through trial). Seven hundred and twenty-six women were invited to participate in the study, 221 by practices and 505 by the Clinical Research Network (CRN) West Midlands team at Birmingham Women's and Children's Hospital (BWCH). Overall, the response rate was 9.0%, 8.1% from practices and 9.3% from BWCH. One participant emailed the research team after seeing a poster in the waiting room of her practice.

The onus was on mothers to make contact (via telephone, post or email) with the research team. A total of 726 potential participants were invited to participate in the study, 661 did not respond to the invitation letter and 65 of the 726 women invited contacted the research team. Approximately 68% of participants who were then screened were eligible (n= 44/65). The most common reasons for ineligibility were BMI of less than 25 kg/m² (or 23 kg/m² if of Asian ethnicity) (n=16), and more than eight weeks postnatal (and already attended their infant's first immunisation appointment) (n=5). Four of the 44 participants who were screened for eligibility and met the inclusion criteria were not enrolled in the study due to: loss of contact (n=2); moved practice (n=1) and family illness (n=1). Therefore, 40 participants met the inclusion criteria and participated in the study. All 40 participants accepted and received the treatment they were allocated to receive according to their practice allocation. Nineteen women received the intervention and 21 received usual care.

Figure 7: Flow of participants through the study



3.21 Baseline characteristics of participants

Overall, the baseline characteristics of the groups were similar (Tables 4-5). The overall mean age of participants was 33.3 years (SD 4.5). The average BMI was 31.6 (SD 4.6) kg/m² and 57.5% were living with obesity. Almost 58% were exclusively breastfeeding, 32.5% were

exclusively formula feeding and four (10%) participants were both formula and breastfeeding. Participants were predominantly of White ethnicity (67.5%); in employment (77.5%) and 52.5% had ≥2 children. All participants were non-smokers. Most participants lived with their husband/partner (95%), in areas with a mid-range index of multiple deprivation (IMD) score (mainly in the 3rd and 4th quintiles) (336). About 63% of participants had had a vaginal delivery and 47.5% had experienced a pregnancy-related health complication in the pregnancy related to this study (Table 5). Approximately 63% of participants were getting less than three hours of uninterrupted sleep per night.

At baseline the intervention group were 8.5 kg heavier than the usual care group (an average of 87.9 kg for intervention versus 79.4 kg for usual care). There were also more primiparous participants recruited from usual care practices (57.1%) compared to participants from intervention practices (36.8%).

At baseline mean total physical activity scores in the intervention group were marginally higher (424.4 (SD 170.9) MET-h/wk) compared to the usual care group (346.2 (SD 142.9) MET-h/wk). Intervention participants had marginally higher scores for all sub-groups for physical activity and spent more time performing household and occupational activities compared to the usual care group.

None of the usual care participants' EPDS scores identified postnatal depression at baseline. However, at baseline one intervention participant had a total EPDS score of more than 13 points, suggesting the possibility of postnatal depression; and one participant in the intervention group scored 3 for question 10 of the EPDS, indicating thoughts of self-harm or suicide.

Table 4: Baseline characteristics

Characteristic	Usual care (n= 21)	Intervention (n= 19)
Age, mean (SD):	32.4 (3.9)	34.2 (4.8)
n (%)		
<25 years	1 (4.8)	0 (0.0)
25-35 years	15 (71.4)	12 (63.2)
>35 years	5 (23.8)	7 (36.8)
Ethnicity, n (%):		
Non-White	6 (28.6)	7 (36.8)
Marital status, n (%):		
Single living alone	1 (4.8)	0 (0.0)
Living with partner	20 (95.2)	18 (94.7)
Single living with parents/ family	0 (0.0)	1 (5.3)
Employment status, n (%):		
Employed	16 (76.2)	15 (78.9)
Unemployed	1 (4.8)	1 (5.3)
Homemaker	4 (19.0)	2 (10.5)
Sick/disabled	0 (0.0)	1 (5.3)
IMD scores, n (%):		
Quintile 1 (least deprived)	1 (4.8)	0 (0.0)
Quintile 2	3 (14.3)	1 (5.3)
Quintile 3	4 (19.0)	11 (57.9)
Quintile 4	8 (38.1)	5 (26.3)
Quintile 5 (most deprived)	5 (23.8)	2 (10.5)
Body weight at baseline (kg):		
Mean (SD)	79.4 (12.8)	87.9 (12.8)
Range	65.0-108.8	70.0-113.3
BMI (kg/m²):		
Mean (SD)	30.6 (3.6)	32.7 (5.3)
BMI category, n (%):		
Overweight (25-29.9)	9 (42.9)	8 (42.7)
Obesity 1 (30-34.9)	9 (42.0)	5 (26.3)
Obesity 2 (35-39.9)	3 (14.3)	4 (21.1)
Obesity 3 (40+)	0 (0.0)	2 (10.5)
Parity:		
Mean (SD)	1.9 (1.3)	1.9 (1.0)
Primiparous, n (%)	12 (57.1)	7 (36.8)
Multiparous, n (%)	9 (42.9)	12 (63.2)
Breastfeeding rates at baseline, n (%):		
Exclusively breastfeeding	12 (57.1)	11 (57.9)
Both breastmilk and formula	2 (9.5)	2 (10.5)
Exclusively formula feeding	7 (33.3)	6 (31.6)
Total PPAQ activity score (MET hr/wk):		
Mean (SD)	346.2 (142.9)	424.4 (170.9)
EPDS score:		
Mean (SD)	6.3 (2.5)	5.6 (3.1)

Table 5: Delivery, complications and uninterrupted sleep

Characteristic	Usual care (n= 21)	Intervention (n= 19)
Type of delivery, n (%):		
Vaginal	14 (66.7)	11 (57.9)
Caesarean section	7 (33.3)	8 (42.1)
Pregnancy related health complications, n (%):		
No complications	13 (61.9)	8 (42.1)
Gestational hypertension	0 (0.0)	3 (15.8)
Pre-eclampsia	2 (9.5)	0 (0.0)
Polyhydramnios	0 (0.0)	2 (10.5)
Symphysis pubis dysfunction (SPD)	3 (14.3)	2 (10.5)
Intrauterine growth restriction (IUGR)	1 (4.8)	2 (10.5)
Low PAPP-A levels*	1 (4.8)	0 (0.0)
Gestational diabetes mellitus (GDM)	1 (4.8)	0 (0.0)
Back pain	0 (0.0)	1 (5.3)
Mild asthma exacerbated	0 (0.0)	1 (5.3)
Uninterrupted sleep per night, n (%):		
3 hours or less	13 (61.9)	11 (57.9)
Between 4-6 hours	8 (38.1)	8 (42.1)
Between 7-8 hours	0 (0.0)	0 (0.0)
9 hours or more	0 (0.0)	0 (0.0)

*Pregnancy associated plasma protein- a hormone produced by the placenta. Low levels of this hormone can be associated with low birth weight babies, Down's syndrome and early deliveries

3.22 Feasibility and acceptability of the intervention

3.22.1 Participant withdrawal and follow-up

No participants withdrew from the study and two participants (from usual care practices) did not complete their follow-up appointment (Figure 7). One participant was lost to follow-up due to a lack of contact and the other participant moved abroad, thus the follow-up rate was 95% (intervention = 19/19; usual care = 19/21).

3.22.2 Participant compliance

The completion of study questionnaire booklets by both usual care and intervention participants was used to gauge if the length of the questionnaire booklets affected rates of

compliance. Completion of the booklets was very high for all participants, with only one participant (intervention group) refusing to answer specific questions at follow-up.

3.22.3 Frequency of self-weighing

A total of seven (36.8%) participants weighed themselves on average more frequently than once a week between their baseline and follow-up appointments (Table 6). One participant weighed herself once, and another participant did not weigh herself at all. The data showed that on average, the 10 (52.6%) remaining participants weighed themselves less frequently than once a week. Overall, it appeared as though the higher the frequency of self-weighing, the greater the tendency to lose more than 2 kg in weight (Table 6).

3.22.4 Completion of weight record cards

A total of 15/19 (78.9%) of the intervention group used their weight record card. Most women who used the weight record card to document their weight had also recorded how they were feeling about their weight, except for one participant who only recorded weight data after week 11 of the study (Table 7). Between weeks 1-4, 13 (68.4%) participants consistently recorded their weekly weight on the record card. This decreased to 11 (57.9%) between weeks 5 and 8, reducing to eight (42.1%) between weeks 9-12.

On average, participants did not report feeling upset after weighing themselves, they generally reported feeling 'alright' about their weight, but almost all participants (93.3%) reported feeling either upset or disappointed at least once throughout the duration of the study after weighing themselves.

Table 6: Frequency of self-weighing (intervention only) as measured by Body Trace

Participant	Frequency of self-weighing between baseline and follow-up	Number of weeks between baseline and follow-up	Frequency of self-weighing ÷ number of weeks (%)	Weight (kgs) lost or gained at follow-up compared to baseline?
026	18	16	112.5	-4.6
024	10	12	83.3	-4.0*
060	28	13	215.4	-3.6
022	18	15	120.0	-3.2*
061	10	13	76.9	-2.8
049	11	16	68.8	-2.7
050	50	14	357.1	-2.7
013	12	15	80.0	-2.3*
034	4	14	28.6	-2.2
051	17	14	121.4	-2.0
015	12	15	80.0	-1.6
018	11	13	84.6	-0.6
032	16	13	123.1	-0.1
029	0	13	0.0	1.0
023	1	14	7.1	1.2
052	8	13	61.5	1.8
009	9	13	69.2	2.0
035	15	14	107.1	4.2
045	5	16	31.5	9.7

* Data from weight record card due to problems with switchover between 2G to 3G BT scales and USB scales

3.22.5 Engagement with One You website

A total of 18/19 intervention participants (94.7%) stated that they had accessed the One You website at least once. Eight (42.1%) of the intervention participants reported they had used the One You website, (particularly the “Active 10” and “One You Easy Meals” app) to help with their weight management. No usual care participants reported they were familiar or had accessed the One You website.

Table 7: Weight record card completion by intervention participants

Week in Study	Recorded weight (n, %)	Did not record weight (n, %)	Recorded feelings (n, %)	Average feeling
1	15 (78.9)	4 (21.1)	15 (78.9)	Alright
2	13 (68.4)	6 (31.6)	13 (68.4)	Alright
3	14 (73.7)	5 (26.3)	14 (73.7)	Alright
4	14 (73.7)	5 (26.3)	14 (73.7)	Alright
5	13 (68.4)	6 (31.6)	13 (68.4)	Alright
6	13 (68.4)	6 (31.6)	13 (68.4)	Alright
7	13 (68.4)	6 (31.6)	13 (68.4)	Alright
8	11 (57.9)	8 (42.1)	11 (57.9)	Alright
9	12 (63.2)	7 (36.8)	12 (63.2)	Alright
10	11 (57.9)	8 (42.1)	11 (57.9)	Alright
11	11 (57.9)	8 (42.1)	10 (52.6)	Alright
12	9 (47.4)	10 (52.6)	8 (42.1)	Alright

* total n=19

3.22.6 Participant acceptability questions

Table 8 describes the responses to the acceptability questions the intervention participants were asked. Seventeen participants in the intervention group (89.5%) reported that they would recommend the study to a friend. Fourteen intervention participants (73.7%) stated that they found it helpful to be weighed by a nurse and to weigh themselves once a week as a form of weight management. Sixteen (84.2%) intervention participants felt that it was appropriate for the nurse to weigh them during baby immunisation appointments. Eleven (57.9%) participants reported that receiving the intervention did not make them feel anxious about their weight.

Table 8: Acceptability of intervention

Would you recommend study to a friend? (1 Very unlikely- 10 Very likely), n (%)									
1	2	3	4	5	6	7	8	9	10
1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	3 (15.8)	2 (10.5)	4 (21.1)	3 (15.8)	5 (26.3)
How helpful has being weighed by nurse and weighing yourself weekly been for managing your weight? (1= Not very helpful – 10= Very helpful), n (%)									
1	2	3	4	5	6	7	8	9	10
1 (5.3)	1 (5.3)	0 (0.0)	0 (0.0)	3 (15.8)	2 (10.5)	5 (26.3)	1 (5.3)	4 (21.1)	2 (10.5)
How appropriate was it for the nurse to weigh you at your baby's immunisation appointment? (1= Very inappropriate – 10= Very appropriate), n (%)									
1	2	3	4	5	6	7	8	9	10
1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (10.5)	1 (5.3)	1 (5.3)	4 (21.1)	4 (21.1)	6 (31.6)
How anxious did the study make you about your weight? (1= Very anxious – 10= Not anxious at all), n (%)									
1	2	3	4	5	6	7	8	9	10
0 (0.0)	1 (5.3)	2 (10.5)	1 (5.3)	4 (21.1)	1 (5.3)	2 (10.5)	3 (15.8)	2 (10.5)	3 (15.8)

*total n=19

3.23 Feasibility of intervention for practice nurses

The feasibility of the intervention for the nurses participating in the study was determined by the frequency of weight data that was recorded by nurses in the weight record card attached to the red book during immunisation appointments.

3.23.1 Nurse completion of weight record card

Overall nurses delivered the intervention according to the protocol, although this decreased over time (Table 9). Out of the 19 participants who received the intervention, 84.2% had their weight measured and recorded by a nurse during their child's first immunisation appointment. Fifteen (78.9%) participants were weighed by a nurse during their baby's

second immunisation appointment and 63.2% (n=12) during the third immunisation appointment.

During the first immunisation appointment, 50% of the nurses weighed participants before child immunisations were administered, this increased to almost 60% by the second immunisation, but reduced to 53% at the third immunisation. However, there was missing data with nurses not always recording whether participants were weighed before or after immunisations.

3.23.2 Weight change

Table 10 shows the unadjusted and adjusted mean body weight changes at baseline and three-month follow-up. In general, both groups had lost weight at follow-up. The intervention group lost on average -0.7 kg in weight between baseline and follow-up and the usual care group lost -1.5 kg.

The adjusted mean difference between the groups at follow-up (adjusted for baseline weight) was 0.10 kg (95% CI, -2.0 to 2.3, p=0.9). There was one outlier from the intervention group who had gained 9.70 kg at follow-up. A sensitivity analysis (adjusted for baseline) was performed, removing this participant from the analysis which resulted in the intervention group being 0.11 kg lighter than the usual care group (95% CI, -2.0 to 1.8, p=0.9) at follow-up.

When participants were categorised according to whether they had lost weight, remained the same or gained weight, 13 (68.4%) of the intervention participants had lost weight at

follow-up compared to six (46.2%) of the usual care group, and this was statistically significant (p=0.02).

Table 9: Immunisation appointments (intervention only)

	First (2-month) appointment (n= 19)	**Second (3-month) appointment (n= 19)**	**Third (4-month) appointment (n= 19)**
Nurse weighed and recorded weight, n (%):			
Yes	16 (84.2)	15 (78.9)	12 (63.2)
No	2 (10.5)	2 (10.5)	2 (10.5)
Not recorded	1 (5.3)	2 (10.5)	5 (26.3)
Mum weighed before/after immunisations, n (%):			
Before	8 (42.1)	10 (52.6)	9 (47.4)
After	8 (42.1)	5 (26.3)	3 (15.8)
Not recorded	1 (5.3)	2 (10.5)	5 (26.3)
Not weighed	2 (10.5)	2 (10.5)	2 (10.5)
Nurse checked participant was self-weighing, n (%):			
Yes	15 (78.9)	14 (73.7)	10 (52.6)
No	3 (15.8)	1 (5.3)	3 (15.8)
Not recorded	1 (5.3)	4 (21.1)	6 (31.6)
Nurse signposted to One You, n (%):			
Yes	14 (73.7)	13 (68.4)	11 (57.9)
No	3 (15.8)	2 (10.5)	1 (5.3)
Not recorded	2 (10.5)	4 (21.1)	7 (36.8)

Table 10: Participant weight change

	BASELINE		**FOLLOW-UP**			
	UC (n=21)	**INT (n=19)**	**UC (n=19)**	**INT (n=19)**	**Adjusted mean difference (INT vs UC)***	**p-value**
Mean weight (SD)	79.4 (12.8)	87.9 (12.8)	79.2 (13.3)	87.2 (15.1)	0.1 (-2.0-2.3)	0.9

*Adjusted for baseline score

3.23.3 Secondary outcomes

3.23.4 Physical activity

The mean total physical activity score at the three-month follow-up was 334.3 METs (SD 91.7) for the intervention group and 351.1 METs (SD 100.0) for the usual care group. The adjusted mean difference (adjusted for baseline score) was -37.9 METs (95% CI, -100.3 to 24.4, p=0.2) (Table 11). Adjusted mean differences for total energy expenditure by intensity and by type of activity were calculated, none of which showed differences between the intervention and usual care groups that were statistically significant at three-month follow-up.

Table 11: Physical activity scores (PPAQ)

	BASELINE		FOLLOW-UP			
	UC (n=21)	**INT (n=19)**	**UC (n=19)**	**INT (n=19)**	**Adjusted mean difference (INT vs UC)**	**p-value**
Total activity MET/hr/week Mean (SD)	346.2 (142.9)	424.4 (170.9)	351.1 (99.9)	334.3 (91.7)	-37.9 (-100.3-24.4)	0.2
Total energy expenditure by intensity (MET/hr/week)						
Sedentary activity Mean (SD)	72.0 (35.0)	80.7 (30.0)	34.7 (17.0)	45.1 (20.8)	8.8 (-3.9-21.5)	0.2
Light activity Mean (SD)	141.1 (61.7)	167.6 (67.6)	143.2 (49.7)	139.5 (39.8)	-13.7 (-39.7-12.2)	0.3
Moderate activity Mean (SD)	131.1 (82.1)	169.9 (101.7)	159.4 (46.2)	139.4 (50.1)	-27.3 (-59.4-4.7)	0.1
Vigorous activity Mean (SD)	1.6 (2.7)	4.2 (10.2)	6.4 (6.8)	5.1 (7.2)	-1.1 (-5.8-3.7)	0.7
Total energy expenditure by type of activity (MET/hr/week)						
Household Mean (SD)	182.6 (81.5)	214.2 (88.5)	230.5 (68.0)	231.0 (73.9)	-15.7 (-61.0-29.6)	0.5
Occupational Mean (SD)	77.2 (92.9)	104.6 (89.0)	13.3 (33.6)	5.5 (11.1)	-7.4 (-24.2-9.5)	0.5
Sport/Exercise Mean (SD)	10.6 (9.3)	17.1 (28.5)	28.1 (19.0)	19.3 (18.0)	-10.1 (-22.5-2.3)	0.1

3.23.5 Body image

After adjusting for baseline BISS scores, a mean difference of -0.83 (95% CI -1.7 to 0.02, p=0.06) was calculated for the intervention group compared to usual care (see Table 12).

Table 12: Body Image States Scale (BISS)

	BASELINE		**FOLLOW-UP**			
	UC (n=21)	**INT (n=19)**	**UC (n=19)**	**INT (n=19)**	**Adjusted mean difference (INT vs UC)**	**p-value**
Mean BISS score (SD)	4.0 (1.0)	4.5 (1.1)	4.9 (1.2)	4.2 (1.3)	-0.83 (-1.7-0.02)	0.06
	n (%)	**n (%)**	**n (%)**	**n (%)**		
More positive body image (score 6+)	1 (4.8)	3 (15.8)	2 (10.5)	3 (15.8)		
Positive body image (score 4-5)	15 (71.4)	14 (73.7)	11 (57.9)	12 (63.2)		
More negative body image (score 0-3)	5 (23.8)	2 (10.5)	6 (31.6)	4 (21.1)		

3.23.6 Depression

The adjusted mean difference in depression scores was -0.8 (95% CI, -2.4 to -0.9, p=0.3) for the intervention group compared to usual care (Table 13). The number of participants with possible depression (*i.e*. a score greater than 10) had increased from two to five participants in the intervention group and reduced from four to three for the usual care group.

Table 13: Edinburgh Postnatal Depression Score (EPDS)

	BASELINE		FOLLOW-UP			
	UC (n=21)	**INT (n=19)**	**UC (n=19)**	**INT (n=18)**	**Adjusted mean difference (INT vs UC)**	**p-value**
Mean EPDS score (SD)	6.3 (2.5)	5.6 (3.1)	5.3 (3.5)	6.7 (3.4)	-0.8 (-2.4-0.9)	0.3
EPDS score ≤8 (%)	17 (81.0)	16 (84.2)	15 (78.9)	12 (66.7)		
EPDS score 9-11 (%)	4 (19.0)	2 (10.5)	3 (15.8)	5 (27.8)		
EPDS score 12-13 (%)	0 (0.0)	0 (0.0)	1 (5.3)	1 (5.6)		
EPDS score ≥14 (%)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)		
Positive EPDS score (1,2, or 3) on question 10 (suicidality risk)	0 (0.0)	1 (5.3)	1 (5.3)	0 (0.0)		

3.23.7 Immunisation uptake

All of the participants who received the intervention took their infant to their first three immunisation appointments, usually on their own (Table 14). When someone accompanied the participant and infant to these appointments, it was usually the woman's partner.

Table 14: Immunisation uptake (intervention only)

Baby immunisation appointment	**Participant attended alone n, (%)**	**Participant attended with partner n, (%)**
1st (2-months)	13 (68.4)	6 (31.6)
2nd (3-months)	17 (89.5)	2 (10.5)
3rd (4-months)	12 (63.2)	7 (36.8)

3.23.8 Breastfeeding rates

At three-month follow-up, exclusive breastfeeding rates had reduced in both groups and by a similar amount (Table 15). The participants who were no longer exclusively breastfeeding

had either commenced weaning their infant; combined breastfeeding with formula; or changed to exclusively formula feed.

Table 15: Breastfeeding rates

Infant feeding method	BASELINE		FOLLOW-UP	
	UC (n=21)	INT (n=19)	UC (n=19)	INT (n=19)
Exclusively breastfeeding n, (%)	12 (57.1)	11 (57.9)	7 (36.8)	7 (36.8)
Both breastfeeding and formula feeding n, (%)	0 (0.0)	2 (10.5)	2 (10.5)	2 (10.5)
Exclusively formula feeding n, (%)	9 (42.9)	6 (31.6)	5 (26.3)	5 (26.3)
Breastfeeding and weaning n, (%)	0 (0.0)	0 (0.0)	1 (5.3)	2 (10.5)
Formula feeding and weaning n, (%)	0 (0.0)	0 (0.0)	4 (21.1)	3 (15.8)

3.24 Discussion

3.24.1 Main findings

This study aimed to examine the feasibility and acceptability of a brief weight management intervention during routine child immunisation appointments. The feasibility and acceptability of the intervention was based primarily on the recruitment rate and levels of adherence to weekly self-weighing by participants. The study recruitment rate was low at 9%, and despite extending the recruitment period, the study was unable to recruit the proposed sample size of 80 participants in the time available. However, a follow-up rate of 95% may suggest that the participation requirements of the study were feasible and acceptable to those women recruited. Almost 90% (17/19) of participants said they would recommend the study to their friends, adding further evidence of potential acceptability. Nevertheless, 661 (91.0%) women who were sent a study invitation letter did not respond, the high refusal rates indicate that participating in a weight management intervention study during the early postnatal period may not be acceptable to new mothers. Weight record

card data showed that nurses were able to weigh women during over half of child immunisation appointments. Practice nurses weighed 84.2%, 78.9% and 63.2% of women during the first, second and third immunisation appointments respectively, demonstrating it is possible for the intervention to be delivered by nurses per protocol. Overall, despite both participants and nurses being able to deliver and engage with the intervention relatively well, low recruitment rates may be an indication that very early postnatal weight management is not a priority for new mothers.

3.24.2 Comparison with the literature

3.24.2.1 Recruitment

The recruitment rate for this study was low at 9% and there may be a number of explanations for this. Participants received letters inviting them to participate in a weight management study at about 4-6 weeks after giving birth. This is a time in which mothers and their families are adjusting to having a new-born baby and therefore weight loss may not be considered a priority at this time. Furthermore, there was a maximum period of one month available between women receiving the study invitation letter and being able to receive their baseline assessment, prior to their child immunisation appointment. This limited timeframe may have deterred some women from participating. It is also possible that women do not want a weight management intervention shortly after giving birth, although this is not consistent with literature, which has reported women do want early intervention (104, 178). A prospective longitudinal study that aimed to identify the most suitable time to initiate postnatal weight management interventions estimated that by eight weeks postnatal, 84% of women were already attempting to, or were ready to start managing their

weight (337), suggesting that women may be open to early intervention after giving birth. Similarly, an online survey recruited 1,015 women who had given birth in the last two years and had joined Slimming World for the first time after having their baby reported that approximately 45.6% (n=463) started attending meetings between 1.5-6.5 months postnatally (338).

Previous literature has revealed that slower than expected recruitment rates are not uncommon in postnatal weight management studies (257, 339-341). Chang *et al.* tested a community-based weight management intervention for low-income postnatal women with overweight and obesity and reported a recruitment rate of 64% (342). However, Chang *et al.* implemented additional intensive recruitment strategies for example using trained peer recruiters, conducting cognitive interviews to develop a pictorial poster to advertise the study and recruiting women up to five years after giving birth (342). In contrast, this study aimed to recruit women within the first two months of giving birth. Nevertheless, this study was able to obtain a similar or higher recruitment rate compared to other studies (which ranged from 7-28%) that recruited women to a lifestyle intervention (e.g. web-based pedometer use, personalised diet and physical activity schedules, weight loss programme delivered via Facebook, home-based physical activity using Wii Fit) within the first six months of giving birth (257, 340, 343-346).

Another strategy to increase recruitment might be to consider approaching women antenatally and/or opportunistically after birth (232, 347, 348). Alternatively, employing an opt-out recruitment method would perhaps allow the research team to contact potential participants if they have not responded stating that they do not wish to participate, thereby

potentially boosting recruitment (349). Whilst it is fundamental to acknowledge the ethical challenges which may arise with this method, some systematic reviews of RCTs have reported higher response and recruitment rates when studies employ opt-out methods (350, 351). A meta-analysis including three studies estimated that opt-out may improve recruitment by 19% (95% CI, 3% to 35%) (350).

Another consideration could be to make changes to the timing of the intervention by delaying the first intervention contact and then assess whether this is more appealing to women and evaluated by the recruitment rate.

3.24.2.2 Adherence

Adherence to weekly weighing was modest. The weighing data collected via the objective Body Trace scales showed that approximately 50% of the intervention group were able to weigh themselves at least once a week during the intervention period. The intervention group were also asked to weigh and record their weight each week. Adherence to this instruction was initially good at 68.4% during the first month of the intervention, but reduced over time to less than half (42.1%) by the third month of the intervention. Findings from a systematic review indicated that regular reminders sent via SMS can improve adherence and may therefore may have been beneficial in this study (352).

Adherence to study procedures by the nurses was relatively good but reduced after the first child immunisation appointment. There were some missing data particularly with regards to whether nurses had signposted participants to the One You website. Given the low levels of participant recruitment, regular contact from the research team with the nurses may have kept the study and its requirements fresh in the nurses' minds.

3.24.2.3 Adverse effects from self-weighing

Previous studies have shown that regular self-weighing is an important strategy in facilitating weight loss (14, 188). Nevertheless, there has been some debate as to whether regular self-weighing may lead to adverse psychological health outcomes (353-356). However, evidence from systematic reviews and the findings from this study do not support such a view (357, 358). For example, in the systematic review by Benn *et al.*, no associations were found between self-weighing and adverse psychological outcomes (357). Nonetheless, some consideration should be given to a small amount of evidence from a literature review that has suggested that self-weighing could lower self-esteem (357). A systematic review of peer-reviewed literature conducted by Pacanowski *et al.* concluded that self-weighing appeared to be associated with negative outcomes in younger women (359). Overall, postnatal women in this study reported feeling "alright" when they weighed themselves and reported they would recommend this study to their friends. It is also important to note however, that Hartman-Boyce *et al.* reported the existence of a polarisation of views in participant's attitudes and beliefs in relation to the long-term use of self-monitoring techniques; some expressed experiencing a reduction in attentiveness, shame and even fear over time, whereas others claimed self-monitoring increased levels of self-accountability, self-control and self-efficacy (264). In addition, a focus group study by Zheng *et al.* also reported conflicting views from participants on their experiences of daily self-weighing (360). These contrasting views and beliefs of self-monitoring may therefore be a plausible explanation for the variability in adherence and frequency of self-weighing reported in this study.

3.24.2.4 Online weight management programme (One You)

Only one intervention participant did not access the One You website (5.3%) and 42.1% stated that they had used the website to help with their weight management, highlighting that some postnatal women are keen to use technology to access information about weight management. Technological advances have reduced the cost and improved the accuracy of portable activity and health tracking devices, ultimately enhancing their appeal to the general population (361, 362). The One You website has been designed to target the general population and includes several mobile-friendly, health promoting and tracking apps, including a physical activity tracker. A study investigating sociodemographic biases in the use of technology for physical activity in the UK suggested that the people using physical activity trackers tended to be younger, more physically active and more affluent (363). The free One You physical activity tracker and apps therefore have the potential not only to reach and encourage a broad spectrum of the population, but also appear to be appealing, albeit useful to some postnatal women from a wide range of social contexts and physical activity levels.

3.24.2.5 Raising the topic of weight during immunisation appointments

UK guidelines advise all health care professionals to screen for obesity and encourage weight loss via the provision of information and signposting to available weight management services (72). Yet evidence has revealed that health professionals are reluctant to raise the topic of weight with their patients for fear of negative consequences such as causing offence (210, 212, 364). For example, a qualitative study interviewing 34 GPs and practice nurses reported that many were hesitant to raise the topic and expressed many potential consequences, including stigmatisation and fear of losing patient trust (210). Furthermore,

Kaplan *et al.* suggested that health care providers were comfortable raising the topic of weight but time constraints prevented this from occurring during routine appointments (365). This study showed that practice nurses were mostly able to deliver the intervention as per protocol and women reported that it was acceptable for the nurse to weigh them during child immunisation appointments. Moreover, most women accessed the One You website highlighting that women want advice and support about their lifestyle behaviours. Previous studies have suggested that discussing weight and providing support from GPs and nurses was viewed positively and deemed acceptable by many patients with obesity (366-370). A recent online survey involving people with obesity and healthcare professionals from 11 countries, including the UK, reported that almost 70% of people with obesity like or would like their health care professional to raise the topic of weight during appointments (370). With this in mind, recruitment may have been improved if nurses raised the topic of postnatal weight during the first child immunisation appointment and after gauging patient receptiveness, invited them to participate in the study.

3.24.2.6 Secondary outcomes

Both groups lost a similar amount of weight when measured as a continuous variable. One possible explanation for this is that the usual care group were aware that they were in a weight management study and that weight data would be collected, thereby altering their behaviour to fit with this (contamination). In addition, a systematic review has shown that people who are motivated to lose weight can lose approximately one kilogram even if they do not receive an intervention (371). It was interesting to note that when participants were categorised as having lost weight or not, more women in the intervention group were

categorised as having lost weight compared to the usual care group (68.4% versus 28.6%). It is not clear why a higher proportion of women who did not receive the intervention lost weight relative to the intervention group, and as diet was not assessed, food consumption could not be looked at as a potential explanation for this finding.

Overall physical activity levels were 383.36 (SD 159.8) MET-h/week at follow-up, this is approximately 200 MET-h/week below the minimal recommendation (at least 150 minutes of moderate activity per week or 75 minutes of vigorous activity per week) (372, 373). The Start Active, Stay Active report calculated that approximately 72% of adult women in England were not meeting physical activity guidelines of at least 30 minutes of moderate intensity physical activity five times a week (374). A tentative conclusion was made that the intervention did not appear to increase physical activity levels in the intervention group relative to usual care in this feasibility cluster trial, as the study was not statistically powered to detect such effects. Future studies might consider providing participants with a method to self-monitor their physical activity, such as a tracker device or pedometer, which have been shown to increase physical activity levels in a range of populations (375-377).

The postnatal period is a sensitive time, and it may be argued that encouraging postnatal women having overweight and obesity to lose weight may negatively impact their mental health and well-being (359). Nevertheless, introducing the notion of weight management during this early postnatal period may boost mood and energy levels by promoting more physical activity (378, 379) and minimise the number of postnatal women who gain additional weight. This may in turn reduce the likelihood of postnatal depression (378) which may in itself exacerbate weight gain (140).

