The Healthy Eating and Lifestyle in Pregnancy cluster randomised controlled trial: a 24 months postpartum follow-up study.

An evaluation of the effect of a weight management intervention for maternal obesity, on maternal and child outcomes at 24 months following birth.

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Thesis for the degree of Doctor of Philosophy

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DECLARATION- DETAILED

- This PhD study is a follow-up to the Healthy Eating and Lifestyle in Pregnancy trial which was designed and conducted by a team of researchers in Cardiff University, and funded by the National Prevention Research Initiative. I assisted in this work within my role as Data Manager/ Research Assistant within this team. However, it is clearly acknowledged that the HELP intervention was not carried out for the purpose of this thesis and data used from the HELP trial was previously analysed by the HELP trial team.
- I assisted the primary research supervisor (SS) in the REC application during set-up of this study, including drafting study documents, and managing later amendments.
- I identified local researchers and managed all regulatory approval processes in study sites, including drafting contracts between health trusts and the study sponsor.
- I performed the search and review of the literature to summarise the evidence base related to maternal obesity and childhood obesity.
- The measures used for maternal outcomes were determined by the HELP trial team. However, I identified child outcomes and appropriate measures for these outcomes. Advice was sought from other researchers conducting similar work including Professor Lucilla Poston and Dr Angela Flynn from the UPBEAT trial consortium, and Dr Megan Jarman from the Southampton Initiative for Health team, who advised on measurement of diet.
- I designed the data collection forms used, and additional materials e.g. portion guidance.
- The sample size calculations were completed by Dr Cannings-John.
- I completed 32 of 241 face-to-face participant home visits to collect data, with travel across four sites in England. The remaining 209 follow-ups were completed by local researchers at sites.
- I trained local researchers before data collection and supported them throughout the data collection period.
- I assisted Vince Poile, a CTR programmer, in developing the SQL database.
- Data entry was completed by CTR administrators. I trained administrators and conducted a 10% QC of the data entry.
- I cleaned all study data, under the supervision of Dr Cannings-John, and completed all of the analyses, apart from the two-level logistic regression or ordinal regression analyses, which were completed by Dr Cannings-John. I interpreted and presented all of these results.
- I developed the topic guide and interview schedules, with guidance from the research supervisors.
- I recruited participants and conducted all 18 interviews (as interviewer) completed as part of the qualitative research. Transcription of interview data was completed by an external company 'Essential Secretary'. I analysed the interview data, under the supervision of Dr Brookes-Howell, who assisted in double coding the data and interpreting the analysis.
- I presented aspects of this work at seven national and international conferences.
- I wrote this thesis.

'The student' is used in this thesis to refer to Dunla Gallagher who carried out this work for part fulfilment of a PhD, under the supervision of the research supervisors.

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The Healthy Eating and Lifestyle in Pregnancy (HELP) cluster randomised controlled trial: a 24 months postpartum follow-up study

By Dunla Gallagher

Background: Obesity in pregnancy, and excessive gestational weight gain, are associated with short and long-term adverse health outcomes for mothers and their offspring, including childhood obesity. The Healthy Eating and Lifestyle in Pregnancy (HELP) cluster randomised controlled trial compared the effectiveness of a group-based weight management intervention, delivered during pregnancy and postpartum, with National Health Service routine maternity care. In total, 598 pregnant women, aged 18 years and over, with a BMI of ≥30 kg/m^2, and between 12 and 20 weeks gestation, were recruited across 20 study centres in England and Wales, United Kingdom. The aim of the HELP trial was to improve health outcomes in these women with obesity. The present study followed up these women and their children at 24 months postpartum and aimed to assess longer-term maternal and child outcomes. It also aimed to explore the experiences of these women.

Methods: A sequential mixed methods approach was used. The first, quantitative phase, examined the effectiveness of the HELP intervention on primary outcomes, maternal BMI and child BMI-for-age *z*-scores, and secondary outcomes, including weight, diet, and physical activity behaviours of mothers and children. Outcomes were analysed using multilevel linear, logistic and ordinal regression models. The second, qualitative phase, used telephone interviews to explore women's experiences. Thematic analysis was used to organise and interpret the interview data. Findings from the two approaches were triangulated for discussion.

Results: The 24 months postpartum follow-up included 241 women and children, across 19 clusters. The analyses found no evidence of between groups differences in the primary outcomes, maternal BMI at 24 months postpartum (adjusted percentage difference: -0.01, 95% CI -0.04 to 0.02; ICC <0.001; p= 0.664) and child BMI-for-age *z*-scores (adjusted difference in means: 0.24, 95% CI -0.17 to 0.64; ICC <0.001; p=0.250), or the secondary outcomes. Subsequently, 18 of these women completed a telephone interview. Maternal attitudes towards their own and their child's weight and health behaviours, before, during and after pregnancy, were described in three themes: 1) pregnancy specific attitudes and behaviours; 2) wider weight control attitudes and experiences; and, 3) maternal perceptions and influences on children's weight, diet and activity.

Discussion: The HELP intervention did not improve outcomes for women and their children at 24 months postpartum. Women have a strong desire to be healthy for their unborn babies during pregnancy. Non-judgmental support may help them adopt healthier behaviours to achieve short-term goals. However, more support would be needed to help women achieve better long-term outcomes. Women's lived experiences of obesity are complex, and it is important to incorporate their beliefs and motivations into interventions. Rather than viewing pregnancy as a short window of opportunity for initiating behaviour change, it should be used as a unique motivator which could give women a purpose for change over a longer term. Exploring options for intervening in the preconception period to address attitudes and weight loss before pregnancy, supporting women during pregnancy to be healthy for their babies, and building on this postpartum to help women shift their goals to weight loss, self-regulation of weight management, being a positive role model for their children and health-promoting feeding practices; may be more effective for improving maternal and child outcomes.

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List of Abbreviations

7-day PAR	7-day physical activity recall
AUDIT-C	Alcohol use disorders identification test consumption
BCT	Behaviour change technique
BMI	Body mass index
CTR	Centre for Trials Research
CFPQ	Comprehensive feeding practices questionnaire
CFQ	Child feeding questionnaire
CI	Confidence interval
CM	Centimetres
CU	Cardiff University
CONSORT	Consolidated standards of reporting trials
COREQ	Consolidated criteria for reporting qualitative research
CRF	Case report form
DINE	Dietary instrument for nutrition education
EPAQ	Eating and physical activity questionnaire
EQ-5D	Euro quality of life 5-dimensions questionnaire
GCP	Good clinical practice
GDM	Gestational diabetes mellitus
GI	Glycaemic index
GP	General practitioner
GHQ	General health questionnaire
GWG	Gestational weight gain
HCRW	Health and Care Research Wales
HELP	Healthy Eating and Lifestyle in Pregnancy
HELP 24m	Healthy Eating and Lifestyle in Pregnancy 24 months postpartum study
HRQoL	Health related quality of life
ICC	Intracluster correlation coefficient
IOM	Institute of Medicine
IPDMA	Individual patient data meta-analysis
IQR	Interquartile range
ITT	Intention to treat
I-WiP	International weight management in pregnancy collaboration
KCAL	Kilocalories
KG	Kilograms
LGA	Large for gestational age
M	Metres

MRC	Medical Research Council
MSES	Multidimensional self-efficacy for exercise scale
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
NISCHR	National Institute of Social Care and Health Research
NS-SEC	The national statistics socio-economic classification
OR	Odds ratio
PA	Physical activity
PCU	Permissions co-ordinating unit
PhD	Doctorate of Philosophy
PICO	Population/ Intervention/ Comparison/ Outcome
QC	Quality control
R&D	Research & development
RCT	Randomised controlled trial
REC	Research ethics committee
RRR	Relative risk ratio
SD	Standard deviation
SES	Socioeconomic status
SEM	Social ecological model
SGA	Small for gestational age
SPSS	Statistical package for the social sciences
SQL	Structured query language
SRQ	Self-regulation questionnaire
SSEH	Social support for eating habits questionnaire
SSEX	Social support for exercise habits questionnaire
SW	Slimming World
TRSD	Treatment self-regulation for diet questionnaire
TRSE	Treatment self-regulation for exercise questionnaire
TSRQ	Treatment self-regulation questionnaire
UK	United Kingdom
US	United States of America
VAS	Visual analogue scale
WEL	Weight efficacy lifestyle questionnaire
WHO	World Health Organization
WMS	Weight management services

1 Introduction

1.1 Introduction

The treatment and prevention of maternal obesity is a major public health concern. Maternal obesity is now the most common condition experienced by women of reproductive age and has both immediate and long-term health consequences for the mother and baby.(1) In addition, many women who start their pregnancy with a high pre-pregnancy Body Mass Index (BMI), gain excessive gestational weight. For mothers, this exacerbates the pre-existing problem and poses risks for long-term weight retention and health. For their children, it may negatively impact their future health.

This Chapter introduces the problem of maternal obesity and weight gain trends surrounding pregnancy, and summarises the risks associated with these conditions. One key risk of maternal obesity, and excessive gestational weight gain (GWG), is the independent associations they have with childhood obesity; this will be discussed in more detail. The aim of this Chapter is to demonstrate that maternal weight management surrounding pregnancy is an important public health priority which, if addressed effectively, could have a large impact on the health of women and the health of their offspring.

1.2 Obesity

1.2.1 Definition, prevalence and etiology

Obesity is defined as '*a condition of excess body fat to the extent that it may have an adverse effect on health'*.(2) It is a risk factor for many other conditions, including cardiovascular disease, type 2 diabetes, cancer and depression.(3) Assessment of obesity involves measuring body composition, and the most common measure used is BMI, which is a person's weight in kilograms (kg) divided by the square of their height in metres (m).(4) The World Health Organization (WHO) recommends the following classifications for BMI in adults: a healthy BMI is between 18.5 and 24.9 kg/m^2, a BMI between 25.0 and 29.9 kg/m^2 is indicative of overweight which may indicate risk for the development of obesity; and a BMI equal or greater to 30 kg/m^2 indicates obesity.(5) Furthermore, a BMI of 30.0 to 34.9 kg/m^2 is defined as Class I obesity, a BMI of 35.0 to 39.9 kg/m^2 defined as Class II or severe obesity,

and a BMI of 40 kg/m^2 and over defined as Class III or morbid obesity; to acknowledge the continuous relationship between BMI and morbidity and mortality.

Globally, the prevalence of obesity in adults has increased from 6.4% in 1975 to 14.9% in 2014, including developing countries.(6) Rates of obesity in the United Kingdom (UK) have doubled since the 1980s. It was predicted that by 2025, prevalence rates in 21- 60 year olds would be 47% of men and 36% of women, compared with 23.6% of men and 23.8% of women in 2004.(7)

Excess food consumption and a lack of physical activity (PA), are clearly implicated in the development of obesity.(3) However, to view obesity to be a result of an individual's energy intake exceeding energy expenditure, although correct, is too simplistic.(7) Some people are more likely to develop obesity than others; income, social deprivation and ethnicity have all been identified as factors effecting the likelihood of becoming obese.(8) The Social Ecological Model (SEM) (9) developed by McLeroy and colleagues, maps out different levels which need to be considered in understanding the determinants of health.(10) The SEM is derived from Ecological Systems Theory developed by Bronfenbrenner.(11) This emphasises the need to consider context when understanding a behaviour, and proposes the role of five environmental systems which interact over time in the development of human behaviours. These are the microsystem, mesosystem, exosystem, macrosystem and chronosystem.(11) When applied to the determinants of health behaviours and health, according to McLeroy and colleagues, the levels of importance are the intrapersonal, interpersonal, institutional, community and public policy.(9)

This view attributes the etiology of obesity to a complex interaction of causal pathways related to individual biology and health behaviours, set within a social, cultural and environmental landscape, which differ between populations and across a person's life course.(7, 12) The SEM can be used to map out relationships between the multiple factors influencing weight and its related behaviours, and ultimately health outcomes. The intrapersonal level relates to individual factors associated with the development of obesity which includes genetic characteristics, as well as knowledge, attitudes and behaviours linked to weight.(12) The interpersonal environment includes the relationships within a person's social networks, such as family influences surrounding weight and its associated behaviours, as well as cultural factors influencing choices and beliefs.(12) At the institutional level, settings may have an important influence, for example workplaces might impact on health in terms of food availability and opportunities to be active.(12) The community context in which obesity develops includes community and cultural norms and beliefs surrounding weight,

such as social norms for participating in exercise.(12) Public policy influences health behaviours through regulatory and legislative factors, such as taxation and labelling of food products. This environment also influences accessibility to and affordability of healthy foods, green spaces and leisure facilities for activity, and healthcare services.(12)

It would be challenging to provide an exhaustive list of the influences at play in the development of obesity. The Obesity System Map developed by the authors of the Foresight Report, 'Tackling Obesities: Future Choices', attempted to do so.(7) This report emphasises the large number of factors, and complex interaction of these, which are influential in the development and maintenance of obesity. It is this complexity that makes the prevention and treatment of obesity challenging as there is no 'one size fits all' approach.(7) However, it provides an indication of the importance of context, and the need for interventions that consider more than one level, as well as the multiple interacting factors which need to be considered.

1.2.2 Financial implications of obesity

It was estimated that National Health Service (NHS) expenditure as a result of overweight and obesity was £4.2 billion in 2007, and was forecast to rise to £8.3 billion by 2025 based on obesity prevalence estimates.(7) This prediction appears to be proving accurate as the NHS in England (which accounts for approximately 85% of spending in the UK), spent £5.1 billion on overweight and obesity-related ill-health in 2014/15.(13) Hospital admissions, bariatric surgery and prescriptions were major contributors to these costs.(7) The total economic and social costs as a result of obesity are difficult to ascertain, but are likely to be significant, with the costs associated with morbidity, reduced productivity and dependence on state benefits estimated to be £37.2 billion by 2025.(7)

1.3 Maternal Obesity

1.3.1 Definition, prevalence and costs

'Maternal obesity' describes the presence of the condition of obesity in a pregnant woman. With the increase in obesity levels in adults generally, as expected the levels of obesity in women of reproductive age has increased.(14, 15) Trends in England and Wales in 2014, indicated around 20% of women between 16 and 44 years had obesity, and a further 25% overweight.(16) Many of these women will become pregnant, meaning a rise in the

prevalence of maternal obesity and those entering pregnancy with weight-related issues.(17-19) A retrospective epidemiological study across England, examined demographic characteristics of women entering pregnancy, and indicated a dramatic rise in maternal obesity from 7.6% to 15.6% between 1989 and 2007.(19) There were evident health inequalities underlying these trends, in that deprivation, age, parity and black ethnicity increased the likelihood of a mother starting pregnancy with obesity.(19-23)

Advances in healthcare provision and research, and efforts to increase awareness of obesity related risks, have failed to halt the rise in maternal obesity rates.(17) Obesity trends in women increase further beyond 44 years, suggesting that weight gain experienced during childbearing is retained.(16) Many women with obesity attribute the onset of the condition to weight gained in pregnancy.(24) Thus pregnancy is a period of significant risk for the development of longer term obesity, especially in women who start their pregnancy with obesity.(25-27)

There are financial implications specifically associated with caring for a pregnant woman with obesity, due to an increased chance of complications in pregnancy and birth, and the increased monitoring and surveillance required. In comparison with a healthy weight mother, the costs associated with caring for a mother with obesity were estimated to increase between 5.4 and 16.2 fold, dependent on the degree of obesity.(28, 29)

1.3.2 Risks associated with maternal obesity

Women with obesity who go through pregnancy and childbirth, are at an increased risk of many antenatal, intrapartum, postpartum and neonatal complications, leading to adverse physical and mental health outcomes for both themselves and their babies.(30, 31) A positive relationship between increasing BMI and adverse outcomes is indicated.(32) In 2015, a systematic review linked maternal obesity to increased risks for the mother of gestational diabetes mellitus (GDM), a state of glucose intolerance first emerging or recognised in pregnancy, pre-eclampsia, gestational hypertension, depression, instrumental and caesarean birth and surgical infections.(31) In babies of women with obesity, they identified a greater risk of pre-term birth (<32 weeks), being born large-for-gestational-age (LGA) (birthweight ≥90th centile), foetal defects, congenital abnormalities and perinatal death.(31) Similarly, a retrospective study of maternal and neonatal outcomes of 30,298 singleton pregnancies between 2004 and 2011, showed that in comparison with women of healthy weight, women who are overweight or obese were at a significantly increased risk of hypertensive disorders, induction of labour, caesarean section, postpartum haemorrhage

(blood loss > 500 millilitres) and delivering an infant with macrosomia (birthweight above 4kg).(33) Women with Class III obesity were also at risk of experiencing pre-term delivery, stillbirth, postnatal stay > 5 days, and their infant requiring admission to a neonatal unit.(33) Many studies have supported these findings.(21, 25, 30, 32, 34-43)

Other reports have shown that women with obesity in pregnancy are more likely to experience: venous thromboembolism and pulmonary embolism during pregnancy and into the postpartum period;(44) induction and instrumental delivery which are less likely to be successful leading to foetal distress, failure to progress in labour, and higher emergency caesarean sections;(25, 30) and genital and urinary tract infections associated with postpartum haemorrhage.(42, 45) Higher incidences of caesarean sections carries potential complications with anaesthesia, post-surgery wound infections and an increased likelihood of requiring caesarean section in subsequent pregnancies.(46, 47) As a result of increased complications, length of stay in hospital post-birth is likely to be longer, and women may require increased drugs, blood transfusion, fluids, and theatre or intensive care treatment.(25) A report into maternal deaths in the UK described obesity as '*one of the greatest and growing overall threats to the childbearing population'.*(48) Although UK mortality rates in pregnancy are low, of the deaths reviewed in this report, over half of these women had obesity or overweight, and died due to conditions associated with a higher BMI.(48)

Research has demonstrated that maternal obesity is a mechanism for adverse infant health outcomes.(49) Exposure to maternal complications has consequences for the developing foetus, for example a mother developing GDM increases the chances of the child developing insulin resistance in later life.(50) Poorer maternal mental health can be detrimental to foetal programming of the child's stress response system which has consequences for their future health.(51) Perhaps most alarmingly, moderate to strong increases in risk of infant death at any stage between gestation and one year post-birth, were found to be associated with increasing maternal BMI.(52) Difficulties in foetal scanning and heart monitoring during pregnancy and labour, as a result of maternal adiposity, pose risks for infants.(46, 53) Apgar scores were more likely to be lower at five minutes for infants of women with obesity, indicating slower recovery after delivery.(25) The greater likelihood of being born pre-term increases the likelihood of developmental problems.(54) Maternal pre-pregnancy BMI is a strong predictor of infant birthweight, increasing the risk of babies being born LGA, small for gestational age (SGA) (birthweight <10th percentile), with macrosomia, and with increased head circumference.(30, 37) Birthweight is linked to long-term weight and health for the offspring. Birthweight >4kg doubles the risk of an infant being overweight in adulthood, in

comparison with being born a healthy weight (2.5- 4kg),(55) and being born LGA was associated with obesity, cardiovascular disease and type 2 diabetes in later life.(56) The determinants of childhood obesity and the intergenerational cycle of obesity are considered further in section 1.4.

1.3.3 Gestational weight gain (GWG)

Pregnancy is considered a risky time for excess weight gain. It was estimated that between 40 and 65% of women in the UK gain too much weight;(57) but women who start their pregnancy with obesity are more likely to have higher GWG,(58, 59) as well as those with lower socioeconomic status (SES).(60) Excessive GWG carries similar risks to those associated with maternal obesity described in section 1.3.2, even for women who start pregnancy with a healthy BMI.(61) The interaction between high pre-pregnancy BMI and excessive GWG puts women and babies at even greater risk of adverse health outcomes.(60)

Children who experience over nutrition in the intrauterine environment are more likely to have greater adiposity throughout childhood into adolescence and adulthood, negatively impacting on health throughout the life course.(62) Maternal GWG has been positively associated with child BMI, independent of birthweight, at different points in childhood and early adulthood.(57, 63-66) Excessive GWG was also related to greater offspring fat mass at birth, four and six years, compared with offspring of mothers who had adequate GWG.(57) At seven years, the odds of a child being overweight was 48% greater for children of mothers who gained more weight than recommended (according to the Institute of Medicine (IOM) guidelines).(65) The effects of GWG combined with maternal obesity are thought to be mediated by a change in insulin resistance and glucose intolerance, leading to an increased risk of foetal overgrowth, macrosomia and LGA babies.(22, 49, 62)

1.3.4 Postpartum weight: retention and gain

Postpartum weight retention is any increase in weight between pre-pregnancy and postpartum. However, there is no specific timing applied to the definition of postpartum weight. Some suggest that this should be weight retained up to one year after birth due to the physiological changes which continue during this time.(67) The term is used here to describe weight gained in pregnancy and never lost. Pregnancy is found to be a risky period for the initiation and exacerbation of weight related problems and increased BMI.(68-71) Excessive GWG and high pre-pregnancy BMI are predictors of postpartum weight

retention,(26, 69-72) and failure to lose pregnancy related weight by six months postpartum is considered an important predictor of obesity and associated conditions in midlife.(73, 74) For women who start their pregnancy with obesity, additional pregnancy weight retention will only increase their risk of ill-health further,(58) and there may be consequences for subsequent pregnancies. A large interpregnancy weight gain was associated with increased adverse perinatal outcomes in a subsequent pregnancy, compared with the first.(75-77) Whereas for women who enter their first pregnancy and are overweight, but lose weight before entering their second, the risk of neonatal mortality in this second pregnancy was reduced.(77) Lipsky, Strawderman and Olson (2012) (72) have highlighted the risk of further weight gain in the postpartum period, in particular between one and two years postpartum.

Many maternal factors are likely to influence postpartum weight including dietary and activity behaviours, breastfeeding, smoking, income, maternity leave, contraception method and age, but difficulties in measuring these variables means few associations have been reliably established.(26) Nevertheless, pregnancy and motherhood are major life events, and changes in lifestyle and maternal priorities, may help explain weight retention and further weight gain trends.(71, 78) The environmental factors that determined women's pre-pregnancy BMI, continue to be of influence in the postpartum period; added to the additional barriers posed by the demands of caring for a young child, such as lack of time, tiredness, and prioritising children's needs.(79, 80)

1.4 Childhood obesity

Childhood obesity is another pressing public health issue which requires effective intervention.(7) As with adult obesity, the etiology of childhood obesity is complex, but it is clear that mothers play an important role in the development of obesity in their children. The associations between maternal obesity, GWG and childhood obesity were introduced in sections 1.3.2 and 1.3.3. To fully understand the short and long-term consequences of maternal obesity requires consideration of how this may also determine childhood obesity.

1.4.1 Definition and prevalence of childhood obesity

Although obesity in children is also defined as excessive fat accumulation that may impair health,(5) there is more variation in this definition than in adults. Assessment of body fat is the most reliable indicator of obesity in children,(4) but BMI is more commonly used.(2, 4) It

is more complicated to assess BMI in children as it changes according to age and sex, as patterns of growth differ.(81) BMI measurements, such as *z*-scores and percentiles, which take into account the age and sex of the child based on the distribution of a reference population are used.(81-84) This allows comparison of children across age and sex, and for BMI to be defined within thresholds to highlight problematic growth, such as obesity.(84) However, there are different growth references available, and the thresholds for obesity are dependent on the population on which the tool has been developed.(4) Although childhood obesity has been linked to adverse health, there has been no specific BMI value linked to risk.(4) This means that comparisons cannot be made directly with adult thresholds, and obesity cannot be tracked from childhood to adulthood.(4) However, there is a body of evidence indicating that a high BMI in childhood is likely to continue into adulthood thus a continued heightened risk of future health problems.(81, 85, 86) Therefore, BMI is an appropriate marker of obesity and disease risk.(4)

Childhood obesity is considered one of the most serious global health challenges of the 21st century. Levels have dramatically risen, with onset of the condition at increasingly earlier ages, linked to early onset of related conditions, such as type 2 diabetes and hypertension, and an increased risk of continued obesity and ill-health in adulthood.(87-90) Obesity in childhood can be detrimental to mental health and social inclusion where children with obesity suffer from poorer self-esteem, depression and negative judgment by others.(91)

Globally, 43 million children aged 0-5 years are estimated to have obesity.(92) The 2015/16 UK National Child Measurement Programme found that 11.6% of 4 to 5 year olds entering the school system in Wales already had obesity, with a further 14.5% overweight, and similar levels were identified in the rest of the UK.(93) This was one in four children presenting as overweight by school age and these rates rose in later childhood.(93) There has been some evidence that UK rates of obesity in children under 10 years have plateaued in recent years;(94) however, rates remain high, and the burden of obesity falls hardest on those children from low-income backgrounds compared with their more affluent peers.(13) Rates of obesity continue to rise for those children from higher levels of social deprivation.(94)

1.4.2 Determinants of childhood obesity

An ecological systems theory perspective was once again adopted to consider the context of the development of childhood obesity.(11) Davison and Birch (2001),(95) provide a visual representation of this theory as applied to influences on children's weight and outline the potential determinants within multiple contexts. The etiology of obesity starts from

conception, and genetic factors, for example ethnicity, play a role in determining individual predisposition for excess weight.(91) However, the increasing prevalence and rapid development of childhood obesity rates over the past few decades, within genetically stable populations, signifies that adverse environmental and perinatal factors are at the heart of this epidemic.(91, 96)

A child's environment is complex, and includes parents, families, schools, community and the society at large.(97) Many of the determinants of adult obesity mapped out in the obesity system map in the aforementioned Foresight report,(7) are also applicable to the development of childhood obesity. High levels of obesity in children have been partly attributed to problematic social trends and lifestyle changes, including a fall in PA opportunities, alongside a rise in sedentary activities, wider availability, convenience and marketing of energy dense foods, and greater volumes of food consumption.(98, 99)

Children from families with higher deprivation, are more likely to have greater weight due to poor nutrition and less access to PA facilities.(91) The report 'Childhood Obesity: a plan for action' released by the Department of Health (2016), outlined steps being taken at a public policy level, to try to improve these problematic social trends, such as a soft drinks tax levy and increased funding for school sports.(13) However, given the many environmental determinants of childhood obesity, prevention requires intervention from the individual level to the societal level.

Optimal health during gestation and the early years of life is recommended, as these are important periods for establishing future health and wellbeing.(100) Many early life risk factors associated with the development of obesity have been identified. These include pregnancy overnutrition, parental obesity, birthweight, rapid or excess weight gain in infancy, catch-up growth and early adiposity or BMI rebound, sleep duration, early weaning or prolonged formula feeding, television viewing and sedentary parents, availability of energy dense foods and poor access to lower energy dense foods, low parental education, disinhibited eating and feeding practices which are not responsive to infant cues, and parents who do not accept excess weight as a problem.(101-106) Interventions focusing on pregnancy and the preschool years may be central to prevention of childhood obesity.(97, 99, 107, 108) Parents with obesity are more likely to have children with obesity,(109) and although these children may have a genetic predisposition for the condition,(110) it is their environment that will allow these genetic factors to be played out.(98) An 'obesogenic environment' is the extent to which environmental factors may promote obesity by determining energy intake and expenditure.(7) Obviously mothers have a clear role in

supporting health during the foetal period, but a young child's world is shaped by the adults around them.(7) Mothers are often critical in directly determining their child's physical and social environment, and indirectly influencing their behaviours, habits and attitudes through social interactions and modelling.(111) Therefore, in the context of discussing maternal obesity, understanding the determinants of childhood obesity in pregnancy and early childhood, and how maternal and family factors may impact these environments, is important.

1.4.3 Maternal and family determinants of childhood obesity

Whitaker (2004) states, *"perhaps one of the greatest concerns related to obesity in pregnancy is the perpetuation of it in childhood in the offspring"*.(112) In sections 1.3.2 and 1.3.3, the intergenerational cycle of obesity was highlighted by the independent associations between both maternal obesity and GWG, and the increased likelihood of subsequent obesity for the offspring.(56, 103, 106) Theories of developmental origins of health and disease are used to explain the adverse infant outcomes associated with maternal obesity and GWG. It is theorised that the conditions a foetus is exposed to in the intrauterine environment will have short and long-term consequences for health through foetal programming and epigenetic mechanisms.(113, 114) Insulin resistance is heightened for pregnant women with obesity, putting them at greater risk of developing GDM and increasing the availability of glucose, other nutrients and fatty acids to the developing foetus.(58) Similarly, overnutrition in the intrauterine environment, linked to maternal excessive GWG, can have the same effect. These conditions can have a negative impact on developmental programming and placental functioning, which can have negative consequences for foetal growth, birthweight, metabolic traits and risk of adiposity and obesity in childhood prevailing into later life.(23, 55, 56, 115) Hayes and colleagues(116) visually demonstrate this cycle of maternal obesity leading to adverse metabolic health for the offspring.

In early childhood, the maternal and familial influences on the 'obesogenic' environment, and how maternal obesity might mediate those influences, falls within three domains: food, PA, and sedentary behaviour,(117, 118) and these are discussed next.

Food

Breastfeeding intentions, initiation and duration are lower in women with increased BMI, attributed to delayed lactation, physiological barriers due to size, and higher rates of caesarean delivery and special neonatal care leading to separation of mothers and babies following birth.(25, 58, 119) Other psychological, behavioural and cultural components are

also likely to play a role.(119) Breastfeeding, dependent on duration, shows benefits for maternal postpartum weight retention,(58, 120) but protects against the development of obesity in children.(119-121) Being breastfed may encourage regulation of appetite and attendance to satiety cues.(120, 122) In addition, the introduction of flavours are passed through breastmilk increasing exposure, and making foods more likely to be accepted in later childhood.(96, 123, 124)

Beyond milk feeding, patterns of food choice and consumption, and interactions with caregivers surrounding food, start from birth. Dietary habits formed in childhood are likely to be established as lifelong behaviours that will have implications for future health.(96, 122, 125) Young children mainly rely on others to make food choices for them, and much of the research in this area focuses on the strong influences that mothers have,(117, 126, 127) although fathers and the wider family are also influential.(109)

The development of food preferences is a complex mix between children's innate partiality for certain foods, and the learned features of foods.(128) Children can learn preferences for healthy foods,(129) and Social Learning Theory has explained how mothers influence this. Children, including toddlers, are shown to mimic the food preferences of their mothers, and the quality of children's dietary intake is comparable to their mothers' intake.(122, 124, 130-135) Mothers with a higher BMI are likely to have obesity promoting dietary behaviours which they role model to their children.(126) These children are more likely to consume a diet characterised by consumption of energy dense foods and lower intakes of fruit, vegetables and wholemeal bread.(135)

Maternal influence on the child food environment often stems from their responsibility for food availability and preparation in the home.(136) Provision of foods high in sugar, sodium and saturated fat can lead to preferences for these foods and is likely to reduce diet quality, encouraging the development of intake patterns that, over the long-term, would be detrimental to health.(137) Repeated exposure to foods and familiarity is associated with increased consumption,(96, 138) and parents are recommended *"to provide a healthy array of foods in the correct portion size and allow children to decide what and how much to eat".*(122) However, barriers that women experience in adopting healthy dietary behaviours themselves, such as poor self-efficacy for preparing healthy meals, are likely to impact the food choices that they make for their children.(139) Nutritional knowledge impacts a mother's ability to choose healthy foods, which is shown by the association between maternal educational attainment, nutritional knowledge, and dietary quality in children.(135, 140) Health may not always be a priority for the mother in choosing foods, rather 'convenience to

prepare' and 'child's taste preferences', may guide food choices.(140) The setting of children's food consumption is believed to be important in encouraging healthy dietary patterns,(141) and the practice of family mealtimes, away from the television, has been linked with increased dietary quality and portion control.(124, 134, 142)

The strategies mothers may employ in an attempt to control children's dietary behaviours, can shape what foods a child is offered, and the timing, portion sizes, social context and emotional climate of eating.(131, 143) Mothers often have a goal of what foods they do and do not want their child to eat, along with a belief that children need help in determining what and how much to eat.(138, 144) They may exert controlling practices over child feeding believing that this will positively influence healthy food intake and weight. However, these practices can have a negative impact on children's eating behaviours and can lead to accelerated weight gain and higher weight,(145, 146) although the causal pathway is not always clear.(147) Pressure to eat includes encouragement to 'clear the plate' or to eat particular foods. This strategy can teach children to attend to external cues on what and how much they should eat rather than internal cues of hunger, and they lose the ability to self-regulate their appetite.(145) Coercion into eating particular foods, such as vegetables, can lead to dislike of that food and lower consumption,(136) but can be positively associated with consumption of some foods, including fruit.(148) Restrictive practices to withhold foods have been implicated in encouraging uninhibited eating and accelerating child weight gain,(145, 147) and lower consumption of fruits and vegetables.(136) However, restriction of unhealthy foods has been associated with lower consumption of these foods.(149) It may be that restricting access to energy dense foods does not necessarily lead to increased consumption of healthy foods. Farrow & Blissett (2008) propose that these practices could be supportive of health in infancy, but may lead to disinhibition and greater weight in later childhood, when children gain more independence in choosing foods.(150) Instrumental feeding is where parents use food as a reward or bribe to control behaviour or to encourage the consumption of other foods.(147) Offering a 'reward' food in exchange for eating another food, often a healthy option, may increase the attractiveness of the reward food and increase negativity associated with the 'access' food.(130) Food used for controlling behaviour may increase consumption in the absence of hunger. Similarly, using food for the purposes of emotional regulation, that is to pacify children when they are upset,(147) increases eating in the absence of hunger.(151)

In terms of understanding the 'obesogenic' environment, there are conflicting findings on the influence of controlling feeding practices, and mothers with obesity are no more likely to employ these feeding strategies compared with normal weight mothers.(152) It could be the

use of less control in these mothers that is influential on higher child weight status.(152) Ogden, Reynolds and Smith (2006) offer an alternative explanation for these contradictory findings; they propose that some aspects of control are beneficial whereas others are not, and emphasise the differential influences of overt and covert control over the food environment.(153) Overt control is that which can be detected by a child and describes the practices previously outlined, where mothers explicitly exert control in an attempt to influence food consumption. Covert control, that which cannot be detected by a child, may be used to positively manage the food environment, such as avoiding taking a child to places which sell unhealthy foods.(153) The extent to which a parent overtly or covertly controls their child's access to foods can influence child food intake. Overt control has been associated with increased consumption of healthy snacks but can lead to increased intake of unhealthy snacks and meals, whereas covert control has been linked to reduced consumption of unhealthy snacks and meals.(153, 154) It may be that mothers with obesity are less likely to covertly manage their children's food environment.

Physical activity (PA)

PA is an important behaviour that effects child weight and health; and public health guidelines recommend that preschool children should achieve three hours of daily activity.(155) Variances in children's activity levels are predominantly explained by environmental influences.(156) Children of parents with obesity are likely to be less active,(98, 157) with increasing parental BMI shown to be negatively associated with children's PA.(157) Parents facilitate active play by interacting with their children in a physically active way and by creating opportunities for them to be active.(142) Engaging in active family activities is likely to reinforce the child's activity behaviours and foster positive attitudes towards being active.(142) Parental role modelling of PA behaviours, has been shown to influence these behaviours in their children, but mothers with obesity are less likely to be active.(122, 131, 158-160)

Sedentary behaviours

Sedentary behaviours impact on health independently of PA, even when young children achieve the recommended levels of activity they may be engaging in risky levels of sedentary behaviours.(155) It is advised that for preschool children, extended periods of time spent being sedentary, outside of sleeping, should be kept to a minimum, including avoiding prolonged restraint in car seats and prams, or engaging in screen time behaviours. The extent to which mothers both control and role model sedentary behaviours will be influential on children's weight.(155, 161) Television viewing, in particular, is considered a risk factor for development of excess weight as it not only reduces activity but is linked to increased

energy intake,(91) reduced diet quality at mealtimes,(142) and is likely to be indicative of other sedentary behaviours.(162) Parents and families who spend a lot of time watching television are normalising these behaviours, and when caring for young children, it is likely that the child will be adopting the same behaviours.(162) Mothers with obesity are more likely to be engaging in riskier levels of sedentary behaviours.(163)

The focus for this thesis was the maternal and family determinants of childhood obesity, to examine how mothers might play an important role in its prevention. The substantial influence that mothers and families may have on shaping food and activity behaviours for young children is evident. However, it is important to recognise that young children may also spend time in other settings, such as childcare, which may have a significant influence on these behaviours.(164) Increased formal childcare in the first year of life has been linked to increased odds of overweight and obesity in children aged 12 months.(165) However, children aged three to four years were more likely to be active and less sedentary when they were in a preschool or nursery setting compared with a home setting.(166) Informal childcare, from grandparents in particular, has been linked to adverse effects on weight, diet and activity, and undermining of parental goals for their child's healthy lifestyle.(167) Regardless of the type of childcare received, the increasing amount of time a child spends in childcare settings, will reduce the level of influence that a mother might have over that child's behaviours.

It was also recognised that the development of weight and lifestyle behaviours in children is influenced by a complex interaction of societal and biological factors. A mother's ability to manage her child's environment, is subject to the constraints within her own social context, and her 'capability' and 'opportunity' to influence her child's behaviours.(168) Adverse environmental factors, such as lack of education and skills, or lower SES, may restrict the choices a mother can make, and overwhelm her efforts to manage energy intake and PA for her children.(169)

1.5 Summary

This introduction has highlighted the problems of maternal obesity and excessive GWG. It has introduced the associated issue of childhood obesity and described how mothers and families might influence the development of obesity in children during pregnancy and early childhood. Pregnancy should be a positive life transition, but for many women with obesity it is a life stage that potentially increases the risk of ill-health for themselves and their offspring. Furthermore, the risks associated with obesity and GWG during pregnancy, the

postpartum period and beyond, are likely to place significant demands on the NHS in both primary and secondary care settings. Given the burden on individuals and society, it is important to understand the measures being taken to address these issues. Chapter 2 will provide a review of the current care pathways and guidance for mothers with obesity in pregnancy and describe intervention studies that aimed to improve maternal and child outcomes associated with maternal obesity.

2 Literature review: improving maternal and child outcomes related to maternal obesity

2.1 Introduction

The purpose of this Chapter is to provide a review of the literature related to weight management during and after pregnancy to improve the adverse outcomes associated with maternal obesity, to identify knowledge gaps, and to provide justification for expanding this field of research. This Chapter includes a description of the 'usual care' pathway in NHS maternity care for mothers with obesity and offers a critical evaluation of this current model of care. Lifestyle interventions for mothers with obesity to reduce GWG and improve short and long-term maternal and child outcomes, will be described; and the results of some of the key intervention trials will be discussed. One such study, the Healthy Eating and Lifestyle in Pregnancy (HELP) cluster RCT, on which this thesis is based, will be described.(170) This Chapter provides a rationale for the further evaluation of outcomes in the population recruited to this trial. In particular, to explore the potential of the HELP intervention to reduce the risks associated with maternal obesity, including the development of childhood obesity. The Chapter concludes with the thesis research questions which seek to address the identified gaps in this field of research.

A literature search was performed from July to October 2013, to provide a review of the existing body of knowledge in this area. MEDLINE, PsycINFO, EMBASE and the Cochrane Library databases were used, and the review adopted a rigorous search approach (described in more detail in Appendix A). Key terms were used to identify relevant articles. When reviewing relevant articles, a snowballing technique was used wherein reference lists were searched for additional publications of interest. Relevant documents in the grey literature were also identified. Websites for governmental departments and other relevant organisations, such as the Royal College of Paediatrics and Child Health, were searched and reports retrieved. With guidance from the research supervisors, five recommended

researchers conducting work in this field were also contacted. A further search of the literature was completed in November 2017 and March 2018 to update this review.

2.2 UK guidance and care for pregnant mothers with obesity

2.2.1 NHS maternity 'usual care'

During early pregnancy (eight to 12 weeks gestation), all women are to have their height and weight measured to calculate their BMI.(171) Women with a BMI of ≥ 30 kg/m^2, follow an adapted care pathway, centred on the management of risks associated with maternal obesity.(46, 172) This adapted care pathway offers an intensive treatment plan, compared with healthy weight mothers, involving increased monitoring and screening for clinical conditions, such as GDM.(46, 53, 171) Women's care often involves obstetricians and specialist teams to monitor maternal and infant health, and to develop individualised care plans.(46) For these women, increased care continues into the postpartum period where they may undergo tests to check that pregnancy conditions, such as GDM, have resolved.(46)

2.2.2 Appropriate weight gain in pregnancy

There are no guidelines within the UK which offer women recommendations on optimal weight gain in pregnancy. In the United States of America (US), the IOM has developed guidelines for appropriate weight gain dependent on a woman's BMI and, therefore, her level of risk.(173) For women who start their pregnancy with a BMI ≥ 30 kg/m^2, a weight gain of five to nine kg is recommended, to support positive maternal and infant outcomes.(62) These guidelines, or amended versions of them, have been adopted by many countries,(174) and there is some evidence to suggest that guideline adherence does not have any harmful outcomes for the mother or infant, and could have a positive impact on long-term weight for both.(57, 68, 175, 176) However, policy makers in the UK have not adopted the IOM guidelines due to the absence of robust evidence indicating that adherence to recommendations would result in improved pregnancy outcomes,(177) although they are used by several NHS health trusts.(61) The IOM guidelines were based on a US reference population and may not be transferable for use in the UK.

2.2.3 Routine weighing in pregnancy

Weight is measured in early pregnancy but only repeated later if it may have an impact on clinical treatment planning, such as equipment required for labour.(46, 178) There is a debate about whether routine weighing should be introduced into antenatal care as an aid for monitoring GWG,(179-181) and many other countries adopt this practice.(174) Those opposing routine weighing have suggested that there may be anxiety for women surrounding the practice, but a study found that this was not the case provided that monitoring had been discussed with women.(179) However, there is a paucity of evidence to support the argument that routine weighing in usual care would, alone, promote healthy weight gain.(182) More evidence is needed on whether it would offer clinicians an opportunity to discuss weight gain with women.(182) The pending report of a randomised controlled trial (RCT) of an intervention using weighing and weight gain charts to set targets for GWG, will add to this evidence.(180)

2.2.4 Supporting weight management before, during and after pregnancy

Given that there are no weight gain recommendations offered to women in pregnancy, focus is placed on health professionals encouraging women who are pregnant, planning a pregnancy or within two years of having a baby, to eat healthily and keep active.(46, 61, 172) As a preventative measure to combat the effects of maternal obesity, women with a high BMI are to be advised of the benefits of weight reduction before conception, and offered a weight-loss support programme.(172)

During pregnancy, women with obesity should be informed of the related risks, and offered advice on reducing these risks through lifestyle changes.(46) Dietary recommendations to support healthy GWG, include eating a varied diet based on consumption of starchy and fibre rich foods, fruits and vegetables, avoidance of high fat and high sugar foods, eating breakfast and monitoring portion sizes.(172) Health professionals are to dispel *'eating for two'* myths about the requirement for increased food intake in pregnancy, and advise women on maintaining pre-pregnancy energy intake, increasing to an extra 200 calories a day in the third trimester.(172) PA is recommended, and pregnant women are advised to aim for completion of 30 minutes of moderate-intense PA per day, five times a week;(172, 183) and to gradually increase PA to meet these recommendations.(172, 184, 185) PA can: help women cope better in labour;(186) enhance psychological health so women experience less fatigue, anxiety, and depression, and cope better with bodily changes;(184) encourage appropriate GWG and in doing so reduce the risks associated with excess GWG;(59, 186)

and, improve insulin sensitivity and glucose control decreasing the risk of developing GDM.(187-190)

To support weight management in the postpartum period, women should be offered advice on weight reduction, healthy diet and PA, including signposting to a reputable source of information or community based weight loss group.(172) Those with obesity, should be encouraged to reduce their weight before another pregnancy and offered referral to a dietician or appropriately trained health professional for a more individualised behaviour change plan.(172)

2.2.5 Specialist weight management services (WMS)

The National Institute of Health and Care Excellence (NICE) have advocated the commissioning of specialist WMS within maternity care, for pregnant women with obesity, to support their behaviour change towards a healthy lifestyle, and reduce the burden of maternal obesity.(172) Initiatives vary across health trusts, and two examples of specialist WMS are presented below.

One example was the Maternal and Early Years Healthy Weight Service, a referral pathway for pregnant women with obesity, used in 17 primary care trusts in England.(191, 192) Women received home visits by a healthy weight advisor from early pregnancy and up to two years postpartum. They were provided with individualised advice on diet, PA and child feeding, support for behaviour change, and regular weight monitoring, with the aim of improving maternal and child outcomes. Dinsdale and colleagues (2016) reported on patients' experiences of another WMS; three care pathways for pregnant women allocated by class of obesity, implemented by an NHS health trust in England.(193) This WMS aimed to provide an appropriate level of antenatal intervention to manage risks associated with obesity in pregnancy. For example, pathway 3 for those with a BMI ≥40 kg/m^2, offered a 'healthy lifestyles clinic' up to four times in pregnancy, which involved separate consultations with a midwife and a dietician.(193)

2.3 Critical evaluation of the UK guidance and care for pregnant mothers with obesity

2.3.1 Costs associated with caring for maternal obesity

As introduced in Chapter 1 (section 1.3.1), caring for a pregnant woman with obesity is likely to have resource implications and an impact on service provision within the NHS, through increased frequency and duration of healthcare usage as a result of related complications.(22, 25, 28, 29) Compared with women of healthy weight, mean total costs of healthcare usage have been found to be 37% higher among women with obesity, without consideration of the costs of neonatal care.(194) Increased costs are mainly attributed to higher rates of: general practitioner (GP) and outpatient visits, hospital admissions, prescriptions, consultant led care and input from other specialists, additional scans and tests, a higher rate of medical intervention during labour, and delivery by caesarean section.(22, 25, 31, 47, 53, 194, 195) Caesarean section is markedly more costly at £6255.78, compared with £1643.01 for vaginal delivery with no medical intervention.(195) To allow the safe and sufficient care of women with a higher BMI, other costs may be associated with the provision of: wider accessibility in doorways; appropriate sized equipment such as beds, blood pressure cuffs, wheelchairs, ultrasound couches, longer spinal and epidural needles, and weighing scales; and increased staffing levels for labour and delivery.(46)

It is difficult to estimate the true financial cost of maternal obesity as maternity care records differ throughout the UK, and the costs extend to the economic and social impacts.(7, 28) Nevertheless, it is clear that caring for a pregnant woman with obesity under the current model of care is likely to increase NHS costs, in comparison with caring for a mother of healthy weight.

2.3.2 Communication between healthcare professionals and pregnant mothers with obesity

To advise pregnant women on healthy diet and PA in pregnancy, healthcare professionals, often midwives, are expected to understand the risks associated with maternal obesity, have good communication with their patients, be sensitive to women's weight concerns, and deliver individualised advice on maintaining a healthy lifestyle.(46, 171, 172) Furthermore, this is expected to be done in short patient consultation windows, within an overstretched

and under-resourced NHS.(196) Unsurprisingly, evidence indicates that weight management is not routinely discussed in antenatal consultations even for those with a higher BMI.(69, 197) Midwives report barriers to offering women personalised advice on lifestyle including: a lack of skills, confidence or time to address this issue, concern about their own weight, fear of insulting or stigmatising women, and a risk of harm to the clinician/ patient relationship.(196, 198-202)

Inadequate communication of the risks associated with obesity in pregnancy, by health professionals to women, can lead women to believe their pregnancy is low risk.(203) Women have also reported receiving confusing and inconsistent weight management advice from healthcare professionals, which has made them hesitant to initiate lifestyle changes.(199, 204) Women have felt embarrassed and guilty as a result of judgmental and stigmatising communication from health professionals,(193, 205, 206) and the use of insensitive language verbally or in medical notes.(207) They have felt that the focus of their antenatal care became about their weight and related risks which 'medicalised' their pregnancy and depersonalised it from being about them and their baby;(206) which is contrary to the patient-centred care that healthcare professionals aim to achieve.(208)

2.3.3 Barriers to adopting weight management advice in pregnancy

Although women can be aware of the risks linked to maternal obesity and the benefits of healthy eating and PA, and can themselves express concerns about GWG and an interest in receiving advice,(24) there are many barriers to successful weight management in pregnancy.(199, 204)

When women receive lifestyle advice from healthcare professionals, they may also receive conflicting information from family, friends and the media.(199, 204) Behaviours in pregnancy are strongly influenced by the social structures around women, and pregnant women have reported being encouraged by family and friends to rest and to increase their dietary intake.(199, 209) Other reported barriers to adopting lifestyle advice include: a lack of cooking skills to make healthy foods,(143) and a lack of facilities offering pregnancy specific exercise.(204) Physical states during pregnancy, including cravings, nausea and physical discomfort, may influence women's ability to follow advice, but also their attitudes.(209) Responding to physical states may justify over-eating and reducing PA.(199)

Women may perceive pregnancy as a time of liberation where they have freedom to 'indulge' and abandon usual behaviours.(206, 210). Those with a larger body size may welcome the

changes in pregnancy as they perceive their body to become more socially acceptable, which is likely to decrease their motivation for change.(199, 210, 211) Normalisation of obesity can make it difficult for health messages to be taken on board.(204) Women may view pregnancy weight gain to be 'inevitable' and perceive a lack of control over how much weight they gain.(199, 206) Women can hold misconceptions in relation to pregnancy weight gain and healthy behaviours including: that excess gain is good for the baby but physical exertion can cause harm, or that their own weight will return to 'normal' postnatally.(212-215)

There are many physical and psychosocial factors that need to be considered alongside the provision of information in order to affect lifestyle change.(216) The current care pathway fails to provide a feasible way to address the psychological factors that play a role in behaviour change and weight management in pregnancy, and health professionals are unlikely to be equipped with the skills or the time to effectively help women address these factors.(196)

2.3.4 Limitations of the UK guidance and care for pregnant mothers with obesity

Ahluwalia (2015) argued that not enough is being done within services to educate women and to support them to change their behaviour, rather a medicalised approach is taken which focuses on managing the risks associated with maternal obesity.(217) This approach limits women's opportunities to make informed choices about their care; such as on where to give birth.(53, 208) The current demands on the NHS, related to maternal obesity, makes the identification, treatment and prevention of the associated complications a daunting task from a medical and obstetric perspective,(218) which leaves limited resources to deal with the underlying issues and demonstrates no long-term strategy to help people change to improve their future health, and that of their families.(217)

The current guidance encourages efforts to address obesity in the pre-conception period, which could be an effective way of preventing maternal obesity and reducing the associated costs to the NHS. However, there is a paucity of evidence showing the effectiveness of pre-pregnancy health promotion on pregnancy outcomes,(219, 220) and there remains a high number of women entering pregnancy with obesity.(19) Opportunities to target women before pregnancy are difficult to establish given the unplanned nature of a lot of pregnancies in the UK.(221) Of those planning a pregnancy, only a small proportion of women follow nutrition and lifestyle recommendations.(222, 223) More research is needed into successful

public health interventions to address obesity in this pre-conception period and encourage behaviour change for women of reproductive age.(25)

During pregnancy, women's efforts to comply with weight management guidelines, including dietary, PA and IOM weight gain recommendations, would be likely to result in appropriate GWG.(176) However, evidence indicates that during pregnancy, women often increase dietary intake and reduce their amount and intensity of PA.(24, 59, 224, 225) Women accessing maternity services continue to report limited knowledge about the risks or cost implications associated with maternal obesity and excessive GWG,(24, 53, 60, 69, 214, 217, 226) and a lack of self-efficacy in their ability to make lifestyle changes.(226) Women have expressed a desire to have more input and support from healthcare professionals on GWG, including weight monitoring,(197, 209) but have called for personal and pregnancy-specific advice rather than general information.(227) Delivering individualised behaviour change plans would be difficult for clinicians to achieve within the current constraints of healthcare consultations. However, generic advice for behaviour change, which does not take into account individual circumstances, is unlikely to lead to change.(177) To deliver individualised advice, healthcare professionals would require training on effective communication skills and behaviour change strategies.(204, 228)

Clinicians are also likely to struggle to advise women about GWG in the absence of evidence to support routine weighing in pregnancy, and with no UK recommendations on appropriate weight gain.(53, 61) However, when guidelines are used, such as those from the IOM, most women remain unaware of BMI specific weight gain goals and still gain excessive GWG.(20, 60, 209, 229) These guidelines offer no advice to women on how to achieve the GWG recommendations.(177) They also do not provide ethnic specific recommendations which may be important for highlighting the risk variation within different populations.(60) The authors of the IOM guidelines suggest that women with obesity would probably require additional intervention to help support them in meeting GWG goals.(62)

Currently in UK antenatal care, women should be offered a weight-loss support programme and dietetic input,(172) but evidence based referral options remain limited and current resources do not always allow for dieticians.(53) Specialist WMS are sometimes offered, but women's options differ by hospital dependent on availability of resources, local policies and health professionals, and there is a limited evidence base for these WMS.(53, 172) Uptake of these services is generally low with many women declining to attend or disengaging early.(200, 201, 230) Some women have valued the additional support,(227) whereas others have expressed a disinterest and lack of need for such a service.(191, 231) There is a lack

of perspective from women themselves about what services they want, which may discourage engagement,(191, 230, 232) so WMS offered need to be more women-centred.(201) Referral practices by midwives differ, with some referring all eligible women and others offering women the option of whether to be referred or not.(200) Midwives may not have adequate knowledge of the service, or may avoid offering a referral to those they think might refuse.(200) This may mean that WMS only benefit those who were already motivated to change their behaviours.(201)

Providing weight management advice in the postpartum period could be an ideal time for intervention, as women have shown motivation to lose weight during this time.(204, 227) However, currently women perceive a lack of support in the postpartum period.(69, 193)

The continual rise in the prevalence of maternal obesity suggests that current maternity care provision is not successfully addressing this issue. The associated costs linked to care of mothers with obesity places a burden on the limited resources of the NHS. Safe and effective evidence based interventions which seek to help women understand the consequences of maternal obesity and achieve appropriate GWG, to reduce the risks and costs associated with maternal obesity, and to encourage behaviour changes in pregnancy that are sustained into the postpartum period, are needed.(214)

2.4 Interventions to improve outcomes associated with maternal obesity

In recent years, there has been growing interest in the potential for lifestyle behaviour change interventions, applied during pregnancy and/or postpartum, to help women with obesity limit their GWG to reduce adverse pregnancy outcomes for the mother and child, and to support their weight loss postpartum.(49) The rationale for these interventions, and some of the key study findings, are described below.

2.4.1 Pregnancy as a 'window of opportunity'

There are periods in the life course which may be critical opportunities for the prevention and treatment of obesity.(7) Pregnancy is one such period, considered a 'teachable moment', when women may reflect on their sense of identity and maternal responsibilities and become more conscious of how their lifestyle choices may impact their health, and that of their unborn baby.(233) It may be a unique time in which to change health behaviours as women

are motivated for change and perceive that the needs of their unborn child should take precedence over their own needs.(199, 204, 233) Women often make lifestyle adjustments in pregnancy based on their perceptions of what is acceptable behaviour for someone that is pregnant, including exclusion of toxins and changes to their dietary intake.(223, 234) If women are already engaged in behaviour changes and open to information from healthcare professionals, then pregnancy may be an ideal time to intervene to encourage further behaviour change for health and control of GWG. Women also access healthcare services more frequently during pregnancy so there are increased opportunities for intervention.(183, 233) Pregnancy is thus a prime opportunity to address the issue of obesity from a wider family perspective and could allow the implementation of long-term strategies to bring about population level changes in obesity.(217)

2.4.2 Psychological theory applied to lifestyle interventions in pregnancy and the postpartum

There is mounting evidence to suggest that information provision in pregnancy is not enough to support long-term behaviour change. Rather, education alongside interventions based on psychological theory are more likely to be effective.(216, 235) A health intervention which is based on psychological theory provides a model for hypothesising outcomes in the design and evaluation of the intervention,(216, 236, 237) and allows for consideration of individual factors important for behaviour change, such as motivation. The aim is to affect change in mediating variables or psychological constructs that, based on theory, are expected to be the causal mechanisms of the behavioural change of interest.(238)

It is difficult to identify which behaviour change theories are most useful in explaining and changing lifestyle behaviours in pregnancy for the control of GWG, and for weight loss in the postpartum, as very few studies report the theoretical content of interventions.(239) Theories that have been applied in developing interventions aimed at lifestyle behaviour change in pregnancy and postpartum, such as the Theory of Planned Behaviour,(186) are criticised for failing in their ability to explain variability or inform on how to change health behaviours.(240, 241) Experts in behaviour change theory recommend a move towards self-regulatory theories which are more flexible in their explanation of behaviour.(240)

In terms of the psychological constructs that may be important for lifestyle behaviour change in pregnant women with obesity, a higher perceived sense of control and self-efficacy have been implicated as important factors for adherence to dietary recommendations in pregnancy.(242) Women's perceived lack of control and lack of belief in their ability to

change are reported as barriers to weight management.(199, 206, 226) Higher self-efficacy has been associated with lower body weight in early pregnancy and at two years postpartum;(58) and is identified as a significant predictor of PA in pregnancy.(186) Lower social support and self-efficacy are associated with poorer mental health in pregnancy, which is inversely related to health behaviours.(243) Social support is important as many of the barriers to healthy behaviours in pregnancy are influenced by the social network of pregnant women.(199) Non-judgmental support from midwives and family members, to help women change behaviours in pregnancy, is valued by pregnant women.(244)

To effect the theoretical mechanisms of change and allow replication and synthesising of study data, interventions need to include 'active ingredients' or behaviour change techniques (BCTs) intended to manipulate the mediating variables.(238, 245-248) Reporting this intervention content also allows for better evaluation of the intervention in that effective components or combinations of techniques may be identified.(245, 249) There is a paucity of evidence on the BCTs that are likely to be effective specifically in a pregnant population with obesity or for weight loss in the postpartum period. NICE guidance on obesity and behaviour change in the general adult population, recommends the use of self-monitoring and feedback on performance, goal setting, planning and social support techniques.(250, 251) However, several systematic reviews of maternal obesity interventions which had used these, and other BCTs, were unable to draw conclusions on the importance of these components for changing diet and activity behaviours, and outcomes in pregnancy, as this had been poorly evaluated.(221, 239, 252, 253) However, the use of goal setting strategies, performance feedback, information provision on the consequences of behaviour, providing rewards contingent on successful behaviour, prompting self-monitoring of behaviour and motivational interviewing have been identified as important in preventing excessive GWG.(254, 255)

In interventions aimed at changing diet and PA behaviours in non-pregnant populations, those which adopted techniques related to control theory were more likely to be effective in changing behaviours leading to greater weight loss.(248) Control theory proposes that self-regulation will encourage health-promoting behaviours. Self-regulatory BCTs include intention formation, prompting goal setting and reviewing behavioural goals, prompting self-monitoring of behaviours, and providing feedback on performance.(249, 256) Interventions that encourage self-monitoring alongside one or more self-regulation techniques derived from control theory, are shown to be more effective than other interventions.(249) In addition, self-monitoring of weight has been associated with greater postpartum weight

loss.(257) The use of control theory and self-regulatory BCTs may have promise to influence lifestyle behaviour change in pregnant populations.

This evidence on relevant theory and BCTs could inform the design of effective lifestyle interventions in pregnancy, and the postpartum period, to reduce the burden of maternal obesity, but at present there have been few evaluations of the usefulness of particular theories and BCTs, or how they interact with context, in improving outcomes in a pregnant population with obesity.

2.4.3 Lifestyle interventions during pregnancy to improve maternal and child outcomes associated with maternal obesity and GWG

At the start of this decade, and in recognition of the problems with the current model of care for mothers with obesity in pregnancy, there was a call to establish the characteristics of effective interventions that could support better outcomes for these mothers and their children. Several systematic reviews and meta-analyses were conducted to explore the effectiveness of studies using lifestyle interventions, to reduce the impact of overweight and obesity, or excessive GWG, on pregnancy and neonatal outcomes.(199, 221, 239, 258-260) There were no studies identified that had looked at weight loss starting in pregnancy to improve outcomes.(261) The evidence did suggest that interventions based on diet and PA modifications could be successful in supporting pregnant women to have a healthier GWG,(252) which could lead to a positive impact on long-term weight retention and caesarean section rates.(260) However, the effectiveness of interventions for women with obesity, or exactly what a tailored intervention might involve for these women, was unclear.

A Cochrane review and meta-analysis of 27 intervention studies to prevent excessive GWG, found that interventions aimed at reducing weight gain in general clinical populations were successful, but not those aimed at high risk groups, such as mothers with obesity.(259) However, a systematic review by Oteng-Ntim and colleagues (2012) included any lifestyle interventions specifically for women who entered pregnancy overweight or obese. Based on their meta-analysis of 13 RCTs with pooled data for 1,228 women, their results suggested that modest reductions in GWG as a result of interventions could be achieved (mean difference -2.21 kg; 95% confidence interval (CI) -2.86 to -1.59 kg), with a trend towards a reduction in incidences of GDM also indicated.(221) A strength of this review was that separate meta-analyses were completed of the randomised and non-randomised data. A later meta-analysis of PA or PA plus diet interventions, for women who are overweight or obese, replicated this positive impact on GWG for all interventions compared with control

groups, although the strongest intervention effect was for those that combined structured PA with dietary advice.(262) However, there remained limited evidence for further benefits on maternal and child health.

A meta-analysis of RCTs and observational studies which sought to influence maternal weight and related outcomes, through any dietary and lifestyle intervention, and included women across the BMI range, examined the effects of these interventions on obstetric outcomes.(258) The authors analysed the randomised evidence, with inclusion of 44 studies and combined data for 7,278 women. Their results indicated an overall reduction in GWG of 1.42 kg (95% CI 0.95 to 1.89 kg), as a result of any intervention, compared with control groups. Interventions which included a dietary component showed the largest reduction in GWG (3.84kg), with improvement in some obstetric outcomes also, compared with other interventions. However, interventions which included a PA component were also shown to reduce infant birthweight, and those interventions that combined diet and PA advice led to a reduction in risk of pre-eclampsia. Due to the indications that including dietary or PA components in interventions could have independent benefits on outcomes, it was concluded that interventions based on both components may be most successful in supporting women to control GWG and improve outcomes.(120)

The evidence base of systematic reviews and meta-analyses indicated that lifestyle interventions in pregnancy may have the potential to reduce GWG and postpartum weight retention.(175, 263) Yet there was little convincing evidence of further benefit on women meeting IOM weight gain recommendations, or on maternal and child health; for those with a high pre-pregnancy BMI.(221, 258, 260) However, the inferences that could be drawn from this evidence were limited by the quality of the included studies.(264) Available studies were of low to medium quality, non-randomised populations were included, and there was a lack of evidence specifically in populations with obesity. Sample sizes of the studies were small, and even the pooling of data provided inadequate power to examine effects.(221, 259) There was marked heterogeneity in included studies, with differences in study design, participants, interventions, and outcomes, and under-reporting of intervention content.(239) There was limited reporting of the intervention theory or BCTs in the available studies, which made it difficult to determine the important psychological components of these behaviour change interventions.(239) The limited effectiveness of interventions was also likely due to a failure to address the psychosocial barriers to weight control in pregnancy.(199) As a result of these methodological shortcomings, it was not possible to draw definitive conclusions about the effectiveness of interventions, or make evidence-based recommendations for clinical practice in antenatal care. Importantly, the studies discussed above suggested that

there was no harm to mothers or infants associated with controlled manipulation of diet (based on improving diet quality) and PA in pregnancy. On the other hand, they highlighted a need for more high quality RCTs, with adequate sample sizes, focusing on clinically relevant outcomes; to improve the quality of evidence on lifestyle intervention in pregnancy for women with a high BMI. The requirement for better reporting of intervention content, to allow evaluation of the effective components of behaviour change interventions, was also evidenced.

By 2015/16, the quality of the available evidence had greatly improved. Flynn and colleagues (2016) identified 13 RCTs of interventions that were specifically aimed at dietary change, and in some cases PA also, in pregnant women who are overweight or obese.(265) Several of the included RCTs were of high quality, with adequate sample sizes to examine effect. Furthermore, a 2015 Cochrane systematic review and meta-analysis of diet and/or PA interventions to support control of GWG, included 49 RCTs involving 11,444 women.(266) Many of these studies were also deemed to be medium to high quality. This meta-analysis found that women in receipt of any intervention were more likely to experience lower GWG than those in control groups.(266) Interventions reduced the risk of excessive GWG on average by 20% overall (average risk ratio 0.80, 95% CI 0.73 to 0.87; n=7,096 over 24 studies).(266) Interventions based on low glycaemic load diets, supervised or unsupervised exercise only, or diet and exercise combined, all led to similar reductions in the proportion of women experiencing excessive GWG.(266)

The most relevant high quality RCTs examining the effectiveness of interventions in pregnant women with high pre-pregnancy BMI, or having experienced adverse outcomes related to high BMI in pregnancy, have been summarised in Table 1. These summaries focus on pregnancy and birth outcomes for the mother and child, and long-term maternal outcomes. Evidence on the effectiveness of interventions on child outcomes beyond birth will be discussed in section 2.7.2. Overall, these lifestyle interventions in pregnancy for improving outcomes related to maternal obesity, have shown moderate success in supporting women to increase dietary quality and PA, and to control GWG, with a modest 1-2 kg difference between those receiving interventions and those receiving standard care. However, they have failed to show a convincing improvement in pregnancy and perinatal outcomes.(267-269)

Table 1: Summary of key trials of interventions for pregnant women with obesity, to improve pregnancy and neonatal outcomes

RCT	Setting	Participants	Intervention	Outcomes	Summary evaluation
LIMIT (226, 268, 270-276)	Australia	2212 pregnant women with BMI ≥25kg/m^2, recruited between 10 and 20 weeks gestation, across three maternity hospitals	➢ Diet & PA intervention aimed at limiting GWG to improve pregnancy and birth outcomes, plus standard antenatal care. ➢ Dietary intervention: advice consistent with Australian dietary standards, individualised plan for behaviour change set by a dietician and reviewed by study team. ➢ PA intervention: advice to increase walking and incidental activity. ➢ Theoretical design: informed by stage theories of health decision making. Participants were encouraged to use goal setting, self-monitoring and problem solving. ➢ Comparison: standard antenatal care, no provision of behaviour advice.	➢ Primary outcome: rate of infants born LGA, no significant difference between the groups. ➢ Secondary outcomes: intervention improved infant macrosomia, respiratory distress syndrome and length of hospital stays post-birth, maternal dietary quality and PA levels during pregnancy. Differences in diet & PA not sustained at 4 months postpartum. ➢ No impact on other clinical outcomes associated with maternal high BMI, or GWG, dietary glycaemic load/ energy intake, or maternal or infant body composition. ➢ Nested trials: uptake of structured exercise intervention was poor, women preferred less supervision in PA. An educational DVD to deliver diet and lifestyle advice, alongside LIMIT intervention, achieved higher healthy eating scores in late pregnancy. ➢ Intervention found to be cost neutral, the cost of delivering it was estimated to offset the costs that would result from birthweight >4kg. ➢ Women's evaluations: Only half concerned about GWG and many unaware of the risks. Women valued advice but few felt it would make them change or had the confidence to implement advice.	➢ High participation decline may have introduced bias. ➢ Suffered from intervention non-compliance. ➢ Intervention delivered in pregnancy only. ➢ Intervention may have helped women feel more confident about their health and the health of their baby. ➢ Authors concluded intervention intensity may have been inadequate to support change but higher intensity would negatively impact compliance and have cost implications. ➢ No theoretical evaluation reported.

RCT	Setting	Participants	Intervention	Outcomes	Summary evaluation
UPBEAT (269, 277-283)	UK	1555 pregnant women with BMI ≥30 kg/m², recruited between 15 and 18 weeks gestation, aged 16 years or older, across eight antenatal clinics	➢ Diet & PA intervention aimed at encouraging lower glycaemic index (GI) and saturated fats diet, and increasing PA by walking, plus standard antenatal care. ➢ Diet and PA intervention: 1-to-1 session the 8 weekly group sessions with NHS health trainer. Participant received handbook, DVD, pedometer, and logbook. ➢ Theoretical design: Control and social cognitive theories. Health trainer employed goal setting, problem solving and relapse prevention BCTs. Women encouraged to self-monitor, seek social support and opportunities for social comparison. ➢ Comparison: received standard NHS antenatal care.	➢ Primary outcomes: incidences of GDM and LGA babies, no significant difference between the groups. ➢ Secondary outcomes: intervention led to reductions in maternal dietary glycaemic load, improved dietary quality (reduced intake of processed and snack foods), lower GWG and sum-of-skinfold thicknesses, and increased PA; during pregnancy. ➢ Sustained reduction in dietary glycaemic load and saturated fat intake at six months postpartum, but not in PA.	➢ First UK trial reporting comparison of intervention with NHS usual care. ➢ Differential effect of dietary intervention for ethnic minorities, who were more resistant to change. ➢ Intervention delivered in pregnancy only. ➢ The usefulness of the theoretical design has not been clearly evaluated or reported.

RCT	Setting	Participants	Intervention	Outcomes	Summary evaluation
ROLO (284-290)	Ireland	800 pregnant second time mothers at risk of delivering a baby with macrosomia (history of baby born >4kg), recruited in early pregnancy, within one maternity hospital. Mean BMI was 26.8 kg/m^2.	➢ Diet intervention aimed at improving maternal glucose control to reduce incidences of infant macrosomia, plus standard antenatal care. ➢ Diet intervention: initial 2-hour small group session with dietician at 12-16 weeks gestation, plus written materials and two further dietician sessions during pregnancy. Advice on general healthy diet and specifically on how to follow a low GI diet in pregnancy. ➢ Comparison: received standard care which did not include any formal dietary or GWG advice.	➢ Primary outcome: infant birthweight, birthweight centile or ponderal index, no significant differences between the groups (recurrence of foetal macrosomia in intervention group was 50.7%, compared with 51.5% in control). ➢ Secondary outcomes: intervention slowed GWG in later pregnancy (>28 weeks) and increased GWG within IOM guidelines. Higher glucose intolerance during pregnancy in the control group. No difference between groups in maternal insulin resistance at 28 weeks gestation, but intervention reduced overall change in insulin concentrations. No other differences in maternal or foetal metabolic markers or foetal growth. Intervention improved GI dietary intake including lower energy, higher fibre and higher protein intakes. Lower GI diet was maintained at three months postpartum, but there was no difference in maternal BMI between the groups at two years postpartum.	➢ Relatively low intensity intervention which would be easy to implement. ➢ High proportion of women (80%) reported intervention compliance 'some' or 'most' of the time. ➢ Intervention did not include a PA component. ➢ Intervention delivered in pregnancy only. ➢ No theoretical design or behavioural components reported.

RCT	Setting	Participants	Intervention	Outcomes	Summary evaluation
LiP (291, 292)	Denmark	360 pregnant women with BMI 30-45 kg/m^2, recruited between 10 and 14 weeks gestation, aged 18-40 years, across two maternity hospitals	➢ Diet & PA intervention aimed at reducing GWG and improving obstetric outcomes, plus standard antenatal care. ➢ Diet intervention- advice consistent with Danish dietary standards. Dietary counselling delivered by dieticians at four time points during pregnancy. Individualised energy requirement goals set. ➢ PA intervention: advice to increase PA to 30-60 minutes daily. Pedometer, six-month gym membership, a weekly training session with a physiotherapist, and group coaching, used to support PA goal. ➢ Comparison: standard antenatal care plus study information and access to website providing diet and PA advice.	➢ Primary outcomes: GWG, pre-eclampsia, hypertension, GDM, caesarean section, macrosomia/ LGA, and infant admission to neonatal intensive care. Intervention reduced GWG and GWG exceeding the IOM guidelines. No significant differences in other maternal or neonatal outcomes between groups. Higher mean infant birthweight in intervention group. ➢ Secondary outcomes: intervention increased dietary quality and leisure time PA during pregnancy, but differences were not sustained at six months postpartum. Those with GWG within IOM recommendations had lower rate of weight retention and better diet at six months postpartum. Weight retention was negatively associated with breastfeeding for six months or longer. Breastfeeding initiation rates were comparable between the groups.	➢ Intervention delivered in pregnancy only. ➢ Results were interpreted with caution due to issues with study power. ➢ Poor compliance to PA sessions (50%) due to pregnancy related ailments and time commitments. ➢ Improvements in diet shown in both groups compared with trends in the wider Danish population of pregnant women with obesity. 20% of participants in the control group reported improving diet as a result of taking part. ➢ No theoretical design or behavioural components reported.

RCT	Setting	Participants	Intervention	Outcomes	Summary evaluation
TOP (293, 294)	Denmark	425 pregnant women with BMI ≥30 kg/m², recruited before 16 weeks gestation, within one maternity hospital.	➢ Diet and PA, or PA only, interventions aimed at reducing GWG and pregnancy and delivery complications, plus standard antenatal care. ➢ Diet intervention: individualised advice based on a hypocaloric Mediterranean-style diet, and problem-solving, delivered by a dietician every two weeks by telephone and outpatient visits. ➢ PA intervention: advice to increase PA by walking, using step count targets and pedometer. Reminders of advice given, but no feedback on performance. ➢ Comparison: standard antenatal care included a 1-to-1 meeting with a dietician who provided recommendations for healthy diet in pregnancy.	➢ Primary outcome: GWG, both interventions reduced GWG compared with control. No difference in effect on GWG between interventions. ➢ Secondary outcomes: interventions supported GWG within IOM guidelines, diet and PA intervention indicated a reduction in emergency caesarean sections. No other differences between the groups in clinical outcomes. ➢ Diet intervention modestly improved diet quality, compared with control group, including increased protein and polyunsaturated fatty acids intakes, and decreases sugars and saturated fats intakes. Added sugar influential on GWG. Women who consumed more sweets (e.g. chocolates, jellies) and artificially sweetened beverages in early pregnancy, were more likely to have higher GWG.	➢ Stratified randomisation by parity ensured a balance of nulliparous/ multiparous women across groups. ➢ PA as a standalone intervention could be effective in reducing GWG in women with obesity. ➢ Diet intervention was poorly reported so unable to determine what this involved. ➢ Intervention delivered in pregnancy only. ➢ No theoretical design reported, although used problem solving, goal setting and prompting self-monitoring. ➢ A reduction in non-nutritive foods may help reduce excessive GWG.

RCT	Setting	Participants	Intervention	Outcomes	Summary evaluation
Healthy Moms (295, 296)	US	114 pregnant women with BMI ≥30 kg/m², recruited between early pregnancy and 21 weeks gestation, across eight obstetrics and gynaecology clinics within one health maintenance organisation.	➢ Diet & PA intervention aimed at achieving GWG within 3% of baseline weight, plus standard care. ➢ Diet intervention: individualised plan and energy requirements. ➢ PA intervention: advice to increase PA by walking and using step count targets and pedometer. ➢ Delivered by dietician in two 1-to-1 sessions followed by weekly group sessions until birth. Groups discussed diet, PA, behaviour change. ➢ Theoretical design: no one theory. BCTs included goal setting, action planning, develop sources of reinforcement and social support, self-monitoring, problem solving, and performance feedback. ➢ Comparison: standard antenatal care including one session with dietician to discuss a healthy diet.	➢ Primary outcome: GWG, significant difference between groups in mean weight change (-2.6 kg intervention vs. +1.2 kg control). ➢ Secondary outcomes: intervention increased rate of GWG within IOM guidelines and reduced risk of delivering LGA baby, compared with control. No other differences were found in maternal and neonatal clinical outcomes between groups.	➢ GWG was measured at 2 weeks postpartum, accounting for weight related to products of pregnancy. ➢ High intensity intervention based on effective weekly group-based interventions in non-pregnant populations to improve lifestyle. ➢ Intervention delivered in pregnancy only. ➢ Conducted in a health maintenance organisation which requires membership, suggests a potential selection bias towards a more affluent population.

Although many of these trials were robustly designed, there have continued to be methodological limitations. There have been issues with non-attendance and drop out from interventions, which is common for interventions targeting weight loss (variation of 10-80% in attrition).(265, 297) The need for greater application of psychological theory in interventions to address behaviour change has been established,(216) and some of these trials have designed their interventions based on such theory. However, others have not included a theoretical foundation. Moreover, there has been limited evaluation of the usefulness of different theories and BCTs for behaviour change in pregnancy, and poor reporting of the BCTs employed or of how barriers to behaviour change were addressed or context considered, in interventions. There is variability in the approaches taken to changing dietary and PA behaviours in pregnancy and the health professionals who were involved in delivering these interventions. These factors may have impacted the success of these interventions but the variability in methodologies across trials makes it difficult to evaluate what a successful intervention should entail and who should be involved in delivering such an intervention. The outcomes assessed across studies are fairly heterogeneous with some trials aiming to reduce GWG and others aiming to improve neonatal outcomes, such as birthweight. Therefore, these trials were powered to detect an effect on different outcomes, which limits comparison across the studies and our ability to draw conclusions for practice. Clinically important outcomes are not always included in RCTs of lifestyle interventions in pregnancy.(298, 299)

Due to the lack of power to detect an effect on secondary clinical outcomes in these trials, the International Weight Management in Pregnancy (i-WIP) collaborative group, conducted an individual participant data meta-analysis (IPDMA) from 36 RCTs (n=12,526 women) of diet and lifestyle interventions in pregnancy, aimed at reducing GWG and improving maternal and neonatal outcomes.(74) Using IPDMA to increase power to explore effectiveness of interventions on these outcomes found that interventions were successful in reducing GWG (mean difference −0.70 kg, 95% CI −0.92 to −0.48 kg, I^2=14.1%; 33 studies, 9,320 women), and reducing the odds of caesarean section (odds ratio (OR) 0.91, 95% CI 0.83 to 0.99, I2=0%; 32 studies, 11,410 women) compared with receiving standard care.(300) However, in terms of clinical significance, this small difference in GWG was not associated with an improvement in pregnancy complications, and no significant interventions effects on any other pregnancy or birth outcomes were found.(300)

Several of the interventions, described in Table 1, resulted in some maintained maternal behavioural changes postpartum, but the impact on maternal outcomes beyond pregnancy has thus far been limited. However, there is a paucity of evidence on maternal outcomes

beyond 12 months postpartum, with only one study evaluating maternal outcomes at two years postpartum.(290) Furthermore, the included interventions were delivered during pregnancy only. To affect long-term health for women and their families, it may be that women need more support beyond pregnancy to achieve this. This may be important for this population, in light of the evidenced trends towards postpartum weight retention and further weight gain in those who enter pregnancy with a high BMI, as highlighted in Chapter 1.