Several studies have reported that postnatal women prefer group-based interventions (261), whilst other studies that incorporated group-based elements to the intervention reported poor adherence rates (232). Despite evidence suggesting that commercial weight management interventions may be useful and cost-effective in primary care for the general population (170, 175), the regular group attendance required may not be suitable for this population of women. Group-based interventions can be costly to deliver at a national level, but the very nature of this intervention may create natural groups of women to form as they wait in general practices for their babies to be immunised. Furthermore, replacing the One You website with one which enables group chats and social interaction, may be worthy of consideration in the future (312).

3.24.2.7 Implications

The implementation of an intervention like this across the NHS may ensure the accessibility of a weight management intervention to all women who give birth in the UK. This intervention may therefore have the potential to ensure that hard to reach women have the opportunity to receive support with postnatal weight management. This includes women that are more likely to be affected by overweight and obesity, such as women with low levels of education; living in more deprived areas and/or ethnic minorities. Embedding a weight management intervention into routine child immunisation appointments, presents an opportunity to identify and treat more women with overweight and obesity that would not normally seek assistance prior to the onset of some of the symptoms associated with the co-morbidities linked to obesity (380). The intervention tested here is brief and simple to deliver, that if proven effective in a larger phase III trial, may be cost-effective for the NHS.

3.24.3 Strengths and limitations

This study has several important strengths and makes a unique contribution to the literature in a number of ways. To the best of this author's knowledge, this is the first study to assess the merits of a weight loss intervention embedded within a child immunisation programme. In addition, this feasibility cluster RCT showcases the merits of conducting feasibility studies prior to investing time and money on larger trials. Study participation was equally appealing to both first-time and multiparous women, suggesting that weight management during the postnatal period is a concern to women irrespective of the number of children they have given birth to. In addition, whilst the overall sample was small, women varied in terms of their socio-economic and infant feeding method. An intervention that is appealing to a broad range of postnatal women may help more women to return to their pre-pregnancy weight or return to a healthy BMI range before they become pregnant again, thus improving their potential weight trajectories during their reproductive years and beyond (317).

The likelihood of contamination between the treatment arms was minimised by using general practices as the unit of randomisation, thereby reducing the chances of practice nurses from different treatment arms being in regular contact.

Process evaluations are often not used when evaluating complex interventions but can be advantageous especially when a cluster RCT design is used as a single intervention has the potential to be delivered and received in contrasting ways at each site (381). This study included a detailed process evaluation of the intervention in relation to the setting, implementation and its reception (381, 382). This was achieved by collecting data on the frequency of nurse weighing; placement (before or after) of intervention in relation to the

nurse providing child immunisations; the frequency of self-weighing by women as well as how women felt about being weighed and weighing themselves.

Many weight management studies rely on self-reported weight at baseline and follow-up. In contrast, assessments of weight were objectively measured to ensure the data was accurate and not prone to bias or under-reporting. This process also minimised the probability of missing data. Weight loss studies can often experience low follow-up rates but in this study, the high retention rate and satisfactory completion of study tools demonstrate that the strategies employed to avoid high levels of loss to follow-up were effective. Baseline and follow-up data were collected at home visits to minimise inconvenience to participants and they were also offered a £10 high street shopping voucher.

Randomisation was performed by a researcher not involved in the research ensuring these procedures were conducted independently. Data on attendance at immunisation appointments was collected from primary care records so that the impact of the intervention on this outcome could be objectively assessed. Ensuring the intervention did not adversely impact immunisation rates is critical to the integrity and safety of the intervention. Gaining insight into the views and opinions of participants receiving and those delivering the lifestyle intervention can provide valuable understanding and lead to the development of more acceptable, and possibly more effective interventions. To address this both participants and practice nurses participated in semi-structured interviews about their experiences of the study and this will provide important information in which the results of this chapter can be understood and interpreted further (Chapter 4).

This study should also be interpreted in light of some methodological weakness. The methods of recruitment used may have attracted postnatal women already motivated to lose weight. This may explain why for 16 of the 21 women considered ineligible at screening and therefore excluded was due to having a BMI outside the study range. Despite Birmingham being an ethnically diverse city, few non-White women were recruited (32.5%). Groth and David reported that considerations on the importance of weight by postnatal women differed by ethnicity (177); which may suggest that women from ethnic minority groups did not find this study appealing or could not speak or read English fluently.

The results of this study are also limited by the sample size, thus require confirmation with a fully powered trial, particularly as this intervention was designed to be embedded within the national child immunisation programme, and therefore available to every postnatal woman. Future trials should consider recruiting postnatal women from other areas across the UK to determine the wider generalisability, effectiveness and cost-effectiveness of similar interventions. This feasibility RCT adopted a cluster design which may be problematic in a larger trial due to the larger sample sizes required with this study design, due to the poor recruitment rates experienced in this study and commonly reported in other studies with this cohort.

Women self-reported their physical activity levels therefore the data may be prone to bias and over-reporting. Future studies should consider including an objective assessment of physical activity. A more detailed analysis of body composition would have been useful as some studies have reported fluctuations in body fat percentage during the year following childbirth and that the trajectories differ between women with obesity and those without

(383). The practical benefits of a weight management intervention delivered online have been documented in other postnatal weight management studies (242, 312). Most participants in the intervention group accessed the One You website but we did not collect usage data. This would be an important consideration for future research.

As a feasibility cluster trial, the intervention was not included in the 12-month child immunisation appointment, the longer-term effects of regularly weighing and subsequent lifestyle behaviour change were therefore not assessed. It is possible that as mothers become more accustomed to a routine with their baby, they may be able to dedicate more time to their own health and fitness (384), this may translate into greater behaviour change. An opportunity to measure an important time period or opportunity for change may therefore have been missed.

Sleep deprivation is common for many women during the postnatal period and can affect mood and energy levels (143). A small cross-over study determined that shorter sleep times in overweight, non-smoking adults significantly reduced the amount of weight lost as fat and increased the loss of fat-free body mass during caloric restriction (385). The amount of uninterrupted sleep was measured (self-reported) at baseline but not at follow-up. In order to attain more accurate and detailed data on this variable, future studies should consider asking women to record their sleep quality in diary format or use a sleep tracker app to collect real time, objective data on the amount of sleep postnatal women are achieving. As weight loss has been linked to sleep duration and quality (143, 385-387) and such this type of data may be a key explanatory variable.

3.25 Conclusions

Despite practice nurses mostly being able to deliver the intervention as per protocol, the feasibility and acceptability of this intervention could be questioned due to the low recruitment rate, and variable adherence to regular self-weighing by participants. Prior to the development of a phase III trial, adjustments to the timing of the intervention in addition to considering alternative methods of recruitment are advisable.

CHAPTER 4

A NESTED QUALITATIVE STUDY EXPLORING THE VIEWS AND EXPERIENCES OF INTERVENTION USERS (MOTHERS) AND DELIVERERS (PRACTICE NURSES)

This chapter describes a qualitative study that was nested within the trial presented in Chapter 3. The present chapter explores the feasibility and acceptability of the postnatal weight management intervention with the aid of semi-structured interviews conducted with both the mothers and nurses who participated in the trial.

4.1 Mixed methods research

In 2008, the Medical Research Council advocated the use of feasibility and acceptability studies prior to more comprehensive and costly evaluations of complex interventions to allow for any potential issues that may affect the delivery and acceptance of the intervention to be identified (382). The use of qualitative research to assess the feasibility of trials has become more common (388). Qualitative research can be used to help determine the feasibility of an intervention as it can be useful to explore in detail, information related to the acceptability, implementation and practicality of the intervention (326, 389). This chapter formed part of the mixed methods study and, was nested within the trial discussed in Chapter 3. Mixed methods research permits research questions that cannot be addressed exclusively by either qualitative or quantitative research to be answered (390). Creswell and Plano Clark have suggested that using qualitative and quantitative research methods simultaneously in a singular study, can enhance the accuracy of research findings (391). Almost a decade ago, mixed methods research was less common, but its popularity since has

gained momentum, especially with RCTs of complex healthcare interventions and in studies assessing the feasibility of RCTs (388, 392, 393).

Qualitative research is commonly used to capture participant perspectives in relation to an experience or to add meaning to a specific topic under investigation (394). The use of qualitative research alongside RCTs can help generate a more comprehensive understanding of the patient experience and reveal some of the difficulties related to the provision and implementation of suitable healthcare interventions (395). Davidsen suggested that qualitative research methods "recognise the influence of history and culture and appreciate how such knowledge is constructed intersubjectively" (p. 319 (396)), implying that qualitative research methods can be used to explore shared thoughts about shared experiences. By understanding the views and opinions of patient and service providers, researchers can remain sensitive to the people for whom the interventions are being designed for and thus ensure the provision and implementation of more effective and acceptable interventions (397, 398).

4.2 Purpose and rationale

The aim of this qualitative study was to use semi-structured interviews to elicit detailed information relating to the women's and nurse's experiences of receiving and delivering the weight management intervention. These findings would later be used in conjunction with the quantitative data from the trial, to evaluate the feasibility and acceptability of the intervention.

This qualitative study would allow a more detailed investigation of the issues that affected the implementation and reception of the intervention, thereby revealing issues that may have affected the feasibility and acceptability of the intervention (399, 400).

4.2.1 Objectives

- To capture mothers' views on how useful the intervention was at helping them to manage their weight and determine if the intervention caused the mothers anxiety or psychological harm.
- To determine what elements of the intervention facilitated and/or impeded its acceptability and explore what participants found helpful and unhelpful about the intervention.
- To investigate what aspects of the intervention were acceptable or unacceptable to participants and practice nurses, as well as the reasons for these feelings and opinions in order to identify any parts of the intervention that may need to be altered.
- To explore whether child immunisation appointments are a suitable setting for delivering weight management.
- To capture nurses' views on the impact that delivering the intervention had on the structure and duration of the child immunisation appointments.
- To gain insight into the culture of the nurses providing the intervention and look at how this along with their personal views and beliefs shaped their experiences of delivering the intervention to mothers with overweight and obesity during routine child immunisation appointments.

4.3 Methods

4.3.1 Qualitative methodology

The approaches to qualitative research are vast and diverse as it is open to different interpretations, it can therefore be undertaken in many ways, depending on factors such as the purpose of the research, epistemological and ontological standpoints (401, 402). As the aim of this qualitative research was to explore women's and nurse's experiences of receiving or delivering the intervention, it was necessary to use a methodology that would ensure the participant's voices were heard.

Phenomenology is the study of the meanings attached to experiences from a first-person perspective (403). Pollio and colleagues describe phenomenology as a qualitative research method with a degree of sensitivity to enable the study and interpretation of daily human activities from another perspective (404). Phenomenology has been used to make improvements to healthcare interventions by exploring the lived experiences as it allows for participants with similar experiences to be included in the same study (405). A phenomenological perspective in this study would therefore allow a detailed exploration and interpretation of the ways in which the participants in the study made sense of their engagement with the intervention, in relation to their personal and social surroundings.

Outwardly, feminist phenomenology can be perceived as the study of how women specifically experience the worlds they live in and provide meaning to from a subjective point of view (405). However, Mann describes feminist phenomenology as using the underpinnings of phenomenology to study the values and meanings associated with a lived experience of women that phenomenology has not yet countenanced (p. 51 (406)). This may

therefore be a useful approach to understanding participants' experience of the PIMMS weight management intervention. A feminist approach was also considered helpful because the research team comprised entirely of females and the subject under investigation related primarily to improving the lives of women by gaining insight from women on their experiences with the intervention under investigation. The use of a feminist approach would therefore consider the influence of society on the construction of motherhood (407-409); how changes to the physical body through childbearing interact with the socially constructed views of the female body as a vector to convey beauty (410).

By studying what is important to women whilst considering their roles and social interactions, feminist research is conducted by women who aim to improve the lives of women (405). When merged, the paradox between the phenomenological and feminist stances (411, 412) become a powerful means through which insights into the individual and societal familiarities and judgements about postnatal weight and postnatal weight management can be made. Feminist phenomenology achieves this whilst taking into consideration western socially constructed ideologies of being female, having a female body and being a mother (403, 407-410).

4.3.2 Reflexivity

The use of reflexivity is common in both feminist and phenomenological research (393, 413). Reflexivity enables self-awareness of the social, cultural and personal views and experiences that shape our beliefs, perception and interpretation of the world around us (414, 415). The process of interpretation is based on the continual reflection of events (413). As a female researcher with a background in health and nutrition, who has not struggled greatly with

weight management and is not a mother, these factors may inevitably have influenced the interpretation of the data (414, 416). These factors may have also impacted on the information and experiences participants were willing to share with the interviewer (414). Being reflexive throughout the process of data collection enabled the researcher (J.A.F) to remain aware of how these issues may have affected the interpretation of the data, thereby enhancing the trustworthiness of the data.

4.3.3 Study design

This nested qualitative study employed individual, face-to-face (or telephone) semi-structured interviews. They are a reputable qualitative approach to use, and a popular method for data collection in feminist research (393, 417, 418). Semi-structured interviews are ideal when exploring individuals' views and opinions on a topic(s) of interest (419), as they are flexible enough to allow the researcher to probe for clarification or ask for more information and, are particularly useful when exploring issues that are emotive or of a sensitive nature (420).

Semi-structured interviews were conducted with participants who had experienced the trial intervention and practice nurses who facilitated the intervention.

4.3.4 Setting

4.3.4.1 Women

In order to achieve maximum variation of the sample, every woman who had participated in the trial (see Chapter 3) and received the intervention was invited to take part in an interview after completing their three month follow-up home visit (421).

4.3.4.2 Nurses

Practice nurses were verbally informed during the initial training sessions that they may be invited to participate in an interview to discuss their experiences of delivering the intervention.

Interviews with trial participants were conducted between April 2017 and January 2018 and between April and July 2018 with practice nurses. Ethical approval was obtained from the University of Birmingham and the Black Country Health Research Authority (Ref: 15/WM/0445).

4.3.5 Data source

In line with the feminist approach, the topic guides were designed by a feminist researcher (J.A.F) and covered areas and questions that would enable postnatal women's perspectives of weight management to be explored and understood in relation to their lives as women and mothers in society. Furthermore, the questions were designed to encourage each woman's response to not only be detailed, but to also encourage them to express themselves and their emotions freely (422, 423). The questions in the topic guide were formulated in a manner that the questions posed were non-judgemental and treated the women with dignity (405, 424). The creation and use of a topic guide can improve the trustworthiness of semi-structured interviews in qualitative research as they can improve the rigour of the study by helping to ensure interview consistency (419). The topic guides were designed to cover key areas yet remain flexible enough for unexpected areas that concerned participants to also be explored.

The topic guide used with the women (Appendix 23) initiated the interview with an opening question enquiring about participants' previous weight loss attempts. The interview guide then comprised of open-ended questions and prompts to explore the women's reflections of key elements of the intervention, including their experiences of regular self-weighing; being weighed by nurses during child immunisation appointments; thoughts on being referred to a website for weight management advice and information and their overall views on the intervention including its timing.

The semi-structured interview guide for nurses (Appendix 24) explored their reflections on delivering the intervention. The nurses' topic guide started the interview by enquiring how long the nurse had been working at their current practice or as a nurse. The nurses' topic guide covered the following: general warm-up questions relating to their career and how their practice books in immunisation appointments, their experiences of the intervention training provided, their experiences of delivering the intervention, and their thoughts on referring women to use a website (One You) for weight management.

Demographic data collected during the trial was also used in this qualitative study to compare the women that were interviewed to the women who participated in the study.

4.3.5.1 Procedure

4.3.5.1.1 Women

As the phenomenon under investigation was specific (*i.e*. the experience of receiving the trial intervention), the number of eligible participants was constrained to women who had participated in the trial and received the intervention. When invited to participate in the

trial, potential participants were informed that they may also be invited to participate in semi-structured interviews after participating in the trial.

Out of the 19 women who received the intervention, 14 took part in the qualitative study. From the remaining five women who received the intervention, two declined to be interviewed, one was unable to participate due to family illness; one participant had moved abroad, and one participant was uncontactable by phone.

4.3.5.1.2 Nurses

Contact was made with each of the practices delivering the intervention after the last participant from their practice had completed their baby's four-month immunisation appointment and every nurse responsible for providing child immunisations was invited to be interviewed. Out of the thirteen nurses that received intervention training, seven participated in this qualitative study. Two of the nurses that were not interviewed had moved to different general practices, one nurse was on maternity leave and the remaining three did not respond.

Sample sizes similar to these have been shown to be sufficient to attain data saturation (425, 426), which is important for content validity and the quality of the study (427). Qualitative data saturation exists when no more new information (or themes) can be generated from the data (428). Some researchers argue that as data saturation originates from grounded theory, its generic application to all qualitative research is unfounded (429). Contrastingly, other researchers believe that the sample size adequate for analysis should be determined by the amount of information power (430) or richness (427) contained within the sample to determine an adequate sample size. As every effort had been made to interview every

possible participant exposed to the intervention, data saturation was deemed a suitable option for this study as no further sampling was possible (431).

In addition, the presence of a clear objective in this study (to determine the acceptability of the intervention), the use of topic guides, which added some structure and consistency during the interview process, and the recruitment of a relatively homogenous sample can help to ensure data saturation for the sample size (428).

4.3.6 Data collection

A feminist perspective created a space in which an equal exchange of information occurred between the researcher and each participant before, during and after each interview (405, 432).

4.3.6.1 Women

After seeking written informed consent (Appendix 25) all, but one of the face-to-face, semi-structured interviews with the women were conducted in participants' homes. One interview was conducted at the University of Birmingham. Interviews lasted approximately 45 minutes, but ranged between 30 and 61 minutes. All interviews were audio-recorded and professionally transcribed.

4.3.6.2 Nurses

Written informed consent (Appendix 26) was obtained from the nurses that were interviewed face-to-face and both audio-recorded and written consent was attained for nurses interviewed by telephone. Three nurse interviews were conducted face-to-face at the practice where the nurses worked, and four interviews were conducted by telephone.

Research suggests that the use of the telephone to conduct interviews is feasible as telephone conversations follow a similar structure to face-to-face semi-structured interviews (433). The interviews lasted 21-29 minutes.

4.3.6.3 Field notes

The researcher (J.A.F) wrote field notes after each interview to reflect and produce a reflexive diary of how the researcher's personal experiences and position may have influenced the direction and quality of the interviews, and therefore what data were collected (434, 435). This was used to consider any environmental cues that may have influenced the interview and add context when the transcripts were being analysed (416). The secondary purpose of the field notes was to serve as an informal audit trail (436) that could help increase the rigour and methodological transparency of the qualitative study (415, 437).

4.3.7 Data analysis

4.3.7.1 Data management

The transcripts were anonymised with participants' unique study identification number. Nurse transcripts were also anonymised by excluding the name of the general practice and the name of the nurse from the transcripts.

The researcher (J.A.F) transcribed one interview to gain some experience of this process, and the remaining interviews were transcribed verbatim by a professional transcription company. The transcripts will be stored securely for 10 years and then be destroyed, in line with the University of Birmingham's data storage guidelines and ethics procedures (438).

All the interview transcripts were manually coded. This approach was felt to be appropriate here as the use of manual coding is favoured when data sets are small and when the questions asked are relatively straightforward (439). This was especially useful as it ensured meanings, assumptions and descriptions remained in context and that they were used collectively to create initial category clusters (426). Despite the benefits associated with computer-assisted qualitative data analysis software (CAQDAS) programmes, such as the ease of analysing large data sets and enabling group work (440), it has been suggested that by using CAQDAS, the narrative can get lost (441). The use and referral back to paper-based print outs of the interview transcripts kept the interview intact and aided in the retention of the narrative. It was also considered important to spend time becoming thoroughly familiar with the data, a form of reflexive iteration (442), which would be useful since almost all of the interviews were transcribed outwith the research team rather than learn how to use a CAQDAS programme. Reflexive iteration is a key stage of the feminist approach, phenomenology and framework analysis (393, 413, 443) (discussed in more detail below), and a worthwhile process.

4.3.7.2 Framework approach

The framework method developed by Ritchie and Lewis (443) was employed to systematically analyse, display clearly and interpret both data sets. The framework analysis was chosen as it is suitable when an all-inclusive descriptive summary is sought from participants regarding a similar topic, in this case the trial intervention (444). Its prescriptive nature makes it a useful method of analysis when members of the research team, like the researcher (J.A.F) are inexperienced qualitative researchers (444). Additionally, the

methodical, in-depth approach that allows links between the individual interviews and specific themes to be retained within the data set (395, 444) and transparency (445) of the framework approach was favourable as it can improve the methodological quality of the study. Analysis followed the five main stages of the framework method:

1. Familiarisation - each transcript was read listened to at least twice.
2. Identifying a thematic framework - using the aims of the study to create codes, themes and ideas.
3. Indexing - every transcript was read and coded using the same types of codes.
4. Matrix - two separate charts (one for the nurses and one for the women) were created. Codes and/or themes were inputted into the columns and the rows contained relevant notes and quotes from each woman and nurse.
5. Interpretation - themes and sub-themes were generated based on reviewing the data contained within the charts.

Each interview was read and listened to at least two or three times to become familiar with the raw data. Each time the transcripts were read and highlighted, researchers' thoughts and codes were recorded along the margin to summarise what the participant was saying (395). In order to ensure rigour in the identification of emerging codes and that descriptive labels were valid and consistent (439) the first two, randomly selected transcripts were read independently by three additional researchers (S.M.G, H.M.P and A.J.D) from a variety of disciplines including medicine, psychology and sociology. There were no disagreements on initial coding and the remaining nineteen (12 women and seven nurse interview) transcripts were then read and coded by the same researcher (J.A.F). Regular meetings were held with

the entire multidisciplinary research team to discuss additional codes and ideas to achieve consensus that would improve both the quality and rigour of the study (446). This was also beneficial as the team included an experienced qualitative researcher (S.M.G) who guided the framework analysis process.

The “one sheet of paper” method was applied to summarise each interview transcript (447). Provisional categories were created based on the topic guide as well as any additional topics and codes that were identified (447). This meant that initially a deductive approach was used as specific questions relating to the acceptability of different elements of the intervention were used to generate a coding matrix (444, 448). Each participant was represented by a row, and each code or category (a potential theme) was placed in a column. The matrix was initially completed by hand and then entered into a matrix created in Microsoft Excel. The names of the categories altered, new ones arose, and others were merged as each transcript was read and coded and re-coded. The coding matrix enabled relationships between the categories to be identified ultimately assisting in the development of the various themes and sub-themes to be systematically identified and populated directly from the data. These themes and sub-themes were altered as new ideas were conceived and the transcripts were re-read. The feminist perspective directed focus to the language used when the women described their experiences and their bodies.

4.4 Results - women

To provide contextual information, the demographic data of participants are presented in Table 16. Data previously collected during the trial, showed that apart from a few slight differences, the women interviewed were similar to the women who participated in the trial

and received the intervention. Fourteen postnatal women between the ages of 28 and 42 years were interviewed. Most of the women interviewed were of White ethnicity, similar to the trial, but slightly fewer non-White women (n=5) were interviewed. Sixty-four percent of the women (n=9/14) interviewed successfully lost weight during the study, compared to 68.4% of women (n=13/19) in the trial who received the intervention. Despite this difference in weight loss, women with similar BMI categories to those in the trial were interviewed; 43% were overweight, 43% with obesity and 14% with severe obesity at follow-up. The women that were interviewed had very similar IMD scores, infant feeding practices and parity to women in the trial (see Tables 2 and 3 in Chapter 3).

Six main themes, each with sub-categories arose from the data during analysis (Figure 8). The themes are ordered to show women's reasons for participating in the study; give an account of their experiences of interacting with the intervention components and their views on the acceptability of the intervention. The last theme consolidated the women's opinions on what components should be included in a weight management intervention for postnatal women, based on their maternal experiences.

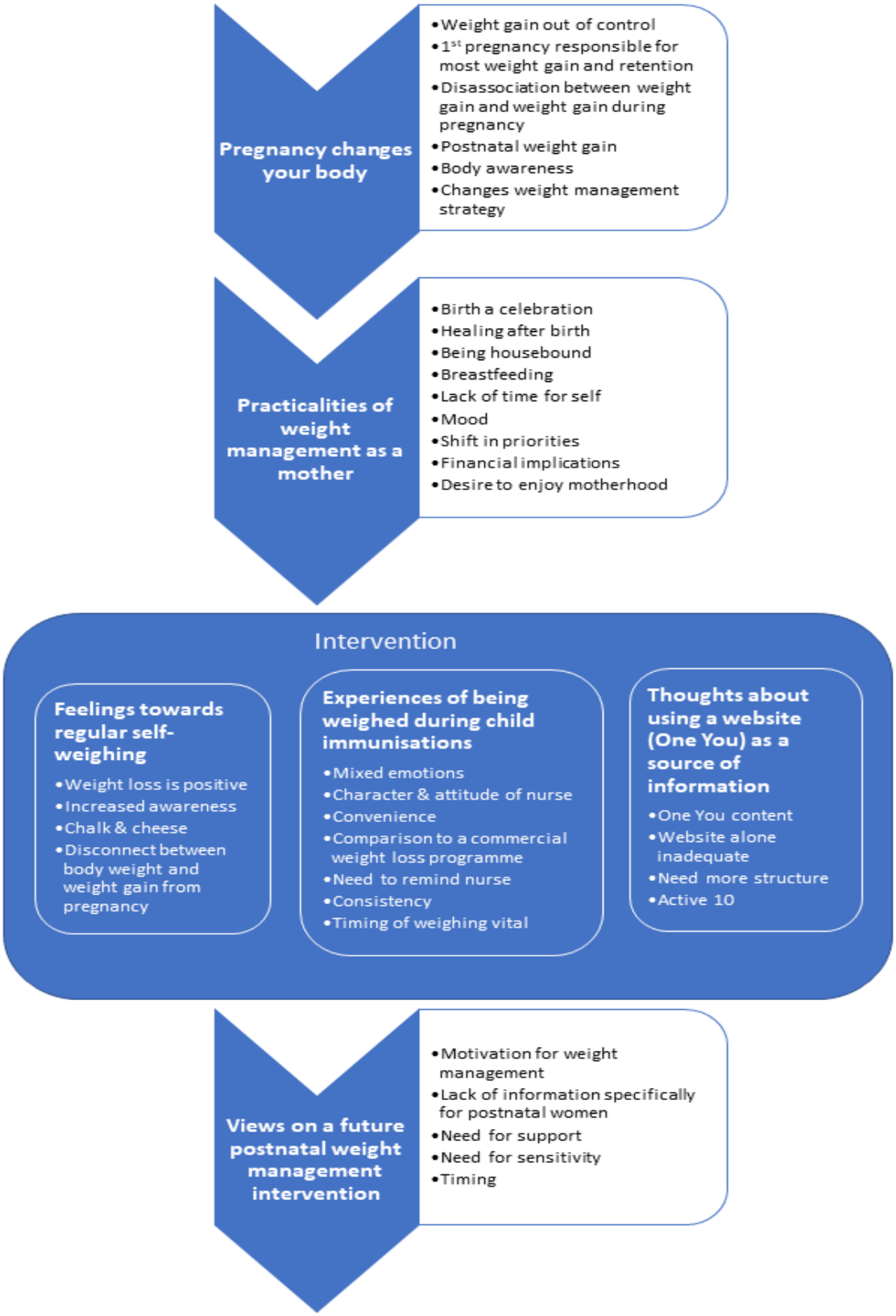
The interviewee identifiers after the quotations presented below relate to the identifiers in Table 16.

Table 16: Participant characteristics

Participant ID number	Age (years)	BMI category	Number of births	Ethnicity	Marital status	IMD Score (336) (quintile)*	Weight loss or gain	Infant feeding method at follow-up
009	28	Overweight	2	White European	Living with partner	4	Gain	Breast feeding
013	40	Severely obese	2	Pakistani	Living with partner	3	Loss	Formula feeding
022	38	Obese	2	White British	Living with partner	3	Loss	Formula feeding
023	34	Obese	1	White British	Living with partner	4	Gain	Formula feeding
032	39	Overweight	2	White British	Living with partner	3	Loss	Breast feeding & weaning
034	33	Obese	3	Mixed	Living with partner	2	Loss	Breast feeding
035	26	Obese	5	White British	Living with partner	4	Gain	Formula feeding & weaning
045	33	Severely obese	1	Black African	Living with partner	5	Gain	Breast feeding
049	32	Overweight	2	Indian	Living with partner	4	Loss	Breast feeding
050	31	Obese	1	White British	Living with partner	5	Loss	Breast feeding
051	36	Overweight	1	White British	Living with partner	3	Loss	Formula feeding
052	25	Overweight	1	White British	Living with partner	3	Gain	Formula feeding & weaning
060	31	Obese	1	White British	Living with partner	5	Loss	Formula feeding
061	31	Overweight	2	White British	Living with partner	3	Loss	Breast feeding

* Quintile 1= Least deprived, Quintile 5= Most deprived

Figure 8: Model of six key themes (and sub-themes) for mothers



4.4.1 Theme 1: Pregnancy changes a woman's body

This first theme encapsulates the key reason many of the women were interested in participating in the study: pregnancy related changes to a woman's body and their feelings about those changes. Many women highlighted the fact that pregnancy had caused drastic changes to their body shape and weight that were both expected and unexpected:

"My body did change shape completely while I was pregnant [laughter] and I don't know if it was the hormones, or what it was, but about week 25, 26 of my pregnancy, I just felt really, really ugly suddenly" (023, 34 years, obesity, primiparous, gained weight).

4.4.1.1 Weight gain out of control

Participants predominantly considered their weight gain to be associated with childbearing and therefore somewhat out of their control. One participant commented that despite expecting weight gain during pregnancy, she was unprepared to gain as much weight as she had:

"I put on quite a lot of weight and weight I didn't necessarily expect to" (051, 36 years, overweight, primiparous, lost weight).

Many women acknowledged that pregnancy had resulted in a significant amount of weight gain, with several participants expressing that pregnancy had caused them to gain the most they had ever weighed:

"You know I'm the heaviest I've ever been really" (050, 31 years, obesity, primiparous, lost weight).

"I mean I know it's nine months but it's far more weight than I've ever put on in such a short time if you know what I mean" (013, 40 years, severe obesity, multiparous, lost weight).

A couple of participants contradicted this by acknowledging that they had some part to play in the amount of weight they gained, and this was linked mainly to their diet and how much they chose to eat while they were pregnant.

"I got pregnant so then I was kind of like, oh I can eat for two now! But erm I saved myself because at first, I was really hungry all the time but then I was like no I can't eat for two the whole way through otherwise I'm going to be an absolute whale but [laughs]…" (052, 25 years, overweight, primiparous, gained weight).

A mother of three acknowledged that the adage of *"eating for two"* during pregnancy had applied to her situation*:*

"…just before giving birth you do put on a lot - well, I put on a lot of - I fell into the trap of you're eating for two" (034, 33 years, obesity, multiparous, lost weight).

4.4.1.2 First pregnancy causes most weight gain and weight retention

Some women who had had more than one pregnancy noted that their first pregnancy had caused them to gain weight and that they had struggled or were unable to lose all of the weight they had gained during that first pregnancy:

"After my first pregnancy I put on a lot of weight, so I put on 10 kgs after my first pregnancy so and I tried different things like going to the gym and all, but nothing was happening…I realised very soon I wasn't going to lose weight" (049, 32 years, overweight, multiparous, lost weight).

4.4.1.3 Disassociation between weight gain and weight gain from pregnancy

A few women reported a disassociation between body weight when not pregnant and weight gain as a result of pregnancy:

"…as soon as you are not pregnant, automatic thought is ok I'm just going to try to come back to myself as quickly as I can" (009, 28 years, overweight, multiparous, gained weight).

One participant suggested that there was a difference between losing weight generally and losing the weight gained during pregnancy:

"I haven't really seen any like weight loss result, not really, I have lost a little bit of weight, but I think only because erm I kind of… I was still kind of losing my baby weight a little bit I don't think I've lost any additional weight on top of that" (052, 25 years, overweight, primiparous, gained weight).

4.4.1.4 Postnatal weight gain

A couple of women also noted that the early postnatal period was a time when they had gained additional weight. One multiparous participant explained that gaining weight postnatally after the birth of her previous child was part of her reason for participating in the study:

"I knew from my first that weight, you know I put on weight after giving birth, er, for whatever reason, er, and I didn't want that to happen again, it did happen again so I think now in hindsight that's just something that's going to happen to me after I give birth" (061, 31 years, overweight, multiparous, lost weight).