2.4.4 Lifestyle interventions postpartum to reduce pregnancy weight retention and long-term maternal outcomes associated with maternal obesity and GWG

Failure to lose weight gained in pregnancy can be detrimental to long-term weight and health.(70, 301) Women may have a desire to lose weight in the postpartum period,(206) but changes in lifestyle due to having a baby can increase barriers for mothers in managing their weight.(78) There is evidence to suggest that PA and diet interventions delivered postpartum have a moderate but positive influence on maternal weight.(67, 257, 262, 302, 303) A Cochrane review of diet and/ or PA interventions delivered to women postpartum (recruited up to 24 months after birth), and using meta-analysis to pool the data from 12 trials (n= 910), found a reduction in weight in favour of the diet, and combined diet and PA, interventions; but not in PA only trials.(67) Similarly, a meta-analysis of 32 RCTs (n= 1,892) concluded that interventions combining diet and PA to reduce weight in the postpartum period were more successful.(257) However, a meta-analysis of PA or PA plus diet interventions for women who are overweight or obese showed a reduction in weight as a result of all interventions delivered postpartum.(262) These studies supported the notion that lifestyle interventions in the postpartum period could be effective in improving postpartum weight retention and, in doing so, women's long-term health. In addition, women themselves have highlighted a need for weight management support during this time.(257)

2.4.5 Lifestyle interventions in pregnancy and postpartum, to improve outcomes associated with maternal obesity

The hypothesis that pregnancy may be a 'window of opportunity' for behaviour change, and the evidence to support the effectiveness of postpartum interventions to improve weight outcomes, suggests that an intervention which combined these approaches may be effective in improving short and long-term outcomes associated with maternal obesity. The HELP study, described below, was a unique RCT that examined the effectiveness of a lifestyle intervention starting in pregnancy and continuing into the postpartum period, for pregnant women with obesity. The evaluation of the HELP intervention conducted, thus far, will be

described. No other adequately powered RCTs could be identified that had evaluated an intervention with all of these design components. However, two pilot studies and an evaluation of a care pathway delivered in 17 primary care trusts in England, have shown that this type of intervention may have the potential to positively influence postpartum weight and early infant feeding.(193, 304, 305)

2.5 The Healthy Eating and Lifestyle in Pregnancy (HELP) Study

2.5.1 The HELP cluster randomised controlled trial

This section describes the Healthy Eating and Lifestyle in Pregnancy (HELP) cluster RCT on which this thesis is based. Following on from a successful feasibility study of the HELP intervention (306) and interviews with patient representatives to inform the intervention design, a definitive pragmatic cluster RCT was conducted to examine the effectiveness and cost effectiveness of the HELP intervention, which aimed to improve the health and lifestyles of pregnant women with obesity, in order to improve maternal and child outcomes for these women, in comparison with usual NHS maternity care. The trial design will be summarised here but a detailed protocol is reported elsewhere (Appendix B).(170) A PICO was generated to describe the population, intervention, comparator and outcomes for the HELP cluster RCT (Table 2).

Table 2: PICO table for the HELP cluster RCT

Table **Population**	**Intervention**	**Comparison**	**Outcomes**
Pregnant women with obesity (BMI ≥30 kg/m^2) attending 20 maternity units in England and Wales. Pregnant women aged 18 years or over. Pregnant women between 12 and 20 weeks gestation. Pregnant women with sufficient understanding of the English language.	A weekly 1.5 hours weight management group from the time of recruitment to the study, in early pregnancy, up to six weeks postpartum. Weight management advice focused on healthy eating and physical activity behaviour change, appropriate for a pregnant population, delivered by Slimming world consultants and NHS midwives, in a group setting with other pregnant women.	Standard NHS maternity care.	Reduce women's BMI at 12 months postpartum. Improve secondary health outcomes for mothers and babies, including dietary intake, physical activity and psychological wellbeing Improve secondary clinical outcomes for mothers and babies, decrease obesity-related risks in pregnancy and birth. Reduce NHS costs.

Women were recruited through antenatal care services across England and Wales, with maternity unit used as the unit of clustering to randomise sites to the intervention or control group. Women recruited in control clusters received usual antenatal care (based on the guidelines described in section 2.2) along with two leaflets providing general advice on diet and PA in pregnancy. Women recruited within intervention clusters, in addition to usual care and these leaflets, were invited to attend a weekly 1.5-hour weight management group from the time of recruitment (between 12 and 20 weeks gestation) up to six weeks after giving birth. The intervention midwives also contacted the women by telephone at three and six months postpartum, to enhance long-term support. The weekly groups were held in the antenatal clinic and were facilitated by a Slimming World (SW) consultant and an NHS midwife. The role of the SW consultant was to provide expertise on dietary advice, and guidance on following the SW 'Food Optimising' system, which focused on achieving dietary quality based on the Eatwell guide.(307) NHS midwives were to provide PA and clinical advice to the women, and to monitor their wellbeing. The PA component of the intervention was the introduction of a walking programme to encourage women to gradually increase their PA during pregnancy and beyond. Pedometers were distributed for monitoring step counts, and individualised step count goals were set and reviewed with the intervention midwife, who also gave advice on other appropriate PA in pregnancy. The group sessions covered weight monitoring, weekly topics selected by the facilitators or participants, group discussions and exchange of ideas, and problem solving. The key difference in the design of the HELP intervention, compared with other trials of lifestyle interventions for maternal obesity, was that the intervention started in pregnancy and continued to six weeks postpartum.

2.5.2 Theoretical approach

The design of the HELP intervention was informed by aspects of Control Theory and Social Cognitive Theory. The mechanisms by which the HELP intervention was intended to improve short and long term maternal and child outcomes is mapped out in the logic model (Figure 1). The theoretical mechanisms of change underpinning the intervention were self-regulation, intrinsic motivation, self-efficacy and social support. BCTs used were in line with these theories and included information provision on consequences of behaviours, goal setting and review of behavioural goals, relapse prevention, prompting self-monitoring of weight, diet and PA behaviours, and planning coping strategies. The group setting was to facilitate social support, social comparison, and normative information and approval from others, and to empower women to lead the group content and problem solve for each other; to improve self-efficacy.

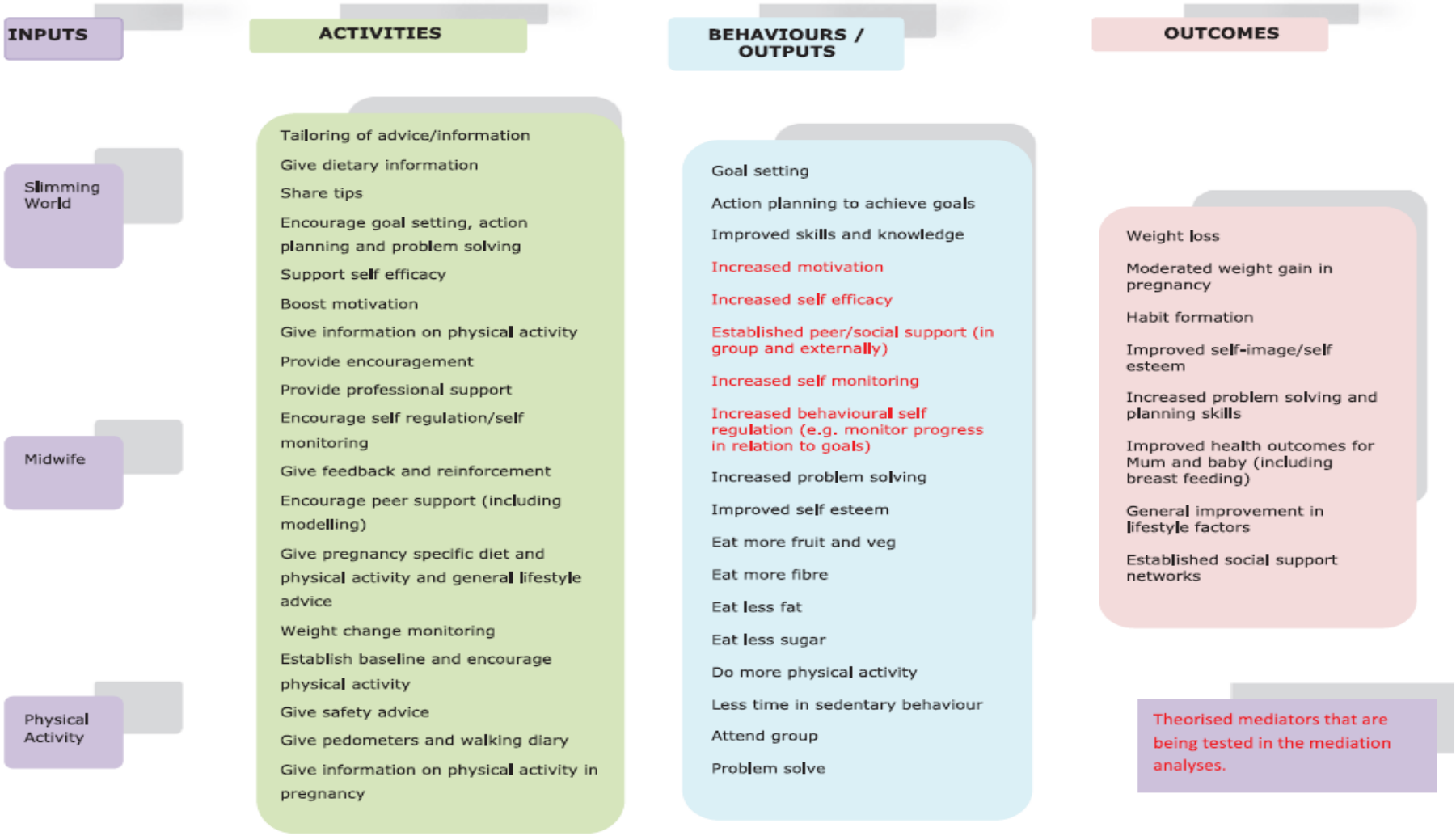

Figure 1: HELP intervention logic model mapping the theory of the intervention

The HELP intervention aimed to utilise this key time when women were accessing maternity services to offer this group of women a more individualised approach to their care. The group sessions aimed to increase their knowledge of the risks associated with excessive GWG. It aimed to support them in a group environment and, with the help of experts, to equip them with the skills to bring about long-term behaviour changes. In turn, this would allow them to make healthier choices for themselves and those around them, including their unborn child. Not only did the intervention aim to help women avoid excessive GWG and have a healthier pregnancy with fewer complications, it was also intended to extend into the postpartum period to help support women to maintain their weight management and healthy lifestyles, and to prevent postpartum weight retention.

2.5.3 Outcomes up to 12 months postpartum

A total of 20 maternity units were recruited and randomised, ten each to the intervention and control groups. Across the sites, 598 women aged 18 years or over, with a BMI of ≥ 30 (kg/m^2) and between 12 and 20 weeks gestation were recruited. A CONSORT diagram providing the flow of participants through stages of this trial is presented in Chapter 4 (Figure 2).

Outcomes were measured at 36 weeks gestation, birth, 6 weeks postpartum, 6 months postpartum and 12 months postpartum. The primary outcome was the effectiveness of the HELP intervention in reducing women's BMI at 12 months following birth. Secondary outcomes included diet, PA, GWG, quality of life, mental health, pregnancy and birth outcomes, social support, self-regulation, motivation and self-efficacy. A cost effectiveness analysis was conducted as the intervention aimed to reduce health service costs within this population. A process evaluation utilising mixed methods was also carried out alongside the trial to evaluate implementation and fidelity of intervention delivery and adherence, contamination and to explore participants' views.(237) Results of the evaluations of this intervention, thus far, will be summarised here. A full report of these study results will be reported elsewhere (Simpson et *al,* in draft).

There was a slight difference in BMI at 12 months postpartum in favour of the intervention group (adjusted percentage difference: 0.02, 95% CI -0.01 to 0.04; ICC= 0.044; p=0.17), but this 2% difference in log transformed values was not statistically significant. However, women in the intervention group had significantly lower GWG (adjusted percentage difference: 0.01, 95% CI 0 to 0.20; ICC= 0; p= 0.04) (1% difference between groups in BMI change at 36 weeks gestation from baseline) compared with women in the control group,

and were more likely to gain weight within IOM guidelines. Improvements in diet quality in the intervention group were indicated at 12 months postpartum and these women were more likely to be attending a commercial weight loss group at follow-up. There were no other differences in outcomes between the groups. The embedded process evaluation suggested that the intervention was generally delivered with good fidelity, although delivery of the PA component was variable and had low participant compliance. Attendance at the groups was comparable with similar trials; almost half of the women (49%) attended between 26% and 100% of all available sessions and almost a quarter (23%) never attended any sessions. This varied considerably across centres (6%-48%). Also, a high number of women withdrew from the study due to non-attendance at intervention sessions.

Interviews with participants, and focus groups with midwives, suggested that the intervention provided a positive referral option for these women to support pregnancy weight management. The women valued the social support received by intervention facilitators and other women in the groups. Some of the women said they would have valued more support postpartum, and the follow-up support telephone calls were perceived as of limited value. Women often reported making positive behaviour changes for themselves and their families as a result of the intervention.

2.6 Interim summary

From the review of the evidence so far, it has been determined that there is a need to establish effective interventions to improve outcomes associated with maternal obesity in pregnancy. However, the evidence base is limited and studies that have been conducted suffer from methodological shortcomings. Studies testing lifestyle interventions during pregnancy, for women with a high BMI, have shown that these interventions can be effective in reducing GWG, and improving diet quality and increasing PA in pregnancy.(269, 288) However, there have been limited improvements in clinical pregnancy and birth outcomes.(300) The evidence of a lack of an impact on clinical outcomes is an important addition to our knowledge, as these moderate changes in GWG may not be enough to impact on clinical outcomes associated with maternal obesity. However, there is some evidence to suggest that dietary behaviour changes made in pregnancy can be maintained beyond pregnancy.(283) More evidence is needed on the effectiveness of lifestyle interventions in pregnancy and postpartum, on maternal weight gain and health outcomes further into the postpartum period.

2.7 Prevention of childhood obesity

2.7.1 Prevention of childhood obesity from the start of life

Most intervention efforts targeting childhood obesity are aimed at children aged six to 12 years, and there is strong evidence to support beneficial effects of these programmes on child BMI.(308) However, due to the high volume of children already showing overweight at school entry,(93) there is a need for 'solution oriented' rather than 'problem oriented' efforts, to prevent the development of child obesity.(99, 117, 309) Early growth patterns provide the only period in which there is clear evidence to support the concept of a critical period of development associated with long-term consequences.(7, 310) The 'first 1,000 days' public health campaign reiterates this message, and emphasises the importance of the period between conception and birth as the most influential in terms of children's future development and health.(311-313) Experts recommend that prevention initiatives for childhood obesity should focus on parents as the agents of change, given their influence on children's access to healthy foods and PA opportunities, and the impact of parental beliefs, attitudes, perceptions and behaviours on the development of child weight.(91, 131, 309, 314-317)

Mothers have a major influence on the weight status of their children through their influence on the intrauterine and early years environments, as discussed in Chapter 1. It was hypothesised that an intervention, such as the HELP intervention and those described in Table 1, which aimed to help women manage their weight during pregnancy and lose weight postpartum, could be effective in improving short and long-term outcomes for their children. By improving maternal weight and health behaviours in pregnancy, this may reduce the impact of maternal obesity and GWG on infant birthweight and developmental programming. It might also be hypothesised that through educating and motivating women to have a healthier lifestyle, this may impact on the environment they provide for their children.(7)

Encouraging behavioural change in parents has been found to promote positive role modelling of healthier eating and increased PA leading to weight reduction in both parents and children.(316, 318) However, currently there is a paucity of interventions for pregnant women with follow-up during early life, which aim to address the risk factors of childhood obesity.(313, 319) This is considered to be a priority for future research.(319) Two RCTs in Australia have shown the effectiveness of interventions delivered to mothers during pregnancy and early postpartum, and targeting maternal and family behavioural determinants of childhood obesity in the early infant environment, to encourage mothers to

make healthier choices for their children from the start of life. This led to improvements in child BMI, parental feeding and child screen time behaviours at age two years.(320, 321) However, these trials were only aimed at improving obesity related outcomes for the children, and were conducted in a general population of mothers, rather than a population with obesity. A combined approach which aims to both treat maternal obesity and promote positive parental role modelling for the prevention of childhood obesity, if effective, would be a useful investment of resources.(7)

With reference to Table 1, some of the presented trials have conducted assessments of the effectiveness of these interventions on long-term child outcomes. These evaluations are discussed below.

2.7.2 Lifestyle interventions during pregnancy to improve long-term child outcomes associated with maternal obesity

The ROLO study examined the effectiveness of an antenatal low GI diet intervention aimed at improving maternal glucose control, to reduce incidences of infant macrosomia. The impact of the intervention on child adiposity has been measured at several time points. The intervention led to a reduction in infant thigh circumference measurements shortly after birth, but not in any other measures of body composition, or skinfold measurements in a subset of the sample.(285, 322) Further, this early difference in neonatal thigh circumference, between groups, was not maintained at six months postpartum; and there were no other differences in child body composition or infant feeding measured at this time point.(323) However, they found associations between mother's trimester-specific nutrient intakes in pregnancy and later child adiposity, indicating a potential impact of improved maternal diet quality during pregnancy on later child outcomes.(290, 323) Furthermore, maternal BMI at two years postpartum was positively associated with child BMI-for-age *z*-scores at two years.(290) Importantly, this suggested that interventions successful in improving maternal BMI may be opportunities for impacting on childhood obesity.

The UPBEAT trial evaluated the effectiveness of a theory based antenatal diet and PA intervention, aimed at encouraging lower GI and saturated fats diet, and walking, on child adiposity and early feeding behaviours at six months postpartum.(283) Of the 1,555 women recruited to the trial at baseline, 698 children provided measurements for the primary outcome of skinfold thickness. The intervention indicated slightly lower mean subscapular skinfold thickness (5% difference) in comparison with usual NHS care, which may have been mediated by healthier GWG.(283) Although breastfeeding initiation rates were similar

between the groups, there was a significant interaction between the intervention and the reduction in skinfold thickness in terms of duration of breastfeeding beyond 3 months. No other differences were found in child body composition or behaviours between the intervention and control groups.(283)

The LiPO study, a follow-up of children in the LiP trial of an antenatal diet and PA intervention aimed at reducing GWG, assessed whether the observed reduction in maternal GWG had an influence on the anthropometrics and body composition of the offspring at 2.5-3 years, compared with the control group. They also looked at how the trial sample compared with a reference group of children born to mothers of healthy BMI.(324, 325) A total of 157 children of mothers from the LiP trial and 97 reference control children, were included in the study. They found no differences in children's anthropometric and body composition measurements, or breastfeeding outcomes, between the randomised groups. Similarly, there were no differences between children of mothers who participated in the trial and those who were born to mothers of healthy BMI in the reference group.

The Healthy Moms trial assessed the effectiveness of an antenatal diet and PA intervention aimed at achieving GWG within 3% of baseline weight, on child anthropometric and body fat measurements at one year postpartum.(326) There were no differences between the groups in terms of change in measurements from birth, apart from an indication that weight-for-age *z*-scores were slightly lower in children of mothers in the intervention group.(326)

2.7.3 Interim summary

The findings of the effectiveness of maternal lifestyle interventions in pregnancy on long-term child outcomes are mixed. Some studies have shown positive effects of interventions on child outcomes beyond the early postpartum period,(283) whereas others have not.(325, 326) There has been a notable loss to follow-up in some of these studies, especially where invasive anthropometric measurements have been used. More studies powered to examine child outcomes are required.

The trials of interventions described above, which have conducted follow-up of child outcomes beyond birth, were delivered in pregnancy only. Given the many maternal and family determinants of childhood obesity that can be present in the early years environment, it may be that a maternal lifestyle intervention delivered in pregnancy and into the postpartum period, might be more likely to have an impact on long-term child outcomes associated with maternal obesity. The current evaluations of intervention effectiveness on

maternal determinants of obesity within the home environment are limited to breastfeeding and weaning patterns up to six months postpartum, and do not provide information beyond this on child diet and PA behaviours, or the home environment.

Horan and colleagues (2016), authors of the ROLO trial, showed an association between maternal BMI and child BMI-for-age *z*-scores at two years postpartum, independent of maternal BMI in early pregnancy and GWG. This suggests environmental factors may be important. However, the available evidence is unable to identify whether a maternal lifestyle intervention to improve outcomes associated with maternal obesity, might influence the environmental factors related to childhood obesity, beyond early infant feeding and weaning. Additionally, given the many determinants of childhood obesity and the importance of maternal and family influences, there is currently a lack of research into the perspectives of mothers in relation to their experiences of a lifestyle intervention in pregnancy and the postpartum period, and its potential impact on their child, or their food and PA environment.

2.8 Conclusions and research questions

2.8.1 Conclusions and study rationale

There are gaps in our current knowledge of the impact of lifestyle interventions delivered during pregnancy and into the postpartum period, on maternal and child outcomes beyond 12 months postpartum. Improvements in GWG and maternal diet have been found in pregnancy and in the early postpartum period, but we are currently unsure if these differences could translate into improved outcomes for the mother and child in the longer term.

There are many barriers to behaviour change in pregnancy and postpartum, and beliefs about the consequences and importance of behaviours are likely to play a key role in adopting new behaviours.(7) Interventions based on psychological theory are more likely to be effective in tackling these barriers and changing behaviours.(216) Women's views about weight management before, during and after pregnancy, and the identification of barriers and facilitators of behaviour change from women's perspectives has helped inform the design of interventions. However, the available evidence does not provide clarity on the importance of context or the usefulness of psychological theory underpinning behaviour change interventions in pregnancy for reducing the impact of maternal obesity on maternal and child outcomes. Only a few studies have reported the perspectives of women with

obesity, experiencing weight management specific interventions or care pathways.(232, 327-329) Although women have generally reported these experiences as positive, there continues to be a lack of understanding as to what specific intervention strategies may be effective in this group. Further consideration of the perspectives of the women to which the theory is applied is needed.(235, 254)

The complex nature of childhood obesity development makes it difficult to establish to what extent prenatal and postnatal conditions contribute to obesity, and whether the conditions provided in the intrauterine environment can influence postpartum factors. Given the ever increasing rates of childhood obesity, prevention from the start of life is suggested as the only feasible solution to this crisis.(98) More evidence of the impact of maternal lifestyle interventions in pregnancy, for reducing the risks associated with maternal obesity on longer term child outcomes is warranted. In particular, we do not currently know if interventions delivered to mothers in pregnancy and postpartum, can impact the extent to which their preschool children's home environments are obesity-promoting.

Mothers' beliefs and attitudes about weight and health behaviours are likely to have an influence on their children's behaviours. To better understand the potential of lifestyle interventions during pregnancy and into the postpartum period to improve child health outcomes, an understanding of mothers' experiences, perceptions and practices in relation to their children's weight and health behaviours, in the context of having taken part in such an intervention, is required.

A life-course approach for the treatment and prevention of obesity and its associated conditions is recommended.(7, 330) Lifestyle interventions for pregnant women, if well designed and theory based, are hypothesised to be a potential way of positively influencing maternal weight and health behaviours, as well as improving the foetal and early years environments for the child. In turn, this could be a cost-effective way of helping to simultaneously treat maternal obesity and prevent childhood obesity. It is likely the hypothesis that pregnancy may be a good time period to intervene is still valid. However, there is a need to continue to work with women during pregnancy and the postpartum, to provide a better picture of the key barriers, facilitators and drivers of behaviour at this time, and the impact of interventions on maternal and infant outcomes. Experts have called for RCTs, with adequate sample size and controlling for confounders, that are designed to modify GWG and include follow-up of children. These studies would evidence whether intensive public health efforts to control excessive GWG are warranted, by producing measurable long-term positive outcomes for mothers and babies.(62)

The HELP trial involved a unique theory-based intervention that started in pregnancy and continued beyond birth, and women were followed up to 12 months postpartum. A further follow-up of women recruited to the HELP trial, and their children, provided an opportunity to address some of the knowledge gaps that were identified by this review of the literature. Conducting a follow-up of the HELP cohort could establish whether an intervention delivered in pregnancy and continuing into the postpartum period could potentially be effective in improving maternal and child outcomes beyond 12 months postpartum. By examining later child outcomes related to the HELP intervention, further insights into the role of obesity "programming" in pregnancy and tracking of the development of obesity could be provided. Furthermore, the impact of the intervention on the food and activity environment for the child in early childhood could be examined. The unique experiences of the cohort of women in the HELP trial, provided an opportunity to explore their views of weight management in pregnancy and postpartum, and of their experiences of the HELP intervention. This could address the need to further identify the barriers, facilitators and drivers of behaviours both during pregnancy, but crucially beyond pregnancy. It would also allow an exploration of these women's attitudes surrounding their child's weight development and health behaviours in childhood, in the context of having taken part in a lifestyle intervention aimed at improving their own weight and health behaviours in pregnancy and after birth. By exploring the experiences of the women who took part in the HELP trial, we might better understand the importance of contextual factors in short-term and long-term maternal and child outcomes related to maternal obesity, and in the success of this intervention. This could enhance our understanding of the theoretical basis of the intervention. Taken together these findings may help inform future steps for tackling weight management behaviours in pregnancy and postpartum, both from a policy perspective and in supporting women to make informed choices and improving interventions for maternal obesity going forward.(235)

The present study conducted a follow-up of women, and their children, who had taken part in the HELP trial at 24 months postpartum. This time point was selected as it allowed longer term changes in maternal BMI postpartum to be established. At the same time, 24 months represents the end of the critical first 1,000 days for child development.(312) A follow-up of children at this time point would allow the potential of the HELP intervention to impact on determinants of childhood obesity in early childhood to be examined. Furthermore, a follow-up of the HELP cohort at 24 months postpartum made comparison of study findings with other similar trials possible.(290, 325)

2.8.2 Research questions

Based on the research which has been presented in this Chapter, this thesis aims to address the following questions:

- Can a theory-based intervention delivered to women with obesity during pregnancy and postpartum, with the aim of improving diet and lifestyle, be effective in reducing their BMI and improving other secondary maternal outcomes, 24 months after birth?

- Can a theory-based intervention delivered to women with obesity during pregnancy and postpartum, with the aim of improving diet and lifestyle, have an impact on their child's BMI and other secondary child outcomes, 24 months after birth?

- For women who participated in the HELP trial, what are their experiences, attitudes and beliefs surrounding issues related to their weight, 24 months after birth?

- For women who participated in the HELP trial, what are their experiences, attitudes and beliefs surrounding their child's weight and health behaviours, 24 months after birth?

2.8.3 Research hypothesis

In section 2.5 of this Chapter, the mechanisms by which the HELP intervention was hypothesised to improve maternal and child outcomes were outlined (see logic model in Figure 1). It was suggested that the HELP intervention would improve women's motivation, social support, self-efficacy and self-regulation to adopt healthier behaviours, including improved dietary quality and physical activity. Improving these behaviours would lead to a reduction in weight gain during pregnancy, long term weight and the formation of healthier habits. In turn, based on the literature indicating an influence of maternal weight, and dietary and activity behaviours, on the same characteristics and behaviours in their children, it was hypothesised that, if successful, the HELP intervention could lead to better weight and health outcomes for the offspring. Therefore the hypothesis of the present study is that:

- The HELP intervention will lead to a reduction in women's BMI at 24 months postpartum and, as a result, will reduce children's BMI-for-age *z*-scores at age 24 months; in comparison with mothers and children in the control group.

Based on this research hypothesis, maternal and child outcomes are correlated in that it is suggested that improvements in maternal weight-related outcomes and lifestyle will lead to healthier environments for the children during pregnancy and the early years, leading to better child weight and health-related outcomes at age 24 months. The methodological impact of maternal and child outcomes being correlated will be considered further in the discussion of study sample size in Chapter 3 (section 3.6.2).

2.9 A mixed methods thesis

This thesis will use a mixed methods approach, that is one which uses multiple ways to explore a research problem by seeking to combine quantitative and qualitative research methods.(331) The use of this approach follows the perspective that all forms of scientific inquiry have their own strengths, weaknesses, limitations and biases, and adopting one particular method narrows the conclusions that can be drawn from that study.(332) By interlacing quantitative and qualitative methods, each method will provide different, but complementary, strengths and weaknesses; enabling us to ask and answer different kinds of questions that the use of one method cannot.(331)

The strengths of positivistic experimental research, using quantitative methods, have long been central to the notion of evidence based medicine.(331) Systematic and controlled experimental conditions are used to understand human behaviours, making it possible to make useful and rigorously founded inferences about the phenomena of study. In doing so, causal pathways and knowledge, independent of the observer, can be obtained. Here, the focus of the methods is on reliable measurement and reduction of error to ensure validity, reliability and generalisability of the study findings.(333) However, the conclusions that can be drawn from using these methods are dependent on the data conforming to the assumptions of those methods.(332) Furthermore, it is argued that *"mind cannot be uncoupled from matter"* (332) and that the confounds that are disregarded in quantitative research, may be the very factors that might explain human behaviours. Solely taking an objective line of inquiry ignores the rich contextual influences within the phenomena of study.

Qualitative methods, on the other hand, aim to identify and incorporate these contextual influences to address the everyday realities of human experiences and behaviours. A qualitative stance aims to embed the study of human behaviour and action within individuals' historical, societal and cultural contexts, which embraces the subjectivity and agency of research participants and the diversity of responses.(332) It examines the patterned ways

that we have come to think about and act in our life worlds, to provide a real world context to the phenomena of investigation.(332) This adds contextual validity to the study and establishes whether important factors have been considered in the theoretical model of the phenomena.(332) However, it too is subject to bias as it is more subjective, the findings will be influenced by the process itself, and causality cannot be truly established or generalised.(333)

It is for this reason that a mixed methods approach is recommended in the development and evaluation of complex interventions.(237) The two methodologies capture different aspects of the same phenomena. Combining these findings, may provide a fuller and more informative picture of human behaviour, which will be more rounded, nuanced, and valid than that produced by a single method.(334) This enhances the ability to draw useful and valid conclusions than when using either of these methods alone.(331-334)

The aim of this thesis was to answer the research questions relating to the effectiveness of the HELP intervention in improving maternal and child outcomes and to advance understanding of the contextual factors that might influence or explain these outcomes, to inform our current theoretical model. These questions neither sit wholly within a quantitative paradigm, nor a qualitative paradigm. Rather, a mixed methods pragmatic stance, which focuses on the research questions to be answered, and allows the selection of methods that might be most appropriate to providing different types of knowledge, was considered a closer fit with the purpose of this study.(331, 332)

In this thesis, a two-phase, sequential explanatory mixed methods approach was adopted to answer the research questions.(331) This mixed methods approach is characterised by two distinct phases of study, the first involving quantitative methods and the second using qualitative methods. As recommended in triangulation protocols, each phase of study was reported separately followed by data integration.(335, 336) The first phase of study used quantitative methods to address the question of effectiveness of the HELP intervention, compared with usual care, on maternal and child outcomes. This provided a deductive approach to test the existing hypotheses outlined in this Chapter, that a lifestyle intervention delivered in pregnancy and postpartum, might have a beneficial impact on long-term maternal and child outcomes associated with maternal obesity. The methods and results were reported as a distinct phase (Chapters 3 and 4).

This was followed by a second phase of study, informed by the first, which used qualitative interviews to seek relevant information that may lend interpretation or explanation to the observed maternal and child outcomes.(331) An inductive approach was employed, to capture the subjective experiences of the women, who were the subjects of study in the first phase, in order to better understand the contextual factors that were influential on the quantitative results. Again, the methods and results were written as a distinct phase (Chapters 5 and 6). Within both of these phases, attempts were made to achieve rigour and validation appropriate to that methodological approach, ensuring data quality throughout the study.

The mixing of methods was completed in the discussion and interpretation of the study, to address the research questions (Chapter 7). The findings of the quantitative and qualitative phases, were brought together using triangulation protocols,(335, 336) to interpret how the qualitative findings might help to extend or elaborate the quantitative results. The assumption in the application of mixed methods, was that these two research methods may be simultaneously capable of providing valuable findings in relation to the same research questions, and employing different intellectual tools would allow different perspectives to be generated.(334) This might further inform the existing theory, and future interventions.

This thesis builds on the previous work carried out as part of the HELP trial by a team of researchers in Cardiff University (CU).

3 Quantitative phase: methods

3.1 Introduction

A follow-up study of the cohort recruited to the HELP trial was conducted, to assess the effectiveness of the HELP intervention,(170) on maternal and child outcomes at 24 months postpartum. This Chapter describes the methods that were used in order to answer the following research questions:

Can a theory-based intervention delivered to women with obesity during pregnancy and postpartum, with the aim of improving diet and lifestyle:

- be effective in reducing their BMI and improving other secondary maternal outcomes, 24 months after birth?
- have an impact on their child's BMI and other secondary child outcomes, 24 months after birth?

Outcomes up to 12 months postpartum in the HELP trial have been summarised in Chapter 2 (section 2.5.3). The HELP 24 months postpartum study (HELP 24m study) extended the data previously collected, by examining the same outcomes at 24 months postpartum, in addition to collecting additional outcomes of interest to the research questions. This Chapter will describe the rationale for the chosen outcomes for the HELP 24m study, and the methods for assessing and analysing these outcomes.

3.2 Study design

3.2.1 The HELP trial and HELP 24m study

HELP trial

Randomised controlled trials (RCTs) are quantitative, controlled experiments which assess the effects of one or more interventions. A sample of the population of interest is selected, individuals are randomly assigned to one of the comparative groups, then followed up for a specified period of time.(337) Within a hierarchy of evidence quality, the RCT is considered to be able to provide the most reliable evidence on the 'true effect' of health interventions,

because by using appropriate processes, such as randomisation, during the conduct of an RCT, the risk of confounding factors influencing the results can be minimised.(337)

Increasingly in healthcare settings the cluster RCT design is used, where groups of patients rather than individuals are randomised to comparative study groups.(338) The HELP study was a prospective cluster RCT, where maternity units (clusters), were randomly allocated to the intervention or control groups. Allocation concealment from the trial team and maternity units, until after maternity unit recruitment was complete, was used to help prevent the participation of clusters being influenced by group assignment. Pregnant women with obesity were subsequently recruited within these randomised clusters. The cluster RCT design was selected as it provided protection against contamination across trial groups within maternity units, avoiding confounding of the intervention effect through midwife care or participant to participant. The HELP trial used appropriate methods to achieve rigour in the study design, such as publishing a protocol paper which contained detailed reporting of trial methods, randomisation, allocation concealment, appropriate sample size powered to detect a minimally clinically important intervention effect, ITT analysis, and comparison of intervention groups on pre-specified clinically relevant study outcomes (Appendix B).(170) Due to the nature of the intervention, blinding of allocation was not possible, which may have increased the risk of differential treatment of trial groups or assessments of outcomes.

The MRC guidance on evaluating complex interventions recommends re-contacting study participants as a highly informative way to assess long-term outcomes from the original study, and to determine maintenance of any short-term changes.(237)

HELP 24m study

The HELP 24m study was a follow-up to the HELP trial with the aim of answering the research questions relating to long-term effectiveness of such the intervention. The follow-up time point was selected as there was a paucity of evidence on post-intervention outcomes for mothers and children beyond 12 months postpartum, and the aim was to understand the importance of the early child environment and health behaviours from the start of life, on weight trajectories for the child. The methods presented in this Chapter aim to demonstrate how rigour was intended to be retained within the HELP 24m study design.

3.2.2 Ethical approval and sponsorship

Participants in the HELP trial had only consented to participate in the study up to 12 months postpartum. Further approval was sought from the Health and Care Research Wales

(HCRW) NHS Research Ethics Committee (REC) 3, to conduct a follow-up of these women at 24 months postpartum. As the management of the follow-up study differed to the trial management (i.e. PhD student), it had to be submitted for ethical approval as a new study.

The HELP 24m study was conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. Ethical approval was granted by the HCRW NHS REC 3 (Reference Number 13/WA/0017) on 27th February 2013. Two substantial amendments were submitted throughout the study (these are outlined in Appendix C). Cardiff University (CU) agreed to act as sponsor for the study, as required by the UK Research Governance Framework for Health and Social Care.(339)

3.2.3 Recruitment of local researchers to conduct data collection

Women eligible to take part in the study were located in 20 geographical areas within England and Wales, according to the location of maternity units in the HELP trial. Where possible, local researchers at sites were recruited to manage approach, consent and follow-up of women within these areas. The study aimed to recruit the local researchers who had supported data collection for the HELP trial, as continuity of researcher may encourage participants to take part and enable easier contact (340).

In England, previous local researchers were asked if they would be interested in conducting data collection at 24 months postpartum. Where these researchers declined to be involved, a different local researcher was sought by contacting the previous Principal investigator or the Head of Midwifery services.

In Wales, Health and Care Research Wales (HCRW) provide support in the delivery of research studies. The study was adopted on to the HCRW research portfolio, as per the process used for data collection in the Welsh sites in the HELP trial, and HCRW research officers were recruited to assist in data collection in the five Welsh study sites.

Where an appropriate local researcher could not be recruited, the student conducted the consent and collection of follow-up data from participants in these areas, assisted by Centre for Trials Research (CTR) administration staff who made initial contact with eligible women, invited them to take part and arranged home visits for the student to complete. For all sites, appropriate approvals were set up as described below.

3.2.4 NHS and regulatory approvals

The HELP 24m study did not involve recruitment of NHS patients. However, where NHS staff intended to support approach, consent and follow-up of women, Research & Development (R&D) approvals were required from their health trust of employment, to agree responsibility for the work that was being undertaken on behalf of the study.