4.4.1.5 Body awareness

Some of the women expressed a desire to either lose weight or return to their pre-pregnancy body shape or weight:

"Yeah definitely you know cos I've got you know wardrobes, two wardrobes of clothes I want to get back into [laughing] erm I don't want to look, yeah, I don't want to stay in like these kind of loose, baggy clothes that I got for like pregnancy. You know I'd like to go back to the clothes I had before that were pretty and nice" (013, 40 years, severe obesity, multiparous, lost weight).

4.4.1.6 Changes weight management strategy

A few of the women who had mentioned using exercise before they got pregnant to manage their weight noted that it had become ineffective post-pregnancy, therefore more focus was given to their diet to manage weight:

"I did a lot more exercise, but after having my other two children exercise got out the window erm and it - so I concentrated more on the food this time so didn't feel like I needed to do anything before…So, I, I was part of the gym erm just before Slimming World but it didn't make any difference" (034, obesity, multiparous, lost weight).

4.4.2 Theme 2: Practicalities of weight management as a mother

There was a general consensus amongst the women who took part in the interviews that becoming a mother triggered a shift in priorities as they took on a new role. Fulfilling this maternal role inevitably impacted on all aspects of their life including their ability to manage their weight. Many of the participants understood the importance of a healthy lifestyle (diet and physical activity) and often discussed what necessitated successful weight management,

however, their maternal role often inhibited the successful, albeit consistent implementation of weight management strategies into their daily lives.

4.4.2.1 Birth of baby a time for celebration and to take it easy

Several participants reported friends and family members buying them cakes and chocolates to celebrate becoming a parent being one of the initial instigators of poor food choices during the early postnatal period:

"…I suppose it's a gradual thing because you start off, you give birth and you get brought a whole load of high calorie treats and told to look after yourself, have a treat, go for a coffee, have a cake, er sit down, watch telly etc. And in the first few weeks when the weight from pregnancy is dropping off it's sort of okay to do that because you're still seeing your weight go down. But then you're at a point where the weight then stops losing but you're still in pattern of eating high calorie foods and sitting watching telly and – and not living a healthy, active lifestyle" (061, 31 years, overweight, multiparous, lost weight).

4.4.2.2 Healing after childbirth

Several women brought up the topic of needing time to heal from the experience of childbirth and that this meant that weight management attempts could not take place until they felt physically ready:

"Pregnancy and labour is such a huge thing and they do, it does take time to recover, to recover because there is such a hormonal changes in the body after pregnancy as well, all the hormones suddenly just drop and there are so many other issues, health issues that can come up on the back of it" (009, 28 years, overweight, multiparous, gained weight).

Some women who had undergone a caesarean section still felt some of the discomfort associated with the major surgery and were cautious or unsure what forms of physical activity they could perform safely:

"what, what is safe to do at the moment and what isn't because there's a lot of information on the webs-, - on, online – on websites but erm, you know, it's not for someone that's just had an opera-, - a major operation like I have or been through pregnancy, or – you know…" (023, 34 years, obesity, primiparous, gained weight).

4.4.2.3 Being housebound

Several women described how being homebound following childbirth meant that the availability of food in close proximity made them more prone to snacking, particularly when they were exhausted. In contrast, being at work for most of the day was seen by some as an effective means of preventing unnecessary snacking which aided weight management:

"You want sugar, you need to get back up because of course your energy is completely gone as well, it's not just hunger, you need something to perk you back up so yeah that's the problem. And at work you can push through it because you haven't necessarily got something to eat but when you're at home you've got the kitchen" (061, 31 years, overweight, multiparous, lost weight).

4.4.2.4 Breastfeeding

Despite women being conscious of wanting to manage their weight, this was not always viewed as attainable whilst breastfeeding as they were exclusively responsible for ensuring their baby was being well fed. All the women interviewed who were breastfeeding expressed a requirement to eat well and frequently due to the demands of breastfeeding:

"I'm breastfeeding you see. Eating vegetables alone maybe would, would help for somebody but it wouldn't work for me because I'm breastfeeding and it's taking more, so I need to replace it…within a small time you get hungry" (045, 33 years, severe obesity, primiparous, gained weight).

Attempts by breastfeeding women at reducing their caloric intake resulted in repercussions that increased the frequency of needing to breastfeed as well as a sense that baby was still hungry:

"My milk supply was heavily dependent on calories. So if I had, you know there was a point I was like, right that's it I'm going to start dieting, er cut down what I was eating and my supply went, and she was suddenly then upping her feeds, getting less satisfied after a feed so I upped the calories and the milk went up again" (061, 31 years, overweight, multiparous, lost weight).

Some of the women described an insatiable hunger that thwarted their efforts to eat healthily. Hunger, in conjunction with time constraints and inadequate sleep tended to exacerbate cravings for "junk food":

"I definitely can tell it was too early for me because I was breastfeeding, and I felt erm hungry all the time and err I felt exhausted from like not sleeping nights properly and all I did was snack throughout the day erm, so even though I had it in my mind that I want to lose weight, I couldn't help myself basically" (009, 28 years, overweight, multiparous, gained weight).

4.4.2.5 Lack of time for self

Many women commented that they did not have much time to themselves as daily childcare responsibilities consumed most of their time. Women mentioned the time commitment and daily discomfort experienced with breastfeeding:

"But the early stages the baby is small and you see he's crying and he's breastfeeding and you sit down, stretch out, even as I'm telling you I'm having back pains and waist pain because sitting down breastfeeding for a long time is not easy" (045, 33 years, severe obesity, primiparous, gained weight).

Becoming a mother meant that some of the women in the study who had previously incorporated regular structured exercise into their routine had less time to themselves in which they could do some of the things that they were able to do before they had children:

"It's a shame because I do like exercise, but it was just trying to figure something that was right for the time and fitting it in, but I did like the quick walking" (061, 31 years, overweight, multiparous, lost weight).

The creation of a routine was seen by some participants as fundamental if elements of a healthy lifestyle were to be incorporated into their daily lives, and anything that could disrupt this routine could jeopardise their weight management attempts. Some of the women in the study frequently discussed their weight management being affected by the time of year. Holidays like Christmas were often a time that many women said they struggled with weight gain due edible gifts and the cold making them crave specific food:

"I've felt like me having a routine with the baby is really important and Christmas sort of threw that out…I only really started getting back onto how I was feeling before after

Christmas, I felt quite miserable to be honest because I thought oh gosh how am I going to get back into doing all these things all the time…" (050, 31 years, obesity, primiparous, lost weight).

Winter weather was viewed by some participants as an inhibitor to physical activity and increased time remaining housebound. Furthermore, those with other children were affected by their children being off from school affecting their routine and making them more vulnerable to snacking.

"I knew that um timing wise because I had my um eldest off school um so school holidays, snacks, ice creams in the park, things like that, I kind of knew it wouldn't be the perfect time to lose weight" (032, 39 years, overweight, multiparous, lost weight).

4.4.2.6 Mood

A couple of participants expressed that their mood could influence their food choices:

"If I was down, or not feeling too great I tended to eat more, what would be known as junk food. Whereas when I was happier and upbeat, and I'd been more active, and I wouldn't eat quite as much junk food and stuff like that. I'd eat more fruit and maintain a more balanced diet" (035, 26 years, obesity, multiparous, gained weight).

While other women expressed that what they ate could influence how they felt:

"I feel like if you're healthy and eating well, it's also good for your mental health…when I'm active then I feel more positive and eating healthily I feel more positive and it all feed in" (050, 31 years, obesity, primiparous, lost weight).

4.4.2.7 Shift in priorities

Attempts at regular self-weighing and healthy eating for weight management were not always easy for some mothers to achieve due to the daily demands of motherhood. The unpredictable nature of motherhood meant that consistency with weight management was not always possible.

"something would always come up and stop that from happening" (035, 26 years, obesity, multiparous, gained weight).

4.4.2.8 Financial implications

For many women, money was a significant factor. Several participants mentioned the need to fit back into their old clothes because of the costs associated with buying a new wardrobe. Others spoke about the expenses incurred for gym memberships and exercise classes. Wasting money on food was another money-related area discussed by a couple of participants. One mother (052) did not want to try too many of the recipes available from the One You healthy eating app due to the cost of some of the ingredients that she would only use once:

"I'm not going to go and buy all this stuff just for the sake of making one meal… I kind of just wanted inspiration on different meals that we could eat that were kind of healthier and erm you know better for us but not something that's really complicated or going to be really expensive to buy the ingredients" (052, 25 years, obesity, primiparous, gained weight).

One mother admitted to eating her toddler's leftovers in order to prevent food waste:

"You know, you know things like I said like carbohydrates and cheese and that sort of thing and I would try and not buy them in the first instance so that I wouldn't be like I'm

tempted and because they are in the house, because you know I'm trying to feed her a balanced diet and things. If she doesn't eat them, I sometimes feel like oh it's going to go to waste and I haven't had anything to eat all day and then I end up having what she, what I was going to give her" (013, 40 years, severe obesity, multiparous, lost weight).

4.4.2.9 Desire to enjoy motherhood

Several women expressed a strong desire to enjoy motherhood, commonly noted amongst women that were on maternity leave. They reported that they did not want anything to detract their attention from the limited time they had at home with their baby:

"I know that I still need to um loose a bit to get back to my pre-baby weight but at the same time I'm kind of like nine months on, nine months off, and I want to enjoy my maternity leave" (032, 39 years, overweight, multiparous, lost weight).

4.4.3 Theme 3: Feelings towards regular self-weighing

Overall, the women stated that self-monitoring their weight on a regular basis made them more conscious of what they were eating during the early postnatal period. However, they also commented that the demands associated with caring for a small infant made it harder to implement health behaviours (*i.e.* physical activity and healthy eating) that they knew would help them manage their weight.

4.4.3.1 Weight loss is positive, weight gain is negative

In general, the women interviewed used words that described positive emotions when they had lost weight and used negative words to describe their emotions when they had gained weight. Others were content if their weight remained the same, whereas this lack of change made others feel despondent and like their weight management efforts were ineffective:

"Obviously on days when I saw a difference, a good difference, a loss, a bit of a loss, when I lost a bit of weight I was like oh that helped, oh that was nice but obviously on days when it was the same I'm like mmm maybe I'm not doing something right, I mean I'd think like sometimes I would when for two weeks in a row it just showed me the same weight, I was like oh I can't be bothered, it's not making a difference" (049, 32 years, overweight, multiparous, lost weight).

4.4.3.2 Increased awareness

Some of the women in the study stated that self-weighing had been an asset to them as it had made them more aware of their weight. Self-weighing was viewed by some mothers as a method to keep an eye on their weight, but not necessarily to gauge weight loss:

"So, I don't mind necessarily what the number is as long as I know where I, where I am so I know what I have to do and what not to do" (034, 33 years, obesity, multiparous, lost weight).

"And I'm, I'm not sure if this study necessarily helped me lose weight as such but it certainly stopped me from putting any on because I was actually- it was at the back of my mind, you know" (023, 34 years, obesity, primiparous, gained weight).

4.4.3.3 Chalk and cheese

Self-weighing was viewed as either an effective or ineffective self-monitoring tool for weight management. Some of the participants that stated that they had had a positive experience with self-weighing, also owned their own weighing scales and had weighed themselves regularly prior to participating in the study:

"I was quite happy to do it to be honest because I have my own scales" (050, 31 years, obesity, primiparous, lost weight).

Participants that were unable to weigh themselves regularly or were upset by the progress they were making received much less pleasure from self-weighing and were more likely to view it as a negative experience:

"Erm, well in reality, because it didn't really work for me. So, it was you know- that's a slightly depressing thing for me really…" (023, 34 years, obesity, primiparous, gained weight).

4.4.3.4 Disconnect between body weight and body shape

Several women stated that there was a discrepancy between the visible changes they could see on their bodies and the weight shown on the weighing scales:

"…so I found that I was losing a lot of inches and I was fitting back into my pre-pregnancy clothes but I didn't seem to actually lose that many pounds" (051, 36 years, overweight, primiparous, lost weight).

4.4.4 Theme 4: Experiences of being weighed during child immunisations

The experiences of child immunisations varied quite a lot between the women based on the amount of trepidation experienced about being weighed by the nurse as well as if they were weighed before or after their baby had been vaccinated. In addition, the interaction (both verbal and non-verbal) with the nurse was pivotal to their experience of being weighed by the nurse.

4.4.4.1 Mixed emotions

Some women commented on feeling slightly nervous, uncomfortable or ashamed about being weighed by someone else at first, but that these emotions quickly dissipated:

"when somebody else was doing your weight, you do feel erm you do feel like, 'I hope I haven't - I'm not going to break the scales. I hope it's not going up to too much,' you know. I don't know, you do - weight's one of those issues that it's okay when you're weighing yourself but you don't necessarily want everybody else to weigh… but yeah, for a split second you do think, 'Oh,' then it's done and you're, you're off again. So I think it's a good idea for the nurse to weigh you ..." (034, 33 years, obesity, multiparous, lost weight).

Participants 052 and 013 both mentioned that they had been weighed regularly throughout their pregnancies which meant that they were not as concerned about being weighed by the nurse during child immunisation appointments, particularly as the nurse had not remarked on their weight:

"I think at this point I was kind of like, I'm used to it, erm they never said erm, I would have felt conscious if they'd said something, made a comment or something like that but they didn't, they just said oh we need to weigh you as part of the study…" (052, 25 years, overweight, primiparous, gained weight).

A significant number of women were empathetic towards women who may find being weighed by someone else uncomfortable.

4.4.4.2 Character and attitude of nurse

There were notable differences in the women's descriptions of being weighed by the nurses that appeared to be dependent on the demeanour of the nurse and how the nurse interacted with the woman:

"It depends on the nurse that you have. I think it depends on how open and brought in how much, erm, you know, they might talk to you about it" (022, 38 years, obesity, multiparous, lost weight).

The mothers that had had a positive experience and that were able to establish a rapport and engage in a general chat with the nurses tended to have a high regard for the nurses and valued the interaction:

"The nurse at the immunisation was okay. She was also okay. She's old person so she's like your mother. She was just talking to me so nicely…she was encouraging me" (045, 33 years, severe obesity, gained weight).

One participant 023 had been dealing with a death in the family and talked about how she felt like the nurse was judging her progress during her baby's three-month immunisation appointment:

"I got the impression from the nurse's body language that she thought that I wasn't trying hard enough, that I should have maybe done better by that point but as I say at that point in my life, at that time, it was a really tough time" (023, 34 years, obesity, primiparous, gained weight).

There was no apparent association between positive reinforcement from the nurse and women that were more motivated to self-weigh or access the One You website.

4.4.4.3 Convenience

Some participants commented on the convenience of being weighed during child immunisation appointments as it was principally merging two appointments into one:

"To be honest I think I probably wouldn't go to an appointment just for me anyway, about weight loss, so I think it kind of works to have it in that appointment" (050, 31 years, obesity, primiparous, lost weight).

4.4.4.4 Comparison to a commercial weight management programme

A few women considered being weighed by the nurse similar to being weighed at a commercial weight management programme. Some women seemed to like the idea of someone else weighing them, especially since there was no pressure to lose weight by the next immunisation appointment:

"I think it's the same as going to slimming world" (050, 31 years, obesity, primiparous, lost weight).

4.4.4.5 The need to remind nurses

Some participants reported having to remind nurses to weigh them during immunisation appointments. They tended to raise this before any of the vaccinations were given as mothers were aware that their babies would be upset after the immunisations:

"I needed to remind them and the reason was because I knew that had to be done as well, maybe they would have asked me about this but because I knew it had to be done and I was mindful that I need to weigh myself first because again afterwards you don't want to have the baby upset so I would remind them, I'd say I need to be weighed first [laughs]" (009, 28 years, overweight, multiparous, gained weight).

4.4.4.6 Consistency

Being able to see the same nurse for each immunisation appointment was beneficial and valuable to some participants, as it helped develop a relationship between the mother and nurse and ensured continuity in the information and support that was provided:

"but I think having the same nurse, it was nice because you had that central point whereas maybe three different nurses you probably wouldn't because one might say one thing, one might say something else to you…" (022, 38 years, obesity, multiparous, lost weight).

4.4.4.7 Importance of the timing of being weighed

There were a range of reasons why women were weighed after the nurse had vaccinated the baby. The main reason was because both mother and nurse had forgotten or because the nurse had insisted on weighing after the vaccinations had been given. Nevertheless, all the women that had been weighed after immunisations talked about it making them feel stressed:

"I said oh I think you've got to weigh me, she then said oh I'll do that after the immunisation, erm for the baby, so didn't really give me an option to do it before or after. I… it was actually really distressing to have it done after because he'd just been immunised, he was screaming, I just wanted to cuddle him and actually at that point the last thing I wanted to do was be weighed but I wasn't given a choice at the beginning" (060, 31 years, obesity, primiparous, lost weight).

"I think being weighed before, particularly when there was quite a few injections probably worked better because I think I was aware of the fact that the last time there was, I

think we had two in one leg and then one in the other and he was quite upset after that. I think if I had to be weighed it would have been quite tricky to put him down then get weighed" (013, 40 years, severe obesity, multiparous, lost weight).

4.4.5 Theme 5: Thoughts about using a website (One You) as a source of information

Women were asked their views on being referred to a website as a source of information on postnatal weight management. Overall, they liked the idea of being able to access information online and at a time that was most convenient for them, but felt that the One You website did not address their specific postnatal weight management requirements.

4.4.5.1 One You content

Many of the participants thought that the website was too generic and provided information they already knew and perceived as common sense, and that "*it wasn't something mother-friendly" (049, 32 years, overweight, multiparous, lost weight)*:

"*I couldn't really take anything specific out for myself from there, yeah. And for somebody who doesn't know what a healthy lifestyle is, they might find it more useful, but I know that those things are good for you anyway"* (009, 28 years, overweight, multiparous, gained weight).

4.4.5.2 Website alone inadequate

Some of the mothers interviewed did not think a referral to a website was enough support and they expressed a desire for more engagement with the nurse:

"…maybe more of a discussion about um ideas, discussing things from the website maybe to see what I actually access rather than just say have you accessed the website. Actually, having a discussion about which parts of the website I'd accessed and what I

thought of it. And maybe bring in um sort of a more um yeah so, an actual discussion rather than just this is the advice from the website, actually talking about it and bringing a more personal approach to it possibly might have been good" (032, 39 years, overweight, multiparous, lost weight).

One participant even stated that being referred to a website would work better if the nurse highlighted specific parts of the website that may be of interest or useful to the mother during immunisation appointments:

"I think it's useful, erm, erm perhaps going through with a professional might have given me the position that I don't know, might have had more of an impact, even if you combined the two and sort of pointed out what were the most useful things on the website" (050, 31 years, obesity, primiparous, lost weight).

It was noted that being referred to a website did not subject the women to any additional pressures, but the result was that some women did not feel obliged to visit the website and engage with it:

"plus, as well if you don't want to look at it, you don't have to look at it" (022, 38 years, obesity, multiparous, lost weight).

4.4.5.3 Active 10

The Active 10 app (a physical activity app included in the One You website) was frequently downloaded and received positive feedback due to the achievable goal of at least one period of ten active minutes per day in a row. The mothers stated that this meant that it was easier for them to fit it into their daily routines:

"So, it has motivated me the other day to kind of think, 'Yeah, I need to get my 'Active 10', so I'm just going to take baby to the park and just do a really quick walk round just to get that..." (023, 34 years, obesity, primiparous, gained weight).

4.4.6 Theme 6: Views on a future postnatal weight management intervention

Many women discussed how important suitable postnatal weight management interventions were to them and shared their opinions on what they considered suitable components for an intervention

4.4.6.1 Motivation for weight management

Participants described positive emotional responses when the scales showed that they had lost weight, but many reported that their feelings about their body were more important to them than the number on the scales:

"Yeah and just doing more about body positivity in that way really, more about how I feel rather than what the number says" (061, 31 years, overweight, multiparous, lost weight).

Many expressed a desire to feel healthy and this definition of healthy varied from being comfortable in their clothes, to being more physically active, to having a healthy BMI.

"…if someone just said to me, oh you've put on two stone but you still fit into all your clothes and actually from a health perspective you are very fit and healthy, the weight loss wouldn't bother me so I'd be happy at the current weight, whereas at the moment I don't feel that healthy and I feel I could be much healthier so weight loss is almost a secondary thing to me, it's the inches and the health side of it" (051, 36 years, overweight, primiparous, lost weight).

One participant verbalised that being fit to her included losing weight:

"I think when I start to feel a little bit more tired, a bit like erm lethargic I guess and I think right I'm going to get fit, I'm going to lose a bit of weight and then I do that for a while and then stop!" (052, 25 years, overweight, primiparous, gained weight).

A couple of women mentioned that they tried to get more active because they wanted to improve their health:

"…mostly to get more healthy because I had a bit of a problem with my back err, back pain…" (009, 28 years, overweight, multiparous, gained weight)

Whereas poor health inhibited another participant from engaging in physical activity:

"I had a back problem which stopped me from exercising…" (032, overweight, multiparous, lost weight).

Having overweight or obesity was not a concern for some participants as long as it did not affect their general health:

"…I am concerned by health, but you know a few extra pounds you know is fine, yeah it's not one of my huge concerns" (032, 39 years, overweight, multiparous, lost weight).

Other women seemed to accept that pregnancy had changed their bodies and were trying to come to terms with their new bodies by attempting to embrace a more body positive attitude and dressing for their new shape:

"Yeah, I just want to get to a point where I can walk down the street and think, I look okay…whereas now I'm walking down the street and thinking, oh God I'm bulging over these trousers. Er, or oh she's wearing, we're the same size but she's wearing better clothes that fit

her and so she looks better, I'm still wearing my old clothes that are too small. Er, so just being at a point where I'm happy with what I look like regardless of what that is, er, I mean ideally, I'd like to be not having to think, oh God I'm bulging over these trousers because I don't want the bulge over my trousers" (061, 31 years, overweight, multiparous, lost weight).

4.4.6.2 Lack of information specifically for postnatal women

Many participants commented on the limited availability of information specific to postnatal weight management. Many discussed how difficult it was to find reliable information and support (such as exercise classes) that was available locally. Some stated that they had only discovered some of the existing services through word of mouth whilst attending other baby-centred activities:

"… but as I said I wouldn't have known about the free stuff had I not spoken to one of the mums from antenatal that I got on quite well with" (022, 38 years, obesity, multiparous, lost weight).

Women expressed concerns regarding the conflicting information given online, which caused them to be unsure about which forms of physical activity and specific exercises were safe to perform during the postnatal period.

"I assumed it would be something quite tailored to new mums you know like what, what is safe to do at the moment and what isn't because there's a lot of information on the webs-, online- on websites but erm, you know, it's not for someone that's just had a opera-, a major operation like I have or been through pregnancy…" (023, 34 years, obesity, primiparous, gained weight).

One participant talked about how fortunate she was for being able to find a rare postnatal exercise class. It gave her the confidence to start running and correct her friend when she'd mentioned that running was bad for her pelvic floor muscles.

"I was lucky in that I go to a postnatal exercise class, but I think a lot of people who don't they don't know when they can start exercising, what exercising they can do . Er, you know I had a friend who said to me, oh no you shouldn't be running because of your pelvic floor… Er, whereas the postnatal instructor had said it's actually core and stomach exercises that you need to be, have issue with, running is absolutely fine for your stomach muscles. So people don't really know what they can and can't do" (061, 31 years, overweight, multiparous, lost weight).

4.4.6.3 Need for support

Many of the participants mentioned that group activities with other postnatal women would be beneficial for weight management as it would provide an environment in which women with similar lives and experiences could congregate regularly and share information on effective weight management strategies. The need to socialise with other mothers and get out of the house was a concept many participants welcomed. One participant talked about how these groups could prevent women from being housebound and lonely:

"…for most people who you know don't really even know other mums or whatever, to have someone to say right let's focus on you and your weight and your body confidence and things like that is actually something that would be useful for a lot of people" (061, 31 years, overweight, multiparous, lost weight).

A desire for more attention for mothers during the postnatal period was noted by some participants who described that after the birth of their baby, there was a notable shift in focus from mother to baby. This shift was evident in many aspects of their life including the prevalence of baby centred appointments, playgroups and information:

"I Google everything… there's a lot of stuff on babies and not a lot on mums really so I think for that like it has been good to have a little bit of like, oh that's something for me because you get all the attention, don't you? [addressing the baby]" (052, 25 years, overweight, primiparous, gained weight).

4.4.6.4 Need for sensitivity

Some women were comfortable with their weight being discussed during child immunisation appointments as long as it was done so with sensitivity:

"I think number one, having like the bringing it up in a sensitive way" (050, 31 years, obesity, primiparous, lost weight).

A few participants reported that they did not want to feel pressured to lose weight during the postnatal period or be made to feel like their weight management attempts were inadequate. Not wanting to feel pressured filtered into their views about every mother being weighed during child immunisation appointments. Overall, many participants agreed that weighing every mother during child immunisations was a good idea. Nevertheless, many interviewees stressed that it had to be optional and up to the mother to decide to be weighed:

"I suppose if it was being classed as something that was optional to do we don't have to weigh you but you have the option to because some people I know are quite self-conscious

of their weight and aren't very comfortable doing it but I do think it's quite helpful to have a professional who has got scales that are calibrated regularly to weigh you so you know exactly what you are at…" (051, 36 years, overweight, primiparous, lost weight).

Raising the topic of weight and being weighed by the nurses was considered an issue that the women themselves should raise first. Otherwise it may not be suitable as each woman is different and being forcefully weighed could potentially be detrimental to the mental health and wellbeing of some women:

"Yes, that would be inappropriate because many people might be very sensitive about this and erm everybody has a different level of sensitivity. So, someone might get very upset and you know, disappointed, they could get postnatal depression and things like that triggered and that's not right" (009, 28 years, overweight, multiparous, gained weight).

4.4.6.5 Timing

There were almost two distinct groups of participants in this study, those who were content with the timing of the intervention, and those who felt it was too soon postnatally to start thinking about weight management. One group of mothers felt that it was important for weight management to be something they should at least have in the back of their minds during the early postnatal period:

"Er, when you first contacted me, I was definitely at a point of, right I want to think about this but every other person in the world was saying to me, no you don't need to think about this… I think it is important to think about it from that early probably" (061, 31 years, overweight, multiparous, lost weight).

However, other women felt that weight management should not be considered for the first six months or so after childbirth in order to allow women time to acclimatise to their new role and associated responsibilities:

"Weight's not really of any you know, if it happens, it happened. If it doesn't happen, it doesn't happen. I don't care really, I'm just trying to survive. So, I think maybe yeah, perhaps later on it (weight loss) might be more likely…" (013, 40 years, severe obesity, multiparous, lost weight).

A couple of mothers advocated that it was too early and that postnatal women should not have to think about their weight. Some women implied that mothers that were able to return to their pre-pregnancy bodies quickly placed pressure on them to also do the same:

"…it is too early and erm I think that maybe a woman should be encouraged as well not to you know think too much about it because this, [sigh] in an age of, of those moms that lose weight very quickly that gets to you sometimes but it shouldn't be, it shouldn't be the case" (009, 28 years, multiparous, overweight, gained weight).

Another mother suggested that weight gain during pregnancy did not warrant the same attention that is placed on having obesity for the general population:

"…obviously it's something a lot of people are aware about – you know, obesity and everything and that whole 'Crisis for Britain' and everything and, and I, and I take that completely onboard. I think it is a concern, but I don't think it's a con-, - it's a concern for new mums, you know [laughter]. There are reasons your body's changed shape and everything and it's not because you've been eating all the pies for nine months" (023, 34 years, obesity, primiparous, gained weight).

4.5 Results - nurses

A total of seven out of the 10 nurses that were initially trained to deliver the intervention were interviewed. Two of the nurses interviewed worked at more than one of the practices randomised to deliver the intervention therefore, at least one nurse from each practice was interviewed. Three interviews were conducted face-to-face, and four were conducted via telephone (Table 17). Six of the seven nurses that were interviewed were female and five added during the interview that they themselves were parents.

The practices the nurses worked at were slightly different to each other due to variations in the time allotted to immunisation appointment, which ranged from 10-30 minutes. Two nurses stated that their practice held child immunisation clinics on a specific day each week. The five remaining nurses specified that immunisation appointments were booked in at random at their respective practices. Most practices allocated 20 minutes to each child immunisation appointment, with two practices assigning an additional 10 minutes for the first set of child immunisations at 2 months old.

Six of the seven nurses reported that they had received training on how to deliver the intervention and three nurses read the nurses training manual. The nurse that had not received training was aware of the study and read the nurse's training manual. Two nurses visited the One You website.

Based on the nurse interviews, delivering the intervention added between two to five minutes on to the duration of immunisation appointments. The nurses delivered the intervention to between two and six women each.

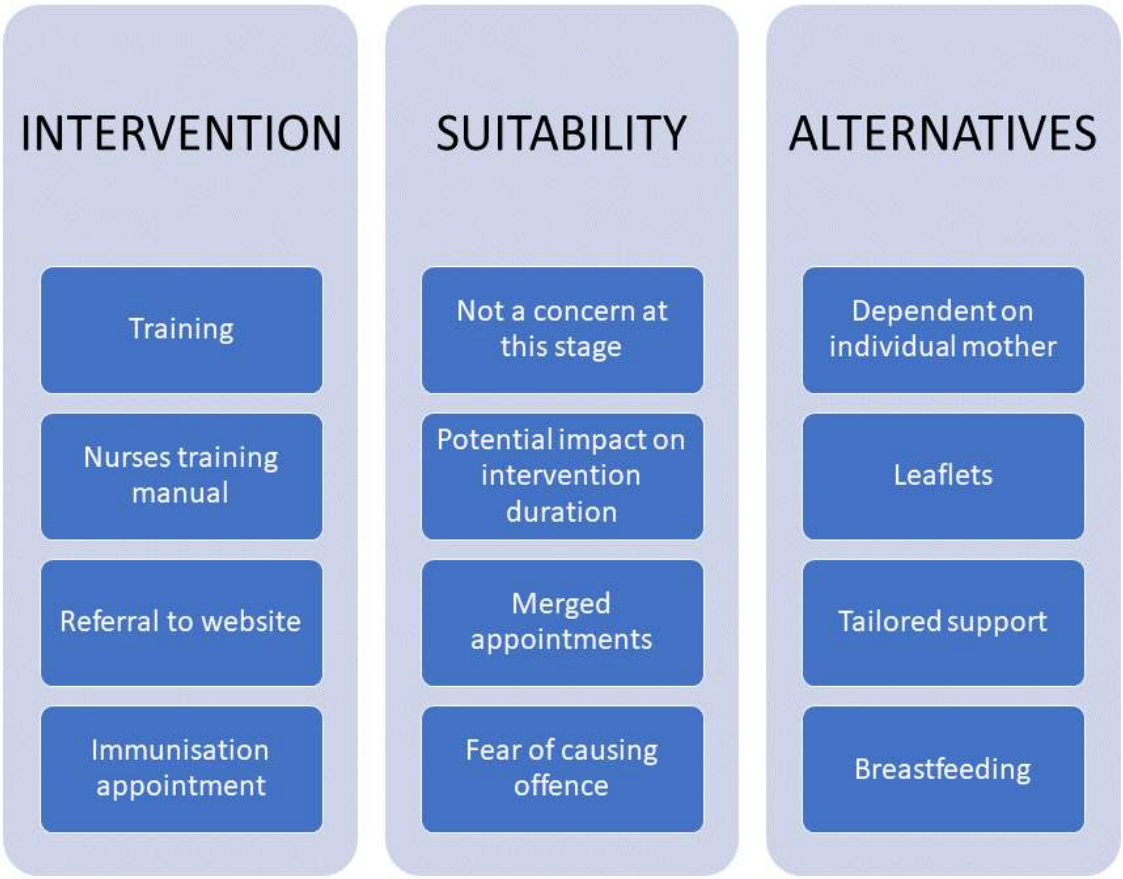
Table 17: Characteristics of nurse and their GP practice

Nurse ID	Gender	Mode of interview	Time allocated for immunisation appointments	Booking of immunisation appointments	Number of immunisation nurses	Received training	Read training manual	Looked at One You?	Time added to appt delivering intervention	Number of women recruited from practice
N001	Female	Face-to-face	15 mins	Ad-hoc	1	Yes	Yes	No	2 mins	2
N002	Female	Face-to-face	20 mins when booked correct, if not 10 mins	Ad-hoc	3	Yes	No	No	2 mins	2
N003	Male	Face-to-face	30 mins 1st imms 15 mins for others	Ad-hoc	2	Yes	No	Yes	3-5 mins	4
N004	Female	Telephone	20 mins	Ad-hoc	2	Yes	No	Yes	5 mins	4
N005	Female	Telephone	20 mins ad-hoc appts either 10- or 20-mins	Immunisation clinic & ad-hoc	1	Yes	Couldn't remember manual	Couldn't remember	2 mins	3
N006	Female	Telephone	30 mins for 1st imms appt 15 mins for others	Ad-hoc	2	No	Yes	No	5 mins	2
N007	Female	Telephone	30 mins	Immunisation clinic & ad-hoc	1	Yes	Yes	No	2 mins	6

*imms abbreviation for immunisation, appt abbreviation for appointment

Using the same framework analysis process as described earlier for the women, three key themes and related sub-themes emerged from the nurse interview data (Figure 9). The themes that emerged from the nurse interviews aligned with the questions asked during the semi-structured interviews as the questions from the interview topic guide were used as headings for analysis. The themes are ordered based on the nurses' experiences of the intervention (from training to delivery); nurse views on the appropriateness of the intervention and suitable alternatives or adjustments that could be made to the intervention.