In England, the relevant R&D departments were contacted and the process for obtaining approvals in that health trust followed. Principal Investigators were identified locally to take responsibility for the study at sites, this was usually the local researcher who had agreed to support consent and data collection. Individual study agreements were drafted between the health trusts and the study sponsor, outlining responsibilities of each party and financial arrangements for follow-up data collection. The health trust was offered a payment of £45 for each participant follow-up successfully completed.

In Wales, global approvals through the NISCHR Permissions Co-ordinating Process (PCU) (now the HCRW permissions service) were sought. The aim of this service was to streamline the process of NHS permissions across Wales. Health trusts involved in the HELP trial were also contacted for local approvals.

The identification of local researchers and the process of obtaining R&D approvals, if appropriate, was prioritised according to the dates by which individuals, within clusters, reached the 24 months postpartum time point.

3.3 Participants

The HELP 24m study aimed to follow-up women who participated in the HELP trial, and their children born during participation in this trial, at 24 months postpartum. A total of 598 women were recruited to the HELP trial; 63 of these women had withdrawn by 12 months postpartum and were not eligible to be approached for follow-up. The study aimed to recruit and follow-up the remaining 535 (Intervention: 259, Control: 276) eligible women. Details on the flow of participants in the HELP trial introduced in this section, are provided in Chapter 4 (section 4.2)

Women had not consented to take part beyond 12 months postpartum in the HELP trial. Additionally, the HELP 24m study was considered a new study by the ethics committee rather than an amendment to the HELP trial protocol, therefore contact details could not be

obtained for these women. To enable women to be recruited to the HELP 24m study, the following two stage process was used:

1) During the HELP trial women were asked to provide written agreement to be contacted about any future research related to the trial.
2) At 24 months postpartum, women who had provided this written agreement were approached and asked to consent to participate in the HELP 24m study.

3.3.1 Participant retention during the HELP trial

The work described here is documented in the HELP trial protocol, but it was an essential step in the set-up of the HELP 24m study and is therefore detailed.

Prior to completion of the HELP trial, and in anticipation of the start of the HELP 24m study, an amendment was made to the trial protocol to add a process for asking women to provide written agreement for retention of their contact details and future contact regarding related research studies, by the trial team. It was made clear to women that they were not agreeing to take part in any studies but only to receive communications regarding such studies. A database of participant contact details, held on CU servers, was created to support participant retention.(340, 341)

Women were either invited to provide this written agreement by the local researchers during the 12 months postpartum follow-up appointment, or they were subsequently contacted by the trial team. Maximum efforts were made to obtain written agreement from all 535 participants enrolled at 12 months postpartum, in order to reduce loss to follow-up and the chance of systematic differences in participants or lack of statistical power in the HELP 24m study. These efforts are described below.

Retention strategies were employed and adapted by the trial team on a participant by participant basis. That is, where one method failed, a decision was made on how to proceed for that individual, rather than a general approach which would have led to repeated failed contacts.(342) HELP trial participants who had not yet agreed to, nor declined the retention of their contact details, were approached initially via telephone if contact details were available, as this was expected to be a more effective method of contact in comparison to postal communication,(343) in addition to a more timely method given the immediate result of contact attempts. If participants agreed to retention of their contact details, a form to capture written agreement and updated details was posted, and women were asked to

return this completed form in an enclosed prepaid envelope. For those that were not contactable by telephone, an invitation letter was posted to them along with the form. Where one method of contact was unsuccessful, the trial team attempted to use any other available details, which may have included post to home address, landline and mobile calls, SMS, email, or contact to a designated person (usually a relative) as provided by the participant at recruitment. A minimum of three attempts was made to each available contact method, on different days, and at different times of day. Where a contact detail was invalid and could not be used, it was not attempted again. Where the participant had agreed to provide their details via telephone but had not returned their form, they were contacted again, by telephone and post as appropriate, and given the opportunity to agree or decline. If no valid contact details appeared to be available for a participant, CTR administrators attempted to use publicly available registers, for example the electoral roll, to obtain contact details.

A database of contact attempts and outcomes was retained and continuously reviewed by the trial team, and a case by case decision was made as to when to cease contact attempts. The aim was to allow as many participants as possible the opportunity to be involved in future studies and to increase the value of such research, but to ensure that harassment of participants did not occur. During contacts it was made clear to women that they were under no obligation to provide agreement and could decline at any time, in which case no further contact attempts were made. Efforts to obtain agreement to retain details were prioritised by the date women reached the 24 months postpartum time point, and by sites where lower levels of agreement had been obtained, to try to reduce any imbalance between trial groups or clusters in any future study. The student assisted in participant retention efforts in the HELP trial. Results of these efforts are outlined in Chapter 4 (section 4.2.2).

3.3.2 Inclusion criteria for the HELP 24m quantitative phase

Women, and their children, were invited to take part in this study if they:

- had participated in the HELP trial, without withdrawal, inclusive of those that undertook both intervention and control group conditions;
- had provided written agreement to be contacted regarding future research.

3.3.3 Exclusion criteria for the HELP 24m quantitative phase

The study did not seek to exclude women on any other criteria. There were potential scenarios that would require amendment of these exclusion conditions. If a child had been taken into care, follow-up data for the mother would be collected, but no child outcomes

would be assessed. If the mother had died, no attempt would be made to collect data for the child. In the case of child death, women would be given the option to participate, and only maternal outcomes would be assessed. If a woman consented to take part but preferred for her child not to; or if the child was not available or unwilling to take part, then only maternal outcomes and parent-reported child outcomes would be assessed, other child measures were recorded as missing.

3.3.4 Recruitment procedure and informed consent

The local researcher was contacted via email by the student, three weeks before an individual meeting the inclusion criteria (section 3.3.2) reached the 24 months postpartum time point. The local researcher was asked to make contact with the woman via telephone, email or post, to invite her to take part in the HELP 24m follow-up. On initial contact, the local researcher provided a brief description of the study, and for those women interested in taking part, an appointment was made for follow-up at a time and place convenient to them, usually their home. An appointment letter (Appendix D) and participant information sheet (Appendix E), was then posted to the woman.

Women to be recruited by the student were contacted by CTR administration staff via telephone and provided with information about the study. For those women who agreed to take part, appointments were arranged for the student to conduct visits, and the same information was then posted to these women. The day before arranged appointments, the student made contact with women by SMS or telephone, to confirm arrangements.

During visits, women were given time to read the information sheet and to ask questions. Women were reminded during all contacts and visits that they were free to decline their own or their child's participation and retained the right to withdraw consent for participation in any aspect of the study without their care, or the care of their child, being affected. If a woman agreed to her and her child taking part, she was asked to provide written consent (Appendix F). The local researcher, or student, then proceeded to collect the follow-up data. A screening log (Appendix G) was retained to record details of women who declined to take part in the study, and at what stage they declined.

Every effort was made to reduce loss to follow-up in order to avoid bias in the sample recruited to the study. Women could choose a convenient setting for the visit which aimed to improve response rates.(341) They were also given a £10 voucher as a thank you for taking part and to encourage participant retention.(344) Steps followed during recruitment aimed to

ensure that all eligible women were invited to take part, and these steps are described below.

Attempts to contact eligible women were made using any valid method available. If local researchers had not had successful contact with an individual five days before their 24 months postpartum date was reached, they were to inform the student. CTR administrators then attempted to contact the individual using any available details, which may have included post to home address, landline and mobile calls, SMS, email, or contact to a designated person. A minimum of three attempts was made to each available contact method on different days and at different times of day, provided the method of contact appeared to be valid. A database of contact attempts and outcomes was retained and continuously reviewed, to manage efforts but also to monitor loss to follow-up and to record the associated reasons. If CTR administrators successfully contacted an individual and they were willing to take part, a visit from the student was arranged, or it was referred back to the local researcher to arrange an appointment, as appropriate.

3.4 Study outcomes

The previous work completed by the HELP trial team, and the evidence presented in Chapters 1 and 2, informed the selection of study outcomes associated with maternal and child obesity, which were hypothesised to be impacted by the HELP intervention. To provide long-term outcomes at 24 months postpartum for women who took part in the HELP trial, maternal outcomes collected at 12 months postpartum in the HELP trial were repeated. A novel part of this study was the opportunity to assess the impact of the intervention on their children.

3.4.1 Primary outcomes

The primary outcomes of the HELP 24m study were:

- Maternal BMI;
- Child BMI-for-age *z*-score.

3.4.2 Secondary outcomes

The secondary maternal outcomes of this study, all at 24 months postpartum, were:

- Maternal body composition: weight (kg), waist and hip circumferences and waist-hip ratio (centimetres (cms));
- Diet;
- PA;
- Alcohol;
- Smoking;
- Mental health;
- Health related quality of life (HRQoL);
- Social support;
- Motivation;
- Self-regulation;
- Self-efficacy;
- Self-monitoring;
- Weight control;
- Breastfeeding (also a child outcome);
- Subsequent pregnancies: delivery and breastfeeding.

The secondary child outcomes of this study, all at 24 months of age, were:

- Weight (kg);
- Diet;
- PA;
- Sedentary behaviours;
- Family environment: mealtimes, activities, maternal feeding practices;
- Childcare.

3.5 Materials

3.5.1 Measures used to assess outcomes

Table 3 summarises the study outcomes and how they were measured, including detail on when measures were repeated and adopted from the HELP trial materials. To examine outcomes of interest related to the research questions, not previously measured in the HELP trial (mainly child outcomes), previously published scales were used, when available. Other

questions were generated through discussion with experts or adopted from similar studies, to make study findings comparable.

In Table 3, ‘BL’’ (baseline), ‘36w’, ‘Birth’, ‘6w’, ‘6m’ and ‘12m’ indicate time points of data collection in the HELP trial. Where data was used from these time points, the data was collected and prepared by the HELP trial team. Where data was collected at these time points and repeated at ’24m’ (indicating the time point of the HELP 24m study), the measures used to assess these outcomes were chosen by the HELP trial team, unless otherwise stated. Where measures were only collected at the ‘24m’ time point, this indicates outcomes and measures that were selected and added by the student.

3.5.2 Assessment of maternal and child outcomes

A description of the measures used to assess maternal and child outcomes, and relevant information on scoring of outcomes and missing data, is available in Appendix H. The outcome measures selected for use in the HELP trial were based on measuring outcomes that were hypothesised to be impacted by the HELP intervention, as mapped out in the study logic model presented in Chapter 2, Figure 1. These included weight, dietary quality, physical activity, and breastfeeding behaviours, as well as psychological factors such as self-efficacy and self-regulation. Validated scales were selected where possible, provided they were applicable for a pregnant population. To allow a long term evaluation of the impact of the HELP intervention, the same outcomes previously assessed in the HELP trial were selected for the present study, along with the adoption of the same method of assessment, so that change over time could be explored. Further details on the selected measures, their strengths and limitations, and the rationale for using them, is available in Appendix H.

Based on the literature presented in Chapter 1 evidencing the influence of maternal weight and dietary and activity behaviours, on the same factors in their children, appropriate outcome measures to assess child outcomes related to maternal obesity had to be identified. The selection of outcome measures focused on the key determinants of childhood obesity that can be influenced by mothers during pregnancy and the early years: food and feeding practices, physical activity and sedentary behaviours. Young children are unlikely to have the cognitive maturity to be able to accurately report their behaviours.(345) It was, therefore, necessary for measures to either be researcher administered or reported by the mother. A further challenge in assessing child outcomes was that measures were added to a large body of maternal measures, and were to be completed during one appointment, so needed to be minimally burdensome to complete, and could not be measured over time. They also

needed to be applicable to the age group of children (i.e. 24 months). The selection of measures to assess outcomes has been described in Appendix H, including strengths and weaknesses of the chosen tools, and rationale for their use.

All measures were participant/parent self-report measures, apart from maternal and child body composition measurements, and the 7-day PAR scale, which were researcher administered.

Table 3: Measurement of maternal and child variables and outcomes

Maternal variables	Measure	HELP trial[a]	HELP 24m study[a]
Demographics: age, parity, ethnicity, marital status, education, weight loss history, SES.	Study specific questions NS-SEC (346) for SES	BL	BL
Weight (kg)	Study specific questions	BL, 36w, 6w, 6m, 12m	BL, 36w, 24m
Height (m)	Study specific questions	BL	BL
Waist and hip circumference (cm)	Study specific questions	12m	24m
Diet	Dietary Instrument for Nutrition Education (DINE) (347) (plus, questions on fruit and vegetables, sugar consumption)	BL, 36w, 6w, 6m, 12m	24m
PA	7 day Physical Activity Recall (7-day PAR) (348, 349)	BL, 36w, 6w, 6m, 12m	24m
Alcohol	Alcohol Use Disorders Identification Test (AUDIT-C) (350)	BL, 36w, 6w, 6m, 12m	24m
Smoking	Study specific questions	BL, 36w, 6w, 6m, 12m	BL, 24m
Mental health	General Health Questionnaire (GHQ) 12 (351)	BL, 36w, 6w, 6m, 12m	BL, 24m
HRQoL	EQ-5D (including visual analogue scale) (352)	BL, 36w, 6w, 6m, 12m	24m
Social support	Social Support for Eating (SSEH) scale Social Support for Exercise (SSEX) scale (353)	BL, 36w, 6m, 12m	24m
Motivation for diet and PA	Treatment Self-Regulation for Diet/ Exercise (TSRD/ TSRE) (354)	BL, 36w, 6m, 12m	24m
Self-regulation	Shortened Self-Regulation Questionnaire (SRQ) (355, 356)	BL, 36w, 6m, 12m	24m
Self-efficacy	Weight Efficacy Lifestyle Scale (WEL) (357) Multidimensional Self Efficacy for Exercise Scale (MSES) (358, 359)	BL, 36w, 6m, 12m	24m
Self-monitoring: monitoring weight and diet	Study specific questions	BL, 36w, 6w, 6m, 12m	24m
Weight control: importance and confidence	Study specific questions	BL, 36w, 6w, 6m, 12m	24m

Maternal variables	Measure	HELP trial[a]	HELP 24m study[a]
Weight control activities undertaken	Study specific questions (24m included types of activities)	BL, 36w, 6w, 6m, 12m	24m
Breastfeeding: initiation and duration	Study specific questions	6w, 6m, 12m	24m
Subsequent pregnancies: pregnant, had another baby, delivery and breastfeeding for other baby	Study specific questions		24m
Child variables	**Measure**	**HELP trial[a]**	**HELP 24m study[a]**
Demographics: delivery method, gestation (weeks), Apgar scores, sex and date of birth	Study specific questions	Birth	Birth
Breastfeeding (as above)	Study specific questions	6w, 6m, 12m	24m
Child weight (g)	Study specific questions	Birth, 6w, 6m, 12m	Birth
Child weight (kg)	Study specific questions		24m
Length (cm)	Study specific questions		24m
Diet	Eating and Physical Activity Questionnaire (EPAQ) (360)		24m
PA and sedentary behaviours	EPAQ (360)		24m
Family environment: mealtimes and activities	Adopted from UPBEAT trial resources (361)		24m
Maternal feeding practices	Child Feeding Questionnaire (CFQ) (143) Parental covert & overt control over snacks and meals scale (153) Comprehensive Feeding Practices Questionnaire (CFPQ) (362)		24m
Childcare	Adopted from UPBEAT trial resources (361)		24m

a BL= baseline; 36w= 36 weeks gestation; Birth= birth information provided by midwives from medical records of birth; 6w= 6 weeks postpartum; 6m= 6 months postpartum; 12m= 12 months postpartum; 24m= 24 months postpartum

3.5.3 Development of data collection tools

All measures were recorded using paper-based methods. A case report form (CRF) and questionnaire (Appendix I) were developed, amending previous forms developed by the HELP trial team. Data collected in the questionnaire was completed by participants, with exception of the 7-day PAR measure,(348) which was completed by the researcher along with data collected in the CRF. To assess ease of completion or problems with forms for the added questions, completion of these sections was piloted with five members of CTR staff who had young children. Feedback was obtained and minor changes were made to forms, where appropriate, such as inserting instructions on how many responses to select.

3.5.4 Data collection procedures

It was required for researchers taking informed consent to be trained in Good Clinical Practice (GCP). Local researchers were trained in study specific procedures by the student. Prior to a start recruitment letter (Appendix J) being sent to sites, the student arranged a telephone training session with the local researcher. Copies of the data collection forms were emailed, in advance, and local researchers were asked to make themselves familiar with the forms. An electronic presentation was developed and used during the training session to discuss data collection procedures, in particular, instructions on taking maternal and child body composition measurements, and avoidance of common mistakes in form completion; to increase data quality. Local researchers were supported throughout data collection by the student, by email or telephone.

3.5.5 Ethical considerations during data collection

Women were asked to provide contact details for their GP or health visitor, if applicable, so that any concerns for participant wellbeing raised during home visits, could be passed to a person responsible for that individual's care, as those conducting follow-ups were not qualified to deal with such issues. If any safeguarding issues arose, related to suspected abuse or threat to participants' or researcher's safety during the course of data collection, those conducting follow-ups were to follow their local procedures for lone working and reporting abuse.

3.6 Randomisation and study power

3.6.1 Randomisation

Allocation was established in the HELP trial based on maternity units (clusters), 10 units were randomised to each of the intervention and control groups. The randomisation was balanced by antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix (% non-white) (described in Appendix B).(170)

3.6.2 Study power and sample sizes

The statistical power is the ability of the study to detect a true difference in outcome between the groups, when such a difference exists. Power depends on type I error (alpha or significance level), the magnitude of the effect of interest in the population (or the minimal clinically important difference), and the size of the sample.(337) Power calculations were conducted to estimate the power that could be achieved for the two primary outcomes, given a reduced sample for the HELP 24m study. Alpha, the probability of accepting a difference between groups when no difference truly exists (reject a true null hypothesis), is set at 5% and although there are two primary outcomes, they are for different populations so no adjustment of alpha is required.

Maternal BMI

A total of 535 (intervention: 257, control: 278) women from 20 maternity units (average 30 women per unit) were available for the HELP 24m study. The fixed sample size was determined by the number of women who had:

- been recruited and included at baseline in the HELP trial;
- not withdrawn from the HELP trial;
- provided written agreement to be contacted.

The HELP trial was powered to examine a moderate effect size of 0.333 using a 0.02 intracluster correlation coefficient (ICC) based on 20 maternity units and 20 women per unit (Appendix B).(170) Reliable estimates of intra-class correlation are required when using clustered randomisation to take into account the setting level variables.(363) The clustering of outcome from the HELP trial was greater than anticipated (ICC= 0.044). Given these numbers, Table 4 shows the effect size detectable given 80% and 90% power (alpha 5%). Given the increase in ICC, it was not possible to detect a small effect size of 0.3 as in the HELP trial (Table 4 row 1). Increasing the effect size to 0.5 (medium effect) to detect a

difference of 2.6 kg/m^2 between the two groups would require 128 women in total for the HELP 24m study. Inflating for clustering and 30% attrition would require 243 women in total (121 per group), which is a conservative response rate of 45% (243/535) (Table 4 row 2). For 90% power, 378 women are required, equivalent to a response rate of 71%.

Table 4: Sample size based on HELP trial data for differing effect sizes and power (5% alpha)

	Power	Control group[a]	Effect size	Difference (intervention) in BMI kg/m^2	Sample size: n per group (total N)		
					Individual RCT	Cluster[b]	+ 30% attrition
1.	80%	36.05 (5.2)	0.333	1.7 (34.32)	n=143 /group (N=286)	Not attainable	-
2.	80%	36.05 (5.2)	0.5	2.6 (33.45)	n=64 /group (N=128)	n=85 /group (N=170)	n=121 /group (N=243)
3.	90%	36.05 (5.2)	0.5	2.6 (33.45)	n=86 /group (N=172)	n=132 /group (N=265)	n=189 /group (N=378)

a based on mean (sd) BMI kg/m^2 outcome at 12 months postpartum from HELP trial
b ICC 0.044 (based on 20 sites and <30 women)

Based on other studies with longer term follow-up it was hoped that drop out would not exceed 30%,(364, 365) but the necessity to obtain written agreement to contact HELP trial participants made it likely that it would be higher, which would reduce the ability to detect an effect. Every effort was made to follow-up all eligible women.

Child BMI-for-age z-scores

No clear guidance regarding a minimum clinically important difference in child BMI-for-age *z*-scores, that should be expected in intervention studies aimed at preventing childhood obesity, could be identified. The National Institute for Health and Care Excellence (NICE) guidelines suggest that lifestyle weight management treatment programmes for children should expect BMI z-score differences of 0.2.(366) Other UK research has previously reported and addressed this issue when designing an intervention programme aimed at reducing infant obesity.(367) Based on discussions with NICE, clinical experts, and a study in which a reduction of 0.25 BMI z-score had led to improved metabolic markers in adolescents, the authors determined that this would be a clinically meaningful reduction for

obesity prevention when considering outcomes at 24 months. This guidance was applied in the HELP 24m study.

The sample size for the child primary outcome is limited to the number of women who consented to take part in the HELP 24m study. Based on 80% power, alpha 5%, the same ICC as for the maternal outcome, a mean (sd) BMI-for-age *z*-score of 0.75 (0.98) at 24 months in the control group,(320, 367) and a clinically meaningful reduction for obesity prevention of 0.25,(367) a sample size of 243 per group would be required, without clustering. This is not achievable in this fixed sample (Table 5 row 1). Basing it on 243 children similar to the maternal outcome, we could detect a medium effect size of 0.5 which translates into a difference of 0.5 in BMI-for-age *z*-score between the groups (Table 5 row 2).

Table 5: Sample size based on HELP trial data for differing effect sizes and power (5% alpha)

	Power	Control group[a]	Effect size	Difference (intervention) in BMI kg/m^2	Sample size: n per group (total N)		
					Individual RCT	Cluster[b]	+ 30% attrition
1.	80%	0.75 (0.98)	0.26	0.25 (0.50)	n=243 /group (N=486)	Not attainable	-
2.	80%	0.75 (0.98)	0.50	0.50 (0.25)	n=64 /group (N=128)	n=85 /group (N=170)	n=121 /group (N=243)

a based on mean (sd) BMI-for-age *z*-score outcome at 24 months from Daniels et al
b ICC 0.044 (based on 20 sites and <30 women)

3.7 Data management

Data management followed appropriate CTR policies and standard operating procedures.

3.7.1 Data handling

Completed follow-up CRFs and questionnaires, along with the consent form, were posted to CU, by the local researcher and using two separate prepaid envelopes. Copies of the forms were retained at site. All paper-based data was stored in locked cupboards in CU, and all electronic data stored in networked folders on the CU secure password protected computer system.

A Structured Query Language (SQL) database (368) for the secure storage of research data, was developed. This system retains an audit trail of actions to ensure high data quality and integrity. A CTR programmer developed the database to meet the needs of the study, as guided by the student. Metadata were produced to define the data to be collected. The student tested database functions using 'dummy' data, to identify and resolve any inaccuracies with data entry, output and export. When complete, this was signed off by the programmer and primary research supervisor.

3.7.2 Data cleaning

CTR administrators recorded receipt of the completed data collection forms on the study database, then they were manually checked by the student to assess completion. Most of the data was participant self-reported, so it was not possible to check data queries. For primary outcome measurements and researcher completed data, queries were sent as soon as possible to local researchers to check missing responses or inaccuracies (e.g. unclear handwriting), and responses amended where applicable. Remaining missing responses were accepted as missing and excluded (with exception of the DINE measure, described in Appendix H). Where a participant had provided two responses for a single response question, the response for this variable was coded as missing during data entry. Patterns of duplicate responses for individual questionnaire items were examined. Due to the low number of missing responses, and the balance of these between groups, low risk of bias in these errors was concluded and no sensitivity analyses was warranted. Any further data cleaning was conducted in Statistical Package for the Social Sciences (SPSS) software v23.0.(369) Records of data cleaning were retained throughout, using manual paper based data log forms and version controlled datafiles in SPSS.

3.7.3 Data entry and quality control (QC)

Manual entry of data, into the SQL database, was carried out by CTR administrators, who were trained by the student. A single entry method was used as double data entry is not found to substantially enhance data quality,(370) and the robust design of the database only allowed appropriately formatted responses to be entered. Any issues during data entry were recorded by study administrators on paper-based forms, and later reviewed by the student to address during data cleaning in SPSS.

A 10% random quality control (QC) of data entry was completed by the student. The acceptable error rate was set at 1% per form, with error rates exceeding this to be discussed with the research supervisors. However, this did not occur and the minimal errors identified were corrected. The remaining data entry was accepted as accurate and the database locked. Data were exported from SQL as .csv files, then imported into SPSS (369) which was used to support statistical analysis as described below.

3.7.4 Definitions and calculations

Further details on the definitions and calculations of the outcome measures used, are available in Appendix H.

- Maternal BMI was calculated from weight (kg) at 24 months postpartum and HELP trial baseline height (m) (kg/m²). BMI values were categorised according to WHO thresholds.(5)
- Waist-hip ratio was calculated from waist and hip circumference measurements at 24 months postpartum (waist in cm/ hip in cm). Waist-hip ratios were categorised according to WHO thresholds.(371)
- Timing of follow-up/ age of child (days) was calculated using child date of birth and date of follow-up completion.
- Child weight (kg) and length (cm) at 24 months postpartum, was used to calculate: BMI-for-age *z*-scores using the WHO Anthro v.3.2.2 and macros program;(372) and UK90 percentiles,(373) using a calculator tool on the NHS website.(374) Percentiles were categorised according to thresholds to indicate normality of growth expressed as 'underweight' (<2nd percentile), 'healthy weight' (≥2nd to ≤84th percentiles), 'overweight' (≥85th to ≤94th percentiles)', and 'very overweight' (≥95th percentile).(98). For BMI-for-age *z*-scores, the WHO software (372) accounted and adjusted for measurement by recumbent length for children aged ≥ 731 days. For percentiles, 0.70 cm was taken off length measurements for children aged ≥ 731 days at follow-up, to correct for the use of recumbent length instead of standing height.(375)
- The following scales were scored: AUDIT-C (350), GHQ-12 (351, 376), 7-day PAR (348, 349), DINE (347), EQ-5D VAS (352), SSEH (353), SSEX (353), WEL (357), MSES (358, 359), SRQ (355, 356), TRSE (354), TSRD (354), EPAQ (360), CFQ (143), parental covert and overt control (153), and, CFPQ (362).

3.8 Statistical analyses

3.8.1 Descriptive analyses

Recruitment and retention

To allow transparency with regards to study rigour and address any potential bias, guidance on Consolidated Standards of Reporting Trials (CONSORT) and cluster RCTs were followed.(377, 378) Flow and retention of participants in the HELP trial was described, to support the sample size calculation for the HELP 24m study, and to make participation through these studies clearer to the reader. Numbers on patient eligibility, recruitment, responders and non-responders were collated for both trial groups and added to the CONSORT flow diagram.

Responders versus non-responders

Cluster and local researcher recruitment were described, and summary statistics on cluster level variables were tabulated, to examine the effect of site drop-out on the balance of factors following randomisation. To examine attrition bias, a comparison was made between demographic details (as measured at trial entry in the HELP trial) of responders and non-responders. Descriptive summaries, such as mean (SD) and N (%), were produced to show cluster level balance of demographic details (at baseline) by responders and non-responders to examine cluster level and group differences in drop-out. Adherence to the intervention was compared between responders and non-responders (intervention group only), to assess any bias in attrition based on compliance, and to describe the intervention receipt of the recruited population. Attendance at intervention group sessions was described as: a percentage of total possible sessions, which differed by participant dependent on the date they were recruited to the HELP trial and the date their child was delivered; and, proportions of individuals who received ‘dose’ of the intervention which was attending seven or more sessions, as determined by the HELP trial team as a meaningful threshold for intervention compliance.

Study sample characteristics

Descriptive summaries (as above) of the recruited populations (mothers and children) by trial group, taken from HELP trial baseline and birth, demographic and clinical data, were tabulated. These summaries were used to check comparability between study groups and generalisability of the study population. Timing of follow-up/ age of child (days) in the HELP 24m study, were tabulated by trial group and cluster level.

Outcome measures

Outcome measure scores were summarised and tabulated for the study groups using descriptive statistics as mentioned before. The distributions of all continuous outcome measures were checked prior to analysis, and any outlier values were checked for data entry error and authenticity. Graphical illustrations (boxplots, histograms and bar charts) were used, where appropriate. Tests of normality were conducted to support the interpretation of distributions and skewed data. Where continuous outcome data were skewed, medians (with 25^{th}-75^{th} quartiles) were reported, and transformations were used, where appropriate. Continuous outcomes were intended to be analysed using parametric statistical tests (as described below), as linear models which fit the data are likely to give the best estimate of intervention effect. However, using such a model on skewed data may give a misleading result. Transformations are commonly used to try to reduce the impact that skewness has on data, to make it fit the assumption of linearity better.(379) Where transformation was used, summary statistics were presented using the untransformed data for ease of interpretation. Where the normality of distribution, assessed by histogram, was ambiguous; the original data were analysed, then the log transformed data was used to check if this changed the residuals in the model. If it made no difference to the conclusion drawn by the results, then the original scale was retained. Where transformation did not reduce the impact of skewness on the distribution of a variable, a different method of analysis was used.

3.8.2 Statistical Method

All comparative main analyses were based on ITT (without imputation) and compared the outcome between the two trial groups (intervention vs. control). ITT analysis, that is including all participants allocated to either group together, regardless of whether or not they received the intended intervention or completed study follow-ups, was used in order to reduce bias in the analyses. This strategy introduces clinical reality by recognising real world dropout from health interventions.(337)

The aim of statistical modelling is to identify the main factors that explain variation in the outcome.(338) An implication of using a cluster RCT design is that participants recruited within one cluster cannot be considered to be independent, as people within particular settings may share certain characteristics, and observations of individuals within one cluster are more likely to be similar to each other, compared with variation across other clusters.(338, 380) This has consequences for the statistical power of the study accounted for by inflating the sample size. However, clustering also needs to be accounted for in the analyses of outcomes, by explaining the level of variation in outcome attributable to

clustering.(338) The method used to analyse the primary outcomes accounting for clustering was multilevel modelling; statistical models of parameters that vary at more than one level. This method allows for the clustered nature of the data, as well as individual effects; without which, standard errors are reduced and there is an increased chance of spuriously significant findings and misleading conclusions.(338)

All analyses involved two-level linear regression models, with mother or child as level 1 clustered within maternity unit (clusters) as level 2. Both levels were considered 'random effects' i.e. mother/child and units were drawn randomly from a larger population of women/children and maternity units. In additional, all models adjusted for cluster randomisation balancing factors (antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix (% non-white).

For continuous outcome variables, a linear regression model was fitted and results presented as a difference in adjusted means (intervention minus control). Where data was log transformed, the intervention effects reported were interpreted as the percentage difference between group means (intervention minus control).(381)

For binary outcomes a logistic model was used and results presented as odds ratios (ORs) and compared the odds of an event in the intervention compared with the control. For ordinal data, an ordinal model was used and results presented as relative risk ratios (RRRs). Multilevel logistic and ordinal regression models were analysed by research supervisor, RCJ, due to the student's software (SPSS) not being able to perform the analysis and access to appropriate software (Stata) being unavailable. However, the output from the logistic regression analyses was interpreted and presented by the student, along with the completion of all other analyses described in section 3.8.

For all outcomes, 95% CIs and p-values were presented. CIs, or margins of error, are important in examining the intervention effects in RCTs, as they reflect the extent to which the findings of effect in the study sample are likely to represent what would be found in the population. The 95% CIs of the estimate, is the range within which we are 95% certain that the true population treatment effect will lie.(337) Narrower CIs indicate a more precise estimate, and this will be influenced by the sample size. P-values, the probability that the results obtained were not due to chance alone, were accepted at the <0.05 level.(382)

ICCs were calculated using post-intervention data, and reported with adjustment and no adjustment for cluster randomisation balancing factors and covariates.(383) The ICC is a

statistical measure of the correlation or relatedness of clustered data.(383) It is a value representing the variance of individuals within clusters, compared with the variance of individuals between clusters, and ranges from 0 to 1, with increasing values indicating greater correlation of individuals within clusters.(380) This value is also related to the sample size, and greater clustering requires an increased sample size of clusters to detect a difference in outcomes,(380) which would not be possible in this study.

The influence of any outlier values on any of the analyses was checked. Any significant influence detected was reported and discussed with the lead statistician.

3.8.3 Primary outcomes

For maternal BMI, a two-level linear regression model adjusted for baseline BMI values as a covariate. Due to the skewed distribution of the maternal BMI data at baseline and follow-up, a log (natural) transformation was performed on the data for analysis.

For child BMI-for-age *z*-scores, the two-level linear regression model was adjusted for birthweight (g).

3.8.4 Secondary outcomes

Maternal outcomes

Continuous outcomes included waist circumference (cm); hip circumference (cm); waist-hip ratio (cm); diet (DINE) (347); fruit, vegetable and sugar intake; mental health score (GHQ-12) (351, 384); HRQoL (EQ-5D VAS); motivation for diet and exercise (TSRD & TSRE)(354); self-regulation for health (SRQ) (355, 356); weight self-efficacy (WEL) (357); exercise self-efficacy (MSES) (358, 359); and, breastfeeding duration (study child). Analysis of weight (kg) at 24 months postpartum was considered with baseline weight as a covariate to aid the clinical interpretation of the intervention effect.

Binary outcomes included waist-hip ratio risk; sweet consumption; alcohol consumption (AUDIT-C) (350); smoking status (at follow-up); psychological distress (GHQ-12) (351, 384); diet monitoring; frequency of self-weighing; importance and confidence to control weight; weight control strategies; and breastfeeding current and initiation.

PA (7-day PAR), HRQoL score (EQ-5D), and, social support for eating habits and exercise (SSEH & SSEX) (353); were originally continuous outcomes and intended to be analysed

using two-level linear regression models. However, due to skewed distributions, they were converted to binary variables (Appendix H) and analysed using two-level logistic regression models.

Child outcomes

Continuous outcomes included mean fruit and vegetable consumption (EPAQ)(360); number and duration of child activities; screen time behaviours (EPAQ)(360); maternal feeding practices (CFQ-five subscales)(143), parental covert and overt control (153) and CFPQ (362). Analysis of weight (kg) at age 24 months was considered, with birthweight as a covariate, to aid the clinical interpretation of the intervention effect.

Binary outcomes included consumption of foods and beverages (EPAQ)(360); mealtime environment (meals together and same foods); and family activities. Preference for spending free time (EPAQ)(360) and mealtime environment (television viewing) were categorical variables and were examined using a multinomial regression.

Two CFQ subscales, perceived parent and child weight,(143) were originally continuous outcomes and intended to be analysed using two-level linear regression models. However, due to skewed distributions, they were converted to binary variables (Appendix H) and analysed using two-level logistic regression models.

3.8.5 Secondary analyses of primary outcomes

Child BMI percentile was considered continuous and analysed used a two-level linear regression model. BMI was categorised using thresholds as described in Appendix H and analysed as a binary outcome.

3.8.6 Subgroup analyses

The impact of individual demographic factors on the intervention effect, using interaction terms included in the primary analysis models, was examined, by modelling interactions between:

Maternal BMI

Intervention uptake and the following pre-specified maternal baseline characteristics;

- Age (<25 / ≥ 25 years)

- Ethnicity (white/ non-white)
- Smoking status (smoker/ non-smoker)
- Previous weight loss history (yes/ no)
- Mental health (GHQ-12) (351) (psychological distress/ no distress)
- SES (346) (managerial and professional / intermediate, small employers, lower supervisory, technical, semi-routine and routine)
- Parity (nulliparous/ multiparous)

Child BMI-for-age *z*-scores

Intervention uptake and the following pre-specified child characteristics;

- Mode of delivery (vaginal and instrumental / caesarean section)
- Gestation at birth (<37/ ≥ 37 weeks)
- Feeding history (breastfed/ not breastfed)
- Breastfeeding length (<9 / ≥ 9 weeks).(385)

These analyses were essentially exploratory and were interpreted with caution. Effect sizes alongside 95% CIs and p-values were reported.

3.8.7 Sensitivity analyses or model testing

- The maternal primary outcome was adjusted for any baseline characteristics that were imbalanced by trial group: smoking, parity, ethnicity, SES, education.
- The maternal primary outcome was adjusted to take into account the timing of completion of follow-up. The child primary outcome already accounted for the age of the child at follow-up.
- The child primary outcome was adjusted to take into account the mother's GWG, calculated from baseline and 36 weeks gestation weight measurements in the HELP trial.
- A comparison was made between mothers who were pregnant at the time of follow-up or had had a baby in the year prior, by trial group, to assess the possible effect on maternal primary outcome. Numbers between groups were compared and a decision made about whether to include or exclude them in the primary outcome analysis.
- A comparison was made between children who attended childcare, by trial group, to assess the possible effect on the child primary outcome. Numbers between groups were compared and a decision made about whether to include or exclude them in the primary outcome analysis.

3.9 Software

Clinical data were managed using a SQL database (368). Child BMI calculations were performed using the WHO Anthro v.3.2.2 and macros program (372) and NHS online tool (374). Data analyses were performed in IBM SPSS v23.0 (369) and StataCorp v13.0.(386)

3.10 Summary

This Chapter has described the quantitative methods used to address the research questions presented in section 3.1. Chapter 4 will present the results of this investigation.

4 Quantitative phase: results

4.1 Introduction

This Chapter presents the findings of the quantitative analysis to examine the effectiveness of the HELP intervention on maternal and child outcomes at 24 months postpartum, as described in the methodology presented in Chapter 3. The aim of this Chapter is to address the following research questions:

Can a theory-based intervention delivered to women with obesity during pregnancy and postpartum, with the aim of improving diet and lifestyle:

- be effective in reducing their BMI and improving other secondary maternal outcomes, 24 months after birth?
- have an impact on their child's BMI and other secondary child outcomes, 24 months after birth?

This Chapter presents the flow of participants from recruitment in the HELP trial through to inclusion in the HELP 24m study. Results of cluster and participant retention in the HELP trial, and recruitment of clusters and participants to the HELP 24 months postpartum follow-up study are described. The extent of any bias present in the sample recruited to the HELP 24 months postpartum follow-up study is assessed. The effectiveness of the intervention in relation to the pre-specified primary and secondary outcomes for the mother and child, are presented. The Chapter concludes with a summary discussion of the findings. The results were presented in line with the CONSORT statement for reporting cluster RCTs (Appendix K).(377)

4.2 HELP trial cohort

The recruitment and retention of clusters and individuals in the HELP trial has been summarised here, to clarify how the sample for the HELP 24m study was obtained.

4.2.1 Recruitment to the HELP trial

In total, 20 maternity units (clusters) were recruited to the HELP trial, and 10 units were randomised to each of the intervention and control groups. Across these sites, 598 eligible women were recruited to the trial between February 2011 and June 2012, 304 in intervention clusters, and 294 in control clusters. Details of the recruitment and follow-up of clusters and individuals in the HELP trial has been summarised in the CONSORT flow diagram in Figure 2. Measurement time points in the HELP trial were included in Figure 2, where data were used in the HELP 24m study (baseline, 36 weeks gestation, post-birth, 12 months postpartum), and withdrawals and retention impacting on the numbers eligible to recruit this follow-up study, summarised.

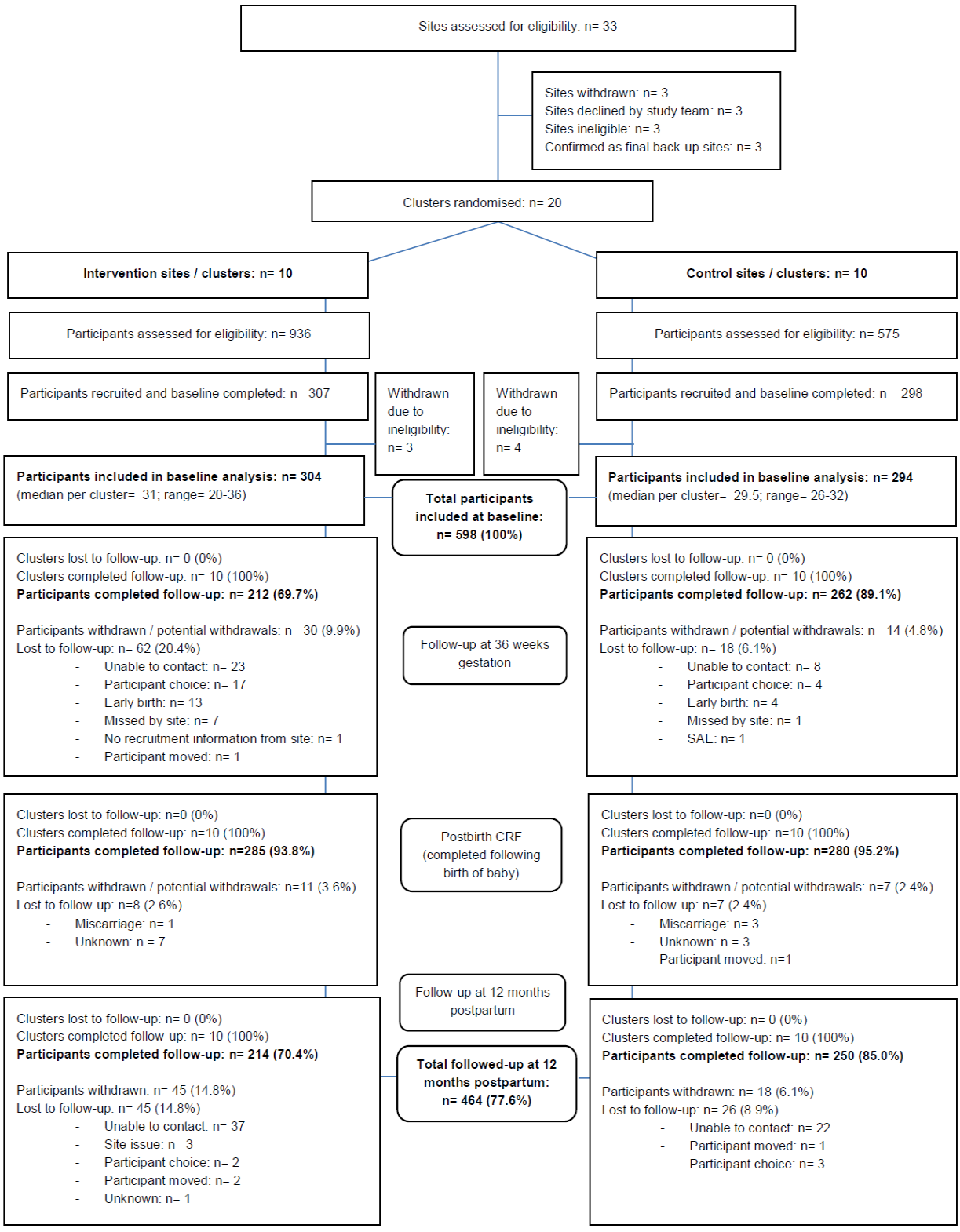

Figure 2: Summary of clusters and participants in the HELP trial, by trial group

4.2.2 Participant retention in the HELP trial

Retaining participants before closure of the HELP trial was an essential step in the set-up of the HELP 24m study, as described Chapter 3 (section 3.3.1). Figure 3 summarises the recruitment and retention of participants in the HELP trial, by group.

Of the 598 (100%) women included at baseline in the HELP trial, 63 (10%) women withdrew from the study, leaving a population of 535 (90%) women who remained enrolled at final follow-up at 12 months postpartum. Of the 464 (77.6%) women who completed the 12 months postpartum follow-up, 246 (41.1%) women provided agreement to be contacted in the future, 7 (1.2%) women declined future contact, and 114 (19.1%) women were followed-up before the introduction of the process to ask for this agreement. There were 97 (16.2%) women who completed the 12-month postpartum follow-up after the introduction of the amended process, who were not invited to provide this consent. This may have been due to the local researcher not adopting the amended protocol or disengaging with the prospect of future research as they were not intending to be involved; as suggested by variability in the numbers invited across sites. An additional 71 (11.9%) women were lost to follow-up at 12 months postpartum, but had not withdrawn, meaning they had not yet been invited to agree to the retention of their details.

The subsequent efforts made by the HELP trial team to obtain agreement for retention of contact details from those women who had not already been approached, resulted in an additional 100 (16.7%) women providing this agreement. This meant a total of 346 (57.9%) women had agreed to the retention of details by the HELP trial closure. The HELP trial team recorded another 36 (6.0%) women who declined the retention of their details, resulting in a total of 42 (7.0%) women declining future contact. The remaining 147 (24.6%) women did not provide consent for their details to be retained. Of these, 91 (15.2%) were unable to be contacted to be invited to provide this consent, and 56 (9.4%) women who agreed over the telephone that they were happy for details to be retained, did not return the form and were subsequently unable to be contacted. Interestingly, of the 71 women who were lost to follow-up at 12 months postpartum, only three women went on to provide agreement to be contacted, four of 71 women declined contact, and 64 of 71 women were unable to be contacted.

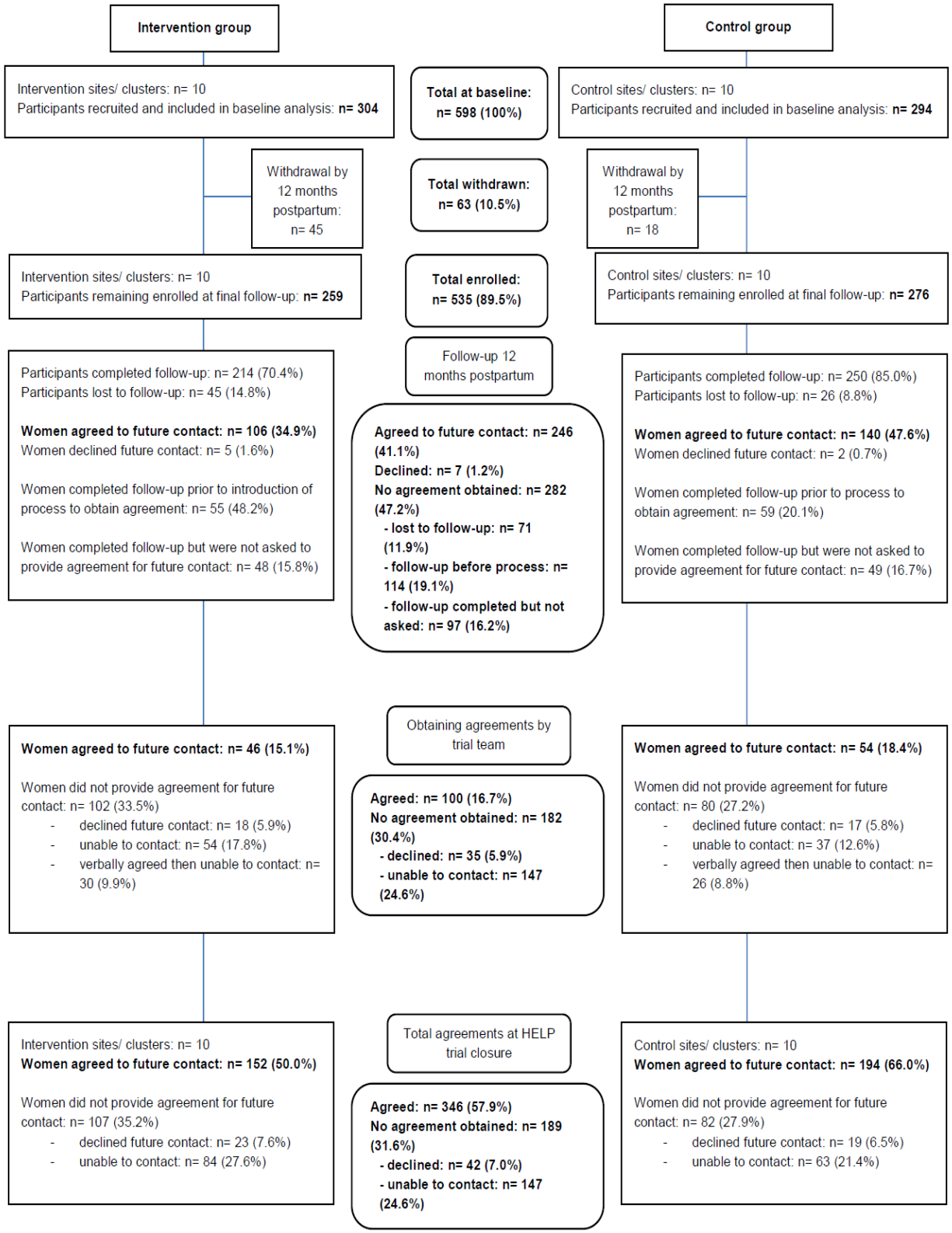

Figure 3: HELP trial clusters and participants providing agreement for future contact, by trial group

4.3 HELP 24m study recruitment

At the HELP trial closure, there were 20 clusters, and 346 (57.9%) women eligible to be approached for the HELP 24m study. This section will summarise the recruitment of clusters and individuals to the HELP 24m study.

4.3.1 HELP 24m study cohort

In total, 241 (40.3% of HELP trial baseline sample) women, and their children, were recruited to the HELP 24m study; 107 (35.2% of HELP trial intervention group sample) women from nine clusters were recruited from the intervention group and 134 (45.6% of HELP trial control group sample) women from 10 clusters were recruited from the control group (percentages based on 598 women included at baseline in the HELP trial; Intervention: 304, Control: 294; as presented in Figure 2). Figure 4 presents the CONSORT flow diagram for the study,(377) and summarises participation of clusters and individuals from those who provided agreement to be contacted prior to closure of the HELP trial, to the 24 months postpartum time point.

4.3.2 Cluster and local researcher recruitment

The processes of identifying local researchers and obtaining appropriate regulatory approvals, commenced after ethical approval was granted. All 20 sites recruited to the HELP trial were approached to take part in the HELP 24m study. NHS R&D approvals were only sought where NHS staff were recruiting participants and collecting follow-up data.

Of the 15 sites located in England, within nine of these sites the local researchers involved in the HELP trial were willing to conduct participant recruitment and data collection at 24 months postpartum. Within six sites, the local researchers involved in the HELP trial were unable to support further data collection due to workloads (n= 4), or the researcher ceasing employment (n= 2). A new local researcher was identified within two of these sites after discussions with the relevant Head of Midwifery. Applications for R&D approval were submitted to 11 sites where local researchers had been identified. One application was subsequently withdrawn as the identified local researcher ceased employment in the health trust and another suitable replacement could not be identified. It took from March 2013 to July 2014, to successfully obtain R&D approval within the remaining ten sites.

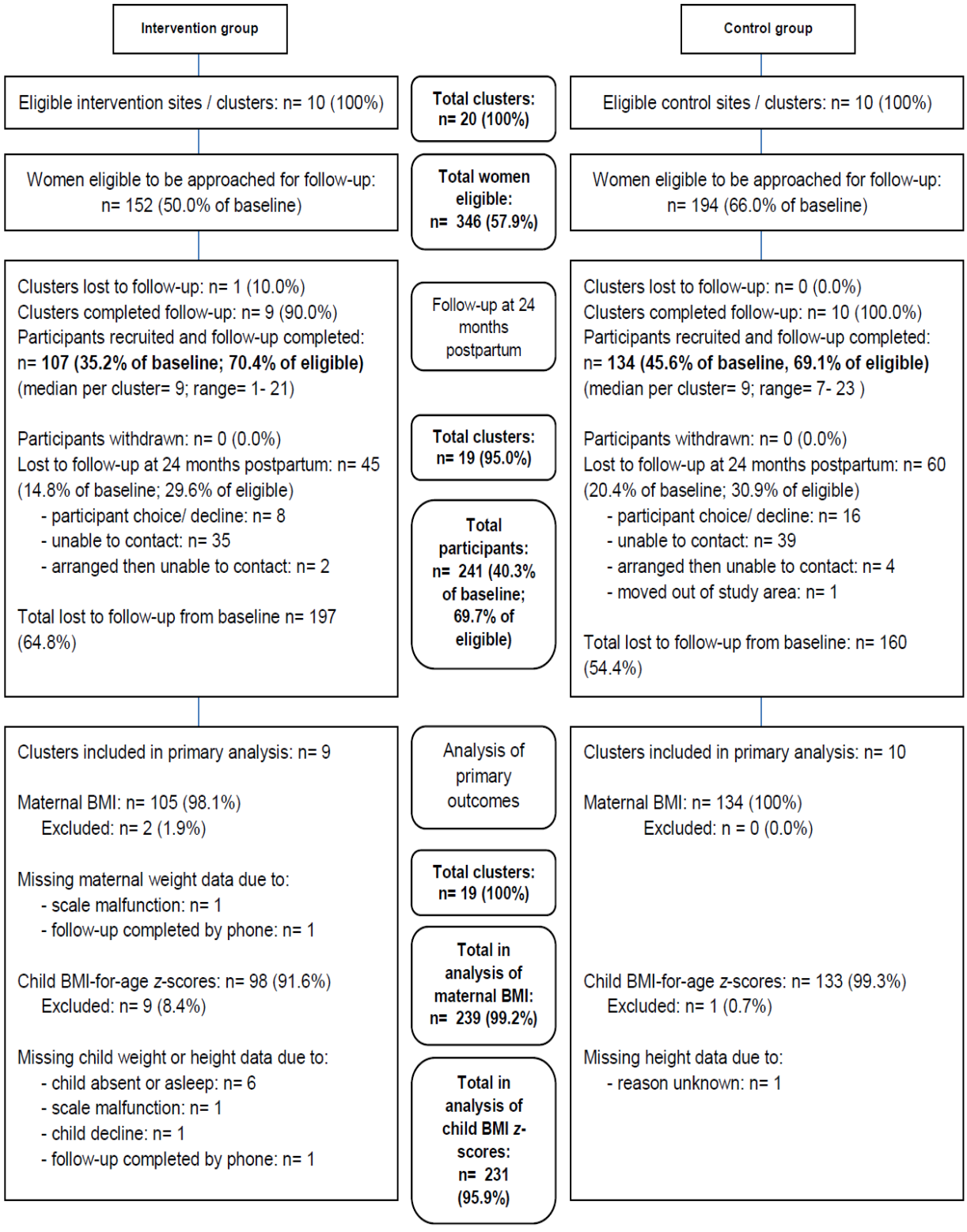

Figure 4: Summary of clusters and participants in the HELP 24m study

This left five sites, located in England, that were unable to identify a local researcher with the capacity to support the HELP 24m study. The student sought to complete recruitment and data collection in these sites. However, within one site no participants were recruited, so the cluster was excluded.

In Wales, the study was adopted onto the HCRW research portfolio in May 2013. Following on from this, HCRW research officers involved in the HELP trial were approached. Within the five sites located in Wales, all local researchers previously involved agreed to conduct participant recruitment and follow-up at 24 months postpartum. A streamlined submission to the NISCHR PCU was completed in September 2013, to obtain approvals for HCRW research officers to support the study across the five sites. Individual health trusts (location of maternity units) were approached to discuss R&D requirements, but as the study did not involve the recruitment of NHS patients, or the involvement of NHS staff within sites, no approvals were required. Approval from NISCHR PCU was obtained in December 2013.

4.3.3 Participant recruitment

With reference to Figure 4, sites started to approach all eligible women (n= 346) in November 2013, and the first participant was recruited to the study on 4th December 2013. As a result of delays in obtaining R&D approvals in some sites, 45 women who went on to be recruited, had passed the 24 months postpartum time point by the start of participant recruitment. The last participant was recruited on 19th May 2015, at which point recruitment was stopped. Considerable attempts had been made to approach all eligible women, and recruitment ended five months after the last 24 months postpartum time point had been reached.

A total of 241 women, and their children, were recruited to the study (intervention: 107, control: 134). All recruited participants met the inclusion criteria. Of 246 women who agreed to a home visit, 240 women consented to take part in the study and provided follow-up data. Another one participant was consented by posted form and follow-up data collected by telephone, as a home visit was not possible. This was a deviation from the study protocol by the local researcher. There were no participant withdrawals. Of the scenarios outlined in the exclusion criteria in Chapter 3 (section 3.3.3), there had been no maternal or child deaths, or children taken into care at the time of participant recruitment. No woman objected to her child participating in the study; however, six children were absent during visits, and one child refused to take part in

study measurements. Numbers completing individual outcome measures are presented later in this Chapter.

The remaining 105 of 346 eligible women were approached but not recruited to the study (Intervention: 45, Control: 60). Reasons for non-participation were: 24 women declined participation (Intervention: 8, Control: 16); and 74 women were uncontactable, mainly due to invalid contact details (Intervention: 35, Control: 39). This includes six of 246 women who agreed to home visits, but who were not at home at the arranged time and were subsequently uncontactable (Intervention: 2, Control: 4). One woman in the control group had moved out of the study area and a visit was not possible.

Two safeguarding issues arose during completion of the home visits, where the local researcher had concerns about the safety and care of children in the home. Each local researcher discussed the incident with their line manager, the student and the primary research supervisor. Following local site procedures, these concerns were passed to social services.

4.4 Comparisons of clusters and individuals recruited to the HELP trial and the HELP 24m study

Descriptive statistics summarising the clusters and individuals recruited to the HELP trial and the HELP 24m study were tabulated and compared, to assess the impact of dropout and the risk of attrition bias, at 24 months postpartum follow-up.

4.4.1 Clusters

Maternity unit factors used to balance the randomisation of clusters to the intervention and control groups in the HELP trial (location, ethnic mix, size of unit in births per year, and proportion of women attending with a BMI ≥ 30), as reported by sites at the time of recruitment, were compared between the HELP trial and HELP 24m study based on recruited sites within each (Table 6).

No loss to follow-up of clusters in the control group at 24 months postpartum occurred; therefore, there was no change in the cluster level variables between the two studies. In the intervention group, one cluster based in south England was lost to follow-up which across sites led to: a reduction in mean % of non-white ethnicity; an increase in the mean % of women with a BMI ≥ 30, and a decrease in the mean number of births per year.

The recruitment of clusters at 24 months postpartum led to a change in the cluster level variables used to give optimal balance in the randomisation of sites to the intervention and control groups in the HELP trial. This resulted in more units situated in Wales and border regions and south England in the control group, and more in north England in the intervention group, although this slight imbalance was not considered to be problematic. It also led to a greater difference in mean proportion of women with a BMI ≥ 30 between the groups, but the difference remained minimal. However, the dropout of an intervention site with a high proportion of non-white ethnicity, resulted in better balance between the groups in % non-white ethnicity. It also led to better balance between the groups in unit size (births per year). The cluster level variables at 24 months postpartum (Table 6) were included in the analysis of primary and secondary outcomes, as will be described in sections 4.6 and 4.7.

Table 6: Cluster level variables for clusters recruited in the HELP trial and HELP 24m study

Sites	Clusters recruited		Cluster level variables *Mean (SD)*			
	HELP trial	**HELP 24m study**	**Site location**	**Ethnicity *(% non-white)***	**BMI ≥ 30 *(% yes)***	**Births per year**
Control						
2	✓	✓	Wales/ border	9.0	21.0	6183
3	✓	✓	Wales/ border	20.0	24.0	5500
4	✓	✓	Wales/ border	11.0	20.0	3646
5	✓	✓	North England	15.0	17.0	2200
6	✓	✓	North England	8.0	15.0	4000
12	✓	✓	South England	48.2	12.0	3800
14	✓	✓	South England	21.8	17.7	5811
16	✓	✓	South England	13.0	15.0	5025
19	✓	✓	Wales/ border	3.0	23.0	1600
20	✓	✓	North England	29.3	17.1	4000
N sites	**10**	**10**		**17.8 (13.1)**	**18.1 (3.8)**	**4176.5 (1498.1)**
Intervention						
1	✓	✓	Wales/border	4.0	24.0	2500
7	✓	✓	Wales/ border	11.0	19.0	8300
8	✓	✓	North England	13.5	18.0	3870
9	✓	✓	Wales/ border	5.0	30.0	2800
10	✓	✓	North England	64.0	19.0	6000
11	✓	✓	South England	17.0	20.0	4600
13	✓	✓	North England	47.0	14.5	7200
15	✓	✓	South England	20.0	16.0	2500
17	✓	✓	North England	10.0	17.0	2800
18	✓	X	South England	46.0	7.5	5000
N sites	**10**	**9**	**HELP trial**	**23.8 (20.9)**	**18.5 (5.9)**	**4557.0 (2065.2)**
			HELP 24m study[a]	**21.3 (20.5)**	**19.7 (4.7)**	**4507.8 (2184.2)**

a Mean values for cluster level variables in the HELP 24m study exclude Site 18, as no participants were recruited.

4.4.2 Cluster level balance of individuals

A comparison of some of the baseline demographic characteristics, known confounders of the outcomes, of responders and non-responders to the 24 months postpartum study, by clusters and groups, was conducted (Table 7). Non-responders were defined as women recruited to the HELP trial and included in baseline analysis (n= 598), who were lost to follow-up at the 24 months postpartum time point (n= 357). This was regardless of dropout time point or reason, including those who had withdrawn from the HELP trial. The numbers of responders were imbalanced across the clusters (intervention sites: median= 9; range= 0-21, control sites: median= 9; range= 7-23), with higher percentage dropout within the intervention group, (64.8%) compared with control (54.4%), and variable dropout across sites (ranging from 96.6% to 23.3%).

Mean BMI (kg/m^2) was comparable between responders and non-responders in both groups, although there was variability within sites. For example, in site 7 non-responders had a markedly higher mean BMI than responders, whereas in site 8 non-responders had a lower mean BMI than responders. Responders compared with non-responders, in both groups, were more likely to be older, which was similar across sites, and be first time mothers, so a greater proportion of women with children, at baseline, were lost to follow-up; although this trend was variable within control sites. Gestation at allocation was comparable between groups and sites for responders and non-responders. Smokers were more likely to be non-responders, although the proportion of smokers who were non-responders varied across the sites. Responders in both groups included a greater proportion of women in managerial or professional jobs reflecting SES, compared with non-responders, indicating a more affluent sample were recruited at follow-up. However, some sites indicated a large difference between proportions of responders and non-responders in senior job roles (site 13: 86.0% vs. 37.0%), others indicated a trend in the other direction (site 1: 29.0% vs. 44.0%). Although, due to high levels of missing data in non-responders, it was difficult to make reliable comparisons in SES. The proportion of non-white ethnicity of responders and non-responders in the intervention group differed. Cluster level differences (Table 6) suggested that this was due to one empty cluster at follow-up (site 18), as this cluster had the highest proportion of women of non-white ethnicity at randomisation. In the control group, responders were slightly more ethnically diverse than non-responders, although this difference was minimal.

Table 7: Cluster and group balance for BMI, age, parity, gestation, smoking, SES and ethnicity, for responders and non-responders

Sites	N		BMI Mean (SD)		Age Mean (SD)		Parity % NP[a]		Gestation Mean (SD)		Smoking % yes		SES % M/P[b]		Ethnicity % non-white	
	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR
Control	**134**	**160**														
2	13	17	39.0 (5.7)	38.9 (6.3)	31.5 (5.7)	25.9 (5.1)	15*	18	16.9 (2.4)	16.2 (2.7)	8	30	27*	20*	15	0
3	13	16	38.3 (5.6)	37.2 (3.6)	27.7 (5.0)	28.0 (6.2)	54	56	14.1 (1.6)	15.1 (2.0)	8	19	50	31*	15	0
4	12	20	34.5 (3.7)	37.9 (6.3)	30.6 (5.7)	27.7 (5.7)	25	50	15.5 (1.4)	14.9 (2.2)	8	10	18*	28*	0	0
5	16	13	35.4 (3.4)	35.6 (3.8)	29.2 (4.7)	27.2 (6.1)	38	31	14.8 (1.9)	15.2 (1.8)	25	8	36*	42*	13	8
6	13	17	36.7 (4.1)	37.3 (6.6)	29.2 (4.5)	26.9 (4.6)	54	53	16.8 (3.1)*	18.2 (2.3)	8	12	46	31*	7*	6
12	23	7	36.0 (4.9)	34.1 (2.9)	32.0 (5.4)	28.4 (4.7)	56	71	15.7 (1.9)	16.6 (1.7)	0	0	67*	0	52*	57
14	12	17	36.4 (5.2)	34.8 (3.7)	30.1 (6.4)	29.3 (5.6)	58	25	16.6 (2.5)	16.2 (1.9)	8	6	50	31*	8	6
16	7	22	35.4 (2.4)	37.1 (4.7)	30.0 (3.1)	31.3 (3.7)	14	36	18.1 (2.0)	17.6 (2.2)	0	9	43	55	0	0
19	15	11	36.5 (6.1)	36.5 (4.8)	26.7 (4.7)	24.0 (4.9)	20	36*	16.7 (2.5)	16.9 (2.7)	20	46	18*	0	0	0
20	10	20	34.6 (3.4)	34.3 (3.1)	29.5 (6.9)	28.3 (5.2)	50	30	14.3 (1.8)	15.7 (2.7)	20	25	40	38*	10	20
Mean (SD) or %	**13 (4)**	**29 (2)**	**36.3 (4.8)**	**36.5 (5.0)**	**29.7 (5.4)**	**27.9 (5.4)**	**54**	**40**	**15.8 (2.4)**	**16.3 (2.5)**	**11**	**15**	**42**	**34**	**4**	**2**
**Missing*							*1*	*1*	*1*				*12*	*38*	*2*	
Intervention	**107**	**197**														
1	16	12	40.7 (5.7)	39.2 (7.9)	29.2 (5.0)	26.8 (4.2)	50	33	15.4 (3.4)	15.2 (2.9)	13	8	29*	44*	0	0
7	11	21	35.1 (5.2)	39.3 (5.8)	31.6 (4.3)	28.8 (6.5)	27	19	14.7 (2.4)	15.4 (1.9)	9	29	70*	15*	0	5
8	17	17	40.2 (9.0)	37.2 (4.1)	28.5 (2.6)	27.5 (4.6)	41*	29	15.4 (2.1)	14.9 (2.1)	6	18	41	31*	6	0
9	19	15	37.0 (5.4)	35.8 (4.3)	30.2 (4.8)	27.8 (5.0)	47	47	15.1 (1.8)	15.7 (2.0)	0	7	67*	46*	0	0
10	7	23	37.2 (4.9)	37.7 (4.6)	25.3 (3.3)	27.8 (5.6)	43	35	17.1 (2.7)	15.4 (2.2)	29	17	25*	37*	43	43*
11	21	15	38.9 (5.9)	38.5 (4.9)	30.3 (4.9)	30.4 (5.3)	52	53	15.3 (2.7)	14.3 (2.2)	5	20	71*	57*	0	0
13	7	22	36.5 (4.0)	38.6 (5.7)	31.4 (4.5)	31.2 (5.8)	57	23	15.4 (2.0)	14.8 (2.2)	0	14	86	37*	0	9
15	8	24	34.0 (2.8)	35.9 (3.4)	28.3 (5.5)	26.8 (4.6)	63	38	13.3 (1.4)	14.1 (2.8)	0	29	63	47*	0	0
17[c]	1	28	34.8	40.2 (6.3)	26.0	29.4 (4.3)	0	32	15	16.4 (3.5)	0	14	0	23*	0	0
18	0	20	X	35.6 (5.8)	X	31.2 (5.5)	X	55	X	16.2 (4.5)	X	5	X	72*	X	65*
Mean (SD) or %	**11 (7)**	**30 (5)**	**38.0 (6.2)**	**37.8 (5.5)**	**29.5 (4.6)**	**28.8 (5.3)**	**47**	**36**	**15.2 (2.5)**	**15.3 (2.8)**	**7**	**17**	**56**	**40**	**1**	**5**
Missing							*1*						*11*	*42*		*2*

Key: R= Responders; NR= Non-responders

a Percentage of women who were nulliparous at baseline

b Percentage of women in managerial or professional job roles at baseline, as measured using NS-SEC

c Values presented for responders represent individual values (n= 1) rather than mean calculations.

4.4.3 Individuals: responders and non-responders

A comparison of the summary baseline demographic characteristics of responders and non-responders to the 24 months postpartum study was conducted (Table 8), to assess possible attrition bias at the follow-up time point.

Responders and non-responders to the HELP 24m study were comparable on age, ethnicity, height, mental health and gestation. However, there were differences at baseline between these samples. A greater proportion of women randomised to the intervention group were lost to follow-up, likely due to imbalance in withdrawals between groups in the HELP trial (Figure 2). Responders were more likely to hold higher educational qualifications and be in a managerial or professional job, although higher levels of missing data for non-responders impacted the conclusions drawn from the comparison of SES data. Responders were also more likely to be married; have slightly lower median BMI and a BMI of < 35.0 kg/m^2, weigh less, and, have been successful in previously losing weight. This may reflect a follow-up sample who were more engaged in weight loss. Responders were less likely to smoke. Those with children at baseline were more likely to be lost to follow-up at 24 months postpartum.

Table 8: Demographics and baseline characteristics of responders and non-responders

Variables	Responders N= 241	Non- responders N= 357
Intervention *N (%)*	107 (44.4)	197 (55.2)
Control *N (%)*	134 (55.6)	160 (45.8)
Maternal characteristics		
Age at baseline *(years) mean (SD)*	29.6 (5.1)	28.4 (5.4)
Ethnicity *N (%)*		
White	214 (89.5)	318 (89.6)
Non-white/ mixed	25 (10.5)	18 (10.4)
Missing	*2*	*12*
SES *N (%)*		
Managerial / professional	105 (48.2)	104 (37.5)
Intermediate/ small employers	69 (31.7)	95 (34.3)
Lower supervisory/ technical/ semi-routine & routine	44 (20.2)	78 (28.2)
Missing	*23*	*80*
Education[a] *N (%)*		
First degree or higher	75 (31.6)	55 (15.7)
A / AS / S levels / Diploma	72 (30.4)	103 (29.3)
O Levels / GCSE / Other/ None	90 (38.0)	193 (55.0)
Missing	*4*	*6*
Marital status *N (%)*		
Married/ co-habiting	207 (86.3)	280 (78.7)
Single/ divorced	33 (13.7)	76 (21.3)
Body composition		
BMI *(kg/m^2) median (25th-75th quartiles)*	35.8 (32.8- 40.6)	36.2 (33.3- 39.9)
<35.0 kg/m^2 (overweight or obesity) N (%)	106 (44.0)	140 (39.2)
≥35.0 kg/m^2 (severe or morbid obesity) N (%)	135 (56.0)	217 (60.8)
Weight *(kg) median (25th-75th quartiles)*	96.9 (88.8- 111)	98.9 (89.3- 109.7)
Range	*73.3 - 190.8*	*65.0 - 155.9*
Height *(cm) mean (SD)*	1.65 (0.07)	1.64 (0.07)
Previous successful weight loss[b] *N (% successful)*	211 (89.0)	274 (77.6)
Missing	*4*	*4*
Mental health *(GHQ-12)*[c]		
GHQ score median (25th-75th quartiles)	2 (1- 5)	2 (0- 5)
Smoking		
Current smoker N (% yes)	22 (9.1)	57 (16.0)
Cigarettes per day mean[d] *(SD)*	7.4 (4.5)	9.3 (5.9)
Parity *N (%)*		
Nulliparous	104 (43.5)	134 (37.6)
Multiparous	135 (56.5)	222 (62.4)
Missing	*2*	*1*
Gestation at baseline *(weeks) median (25th-75th quartiles)*	15 (13- 17)	16 (14- 18)

a The question wording was 'what is your highest qualification'? Participants were to select 'one' response but n=285 women selected multiple qualifications. Results are based on the highest qualification indicated.
b Based on women's self-report of success in losing ≥ half a stone in the two years prior to baseline assessment.
c Possible scoring for GHQ-12 ranges from 0 to 12; a score of ≥2 indicates psychological distress
d 'Cigarettes per day' was calculated for those who answered 'yes' when asked 'Are you a current smoker?'.

4.4.4 Adherence and dose of the intervention

Attendance at intervention group sessions was examined across intervention clusters, to compare adherence between responders and non-responders to the HELP 24m study. Percentage of sessions attended out of all possible sessions (maximum for any participant: 38 sessions) along with the proportion of those who received the required 'dose' of the intervention (≥ seven sessions) were examined. (Table 9).

Responders had higher intervention adherence, compared with non-responders, and were more likely to have received the 'dose' of intervention. These directional relationships were found within most sites, except site 10 where lower levels of adherence in responders were indicated. A comparison in site 17 was difficult as there was only one responder, however, this individual attended a high percentage of sessions compared with the sample averages and the maximum attendance across sites. A comparison in site 18 was not possible due to cluster dropout at follow-up. However, attendance for non-responders was low compared with responders in other sites.

Table 9: Adherence data for intervention group responders and non-responders **Key: Res= Responders; Non-Res= Non-responders**

Sites	N		Mean % (min to max) of sessions attended		N (%) received required dose ≥ 7 sessions	
	Res	Non-Res	Res	Non-Res	Res	Non-Res
1	16	12	42 (0- 84)	30 (0- 89)*	10 (62.5)	6 (60.0)*
7	11	21	51 (6- 88)	18 (0- 61)*	9 (81.8)	5 (31.3)*
8	17	17	39 (0- 81)	32 (0-87)*	11 (64.7)	6 (46.2)*
9	19	15	54 (0- 89)	22 (0- 73)*	15 (78.9)	4 (33.3)*
10	7	23	30 (0- 59)	35 (0- 80)*	3 (42.9)	9 (60.0)*
11	21	15	35 (0- 74)	11 (3- 30)*	12 (57.1)	1 (8.3)*
13	7	22	57 (0-79)	25 (0- 77)*	6 (85.7)	7 (43.8)*
15	8	24	46 (0-84)	18 (0 -86)*	5 (62.5)	4 (26.7)*
17	1	28	72[a]	27 (0- 86)	1 (100)[a]	13 (46.4)*
18	0	20	X	24 (0- 76)*	X	7 (38.9)*
Totals	**107**	**197**	**44 (0-89)**	**25 (0-89)**	**72 (67.3)**	**62 (40.0)**
*Missing**				*42*[b]		*42*[b]

a Values presented for responders represent individual attendance (n= 1) rather than mean calculations.
b Missing data due to participant withdrawal during intervention delivery, unable to calculate attendance.

4.4.5 Conclusions

Overall, the clusters and individuals recruited to the two studies were different. The dropout of one cluster at follow-up impacted the cluster level variables, and the differential dropout of individuals across sites led to cluster size imbalance at 24 months postpartum. The sample of women recruited to the HELP 24m study were, in general, slightly healthier (BMI and non-smoking), more affluent (SES and education) and more engaged (previous weight loss) than in the HELP trial. This was further evidenced by the higher intervention adherence of responders, which did not reflect the general trend in adherence in the HELP trial. This may indicate attrition bias in the HELP 24 months postpartum follow-up study. The imbalances between clusters and individuals in the two studies, and the impact of these imbalances in relation to the findings, will be discussed in section 4.8.

4.5 Characteristics of the HELP 24m study population

4.5.1 Baseline characteristics of mothers

To examine the balance between intervention and control groups for the recruited population and the possible confounders of outcomes, a comparison of maternal demographic and baseline characteristics, between groups, was conducted (Table 10).

Baseline data indicated that the recruitment at 24 months postpartum retained adequate balance for age, height, previous weight loss, mental health and gestation. Compared with the control group, those recruited to the intervention were more likely to be: white, married, more highly qualified with a first degree and above, and in more senior managerial or professional job roles, reflecting higher SES. Women recruited to the intervention group had a slightly higher group BMI, at baseline, than those in control. However, there was only a slight difference between groups in the proportions of women with BMI categorised as <35.0 or ≥35.0. Furthermore, a similar difference in BMI was observed between groups for the HELP trial population, at baseline. More women recruited to the control group were smokers, but smokers in the intervention group smoked more cigarettes per day. There was a difference in parity in that more women in the intervention group were first time mothers at baseline.

Table 10: Demographics and baseline characteristics of mothers by group

Variables	Control N=134	Intervention N=107
Maternal characteristics		
Age at baseline *(years) mean (SD)*	29.7 (5.4)	29.5 (4.6)
Ethnicity *N(%)*		
White	111 (84.1)	103 (96.3)
Non-white/ mixed	21 (15.9)	4 (3.7)
Missing	*2*	*0*
SES *N (%)*		
Managerial / professional	51 (41.8)	54 (56.3)
Intermediate/ small employers	45 (36.9)	24 (25.0)
Lower supervisory/ technical/ semi-routine & routine	26 (21.3)	18 (18.8)
Missing	*12*	*11*
Education[a] *N (%)*		
First degree or higher	39 (29.5)	36 (34.3)
A / AS / S levels / Diploma	44 (33.3)	28 (26.7)
O Levels / GCSE / Other/ None	49 (37.1)	41 (39.0)
Missing	*2*	*2*
Marital status *N (%)*		
Married/ co-habiting	111 (83.5)	96 (89.7)
Single	22 (16.5)	11 (10.3)
Missing	*1*	*0*
Body composition		
BMI *(kg/m^2) median (25th-75th quartiles)*	35.5 (32.5-39.2)	36.8 (33.6-41.5)
<35.0 kg/m^2 (overweight or obesity) N (%)	61 (45.5)	45 (42.0)
≥35.0 kg/m^2 (severe or morbid obesity) N (%)	73 (54.5)	62 (58.0)
Weight (kg) *median (25th-75th quartiles)*	95.8 (87.3-106.0)	98.7 (90.2-114.8)
Range	*(75.4- 153.7)*	*(73.3- 190.8)*
Height *(cm) mean (SD)*	1.65 (0.07)	1.65 (0.07)
Previous successful weight loss[b] *N (% successful)*	116 (88.5%)	95 (89.6%)
Missing	*1*	*3*
Mental health (GHQ-12)[c]		
GHQ score median (25th-75th quartiles)	2 (1-5)	2 (0-5)
Smoking *Current smoker N (% yes)*	15 (11.2)	7 (6.5)
Cigarettes per day mean[d] (SD)	6.5 (3.8)	9.1 (5.5)
Parity *N (%)*		
Nulliparous	54 (40.6)	50 (47.2)
Multiparous	79 (59.4)	56 (52.8)
Missing	*1*	*1*
Gestation at baseline *(weeks) median (25th-75th quartiles)*	16 (14-17.5)	15 (13-17)
Timing 24m follow-up *(days) median (25th-75th quartiles)*	746 (732-776)[e]	804 (751-864)[e]
Range	*705- 1215*	*681- 1216*

a The question wording was 'what is your highest qualification'? Participants were to select 'one' response but n=141 women selected multiple qualifications. Results are based on the highest qualification indicated.
b Based on women's self-report of success in losing ≥ half a stone in the two years prior to baseline assessment.
c Possible scoring for GHQ-12 ranges from 0 to 12; a score of ≥2 indicates psychological distress
d 'Cigarettes per day' was calculated for participants who answered 'yes' when asked 'Are you a current smoker?
e Follow-up at 24 months + 16 days in the control group, compared with 24 months + 74 days in the intervention.