Figure 9: Nurse themes and sub-themes



4.5.1 Theme 1: Nurse experiences of the intervention

This theme describes nurse attitudes towards the key elements of the intervention, training, signposting to a website and weighing postnatal mothers participating in the study during immunisation appointments.

4.5.1.1 Training

All but one of the nurses had received training from the research team and expressed that it was suitable and straightforward:

"The training itself, was perfectly adequate, so what we had to do, was very straight-forward, what we had to do, erm, quite self-explanatory" (N003, face-to-face).

One nurse did not consider the brief training received as actual training, but that it was appropriate to equip her to deliver the intervention:

"I think I was just told to signpost them to places because I was saying how are we supposed to talk to them about diet and things when we've only got this appointment and they was like, no, no, no you don't have to do anything you just have to signpost them, all you've got to do is weigh them and if they ask you any questions signpost them, that was the extent of it really, there was no real training as such if you know what I mean just telling us what we had to do and that's it" (N002, face-to-face).

The nurse that had not received researcher-led training, commented that a colleague had given her a copy of nurses' training manual. She mentioned that her occupation did not provide her with enough time to read additional material and would therefore have benefited from receiving brief information or training from the research team:

"…more time to read it or somebody just came and just gave a quick chat" (N006, telephone)

This nurse also highlighted the importance of regular contact between the research team and practice staff, to ensure that all practice staff responsible for delivering the intervention are aware of the study:

"Er, one of the other practice nurses, somebody must have spoken to her because she passed that information on and then she went off and had her baby so any queries that nurse has gone off and, er, the person that was given all the information is no longer there so…" (N006, telephone).

The sentiment for regular contact with the nurses during the study was expressed by another nurse:

"…well I haven't had any contact from the beginning until now. Erm, but erm, maybe a brief visit halfway through just to see how things are going maybe…" (N004, telephone).

4.5.1.2 Nurse's training manual

During every practice training session, nurses' training manuals were provided to each nurse responsible for child immunisations. The manual contained details on how to identify participants and instructions on how to deliver the intervention. One nurse could not remember receiving the manual, three claimed they had had a brief look at it and three nurses stated that they had not read the training manual. The three nurses that had reviewed the manual stated that the information was clear:

"…quite simple to read, quite easy to read and didn't have any problems" (N001, face-to-face).

One nurse discussed how busy she was as a practice nurse and was only able to skim through the manual briefly and that if she had been given some protected time, she would have read the manual in full:

"Er, I think that we were just given these, er, folders and to be honest I did have a quick look at it, I didn't go on to any of the websites too closely because again the time and location is something that you've got to do in your own time [yeah], er, which is not always possible in practice nursing. We do other things like – like now, er, I'm trying to catch up on my morning clinics, er, that I've completed everything so…" (N006, telephone).

4.5.1.3 Referral to a website

When the nurse interviewees were asked if they had accessed the One You website, two nurses (both from the same practice) stated that they had visited the website. One nurse had a brief look and the other nurse had familiarised herself with the website and was vocal about the shortcomings she observed:

"The One You website is rubbish, it really is rubbish. There's so little useful content on it. The magazine style is just, you're continually flitting through other screens, it takes you mostly to an NHS Choices website. You know, it's, it's, I think it's confusing and not great, its all, I don't know, it's all fur coat and you know, nothing underneath, really, its, that's my feeling about it" (N004, telephone).

The lack of nurse interest in accessing the website was explained by one nurse as being inadequate as women presenting at their practice seeking weight management advice would prefer to receive support directly from them as opposed to being referred to a website:

"if they try and start to try and talk to you about diet, you know, because sometimes they don't want to go off and look on websites and things like that or they want to actually speak to a person, and that's where I think it would be difficult, if they, you know, if they wanted something there and then because you've got to sort of strike while the iron's hot if you tell somebody oh go away and look it up, chances are they won't, but if they are there and they are motivated then you've probably got a good shot at it really" (N002, face-to-face).

A couple of nurses mentioned that the cohort of patients registered at the practices they worked for were interested in information presented in leaflets:

"I wouldn't say that they prefer it, I did say that they're more receptive to, er, leaflets from seeing patients come in that have been waiting for me and they've picked something up in the waiting room" (N006, telephone).

Several nurses could see some of the benefits of signposting mothers to a website for weight management, especially for women that did not feel comfortable seeking help from them, or women that were comfortable using technology. Nevertheless, it was common occurrence for nurses to view information and support provided face-to-face as the gold standard:

"I think because so many people are internet savvy these days and are so used to looking things up, I think, and having apps to help you left, right and centre, I think it's much more the norm in that generation than my generation. So I think probably they would be much more keen to sort of look at something like that rather than, I mean I think that verbal intervention is always when it's one to one is always good anyway because you can watch the person and you can see how they interact and, er, but sometimes it's quite nice to sort of

you know do it in the privacy of your own home if you're sort of struggling with something and you don't want anybody else to know" (N007, telephone).

4.5.1.4 Immunisation appointment

The timing of the interviews, in addition to the small numbers of women each nurse delivered the intervention to made it difficult for some of the nurses to recount their experiences:

"I can't remember, I really can't remember, I can't even remember the patient's baby or the mum exactly right now" (N006, telephone).

The yellow PIMMS sticker on the front of the personal child health record (red) book made women participating in the study easily identifiable:

"fairly easy because they've got the yellow sticker on the front of their red books" (N005, telephone).

Nurses also stated that many of the women were eager to inform them that they were participating in the study and therefore expecting the nurses to weigh them during child immunisation appointments:

"Erm, there was a sticker, wasn't there, on the front of the red book and Mum would also tell me. Erm, so it was, it was easy to identify on the book, on the baby's record book and Mum, like I say Mum would tell me anyway and remind me" (N001, face-to-face).

One nurse commented that despite the women being keen to be a part of this study, she actively had to raise the topic of weighing them during baby immunisation appointments:

"And a lot of the women were, the few I saw well I think all of them were absolutely happy for it because they weren't sort of saying, oh I wish I hadn't done it or anything like that, so they were quite happy to be weighed. I don't think any of them came in saying, I'm on the PIMMS study don't forget to weigh me, it was me that prompted them every time" (N007, telephone).

Many nurses acknowledged the delicacy related to weighing patients, especially new mothers, but took consolation in the fact that the mothers had agreed to participate knowing that they would be weighed by them:

"Well I mean the thing is they've agreed to it themselves, so I didn't have an issue with that, if I was sort of manually making them get on there against their will that's completely different and so I'm fine with that" (N005, telephone).

Many of the nurses commented on how little time weighing mothers and completing the weight record card took during child immunisation appointments. They stated that delivering the intervention added between two to five minutes to the appointment.

4.5.2 Theme 2: Suitability

This theme captures the nurses' perceptions on the appropriateness of the intervention in relation to the timing of the intervention and its components.

4.5.2.1 Timing of intervention

Many of the nurses highlighted that promoting weight management from two months postnatal was too soon for residual weight retention from pregnancy to be addressed. One nurse considered the intervention very harsh for new mothers:

"And when they're at this really difficult time in their life, I just think it's, I don't know, they're vulnerable, at that point and it almost feels a little bit you know, emotionally abusive that you're getting them and asking them to make other big lifestyle changes you know, if they could lose weight easily, they would have done so before they had the baby you know, asking them to lose weight after a baby, is extremely difficult for you know, for most women I think. It's not a bad goal to have, it's the right goal, and we need to support them, but I think, it just feels the wrong time, I think so" (N003, face-to-face).

Another nurse was concerned that raising the issue of weight at a stage when women are particularly vulnerable may be detrimental and trigger postnatal depression:

"at the same time, you don't want to put mums into postnatal depression really they feel that the baby is the reason why they've put on so much weight and they can't lose it" (N006, telephone).

A few nurses were open to weight management strategies being available to women at this early postnatal stage but explained that this cohort are very individual and that the timing of this intervention may be suitable for some, but others would not be as receptive at this timepoint:

"Erm, it, it's so individualised, isn't it? So, I think it wouldn't harm offering. If they say no, they say no, but I don't think it'll do any harm offering that to them, erm, but again it's everybody, every, every mum's new mum's different so I, to be, to be fair I'd probably name a good few that would, would agree and would be happy to do it whereas I know there's a few that wouldn't" (N001, face-to-face).

Many of the nurses that were parents themselves were especially sympathetic to the prematurity of this weight management intervention:

"but I did feel a bit sorry for her because I just felt you know, you've been through a lot, you've had a baby and now we are checking on your weight so quickly, do you know what I mean? I just thought, me having had two children, that would have been the last thing that I would have wanted somebody checking me after I'd given birth eight weeks ago, you know?" (N002, face-to-face).

One nurse suggested that rolling the intervention out on a national level may impact on breastfeeding rates as mothers may opt to formula feed so that they can diet:

"I also get concerned about you know, potential impact on breast feeding as well and I think that is something that you know, the study needs to be really erm, I don't know whether that's an outcome on your study or whether that's something that's been measured but if we start doing on a population basis, and women erm, feel that erm, the choice people make, it's their life, maybe less compatible with breast feeding if they need to go out to the gym or they feel like they want to change their diet and you know, I think you have to be really careful with new mothers of any intervention that you do, doesn't impact on their breast feeding decisions as well" (N003, face-to-face).

It was also noted by some nurses that there were benefits to combining the two appointments, or at least arranging a weight management appointment with the same nurse just before child immunisation appointments:

"I would say that's the best isn't it, because they're reminded to come for the child immunisation, and if they don't turn up, we're ringing them, "Your vaccination is due" so

that's an ideal time isn't it, it's not, they haven't got to make a separate appointment for it so, you may as well do it all in one. And they're more likely, hopefully they're more likely to come for the child vaccination, so, we certainly don't see many DNAs in this surgery, so it's probably the best time really. They haven't got to find any child sitters or anything, so, that's a plus, it's all good" N004, telephone).

4.5.2.2 Impact on appointment duration

Despite intervention delivery having a very modest impact on the duration of immunisation appointments, many nurses were concerned about broaching a sensitive topic like weight during appointments. Some nurses viewed the act of weighing women during immunisations as having the potential to ignite a conversation that would require them to spend time that they did not have during time restricted appointments to offer weight management support:

"the only issue I had was the time available because if you can sometimes open up a can of worms and you don't have that time. I mean my focus in a baby clinic specifically is to deal with the vaccinations that that baby needs and to make sure that they're up to date with that. If then we move off into a different area, talking about weight for mum, yes that's important as well. But I'd feel that I'd probably need another 15 minutes to go through everything so I'd support her, I can't just skim over it and say, let's get you on the scales, let's get your weight, thanks very much and that's the end of it because you need to back that up as well" (N005, telephone).

4.5.2.3 Merged appointments

The concept of managing two patients during one appointment was received with contrasting views by the nurses. Many appreciated that mothers were self-sacrificing and

would be less likely to book and attend appointments for themselves. However, a couple of issues relating to patient safety were raised in relation to managing two separate patients during one appointment:

"…cause with imms, one of the really important things you have to focus on is safety at that appointment. And I think whenever you add in another topic, that is entirely separate and unrelated, there is a risk that your attention is diverted from one thing to the other and actually, the immunisation aspect of it becomes less safe" N003, face-to-face).

"… if you're flicking from child's records to Mum's records, then you're in the danger that you're in the wrong records" (N004, telephone).

4.5.2.4 Fear of causing offence

Some of the nurses were cautious about causing offence, as a result, many talked about gauging the woman's responses to neutral questions related to the study before broaching the topic of weight:

"I often kept the initial questions quite neutral just to get them to kind of just tell me their thoughts and I could kind of gage, you know, how emotionally significant the conversation was going to be for them" (N003, face-to-face).

Some nurses mentioned that they adjusted the depth and amount of weight related conversation they had with the women after they had attempted to evaluate how they were feeling about the intervention:

"It wasn't a big conversation, she was quite, erm, oh you know, I haven't got the time for this kind of thing… not me… not for me weighing her, just hadn't got the time to be

faffing about with a diet you know that was her answer but that was the only one that I seen" (N002, face-to-face).

One nurse commented that she felt uncomfortable initiating weight related conversation with participants who had gained weight and was scared to because she did not want to cause distress:

"maybe because she'd gained and not lost that I didn't comment. Erm, obviously I didn't want to upset her as well. Erm, I think if she'd had lost, I would have, you know, congratulated and encouraged her as well but I think because she had gained, I didn't really say much" (N001, face-to-face).

Being a part of a weight management study eased the topic of weight being brought up by the nurses during child immunisations. However, some nurses voiced that it would be difficult or inappropriate to raise a woman's weight during child immunisation appointments outside of the study:

"I think obviously you know, if they had not been expecting that, then that would have been a real leap at "Why would you be doing that when you've come for the baby imms". But because they were expecting it, its fine" (N003, face-to-face).

One nurse stated that being unaware of women's pre-pregnancy weights, she would be scared to offend women who were overweight or with obesity prior to pregnancy and had already returned to their pre-pregnancy weights:

"*It's just cause some mums as well are actually, erm, overweight before they've even had a baby as well so it's hard if I've not met Mum before, I don't know what, whether she's*

reached her goal or whether she's, she's actually gained a lot of weight or what. So it's, again it's quite difficult to, to tell" (N001, face-to-face).

However, many nurses were reassured that mothers would adjust to being weighed during immunisation appointments if it was part of routine care and offered to all postnatal women:

"…if they all know that every single mother's going through that, then it's not going to be much of an issue, but you're always going to have one person that's, "I don't want to be weighed", you know, you're always going to cross that regardless of what's going on, you know that's always going to be a, there's going to be somebody that isn't going to like it you know, but I wouldn't have thought there'd be many women like that after giving childbirth and stuff" (N004, telephone).

4.5.3 Theme 3: Alternative postnatal weight management interventions

When nurses were asked for suggestions on suitable postnatal weight management interventions, there was often a pronounced pause and many initially admitted that that it was a difficult question to answer. Upon reflection, the nurses were able to offer suggestions on the content of potential postnatal weight management interventions.

4.5.3.1 Governed by the postnatal women

Many nurses stressed that the onus should be on postnatal women to determine when they would like to initiate managing their weight. They also stipulated that no mother should be subjected to weight management interventions if they were not amenable, unless they suffered with severe obesity:

"*if, I personally if I just had a baby and obviously you're going to be a bit heavier than what you normally would be, if a nurse has said to me, 'You need to start looking at your weight and start, erm, identifying ways of reducing your weight', I think I'd be quite offended. So, it's quite, I find it really sensitive to discuss, erm, unless they bring up the subject to me, erm, first and then I'd give advice. But, erm, unless mums are really obese, I wouldn't really mention it to be honest, erm, cause it's quite, quite sensitive"* (N001, face-to-face).

Making weight management services for postnatal women optional and accessible throughout the first year after childbirth was considered by many of the nurses as ideal, because women could decide when and if they saught assistance:

"I think the women who want it, it's probably not a bad time, in that immediate year because that's the time when they're off on maternity leave, they've potentially got that space to you know, make lifestyle changes but for women, you know, who haven't made that choice to address it, it seems like, I don't know, maybe we catch them at the year point, erm, or I don't know or if they're offered it as an optional thing" (N003, face-to-face).

4.5.3.2 Leaflets

Nurses shared that leaflets were frequently used to disseminate information to new mothers. Many nurses therefore considered leaflets to be a convenient vector to share postnatal weight management information as they instigated brief conversations with additional follow-up that was determined by the patient:

"I quite like leaflets personally, erm, and I give them out a lot with all my chronic reviews and, erm, so I do like, I like talking through the leaflet with them and then giving it

them to read at home. So, I do like leaflets. Erm, it's just a case of really website, well I suppose website and the leaflets, whether they've got time to read it. So the leaflets I give at least I explain a little bit, erm, of it and talk through it whereas on a website I wouldn't really have time to get that up, quickly show Mum cause it'd be something that she'd have to do individually rather than me talk through it with her really" (N001, face-to-face).

The use of leaflets was further justified by some nurses who considered giving women a physical item as opposed to verbally signposting them to a website as a plausible alternative:

"I think to give out some paper, some leaflets so they've got it there and then, they are more inclined to just you know to go and have a quick bath or something, read it in the bath or if the baby's gone to sleep, you know, or sitting on the bus or something to read something than start trying to look on websites and things, that's what I'd do personally" (N002, face-to-face).

One nurse discussed the importance postnatal women having incentives to lose weight and suggested that fitting back into their clothes and returning to work could be potential motivators for weight loss:

"…maybe trying to fit back into her work clothes. And maybe the other mums trying to fit back in their informal clothes, I don't know but then some mums take a year or longer or maybe don't go back to work what would the incentive be I'm not sure" N006, telephone).

4.5.3.3 Tailored support

During the first year of life, babies receive regular check-ups from various healthcare professionals. The nurses noted that postnatal women often bring their babies to these appointments and therefore, every healthcare professional that comes into contact with

postnatal women could play an integral role in raising the topic of weight management, and help ensure the continuation of care. One nurse suggested that this could be initiated by placing a weight management leaflet into the packs all women receive shortly after giving birth:

"…a leaflet, you know when they come away from the hospital… maybe in those kinds of packs, some information there to initially start it rolling erm, with regards to exercise and diet, erm and things like that and we can carry, you know, they've already seen it then haven't they? And then we can carry on and promote as we do anyway, you know, like diet education and weight education things then" (N004, telephone).

Postnatal weight management groups were suggested by a couple of nurses as they could be personalised to address the unique needs of postnatal women:

"I think it would be good to have some sort of, er, postnatal weight group like a Weight Watchers or a Slimming World type group where women could go to take their babies along as well and maybe have some sort of you know care for the babies in the background while they're playing and whatever, er, being looked after. And mums then could talk to somebody specifically as a group and bounce off each other as well, I think that would be a nice idea" (N005, telephone).

Groups that consisted of regular weighing were also considered plausible due to the external accountability these provided:

"I do think that some women do like a weight check, I think that is quite useful you know that they are weighing somewhere outside of their home because sometimes you get put off don't you or you get sort of, you think oh, it sounds awful but you know if you've ever

gone to Weight Watchers or anywhere like that you think oh I'll be good because I know I'm going to be weighed by some random person. And it works better than if you're thinking try to do it on your own, in your own home" (N007, telephone).

4.5.3.4 Breastfeeding

Two nurses expressed the belief that breastfeeding promoted weight loss. One of these nurses also suggested that by endorsing breastfeeding, many benefits including weight loss could be attained:

"personally, I find breastfed babies' mums are a lot more in shape, erm, compared to bottle-fed babies unless I'm being quite stereotypical" (N001, face-to-face).

"the best way for them to lose weight is to continue breastfeeding, you know, so maybe actually rather than us weighing women, maybe supporting breastfeeding would be a more cost-effective intervention for all sorts of reasons, yeah." (N003, face-to-face).

4.5.4 Conflicts and similarities between the women and the nurses

There appeared to be some complementary and contradictory links between the interviews with mothers and nurses, these are summarised in Table 18. In general, the nurses recounted that topics related to postnatal weight and weight management were not routinely discussed during child immunisation appointments as the sole focus of these interactions was on providing parents with information related to child immunisations and then vaccinate children. This was mirrored by many women acknowledging that they did not want to feel pressurised by others into managing their weight during the postnatal period, especially if their health was not in immediate jeopardy.

Table 18: Conflicts and similarities between women and nurse interviews

Nurse's interviews	Women's interviews
Do not routinely bring up/ discuss women's weight postnatally	Do not want to be pressured about their postnatal weight
Do not routinely offer support with postnatal weight	Do not get support but some would like this support to be made available if they asked for support Some of the women expected to receive a lot more support with their postnatal weight management from the nurse
Expressed trepidation and/fear of raising the topic of weight with women	In general, they did not want to discuss their weight unless they asked for help
Considered it too soon after childbirth to think about weight loss due to the demands of motherhood	Felt it was too soon after childbirth as body still adjusting as well as adjusting to motherhood. Nevertheless, many liked the idea as it helped keep their weight and weight management in the background
Many nurses did not visit or engage with the One You website	Many of the women had a brief look but did not regularly engage with the One You website. Some found the One You Active 10 Walk Tracker helpful. Many women expressed that they would have benefitted more from guidance from the nurses signposting them to specific parts of the website
Breastfeeding can help with weight loss	Can not lose weight while breastfeeding

Both women and nurses informed the researcher that standard care from general practices did not include postnatal weight management. However, some women commented that they would like this type of support to be made available if they requested it. A few mothers mentioned that they had expected to receive a lot more weight management support from their practice nurse during child immunisation appointments because they were participating in this study.

Many of the nurses confessed to being wary of providing mothers with weight management advice for a number of reasons including insufficient training, personal perspectives that weight loss should not be a primary concern for postnatal women and fear of causing offence. Overall, the mothers justified the nurses' trepidation by stating that they would prefer to discuss weight related issues with nurses only when they asked for assistance.

Most of the nurses that were interviewed expressed that they felt it was too soon for postnatal women to be concerned with their weight and listed some of the factors associated with childcare during the early postnatal period that may not be conducive to postnatal weigh loss.

Mothers in the study also reported that despite agreeing to participate in the study, the realities of motherhood (childcare and family responsibilities) made it too soon after delivery for them to prioritise and find the time to consistently exercise and eat healthily. Nevertheless, mothers felt that participating in the study was helpful, and many claimed that they became subconsciously aware of weight management behaviours.

Almost all of the nurses did not access the One You website whereas, many of the women visited the website at least once. Some women commented that they would have valued receiving weight related advice directly from their practice nurse. Women that reported more positive engagements with the website tended to be those that had downloaded the Active 10 activity tracking app that recorded and notified them when they had achieved a daily goal they set themselves.

4.6 Discussion

This nested qualitative study aimed to provide insight into the perspectives of postnatal women and practice nurses who participated in the brief postnatal weight management intervention study described in Chapter 3. A feminist phenomenological perspective allowed the lived experiences of predominantly female participants on delivering and receiving the postnatal weight management intervention to be explored. Whilst the systematic nature of the framework approach ensured that specific questions relating to the acceptability of the intervention were answered.

4.6.1 Reflexivity

The researcher (J.A.F) was reflexive throughout the research process. The researcher was aware that her accent, dress style, not being a mother and feminist stance may have influenced the interactions with the participants. The researcher let each participant (both nurse and mother) set the tone of the interview and was conscious of their surroundings during the interview. These were then reflected on and recorded in a research diary. These notes enabled the researcher to add context to interview transcripts during analysis.

4.6.2 Feminist phenomenological interpretation

A mother's societal role was successfully accomplished if she considered herself or was viewed as being self-sacrificial (449). Descriptions of daily childcare activities were provided by all the mothers interviewed and reflected their views on the identity of a mother. As motherhood is socially constructed, the desire to fulfil this social expectation is evident in other studies (449).

The role of motherhood was a fundamental concept that linked the interviews conducted with women and nurses in this study. There was resonance from many of the women expressing the social angst created as they strove to be perceived as good and caring mothers to their children and that self-care (which included eating healthy and physical activity) may be considered selfish by others, and would therefore make them bad mothers. This ideology was mirrored by the nurses, most of whom were female, and mothers themselves.

Despite many women admitting that they had hoped to lose weight whilst participating in the study, many reported that because they were mothers, weight loss was no longer a top priority. This sample of women conveyed that to fulfil the role of a good mother, childcare duties took precedence and respite from this maternal role was rare. This was contrasted by many of the women who stated that before becoming mothers, self-care and weight loss were considered top priorities. The women in this study did not view themselves as clinically overweight or obese, but identified the status of their bodies as a construct of motherhood. This belief was also held by many nurses, suggesting that views of women and their postnatal bodies could be socially informed (450).

Both women and nurses expressed opinions that the realities of motherhood hindered consistent weight management attempts. These findings are aligned with previous research which has found that many women are concerned with residual weight retention post-pregnancy (451, 452), but that the demands of having a new baby mean their weight related concerns move down their list of priorities (453). Childcare duties for many women in the study were almost exclusively their responsibility despite all of them stating in the trial they

lived with a husband or partner. As a result, many of the women expressed that they did not have time for themselves due to the demands of childcare, a factor common to many mothers (409).

Throughout each of the interviews conducted with postnatal women were subliminal suggestions (to various degrees), of the presence of real or self-imposed external judgements of their body size and shape. This pressure women in the study felt was noted in their descriptions of their bodies. Negative words and laughter were used by some women when discussing weight gain or when they had engaged in less healthy practices. Laughter can be a way people mask their pain (454).

Western ideologies of the physically perfect woman may have driven the gap in the uptake of commercial/ lifestyle weight management programmes by gender (87, 455, 456). The influence of external societal pressures was also evident in this study as some women described their need to try and control their body in the past or presently by dieting and exercising to reach a specific goal, or revert to their pre-baby body. The issue of weight was something the participants felt that they were either in control or out of control of. Many of the women who had not actively had to try to manage their weight pre-pregnancy were more likely to feel like their weight loss attempts were out of their control.

None of the women explicitly mentioned the influence of males as a factor for their desire to lose weight during the postnatal period. One woman commented on how she kept her weight a secret from her husband while another woman did not mind sharing her weight with her husband. Despite all of them living with their partners, none of the women brought up the subject of their partner/husband's thoughts or comments on their postnatal body.

Women's desire to lose weight appeared to be socially driven by their self-comparison to other women in similar situations to themselves within their communities and social circles. This may be the reason why women seek group-based support as opportunities are created in which they can compare and take solace in the similarities that women experience when they take on motherhood. Perhaps women are putting pressure on themselves and on each other to be viewed by others as being "good" whilst looking a certain way after childbirth.

4.6.3 Main findings

Overall both the mothers and nurses considered it too soon after childbirth for mothers to fully engage with the intervention. Nevertheless, for many of the women being a part of the study increased their self-awareness, and this may have prevented some from gaining weight. These findings support previous research that weight management in the postnatal period is a concern for women (139, 338, 457) and that they would benefit from more support than is currently provided or available in the UK.

Overall, many of the mothers in the study appeared torn between wanting to return to their pre-baby body or losing the "baby weight" and simultaneously successfully fulfilling their role of being a good mother as deemed by society. Their attempts to have a socially acceptable female body were contrasted by their overarching desire to be seen and feel like they were being good mothers by attending exclusively to the needs of their newborn babies and families. In general, being a good mother to many women meant that they did not prioritise themselves and as a result their engagement with the intervention only took place after the needs of their families and baby were met. Many of the women in the study verbalised their awareness of what a healthy lifestyle (diet and physical activity) consisted of

as well as their desire to partake in one, but conveyed an array of obstacles associated with motherhood that prevented them from being able to achieve this. There were five key issues with the intervention discussed in turn below.

4.6.3.1 Need for tailored postnatal information (specifically relating to diet and exercise)

Postnatal women need weight management advice specifically designed for them as a sub-group which takes into consideration their multiple demands as a mother, limited time, healing and recovery post-childbirth. The mothers in this study deemed the generic healthy lifestyle information offered as part of the intervention as impersonal and intangible during this early postnatal period. The website was therefore not appreciated as the women did not think it was relevant for their unique situation.

There was resounding agreement on the scarcity of information available for postnatal women. Women expressed their inability to find reliable sources of information relating to diet and exercise that was suitable for them to perform and incorporate into their postnatal routine. Related to the shortage of information, was the lack of support postnatal women experienced in relation to finding resources that offered them the support they stated they needed postnatally. Some of the women interviewed expressed that the attention they had received whilst being in the study was valued as after delivery, focus shifts almost entirely to the baby.

4.6.3.2 Optional involvement of nurse-weighing and advice

Findings also demonstrated a preference for external accountability to be optional, provided only when requested and to be respectful of a mother's choice. External accountability

sources should namely be practice nurses and be provided with the utmost sensitivity and empathy to the woman's individual situation.

Societal stigma surrounding obesity still exists (6) and may not only be responsible for the cluster feasibility trial's poor recruitment rate, but partially explain the apprehension some of the women experienced prior to being weighed by the nurse. Shame and fear of being judged about having overweight or obesity were factors similarly reported in both general population (458) and perinatal period literature (459). Research suggests that people with obesity and overweight are less likely to present for routine health checks with their GPs and reasons included not wanting to be weighed (211). Mensinger and colleagues suggest that this trepidation may be responsible for healthcare avoidance (460) or as in this study, the participants not wanting the nurses to bring up their weight status unless they initiated conversation. The eradication of obesity stigma (211, 212) during encounters with healthcare professionals by creating a safe environment, free from judgement is an important factor for the acceptability of this intervention (85). The concept of nurse weighing during child immunisation appointments was deemed appropriate only if women could opt out and did not feel pressurised and/or judged for their weight. Fear of being judged is a concern found in other studies of pregnant and postnatal women with a raised BMI (*i.e*. over 30 kg/m^2) (461). This perceived judgement from healthcare providers in relation to body weight can negatively affect the success of weight loss attempts made by individuals with overweight and obesity (462).

4.6.3.3 Need for support

This research identified a strong desire for more postnatal support, namely in the form of peer groups as has been previously identified (463). Women in this qualitative study disclosed a multitude of issues peer support groups may help resolve including: empathy from others in a similar situation; a medium to share information (including suitable diet and exercise for the postnatal period); baby friendly exercises; an excuse to get out the house and for friendship. This expressed desire for group support conflicts with the poor retention rates and attendance noted in studies offering group support (10, 232, 464). Nevertheless, it is apparent that in general, many postnatal women desire some form of peer group-based support. This peer support is considered a useful avenue for mothers to identify and understand who they are both as women and mothers by relating and sharing experiences of motherhood with other women in similar situations, especially for first-time mothers (407, 465). The identification of and comparison with women in similar situations can be used by the women to define their new self which encompasses their multiple societal roles including motherhood (454) with confidence that their self-definition is similar to other women in a similar situation.

The value placed on the interaction and receptiveness of the nurse during child immunisation appointments varied, especially in relation to the intervention. Despite some participants having had positive encounters with the nurses (for example gaining the reassurance they desired, or having a general chat), it did not impact on their weight loss attempts, a finding reported in other studies (466).

4.6.3.4 Recognition that the early postnatal period may be an ideal time for some

It was highlighted that this early postnatal period may be a suitable time for some new mothers. However, it was also acknowledged that it may not be the ideal time for other mothers due to the impact of childbirth and need to adjust to motherhood and focus on fulfilling their maternal duties.

4.6.3.5 Self-monitoring is a viable option

Despite weekly self-weighing not being preferable or as easy for women to implement into their routines, the interviews revealed that regular self-monitoring was seen by many women as vital for weight management. Monitoring their weight regularly was achieved by the women in different ways; recording weights; how their clothes fit and how they felt about their body being the main ones. This shows that many of the women were adopting self-monitoring behaviours to monitor their weight that could fit in easily with each mothers' unique situation and/preferences. Recording their weights in the child record book was noted as inconvenient for some and a couple of participants had changed to using a mobile app to record and track their weight during the study. Some of the mothers suggested that the use of an app would be more appropriate as they usually had their mobile phone in close proximity.

4.6.3.6 Importance of nurse engagement and behaviour

The interviews with nurses suggest that the nurse training sessions should have been a little longer to include details on the content of the One You website to be covered. This may have led to more nurses being familiar with the apps and website content which would have enabled them to signpost women to specific parts of the website. The fundamental basis of

the intervention in promoting self-management was not well understood by some of the nurses. This was evident as some of the nurses assumed that the intervention involved a lot more support from the research team than was provided. It appears from the nurses interviewed in this study that they are used to providing information and support in very set ways, for instance supplying patients with leaflets and having brief conversations about specific health-related issues.