4.5.2 Birth characteristics of children

To further examine the balance between groups for the recruited population, a comparison of child demographics was conducted (Table 11). Baseline measurements for children were taken from data collected shortly after birth in the HELP trial. Groups were comparable for child gestation at birth, proportion of children born by vaginal/ instrumental delivery or caesarean section delivery and sex (50). Median birth weight (kg) was slightly higher for children born to mothers in the intervention group, compared with control. Children of mothers allocated to the intervention group were more likely to have normal Apgar scores at both 5 and 10 minutes, although the differences were minimal, and there was missing data for 143 women, likely to be due to children showing a normal Apgar score prior to the measurement, therefore it is was assumed the groups were comparable.

Table 11: Birth characteristics of children by group

Variables	Control N=134	Intervention N=107
Gestation at birth *(weeks) median (25^{th}-75^{th} quartiles)*	40 (39-41)	40 (38-41)
Sex *N (% Male)*	67 (50.0)	55 (51.4)
Birth weight *(kg) median (25^{th}-75^{th} quartiles)*	3.51 (3.22-3.89)	3.61 (3.23-3.99)
Range	*0.65- 5.21*	*1.24- 4.89*
Delivery *N (%)*		
Vaginal/ instrumental	95 (71.4)	73 (68.2)
Caesarean section	38 (28.6)	34 (31.8)
Missing	*1*	*0*
Apgar Scores *(% normal, ≥ 7)*		
Apgar score at 5 minutes	127 (97.7)	106 (100)
Missing	4	1
Apgar score at 10 minutes	50 (98.0)	47 (100)
Missing	*83*	*60*
Age at 24m follow-up *(days) median (25^{th}-75^{th} quartiles)*	746 (732-776)[a]	804 (751-864)[a]
Range	*705- 1215*	*681- 1216*

a Age at follow-up (control: 24 months and 16 days, intervention: 24 months and 74 days).

There was a notable difference between the groups, in the timing of completion of the HELP 24 months postpartum follow-up; that is, the age of the children at follow-up (Tables 10 and 11). Median child age at follow-up in the intervention group was 804 days (24 months and 74 days) compared with 746 days (24 months and 16 days) in control. To further investigate this difference, the timing of follow-up across clusters was examined (Table 12), and presented by boxplot in Figure 5, with a reference line indicating the 24 months postpartum time point (730

days after birth). Across all sites, and both groups, the median timing of follow-up completion/ child age exceeded the 24 months after birth time point. There was variability across the sites, but Figure 5 indicates that follow-up in intervention sites was later, in general, compared with control sites; particularly in Site 10 (median: 965 days= 24 months and 235 days). The impact of the timing of follow-up completion on the primary outcomes will be considered in section 4.6.

Table 12: Timing of follow-up/ age of child by group and cluster

Intervention sites	N	Timing in days Median (IQR)	Control sites	N	Timing in days Median (IQR)
1	16	849 (813- 896)	**2**	13	736 (730- 795)
7	11	808 (761- 832)	**3**	13	737 (731- 755)
8	17	783 (742- 855)	**4**	12	743 (733- 756)
9	19	757 (713- 829)	**5**	16	790 (769- 828)
10	7	965 (924- 1159)	**6**	13	764 (739- 772)
11	21	754 (740- 764)	**12**	23	744 (732- 749)
13	7	793 (769- 938)	**14**	12	809 (780- 859)
15	8	841 (756-982)	**16**	7	741 (720- 792)
17	1	*859	**19**	15	732 (728- 733)
			20	10	756 (730- 785)
	107	**804 (751-864)**		**134**	**746 (732-776)**
a Value represents follow-up of an individual (n= 1) rather than median.					

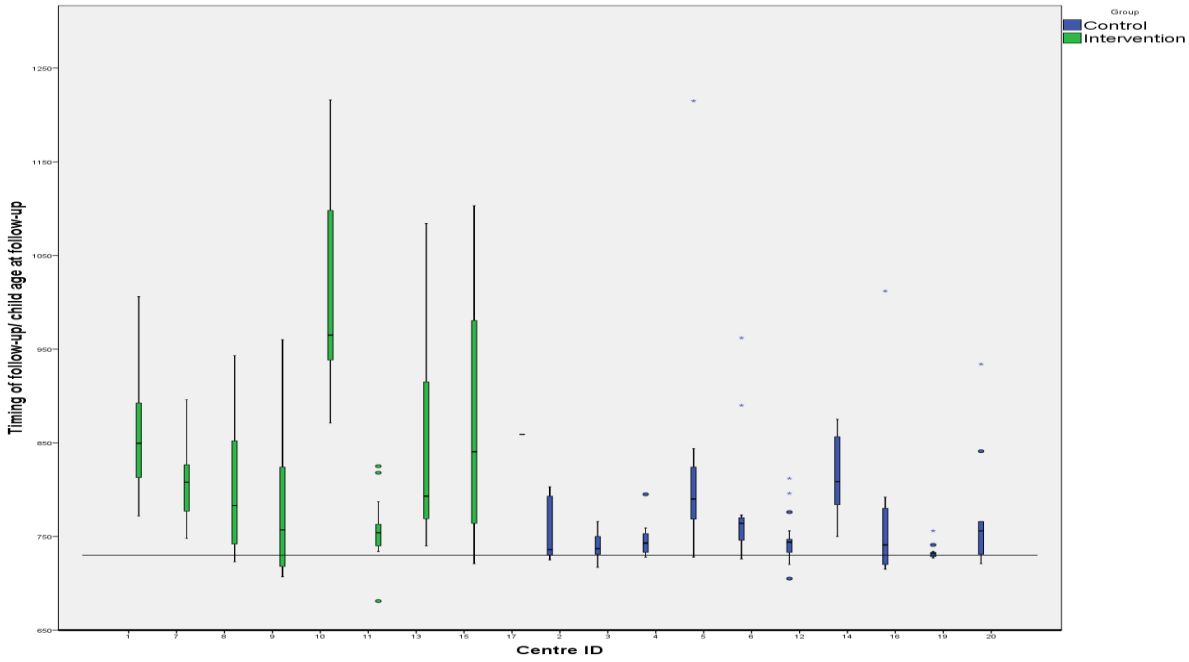

Figure 5: Box plot of the timing of follow-up completion/ age of child in days, by group

4.6 Primary Outcomes

4.6.1 Maternal BMI at 24 months postpartum

The distribution of BMI was slightly positively skewed at baseline and 24 months postpartum follow-up, indicating non-normal distributions (Figure 6 (a and b)). Use of the Kolmogorov-Smirnov test provided significant results (control: $D(134)= 0.13$, $p < 0.001$; intervention: $D(107)= 0.01$, $p =0.020$), indicating that BMI violated the assumptions of normality required for analysis using linear regression modelling. A natural log transformation was performed on maternal BMI data at baseline and follow-up. Figure 6 (c and d) presents the distributions of follow-up BMI by group, before and after log transformation, and indicates that using log transformation supported the analysis using multilevel regression.

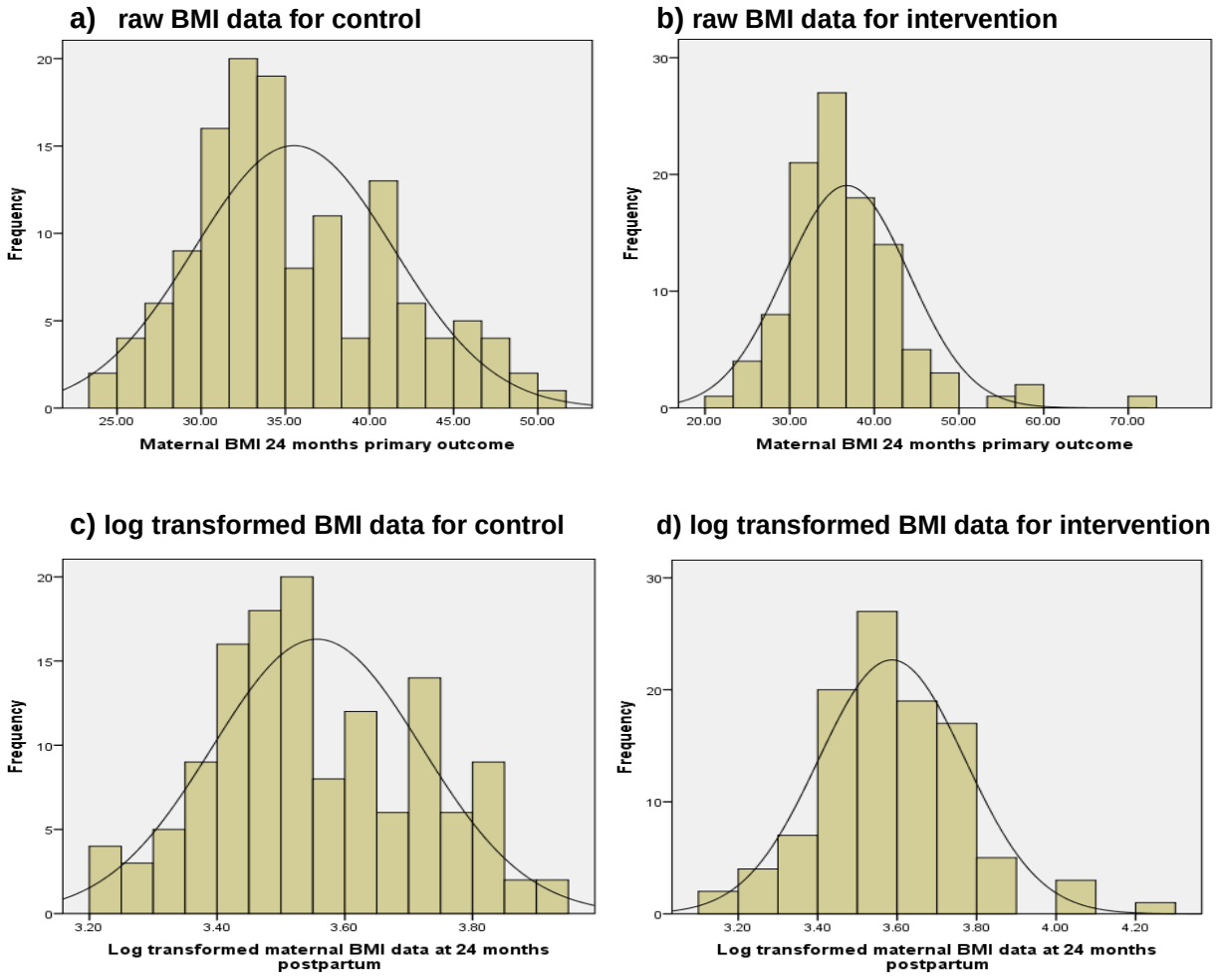

Figure 6: Histograms of maternal BMI at 24 months postpartum, by group, before and after transformation

Of the 241 participants, 239 (99.2%) had BMI measurements at both baseline and follow-up and were included in the analysis (Table 13). Two missing cases of follow-up weight measurements, both in the intervention group, were due to a scale malfunction at follow-up, and a follow-up completed by telephone. BMI calculation was not possible and these cases were excluded. As there were only two cases no imputation was necessary. One extreme outlier in the intervention group data was checked for data entry error, as it was likely to have an impact on the analysis; however, the value was authentic and was retained in the analysis.

Both groups observed a decrease in median BMI between baseline and 24 months postpartum (Table 13). The complete case analysis of maternal BMI, found no evidence of a difference at 24 months postpartum (Table 13). The adjusted intervention effect on the log scale can be interpreted as percentage change, and it can be seen that there was a 1% decrease in BMI in the intervention group, compared with control, which was not statistically significant (adjusted percentage difference: -0.01, 95% CI -0.04 to 0.02; p= 0.664).

Table 13: Maternal BMI at 24 months postpartum by group

	Intervention			Control				
	N 107	**Baseline median (IQR)**	**24 months median (IQR)**	**N 134**	**Baseline median (IQR)**	**24 months median (IQR)**	**ICC**	**Adjusted[a] intervention effect[b,c] (95% CI)**	**p-value**
BMI kg/m^2	105	36.8 (33.7-41.6)	35.1 (32.7-40.2)	134	35.5 (32.5-39.2)	33.8 (31.2-40.2)	0.03	-0.01 (-0.04 to 0.02)	0.664

a Adjusted for baseline BMI and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Baseline and follow-up data used in the model were on the log scale.
c Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.

There were 19 clusters in total, with an average cluster size of 9 (range 1 to 23) and the unadjusted ICC was 0.03 (95% CI 0.002 to 0.256). The ICC values of the unadjusted data, without randomisation variables or covariates, indicated that there was little evidence of clustering of the primary outcome; women within clusters were no more similar to each other than individuals from different clusters, and little variance in BMI scores was explained by the clustering of individuals. The adjusted ICC was <0.001. The importance of using a multilevel approach diminishes in this case.

A single level linear regression analysis showed a mean percentage difference (intervention minus control) between the groups in the unadjusted (without randomisation variables or covariates) transformed BMI data at 24 months postpartum of -0.03 (-0.08 to 0.02), p= 0.183. Adjusting for transformed baseline BMI, resulted in an intervention effect of -0.01 (-0.04 to 0.02), p=0.664; so, baseline BMI accounted for much of the variance seen between the groups in the primary analysis (Table 13). Median maternal BMI at 24 months follow-up was examined between sites and ranged from 29.7 kg/m^2 to 44.1 kg/m^2 (Table 14).

Table 14: Median maternal BMI at follow-up by cluster

Intervention sites	**N 107**	**BMI (kg/ m^2) Median (IQR)**	**Control sites**	**N 134**	**BMI (kg/ m^2) Median (IQR)**
1	16	36.3 (34.5- 43.7)	**2**	13	32.9 (32.0- 40.0)
7	11	32.8 (30.5- 35.2)	**3**	13	37.1 (32.9- 40.8)
8	17	34.5 (32.8- 41.7)	**4**	12	44.1 (28.9- 38.2)
9	19	34.4 (29.7- 39.4)	**5**	16	35.0 (32.2- 37.0)
10	7	34.7 (28.9- 41.5)	**6**	13	36.4 (32.1- 43.9)
11	21	39.3 (34.9- 43.2)	**12**	23	35.2 (31.5- 41.5)
13	7	34.4 (32.3- 36.0)	**14**	12	31.7 (29.6- 42.8)
15	8	34.0 (32.8- 38.1)	**16**	7	29.7 (25.6- 34.5)
17	1	26.8[a]	**19**	15	37.1 (30.2- 41.7)
			20	10	33.1 (31.4- 37.9)
	105	**35.1 (32.7- 40.2)**		**134**	**33.8 (31.2- 40.2)**

a Value represents follow-up of an individual (n= 1) rather than median.

Model Checking

To assess the normality of residuals, a key assumption required for linear regression, maternal BMI data in the raw and log scales were presented against the linear prediction of values (Figure 7). The residuals generally followed a normal distribution, although several outliers impacted the fit at both ends of the line. Log transformation slightly improved the distribution of the residuals (Figure 7b), therefore it was retained.

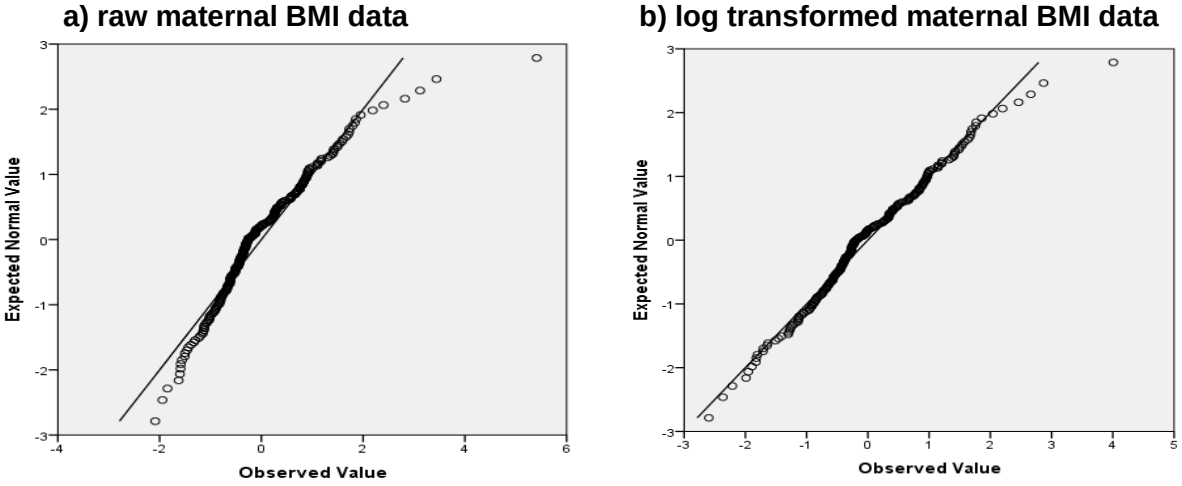

Figure 7: Standardised residuals from linear models of maternal BMI, before and after transformation

To check the goodness-of-fit for the log transformed BMI data, the residuals should have a mean of zero and constant variance. If residuals are normally distributed, then 95% of them should fall between -1.96 and 1.96. Ten observations lie outside this range, 10/239= 4.2% (Figure 8), so the fit was acceptable.

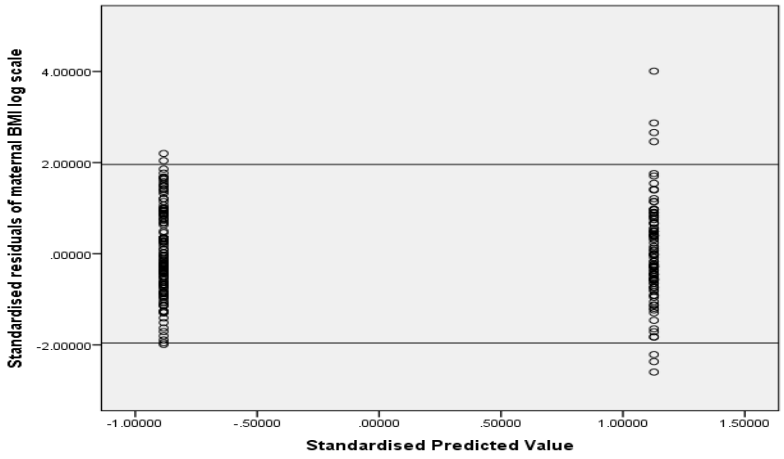

Figure 8: Residual plot for the primary outcome maternal BMI model

Secondary Analyses

To reduce the impact that the outliers might have on examining BMI between the groups, a secondary analysis of the primary outcome examined maternal BMI categorised into thresholds of obesity or severe obesity (≥30 kg/m^2) versus overweight and healthy weight (<30 kg/m^2). The proportion of women in the intervention group who had a BMI at 24 months postpartum ≥30 kg/m^2, indicating obesity or severe obesity, was 87.6%, which was slightly higher compared with 84.3% of women in the control group. The intervention effect is presented as an OR, the odds of having this outcome in the intervention group compared with the control group. The odds of being obese or severely obese was slightly higher in the intervention group, but CIs were wide indicating no evidence of a difference between the groups (Table 15).

Table 15: Secondary analysis of maternal BMI thresholds by group

	Intervention		**Control**				
	N	**N (%)**	**N**	**N (%)**	**ICC**	**Adjusted[a] OR[b] (95% CI)**	**p-value**
	107		**134**				
BMI thresholds *(% obese and severely obese)*	105	92 (87.6)	134	113 (84.3)	0.06	1.38 (0.52 to 3.65)	0.526

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Sensitivity analyses

A sensitivity analysis was conducted to adjust for baseline imbalances between the groups (described in section 4.5.1), which were likely to be confounders of maternal BMI. These were smoking, parity, ethnicity, SES and education. The timing of follow-up was also imbalanced between the groups (section 4.5.2). Length of time after birth could potentially impact the primary outcome, so it was considered necessary to adjust the regression model for this variable. Adjusting for these variables did not alter the results (Appendix L).

Subgroup analyses

Pre-planned subgroup analyses were conducted examining appropriate interaction terms in the regression model to assess any differential effects of the intervention on the following baseline categories: age at recruitment (<25 years/ ≥ 25 years), ethnicity (white/ non-white), SES (managerial or professional/ other), smoking status (smoker/ non-smoker), previous weight loss (yes/ no), mental health (distress/ no distress) and parity (nulliparous/ multiparous) (Table 16). Age, ethnicity, SES, smoking status and mental health demonstrated no differences in the intervention effect between each subgroup. There was a slightly stronger positive effect of the intervention in participants who had previously been successful in losing weight (-0.07 (-0.13 to -0.02), p=0.013) and those who already had children at baseline (-0.04 (-0.08 to -0.01), p=0.027).

Table 16: Subgroup analyses of intervention effect on maternal BMI

Subgroups (at baseline)	N	Adjusted[a] intervention effect[b,c,d] (95% CI)	Interaction p-value
Age			
➢ *< 25 years*	35	-0.02 (-0.08 to 0.05)	0.587
➢ *≥ 25 years*	206	-0.04 (-0.09 to -0.01)	
Ethnicity			
➢ *White*	206	-0.004 (-0.12 to 0.11)	0.932
➢ *Non- white*	33	0.01 (-0.03 to 0.06)	
SES (*NS-SEC)*			
➢ *Managerial and professional*	105	-0.02 (-0.06 to -0.03)	0.460
➢ *Intermediate, small employers; lower supervisory; technical; semi-routine and routine*	113	0.01 (-0.03 to 0.05)	
Smoking status			
➢ *Smoker*	22	-0.03 (-0.03 to 0.09)	0.280
➢ *Non-smoker*	219	-0.05 (-0.14 to 0.03)	
Weight loss history			
➢ *Weight loss*	211	-0.07 (-0.13 to -0.02)	0.013
➢ *No weight loss*	26	0.04 (-0.03 to 0.11)	
Mental Health *(GHQ-12)*			
➢ *Distress*	139	0.01 (-0.05 to 0.03)	0.540
➢ *No distress*	102	-0.004 (-0.05 to 0.04)	
Parity			
➢ *Multiparous*	135	-0.04 (-0.08 to -0.01)	0.027
➢ *Nulliparous*	104	-0.01 (-0.06 to 0.03)	

a Adjusted for baseline BMI and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Baseline and 24 months postpartum BMI data used in the model were on the log scale.
c The interaction between subgroup and trial group- compares the intervention effect in the presented subgroups (e.g. <25 years vs. ≥ 25 years)
d Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.

4.6.2 Child BMI-for-age z-scores

Examination of the distribution of child BMI-for-age *z*-scores (Figure 9) indicated normal distribution for control group data, and slightly negatively skewed distribution with the degree of non-normality within the limits of the methods planned. Multilevel linear regression was deemed appropriate for the primary analysis, and scores were left untransformed.

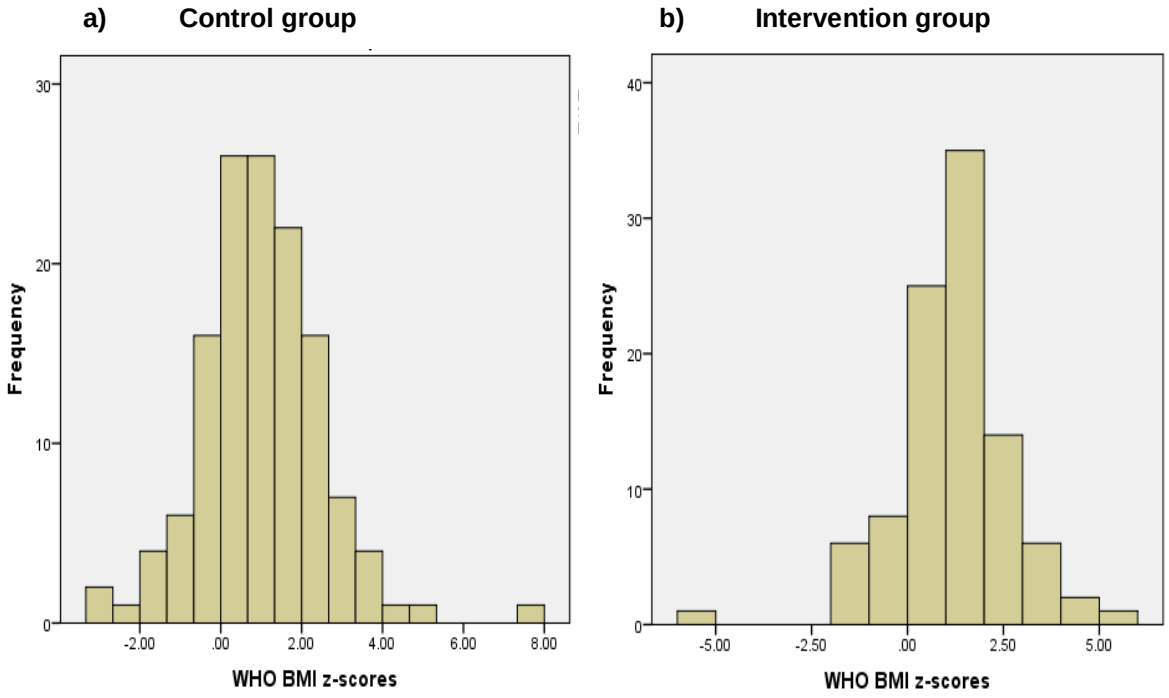

Figure 9: Histograms of child BMI-for-age z-scores by group

Of the 241 children, 231 (95.9%) had both weight measurements at birth, and weight and height measurements at follow-up, and were included in the analysis. Nine missing cases of follow-up weight or height measurements in the intervention group were due to: one scale malfunction, one follow-up being completed by telephone, one child refusing the measurement, and six cases of child absence during the home visit. One missing case of child height at follow-up in the control group was for an unknown reason. BMI-for-age *z*-score calculation was not possible and these cases were excluded. As there were only 10 cases no imputation was necessary.

Based on the WHO growth reference standard used to measure BMI-for-age *z*-scores, it was expected that the range of values would fall between -3.0 and 3.0, with a median value of 0, and

values above and below this interpreted as distance from the average. However, the data collected in this population indicated 21 outlier values outside this range (<-3= 1; >3= 20 suggesting that this population differed to the reference population on which the growth standard was developed, although this could also indicate measurement error. The primary analysis was adjusted for birth weight to account for the small imbalance between groups, as described in section 4.5.2. The calculation of BMI-for-age *z*-scores had accounted for the differences seen in child age at follow-up.

The analysis of complete cases for the primary outcome of child BMI-for-age *z*-scores (Table 17), which adjusted for birth weight and cluster randomisation variables, found no evidence for a difference in mean child BMI-for-age *z*-scores for children of mothers allocated to the intervention group (1.22) compared with children of mothers in control (1.03) (adjusted difference in means: 0.24, 95% CI -0.17 to 0.64; p= 0.250). Excluding the 21 outlier values did not change the conclusions drawn from the analysis.

Table 17: Primary outcome of child BMI-for-age z-scores by group

	Intervention		Control				
	N 107	**Mean (SD)**	**N 134**	**Mean (SD)**	**ICC**	**Adjusted[a] intervention effect[b] (95% CI)**	**p-value**
BMI-for-age *z*-scores	98	1.22 (1.5)	133	1.03 (1.5)	0.06	0.24 (-0.17 to 0.64)	0.250

a Adjusted for birthweight and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).

There were 19 clusters in total, with an average cluster size of 9 (range 1 to 23) and the unadjusted ICC was 0.06. The ICC value of the unadjusted data, without randomisation variables or covariates, indicated that there was some clustering of the primary outcome of BMI-for-age *z*-scores. The adjusted ICC was <0.001.

Model Checking

The chosen model was deemed to be suitable and a reasonable fit for the data, as the residuals mostly sit on the line (Figure 10) and are normally distributed with 95% of residuals indicated to be between -1.96 and 1.96 (11/231 lie outside this range= 4.76%) (Figure 11).

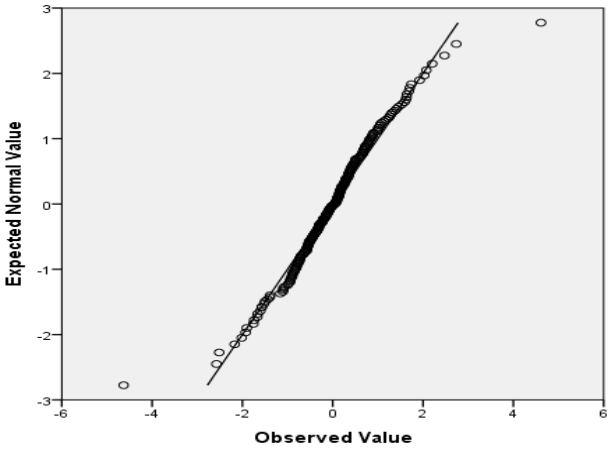

Figure 10: Standardised residuals from linear models of child BMI-for-age z-scores

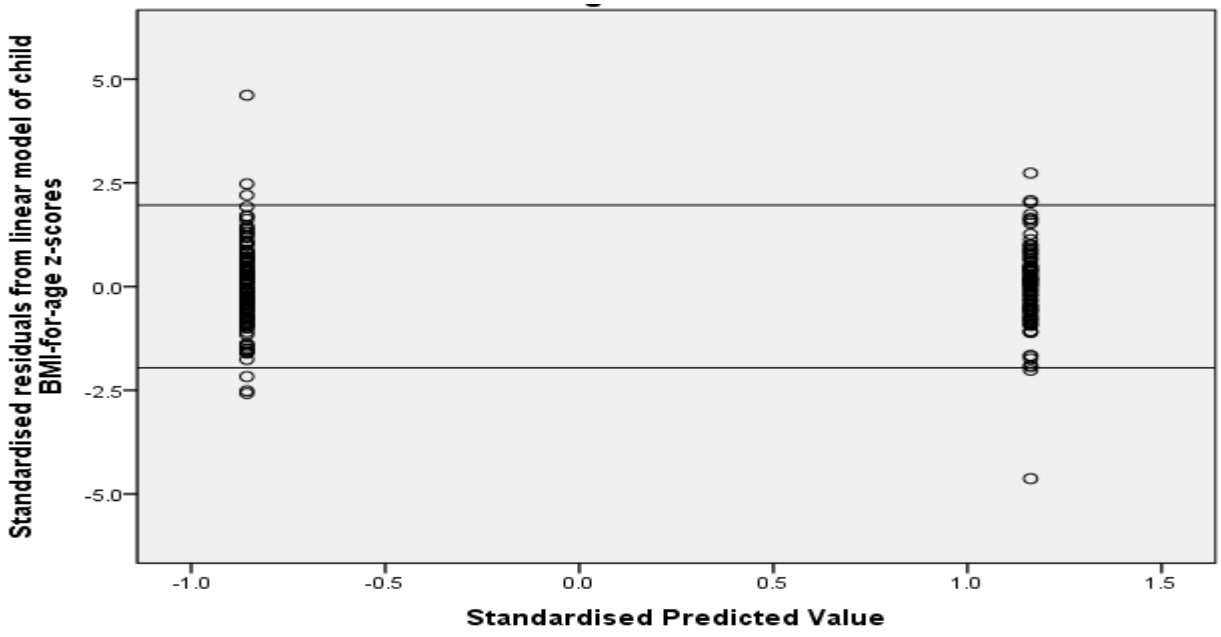

Figure 11: Residual plot of standardised predicted and residual values for child BMI-for-age z-scores

Secondary Analyses

Child BMI was examined as percentiles and by applying thresholds, which were overweight or obesity (≥85th) versus healthy weight or underweight (<85th). Based on the UK90 growth reference used to calculate BMI percentiles, it was expected that the range of values would fall between 0 to 100, with a median value of 50, and values above and below this interpreted as distance from the average. Mean BMI percentile was slightly higher in the intervention group compared with control (Table 18) However, there was no evidence of a statistical difference between the groups. For the categorisation of child BMI percentiles into thresholds, the OR is the odds of being overweight or obese in the intervention group compared with the control group. Children of mothers randomised to the intervention were more likely to be overweight or obese (OR: 1.70, 95% CI 0.95 to 3.04, p=0.072). However, CIs around this estimate were wide indicating no evidence of a statistical difference between groups.

Table 18: Secondary analyses of child BMI percentiles and thresholds by group

	Intervention N 107	Mean (SD) or N (%)	Control N 134	Mean (SD) or N (%)	ICC	Adjusted[b] intervention effect (95% CI)	p-value
BMI percentile *Range*	98	77.5 (26.6) *0- 100*	133	72.2 (29.1) *0- 100*	-	0.09 (-0.15 to 0.33)[a,c]	0.453
BMI thresholds *(% overweight/ obese)*	98	58 (59.2)	133	64 (48.1)	0.09	1.70 (0.95 to 3.04)[d]	0.072

a Data used in the model were on the log scale.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.
d Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

The inclusion of clusters was the same as for the primary outcome. For percentiles the ICC was <0.0001, but the impact of clustering was slightly higher for the percentile thresholds outcome (adjusted ICC= 0.09).

Sensitivity analyses

A sensitivity analysis was conducted to adjust the regression model for maternal GWG as, based on the evidence presented in Chapters 1 and 2, it was determined that this could have an impact on child weight status. Mean GWG (kg) in the intervention group was 6.14 kg (4.9),

compared with 7.70 kg (4.6) in the control. Adjusting for maternal GWG did not alter the results (Appendix L).

Subgroup Analyses

Pre-planned subgroup analyses were conducted examining appropriate interaction terms in the regression model to assess any influences on the difference between the intervention and control groups. The following birth and early feeding subgroups were examined: delivery mode (vaginal/ instrumental and caesarean), gestation at birth (<37 weeks/ ≥ 37 weeks), feeding history (breastfed/ not breastfed) and, if applicable, breastfeeding duration (<9 weeks/ ≥ 9 weeks) (Table 19). Delivery mode, gestation and breastfeeding duration were recoded into two groups for this analysis. Delivery mode, gestation at birth and feeding history, showed no differential effects of the intervention and control groups across the subgroups. Duration of breastfeeding was only performed in a sub sample of children. There was evidence of a significant difference in intervention effect in children breastfed <9 weeks vs. ≥9 weeks, with those breastfed for <9 weeks being of higher than average weight in the intervention group compared to the control, and vice versa in those ≥9 weeks.

Table 19: Subgroup analyses of intervention effect on child BMI-for-age z-scores

Subgroups	N	Adjusted[a] intervention effect[b,c] (95% CI)	Interaction p-value
Delivery Mode			
➢ *Vaginal/ instrumental*	168	0.20 (-0.43 to 0.82)	0.536
➢ *Caesarean section*	72	0.66 (0.10 to 1.22)	
Gestation at birth			
➢ *< 37 weeks*	13	-0.53 (-0.67 to 1.72)	0.386
➢ *≥ 37 weeks*	227	-1.34 (-2.76 to 0.08)	
Feeding history			
➢ *Not breastfed*	73	-0.36 (-1.02 to 0.29)	0.280
➢ *Breastfed*	166	0.37 (-0.19 to 0.92)	
Duration breastfeeding			
≥ 9 weeks	93	0.78 (0.07 to 1.49)	0.031
< 9 weeks	64	-0.15 (-0.85 to 0.55)	

a Adjusted for birthweight and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b The interaction between subgroup and trial group- compares the intervention effect in the presented subgroups (e.g. vaginal and instrumental vs. caesarean section)
c Intervention effect was an adjusted difference in means (intervention minus control).

4.7 Secondary Outcomes

4.7.1 Maternal body composition: weight, waist and hip

Weight (kg) at 24 months postpartum was explored to aid the interpretation of the primary outcome of maternal BMI. Weight data were skewed so were log transformed for linearity regression. The analysis of weight supported the primary outcome findings as it suggested there was a non-significant reduction in weight in the intervention group, compared with control, after adjusting for baseline weight and cluster level variables, -0.01 (-0.04 to 0.02), p= 0.592 (Table 20). Maternal height was added as a covariate, but this did not change the conclusions.

The control group showed lower mean waist circumference (103.7 cm) compared with intervention (109.3 cm) at 24 months postpartum (adjusted difference in means= 5.83cm (1.67 to 9.98), p= 0.006) (Table 20). There were six extreme measurements (control: 2, intervention: 4). A sensitivity analysis was conducted which excluded these values, and although this slightly attenuated the difference seen between the groups, (4.50 cm (0.83 to 8.16), p=0.016), this difference remained. There was no difference between groups in hip measurements but there was evidence to suggest that women in the control group also had lower waist-hip ratios (0.29 cm (0.01 to 0.06), p=0.042) and lower odds of having a high risk (≥0.85 cm) waist-hip ratio (2.44 (1.26 to 4.73), p= 0.008). There were 19 clusters in the analysis of maternal weight, (average cluster size: 9; range 1 to 23) and for the other outcomes presented in Table 20, analysis included 19 clusters (average cluster size: 9; range 1 to 21). The adjusted ICC values indicated some clustering.