Davis and colleagues stated that raising the issue of weight can be a distressing experience for healthcare workers due to fear of causing offence to women with obesity or who are overweight (98). Practice nurses in this study and in previous research have exhibited trepidation in their ability to positively influence patient weight change (467). Moreover, the study by Leverence *et al.* reported that midwives who were themselves overweight or with obesity felt insincere raising weight related topics (467).

The only male nurse in the study identified that his gender may influence his interactions with female patients, especially with those from some ethnic groups, a common experience for men in socially constructed female dominated occupations such as nursing (468).

4.6.4 Strengths and limitations

This trial represents information dense accounts of the experiences and perspectives of receiving and delivering a postnatal weight management intervention and offers insight into what postnatal women and practice nurses would find most useful and suitable for future postnatal weight management interventions. These could be incorporated into the development of future interventions to prevent postnatal weight retention and weight gain to optimise acceptability. The findings of this qualitative study can be used to inform the

design, delivery and implementation of the intervention before it is tested in a phase III RCT (397). The sample of women and nurses interviewed were representative and similar to the women and nurses that received and delivered the intervention in the cluster feasibility trial. Furthermore, at least one woman and nurse from each of the seven GP practices randomised to deliver the intervention was interviewed.

In this study, data saturation may appear to have been unattainable due to the extensive and unique lived experiences and perceptions feminist phenomenology can generate. Nevertheless, Saunders and colleagues advocate the notion that four models of data saturation exist that can be determined by some fundamental assumptions (431). One of these assumptions is that data saturation can be achieved on an individual interview basis when the interviewer feels they have probed and fully comprehend the interviewee's perspective (431). The varying lengths of the individual interviews (both with the nurses and mothers) can attest to this, therefore data saturation was achieved in this qualitative study

A rapport may have been established between the participants and the researcher as they had interacted and met on at least on two previous occasions (at baseline and follow-up) during the cluster feasibility trial. This may have helped the mothers feel more comfortable to discuss weight related issues with the researcher (469).

The use of a topic guide with probes and set topics also ensured that each participant was interviewed in a similar way.

Testing the interview topic guide or a practice interview may have been helpful as the researcher (J.A.F) felt as though her interviewing technique improved with the quantity of

interviews conducted due to no longer being as nervous about ensuring the questions were not leading or that she would forget to raise an important issue for discussion whilst trying to probe and let conversation flow. The lack of theory to guide the content of the topic guide is a limitation. By using a validated theoretical framework, for example theoretical domains framework (470), questions could have been posed that would give insight into what parts of the intervention impeded or were conducive to behaviour change in both the nurses and mothers.

Despite every effort to gain rapport (471) with all interviewees, this was occasionally difficult during telephone interviews conducted with a couple of the nurses that had not received training delivered by the researcher (J.A.F). This ultimately led to silences during parts of the nurse interviews when one-word answers were provided. The nurses may have been cautious of causing offence, especially since I personally delivered many of the training sessions.

Many of the participants asked the researcher (J.A.F) if she had children, and because she did not, given the subject being discussed, the dialogue and the interactions may have been different if she had had children.

Many of the participants' transcripts were often conflicting, with some women speaking positively about the timing of the intervention and then contradicting themselves later. This made it difficult to summarise their overall thoughts in relation to the acceptability of the intervention. However, perhaps this simply reflects the mixture of feelings women may experience about postnatal weight management.

Women who had participated in the cluster feasibility RCT and assigned to usual care were not invited to be interviewed. This is a shortcoming of this study as they may have provided additional insight into the receptivity and acceptability of the intervention from another sample of postnatal women interested in postnatal weight management.

4.6.5 Implications for health policy and research recommendations

Reducing the amount of weight women retain in between pregnancies by implementing effective postnatal weight management interventions that can be delivered on a national level and with minimal costs to the NHS is vital. Interventions like this may help minimise the likelihood of postnatal weight retention that can lead to the development of obesity.

As the UK's population has grown heavier, some evidence suggests that people may have re-calibrated their perceptions about weight and what constitutes a healthy weight (472). This along with the fact that pregnancy is seen by society as a suitable time for weight gain (473) may have de-sensitised a participant's ability to recognise that they have a raised BMI post-pregnancy. Indeed, while many of the participants stated that they wished to be healthy, losing weight was viewed as a marginal concern or a positive by-product in the pursuit of health. Some evidence suggests that body image is at its lowest at approximately six months postnatal (452), nevertheless, it must be noted, that not all women in this study wanted to lose weight but were in fact finding ways to come to terms with their post-baby bodies. This may partly be due to the influence of body positivity campaigners who are encouraging and inspiring women of all shapes and sizes to embrace and love their bodies (474).

4.7 Conclusion

In summary, although its timing was not deemed to be suitable by every woman and nurse, the intervention nevertheless brought the concept of weight management to the forefront of women's minds.

The nurses delivering the intervention found it easy to deliver, but were concerned that it would initiate weight related conversations that would need to be addressed and thus impact on already constricted appointment durations.

Future study design implications include the need to potentially reconsider the timing or at least extend the duration of the study to cover and include the 12 month immunisation appointment as women at follow-up reported feeling more ready to manage their weight now that they had established more of a routine with their baby. Furthermore, the findings suggest that there is a need to design a website that is tailored for postnatal women and addresses their specific diet and physical activity related concerns. The use of online group chats may be an asset and promote the creation of a support network for the mothers, especially since many reported the desire to socialise with women in similar situations to themselves.

By gaining the perspectives of new mothers and nurses, potential modifications to this intervention that may improve its acceptability have been identified. These findings should also be taken into consideration by healthcare professionals and researchers when designing future weight management interventions that focus on the unique situation of women during the postnatal period and reproductive years. In addition, the findings of this study

highlight the limited support many women experience during the postnatal period in relation to postnatal weight management as well as their wider needs and concerns.

CHAPTER 5

DISCUSSION AND CONCLUSIONS

This thesis has presented several studies to advance knowledge about interventions to help women lose weight after having a baby. A variety of methods were used, including a systematic review of systematic reviews, a feasibility cluster randomised controlled trial and a qualitative study to provide different perspectives to this question. The systematic review of reviews identified that interventions to date have been successful in helping women lose −1.7 kg (95% CI, −2.3 to −1.1) of weight. Of importance here, the review also identified that no trials involving routine care contacts in primary care with postnatal women have been tested. The feasibility cluster RCT which tested the feasibility of a brief routine weight management intervention embedded into the national child immunisation programme reported that despite the poor recruitment rates, the provision of the intervention was feasible to both the nurses and postnatal women. The qualitative study using semi-structured interviews and embedded within the feasibility cluster RCT reported that despite the intervention being conducive to raising the issue of postnatal weight, nurses were concerned that initiating conversations linked to weight management during immunisation appointments could impact the appointment timings. Furthermore, in general the women interviewed felt that their maternal responsibilities during this early postnatal period inhibited them from being able to adhere consistently to the intervention. Collectively these studies indicated that for some postnatal women the timing of the intervention was suitable, and being referred to a website was acceptable. Nevertheless, the implementation of a website designed specifically for postnatal women with regularly updated content and that

includes features which enable individualised information may improve engagement and encourage regular use. In addition, nurses felt that they should weigh women prior to immunising infants as this appeared to be more acceptable to women as they were able to console their babies after receiving their immunisations.

This chapter seeks to provide a summary of the principal findings, with reference to the identified strengths and weaknesses of each study and make comparisons to other published studies. The main findings will then be discussed in relation to the potential implications for postnatal women, clinicians and policymakers. This chapter will make recommendations regarding future research.

5.1 Summary of findings

Overall, this thesis has used multiple research methods to investigate weight management interventions to reduce levels of obesity in postnatal women. A literature review (Chapter 1) examined the prevalence of obesity globally and in the UK. The literature review identified that excessive weight gain during pregnancy and postnatal weight retention as important life events that increased the likelihood of women developing obesity in later life. The likelihood of this occurring is exacerbated in the UK as there are no current guidelines for weight gain during pregnancy or weight loss postnatally. Additionally, available literature estimates that over half of the women of reproductive age in the UK are overweight (93) which suggests that should they conceive, they would initiate pregnancy already at an elevated weight and potentially gain and retain additional weight.

The systematic review of systematic reviews with a mega meta-analysis (Chapter 2) was conducted to collate the findings from multiple RCTs and summarise their findings into a

single source for the first time. This review concluded that weight management interventions that included physical activity and/or dietary changes resulted in clinically significant weight loss in postnatal women. Nevertheless, the review cautioned that these findings should be interpreted with care as despite sub-group analyses, differences in the content and types of postnatal weight loss interventions still resulted in moderate levels of heterogeneity.

A mixed methods study (Chapters 3 and 4) investigated and evaluated the feasibility and acceptability of a postnatal weight management intervention that could be used in primary care. Based on a low recruitment rate, it is concluded that a weight management intervention during the early postnatal period may be too soon after childbirth and therefore not acceptable to the majority of women. Despite recruiting a small, albeit potentially biased sample, the low drop-out rates observed may be an indication that that the contents of the intervention may have been acceptable. Semi-structured interviews with the mothers who received the intervention clarified some of the inconsistencies observed in the feasibility cluster RCT. Overall, the interviews revealed that despite women wanting to try and lose weight, fulfilling their maternal duties took priority and consumed most of their time. The daily unpredictability associated with childcare, especially during the early postnatal period also made it difficult for the mothers to weigh themselves consistently throughout the study.

External accountability has been identified as an important motivation for behaviour change in the general population (14, 304). However, external accountability for weight loss from practice nurses during child immunisations did not appear to influence women's weight

management behaviour and many of the mothers and nurses interviewed expressed fear and trepidation prior to child immunisation appointments. Furthermore, referral to the One You website for dietary and physical activity advice was not used regularly as the women expressed that it did not provide information on weight loss specific to them. The generic health-related information available on One You did not provide the women with the weight loss information they sought relating to dieting, whilst breastfeeding and exercises that were safe to perform postnatally, particularly for those who had undergone a caesarean section.

NICE have advocated that primary care healthcare professionals should initiate conversations and implement weight management strategies, particularly for patients with obesity (72). Interviews with practice nurses revealed that despite the intervention being easy to incorporate into immunisation appointments, it raised a few concerns if it were to become part of routine care. Time-pressured appointments made the nurses apprehensive about broaching the topic of weight with women, as they felt they would not be able to provide adequate advice and support during an appointment designed exclusively for child immunisations. Many of the nurses interviewed proposed that signposting patients to a website may not be a suitable method of healthcare provision and suggested the use of leaflets or oral advice as acceptable alternatives. These alternatives were considered suitable as many nurses believed postnatal women were too busy with childcare responsibilities to visit a website for weight management advice.

5.2 Strengths and limitations of the research

The strengths and limitations of each of the individual studies have been previously discussed (see Chapters 2, 3 and 4). The overall strengths and weaknesses of the thesis in relation the study design and conduct of the research will be discussed below.

5.2.1 Study design and methodology

The systematic review of systematic reviews is the first in this field to consolidate the findings from multiple published systematic reviews of RCT studies that have tested the effectiveness of postnatal weight loss interventions. The review and meta-analyses suggested that lifestyle interventions that combined diet and physical activity were more likely to result in clinically significant weight loss during the postnatal period. The systematic review of systematic reviews was an asset to this thesis as it was able to identify the key components of effective behavioural weight loss interventions for postnatal women. The findings not only justified the intervention components and design of the feasibility cluster study but provided a single source of information for other researchers, healthcare professionals and policy makers. The methodological quality of many of the included systematic reviews was moderate to high, as determined by two independent reviewers using the AMSTAR tool (233) suggesting that the included systematic reviews were rigorously designed therefore minimising the chances of systematic errors (bias).

Using a mixed methods study design was a strength as it allowed for the collection of a variety of data (both qualitative and quantitative) thus enabling issues relating the conduct of the trial as well as the feasibility and acceptability of the intervention to be identified. Executing the pragmatic feasibility cluster trial prior to conducting semi-structured

interviews provided quantifiable data that could then be interpreted further by gaining a deeper understanding to the results of the feasibility cluster trial through the interviews. Dual perspectives were also obtained from the practice nurses and postnatal women. These findings can now be used to make changes to the delivery and content of the intervention as well as to the trial to improve recruitment, engagement and adherence to the intervention. These findings however may not be generalisable due to the small, potentially biased sample recruited. As a result, the study findings may not be representative of what experiences would be like if intervention was fully rolled out and delivered during every child immunisation appointment.

Seeking assistance from the CRN West Midlands team at BWCH to identify every woman who had recently given birth from each of the participating practices ensured the recruitment procedure was identical for each cluster, thus avoided differential recruitment rates between intervention and control clusters, a source of bias associated with some cluster RCTs (475). Furthermore, it ensured that every woman from each of the participating clusters, irrespective of age, ethnicity and socio-economic status was invited to participate. Although the study took place in Birmingham with a very diverse population, the study design may not have captured this true diversity as all of the study materials were in English. This may have prevented responses from mothers interested in weight loss and willing to participate, but unable to read or speak English fluently.

There was some concern that the length of the study questionnaires may have impacted negatively on the women's responses and rates of completion (476, 477). Splitting up the questionnaire may have kept participants engaged which may explain the high completion

rates (99%). However, by attempting to reduce the size of the questionnaires, the 20-item food frequency questionnaire was used (333). Unfortunately, the quality of the data collected was poor and therefore excluded from this thesis. The inclusion of diet-related data would have been useful, but studies have shown that dietary recall can be inaccurate (478, 479). Furthermore, it is hard to design short-form questionnaires that encompass every individual's diet and their use can provide inaccurate information on total energy consumption (479).

The scales and questionnaires used in this study to assess body image and body dissatisfaction scores were designed for use with the general population and not specifically with postnatal women. Body satisfaction and image may differ during this period, as women may be subjected to societal expectations for their bodies to "bounce back" now that they are no longer pregnant (480, 481). A longitudinal study that followed 79 women from early pregnancy to one year postnatal reported that women experienced greater body dissatisfaction during the postnatal period which peaked at approximately six months postnatal (482). Furthermore, sections of the questionnaire asked about physical activity in the past three months which may introduce recall bias, as well as the fact that this period covered both the last pregnancy trimester and the first month after childbirth for many of the women in the study.

It may have been beneficial to include other anthropometric measurements to assess weight change. Wharton and colleagues argue that "BMI has significant limitations since it does not always exhibit the risk of other chronic weight related conditions", mainly because it was designed for use with populations of European descent (153). Wharton advocates the use of

the Edmonton Obesity Staging System (EOSS) as it assesses the severity of obesity by considering its implications on the individual's mental and physical health and quality of life (16). Perhaps less relevant for this thesis, the collection of additional body composition data would have been useful as this tends to change more during the early postnatal period compared to body weight (483). Furthermore, some research indicates that having obesity does not necessarily predispose a person to poor health (484-486). In addition, other researchers estimate that one in five adults with obesity in America remain metabolically healthy (484) and that being overweight can protect against all-cause mortality (487). Many of the women interviewed were less focused on attaining a specific number on the scales but desired to feel healthy. Perhaps if the focus of the intervention showcased how eating a well-balanced diet and engaging in daily physical activity can make women feel healthy, weight loss may be achieved as a beneficial by-product.

The feasibility cluster RCT did not ask the women receiving usual care about any self-monitoring behaviours that they practiced regularly and may have been a confounding factor (488). The potential that women may already be practicing self-monitoring techniques was not considered during the questionnaire design phase of the study. It only became apparent during the interviews, when some women revealed that they frequently used how well their clothes fitted to gauge fluctuations in their weight. It is therefore possible that women who did not receive the intervention were also employing similar methods of self-monitoring, including self-weighing that this study did not account for.

Women from practices randomised to deliver usual care were given a healthy lifestyles leaflet with generic health advice in an attempt to minimise between group attrition (489).

There is potential that this advice along with their motivation to participate in a weight loss study may have been conducive to them engaging in lifestyle changing activities. Furthermore, research suggests that people who participate in weight loss studies may not be representative of the general population (371).

It may have been beneficial to include questions relating to social support as well as the delegation of childcare and housework between partners. This may have been useful to better understand each woman's role within the family and construct a clearer picture of what exactly their maternal roles consisted of. It is plausible that I have interpreted the women's descriptions of motherhood during interviews based on in-built knowledge I have constructed based on personal life and social influences (403).

The manufacturer of the Body Trace weighing scales used in the study discontinued the transmission of data from 2G scales a few months into the study. This was unexpected and resulted in some objective weight data being lost as alternative scales with limited capabilities to store large quantities of weight data were used until 3G scales were obtained.

The One You website was not the initial website chosen. It is not a website focused exclusively on weight management and provides generic health advice that was not entirely relevant or specific to postnatal women. But as the aim of this feasibility cluster trial was to find out if mothers were able to access weight management information online, One You was adequate, especially as it has been approved by Public Health England and is publicly available.

It was advantageous that the researcher (J.A.F) had access to a personal vehicle, as it would have been logistically challenging to arrange home-based appointments with participants. The duties associated with trial administration and management were managed almost exclusively by the researcher. Despite the steep learning curves and challenges, it was highly advantageous for a novice researcher to learn many of the mechanisms associated with clinical trials. Furthermore, it may have ensured that identical data collection methods were used and been helpful for the development of relationships with the women which may have impacted on the quality of data collected during qualitative interviews.

5.2.2 Components of the intervention

The pragmatic feasibility cluster RCT is one of the first few attempts at testing a postnatal weight management intervention that had the capacity to be easily implemented across the UK with potentially minimal costs to the NHS. The findings suggested that the intervention may be feasible to practice nurses who weighed and completed the weight record cards as instructed and the qualitative study revealed that the brief 15 minute training nurses received was considered adequate. However, the nurses manual was not read by all nurses or read frequently by the nurses. The qualitative interviews also revealed that many of the nurses felt uncomfortable raising emotive topics like weight without patients initiating the conversation. Many nurses also admitted that under normal circumstances, they would not have broached the subject of postnatal weight, particularly during child immunisation appointments. They expressed fear of causing offence and empathised with the multiple demands caring for a newborn placed on new mothers. Overall, the nurses acknowledged

that postnatal weight retention was an issue, but felt that it was too early postnatally and that child immunisation appointments were not ideal settings for delivering the intervention.

The low recruitment rate to the feasibility cluster RCT and findings from the nested qualitative study suggested that weight management between 4-8 weeks postnatal may not be acceptable or of interest to women. Despite attempts at ensuring multiple contact methods for the research team were available, the short time-period of approximately two weeks in which new mothers were to respond to the study invitation letter may have been too short. This may have been overcome by recruiting women during practice baby clinic days. Unfortunately, this was logistically challenging for the researcher to co-ordinate and arrange whilst undertaking other trial management tasks and baseline appointments. Instructing practice nurses to identify and recruit participants during child immunisation appointments may have been possible, but it could also have created recruitment bias by nurses selecting some eligible women, but not others based on their personal preferences. Furthermore, nurses approaching women directly to participate in a postnatal weight loss study could possibly have caused offence to some postnatal women.

One conceivable explanation for the low recruitment rates may be due to the fact that many of the general practices participating in the study were research active sites, therefore the practice populations may have experienced research fatigue due to being over-researched (490, 491). Nevertheless, altruism was stated by many of the women interviewed as a primary motivator for participating in this study. The low levels of recruitment for postnatal women impacted the number of women the nurses could deliver the intervention to. Some practice nurses delivered the intervention as little as once or twice during the study, which

may have influenced their perceptions about the intervention, and their experiences of delivering the intervention may therefore not be entirely representative.

The time allocated to immunisation appointments varied between the included practices, with some having only 15 minutes. This will no doubt have influenced the nurse's perceptions about having to provide additional services, especially amongst those with less time to provide immunisations. Furthermore, many of the women noted that they experienced high levels of stress during these appointments as their babies would be upset. This was even more stressful for women who had to be weighed after their baby had been vaccinated. The Queen's Nursing Institute conducted a survey with approximately 3,400 general practice nurses reported that practice nurses experience workload pressures due to staff shortages and the frequent diversion of healthcare services from hospitals to primary care settings (492).

Findings from the current study suggest that adjustments to the website used should be considered before a larger trial is executed. Participants suggested group-based interactions. One study found that the use of an online, private Facebook group was enough peer support to assist postnatal women lose weight without the need of face-to-face interaction for meaningful weight loss (312).

Despite previous research reporting that no adverse psychological or emotional effects were associated with regular self-weighing (353, 359), findings from the trial suggest that this may be different for women during the early postnatal period. Overall, the EPDS scores for women who received the intervention were higher at follow-up compared to those who had received usual care.

5.3 Comparisons with the literature

5.3.1 Intervention components

The use of weight loss interventions comprising exclusively of self-weighing have proven ineffective (14), but the benefits of self-weighing have been proven effective when used as part of multi-component weight loss and weight maintenance interventions (166). Many of the postnatal women in this feasibility cluster trial may have attempted to weigh themselves regularly but reported that they did not engage frequently with the other intervention component (One You website). In a similar study conducted in Sweden with postnatal women that also encouraged intervention participants to weigh themselves regularly (three-times a week), in addition to personalised dietary changes and text message support, participants lost an average of 6.1 kg (-8.4, -3.2 kg) compared to 1.6 kg (-3.5, -0.4 kg) after 12 weeks (493). Sustainable weight loss and maintenance was also observed at one and two years follow-up, especially amongst women who continued to self-weigh (493, 494).

A recent survey identified that receiving advice from a GP or practice nurse was the most motivating factor for weight loss, particularly for older participants (366). This study also determined that younger people were more likely to be motivated to lose weight as they were unhappy with their appearance and/or body size and shape (366).

NICE recommend regular physical activity for the general population (495) as well as for women after childbirth (286), which they can initiate gradually from four to six weeks postnatal. Nevertheless, information on types of exercise and physical activity postnatal women can safely engage in is limited (496). The findings from the pragmatic RCT included in this thesis and previous studies have demonstrated that low levels of physical activity are

common for women during pregnancy and the first postnatal year (497-499). Many of the barriers to postnatal physical activity in this study were consistent with those of previous research included: lack of time; need for more support; a shift in priorities (498, 500, 501). Previous research has identified a number of facilitators to postnatal physical activity including pre-pregnancy physical activity (497). One study found that women who exercised before getting pregnant were more likely to exercise after delivery and that women who exercised throughout pregnancy, were more likely to engage in physical activity or exercise during the early postnatal period (502). Other facilitators have been identified including social support, namely from partners (500). Engagement in physical activity during the postnatal period may not always equate in weight loss, but the associated health benefits including improved mood (378, 503) and cardio-respiratory fitness (184, 504) make it a worthwhile endeavour especially for postnatal women.

This intervention may not necessarily be appropriate for culturally diverse populations as the website (One You) did not offer recipes using culture-specific food groups. This was pointed out as a disadvantage by a participant who did not adhere to the intervention and gained almost 10 kg during the study. A systematic review by Kong *et al.* on behavioural interventions to improve diet and weight loss designed specifically for African-American women highlighted that studies that used socio-cultural approaches, especially during the planning and recruitment stages of the study, reported more significant outcomes (505).

Many women interviewed mentioned that they would have enjoyed participating in a weight management intervention that was group-based. Group activities were viewed as a welcomed opportunity to socialise and get out of the house. These findings are consistent

with other research, that has implemented group-based weight management interventions and has reported inconsistent or low levels of attendance (232, 506) as well as a preference for home-based interventions, particularly for those that can be accessed online (191).

5.4 Implications for women, clinicians and policy makers

There is a need for more high-quality research to ensure the consistent development and implementation of policies and guidance for maternal weight gain and postnatal weight loss.

NICE guidance suggests that a mother's weight be taken during her 6-8 week check and weight management advice be offered and co-ordinated by the primary health care team (495). Weighing patients during routine practice appointments may help alleviate the fear many healthcare workers and patients can experience when discussing weight (210, 321). As some of this trepidation is associated with a fear of lack of knowledge, training sessions could be arranged, alternatively, referrals to nutritionists and dieticians may also be beneficial. One study concluded that in order to overcome some of the barriers preventing initial weight loss for postnatal women, several factors were fundamental, including the use of very specific and individual dietary advice. Furthermore, they identified that an emotional bond between the woman and her healthcare worker fostered trust, support and accountability (507). The points discussed above help to showcase the need for more research testing interventions that consist of weighing during routine healthcare appointments throughout pregnancy and postnatal period as well as regular self-weighing to equip women with self-management skills and external support and accountability to manage their weight throughout their reproductive years.

Many of the women interviewed in this study did not associate their weight status as an indicator of current or future poor health as they frequently stated that they did not need to be a specific weight, but just wanted to feel healthy. Despite the body positivity movement being a great step towards embracing a curvier body shape, it could be confusing to people and detract from the health issues associated overweight and obesity. Nevertheless, the body positivity movement can help women come to terms postnatally with the changes pregnancy can make to their bodies. If the classification of obesity as a disease became more widely acknowledged, then there is potential that being overweight would be taken more seriously as it would be considered a precursor to a disease.

5.5 Future research

Attempts should be made to improve the design and conduct of RCTs in this field as it would help improve the quality of the evidence, a key issue identified by the systematic review of systematic reviews (Chapter 3) in this thesis and by other researchers. Perhaps in engaging with and recruiting from populations that are not so heavily involved in research would improve recruitment to university-based community research.

The feasibility cluster RCT showcases the importance of conducting feasibility studies prior to developing and evaluating complex intervention (382). If more pilot and feasibility studies are conducted, there may be greater potential for more resources to be made available to test the efficacy and effectiveness of postnatal weight management interventions.

Conflicting epidemiological evidence on overweight and its association with increased mortality has generated the need for more studies with more streamlined measurements for determining overweight and obesity in different ethnic groups (508).

Comprehensive interventions that encourage physical activity and healthy eating in women that are initiated prior to conception and provide additional support during and in-between pregnancies may prove to be more effective. Furthermore, such interventions have the potential to promote healthier behaviours for the entire family, therefore help to tackle the prevalence of childhood obesity as well (509, 510).

5.6 Conclusions

Overall, this thesis has contributed to research into obesity prevention and management by extending the evidence available on interventions to reduce postnatal weight retention and weight gain during the postnatal period. The optimal timing and components of postnatal weight management interventions are still unknown (188, 193). The results from the feasibility cluster RCT and embedded qualitative study suggest that a brief weight management intervention for postnatal women delivered by practice nurses is not entirely feasible due to the low recruitment rate of postnatal women; the variation in the duration of immunisation appointments and the contrasting views on the acceptability of the intervention. However, the findings also suggest that the timing of the intervention; use of the One You website and embedding the intervention into child immunisation appointments which already have pre-existing time pressures are issues that influenced the acceptability of the intervention during the early postnatal period.

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APPENDICES

Appendix 1: Sample search strategy

1 postnatal.mp. (125916)
2 postpartum.mp. (61793)
3 exp mother/ or post-pregnancy.mp. or exp puerperium/ (173349)
4 1 or 2 or 3 (323384)
5 (weight fluctuation or body weight management or weight or weight gain or weight control
or weight change or weight or weight reduction or weight loss program).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (1293993)
6 (body mass index or body mass).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (371004)
7 (body weight or physical activity).mp. or exp exercise/ or exp physical activity/ [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (954851)
8 (exercise or aerobic exercise).mp. or exp exercise/ [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (436963)
9 obesity.mp. or exp maternal obesity/ [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (447099)
10 (overweight or obesity).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word] (454714)
11 exp diet restriction/ or exp diet therapy/ or exp diet/ or exp low fat diet/ (545128)
12 exp intervention study/ (34852)
13 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 (2663860)
14 4 and 13 (71812)
15 exp systematic review/ (156080)
16 meta analysis/ (137887)
17 15 or 16 (234910)
18 14 and 17 (952)

Appendix 2: Excluded full text papers and reasons for exclusion

Review	Reason for exclusion
An 2017 (511)	Population was not postnatal women
Berger 2014 (512)	No response from authors when contacted with data enquiry
Elliott-Sale 2017 (189)	No methodology reported
Evenson 2014 (513)	Not a systematic review with a summary of weight related data reported only from RCTs
Falivene 2017 (514)	Not a systematic review with a summary of weight related data reported only from RCTs
Fowles 2012 (515)	Focus of review was on interventions for health promotion and not specifically weight management
Hanson 2017 (516)	Not a systematic review of RCTs with a summary of weight related data reported only from RCTs
Harrison 2016 (517)	Not a systematic review of RCTs with a summary of weight related data reported only from RCTs
Hoedjes 2010 (518)	No summary of weight related data reported only from RCTs
Jongen 2014 (519)	No summary of weight related data
Keller 2008 (520)	No summary of weight related data
Malouf 2014 (521)	Did not compare effectiveness of weight management interventions
Moredich 2014 (522)	Population were not exclusively postnatal women
Nagl 2015 (523)	No summary of weight related data reported only from RCTs
Netting 2014 (524)	No summary weight related data
Neville 2014 (525)	Not a systematic review of RCTs with a summary of weight related data reported only from RCTs
Peacock 2014 (526)	No summary of weight related data
Rawdin 2014 (527)	Not a systematic review of RCTs with a summary of weight related data reported only from RCTs
Saligheh 2017 (528)	No summary of weight related data reported only from RCTs
Sikorski 2014 (529)	Abstract only, full paper unavailable
Spencer 2015 (530)	Protocol
Tanensapf 2011(531)	Population were not exclusively postnatal women
Teychenne 2013 (532)	No summary of weight related data
Van der Pligt 2013 (193)	No summary of weight related data reported only from RCTs
Walker 2007 (95)	Not a systematic review of RCTs with a summary of weight related data reported only from RCTs
Weaver 2008 (533)	Not a systematic review of RCTs with a summary of weight related data reported only from RCTs

Appendix 3: RCTs in the included systematic reviews with weight related data

	Kuhlmann (2008)	Amorim (2013)	Choi (2013)	Nascimento (2014)	Elliott-Sale (2015)	Lim (2015)	Guo (2016)	Sherifali (2017)	Lau (2017)
Bertz 2012 (190)				Sweden	Sweden	Sweden			Sweden
Cheung 2011 (534)							Australia		
Colleran 2012 (191)				USA		USA		USA	USA
Craigie 2011 (10)		UK	UK	UK					
Davenport 2011 (535)				Canada					
deRosset 2013 (536)						USA			
Dewey 1994 (537)		USA		USA		USA			
Herring 2014 (192)								USA	USA
Hu 2012 (538)							China		
Huang 2011 (194)		Taiwan				Taiwan			
Kearney 2006 (539)		USA				USA			
Kim 2012 (346)							USA	USA	
Krummel 2010 (540)		USA							
LeCheminant 2014 (246)						USA			
Leermakers 1998 (541)	USA	USA		USA		USA			
Lovelady 2000 (341)		USA	USA	USA		USA			
Lovelady 2009 (542)		USA				USA			
Maturi 2011 (543)					Iran				
McCrory 1999 (544)		USA				USA			
McIntyre 2012 (545)				Australia		Australia	Australia		
Nicklas 2014 (546)						USA		USA	
Østbye 2009 (547)		USA	USA	USA		USA			
O'Toole 2003 (257)	USA	USA		USA		USA			

Reinhardt 2012 (258)						Australia	Australia		
Shek 2014 (548)						China	China		
Shyam 2013 (549)							Malaysia		
Stendell-Hollis 2013 (247)						USA			
Tripette 2014 (345)						Japan			
Walker 2012 (464)			USA	USA		USA			
Wein 1999 (550)							Australia		
Wiltheiss 2013 (551)						USA			
Youngwanichsetha 2013						Thailand			
Zourladani 2011 (552)						Greece			

Appendix 4: Quality assessment of the included reviews using the AMSTAR tool

1. Was an "a priori" design provided?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	No
Choi 2013 (33)	No
Kuhlman 2009 (31)	No
Elliott-Sale 2015 (32)	No
Nascimento 2014 (35)	Yes
Guo 2016 (39)	No
Lau 2017 (38)	Yes
Sherifali 2017 (37)	No
2. Was there duplicate study selection and data extraction?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	Yes
Kuhlman 2009 (31)	Can't answer
Elliott-Sale 2015 (32)	No
Nascimento 2014 (35)	Can't answer
Guo 2016 (39)	No
Lau 2017 (38)	Can't answer
Sherifali 2017 (37)	Yes
3. Was a comprehensive literature search performed?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	Yes
Kuhlman 2009 (31)	Yes
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	Yes
Guo 2016 (39)	Yes
Lau 2017 (38)	Yes
Sherifali 2017 (37)	Yes
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	No
Kuhlman 2009 (31)	No
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	No
Guo 2016 (39)	No
Lau 2017 (38)	Yes
Sherifali 2017 (37)	No
5. Was a list of studies (included and excluded) provided?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	No
Choi 2013 (33)	Yes

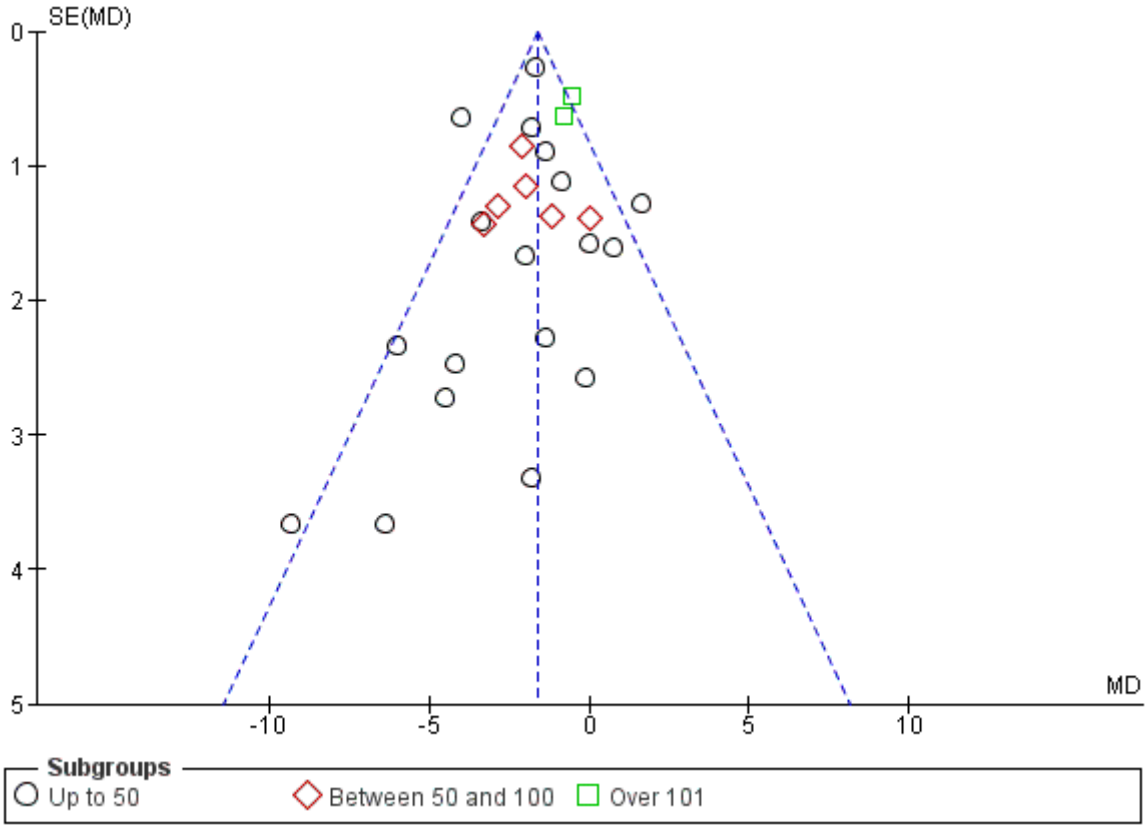
Kuhlman 2009 (31)	Yes
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	Yes
Guo 2016 (39)	No
Lau 2017 (38)	No
Sherifali 2017 (37)	No
6. Were the characteristics of the included studies provided?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	Yes
Kuhlman 2009 (31)	Yes
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	Yes
Guo 2016 (39)	Yes
Lau 2017 (38)	Yes
Sherifali 2017 (37)	Yes
7. Was the scientific quality of the included studies assessed and documented?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	Yes
Kuhlman 2009 (31)	No
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	Yes
Guo 2016 (39)	Yes
Lau 2017 (38)	Yes
Sherifali 2017 (37)	Yes
8. Was the scientific quality of the included studies used appropriately in formulating	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	Yes
Kuhlman 2009 (31)	No
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	Yes
Guo 2016 (39)	Yes
Lau 2017 (38)	Yes
Sherifali 2017 (37)	Yes
9. Were the methods used to combine the findings of studies appropriate?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	Yes
Kuhlman 2009 (31)	Not applicable
Elliott-Sale 2015 (32)	Yes
Nascimento 2014 (35)	Yes
Guo 2016 (39)	Not applicable
Lau 2017 (38)	Yes
Sherifali 2017 (37)	Yes
10. Was the likelihood of publication bias assessed?	

Amorim 2013 (36)	No
Lim 2015 (34)	Yes
Choi 2013 (33)	No
Kuhlman 2009 (31)	No
Elliott-Sale 2015 (32)	No
Nascimento 2014 (35)	Yes
Guo 2016 (39)	No
Lau 2017 (38)	Yes
Sherifali 2017 (37)	No
11. Was the conflict of interest included?	
Amorim 2013 (36)	Yes
Lim 2015 (34)	Yes
Choi 2013 (33)	No
Kuhlman 2009 (31)	No
Elliott-Sale 2015 (32)	No
Nascimento 2014 (35)	No
Guo 2016 (39)	No
Lau 2017 (38)	No
Sherifali 2017 (37)	No

Appendix 5: RCTs with weight related data, but excluded from the mega meta-analysis

Original Study	Reason excluded from meta-analysis
Cheung 2011 (534)	Had BMI data only
Davenport 2011 (535)	Did not randomise the control group, they were matched to the intervention groups by age, parity and BMI.
deRosset 2013 (536)	Had BMI data only
Hu 2012 (538)	Had BMI data only
Huang 2011 (194)	No baseline postnatal weight data
Kearney 2006 (539)	No baseline postnatal weight data
LeCheminant 2014 (246)	Compared resistance training to an active comparison group (flexibility training)
McCrory 1999 (544)	Intervention too short (11 days)
Shek 2014 (548)	Had BMI data only
Stendell-Hollis 2013 (247)	Compared two types of diet (MyPyramid vs a Mediterranean-type diet)
Wein 1999 (550)	Had BMI data only

Appendix 6: Funnel plot of RCTs with weight related data



Appendix 7: Trial protocol

Background

Obesity

Obesity can be defined as a consequence of an imbalance, caused by prolonged exposure to an excess of calories which when combined with low physical activity levels, can result in a positive energy balance (16). Over the years, the number of people who are overweight and obese has increased globally (33). The health consequences of which have a significant impact on the quality of life of the people affected and on our health services, due to the many obesity related health problems (66). Many of these health complications are chronic and include; coronary heart disease, type 2 diabetes, various types of cancer, hypertension and osteoarthritis (21, 22).

The obesity epidemic began in the early nineties and rapidly increased over a 10-year period. From 2006 onwards, the prevalence of overweight and obesity have remained stable, but relatively high (2).

Prevalence of obesity in women of reproductive age

Results from 2014's Health Survey for England Report suggested that approximately 31% of all women were classed as overweight and 27% of all women were classed as obese (2). Comparatively, in 1980 only 8% of women in England were classed as obese (553).

Women are more susceptible to weight gain during puberty and pregnancy (95) due to the physiological changes that occur during these periods (9, 96). The weight of a woman before, during and after pregnancy is of great importance, it not only effects chances of conception,

but will effect a pregnancy, the baby's health and the woman's health and wellbeing thereafter (6, 105). Both quantitative and qualitative research has recognised that pregnancy, the subsequent weight gained, and the weight retained postnatally are potential risk factors in the development of later obesity in women (148, 554). Preventing overweight women becoming obese and encouraging obese women to lose weight is therefore very important. It has been estimated that obese women are more likely to experience reproductive disorders, greater risk of complications during pregnancy and are approximately twelve times more likely to develop type 2 diabetes compared to women who are not overweight or obese (553).

Obesity and pregnancy

The prevalence of maternal obesity has been increasing across Europe, it has been estimated that over 10% of pregnant women in most European countries are obese. This percentage varies between countries, and has been estimated to be as high as 48.4% in Scotland, 35% in Norway and 27% in France (105).

Pregnancy is one of the rare occasions in a woman's life when weight gain may be deemed socially acceptable and encouraged (555). As a result, some women may take advantage of this opportunity and consume more calories (101, 555). Consequently, women often gain more weight than is recommended during pregnancy (97, 98), and those who fail to lose most of this weight postnatally, are more susceptible to retaining this weight long-term, and hence more likely to become obese over time (555).

Becoming pregnant whilst being overweight/obese, or gaining too much weight during pregnancy, are well documented as potential risks which can negatively affect the health

and wellbeing of both the mother and her baby and that of any successive pregnancies (108). Many of these risks are interrelated and can lead to the development of gestational diabetes, pre-eclampsia or gestational hypertension. These conditions exacerbate the risks involved during pregnancy and delivery, as the potential for a range of further complications to develop increases significantly such as macrosomia, newborn hypoglycaemia, jaundice (112), shoulder dysplasia, asphyxiation and stillbirth (96, 111). Between 2011 and 2013, approximately 50% of the women who died during pregnancy in the UK had complications associated with them being overweight or obese (120).

Postnatal weight retention (PPWR)

After giving birth, many women may put the needs of their infant before their own (136). The postnatal period is an instance in the life of a woman, in which drastic changes and new challenges arise and affect not only a new mother's body but also her routine, relationship with her partner and lifestyle choices (136, 139). If this stage is not managed appropriately, it may lead to the formation of behaviours that could be detrimental to a woman's health and wellbeing. Furthermore, a significant amount of research has shown that once these detrimental health behaviours have been established, they are difficult to reverse (144, 145). Additionally, these lifestyle adjustments and parenting concerns are time consuming and can leave new mothers exhausted (142) which can then further reduce the likelihood of women engaging in physical activity or healthy eating.

Postnatal weight management interventions

Research has shown that irrespective of age or race, women in the postnatal period would like to weigh less and are interested in implementing actions to facilitate this (177). Offering

women assistance to manage their weight during the postnatal period is an ideal time to intervene. It can help reduce the number of lifestyle behaviours which can cause excessive weight gain and obesity. During pregnancy and soon after, women may be more receptive to any support and advice they are offered, this is therefore a perfect opportunity to facilitate healthy habit formation (179). Weight management interventions may not only help a new mother lose the weight gained during pregnancy, but have the potential to create a healthier environment for the entire family (180, 181).

Weight management interventions, particularly those which encourage physical activity, during the post-partum period not only facilitate weight loss, but have positive effects on cardiorespiratory fitness, reduce anxiety and encourage mood elevation (288, 556). Furthermore, the majority of effective interventions for managing PPWR have combined elements of both diet and exercise (289). Such lifestyle interventions can therefore help reduce the number of women who experience poor physical, mental and emotional wellbeing during the postnatal period.

There is however, a lack of consensus and clarity in the guidance relating to both weight loss and the resumption (or initiation) of physical activity after having a baby (288). Therefore the recommendations women receive from their healthcare providers is inconsistent, or non-existent (289).

Current evidence and why this study is needed now

Research has shown that women who have recently given birth are concerned about their weight and would like assistance with weight management following the delivery of their baby (104, 178). Several systematic reviews have reported that the majority of studies

conducted with postnatal women have recruited either very small sample sizes, or have tested intensive lifestyle based programmes usually delivered by skilled professionals (184, 186, 193). These studies tested and evaluated interventions which were not rooted within primary care and recruited women mainly from the USA (188, 557). These reviews also highlighted the need for more high quality randomised controlled trials to test interventions which would be most beneficial for postnatal weight management.

With approximately 777, 400 births in the UK annually, 65% of which will be to overweight or obese women (106), there is a need to offer effective yet affordable support to women during this period of their lives. This is important because the NHS does not have unlimited resources. A recent study estimated the cost of providing an intensive weight management programme for 22 weeks to postnatal women would be approximately £4995 per woman (558). Interventions that have this associated cost cannot be made readily available to all women giving birth every year. It is evident that there is a need to develop and test feasible interventions which are acceptable, to both the service users and providers, to help women manage their weight loss goals during the postnatal period.

Self-monitoring and self-management of weight

Research has shown an association between self-monitoring and weight loss, especially in relation to observing dietary intake and physical activity (164, 165). Self-monitoring of weight has also been tested as a means of weight loss maintenance (165, 166). This type of weight management intervention is showing great potential at helping people manage their weight. The potential efficacy of regular weighing (either by the individual or someone else) has its roots embedded in the self-regulation theory (292, 293). This theory suggests that

specific behavioural changes can occur by increasing self-awareness through the process of regular self-observation, self-monitoring and self-evaluation (199). Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours with the goal of increasing self-awareness. The awareness fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change. Strong evidence supports the role of self-monitoring as an effective strategy in the health behaviour change process. A review by Michie *et al* of effective behavioural techniques for healthy eating, physical activity and reduction of alcohol consumption, concluded that self-monitoring was effective alone, but when combined with other techniques, the effect size nearly doubled (202). Recently, a systematic review of RCTs to examine the effectiveness of self-weighing as a strategy for weight loss was conducted and made some valuable conclusions (14). This review included a study which examined self-weighing as a single strategy and was found to be ineffective (-0.5 kg 95% CI -1.3 to 0.3). However, studies which added self-weighing or self-regulation techniques to weight loss programmes resulted in a significant difference of -1.7 kg (95% CI -2.6 to -0.8). Multi-component interventions including self-weighing compared to no or minimal control, also resulted in mean differences of -3.7 kg (95% CI -4.6 to -2.9).

Rationale for this research

It is necessary to test and appraise practical yet economical postpartum weight loss interventions as the population of women of reproductive age who are either overweight or obese is growing. This could add more strain to the UK's health and social care facilities. Such interventions have the potential to save the NHS money, by improving not only the

health of women in-between pregnancies, but also long term and the future health of their children.

Study design

This study aims to determine the feasibility and acceptability of a brief routine weight management intervention, embedded within the national child immunisation programme. As such, it will comprise of two parts; a feasibility cluster randomised controlled trial, followed by semi-structured interviews with both the participants and nurses delivering the intervention.

Intervention overview

The intervention has been designed to be very brief and simple. Women receiving the intervention will be asked to weigh themselves once a week and record this on a weight record card. The weight record card will be attached to their child's personal health record book (red book), which should be taken to every appointment the baby has with a healthcare professional. During the child immunisation appointments, the practice nurses will immunise the babies and provide usual care. They will also weigh the mothers and record this on the weight record card. Additionally, they will encourage women to self-weigh and signpost them to an online healthy lifestyle website developed by Public Health England called, One You.

As there are currently no clinical guidelines specifically for healthy weight loss in postnatal women, the National Institute for Clinical Excellence (NICE) guidelines for weight loss in the general population will be used. They recommend a weight loss of between 0.5 to 1kg per week (559).

I believe that the intervention will have a very minimal effect on nurse time as their involvement will be brief. Nurses will only be asked to signpost women to the website and act as an external source of accountability for the mothers. It is estimated that the intervention will add approximately 1-2 minutes to the immunisation appointment.

Rationale behind the intervention

Child immunisation appointments are already provided as routine care in the UK. According to Public Health England (PHE) data, attendance at these appointments is very high nationally, with a coverage rate of approximately 94.4% (320). Integrating this intervention into pre-existing health contacts could be an ideal setting to deliver a weight management intervention to postnatal women and has previously not been tested. The national child immunisation programme routinely schedules vaccinations for babies across the U.K four times during their first year at 2, 3, 4 and 12 months. This would mean that the mothers will have regular contact with their practice nurse or general practice. Embedding this intervention within the national child immunisation programme would make it readily available to every woman who has given birth in the UK, thus tackle some of the health inequalities within the population (177, 223). Furthermore, it would ensure that the time and financial burden of attending additional appointments is minimal. If this intervention is proven to be feasible and eventually effective, it can be quickly implemented by the NHS relatively cheaply.

In order for an intervention to be effective, its timing is pertinent. It is thought that initiating this intervention soon after women deliver their baby would be ideal. Firstly, weight loss during the first few weeks postpartum is greatest due to factors such as the reduction in

fluid retention and uterus size, as the body attempts to return to its pre-pregnancy state (318). As a result, women may be more motivated and thus more amenable and determined to lose more weight. Secondly, after a mother's six-week postnatal check, any further appointments focus exclusively on the health and development of the infant. Creating an opportunity for attention to be directed towards the mother would therefore be beneficial, as self-care can often be neglected since childcare can be a time-consuming task. It is pertinent to encourage mothers to consider their personal health and wellbeing as early as possible during the postpartum period, as this can ensure healthy lifestyles are incorporated not only into their daily routine, but that of the family. By encouraging mothers to simultaneously adapt to a healthy lifestyle routine whilst they are creating a new routine with the baby, the likelihood of the intervention being successful could potentially improve (139). Furthermore, this may alleviate the high drop-out rates previous research on community based weight management programmes for post-partum women have had (136).

Implementing an intervention to run in parallel with the child immunisation programme, is advantageous as mothers can receive the external accountability that will help them be more conscious of their weight, and steer them towards an information source which may help them manage their weight successfully.

Recruitment

General Practices

General practices will send study invitation letters to postpartum women from the practice on headed paper. I aim to recruit between 8-10 general practices (clusters). Practices will be randomised to either deliver the intervention or offer no intervention (usual care).

Each practice will search their databases to identify women who have given birth in the last four weeks or who are scheduled to attend a six-week postnatal check in the next two weeks. Practices will complete these list searches every two weeks and exclude any mothers whom they feel it would be unsuitable to invite. Eligibility will be determined after a list of all potential women has been screened by a lead general practitioner at the practice. Only those deemed suitable and who meet the study's inclusion criteria (see below) will be invited to take part. The invitation letters will ask participants to contact the research team if they are interested. A patient information sheet will also be enclosed.

Inclusion criteria

- Women aged over 18 years
- Women who have delivered a live baby in the past four weeks
- Women with a BMI of 25 kg/m² or more

Exclusion criteria

- Women with diabetes mellitus
- Women who have had stillbirths
- Women with drug or alcohol dependency

- Women with safeguarding issues
- Women with severe psychiatric problems

In order calculate a recruitment rate of the number of women invited to participate in the study, each practice will send out invitation packs in batches of 20 and they will be asked to return any unused invitation packs.

If recruitment is poor in a particular practice, I will approach women when they attend the practice for their six-week postnatal check to ask if they have received the study invitation letter. We will ask the practice to confirm that women approached in this way are eligible. Posters advertising the study will also be placed in participating general practices as well at children's centres local to the practices involved.

Post-partum Women

As this is a feasibility cluster trial, a statistician has calculated that 80 women who have recently given birth across Birmingham will be enough to estimate the adherence and the questionnaire return rate with a minimum 11% precision, and 95% confidence level.

Women interested in taking part will be visited at home to collect baseline data, including objective height and weight measurements. A leaflet with healthy lifestyle advice will be given to all women at this visit. Women randomised to the comparator group will receive usual care during their baby’s immunisation appointments.

Participants randomised to the intervention group will be asked to weigh themselves weekly and record this on a weight record card for the duration of the intervention. It is hoped that

the combination of regular self-weighing and being signposted to an online healthy lifestyle website will encourage women to self-manage their weight successfully.

All of the participants will be visited again at the end of the intervention, approximately three months later to measure their objective weight and complete a follow-up questionnaire.

Compensation

All participants will be compensated for any out of pocket expenses and their time commitment to the study with a £10 high street shopping voucher. This will be given to each participant during their follow-up home visit. Participants who withdraw will still receive the £10 voucher.

Weight loss goals

Online weight loss programme (One You)

Internet based weight management programmes, especially ones with enhanced features (309) have great potential to provide large numbers of overweight or obese individuals with an accessible way to lose weight. Last year Tang *et al* undertook a review of self-directed interventions for weight loss and suggested that irrespective of their layout, technology based interventions can be useful for weight loss (560). This evidence, together with previous systematic reviews (264, 304, 561, 562), has demonstrated the advantages of self-monitoring and self-directed weight loss interventions when used independently, or alongside more intensive weight management interventions. Additionally, the use of an online weight management intervention, especially with the popularity of smartphones, may

make it more accessible to a wider range of women and address some of the current health inequalities.

PHE have commissioned the development and design of a healthy lifestyle promoting website called, One You (www.nhs.uk/oneyou). The website has a range of information to help people of all ages adopt a healthier lifestyle, including a section dedicated to weight loss. It offers a 12-week weight loss plan with food diaries and activity logs available to download. There is a forum which can offer peer support and it is possible to sign up to receive reminder emails or text messages to keep people motivated. One You also provides healthy recipe ideas and meal plans. It is designed to be very user friendly and has several apps that can be downloaded including an easy meals app and "couch to 5K" physical activity app. This therefore makes it more transportable, enabling women to use the programme irrespective of their location.

The website is very informative and may help the mothers lose weight successfully by educating them on which types of food should be consumed less frequently, portion control and encouraging more physical activity, healthy lifestyle behaviours commonly found with successful weight loss maintainers (563).

Usual care comparator group

Participants from general practices which have been randomly allocated to the control group will not receive the intervention. Instead, they will be provided with a healthy lifestyle leaflet and receive usual care only.

Training practice nurses delivering the intervention

As the intervention is brief, I have estimated that nurse training will take about twenty-five minutes. A standard protocol to train each nurse in an intervention group will be followed. A nurses training manual (Appendix 2) has been designed to assist with the training of practice nurses. It is an instruction handbook for the nurses on how to undertake the additional intervention tasks at child immunisation appointments. It includes a summary of the study, information on the adverse health consequences of postnatal weight retention and the One You healthy lifestyles website. It also provides the nurses with appointment specific instructions on how to weigh and record the mother's weight, as well as examples of initiation and supportive dialogue. This will ensure that the study protocol is adhered to and that the intervention is delivered as uniformly as possible.

Data collection

Women interested in participating will contact the research team by telephone. They will be screened for provisional eligibility before a home visit is arranged. During the initial home visit, baseline data relating to height and current weight will be recorded. Women will also be asked to complete questionnaires relating to their self-reported dietary intake and physical activity. Information about their body image, depression and their feeding preferences for their baby will also be collected. Data about child immunisation uptake (including who attended the immunisation appointment if not the mother, will be recorded by the nurse on the weight record card) and breastfeeding rates (captured in the questionnaires) will also be collected from both the intervention and control groups.

Acceptability of the intervention and fidelity

After the intervention has been delivered, a series of questions will be asked to ascertain how acceptable women found the intervention. Participants will be asked (on a scale of 1-10):

- Would you recommend this study to a friend?
- Did the intervention help you manage your weight?
- How appropriate was it for the nurse to weigh you at your child's immunisation appointment?
- Did participating in this study make you anxious about your weight?

Additionally, semi-structured interviews with eight practice nurses and fifteen women who received the intervention will be used to obtain more detailed feedback on their experience and views of the intervention. Interview schedules have been designed and will be adhered to in order for data collection to be consistent whilst remaining flexible enough for individuals to be able to express themselves. These will be tape recorded, transcribed and analysed.

To help assess the practicalities of implementing the intervention during child immunisation appointments and with prior consent, I will directly observe and/or tape record at least two intervention appointments per nurse.

Public and patient involvement (PPI) in the research

In January 2014, an initiative by the National Institute for Health Research in partnership with Collaborations for Leadership in Applied Health Research and Care West Midlands (NIHR CLAHRC-WM) started. Their aim is to improve the delivery of patient services by

creating long-term, successful collaborations between local authorities, health and social care organisations and universities (Birmingham, Keele, and Warwick). One of their main areas of focus is maternal and child health. They have an active maternity public and patient involvement group named PRIME who support and guide maternity related research. A version of this protocol was presented to 6 members of PRIME and their views and opinions have also been incorporated. As a group they were very supportive and understood the necessity of this study. They expressed that they themselves would have appreciated any support to help them manage the excess weight gained post-delivery. Three of the women raised a valid concern regarding the setting of the intervention. They expressed concern that the first immunisation appointment was a very stressful time to be considering weight management, but simultaneously appreciated how easily this intervention could be executed. This is a reasonable observation and I am aware that this has the potential to affect the overall acceptability of this intervention. Therefore, this will be explored in detail during the semi-structured interviews. The PRIME group appreciated the convenience of the intervention, particularly that there was no need for women to attend any additional appointments and that an external source would be monitoring their weight, they thought this would be highly beneficial.

Appendix 8: Participant invitation letter

As Postmark

Dear Patient

We would like to invite you to take part in a study investigating two simple approaches to managing your weight after having a baby. The approaches are easy and will not require you to attend any additional appointments or take up too much of your time.

Please take some time to read the enclosed leaflet which contains more information about the study, including who can take part and what it would involve for you. This study is being conducted by a research team from the University of Birmingham.

If you would like to be a part of the study, we would be very grateful if you could please contact the PIMMS research team at the University of Birmingham **within 10 days from the date you receive this letter**. Please contact - Janice Ferguson 07471 744992 or Dr Helen Parretti 0121 414 3766.

If you are eligible to take part a researcher from the university will visit you at home to discuss taking part in the study.

If you have any further questions please do not hesitate to contact the University of Birmingham research team who will be happy to answer your queries.

Thank you for considering taking part in this study.

Janice Ferguson
Trial Manager

Enclosed: *Information leaflet*, postal reply form & reply paid envelope

Appendix 9: Trial patient information sheet

Invitation

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take as much time as you need to read the following information carefully. Talk to others about the study if you wish. You might want to talk to your midwife, doctor or contact us if anything isn't clear or you would like more information.

What is the study about?

Pregnancy and the postnatal period are vulnerable life stages for gaining excess weight. Many women have reported that pregnancy is an important factor that has led to weight problems later on in life. This can significantly increase the risk of obesity and other serious chronic illnesses including type 2 diabetes, heart disease and cancer. It is therefore important to find ways to help new mothers lose weight gained during pregnancy and return to their pre-pregnancy weight.

Currently women do not receive any advice or support about weight management after giving birth. We are investigating two different approaches to giving women information and support on managing their weight after giving birth. This study is investigating which of these approaches women prefer and we will use this information to determine which method is most effective in helping women lose weight over the longer term.

Why have I been invited?

You have received this information leaflet because you have recently given birth and are over 18 years old. You will only be asked if you want to take part in the study if your body mass index (BMI) is 25kg/m² or more when we come and visit you in your home.

What will I have to do?

This study has been designed so that you don't have to have any additional visits to your nurse, GP or hospital. However, you will be visited at the start and end of the study at home with your permission to measure your weight and complete some questionnaires about your health and well-being. Your involvement in the study will last 3 months.

Your GP practice (and therefore you) will be randomly allocated to one of two groups (like tossing a coin). You have an equal chance of being assigned to either of the two groups.

Both groups will be given written information, but one group will also receive brief support from their nurse at their baby's immunisation appointments. Irrespective of which group you are allocated to, both you and your baby will receive all of the care you would normally receive from your practice and health visitor.

You may also be asked to take part in an interview at about your experiences of taking part in this study. This will take about 30 minutes.

Your GP will also be informed that you are taking part in the PIMMS study.

Do I have to take part?

It is up to you to decide if you want to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without giving a reason and this will not affect the standard of care you or your baby receives from your healthcare team.

What happens if I have a complaint about the study?

If you have a concern about any aspect of this study, you should ask to speak to the researchers at the University and they will answer your concerns. If you remain unhappy about the way you have been treated you can make a formal complaint by contacting Charlene Mulhern at Birmingham Public Health on 0121 303 4454 or by email at charlene.mulhern@birmingham.gov.uk.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will not release any information about you to any external organisation.

Who is organising and funding the research?

Researchers at the University of Birmingham are organising the research. The research is being funded by the University of Birmingham.

THIS STUDY IS BEING CONDUCTED IN PARTNERSHIP WITH BIRMINGHAM PUBLIC HEALTH AND THE NATIONAL INSTITUTE FOR HEALTH RESEARCH, SCHOOL FOR PRIMARY CARE RESEARCH.

Who has reviewed the research?

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 by a NHS research ethics committee and it has been given a favourable opinion. The study reference number is 15/WM/0445.

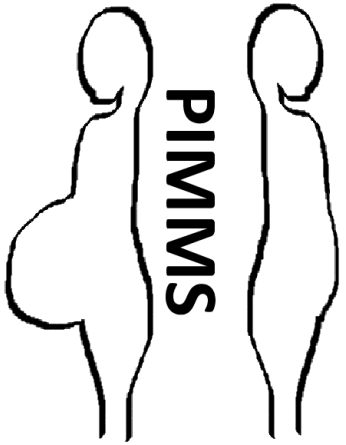
What will happen to the results of the study?

The results of the study will be published in an academic journal. No individual will be able to be identified in the published information. A summary of the results of this study will be sent to you sometime in late 2017, at your request.

Contact details for further information

For further information please contact Janice Ferguson 07471 744 992 or Dr Helen Parretti 0121 414 3766 at the University of Birmingham.

Patient Information Sheet for PIMMS Study



Appendix 10: Participant expression of interest form (postal)

UNIVERSITY OF BIRMINGHAM

PIMMS Study (Postnatal Weight Management) Postal Reply Form

☐ **Yes,** I wish to participate in the PIMMS study

☐ **Not sure** if I would like to participate in the study and would like the opportunity to discuss this further with one of the study team before agreeing.

Name: .....

Contact number .....

When would be the most suitable time for us to call you? .....

.....

Appendix 11: Trial poster

Want to lose weight after having a baby?

Help us find out which one of two interventions is best at helping with postnatal weight loss.

Who?

We are looking for women (over 18 years) who have recently given birth.

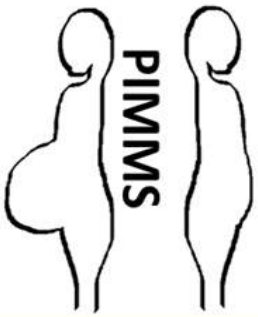
What do I have to do?

As a participant in this study you will receive one of two interventions offering different types of information and support to help you manage your weight. You will be asked to complete some questionnaires about your general health & wellbeing and allow us to measure your weight.

You may also be asked to take part in a short interview at the end of the study to help us find out what you thought about being in the study.

How long will it take?

Overall you will be involved in the study for 3 months. Completing the questionnaires should take no longer than 30 minutes.



In reimbursement for your travel expenses, you will receive a £10 voucher at the end of the study.

UNIVERSITY OF BIRMINGHAM

INTERESTED?

Please contact:
Janice Ferguson
Tel: 07471 744 992
Email:
jaf584@student.bham.ac.uk

This study has been reviewed by, and received ethics clearance through West Midlands - Black Country Research Ethics Committee

PIMMS Poster Version 8 25/04/2016

Appendix 12: Trial telephone screening form

UNIVERSITY OF BIRMINGHAM

PIMMS Study

Telephone Screening for Eligibility

Thank you for calling to find out more about our research study. My name is Janice Ferguson, and I am a researcher at the University of Birmingham.

The purpose of our research study, PIMMS, is to look at what effect providing new mothers with information relating to post-natal weight management and support has on their weight. We will be following new mums like you for three months to determine what effect if any providing this information has.

All that is required from you is to attend your baby's immunisation appointments at your GP practice and agree to meet with one of our researchers in your home to complete a couple of questionnaires at baseline and then at the end of the study. You may then be asked to be interviewed to find out how you felt about the information you were provided and how useful this was for you.

Do you have any questions or concerns so far?

Now that you have a basic understanding of the study, do you think you might be interested in participating?

If **NO**, thank and end call.

If **YES**,
Before enrolling people in this study, we need to determine if you may be eligible to participate. I will now ask a few questions that will help us determine if you are eligible. Remember, your participation is voluntary; you do not have to complete these questions. Please feel free to stop me at any time if you have any questions or concerns. Do I have your permission to ask you these questions?

Date: ___ ___ / ___ ___ / ___ ___

1. First name: ……. Surname: ……
2. GP Practice: ……
3. When did you give birth? ____ ____ / ____ ____ / ____ ____
4. Number of weeks post-delivery: ……
5. Height: ……feet/cm
6. What is your current weight? ……stones/lbs/kg
7. BMI= ……kg/m²
8. Date of Birth (dd/mm/yy):- ____ ____ / ____ ____ / ____ ____
9. Address: ……

   ……..

   ……

10. Home number: …… Mobile number: ……
11. Email: ……..
12. Are you currently, or have you recently been involved in any other research studies? **Yes / No**

    ……

    ……..
13. Potentially meets inclusion criteria? **Yes / No**

Based on your answers to the questions, it appears you may eligible to participate in the research study. Would you like to schedule a time to meet with a member from the research team to get your height and weight and go through a questionnaire at your home?