Table 20: Maternal weight, waist and hip measurements at 24 months postpartum by group

	Intervention			Control				
	N	Baseline mean (SD)	24m mean (SD) or N (%)	N	Baseline mean (SD)	24m mean (SD) or N (%)	ICC	Adjusted[c] intervention effect (95% CI)	p-value
Weight *(kg)*	105	103.1 (18.2)	99.8 (21.4)	134	99.0 (16.3)	96.7 (19.6)	0.02	-0.01 (-0.04 to 0.02)[a,b,d]	0.592
Waist *(cm)*	106	-	109.3 (18.3)	132	-	103.7 (13.9)	0.07	5.83 (1.67 to 9.98)[e]	0.006
Hip *(cm)*	106	-	125.3 (15.9)	132	-	122.6 (13.6)	0.01	0.02 (-0.01 to 0.05)[b,d]	0.230
Waist-hip ratio *(cm)*	106	-	0.87 (0.8)	132	-	0.85 (0.7)	0.13	0.29 (0.01 to 0.06)[e]	0.042
Waist-hip ratio *N (% high risk)*	106	-	65 (61.3)	132	-	61 (46.2)	0.002	2.44 (1.26 to 4.73)[f]	0.008

a Further adjusted for baseline weight.
b Weight and hip circumference data used in the models were on the log scale.
c Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
d Intervention effect was interpreted as percentage difference in means (intervention minus control) due to log transformation.
e Intervention effect was an adjusted difference in means (intervention minus control).
f Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

4.7.2 Maternal health behaviours

Maternal diet

Maternal dietary intake was assessed by DINE plus questions measuring fizzy drinks, added sugars and sweets. Higher scores for 'healthy eating', 'fibre', and 'fruits and vegetables' indicate a better-quality diet, higher scores for 'fat' and 'unsaturated fat', indicate poorer diet quality. DINE fibre scores range from 2 to 176, with scores defined as: <30= low intake, 30 to 40= medium intake, >40= high intake. DINE fat scores range from 7 to 122, with scores defined as: <30= low intake, 30 to 40= medium intake, >40= high intake. The healthy eating score is calculated from these two scores (fibre minus fat) and can range from -120 to 169). DINE unsaturated fat scores range from 3 to 12, with scores defined as: <6= low intake, 6 to 9= medium intake, >9= high intake. High fruit and vegetable consumption= >5. There was no

evidence of an intervention effect for any of the maternal diet measures at 24 months postpartum (Table 21). There were 19 clusters in the analysis of maternal diet outcomes in Table 21 (average cluster size: 9; range 1 to 23), with exception of the healthy eating score analysis which included 18 clusters (average cluster size: 9; range 2 to 18). The adjusted ICC values were <0.0001.

Table 21: Maternal diet by group

	Intervention		Control				
	N 107	**Mean (SD) or N (%)**	**N 134**	**Mean (SD) or N (%)**	**ICC**	**Adjusted[a] intervention effect (95% CI)**	**p-value**
DINE Healthy Eating	107	8.0 (13.2)	134	5.8 (13.1)	-	2.15 (-1.36 to 5.67)[b]	0.229
Range		*-28.0 - 39.0*		*-26.0 – 52.0*			
DINE Fibre	107	30.4 (10.8)	134	28.0 (12.3)	-	2.51 (-0.58 to 5.61)[b]	0.111
Range		*7 - 60*		*2 – 69*			
DINE Fat	107	22.4 (7.2)	134	22.2 (8.4)	-	0.36 (-1.73 to 2.45)[b]	0.733
Range		*9 - 42*		*7 – 44*			
DINE Unsaturated Fat	107	9.5 (1.7)	134	9.6 (1.6)	-	-0.14 (-0.58 to 0.29)[b]	0.515
Range		*3 – 12*		*5 - 12*			
DINE Fruit & Vege	107	5.2 (2.7)	134	5.5 (2.6)	-	-0.16 (-0.86 to 0.54)[b]	0.660
Range		*0 – 16*		*0 - 16*			
Fizzy drinks *(cans per day)*	107	0.3 (0.7)	134	0.4 (1.2)	-	-0.1 (-0.3 to 0.2)[b]	0.573
Added sugar *(tsp per day)*	107	1.0 (3.2)	134	1.1 (2.2)	-	-0.2 (-0.9 to 0.6)[b]	0.662
Sweet consumption (% weekly or more)	107	32 (29.9)	134	35 (26.1)	-	1.20 (0.66 to 2.20)[c]	0.549

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).
c Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Missing DINE responses were coded as 'none' (i.e. none consumed) for the primary analysis. An examination of missing responses by group was undertaken. There was a higher rate of missing responses in the control group across the DINE scale (4.2%) compared with intervention (2.1%). As a result of this difference between groups, a secondary analysis was conducted with blank responses coded as missing. This did not change the conclusions drawn from the analyses of DINE scores. Site differences were noted in the levels of missing data, with two sites making up a large proportion of missing cases, so this was likely a due to a measurement issue. Cases were missing at random.

Maternal PA

A higher 7-day PAR score of energy expenditure (kcal/kg/day) was interpreted as greater PA. The median (IQR) score was higher in the intervention group (1132.9 kcal/kg/day (825.0- 1256.1)) compared with control (993.3 kcal/kg/day (825.0- 1260.7)). The distribution of scores was impacted by extreme values in both groups (Figure 12), which would likely bias a linear regression multilevel model as they would affect the estimated regression co-efficients. Transforming the data was not shown to linearise the scores, instead PA scores were converted to a binary variable using the sample median (1050.0 kcal/kg/day) as a cut-off for lower/ higher PA and analysed using a logistic regression multilevel model (Table 22).

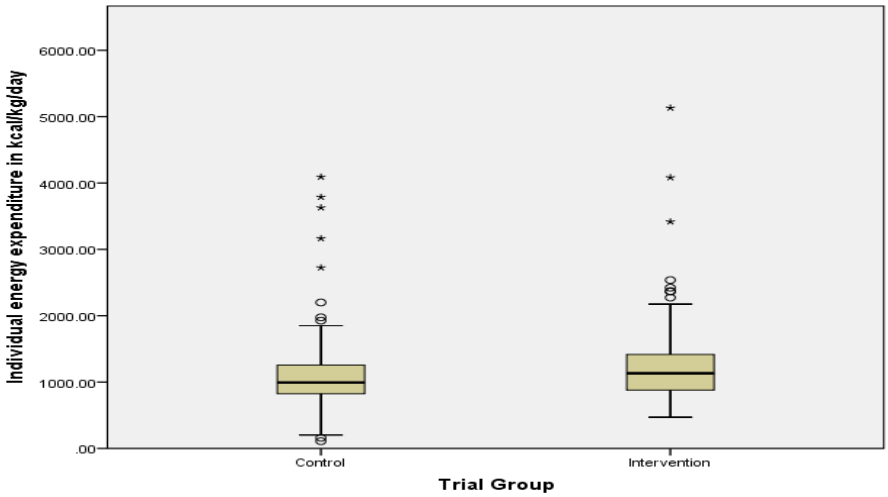

Figure 12: Box plots of maternal PA scores by group

In the intervention group, 57.1% of women had higher PA, compared with 44.0% of women in control. There was some evidence of a between groups difference in the odds of reporting equal to or greater than average maternal PA (OR= 2.61 (0.90 to 7.57), p= 0.077), although the CIs were too wide to consider this a true intervention effect. There were 19 clusters in the analysis of maternal PA (average cluster size: 9; range 1 to 23), and there was some clustering (adjusted ICC= 0.17).

Table 22: High and low daily energy expenditure by group

7-day PAR	Intervention		Control				
	N 107	N (%)	N 134	N (%)	ICC	Adjusted[a] OR[c] (95% CI)	p-value
Energy expenditure *(% higher PA)*	105	60 (57.1)	134	59 (44.0	0.17	2.61 (0.90 to 7.57)	0.077

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Unable to calculate score for two cases due to missing weight data.
c Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Alcohol Consumption

The AUDIT-C measure was used to assess alcohol consumption through three variables: frequency, quantity and binge drinking. Women were categorised as high risk or low risk for each variable. It was not possible to compare the groups for high risk drinking based on frequency (≥4 days per week) as the numbers were too small (control: n= 3 (2.2%), intervention: n= 0 (0.0%). There was no evidence of a difference between the groups in the odds of women engaging in drinking risky quantities or binge drinking (Table 23). There were 18 clusters in the analysis of drinking quantity (average cluster size: 9; range 3 to 19) and 19 clusters in the analysis of binge drinking (average cluster size: 9; range 1 to 19). The adjusted ICCs values were <0.0001.

Table 23: Maternal alcohol consumption by group

	Intervention		**Control**				
AUDIT-C[a]	**N 107**	**N (%)**	**N 134**	**N (%)**	**ICC**	**Adjusted[c] OR[d] (95% CI)**	**p-value**
High risk drinking quantity *(≥3 drinks / occasion) (% yes)[b]*	72	33 (45.8%)	101	42 (41.6%)	-	0.98 (0.49 to 1.95)	0.956
Missing		*5*		*1*			
High risk binge drinking *(≥1 occasion / month) (% yes)[b]*	77	48 (62.3%)	102	65 (63.7%)	-	0.88 (0.45 to 1.73)	0.712

a Unable to use original AUDIT-C scoring due to wording error. Individual item scores categorised into binary outcomes
b Question only applicable to drinkers. For those who indicated they 'never drank' this response was coded as missing.
c Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
d Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Smoking Behaviours

Women reported whether they currently smoked and, if so, how many cigarettes per day. There were 200 cases of non-smokers, where the value of 'cigarettes per day' was assumed to be zero and were excluded from analysis. There was no missing data for 'cigarettes per day' for women who indicated they were smokers.

Women in the control group were statistically more likely to be current smokers (adjusted OR 0.30 (0.13 to 0.71); p=0.007) (Table 24). There was also a significant difference in number of cigarettes smoked per day but this was lower in the control group by 0.5 of a cigarette per day (adjusted percentage difference 0.92, 95% CI 0.3 to 1.5; p= 0.004). There were 19

clusters in the current smoker analysis (average cluster size: 9; range 1 to 23), but 15 clusters in the cigarettes per day analysis (average size: 12; range 1 to 6). There was low clustering in these variables.

Table 24: Maternal smoking by group

	Intervention		Control				
	N 107	Median (IQR) or N (%)	N 134	Median (IQR) or N (%)	ICC	Adjusted[c] intervention effect (95% CI)	p-value
Current smoker *(% yes)*	107	10 (9.3)	134	31 (23.1)	0.006	0.30 (0.13 to 0.71)[d]	0.007
Cigarettes *(per day)*[a]	10	10.5 (9.5-14)	31	10 (4-13)	-	0.92 (0.3 to 1.5)[b,e]	0.004

a Question only applicable to smokers. For those who indicated they were not current smokers this response was coded as missing.
b Data used in the model were on the log scale.
c Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
d Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.
e Intervention effect was interpreted as percentage difference due to log transformation.

4.7.3 Maternal mental health and HRQoL

Mental health

Maternal mental health was scored in two ways: first, a GHQ-12 score was obtained (minimum 0 to maximum 12), a higher score indicating poorer mental health. Second, thresholds were applied to these scores to assess presence (≥2) or absence (<2) of 'psychological distress'. There was no evidence of a difference between the groups in these measures of mental health (Table 25). There were 19 clusters (average cluster size: 9; range 1 to 23) in the both analyses, and the adjusted ICCs values were <0.0001.

Table 25: Maternal mental health by group

GHQ-12	Intervention		Control				
	N 107	Mean (SD) or N (%)	N 134	Mean (SD) or N (%)	ICC	Adjusted[a] intervention effect (95% CI)	p-value
Mental health score *Range*	106	2.5 (3.3) *0- 12*	131	2.4 (3.5) *0- 12*	-	-0.14 (-1.07 to 0.77)[b]	0.750
Psychological distress *(% present)*	106	47 (44.3%)	131	52 (49.1%)	-	1.11 (0.64 to 1.92)[c]	0.720

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).
c Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

HRQoL

Due to skewed distribution, EQ-5D index scores were categorised into 'perfect health' (=1) and 'less than perfect health' (<1) and analysed using a logistic regression multilevel model (Table 26). The EQ-5D VAS scored 'health state' on a scale of 0-100, with a higher score indicating better health. Also skewed, this data was log transformed for multilevel linear analysis (Table 26). Women in the intervention group had lower HRQoL, but there was no evidence of a significant difference between groups on either of these measures. There were 19 clusters (average cluster size: 9; range 1 to 22) in the index scores analysis, and the same with a range of 1-23 in the VAS analysis.

Table 26: Maternal HRQoL by group

EQ-5D	Intervention		Control				
	N 107	Mean (SD) or N (%)	N 134	Mean (SD) or N (%)	ICC	Adjusted[a] intervention effect (95% CI)	p-value
Index scores *(% perfect health)*	106	63 (59.4)	133	75 (56.4)	-	1.04 (0.58 to 1.87)[b]	0.901
Health state (VAS) *Range*	105	67.2 (19.2) *3- 97*	133	71.0 (20.7) *10- 100*	-	-0.15 (-0.55 to 0.25)[c,d]	0.456

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.
c Data used in the model were on the log scale.
d Intervention effect was interpreted as percentage difference due to log transformation.

4.7.4 Theoretical outcomes related to behaviour change

Social Support for Diet

The six variables collected using the SSEH were examined as continuous outcomes. Due to skewed distributions, the SSEH variables were converted to binary measures according to women's reports of receiving any encouragement (positive social support) and sabotage (negative social support) for a healthy diet, from family and friends. These binary outcomes were analysed using multilevel logistic regression (Table 27).

Women in the intervention group were more likely to report receiving encouragement from family for eating habits (intervention: 53.3%, control: 48.5%), but were also more likely to report receiving sabotage from family when trying to maintain a healthy diet (intervention: 26.5%, control: 20.0%). Although the odds of both of these aspects of social support were greater in the intervention group, the CIs were wide around the estimate so it is unlikely that these are significant differences. Furthermore, there were no differences between the groups in the combined variables indicating overall social support for these aspects of maintaining a healthy diet. There were 19 clusters (average cluster size: 9; range 1 to 21) included in analysis of the SSEH variables. The adjusted ICCs were <0.0001.

Table 27: Maternal social support for eating habits by group

SSEH	Intervention		Control		ICC	Adjusted[b] OR[c] (95% CI)	p-value
	N 107	N (%)	N 134	N (%)			
% receives some:	[a]		[a]				
Encouragement:							
Family	107	57 (53.3)	130	63 (48.5)	-	1.06 (0.61 to 1.84)	0.845
Friends	100	27 (27.0)	126	37 (29.4)	-	0.87 (0.47 to 1.61)	0.654
Combined	100	29 (29.0)	126	36 (29.0)	-	0.87 (0.47 to 1.61)	0.647
Sabotage:							
Family	102	27 (26.5)	130	26 (20.0)	-	1.33 (0.69 to 2.58)	0.398
Friends	85	9 (10.6)	122	16 (13.1)	-	0.83 (0.31 to 2.24)	0.716
Combined	85	8 (9.4)	122	19 (15.6)	-	0.55 (0.20 to 1.48)	0.237

a Analysed numbers exclude participants who responded 'not applicable'.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Social Support for Exercise

As with the SSEH, the distribution of SSEX variables was skewed, so these were converted to binary measures in the same way, creating nine variables of social support for exercise related to participation, support (positive social support), and punishment (negative social support), from family and friends. A multilevel logistic regression was used for analysis (Table 28).

It was not possible to compare the groups for friends' punishment (intervention: 0 (0.0%), control: 1 (0.9%), or combined punishment (intervention: 1 (1.1%), control: 2 (1.7%) for exercise, as numbers reporting receiving this negative social support were too small. Women in the intervention group consistently reported receiving more positive support, participation and support, from friends and family, compared with control. There was some evidence to suggest that there was a true difference between groups in participation from family, and family combined with friends, in favour of the intervention group. There was no evidence of clustering (ICCs <0.0001). There were 19 clusters (average cluster size: 9; range 1 to 21) included in analysis of the SSEX variables.

Table 28: Maternal social support for exercise by group

	Intervention		**Control**				
SSEX	**N**	**N (%)**	**N**	**N (%)**	**ICC**	**Adjusted[b] OR[c]**	**p-value**
	107		**134**			**(95% CI)**	
% receives some:	[a]		[a]				
Participation							
Family	105	61 (58.1)	129	45 (34.9)	-	2.94 (1.64 to 5.30)	<0.001
Friends	95	36 (37.9)	122	36 (29.5)	0.03	1.29 (0.64 to 2.60)	0.481
Combined	95	35 (36.8)	121	21 (17.4)	-	2.87 (1.45 to 5.69)	<0.003
Support							
Family	102	69 (67.6)	26	81 (64.3)	-	1.43 (0.77 to 2.65)	0.261
Friends	94	43 (45.7)	119	45 (37.8)	-	1.46 (0.81 to 2.65)	0.208
Combined	94	42 (44.7)	119	47 (39.5)	-	1.40 (0.78 to 2.54)	0.262
Punishment							
Family	104	10 (9.6)	125	9 (7.2)	-	2.68 (0.50 to 14.44)	0.252

a Analysed numbers exclude participants who responded 'not applicable'.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Motivation for healthy diet and regular exercise, and self-regulation for health

The impact of the intervention on women's self-regulation for diet, exercise and health were assessed. Higher scores suggest better intrinsic motivation and self-regulation for diet (TSRD: min 0 to max 6), exercise (TSRE: min 0 to max 6) and maintaining health (SRQ: min 5 to max 40). There was no evidence of a between groups difference in the reported autonomy and self-regulation for diet, exercise or health (Table 29). There were 19 clusters (average cluster size: 9; range 1 to 23) included in analysis of TSRD score, 19 clusters (average cluster size: 9; range 1 to 21) in the analysis of TSRE score, and 19 clusters (average cluster size 9; range 1-22) in the analysis of SRQ. The adjusted ICCs were <0.0001.

Table 29: Maternal motivation for diet and exercise, and self-regulation for health by group

	Intervention		**Control**				
	N 107	**Mean (SD)**	**N 134**	**Mean (SD)**	**ICC**	**Adjusted[a] difference in means[b] (95% CI)**	**p-value**
TSRD score *Range*	107	2.2 (1.3) *-1.33- 5.67*	133	2.4 (1.3) *-0.83- 5.67*	-	-0.18 (-0.54 to 0.17)	0.313
TRSE score *Range*	103	2.3 (1.4) *-1.0- 6.0*	128	2.6 (1.4) *-0.17- 5.83*	-	-0.25 (-0.62 to 0.13)	0.201
SRQ score *Range*	107	27.2 (6.0) *5- 39*	131	27.6 (5.4) *15- 40*	-	-0.38 (-1.89 to 1.14)	0.625

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).

Self-efficacy for weight control and exercise

Women's self-efficacy for controlling weight (WEL score: min 0 to max 180) and exercise (MSES score: min 1 to max 10) were examined. Lower scores were interpreted as lower self-efficacy. There was no evidence of a difference between groups in self-efficacy for weight control and exercise (Table 30). There were 19 clusters (average cluster size: 9; range 1 to 23) included in the analysis of both outcomes. The adjusted ICCs were <0.0001.

Table 30: Maternal self-efficacy for weight and exercise by group

	Intervention		Control				
	N 107 [a]	Mean (SD)	N 134 [a]	Mean (SD)	ICC	Adjusted[b] difference in means[c] (95% CI)	p-value
WEL score	103	107.5 (26.3)	131	115.1 (34.6)	-	-7.32 (-15.8 to 1.1)	0.089
Range		*41- 175*		*17- 180*			
MSES score	102	5.6 (1.9)	128	5.6 (1.9)	-	0.02 (-0.50 to 0.54)	0.941
Range		*1- 10*		*2-10*			

a Analysed numbers exclude participants who responded 'not applicable'.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was an adjusted difference in means (intervention minus control).

Self-monitoring behaviours

Examination of self-monitoring weight and diet behaviours, showed no difference in the proportions of women who weighed themselves infrequently (less than once a week) (Table 31), but the odds of women reporting monitoring of food intake was higher in the intervention group (intervention: 42.5%, control: 32.8%), although this was unlikely to be a significant difference based on the CI around the estimate, 1.80 (1.00 to 3.24), p= 0.051. There were 19 clusters (average cluster size: 9; range 1 to 23) included in the analysis of both outcomes, and the adjusted ICCs were <0.0001.

Table 31: Maternal self-monitoring by group

	Intervention		Control				
	N 107	N (%)	N 134	N (%)	ICC	Adjusted[a] OR[b] (95% CI)	p-value
Self-weighs *(% less often than weekly)*	105	40 (38.1)	132	63 (47.7)	-	0.71 (0.41 to 1.25)	0.242
Monitors diet *(% yes)*	106	45 (42.5)	134	44 (32.8)	-	1.80 (1.00 to 3.24)	0.051

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

Weight control

Higher perceptions of the importance of weight control, as well as the confidence to control weight was considered positive enablers of behaviour change. In addition, engaging in more strategies to control weight was considered positive in attempting to improve health. There

were no between group differences in these measures of weight control (Table 32). Almost 62% of women in both groups reported making some attempts to control their weight. There were 19 clusters (average cluster size: 9; range 1 to 23) included in the analysis of these outcomes, and no evidence of clustering.

Table 32: Maternal perceptions of weight control by group

	Intervention		**Control**				
	N 107	**N (%)**	**N 134**	**N (%)**	**ICC**	**Adjusted[a] OR[b] (95% CI)**	**p-value**
Importance *(% important or higher)*	106	97 (91.5)	134	113 (84.3)	-	2.57 (0.99 to 6.67)	0.052
Confidence *(% confident or higher)*	106	60 (56.6)	134	79 (59.0)	-	0.83 (0.48 to 1.46)	0.526
Attempts *(% yes)*	107	66 (61.7)	134	83 (61.9)	-	1.02 (0.57 to 1.83)	0.948
Strategies used[c] *(% use):*							
➢ Commercial weight loss groups	65	51 (78.5)	83	70 (84.3)	-	1.49 (0.18 to 1.35)	0.168
➢ Physical activity	65	31 (47.7)	83	29 (34.9)	0.17	2.19 (0.64 to 7.50)	0.212
➢ Apps or online resources	65	16 (24.6)	83	23 (27.7)	0.02	0.71 (0.29 to 1.75)	0.462
➢ Devices or equipment	65	9 (13.8)	83	10 (12.0)	-	1.28 (0.42 to 3.90)	0.665

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.
c Question only applicable to those who attempted to control weight. For those who indicated they did not these responses were coded as missing.

4.7.5 Maternal behaviours and child outcomes (study child and subsequent infant)

Breastfeeding behaviour (study child)

There were nine missing cases of breastfeeding duration (control: 8, intervention: 1) where the participant had indicated that they initiated breastfeeding but did not provide a response for breastfeeding duration; these cases were excluded from the analysis (Table 33).

In total, 11 women were still breastfeeding at follow-up, intervention: 6 (5.6%), control: 5 (3.7%). There was a slightly higher rate of breastfeeding initiation in the intervention group compared with control (71.7 vs 67.7%). Whereas, breastfeeding duration was slightly longer in the control group (28.1 vs. 26.3 weeks). These differences were non-significant. There were 19 clusters (average cluster size: 9; range 1 to 23) included in the analysis of current breastfeeding initiation, the range dropped to 1-22 for breastfeeding duration. There was no evidence of clustering.

Table 33: Breastfeeding for study child by group

	Intervention		Control				
Study Child Breastfeeding	**N 107**	**Mean (SD) or N (%)**	**N 134**	**Mean (SD) or N (%)**	**ICC**	**Adjusted[a] intervention effect (95% CI)**	**p-value**
Still breastfeeding *(% yes)*	107	6 (5.6)	134	5 (3.7)	-	3.47 (0.39 to 30.58)[b]	0.262
Breastfeeding initiated *(% yes)*	106	76 (71.7)	133	90 (67.7)	0.04	1.36 (0.65 to 2.83)[b]	0.417
Breastfeeding duration[c] *(weeks)*	75	26.3 (31.7)	82	28.1 (29.5)	-	0.02 (-0.38 to 0.41)[d,e]	0.933

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.
c Where participants indicated that they did not initiate breastfeeding, breastfeeding duration was assumed to be zero and these values were excluded from the analysis (n= 73).
d Data used in the model were on the log scale.
e Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.

Subsequent pregnancy outcomes (another infant)

Where the participant had indicated that they had not had another baby since the study child, they were excluded from the analysis of subsequent infant outcomes (n= 222). The number of subsequent pregnancies was too low to conduct any reliable comparisons. Table 34 describes the outcomes related to subsequent pregnancies between the groups. There were 18 pregnant women at the time of follow-up, nine in each group; and 19 women had given birth to another baby (intervention: 12 (11.2%), control: 7 (5.2%). The mean age (weeks) of these infants, was older in the control group (35.4), compared with intervention (18.7); 16 of infants had been born within the year prior to follow-up (intervention: 12 (100%), control: 4 (57.1%). No formal examination of the impact on the primary outcome was conducted. This will be discussed in terms of the study findings.

In relation to subsequent infant outcomes, women in the intervention group had higher rates of vaginal delivery (planned: 100%, actual: 75%), compared with control (planned: 57.1%, actual: 28.6%). Seven women in the intervention were breastfeeding this infant (58.3%), compared with 1 (14.3%) in control, although control infants were older, making it more likely that mothers would have stopped breastfeeding. However, a greater proportion of women in the intervention group indicated breastfeeding initiation (91.7% vs 57.1%). There was one missing case of breastfeeding duration in the control group, where the participant had indicated that they initiated breastfeeding, but did not provide a response for breastfeeding duration. This case was excluded.

Table 34: Subsequent pregnancies by group

Subsequent pregnancy outcomes	Intervention		Control	
	N 107	Mean (SD) or N (%)	N 134	Mean (SD) or N (%)
Currently pregnant *(% yes)*	107	9 (8.4)	134	9 (6.7)
Had another baby *(% yes)*	106	12 (11.2)	144	7 (5.2)
➢ Planned delivery method *(% vaginal)*	12	12 (100)	7	4 (57.1)
➢ Actual delivery method *(% vaginal)*	12	9 (75.0)	7	2 (28.6)
➢ Still breastfeeding *(% yes)*	12	7 (58.3)	7	1 (14.3)
➢ Breastfeeding initiated *(% yes)*	12	11 (91.7)	7	4 (57.1)
➢ Breastfeeding duration *(weeks)*	11	12.6 (11.1)	3	17.3 (22.4)

4.7.6 Child weight

Child weight (kg) was explored to aid the interpretation of the primary outcome of child BMI-for-age *z*-scores (Table 35). There was no evidence of a difference between groups for child weight at 24 months postpartum, after adjusting for birthweight, age at follow-up and randomisation balancing factors. There were 19 clusters (average cluster size: 9; range 1 to 23) included in this analysis. The adjusted ICC was <0.0001.

Table 35: Child weight at age 24 months by group

	Intervention		Control				
	N 107	Mean (SD)	N 134	Mean (SD)	ICC	Adjusted[a] intervention effect[b] (95% CI)	p-value
Weight *(kg)*	101	13.8 (1.8)	134	13.2 (1.6)	-	0.25 (-0.19 to 0.70)	0.262

a Adjusted for age, birthweight and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).

4.7.7 Child health behaviours

Dietary intake of obesity related foods and beverages

Data on intake of obesity related foods and beverages variables were scored as binary measures of those who consumed or did not consume the food or beverage. Fast food was measured on Likert scale and converted to ≥ once per week or < once per week. These variables were analysed using multilevel logistic regression (Table 36). Consumption of fruit, vegetables, water and plain milk were considered to be obesity-protective. Consumption of packaged snacks, confectionery/ chocolate, cakes/ biscuits, fast food, and sugar sweetened beverages (squash, fruit juice, flavoured milk) were considered to be obesity-promoting. There were no differences in consumption of these foods and beverages between the groups. There were 19 clusters (average cluster size: 9; range 1 to 21) included in the analysis of each of the foods and beverages. There was low clustering. In terms of the reliability of these outcomes to reflect general food intake habits, 78% of mothers reported that their responses reflected 'typical' consumption, with numbers comparable between the groups.

Table 36: Child dietary intake of obesity-related foods and beverages by group

EPAQ	Intervention		Control				
	N 107[a]	N (%)	N 134[a]	N (%)	ICC	Adjusted[b] OR[c] (95% CI)	p-value
Fruit *% consume*	107	100 (93.5)	132	120 (90.9)	-	1.12 (0.35 to 3.58)	0.845
Vegetables *% consume*	107	96 (89.7)	130	118 (90.8)	-	0.89 (0.38 to 2.10)	0.786
Packaged snacks *% consume*	106	55 (51.9)	131	81 (61.8)	-	0.68 (0.39 to 1.20)	0.184
Confectionery *% consume*	106	66 (62.3)	131	76 (58.0)	-	1.005 (0.57 to 1.78)	0.986
Cake/ Biscuits *% consume*	107	54 (50.5)	130	59 (45.4)	-	1.08 (0.62 to 1.88)	0.785
Fast food *% ≥ Once per week*	107	40 (37.4)	130	45 (33.6)	-	1.09 (0.62 to 1.93)	0.754
Fruit Juice *% consume*	107	31 (29.0)	134	53 (39.6)	-	0.72 (0.40 to 1.30)	0.279
Squash/ Soft drink % *consume*	107	84 (78.5)	133	89 (66.9)	0.02	1.50 (0.79 to 2.85)	0.221
Water *% consume*	106	73 (68.9)	132	90 (68.2)	0.01	1.39 (0.71 to 2.72)	0.335
Plain Milk *% consume*	107	92 (86.0)	133	110 (82.7)	-	1.55 (0.73 to 3.32)	0.257
Flavoured Milk *% consume*	107	12 (11.2)	134	16 (11.9)	-	0.75 (0.31 to 1.83)	0.532

a Analysed numbers exclude participants who responded 'don't know'.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

A further assessment of habitual mean fruit and vegetable consumption was conducted (servings per day) (Table 37). There was no evidence of a between groups difference. The analysis of fruit consumption included 18 clusters (average cluster size: 9, range 6 to 23) and the analysis of vegetables consumption included 19 clusters (9; 1 to 23). The adjusted ICC was <0.0001 for all variables except squash (ICC= 0.02).

Table 37: Child daily intake of fruits and vegetables by group

	Intervention		Control		ICC	Adjusted[a] intervention effect[b] (95% CI)	p-value
	N 107	Mean (SD)	N 134	Mean (SD)			
Fruit	103	2.70 (1.4)	129	2.78 (1.4)	-	-0.02 (-0.38 to 0.35)	0.931
Range		*1- 8*		*0- 8*			
Vegetables	103	2.50 (1.3)	129	2.52 (1.2)	-	0.03 (-0.30 to 0.36)	0.864
Range		*0- 8*		*0- 7*			

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).

Child physical activity (PA)

Parents reported the activities that their child engaged in each week, and the duration of each activity. Responses were combined to create a variable for total number of activities completed per week, and total minutes of activity per week. Higher scores represented greater levels of child PA. The two-level regression models did not indicate a difference between the groups in levels of child activity (quantity or duration) (Table 38). Parents in the intervention group reported that their child engaged in, on average, 12 hours of weekly activity; compared with 11 hours and 10 minutes in control. The analysis included 19 clusters (average size: 9; range 1 to 21). The adjusted ICC was <0.0001.

Table 38: Child PA by group

	Intervention		**Control**				
	N 107	**Mean (SD) or Median (25th-75th quartiles)**	**N 134**	**Mean (SD) or Median (25th-75th quartiles)**	**ICC**	**Adjusted[a] intervention effect (95% CI)**	**p-value**
Number of activities *(per week)*	107	3.46 (1.2)	134	3.33 (1.2)	-	0.22 (-0.10 to 0.55)[b]	0.178
Minutes of activity *(per week)*	103	720 (405- 1290)	124	670 (360- 1280)	-	0.18 (-0.06 to 0.42)[c,d]	0.144
Range		*120- 6600*		90- 3540			

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an adjusted difference in means (intervention minus control).
c Data used in the model were on the log scale.
d Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.

The maximum duration of weekly activity reported was 6,600 minutes (>15 hours) of activity per day. To explore the reporting of children's activity, the duration of different types of activity was examined (Table 39 and Figure 13). The highest level of reported activity was for indoor and outdoor play at home, with less time reported for more structured activities, such as swimming.

Table 39: Child PA by activity type and group

	Intervention group		Control group	
	N 107	Median (25th-75th quartiles)	N 134	Median (25th-75th quartiles)
Minutes/ week:				
Outdoor Play	95	180 (105- 420)	112	180 (92.5- 360)
Range		*30- 1900*		*20- 1500*
Indoor Play	88	340 (140- 840)	102	300 (120- 840)
Range		*30- 6000*		*20- 3360*
Soft Play	63	90 (60- 120)	64	120 (60- 120)
Range		*15- 600*		*30- 480*
Playgroup	51	120 (90- 360)	61	120 (60-360)
Range		*30- 3750*		*20- 2400*
Dance/ Music class	8	45 (30- 56.25)	12	52.5 (32.5- 112.5)
Range		*10- 60*		*30- 130*
Swim for fun	33	60 (32.5- 60)	47	45 (30- 60)
Range		*15- 90*		*20- 180*
Swimming lessons	12	30 (30- 30)	6	30 (30- 30)
Range		*20- 45*		*30- 30*

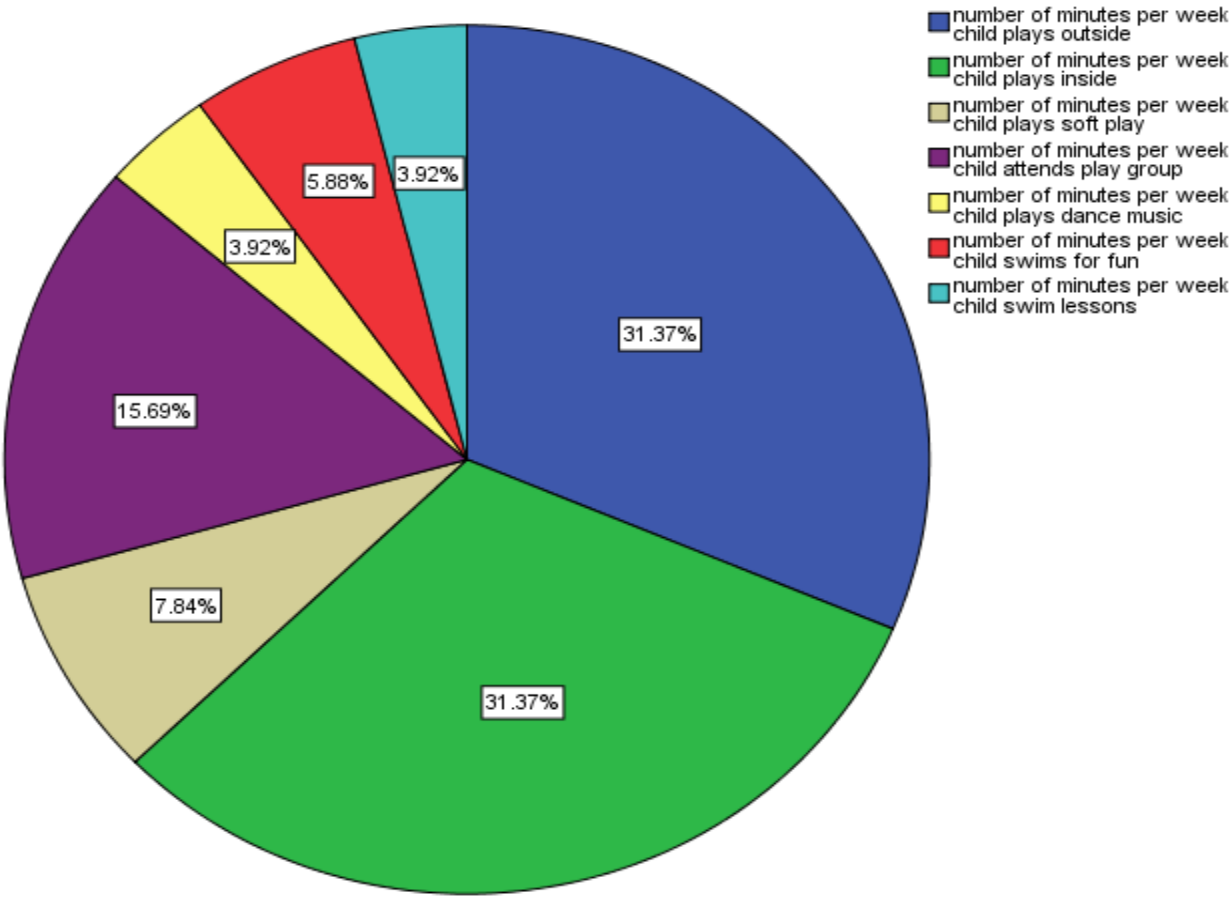

Figure 13: Pie chart of parent-reported child activity per week, by activity type

Child preference for spending free time

There was no difference between groups in the proportion of mothers who reported that their children preferred to spend time being active (Table 40). All 19 clusters (average size: 9; range 1 to 21) were included. The ICC was not possible to calculate in this analysis.

Table 40: Child preference for spending free time by group

EPAQ	Intervention		Control			
	N 107	N (%)	N 134	N (%)	Adjusted[a] RRR[b] (95% CI)	p-value
Preference for spending free time:	107		128			
➢ Being active		63 (58.9)		68 (53.1)	*Reference*	
➢ No preference		34 (31.8)		42 (32.8)	0.89 (0.47 to 1.69)	0.722
➢ Being inactive		10 (9.3)		18 (14.1)	0.51 (0.21 to 1.23)	0.146

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix, but clustering not examined.
b Intervention effect was a relative risk ratio (intervention compared with control). RRR >1 indicates that the outcome was higher in the intervention group compared with the control.

Sedentary behaviours

The child's daily screen time (number of minutes spent watching television, computers, smartphones) was assessed. A greater duration of these sedentary behaviours was considered to be an increasing risk for obesity development. The mean duration of screen time reported was lower in the intervention group (119.3 minutes), compared with control (143.2 minutes); but there was no evidence of a significant difference (Table 41). The analysis included 19 clusters (average cluster size: 9; range 1 to 23).

Table 41: Child screen time by group

EPAQ		Intervention	Control				
	N 107	Mean (SD)	N 134	Mean (SD)	ICC	Adjusted[b] intervention effect[c,d] (95% CI)	p-value
	[a]		[a]				
Screen time	104	119.3 (86.5)	127	143.2 (106.6)	-	-0.09 (-0.43 to 0.25)	0.602
Range		*0- 600*		0- 480			

a Analysed numbers exclude participants who responded 'don't know'.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Data used in the model were on the log scale.
d Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.

4.7.8 Family environment and support for child health behaviours

Mealtime environment

The family mealtime environment was assessed by three variables, by how often: the family ate meals together, children ate the same foods as adults, and the television was watched during dinner (Table 42). Eating meals as a family and the same foods responses were combined into binary variables. 'Mostly or always' engaging in these behaviours signalled a less obesogenic environment. The extent to which the child watched television during dinner was also assessed. Tv viewing 'every day' showed a high-risk environment for the development of obesity, 'sometimes' indicated a medium risk and 'never' indicated a less obesogenic environment. There were no between group differences shown in these measures of mealtime environment; 19 clusters (average cluster size: 9; range 1 to 23) were included.