14. Agrees to home visit? Yes / No
15. Date of home visit: ____ ____ / ____ ____ / ____ ____
16. Time of home visit: ……

Thank you for taking the time to talk with me today. If you have any questions or concerns, please feel free to contact me on this number.

Appendix 13: Body trace scale user's manual

Weighing Scales

Using the scales

The scales will only work on a hard, flat surface. If you use them on carpet they will not provide an accurate weight for you.

Step on to the scales and stand still until the display flashes like in the image below.

Step off the scales and wait for dashes to appear on the display, this means the measurement is being transmitted. Once the measurement has been successfully transmitted, the lines will show a box like the image below.

If you do not see this image, please see the guide below which tells you what to do in the case of an error message.

FAQS

- ***How do I turn the scales on and off?***

The scales will turn on and off automatically when you step on and off them, you do not need to press an 'on' or 'off' button.

❖ ***What do I do if I get an error message?***

Please see the images below and follow the instructions on what to do if you get an error message.

ER 2 rEAD: Measurement error. You may get this during the weighing procedure. You need to stand still on the scales for longer in order to allow the scales time to record your weight.

ER 4 bAtt: Low battery error. You may get this during the weighing procedure after the lines moving around. The batteries need to be replaced, please contact Janice Ferguson on 07471 744992

ER 4 CELL: Network error. You may get this after the lines moving around. No cellular network is found; try moving the scales to a different location.

ER 6 SEnd: Send error. You may get this after the lines moving around. Signal not strong enough, try moving the scales to a different location.

ER 7 Intl: Internal error. You may get this after the lines moving around. Please contact Janice Ferguson on 07471 744992

ER8: SIM error. You may get this after the lines moving around. Please contact Janice Ferguson on 07471 744992

ER 9 Prov: Internal error. You may get this after the lines moving around. Please contact Janice Ferguson on 07471 744992

Appendix 14: Weight record card

2 Month Immunisation Appointment

Date	Weighed before or after immunisation				Weight (kg)	Reminded about One You				Weekly self-weighing			
	Before		After			Yes		No		Yes		No	

3 Month Immunisation Appointment

Date	Weighed before or after immunisation				Weight (kg)	Reminded about One You				Weekly self-weighing			
	Before		After			Yes		No		Yes		No	

4 Month Immunisation Appointment

Date	Weighed before or after immunisation				Weight (kg)	Reminded about One You				Weekly self-weighing			
	Before		After			Yes		No		Yes		No	

Weighing Record Card

Week	Weight (kg, Stone/ lbs)	I feel…. (see faces below & enter relevant number)
Week 1		
Week 2		
Week 3		
Week 4		
Week 5		
Week 6		
Week 7		
Week 8		

Week	Weight (kg, Stone/ lbs)	I feel …. (see faces below & enter relevant number)
Week 9		
Week 10		
Week 11		
Week 12		
Week 13		
Week 14		
Week 15		
Week 16		

				
1. Delighted	2. Happy	3. Alright	4. Disappointed	5. Upset

of tea with a friend can all help, just find something that works to help you relax.

Get a good night's sleep

Sleep gives our body a chance to heal and renew itself, which is vital for good health. Aim to try and get 7 hours sleep a night.

As a new mum, you'll be trying to get baby into a sleep routine. While this happens, nap when baby does to keep your energy levels up.

Work on your relationships

Try to be social and spend time with people. Maybe join a mother and baby group.

Healthy Lifestyle Tips for New Mums

Congratulations you've just had a baby! What better time than now to take some time to assess your health so that you can be your best, (mentally, physically and emotionally) for your new bundle of joy.

The advice enclosed will guide you through some health checks that you can use to gauge your overall health and use to start to make changes that will improve your overall health and wellbeing.

Get on top of any health related issues

A major priority for healthy living is to ensure that any pre-existing health problems or conditions are being treated.

Prevention is better than cure. With that in mind, seek help or treatment to deal with any behaviour or activity which can lead to poor health now or in the future such as a high sugar diet, smoking or living a sedentary life.

Get more active

Research has linked physical activity to living a happier and healthier life. It doesn't need to be hard core, just make it something fun and that you can easily make part of your daily routine. Start slow and set yourself goals.

Revamp your diet

A healthy well balanced diet can help you look and feel great. Why not try to eat more and a bigger variety of different fruit and vegetables?

As a busy mum, plan your meals in advance. This will not only save you time but ensure that you're eating well and regularly, which will keep your energy levels up.

Manage stress

With a new member of the family arriving and the upheaval that follows, life can be a little chaotic and cause a little stress. Meditation, yoga or a cup

Appendix 16: Nurses' information leaflet

UNIVERSITY OF BIRMINGHAM

NURSES INFORMATION LEAFLET

The feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme.

Pregnancy and the postnatal period are vulnerable life stages for gaining excess weight. Many women have reported that pregnancy is an important factor that has led to weight problems later on in life. This can significantly increase the risk of obesity and other serious chronic illnesses including type 2 diabetes, heart disease and cancer. It is therefore important to find ways to help new mothers lose weight gained during pregnancy and return to their pre-pregnancy weight.

Currently women do not receive any advice or support about weight management after giving birth. We are investigating two different approaches to helping women to manage their weight after giving birth. This study is a pilot study to investigate which of these approaches women prefer and we will eventually use this information to help us develop a bigger study to fully evaluate the approach over the longer term. We would also like to find out what practice nurses like you think of the intervention.

Who is organising and funding the study?

Researchers at the University of Birmingham are organising the research. The research is being funded by the University of Birmingham and Birmingham Public Health.

This study is being conducted in partnership with Birmingham Public Health and National Institute for Health Research, School for Primary Care Research.

NHS research ethics committee have reviewed this study and have given a favourable opinion. The study reference number is 15/WM/0445. Permission form the relevant R&D departments has also been gained

What is the aim of the trial?

The study aims to evaluate the feasibility and acceptability of a brief routine weight management intervention embedded within the national child immunisation programme on helping postnatal mothers to manage their weight. We are interested in the views of women who take part and also the views of practice nurses who will deliver the intervention.

How will the study be conducted?

Stage 1: A cluster randomised controlled trial involving 10 general practices

- General practices that have agreed to participate in this study will be randomised to either deliver the intervention or to provide usual care
- WOMEN FROM YOUR PRACTICE WHO HAVE RECENTLY GIVEN BIRTH WILL BE IDENTIFIED BY THE PRACTICE STAFF AND INVITED TO PARTICIPATE IN THE STUDY

Stage 2: Semi-structured interviews

- Approximately 8 practice nurses will be interviewed by the research team to determine their thoughts and feelings about delivering the intervention within child immunisation appointments
- Up to 15 mothers will also be interviewed to understand their views about taking part in the intervention

What will I have to do?

Your involvement will be:

- Complete a 30 minute training session about the study and on how to deliver the intervention
- Deliver the intervention (1-2 minutes per woman)
- Participate in an interview about your views of the intervention (20-30 mins) at the end of the study.

If you have any questions, please contact:

Janice Ferguson
Primary Care Clinical Sciences,
The Learning Centre, Room 125
University of Birmingham
Edgbaston
Birmingham
B15 2TT
E-mail: JAF584@bham.ac.uk

Appendix 17: Nurse training manual

PIMMS

The feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme

Nurses Training Manual

Contents

Introduction

This booklet has been devised to help you understand more about the PIMMS study and it provides details about what we would like you to do. You have received this booklet because your practice has been randomised to deliver the intervention for this study.

Summary of the PIMMS study

Why is this study needed and what is it about?

After the birth of their baby, many women find it hard to lose the weight they have gained during pregnancy. At 1 year after giving birth 25% of women retain more than 4kg of their 'baby' weight. This excess weight increases the risk of developing diseases in later life. Many women would welcome support to lose weight at this time. It is important that nurses are able to offer the best advice possible. Most studies involving overweight/obese mothers during the postnatal period have tested intensive weight loss interventions; these types of intensive interventions cannot be offered by the NHS to all of the 530,000 overweight/obese women who give birth in the UK every year. It would be too expensive to do this, and many women find it hard to find the time to attend additional visits to health care professionals at a time when they are focused on their baby. Instead, low cost interventions that are incorporated within existing health programmes or contacts can be offered to all women after having a baby.

We plan to embed a simple brief intervention alongside the national child immunisation programme. The first step is to test how acceptable our approach is to mothers and how practical it is for nurses to deliver the intervention during child immunisation appointments. The booklet will explain in more detail how we would like to do this. If the intervention is successful in helping women to lose excess weight, it can be immediately implemented as routine practice by the NHS.

What does the study involve?

About 10 practices (clusters) have been randomised to either deliver the intervention or offer no intervention (usual care). Your practice has been randomised to deliver the intervention for this study so mothers at your practice will receive brief additional advice and support to lose weight and be weighed by you at the start of baby's immunisation visit. We plan to recruit about 80 postnatal mothers.

Intervention summary

The fundamental goal of the intervention is to encourage women to self-manage their own weight by weighing themselves weekly and recording this. Women will be advised to aim for between 0.5 to 1kg weight loss per week. To provide accountability ("big brother effect") women will be advised that they will be weighed by the nurse at each child immunisation appointment to assess their progress. An individual who is regularly weighed (either by themselves or someone else) is more likely to stay focussed on changes in their weight and this is also likely to act as a source of motivation to adhere to their weight loss goals. We want women to reflect on their weight loss, what they have been eating and their physical activity levels each week.

We **do not** want nurses to provide any lifestyle counselling; your role is simply to provide regular external accountability for weight loss and to signpost women to using the One You healthier lifestyle support website. We would like you to encourage them to register with One You as they will then be sent regular automated email messages encouraging them to make healthier lifestyle choices that will help them manage their weight. One You also provide links to a downloadable food diary with a weekly weight tracker, free apps that encourage more physical activity as well as quick and easy recipe ideas.

Based on our previous work with community midwives we expect the intervention will take you about 1-2 minutes per immunisation appointment.

Intervention components

Women will be:

- Provided with a set of electronic scales and asked to weigh themselves each week and to record their weight on the One You website or on the yellow weight record card attached to their child's red book.
- Weighed by the practice nurse at each immunisation visit and given brief encouragement to stick to their weight loss goals.
- Signposted to use an online weight management programme for support and advice about weight loss.
- Given a healthy lifestyle advice leaflet.

***NOTE*:** A PIMMS sticker will be placed on the front of the red baby book so you know which mothers are taking part in the study.

What is the study looking at?

This study is investigating how practical and feasible it is for nurses to deliver a very brief weight management intervention to mothers during baby's immunisation appointments. We also want to investigate how mothers feel about receiving this support at their baby immunisation visits. All the women have consented to take part in this study and to provide us with their feedback.

How long will the study take?

In total the study will run for about 12 months. We expect each practice will deliver the intervention to between 6-8 women over about six months, so the time commitment is very small. If there are eight women taking part from your practice, then we expect this intervention will take about 1hr of your time in total (2 mins for the intervention x 8 women x 3 immunisation appointments = 48 minutes).

How are mothers recruited into the study?

Although you will not be directly involved in the recruitment process, it may be useful to know how the mothers have been recruited. Women will be recruited from your practice in one of two ways; either via a regular database search at your practice or by Birmingham Women's Hospital searching regularly and identifying women from your practice who have recently given birth. The mothers will be sent an invitation pack containing an invitation letter and a patient information leaflet. The letter will ask interested women to contact our research team at the University of Birmingham. Women who are interested in taking part will be visited at home by the research team who will explain the study in more detail, take

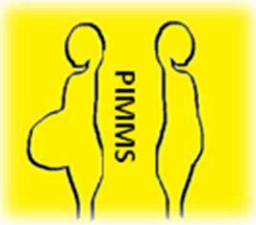
consent, weigh women and ask them to complete some questionnaires about their health. At this visit women will also be told whether they will receive the intervention or usual care.

Who is eligible to take part?

- Aged 18 years or more
- Given birth at least four weeks previously
- BMI 25kg/m^2 or more (calculated by the research team at the time of recruitment)

How much weight are women supposed to try and lose?

In line with current NICE guidance women will be advised to aim for 0.5-1 kg weight loss per week until they are back to their pre-pregnancy weight or BMI.



Immunisation appointments

The intervention should be delivered at the first three immunisation appointments (when the baby is 2, 3 and 4 months old). When handed their baby's immunisation record book, **check** for the PIMMS sticker on the front of their book. It will look similar to the one above. We think it is best to deliver the intervention before you do the immunisation, but it is up to you and the mother to decide this.

What happens <u>before</u> the first immunisation visits?

Before the mother brings her baby to their first immunisation appointment, the research team will ensure that the following take place with each mother:

- Assessed for eligibility

- Asked to provide informed written and oral consent to participate in the study
- Weighed and asked to complete a questionnaire
- Notified of group/practice allocation

MOTHERS IN PIMMS STUDY ONLY

- PIMMS sticker placed on front of red book
- Weight record card attached to back of red book
- Given a One You leaflet and encouraged to access the website
- Given a set of electronic weighing scales
- Asked to start weekly weighing and recording this on their weight record card.

First immunisation appointment (baby 2 months old)

Introducing the study to the mother

- If there is a PIMMS sticker on the front of the red book, the mother will be expecting you to weigh her and record this in the red book.

  "I see you're taking part in the PIMMS study? In that case, I'll need to weigh you today".

Weighing and recording the mother's weight

- Turn towards the back of the red book, there will be a bright yellow weight record card.
- Enter the date of the immunisation appointment in the 2-month immunisation table attached to the red book (see Appendix 1 for an example).

- It is up to you and the mother to decide whether you weigh her before or after immunising her baby. Check the relevant box on the record card to indicate when this was done.
- Ask the mother to remove her shoes as well as any items of bulky clothing.
    - Using the scales provided, take the mother's weight in **kilograms.**
    - Record this weight on the weight record card.
    - Strongly encourage mothers to weigh themselves and record this on their weight record cards at least once per week (women have been given home weighing scales that we would like them to use for this study).

Signposting mothers to the One You website

- Gauge the mother's reaction to the weight you have just recorded and use this as an opportunity to steer the conversation towards One You.
- Tell the mother to use the One You website and record that you have done this on the record card at the back of the red book. It may be helpful if you visit the website (https://www.nhs.uk/oneyou/weight#5rXSJrFRgiTQPJx4.97) so that you are familiar with it yourself.
- Perhaps a little encouragement if they look a little down would be good at this stage.

"Don't be so hard on yourself. You've not long had your baby, why don't you have a look at the One You website? It has lots of really helpful stuff on how to lose weight and lead a healthy lifestyle."

- Give a brief summary of what the One You website offers and how it could be helpful for them, especially if they register with One You after taking the health quiz.

  "One You is a free online source of information on healthy lifestyles and weight loss. It's free, quick and very easy to use. They offer 12 week plans to help you lose weight and then give you information on how to keep the weight off. They've also got apps you can download to help you get more active and healthy meal ideas. They've also got a forum so you can chat and swap ideas with other users."

Self-weighing

- Have a look at their weekly weighing records on the weight record card – have they already started weighing themselves weekly and recording this?
- If she has been recording her weight weekly, tick the Yes box on the complete record card section on the record card. If she has not, tick No.
- Encourage/reinforce weekly self-weighing and recording of weight on the record card.
- Explain that weekly self-weighing and reflecting on weight loss will help towards achieving weight loss goals.

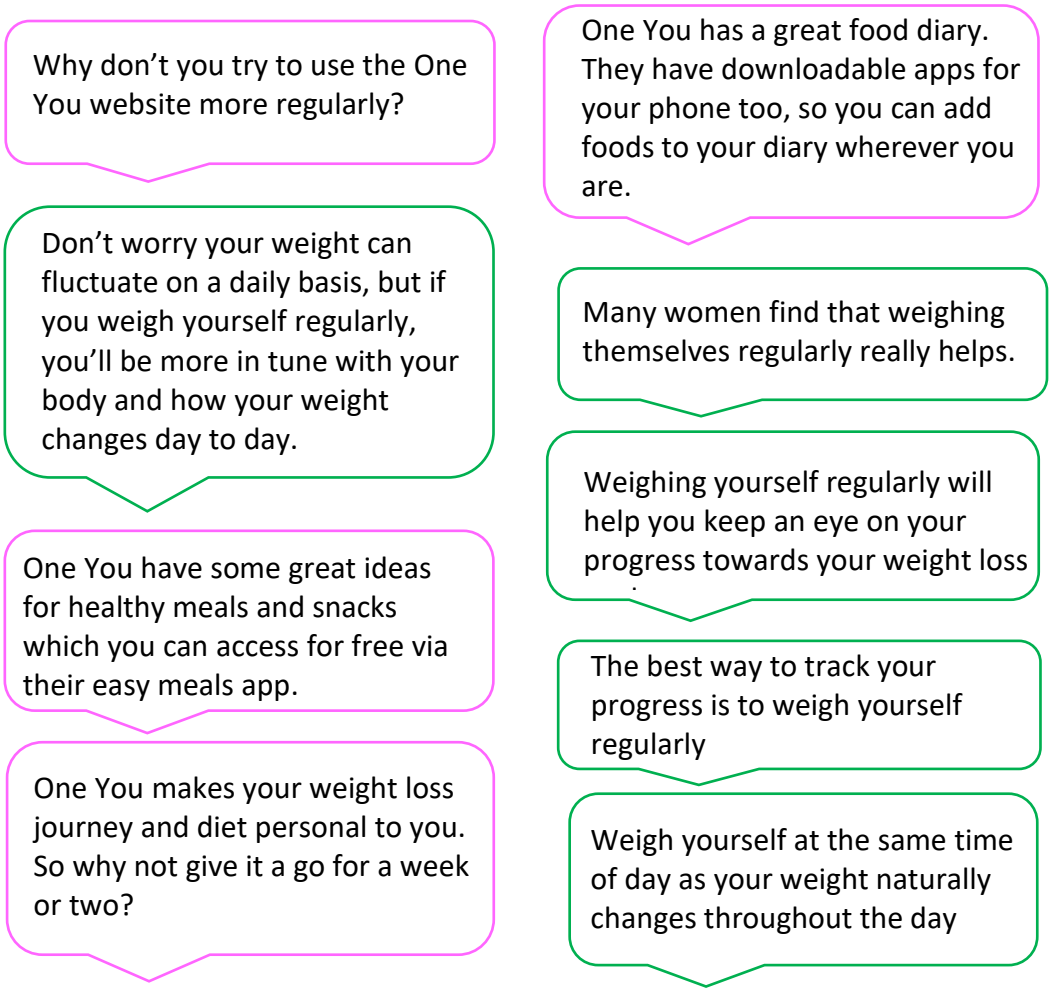
CHECKLIST

By the end of EACH first immunisation appointment please ensure that you have completed the following:

- Weighed and recorded mother's weight on record card
- Checked that she has been weighing herself on a weekly basis
- Asked if she has accessed the One You website
- Signposted mother to One You website
- Have not provided any lifestyle counselling
- Completed 2-month immunisation appointment section on weight record card

Second & third immunisations (baby is 3 & 4 months old)

- Check if there is a PIMMS sticker on the front of red book.
- Turn towards the back of the red book, there will be a bright yellow record card.
- Enter the date of the immunisation appointment.
- Ask the mother to remove her shoes as well as any items of bulky clothing and weigh her. Please use the scales provided and record her weight in **kilograms.**
- Record this weight on record card in the red book.
- Record whether the mother's weight was taken before or after immunising her baby.
- Reinforce the effort she's made by offering some positive feedback regarding the steps she's taken towards managing her weight, even if there is no weight loss.
- If there has been no weight loss emphasise the important role of regular self-weighing and use of the One You website.



Signposting mothers to the One You website

- Ask the mother if she has visited the One You website. If she has not, mentioning One You may act as a reminder for them and may motivate them to visit the website.
- Check the box on their weight record card relating to whether or not they have accessed One You.

Self-weighing

- Have a look at mothers' weekly weighing records on the record card – are they weighing themselves weekly and recording this? If she is not, gently encourage her to do so as this will help her with her weight loss goals.

- Check the box based on her answer

CHECKLIST

By the end of EACH 2nd and 3rd immunisation appointment please ensure that you have completed the following:

- Weighed and recorded mother's weight on record card
- Checked that she has been weighing herself on a weekly basis
- Asked if she has accessed the One You website
- Signposted mother to One You website
- Have not provided any lifestyle counselling
- Completed 3/4-month immunisation appointment section on weight record card
- Offered encouragement to mother to make healthier lifestyle choices
- Checked that she has been weighing herself on a weekly basis and reflected on this
- Asked if she has accessed the choose2bslim website
- Completed the relevant appointment section on weight record card

What happens after the last immunisation appointment?

All women will be visited at home again and will be weighed by the study team. We will also ask women to complete some questionnaires about their health. Some women will also be asked for their feedback about their involvement in the study.

What to do if you need help

If the scales stop working, please contact Janice who will come and replace them.

If the mother refuses to be weighed that is alright, just make a note of it on their weight record card.

If the mothers ask you for detailed lifestyle advice, or initiates a discussion, simply direct them to the One You website for more information.

If the mother does not attend the immunisation appointment with her baby, please make a note on the weight record card.

If you need any further help with this study, please contact the research team (details below).

Research team contact information

If at any time something happens and you are unsure of what to do, please get in touch with a member of the research team who will gladly help. Their contact information is as follows:

Janice Ferguson
Primary Care Clinical Sciences,
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Email: JAF584@student.bham.ac.uk
Telephone: 07471 744 992

Dr Helen Parretti
Primary Care Clinical Sciences
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Email: h.m.parretti@bham.ac.uk
Telephone: 0121 414 3766

Appendix 1: Weight record card

2 Month Immunisation Appointment

Date	Weighed before or after immunisation				Weight (kg)	Reminded about One You				Weekly self-weighing			
	Before		After			Yes		No		Yes		No	

3 Month Immunisation Appointment

Date	Weighed before or after immunisation				Weight (kg)	Reminded about One You				Weekly self-weighing			
	Before		After			Yes		No		Yes		No	

4 Month Immunisation Appointment

Date	Weighed before or after immunisation				Weight (kg)	Reminded about One You				Weekly self-weighing			
	Before		After			Yes		No		Yes		No	

Weighing Record Card

Week	Weight (kg, Stone/ lbs)	I feel…. (see faces below & enter relevant number)
Week 1		
Week 2		
Week 3		
Week 4		
Week 5		
Week 6		
Week 7		
Week 8		

Week	Weight (kg, Stone/ lbs)	I feel …. (see faces below & enter relevant number)
Week 9		
Week 10		
Week 11		
Week 12		
Week 13		
Week 14		
Week 15		
Week 16		

				
6. Delighted	7. Happy	8. Alright	9. Disappointed	10. Upset

Appendix 18: Case report form

PIMMS Study

Participant Contact Details *(Please complete for all participants)*

1. **Participant ID:** | | | | | | | | | | | |
2. **Date of Birth:** | | | - | | | | - | 1 | 9 | | |
3. **Forename(s):** _____
4. **Surname:** _____
5. **Address:** _____
6. **Postcode:** | | | | | | | |
7. **Home Telephone:** | | | | | | | | | | | |
8. **Mobile Telephone:** | | | | | | | | | | | |
9. **Email:** _____
10. **Main language spoken:** _____

Ethnic Group (Please tick the relevant box):

White	☐	Black Caribbean	☐	Black African	☐
Mixed	☐	Black Other	☐	Chinese	☐
Indian	☐	Pakistani	☐	Bangladeshi	☐
Other Asian	☐	Other (Please specify):	_____		

Please insert Participant's ID number on each page: ___ ___ ___ ___

Section 1: Identifying potential participants

1.1 INCLUSION CRITERIA

▪ Aged 18 years or more	Yes		No	
▪ Given birth at least 4 weeks previously	Yes		No	
▪ BMI ≥25kg/m²	Yes		No	
▪ GP screened and considered suitable for trial	Yes		No	

1.2 EXCLUSION CRITERIA

▪ Still birth	Yes		No	
▪ Unable to understand and speak enough English sufficiently to give informed consent and complete the research components	Yes		No	

*NOTE: If **YES** is the answer to **any** of the above questions in the EXCLUSION checklist the patient is **unable** to participate in this study.*

1.3 Recruitment

BWH		Self-referral	

Section 2: Randomisation

▪ Randomisation Group: (Please tick appropriate box)	UC		INT	

▪ Participant's General Practice: _____

▪ Participant's Midwife/ Health Visitor: _____

Please insert Participant's ID number on each page: ___ ___ ___ ___

PIMMS Study

Case Report Form

- Participant ID Number: | | | |
- Date of Birth: ____ /____ / _____
- Randomisation Group **UC** | | **INT** | |

Section 1: Summary Record

Session	Date	Objective Weight	Height	BMI	Scales given/ collected ?	Study QR's Completed / Returned
	dd-mm-yy	kg	cm	kg/m²	Yes/ No	Yes/ No
Baseline Home Visit						
4 Month follow up			N/A			

Notes:

Scale Serial Number: __ __ - __ __ __ __ __ __ - __ __ __ __ __ __ - __

Please insert Participant's ID number on each page: ___ ___ ___ ___

Section 2: Baseline Home Visit

Height: _____cm

Weight: _____kg

BMI: _____kg/m²

Weight retained postpartum: _____ kg

I would like to ask you some questions about your pregnancy

1. **In total how many children have you given birth to?** ☐
2. **Number of children at most recent birth:** ☐

3. **During this last pregnancy, did you have any pregnancy related health complications?**

Yes ☐ No ☐

b) If YES would you mind telling us what those were?

_____

_____

_____

4. **What type of delivery did you have?**

Normal vaginal delivery ☐ Instrumental vaginal delivery (Forceps/ vacuum) ☐

Elective (planned) caesarean section ☐ Emergency caesarean section ☐

Other_____

5. **Did you try to breastfeed your baby?**

Yes ☐ No ☐

Please insert Participant's ID number on each page: ___ ___ ___ ___

6. How are you currently feeding your baby?

Exclusively breastfeeding	☐	Exclusively Formula feeding	☐
Both breastmilk & formula	☐	Other (please specify)	

_____

7. How long do you intend to keep breastfeeding?

3 months	☐	More than 1 year	☐	N/A	☐
6 months	☐	As long as possible	☐		
9 months	☐	Unsure	☐		

8. Have the types of food you eat changed since the birth of your baby?

Yes ☐ No ☐

a. If YES, how have they changed?

Fewer home cooked meals	☐	More ready/ quick meals	☐
Snack more frequently	☐	Other	☐

_____

_____

_____

9. On average how many hours of uninterrupted sleep do you get per night?

3hrs or less	☐	Between 4-6hrs	☐	Between 7-8hrs	☐	9hrs or more	☐

10. How ready do you feel to start trying to lose the weight that you have gained during pregnancy?

Not at all ready	☐	Almost ready	☐
Ready	☐	Very ready	☐
Neither	☐		

Please insert Participant's ID number on each page: ___ ___ ___ ___

Section 3: RA's Checklist- Baseline Home Visit

Before the end of the Home Visit:

Attained written informed consent	Yes		No			
Measured and recorded participant's height and weight?	Yes		No			
Collected the Baseline questionnaire Part A?	Yes		No			
Collected Baseline questionnaire Part B?	Yes		No			
Left Baseline QR Part B & Freepost envelope?	Yes		No		N/A	
Given information leaflet on diet and exercise	Yes		No		N/A	

Intervention group only:

Attached weight recording card to immunisation booklet?	Yes	
Provided participant with weighing scales?	Yes	
Asked participant to self-weigh and record this once a week	Yes	
Informed participant about One You website	Yes	
Stuck PIMMS sticker on red book	Yes	

Name of researcher: _____

Signature: _____

Date of completion: _____/ _____/ _____

Please insert Participant's ID number on each page: ___ ___ ___ ___

Section 4: Trial Checklist (following recruitment)

- Copy of 'Patient Informed Consent Form' placed in participant's records?

  Yes ☐ Date: ☐

- GP sent a letter informing them of patient's trial entry and randomisation?

  Yes ☐ Date: ☐

- Completed CRFs logged?

  Yes ☐ Date: ☐

- Double checked that all possible sections of the CRF are complete at this stage?

  Yes ☐ Date: ☐

- **Name of trial management assessor**: _____

- **Signature:** _____

- **Date:** _____/ _____/ _____

Please insert Participant's ID number on each page: ___ ___ ___ ___

Section 5: 4-month follow up appointment

Participant's Weight: ☐ kg

4-month questionnaire Part A completed and collected at visit	Yes	☐
Participant left with 4-Month QR Part B	Yes	☐
Freepost envelope for QR Part B given	Yes	☐

FOR ALL PARTICIPANTS:

1. Immunisation Appointments: Ask to look at immunization book and record

Immunisation Appointment	Attended? Yes/ No	Who attended Appointment?	Date of Appointment	Weight at Appointment(Kgs)
2 month				
3 month				
4 month				

2. How are you currently feeding your baby?

☐ Exclusively breastfeeding
☐ Exclusively Formula feeding
☐ Both breastmilk & formula
☐ Other (please specify)

3. How long do you intend to keep breastfeeding?

3 months ☐ More than 1 year ☐ N/A ☐
6 months ☐ As long as possible ☐
9 months ☐ Unsure ☐

4. Are you currently trying to lose the weight you gained during pregnancy?

Yes ☐ No ☐

Please insert Participant's ID number on each page: ___ ___ ___ ___

a) How do you feel this is going?

_____
_____
_____

b) What resources have you accessed or used in order to help you with your weight loss?

_____
_____
_____

5. Do you feel that there are people you know, amongst your family and friends who support and encourage you with your postnatal weight loss?

Yes ☐ No ☐

_____
_____
_____

6. Have you accessed the One You website?

Yes ☐ No ☐

a) If answers YES- could you tell me what you think of it? What helpful tips/advice/resources have you accessed and used that you think have helped you maintain/lose weight?

_____
_____
_____
_____

FOR INTERVENTION PARTICIPANTS ONLY

7. You are in the intervention group so have been asked to weigh yourself weekly and get weighed during your baby's immunisation appointments. How has this been going?

_____
_____
_____
_____

Please insert Participant's ID number on each page: ___ ___ ___ ___

Section 5: RA's Checklist- 4 month Home Visit

Before the end of the Home Visit:

Measured and recorded participant's weight?	Yes	
Collected the Follow up questionnaire?	Yes	

Intervention group only:

Collected/ taken a photo of weight recording card?	Yes	
Collected weighing scales?	Yes	

Ask participant to print their name and sign below to confirm they have received a £10 voucher.

"I confirm that I have received a £10 gift voucher for participating in the PIMMS study".

Participant's Name (Please print)	**Participant's Signature**	**Date**

Name of researcher: _____

Signature: _____

Date of completion: _____/ _____/ _____

Please insert Participant's ID number on each page: ___ ___ ___ ___

Appendix 19: Patient consent form

UNIVERSITY OF BIRMINGHAM

PIMMS: Consent Form

Participant Identification Number: _____

Title of Project: PIMMS Study

Name of Researchers: Dr Amanda Daley, Dr Helen Parretti and Janice Ferguson

Please initial box

1. I confirm that I have read and understood the information sheet dated 21/03/2016 (version 5) for the above study and have had the opportunity to ask questions. ☐
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 data collected during the study, may be looked at by individuals from the research team at the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records to allow access to data when auditing. ☐
4. I understand and give permission for the research team to use direct and anonymous quotes from me, when deemed relevant. ☐
5. I agree to my GP being informed of my participation in the study ☐
6. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Researcher taking consent	Date	Signature

When completed: 1 for participant, 1 for researcher file site, 1 for GP Practice patient file

Appendix 20: Baseline questionnaires

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

PIMMS Study

Baseline Health Questionnaire Part A

We would be very grateful if you would answer this questionnaire. It should take you about 10 minutes to complete.

Most of the questions just require you to tick a box as a response. **Please try to answer every question**. If you are unable to answer a question because no option corresponds exactly to the answer you wish to give, please try to answer it as best you can.

Please return your completed questionnaire to the researcher.

Please answer **each** question by marking one box or writing in an answer.

General questions about you

1. Which of these best describes your current marital status? *Please tick one box.*

Single (living alone)	☐	Divorced/Separated (living alone)	☐
Single (living with partner)	☐	Divorced/Separated (living with partner)	☐
Single (living with parents/family)	☐	Divorced/Separated (living with parents/family)	☐
Married	☐	Other: (*please specify*)	☐

_____

2. Which of these best describes your current employment status? *Please tick one box.*

In paid employment	☐	Looking after the home/family	☐
Self-employed / freelance	☐	Sick / disabled	☐
Unemployed	☐	Other (Please specify)	☐
Student	☐	_____	

3. How many cigarettes do you smoke <u>on average each day</u>? *Please tick **one** box*

None ☐ 5 or less ☐ 6-10 ☐ 11-15 ☐ 16-19 ☐ 20+ ☐

As you have recently had a baby, we would like to know how you are feeling. Please tick the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

In the past 7 days:

4. I have been able to laugh and see the funny side of things

As much as I always could	☐	Not quite so much now	☐
Definitely not so much now	☐	Not at all	☐

5. I have looked forward with enjoyment to things

As much as I ever did	☐	Definitely less than I used	☐
Rather less than I used to	☐	Hardly at all	☐

6. I have blamed myself unnecessarily when things went wrong

Yes, most of the time	☐	Not very often	☐
Yes, some of the time	☐	No, never	☐

7. I have been anxious or worried for no good reason

No, not at all	☐	Yes, sometimes	☐
Hardly ever	☐	Yes, very often	☐

8. I have felt scared or panicky for no very good reason

Yes, quite a lot	☐	No, not much	☐
Yes, sometimes	☐	No, not at all	☐

9. Things have been getting on top of me

Yes, most of the time I haven't been able to cope at all	☐
Yes, sometimes I haven't been coping as well as usual	☐
No, most of the time I have coped quite well	☐
No, I have been coping as well as ever	☐

10. I have been so unhappy that I have had difficulty sleeping

Yes, most of the time	☐	Not very often	☐
Yes, sometimes	☐	No, not at all	☐

11. I have felt sad or miserable

Yes, most of the time	☐	Not very often	☐
Yes, sometimes	☐	No, not at all	☐

12. I have been so unhappy that I have been crying

Yes, most of the time	☐	Only occasionally	☐
Yes, sometimes	☐	No, never	☐

13. The thought of harming myself has occurred to me

Yes, quite often	☐	Hardly ever	☐
Sometimes	☐	Never	☐

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

Your Eating Habits

Over the past month how often have you eaten these foods? (Please tick one box for each food item)

		Never	Once a Month	Once every two weeks	1-2 Times per Week	3-6 Times per Week	Once a day	More than once a day
14.	Roast Potatoes or chips							
15.	Peppers or watercress							
16.	Tomatoes							
17.	Meat pies							
18.	Vegetable dishes							
19.	Courgettes, marrow or leeks							
20.	Sausages or sausage rolls							
21.	Gravy							
22.	Green salad							
23.	Wholemeal bread							
24.	White bread							
25.	Onion							
26.	Vegetarian food							
27.	Pasta							
28.	Yorkshire pudding or savoury pancakes							
29.	Crisps or savoury snacks							
30.	Beef							
31.	Spinach							
32.	Approximately how many teaspoons of **sugar** do you add each day to breakfast cereals, tea and coffee, etc.?						teaspoons	
33.	How much **full-fat milk** on average do you use per day in your drinks, added to breakfast cereals, etc.?						pints	

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

PIMMS Study

Baseline Health Questionnaire Part B

We would be very grateful if you would answer this questionnaire. It should take you about 10 minutes to complete.

Most of the questions just require you to tick a box as a response. **Please try to answer every question**. If you are unable to answer a question because no option corresponds exactly to the answer you wish to give, please try to answer it as best you can.

Please return your completed questionnaire to the researcher or in the **FREEPOST** envelope provided.

Please answer **each** question by marking one box or writing in an answer.

1. **For each of the items below, tick the box beside the one statement that best describes how you feel RIGHT NOW AT THIS VERY MOMENT. Read the items carefully to be sure the statement you choose accurately and honestly describes how you feel right now.**

a) Right now I feel…

- ☐ ***Extremely dissatisfied*** with my physical appearance
- ☐ ***Mostly dissatisfied*** with my physical appearance
- ☐ ***Moderately dissatisfied*** with my physical appearance
- ☐ ***Slightly dissatisfied*** with my physical appearance
- ☐ ***Neither dissatisfied nor satisfied*** with my physical appearance
- ☐ ***Slightly satisfied*** with my physical appearance
- ☐ ***Moderately satisfied*** with my physical appearance
- ☐ ***Mostly satisfied*** with my physical appearance
- ☐ ***Extremely satisfied*** with my physical appearance

b) Right now I feel…

- ☐ ***Extremely satisfied*** with my body size and shape
- ☐ ***Mostly satisfied*** with my body size and shape
- ☐ ***Moderately satisfied*** with my body size and shape
- ☐ ***Slightly satisfied*** with my body size and shape
- ☐ ***Neither dissatisfied nor satisfied*** with my body size and shape
- ☐ ***Slightly dissatisfied*** with my body size and shape
- ☐ ***Moderately dissatisfied*** with my body size and shape
- ☐ ***Mostly dissatisfied*** with my body size and shape
- ☐ ***Extremely dissatisfied*** with my body size and shape

c) Right now I feel…

- ☐ ***Extremely dissatisfied*** with my weight
- ☐ ***Mostly dissatisfied*** with my weight
- ☐ ***Moderately dissatisfied*** with my weight
- ☐ ***Slightly dissatisfied*** with my weight
- ☐ ***Neither dissatisfied nor satisfied*** with my weight
- ☐ ***Slightly satisfied*** with my weight
- ☐ ***Moderately satisfied*** with my weight
- ☐ ***Mostly satisfied*** with my weight
- ☐ ***Extremely satisfied*** with my weight

d) Right now I feel…

- ☐ ***Extremely*** physically ***attractive***
- ☐ ***Very*** physically ***attractive***
- ☐ ***Moderately*** physically ***attractive***
- ☐ ***Slightly*** physically ***attractive***
- ☐ ***Neither attractive nor unattractive***
- ☐ ***Slightly*** physically ***unattractive***
- ☐ ***Moderately*** physically ***unattractive***
- ☐ ***Very*** physically ***unattractive***
- ☐ ***Extremely*** physically ***unattractive***

e) Right now I feel…

- ☐ ***A great deal worse*** about my looks than I usually feel
- ☐ ***Much worse*** about my looks than I usually feel
- ☐ ***Somewhat worse*** about my looks than I usually feel
- ☐ ***Just slightly worse*** about my looks than I usually feel
- ☐ ***About the same*** about my looks than I usually feel
- ☐ ***Just slightly better*** about my looks than I usually feel
- ☐ ***Somewhat better*** about my looks than I usually feel
- ☐ ***Much better*** about my looks than I usually feel
- ☐ ***A great deal better*** about my looks than I usually feel

f) Right now I feel…

- ☐ ***A great deal better*** than the average person looks
- ☐ ***Much better*** than the average person looks
- ☐ ***Somewhat better*** than the average person looks
- ☐ ***Just slightly better*** than the average person looks
- ☐ ***About the same*** than the average person looks
- ☐ ***Just slightly worse*** than the average person looks
- ☐ ***Somewhat worse*** than the average person looks
- ☐ ***Much worse*** than the average person looks
- ☐ ***A great deal worse*** than the average person looks

PLEASE TURN OVER FOR THE NEXT SECTION OF THE QUESTIONNAIRE

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

Your Physical Activity

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 did **during the last 3 months.**

During the last 3 months, when you were NOT at work, how much time did you usually spend:

2. Preparing meals (cook, set table, wash dishes) ☐ None ☐ Less than ½ hour per day ☐ ½ 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	**3. Carrying children** ☐ None ☐ Less than ½ hour per day ☐ ½ 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
4. Dressing, bathing, feeding children while you are sitting ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Taking care of an older adult** ☐ None ☐ Less than ½ hour per day ☐ ½ 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
6. Dressing, bathing, feeding children while you are standing ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Sitting and using a computer or writing while not at work** ☐ None ☐ Less than ½ hour per day ☐ ½ 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 sitting or standing ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Watching TV or a video** ☐ None ☐ Less than ½ hour per day ☐ ½ to almost 2 hours per day ☐ 2 to almost 4 hours per day ☐ 4 to almost 6 hours per day ☐ 6 or more hours per day

10. Playing with children while you are <u>walking or running</u> ☐ None ☐ Less than ½ hour per day ☐ ½ 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 reading, talking, or on the phone, while <u>not</u> at work** ☐ None ☐ Less than ½ hour per day ☐ ½ to almost 2 hours per day ☐ 2 to almost 4 hours per day ☐ 4 to almost 6 hours per day ☐ 6 or more hours per day
12. Playing with pets ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Heavier cleaning (vacuum, mop sweep, wash windows)** ☐ None ☐ Less than ½ hour per week ☐ ½ 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
14. Light cleaning (make beds, laundry, iron, put things away) ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Mowing lawn while on a riding mower** ☐ None ☐ Less than ½ hour per week ☐ ½ 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 day
16. Shopping (for food, clothes, or other items) ☐ None ☐ Less than ½ hour per day ☐ ½ 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	**17. Mowing lawn using a walking mower, raking, gardening** ☐ None ☐ Less than ½ hour per day ☐ ½ 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

PLEASE TURN OVER FOR THE NEXT SECTION OF THE QUESTIONNAIRE

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

Going Places…

During the last 3 months, how much time did you usually spend:

18. Walking slowly to go places (such as to the bus, work, visiting) Not for fun or exercise

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

19. Driving or riding in a car or on public transportation

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

20. Walking quickly to go places (such as to the bus, work or school) Not for fun or exercise

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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 Exercise

During the last 3 months, how much time did you usually spend:

21. Walking slowly for fun or exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

22. Swimming, water walking, or water exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

23. Walking more quickly for fun or exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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. Dancing

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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 ½ hour per week
- ☐ ½ 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

26. Yoga, Pilates, stretching, core strengthening exercises, or yoga/Pilates/stretching exercise videos or computer games

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ to almost 1 hour per week
- ☐ 1 to almost 2 hours per week
- ☐ 2 to almost 3 hours per week
- ☐ 3 or more hours per week

27. Jogging

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ to almost 1 hour per week
- ☐ 1 to almost 2 hours per week
- ☐ 2 to almost 3 hours per week
- ☐ 3 or more hours per week

28. Cardiovascular exercise machines (treadmill, stationary bike, elliptical stair climber, rowing machine)

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

29. Prenatal exercise class

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

30. Aerobic exercise classes, aerobic exercise videos or computer games

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

31. Weight lifting, resistance exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

32. Team sports (volleyball, basketball, softball, etc.)

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

33. Doing something else for fun or exercise? Please tell us what it is.

_____

Name of Activity

None	☐	1 to almost 2 hours per week	☐
Less than ½ hour per week	☐	2 to almost 3 hours per week	☐
½ to almost 1 hour per week	☐	3 or more hours per week	☐

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, please **SKIP**.

At work…

During the last 3 months, how much time did you usually spend:

34. Sitting at work or in class

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

35. Standing or slowly walking at work (while carrying things (heavier than a 1 gallon milk jug)

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

36. Standing or slowly walking at work not carrying anything

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

37. Walking quickly at work while carrying things (heavier than a 1 gallon milk jug)

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

38. Walking quickly at work not carrying anything

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Appendix 21: Follow-up questionnaires (Part A UC and INT)

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

PIMMS Study

Follow up Health Questionnaire Part A

We would be very grateful if you would answer this questionnaire. It should take you about 10 minutes to complete.

Most of the questions just require you to tick a box as a response. **Please try to answer every question**. If you are unable to answer a question because no option corresponds exactly to the answer you wish to give, please try to answer it as best you can. Please return your completed questionnaire to the researcher. Please answer **each** question by marking one box or writing in an answer.

General questions about you

As you have recently had a baby, we would like to know how you are feeling. Please tick the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

In the past 7 days:

1. I have been able to laugh and see the funny side of things

As much as I always could	☐	Not quite so much now	☐
Definitely not so much now	☐	Not at all	☐

2. I have looked forward with enjoyment to things

As much as I ever did	☐	Definitely less than I used	☐
Rather less than I used to	☐	Hardly at all	☐

3. I have blamed myself unnecessarily when things went wrong

Yes, most of the time	☐	Not very often	☐
Yes, some of the time	☐	No, never	☐

4. I have been anxious or worried for no good reason

No, not at all	☐	Yes, sometimes	☐
Hardly ever	☐	Yes, very often	☐

5. I have felt scared or panicky for no very good reason

Yes, quite a lot	☐	No, not much	☐
Yes, sometimes	☐	No, not at all	☐

6. Things have been getting on top of me

Yes, most of the time I haven't been able to cope at all	☐
Yes, sometimes I haven't been coping as well as usual	☐
No, most of the time I have coped quite well	☐
No, I have been coping as well as ever	☐

7. I have been so unhappy that I have had difficulty sleeping

Yes, most of the time	☐	Not very often	☐
Yes, sometimes	☐	No, not at all	☐

8. I have felt sad or miserable

Yes, most of the time	☐	Not very often	☐
Yes, sometimes	☐	No, not at all	☐

9. I have been so unhappy that I have been crying

Yes, most of the time	☐	Only occasionally	☐
Yes, sometimes	☐	No, never	☐

10. The thought of harming myself has occurred to me

Yes, quite often	☐	Hardly ever	☐
Sometimes	☐	Never	☐

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

Your Eating Habits

Over the past month how often have you eaten these foods? (Please tick one box for each food item)

		Never	Once a Month	Once every two weeks	1-2 Times per Week	3-6 Times per Week	Once a day	More than once a day
11.	Roast Potatoes or chips							
12.	Peppers or watercress							
13.	Tomatoes							
14.	Meat pies							
15.	Vegetable dishes							
16.	Courgettes, marrow or leeks							
17.	Sausages or sausage rolls							
18.	Gravy							
19.	Green salad							
20.	Wholemeal bread							
21.	White bread							
22.	Onion							
23.	Vegetarian food							
24.	Pasta							
25.	Yorkshire pudding or savoury pancakes							
26.	Crisps or savoury snacks							
27.	Beef							
28.	Spinach							
29.	Approximately how many teaspoons of **sugar** do you add each day to breakfast cereals, tea and coffee, etc.?						teaspoons	
30.	How much **full-fat milk** on average do you use per day in your drinks, added to breakfast cereals, etc.?						pints	

31. We would like to know what it was like for you being weighed by the nurse at your baby's immunisation appointment as well as weighing yourself at home once a week.

Using the scales below each question, please circle the number that best describes your response.

a. Would you recommend this study to a friend?

1	2	3	4	5	6	7	8	9	10
Very unlikely				Neither				Very likely	

b. How helpful has being weighed by the nurse and weighing yourself weekly been for managing your weight?

1	2	3	4	5	6	7	8	9	10
Very unhelpful				Neither				Very helpful	

c. How appropriate was it for the nurse to weigh you at your baby's immunisation appointment?

1	2	3	4	5	6	7	8	9	10
Very inappropriate				Neither				Very appropriate	

d. How anxious did the study make you about your weight?

1	2	3	4	5	6	7	8	9	10
Very anxious				Neither				Not at all anxious	

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Appendix 22: Follow-up questionnaire (Part B)

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

PIMMS Study

Follow up Health Questionnaire Part B

We would be very grateful if you would answer this questionnaire. It should take you about 10 minutes to complete.

Most of the questions just require you to tick a box as a response. **Please try to answer every question**. If you are unable to answer a question because no option corresponds exactly to the answer you wish to give, please try to answer it as best you can.

Please return your completed questionnaire to the researcher or in the **FREEPOST** envelope provided.

Please answer **each** question by marking one box or writing in an answer.

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

1. **For each of the items below, tick the box beside the one statement that best describes how you feel RIGHT NOW AT THIS VERY MOMENT. Read the items carefully to be sure the statement you choose accurately and honestly describes how you feel right now.**

a) Right now I feel...

- ☐ ***Extremely dissatisfied*** with my physical appearance
- ☐ ***Mostly dissatisfied*** with my physical appearance
- ☐ ***Moderately dissatisfied*** with my physical appearance
- ☐ ***Slightly dissatisfied*** with my physical appearance
- ☐ ***Neither dissatisfied nor satisfied*** with my physical appearance
- ☐ ***Slightly satisfied*** with my physical appearance
- ☐ ***Moderately satisfied*** with my physical appearance
- ☐ ***Mostly satisfied*** with my physical appearance
- ☐ ***Extremely satisfied*** with my physical appearance

b) Right now I feel...

- ☐ ***Extremely satisfied*** with my body size and shape
- ☐ ***Mostly satisfied*** with my body size and shape
- ☐ ***Moderately satisfied*** with my body size and shape
- ☐ ***Slightly satisfied*** with my body size and shape
- ☐ ***Neither dissatisfied nor satisfied*** with my body size and shape
- ☐ ***Slightly dissatisfied*** with my body size and shape
- ☐ ***Moderately dissatisfied*** with my body size and shape
- ☐ ***Mostly dissatisfied*** with my body size and shape
- ☐ ***Extremely dissatisfied*** with my body size and shape

c) Right now I feel...

- ☐ ***Extremely dissatisfied*** with my weight
- ☐ ***Mostly dissatisfied*** with my weight
- ☐ ***Moderately dissatisfied*** with my weight
- ☐ ***Slightly dissatisfied*** with my weight
- ☐ ***Neither dissatisfied nor satisfied*** with my weight
- ☐ ***Slightly satisfied*** with my weight
- ☐ ***Moderately satisfied*** with my weight
- ☐ ***Mostly satisfied*** with my weight
- ☐ ***Extremely satisfied*** with my weight

d) Right now I feel...

- ☐ ***Extremely*** physically ***attractive***
- ☐ ***Very*** physically ***attractive***
- ☐ ***Moderately*** physically ***attractive***
- ☐ ***Slightly*** physically ***attractive***
- ☐ ***Neither attractive nor unattractive***
- ☐ ***Slightly*** physically ***unattractive***
- ☐ ***Moderately*** physically ***unattractive***
- ☐ ***Very*** physically ***unattractive***
- ☐ ***Extremely*** physically ***unattractive***

e) Right now I feel...

- ☐ ***A great deal worse*** about my looks than I usually feel
- ☐ ***Much worse*** about my looks than I usually feel
- ☐ ***Somewhat worse*** about my looks than I usually feel
- ☐ ***Just slightly worse*** about my looks than I usually feel
- ☐ ***About the same*** about my looks than I usually feel
- ☐ ***Just slightly better*** about my looks than I usually feel
- ☐ ***Somewhat better*** about my looks than I usually feel
- ☐ ***Much better*** about my looks than I usually feel
- ☐ ***A great deal better*** about my looks than I usually feel

f) Right now I feel...

- ☐ ***A great deal better*** than the average person looks
- ☐ ***Much better*** than the average person looks
- ☐ ***Somewhat better*** than the average person looks
- ☐ ***Just slightly better*** than the average person looks
- ☐ ***About the same*** than the average person looks
- ☐ ***Just slightly worse*** than the average person looks
- ☐ ***Somewhat worse*** than the average person looks
- ☐ ***Much worse*** than the average person looks
- ☐ ***A great deal worse*** than the average person looks

PLEASE TURN OVER FOR THE NEXT SECTION OF THE QUESTIONNAIRE

Study ID: ___ ___ ___ ___

UNIVERSITY OF BIRMINGHAM

Your Physical Activity

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 did **during the last 3 months.**

During the last 3 months, when you were NOT at work, how much time did you usually spend:

2. Preparing meals (cook, set table, wash dishes)

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

3. Carrying children

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

4. Dressing, bathing, feeding children while you are sitting

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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. Taking care of an older adult

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

6. Dressing, bathing, feeding children while you are standing

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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. Sitting and using a computer or writing while not at work

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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 sitting or standing

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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. Watching TV or a video

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

10. Playing with children while you are <u>walking or running</u> ☐ None ☐ Less than ½ hour per day ☐ ½ 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 reading, talking, or on the phone, while <u>not</u> at work** ☐ None ☐ Less than ½ hour per day ☐ ½ to almost 2 hours per day ☐ 2 to almost 4 hours per day ☐ 4 to almost 6 hours per day ☐ 6 or more hours per day
12. Playing with pets ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Heavier cleaning (vacuum, mop sweep, wash windows)** ☐ None ☐ Less than ½ hour per week ☐ ½ 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
14. Light cleaning (make beds, laundry, iron, put things away) ☐ None ☐ Less than ½ hour per day ☐ ½ 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. Mowing lawn while on a riding mower** ☐ None ☐ Less than ½ hour per week ☐ ½ 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 day
16. Shopping (for food, clothes, or other items) ☐ None ☐ Less than ½ hour per day ☐ ½ 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	**17. Mowing lawn using a walking mower, raking, gardening** ☐ None ☐ Less than ½ hour per day ☐ ½ 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

PLEASE TURN OVER FOR THE NEXT SECTION OF THE QUESTIONNAIRE

Going Places...

During the last 3 months, how much time did you usually spend:

18. Walking slowly to go places (such as to the bus, work, visiting) Not for fun or exercise

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

19. Driving or riding in a car or on public transportation

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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

20. Walking quickly to go places (such as to the bus, work or school) Not for fun or exercise

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ 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 Exercise

During the last 3 months, how much time did you usually spend:

21. Walking slowly for fun or exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

22. Swimming, water walking, or water exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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

23. Walking more quickly for fun or exercise

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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. Dancing

- ☐ None
- ☐ Less than ½ hour per week
- ☐ ½ 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	26. Yoga, Pilates, stretching, core strengthening exercises, or yoga/Pilates/stretching exercise videos or computer games
☐ None ☐ Less than ½ hour per week ☐ ½ 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	☐ None ☐ Less than ½ hour per week ☐ ½ to almost 1 hour per week ☐ 1 to almost 2 hours per week ☐ 2 to almost 3 hours per week ☐ 3 or more hours per week
27. Jogging	**28. Cardiovascular exercise machines (treadmill, stationary bike, elliptical stair climber, rowing machine)**
☐ None ☐ Less than ½ hour per week ☐ ½ 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	☐ None ☐ Less than ½ hour per week ☐ ½ 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
29. Prenatal exercise class	**30. Aerobic exercise classes, aerobic exercise videos or computer games**
☐ None ☐ Less than ½ hour per week ☐ ½ 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	☐ None ☐ Less than ½ hour per week ☐ ½ 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
31. Weight lifting, resistance exercise	**32. Team sports (volleyball, basketball, softball, etc.)**
☐ None ☐ Less than ½ hour per week ☐ ½ 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	☐ None ☐ Less than ½ hour per week ☐ ½ 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

33. Doing something else for fun or exercise? Please tell us what it is.

_____

Name of Activity

None	☐	1 to almost 2 hours per week	☐
Less than ½ hour per week	☐	2 to almost 3 hours per week	☐
½ to almost 1 hour per week	☐	3 or more hours per week	☐

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, please **SKIP**.

At work...

During the last 3 months, how much time did you usually spend:

34. Sitting at work or in class

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

35. Standing or slowly walking at work (while carrying things (heavier than a 1 gallon milk jug)

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

36. Standing or slowly walking at work not carrying anything

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

37. Walking quickly at work while carrying things (heavier than a 1 gallon milk jug)

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

38. Walking quickly at work not carrying anything

- ☐ None
- ☐ Less than ½ hour per day
- ☐ ½ to almost 2 hours per day
- ☐ 2 to almost 4 hours per day
- ☐ 4 to almost 6 hours per day
- ☐ 6 or more hours per day

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Appendix 23: Interview schedule- women

Interview Topic Guide- Mothers

Thank you again for meeting and agreeing to talk to me today. Are you comfortable and ready to get started?
I'd like to talk with you today because you've taken part in the PIMMS study and now we'd like to find out as much as we can about what you thought of the study and what it was like for you to be a part of this study.
So with your permission, I will record our conversation and then combine all the interviews we conduct with mums in the study and use this to summarise what mums thought of the PIMMS weight management intervention. As I'll be recording our conversation and want to keep what you say anonymous, I will start the recording by mentioning your study number and avoid addressing you by name while we chat. I will be recording our conversation on an encrypted digital recorder. After we finish up here, I'll take the recording to university then download and save it onto my desktop computer which is password protected. Any direct quotes from you may be used in the write up of my PhD thesis or a journal article, if they are, they will be completely anonymous so that no one will be able to identify you.
Once we've finished talking (the interview), there will be an opportunity for you to raise any concerns you have, but you can stop me at any time and if you do not wish to answer a particular question or want to terminate the interview at any time that is absolutely fine.

Warm up
How old is your baby now?
How's it all going?

Pre-pregnancy weight maintenance
Now I'd like to talk about any previous weigh loss attempts you made before your last pregnancy.

- Before joining this study, had you ever tried to lose weight?
- What type of things did you do to try and manage your weight in the past?

Reasons for participating in study

- Can you tell me about what it's been like for you being involved in the PIMMS study?
  - What were you hoping to get out of being a part of PIMMS?
  - Why did you want to take part?

Self-weighing

- Could you tell me what you thought about having to weigh yourself once a week?
- Can you tell me how weighing yourself made you feel?
- How useful did you find weighing yourself regularly?
- Were you able to weigh yourself once a week?
  - Was it easy to remember to weigh yourself regularly?
- Can you tell me how important the number on the scales was for you and why?

Current weight management

- Are you still attempting to manage your weight?
- Can you tell me a bit about what you do to manage your weight presently?
- What do you use to help you measure/gauge your progress?

Immunisation appointments

I would now like to talk about what happened during baby's immunisation appointments.

- Could you describe a typical immunisation appointment? Could you walk me through what would happen during these appointments?
- You mentioned that the nurse....did the nurse ask if she could weigh you during these appointments?
- How did you feel when the nurse was weighing you?
- What did you think of having the nurse weigh you during your baby's immunisation appointment?
- Could you tell me a little bit about what the nurse said to you while she was weighing you?
- Did the nurse hold your baby while you were on the scales?
- Can you tell me how you felt knowing that you would be weighed at your baby's immunisation appointments?

One You website

Now I want to ask you about the One You healthy lifestyle website.

- Were you able to access the site?
- Can you tell me what sort of things you looked at on the website?
- What did you think of the website?
- What did you think about being referred to a website for weight management advice instead of being offered it during the immunisation appointment?

Additional questions

- Now that you've been involved in the PIMMS study, how do you feel about managing your weight?
- Can you tell me what sort of things we could have done differently to make things easier for you?
- Can you tell me what would you think we should have done to make being involved in the PIMMS study better for you?
- What sort of things do you think would help women lose weight after pregnancy?
- Would you recommend the study to your friends or other new mums?

Is there anything else you'd like to tell me?

Thank you so very much for your time and for raising such interesting points. On behalf of the entire PIMMS research team, I would like to say thank you for taking part in our study and inviting us in to your house.

Appendix 24: Interview schedule- nurses

Interview Topic Guide-Nurses

Thank you again for meeting and agreeing to talk to me today. Are you comfortable and ready to get started?

I'd like to talk with you today because you've taken part in the PIMMS study and now we'd like to find out as much as we can about what you thought of delivering the brief weight management intervention during baby immunisation appointments and what your experiences were of being a part of this study.

With your permission, I will record our conversation and then combine all the interviews we conduct with other nurses who took part in the study and use this to summarise what all the nurses thought of the PIMMS weight management intervention. As I'll be recording our conversation and want to keep what you say anonymous, I will start the recording by mentioning your study number and avoid addressing you by name while we chat. I will be recording our conversation on an encrypted digital recorder. After we finish up here, I'll take the recording to university then download and save it onto my desktop computer which is password protected. Any direct quotes from you may be used in the write up of my PhD thesis or a journal article, if they are, they will be completely anonymous so that no one will be able to identify you.

Once we've finished talking (the interview), there will be an opportunity for you to raise any concerns you have, but you can stop me at any time and if you do not wish to answer a particular question or want to terminate the interview at any time that is absolutely fine.

Warm up and general information

- How long have you been a practice/ research nurse?
- How long have you been giving immunisations for?
- How many nurses at this practice carry out baby immunisation appointments?
- How does the practice arrange baby immunisations? Do they occur on a specific day?
- How much time is allocated to one immunisation appointment?
- Who usually brings the baby to these immunisation appointments?
- Since you've been working with new mums, what sort of impact do you think overweight and obesity has had on them?
- When you meet new mums at these appointments, is the topic of weight and weight management commonly raised?

PIMMS Nurses Training

Now I'd like to talk about the nurses training you received on how to deliver the intervention during the immunisation appointments.

- Could you describe the training you received for this study?
- What did you think of the nurses training manual
  - How often do you think you referred back to it?
- What do you think we could have added or changed about the training sessions to make them more effective for you
- After the training how prepared did you feel to deliver the intervention?

Immunisation appointments

I would now like to switch topics a little and talk about what happened during baby immunisation appointments with mothers involved in the PIMMS study.

- How easy was it to identify mothers who were taking part in the study?
- Could you describe a typical immunisation appointment with a PIMMS mum? Could you walk me through what would happen during these types of appointments?
- Can you tell me how you felt knowing that you would be asking to weigh mothers involved in the study?
  - How comfortable/ confident did you feel?
- Could you tell me a little bit about what sort of things you'd say to the mum while you were weighing her?
  - How comfortable do you think the mothers were with you weighing them?
  - Did any women refuse to be weighted?
  - What sorts of reasons did they give for not wanting to be weighed?
- What sort of reactions did you get from mothers who attended these appointments alone compared to those who attended with their partners or mothers?
- Where did the baby get put while the mothers were on the scales and you were recording their weight?
  - Were there practical issues to consider when having to weigh the mothers?
- What did you think of having to record their weight in the red book?
  - Was it easy to remember?
  - Was the weight record card easily accessible?
- How much more time did appointments take when you had to weigh the mothers?
- Can you tell me what you think it would be like if you had to weigh every mother you saw during your baby immunisation clinics?

<u>One You website</u>

Now I want to ask you about the One You healthy lifestyle website.

- Can you tell me what sort of responses you received when you referred mothers who asked you for weight loss advice to the One You website?
- Can you tell me a bit about what the mothers told you about the One You website?
- Were you able to have a look at the One You website?
  - What did you think of the website?
- What did you think about referring mothers to a website for weight management advice during the immunisation appointment?

<u>Additional questions</u>

- Before taking part in this study, what did you tell mothers who asked you for weight loss advice?
- When do you think is the ideal time to try and encourage new mums to start thinking about trying to lose/manage their baby weight?
- What sort of things do you think would help women lose weight after pregnancy?
- Who do you think should be providing mothers with this advice?

- Can you tell me what sort of things we could have done differently to make things easier for you?
- Can you tell me what would you think we should have done to make being involved in the PIMMS study better for you?

Is there anything else you'd like to tell me?

Thank you very much for taking part. On behalf of the entire PIMMS research team, I would like to thank you for helping us test the intervention and for taking time out of your busy day to sit here with me today and tell me what you thought about the study. Thank you.

Appendix 25: Consent form - women

PIMMS: Participant Interview Consent Form

Participant Identification Number: _____

UNIVERSITY OF BIRMINGHAM

Title of Project: *PIMMS Study*

Name of Researchers: Dr Amanda Daley, Dr Helen Parretti and Janice Ferguson

Please initial each box

1. I confirm that I have read and understood the information sheet dated 21/03/2016 (version 5) for the above study and have had the opportunity to ask questions. ☐
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 data collected during the study, may be looked at by individuals from the research team at the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records to allow access to data when auditing. ☐
4. I understand and give permission for the research team to use anonymous quotes from me, when deemed relevant. ☐
5. I consent for my interview to be audio / video recorded. The recording will be transcribed and analysed for the purposes of the research. ☐
6. I consent to verbatim quotes being used in publications. ☐
7. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Researcher taking consent	Date	Signature

When completed: 1 for participant, 1 for researcher file site, 1 for GP practice patient file.

Appendix 26: Consent form - nurses

PIMMS: Nurses Interviews Consent Form

Participant Identification Number: _____

UNIVERSITY OF BIRMINGHAM

Title of Project: *PIMMS Study*

Name of Researchers: Dr Amanda Daley, Dr Helen Parretti and Janice Ferguson

Please initial each box

1. I confirm that I have read and understood the nurses information leaflet (Version 3 21/03/2016) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. ☐
3. I understand that data collected during the study, may be looked at by individuals from the research team at the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records to allow access to data when auditing. ☐
4. I understand and give permission for the research team to use anonymous quotes from me, when deemed relevant. ☐
5. I consent for my interview to be audio / video recorded. The recording will be transcribed and analysed for the purposes of the research. ☐
6. I consent to verbatim quotes being used in publications. ☐
7. I agree to take part in the above study. ☐

Name of Nurse	Date	Signature
Name of Researcher taking consent	Date	Signature

When completed: 1 for participant, 1 for researcher file site.