Table 42: Family mealtime environment by group

	Intervention		**Control**				
	N 107	**Mean (SD) or N (%)**	**N 134**	**Mean (SD) or N (%)**	**ICC**	**Adjusted[a] intervention effect (95% CI)**	**p-value**
Family sit for meals together *(% mostly or always)*	107	80 (74.8)	134	97 (72.4)	-	1.11 (0.60 to 2.05)[b]	0.733
Adults have same food as study child *(% mostly or always)*	106	87 (81.3)	134	102 (76.1)	-	1.50 (0.75 to 3.02)[b]	0.255
TV during dinner:	107		130				
➢ Never		58 (54.2)		69 (53.1)		*Reference*	
➢ Sometimes		37 (34.6)		32 (24.6)		1.54 (0.81 to 2.95)[c]	0.188
(N per week)	37	2.2 (1.2)	32	2.5 (1.4)			
➢ Every day		11 (10.3)		27 (20.8)		0.41 (0.16 to 1.05)[c]	0.063

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix. Clustering not examined for categorical variables.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.
c Intervention effect was a relative risk ratio (intervention compared with control). RRR >1 indicates that the outcome was higher in the intervention group compared with the control group. Clustering not examined.

Parent-child activities

The extent to which a mother encouraged her child to be active by engaging in joint activity, suggesting a more health promoting environment, was assessed by three variables: playing actively with their child, taking their child for a walk, and taking their child to the park/ playground. The responses were combined into binary variables for analysis using a logistic regression multilevel model (Table 43). The numbers were too small in the reference group to assess differences in the extent to which parents actively played with their child, between groups. Most parents reported that they did this at least twice per week (intervention: 99.1%, control: 99.2%). There were no between group differences in the other measures of parent-child activities, 19 clusters (average cluster size: 9; range 1 to 23) were included in the takes child for a walk variable, the range dropped to 1 to 22 for the takes child to park analysis. There was no evidence of clustering.

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Table 43: Parent-child activities by group

	Intervention		**Control**				
	N 107	**N (%)**	**N 134**	**N (%)**	**ICC**	**Adjusted[a] OR[b] (95% CI)**	**p-value**
Takes child for walk *(% ≥ once per week)*	107	99 (92.5%)	132	125 (94.7%)	-	0.68 (0.23 to 2.03)	0.489
Takes child to park *(% ≥ once per week)*	86	86 (80.4%)	130	119 (91.5%)	0.02	0.39 (0.15 to 1.02)	0.055

a Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

4.7.9 Maternal feeding practices

The CFQ measured seven subscales of parent perceptions and practices in relation to child feeding, and higher scores (min: 1 to max: 5) indicated parents who held perceptions, or engaged in behaviours, that were more likely to promote obesity development. The distribution of each subscale was examined. Due to skewed distributions that were not improved by transformation, 'perceived parent weight' and 'perceived child weight' were converted to binary measures to categorise mothers who perceived their own and their child's weight as 'overweight' or not. These were analysed using multilevel logistic regression (Table 44).

The numbers were too small to assess between groups differences in the extent to which mothers perceived their child to be overweight or heavier (intervention: 2 (1.9%), control 2 (1.5%). Nearly all mothers perceived their child to be a healthy weight. There were no statistically significant differences between the groups in the other measures of maternal feeding practices assessed by the CFQ; 19 clusters (average cluster size: 9; range 1 to 23) were included and the adjusted ICCs were <0.0001.

Table 44: Maternal feeding practices (CFQ) by group

	Intervention		Control				
CFQ	**N 107**	**Mean (SD) or N (%)**	**N 134**	**Mean (SD) or N (%)**	**ICC**	**Adjusted[b] intervention effect (95% CI)**	**p-value**
Concern for child weight	107	1.95 (1.0)	133	1.83 (1.0)	-	0.11 (-0.02 to 0.23)[a,c]	0.087
Responsibility for feeding	104	4.61 (0.5)	132	4.52 (0.7)	-	0.03 (-0.02 to 0.07)[a,c]	0.288
Restriction	107	3.41 (0.8)	132	3.23 (0.8)	-	0.10 (-0.11 to 0.31)[d]	0.354
Pressure to eat	107	2.45 (1.0)	132	2.55 (1.0)	-	-0.05 (-0.18 to 0.07)[a,c]	0.385
Monitoring	106	4.21 (0.9)	132	4.23 (0.9)	-	-0.02 (-0.09 to 0.06)[a,c]	0.653
Perceived parent weight *(% overweight)*	106	35 (33.0)	130	41 (31.5)	-	1.24 (0.66 to 2.33)[e]	0.506

a Data used in the model were on the log scale.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.
d Intervention effect was an adjusted difference in means (intervention minus control).
e Intervention effect was an odds ratio (intervention compared with control). OR >1 indicates that the outcome was higher in the intervention group compared with the control group.

The parental overt and covert control scale measured four subscales of parental control over the child's food environment, with higher scores (min: 1 to max: 5) indicating parents who engaged in these controlling practices more often. Higher overt control may be obesity promoting, whereas greater covert control is likely to be obesity protective. There are some indications of a difference between covert control in snacks and meals, with higher scores in the control group compared with the intervention (Table 45). Included in the analysis were 19 clusters (average cluster size: 9; range 1 to 23), and the adjusted ICCs were <0.0001.

Table 45: Maternal overt and covert control over snacking and meals by group

Parent overt and covert control Scale	Intervention		Control				
	N 107	Mean (SD)	N 134	Mean (SD)	ICC	Adjusted[b] intervention effect (95% CI)	p-value
Overt control snacks	107	3.36 (0.92)	132	3.26 (0.93)	-	-0.01 (-0.10 to 0.09)[a,c]	0.911
Covert control snacks	107	2.62 (0.93)	130	2.92 (0.85)	-	-0.11 (-0.21 to -0.01)[a,c]	0.028
Overt control meals	107	3.64 (0.84)	133	3.51 (0.86)	-	0.02 (-0.05 to 0.10)[a,c]	0.560
Covert control meals	106	2.96 (0.93)	131	3.24 (0.75)	-	-0.10 (-0.19 to -0.02)[a,c]	0.020

a Data used in the model were on the log scale.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.

The CFPQ measured seven subscales of maternal feeding practices. Higher scores (min: 1 to max: 5) for 'balance and variety', 'models healthy eating', 'child control', and 'restriction for health' were interpreted as positive parent practices, and higher scores (min: 1 to max: 5) for 'food as reward', ''restriction for weight' and 'emotional regulation' indicated parents practices more likely to promote obesity development. (Table 46). There were no statistically significant differences between the groups in these maternal feeding practices; 19 clusters (average cluster size: 9; range 1 to 23) were included and the adjusted ICCs were <0.0001.

Table 46: Maternal feeding practices (CFPQ) by group

CFPQ	Intervention		Control				
	N 107	Mean (SD)	N 134	Mean (SD)	ICC	Adjusted[b] intervention effect (95% CI)	p-value
Balance and variety	105	4.68 (0.4)	132	4.70 (0.4)	-	-0.01 (-0.03 to 0.02)[a,c]	0.577
Food as reward	106	2.78 (1.2)	132	2.51 (1.2)	-	0.06 (-0.07 to 0.20)[a,c]	0.363
Models healthy eating	107	4.23 (0.8)	133	4.26 (0.8)	-	-0.01 (-0.06 to 0.05)[a,c]	0.752
Restriction for health	107	3.43 (0.95)	132	3.19 (0.96)	-	0.14 (-0.10 to 0.41)[d]	0.243
Restriction for weight	106	2.03 (0.66)	131	2.03 (0.69)	-	0.03 (-0.21 to 0.16)[d]	0.778
Child control	105	2.24 (0.6)	131	2.27 (0.7)	-	0.03 (-0.05 to 0.10)[a,c]	0.508
Emotional regulation	107	1.78 (0.58)	132	1.86 (0.69)	-	-0.13 (-0.30 to 0.04)[d]	0.139

a Data used in the model were on the log scale.
b Adjusted for cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
c Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.
d Intervention effect was an adjusted difference in means (intervention minus control).

4.7.10 Childcare

The use of formal and informal childcare was reported and is presented in Table 47. More children attended some form of childcare (intervention: 76.6%, control: 72.4%), most often this was a formal group care setting, such as a nursery or creche. Furthermore, many children were provided with all meals and snacks in childcare (intervention: 74.4%, control: 53.3%). The impact of childcare on the primary outcome was not assessed. This will be discussed in terms of the results.

Table 47: Childcare use at age 24 months by group

	Intervention group		**Control group**	
	N	**N (%)**	**N**	**N (%)**
	107		**134**	
Uses childcare *(% yes)*	107	82 (76.6)	134	97 (72.4)
➢ Group Care e.g. crèche	82	53 (64.6)	97	55 (56.7)
➢ Childminder home	82	1 (1.2)	97	1 (1)
➢ Childminder another home	82	16 (19.5)	97	15 (15.5)
➢ Relative home	82	20 (24.4)	97	27 (28.1)
➢ Relative another home	82	40 (48.8)	97	35 (36.1)
Meals provided in childcare:	78		79	
➢ All meals and snacks		58 (74.4)		60 (53.3)
➢ Main meals only		4 (5.1)		3 (3.8)
➢ Snacks only		9 (11.5)		15 (19.0)
➢ No meals		7 (9.0)		11 (13.9)

4.8 Discussion

4.8.1 Summary of findings

In this Chapter, the effect of the HELP intervention during pregnancy and postpartum, on maternal and child outcomes at 24 months postpartum has been examined. Trial outcomes at this time point were those related to maternal obesity, including determinants of childhood obesity, as discussed in Chapter 1.

Study sample

Of the HELP trial cohort of 598 women, 241 (40.3%) women and their children were recruited to the HELP 24m study (intervention: 107, control: 134). During the various stages of participant retention, difficulties in re-contacting women led to the majority of loss to

follow-up, rather than women declining their participation. There was variability across the sites in recruited numbers (median: 9, range: 1-23). There was also one empty cluster in the intervention group at follow-up. The sample of women recruited at 24 months postpartum were a population with lower baseline BMI, a greater proportion of non-smokers, non-white ethnicity, and first-time mothers, higher SES and education, greater engagement with weight loss, and higher HELP intervention adherence.

Primary outcomes

There were two primary outcomes at 24 months postpartum. The first, maternal BMI, indicated reductions in median BMI in both trial groups from baseline. However, the main analysis found no evidence that the HELP intervention was effective in reducing maternal BMI at 24 months postpartum. Planned secondary analyses examining maternal BMI as a categorical variable (obesity or severe obesity vs. overweight or healthy weight) supported this finding. Sensitivity analyses to control for group imbalances at baseline in confounders of the outcome and variances in timing of the follow-up completion did not change this conclusion. There was no evidence of differential intervention effects on maternal BMI due to age, ethnicity, SES, smoking or mental health. However, there was some evidence to suggest that the intervention was more likely to be effective for those who had been successful in losing weight in the two years prior to recruitment to the HELP trial (compared with those who had not had successful weight loss) and multiparous women (compared with nulliparous women). However, these analyses were exploratory and the numbers in each subgroup were reduced, therefore these results should be interpreted with caution.

The second primary outcome, child WHO BMI-for-age *z*-scores, showed that children in the intervention group were on average heavier at 24 months postpartum than the control group with no statistical or clinical evidence of a difference between trial groups. This did not change when examined as a continuous outcome based on a UK reference population, UK90 percentiles, or as a categorical outcome of those who had overweight and obesity, compared with those who had healthy weight or below. This sample of children were heavier than the average population matched for age and sex, as measured by WHO BMI-for-age *z*-scores (375) (intervention: 1.22, control: 1.03) and UK90 BMI percentiles (373) (intervention: 77.3, control: 72.2). In light of the evidence presented in Chapter 1 that children of mothers with obesity are also more likely to have obesity, this finding was perhaps not surprising. However, it illustrates that the HELP intervention was not successful in reducing this likelihood. A sensitivity analysis examining GWG as a mediator of effect showed no difference to the overall conclusion. There was no evidence of differential intervention effects on child BMI due to birth variables of delivery mode or gestation, or infant feeding method.

There was some evidence that being breastfed for 9 weeks or longer (compared with <9 weeks) may have led to a more positive effect of the intervention. Again, as these analyses were exploratory and the numbers in each subgroup were reduced, these results should be interpreted with caution.

Secondary outcomes

A reduction in maternal weight was seen in both groups from baseline to 24 months postpartum, with a slightly greater but non-significant difference in the intervention group. Women in the control group showed lower mean waist circumference measurements at 24 months postpartum. There was no evidence of a difference in hip measurements, but the control group also showed lower waist-hip ratios when examined as either a continuous (waist-hip ratio in cms) or categorical (high risk vs. low risk) outcome. However, clustering accounted for some of the variance in outcomes (waist circumference (ICC=0.07), waist-hip ratios (ICC=0.13)). The greater proportion of women who had given birth, and more recently, in the intervention group, may have impacted these measurements. This was not controlled for within the scope of this thesis. Furthermore, in terms of the clinical significance of these findings, both groups had a mean waist-hip ratio defined as high risk (≥0.85 cm) (intervention: 0.87 cm, control: 0.85 cm) so it was doubtful that this difference would have an improved health consequence. It was concluded that these were unlikely to be important findings.

Maternal self-report of food intakes found no evidence of differences between trial groups for any of the reported dietary intakes. The sample were shown to have medium fibre and fat intakes, and high fruit and vegetable intakes (based on recommendations), but both groups reported high unsaturated fat intake and >25% reported eating sweets at least once a week. Women in the intervention group reported higher median PA assessed by energy expenditure in kcal/kg/day compared with the control group (1132.9 vs. 993.3). However, when analysed as a categorical variable of high and low PA based on the sample median, although women in the intervention group were more likely to have higher PA than those in the control group (57.1% vs. 44.0%), there was no statistical evidence for a difference.

There was no evidence of reduced levels of risky alcohol consumption at 24 months postpartum. A high proportion of women in both groups engaged in drinking risky quantities (intervention: 45.8%, control: 41.6%) and binge drinking (intervention: 62.3%, control: 63.7%). There was a statistically significant difference in the proportion of smokers in the groups, which was higher in the control group compared with the intervention group (23.1% vs. 9.3%), whereas, there was a small but significant difference in the higher volume of daily

smoking in the intervention group (10.5 vs. 10; p=0.004). However, these directional trends were present at baseline therefore the significant effects would likely be attenuated by controlling for smoking at baseline. Furthermore, the small sample of smokers included in the analysis of cigarettes smoked per day made this result unreliable. Also, in terms of clinical significance the difference in group medians (0.5 of a cigarette per day) is unlikely to have a health benefit.

There were no between groups differences in self-reported general health, presence of psychological distress, HRQoL, or health state at the time of follow-up. Proportions of women reporting some psychological distress were greater than 40% in both groups (intervention: 44.3%, control 49.1%), and more than 40% had HRQoL which indicated that their health was less than perfect (intervention: 40.6%, control: 43.6%).

The theoretical mediators of behaviour change through which the intervention was expected to improve outcomes, were assessed by maternal self-report at 24 months postpartum. These were social support for diet and exercise, motivation and self-regulation for a healthy diet and exercise, self-regulation for health, and self-efficacy for weight control and exercise. There was no evidence of between groups differences for most of these outcomes, except for social support for exercise. A greater proportion of participants in the intervention group reported receiving family participation in exercise (58.1% vs. 34.9%; p=<0.001), along with higher combined family and friends participation (36.8% vs. 17.4%; p=<0.003), compared with the control group. However, these differences were not observed at 12 months postpartum so were unlikely to be due to the intervention. Women in both groups reported receiving sabotage of healthy eating behaviours (intervention: 26.5%, control: 20.0%) and punishment for exercise (intervention: 9.6%, control: 7.2%) from family or friends. Mean scores of self-regulation for diet and exercise were particularly low in both groups. From a possible score of 0 to 6, women reported low autonomy for maintaining a healthy diet (intervention: 2.2, control: 2.4), and exercise (intervention: 2.3, control: 2.6). There was no evidence of differences between groups for self-monitoring of weight, diet, or weight control attempts. Over 60% of women in both groups reported they were attempting to control their weight. Of those women attempting to control weight, a high proportion attended commercial weight loss groups or followed programmes online (intervention: 78.5%, control: 84.3%).

No difference in breastfeeding outcomes were identified, although this was expected as most women had stopped breastfeeding by the earlier follow-ups. The rate of subsequent pregnancies was low (intervention: 11.2%, control: 5.2%). However, women in the intervention group had a greater rate of subsequent pregnancies and a greater proportion

had given birth more recently (35.4 weeks vs. 18.7 weeks). This may have impacted other outcomes, as discussed.

There was no statistical evidence of a difference between trial groups when assessing children's weight and no evidence of a positive intervention effect on children's diet in terms of the proportions of children who consumed either obesity-promoting or obesity-protective foods and beverages. Between 45% and 79% of mothers reported that their child's daily intake included consumption of packaged snacks, chocolate and confectionery, cakes and biscuits, and squash or soft drinks. Furthermore, fast food was reported to be consumed by greater than 30% of children at least once a week. The greater proportion of children who received all meals and snacks in childcare in the intervention group, may have influenced children's food intakes. This was not examined within the scope of this thesis. There were no differences in measures of the mealtime environment. Greater than 40% of mothers reported their children watched television either every day or on average twice per week. Similar weekly activity levels for children were reported by both groups. The average activity levels of children, per day, were intervention: 1 hour and 43 minutes, control: 1 hour and 36 minutes. The greatest proportion of activity was attributed to indoor play. No difference was found in child preferences for how to spend their free time, daily screen time (sedentary) behaviours (intervention: 1 hour and 59 minutes, control: 2 hours and 23 minutes), or levels of parent-child activities between the groups.

From the assessments of maternal feeding practices using the CFQ, the parental overt and covert control scale, and the CFPQ, it was shown that women in the control group demonstrated statistically significant differences in their greater use of covert control over snacks (adjusted percentage difference -0.11 (-0.21 to -0.01); p=0.028) and meals (adjusted percentage difference -0.10 (-0.19 to -0.02); p=0.020) when compared with the intervention group. There were no other differences between the groups. Generally, mothers reported sometimes using both overt and covert control over snacks and meals, with overt control most often used. Mothers reported relatively low concern for child weight, and less than 2% of mothers perceived their children to be overweight. Mothers reported themselves to have most of the responsibility for feeding their children, and perceived child control as low. They reported high monitoring of children's food intake, and moderate use of pressure to eat and restriction. Restriction for health, rather than weight, was used more often. Mothers reported that they often encouraged balance and variety and modelled healthy eating to their children.

The majority of children in the sample used some form of childcare and the proportions were balanced between the groups (intervention: 76.6%, control: 72.4%). However, a greater proportion of children in the intervention group were provided with all meals and snacks in childcare (intervention: 74.4%, control: 53.3%).

Clustering

Analyses of the primary and secondary outcomes were adjusted for randomisation balancing factors. Additional clustering by site was examined for each of the outcomes. High clustering (range 0 to 1) would indicate that factors that varied by trial site were responsible for differences in outcomes. There was some additional clustering found, but the additional variance due to clustering across all outcomes was less than 4%, with exception of maternal BMI thresholds (ICC=0.06), child BMI thresholds (ICC=0.09), maternal PA (ICC=0.17), waist circumference measurements (ICC=0.07) and waist-hip ratios (ICC=0.13).

4.9 Conclusion

The HELP intervention did not impact upon the two primary outcomes, maternal BMI and child BMI-for-age *z*-scores, at 24 months postpartum. A reduction in maternal GWG in the intervention group did not lead to differences in maternal or child BMI at 24 months postpartum. These findings are novel, as no previous studies could be identified that had conducted a follow-up of participants of a cluster RCT with lifestyle intervention during pregnancy and postpartum, which focused on maternal and child outcomes, including behavioural outcomes such as diet and PA, and also measured maternal determinants of childhood obesity in the home environment. The succeeding qualitative phase of this mixed methods study (Chapters 5 and 6) will describe the methods and results of the exploration of women's perspectives in relation to the maternal and child outcomes that have been presented. This aimed to provide potential explanation for these results.

5 Qualitative phase: methods

5.1 Introduction

An in-depth exploration of women's experiences in relation to their own weight and health behaviours before, during and after pregnancy, and that of their young children, was conducted. This Chapter describes the methods that were employed in order to answer the following research questions:

For women who participated in the HELP trial, what are:

- their experiences, attitudes and beliefs surrounding issues related to their weight, 24 months after birth?
- what are their experiences, attitudes and beliefs surrounding their child's weight and health behaviours, 24 months after birth?

In addressing these questions, this qualitative phase of the HELP 24m study, aimed to provide insight into the contextual and social processes underpinning the findings presented in Chapter 4. Using qualitative methods to explore experiences, attitudes and beliefs related to these observations, may provide a more holistic view in relation to the study research questions.(333) The specific methods of investigation and justification for using them, will be described.

5.2 Theoretical assumptions in using qualitative research methods

The use of qualitative research methods was driven by the study research questions. Qualitative research is a means for exploring and understanding the meaning individuals or groups ascribe to a social or human problem.(331) These methods of inquiry have increasingly been used in the field of health research as a way to explore the 'patient perspective'. That is, for the people receiving a health intervention, what their understandings are of their health and behaviours. Exploring such understandings may help explain observed health outcomes, and a 'lay' perspective to service evaluations can allow for improvements.(387)

The assumption supporting the use of qualitative research methods to explore the understandings of women in the HELP 24m study, was that there were aspects of experiences associated with maternal obesity, which could not be observed or quantified. Rather, the research questions required the discovery of meanings and 'lived realities' behind the complex issues of maternal obesity and weight management, and maternal influence on child weight and health behaviours, for those who have experienced such issues.(331) A phenomenological approach was adopted, where the research aimed to collect detailed descriptions of women's experiences, in order to identify the essence of those experiences and the subjective meanings ascribed to them by the participants.(331, 332) Women are considered 'experts' on their own lives. By exploring their personal experiences related to maternal obesity, and the way in which they construct their reality in terms of thoughts, beliefs and attitudes contributing to actions, we may understand the social context of weight management and health behaviours for these women, and for their children.(388) It may also inform our understanding of the role of context within the delivery of the HELP intervention.

Using qualitative research methods allows a researcher to come to understand 'lived realities', by immersing themselves in the phenomenon of study, and by comparing, contrasting and documenting their understanding of the situation for those engaged in it.(331, 333) Using qualitative methods was considered the best way to gain an insight into the 'how' and 'why' in relation to the research questions.(334, 389) Understanding this 'patient perspective' will inform more effective interventions to support weight management in pregnancy.(388)

5.3 Study design

Qualitative research comes under criticism for its subjective nature; findings are co-produced by an interaction between participants' accounts and the researchers' interpretation of those accounts.(390) However, rigour can be achieved through ensuring detailed planning and reporting at each stage of the study design, and providing clarity of the processes involved and the reasons for these processes.(387) Several frameworks outlining recommendations for the conduct and reporting of qualitative research were consulted and followed to ensure rigour within this study design.(387, 391, 392) Meyrick's framework offered a combined consideration of rigour from across different disciplines of health research, so rather than a definitive list of steps to take, Meyrick proposed adopting the principles of 'transparency', in reporting methods used, and 'systematicity', by adopting evidenced based processes.(387)

Alongside this, the consolidated criteria for reporting qualitative research (COREQ) offered a 32-item checklist for explicit and comprehensive reporting of qualitative studies using interviews, which was followed so that the study design was clear to the reader. This is described below.

5.3.1 Ethical approval

Previously described in Chapter 3 (section 3.2.2).

5.3.2 Semi-structured telephone interviews

Qualitative one-to-one interview, as opposed to other types of data collection, was considered the best method to answer the research questions as it allowed an insight into individual's experiences, beliefs and motivations to provide a 'deeper' understanding of the social phenomena, while maintaining a more natural interaction.(393) The use of methods adopting a group format, such as focus groups, can be beneficial, as participants use social comparison to reflect upon their experiences, generating data and offering comparing and contrasting views within these data.(394) However, these methods can suffer from social conformity where some members of the group may dominate discussions and others hold back from offering an opposing point of view.(394) This investigation aimed to understand the varying experiences of those who took part, in order to explain the effectiveness of the intervention and the mechanisms that led to various outcomes. Therefore, focus groups, where participants may be influenced by the opinions or experiences of others, were not considered as appropriate as one-to-one interviews which would allow participants to relate their own experiences.(395) Furthermore, the sensitive nature of the study topic was thought to be more appropriate to explore through one-to-one interviews, as participants may have been reluctant to offer personal accounts of weight-related issues as part of a group.(393)

The telephone was selected as the medium of data collection as, given the geographical spread of the target population across England and Wales, this was more timely and cost-effective than conducting face-to-face visits.(389) Telephone interviews were also considered to be less burdensome for participants to complete, as they could be arranged at a time suitable to the participant, where a face-to-face interview would need to accommodate the time taken for interviewer travel. Within a population of women with young children, this was thought to make it easier for women to participate.(389) One disadvantage of the telephone interview was that the student was unable to control the interview ambience.(389) When making interview arrangements it was recommended to women to arrange it for a time when they were at home and could be uninterrupted for the duration of

the interview to try to overcome potential issues. Telephone interviews can also be deemed as inferior to face-to-face interviews given the lack of social and non-verbal cues that are available.(389) However, Novick (2008) argued that telephone interviews can yield rich and detailed accounts, and that the relative anonymity of this medium may actually allow participants to respond more freely and openly especially to sensitive topics, such as weight.(396) The student and interviewee not being able to see each other enabled a non-judgemental approach to the discussion of weight. Furthermore, the social cues provided by intonation and voice remain possible to interpret by telephone.(389)

The objectives of this study were to develop a more complex understanding of participants' views on specific topics, such as the HELP intervention, as well as to gain insight into other concepts relevant to the research questions. In turn, this was to facilitate a better appreciation of the important aspects central to behaviour change and weight management during pregnancy and postpartum, and in early childhood. Therefore, a semi-structured interview format was selected to allow the student to ask key questions directing the participants towards particular points of interest but providing flexibility for the participant to steer the interview towards issues of personal importance. This allowed participants to present their beliefs and rationale in their own way,(397) but let the interviewer diverge and expand participants' responses to pursue an idea in more detail.(393, 397)

5.4 Participants

5.4.1 Participant sampling

In qualitative research, it is imperative that an appropriate sample of participants is selected to enable the research questions to be answered and to support the likelihood of capturing good quality data.(387) The cohort of participants recruited to the HELP trial were considered appropriate 'experts' in relation to the study topics, in the years following their participation in this trial.

Based on the mixed methods design of the HELP 24m study, the participant sample for the qualitative phase was limited to those who had taken part in the quantitative follow-up, as described in Chapter 4. Participant selection for the interviews was carefully considered to recognise the diversity and the varied experiences of women within the study population. Purposive sampling was used with an aim to increase the validity of the data, by ensuring

different perspectives in relation to the research questions were captured.(398) Women were targeted for recruitment according to the following criteria:

- Trial sites across intervention and control groups, to understand how experiences of participating may differ across groups and how demographic characteristics may impact experiences.
- Differing weight change across the period of trial participation (baseline to 24 months postpartum) according to weight loss (>3kg), weight gain (>3kg) or minimum change (<3kg), to understand how experiences influence varied weight outcomes.
- Adherence to the intervention (intervention group only), to understand differing experiences of the HELP intervention.

The sampling strategy did not seek to achieve a 'representative' sample as this was not the aim of the study; rather, it was an effort to capture varied and conflicting views to understand the complex nature of the topics of investigation. The findings of this study may not be generalisable to other similar intervention studies but gathering rich and detailed information could help to inform future research. There were no grounds for excluding any women from participating. However, interviews with HELP trial participants had been conducted by the student at six and 12 months postpartum, as part of the trial process evaluation. Therefore, the student aimed to prioritise recruitment of other women who had not previously been interviewed, in order to obtain a broader view of attitudes and knowledge gained, as well as to reduce burden for women already interviewed.

In qualitative research, there is no specified number of people that are required to answer a specific question, rather the sample should be sufficiently large and varied to achieve the aims of the study.(399) The application of two concepts, 'data saturation' and 'information power', in determining the study sample size, will be discussed in section 5.5.4. As a planning estimate, between 15 and 25 women were estimated to be recruited for interview, based on other similar studies.(327)

5.4.2 Recruitment and informed consent

After completion of the follow-up at 24 months postpartum, women were informed that they may be contacted and invited to take part in a telephone interview. The student created a sampling matrix that categorised women by the sampling criteria, to help target women for recruitment accordingly. The student contacted women by telephone to ask if they would be

willing to take part in a subsequent telephone interview expected to last approximately one hour. Telephone contact was useful as it allowed a real time response to recruitment. It also allowed the student to make herself familiar to the women, to alleviate concerns, and to initiate a rapport prior to the interview. This can help in the quality and development of interviews.(393)

Ethical considerations were adhered to throughout the study. The student was trained in GCP and understood the principles of informed consent. On initial contact, it was made clear to women that they were under no obligation to take part and that they could decline or withdraw their participation at any stage. A record of women who were contacted but declined to take part was retained, along with the reason for decline, if provided. If a woman was willing to take part, a convenient time for the interview was arranged. The woman was advised that it was preferable for her be at home and in a quiet environment, without childcare responsibilities, during the interview. Flexible interview times (e.g. after children had gone to bed) were offered to make participation easier.(393) When an interview was arranged, an appointment letter (Appendix M) and participant information sheet (Appendix N) providing further details about the research, were posted to the woman. Again, it was made explicit on the information sheet that women could decline or withdraw their participation at any stage. The day preceding a scheduled interview, the woman was reminded about the arrangement by telephone or SMS, and the student confirmed that the woman was able and willing to proceed. Arrangements were changed when required. This helped to avoid unnecessary contact and resource use, such as meeting rooms.

The student conducted the interviews in a quiet, private room in CU. The women were contacted by telephone at the arranged times, and the student checked that they had received and read the participant information sheet. Where the women said they had not read the information sheet, it was summarised over the phone, alongside a verbal explanation of the interview process, which was delivered to all the women (Appendix O). This explanation outlined the purpose of the interviews and what would happen to the data at each stage of the study process to ensure that the women fully understood what they were agreeing to. The women were informed that the interviews would be audio recorded, and of how anonymity and confidentiality of their information would be maintained. Women were given an opportunity to ask questions or discuss concerns about the research, and again it was made clear that they were under no obligation to proceed. For those women wishing to proceed with being interviewed, verbal informed consent was taken. Women were asked to confirm that they were happy to proceed under the conditions that the interview

was being recorded and that the recording would be transcribed by a third party. Verbal consent was captured on the audio record, the interview was then conducted.

In the event a woman was uncontactable at the scheduled interview time, a message was left when possible, and the student reattempted contact in 10 minutes. If this attempt was unsuccessful, this was recorded on the study database. A follow-up contact was attempted approximately two days later, if the woman had not got in touch. The student confirmed whether the woman wanted to re-arrange the interview and, if so, another appointment was scheduled. For any woman declining to take part, or who was unable to be contacted, details were recorded on the study database.

5.5 Data Collection

5.5.1 Interview structure and topic guide

The interviews were guided by a question schedule (Appendix P) developed by the student, with guidance from the research supervisors, prior to any data collection. This interview schedule was developed from an initial topic guide informed by the research questions, the literature review in Chapter 2, the results of the qualitative study, and the previous HELP trial results, which included the following topics of interest:

- Women's experiences of participating in the HELP trial during pregnancy (also explored in the HELP trial)
- Women's attitudes towards diet, PA and weight management before, during and after pregnancy
- Women's behaviours in relation to diet, PA and weight management before, during and after pregnancy (also explored in the HELP trial)
- Perceived barriers and facilitators to health behaviours (also explored in the HELP trial)
- The function of social support in adhering to a healthy lifestyle
- Reflections on weight experiences since taking part in the HELP trial
- The wider impact of women's experiences on parenting and the family environment
- Women's attitudes surrounding their child's diet, PA and weight at age 24 months

The interview schedule included open ended questions with the avoidance of leading statements, so that participants could construct the meaning in their responses, rather than closed questions which would only allow the interviews to explore the student's pre-

conceptions of important issues.(331) To avoid using stigmatising or judgmental language in the interviews, evidence of patients' preferred terms to discuss 'overweight' and 'obesity' was consulted.(400) As such, 'weight', 'weight related', and 'weight management' were used in the wording of questions and throughout the interviews.

It is recommended to pilot interview content and the method of data collection in order to refine the question schedule and assess the feasibility of the planned interviews.(331) A pilot session was conducted with a female volunteer from within the student's workplace. Research topics related to the women's experiences of weight and health behaviours, were similar to the topics of interest within the HELP trial interviews at six and 12 months postpartum, so the feasibility of exploring these issues had been established. Also, given the specific nature of the participant required for these interviews, i.e. one that had participated in the HELP trial and follow-up at 24 months postpartum, only the content related to exploring issues relevant to the children was piloted. The pilot participant had a child of preschool age which made her suitable to respond to these questions. She was asked to comment on her understanding of the questions asked and her suggestions for missing issues she considered important. Following the pilot session, minor changes to question wording were made to the interview schedule e.g. diet changed to healthy eating. It may have been beneficial to pilot interview content with women from the study population and then discard these interviews if necessary. However, the student decided that this would risk excluding valuable information and reducing the recruitment opportunities for the main study, especially given the limited population from which participants were to be recruited. Using analysis alongside data collection would allow any issues arising in the main interviews to be identified, and the question schedule amended.

The student familiarised herself with the interview schedule prior to each interview in an effort to allow the discussion to flow more naturally.(393) The interview was initiated by an 'ice-breaker' question where the participant was asked to describe herself and her family, such as names of children and her occupation. Starting with this discussion, that would be familiar and easy for participants to talk about, was intended to put them at ease in answering further questions. Field notes were recorded, such as the name of the participant's partner, so that these details could be referred to throughout the interview, to assure the participant that they were being listened to and to aid rapport which is important in terms of encouraging richer accounts.(393) Also, by starting with a less sensitive topic the aim was to build trust before asking women to discuss more sensitive issues related to weight.

The resulting data from interviews are evidently shaped by the questions asked, as well as the influence of social desirability on participants' responses.(401) In an attempt to reduce these limitations, neutral techniques to encourage participants to provide more detail on their individual perspectives were employed. The student strategically used silence and sought to limit her interjections as this can be effective in getting respondents to contemplate their responses, talk more, elaborate or clarify.(393) Probes, for example 'can you tell me more about that', were used to encourage participants to repeat and extend their responses, and to explore meaning to ensure more in-depth data.(402) To overcome the absence of non-verbal cues in telephone communication, utterances, such as 'um' 'ok' and 'yes', were used to reassure the participant that she was being listened to. Prompts were only employed if the participant failed to understand the initial open-ended question or when a response of interest had been raised in previous interviews and the student sought to explore this further, to establish the participant's agreement or disagreement with other respondents. To increase interview validity, the student used feedback of her interpretation of participants' accounts during the interviews, to clarify whether she had understood correctly and to offer participants the chance to disagree or expand on responses.(397) Before ending the interview, the participants were given a chance to sum up or clarify the points they had made, and asked if there was anything further that they would like to discuss. This was important, in case the interview had failed to address issues of importance to the interviewee.(393)

When the interview had concluded, the woman was thanked and the call ended. Participants were subsequently posted a £10 high street shopping voucher as a thank you for their time.

5.5.2 Ethical considerations during data collection

During the interviews, the student asked the participants to enter into a 'trusting' relationship which would only last the length of the interview. Yet during that time, the participant was asked to reveal their personal thoughts and feelings related to a sensitive and stigmatised topic. It was, therefore, ethically important to consider the potential impact of participating in the interviews on the women, and for procedures to be in place to ensure that no harm came to the women as a result of taking part. The women were informed at the start of the interview that should the discussions cause upset or distress, or the student have concerns for their wellbeing or the wellbeing of others around them by what was said, that this would be communicated to a healthcare professional who was responsible for their care such as their GP.

5.5.3 The role of the interviewer

The qualitative interview is a social interaction between the interviewer and interviewee and, as such, the interviewer plays an active role which is likely to influence the data collected.(399) Yet the interviewer aims to set aside his or her own experiences and avoid biasing the responses, he or she is there to guide the discussion around the research topics, to listen and take direction from the interviewee rather than according to his or her own pre-conceived expectations of the findings.(331) Furthermore, the interviewer must create an atmosphere of warmth and empathy, especially when discussing sensitive topics.(397) The success of a research interview and the quality of the data collected are as much determined by the skills of the interviewer as they are by the respondent.(399) It is, therefore, important to reflect on the role of the interviewer within this study.

Achieving participants' trust can be challenging especially when conducting telephone interviews, due to a lack of non-verbal cues. The student (interviewer) tried to set the tone for the interview during the verbal introduction, by providing reassurance to the participants that their opinions were important and that there would be confidentiality of their information. The student aimed to empower women to direct the interviews, by emphasising that she was there to learn from and understand their experiences.

The student, at the time of interviews, was aged 30 years and was married but had no children. Being of a similar age to the participants allowed the student to build rapport by being able to relate to shared experiences, such as getting married. Being a female was likely to have put participants at ease in talking about weight and pregnancy experiences. However, although the student tried to empathise with participants' experiences of pregnancy, parenting and obesity, she had not shared these experiences, which may sometimes have made her hesitant in how to sensitively approach these issues.

The student's professional education, MSc Health Psychology and BSc (Hons) Psychology, entailed training in qualitative research interviews, and her MSc dissertation project involved interviewing parents and school-aged children to study the development of eating behaviours. As a research assistant, she had experiences of leading qualitative data collection on several studies, including the HELP trial. The student felt she had gained skills through these experiences to encourage rich and in-depth accounts from participants, such as allowing silence within the interview; a skill requiring practice to master. Having worked on three different projects studying lifestyle in pregnancy, the student entered into the interviews with knowledge on the topic area. This may have encouraged pre-conceived

ideas about the topics of importance but she acknowledged this issue and was sensitive to recognising the unexpected topics raised by the participants. The participant information sheet informed women that the student was conducting the research as part of a PhD qualification, and they may have been familiar with the student from the HELP trial or the face-to-face follow-ups at 24 months postpartum. This knowledge and familiarity may have introduced further social desirability bias into the responses, if participants believed that the student had an invested interest in receiving positive reports about sustained behaviour change or the HELP intervention.

By the time of final data analysis and reporting, the student had become a mother which was likely to have influenced her interpretation of the data in that she could better relate to and empathise with participants' accounts of pregnancy and parenting. During analysis, the student's knowledge of the background theory had the potential to produce a closed and deductive interpretation of the findings. An 'open coding' method was applied to reduce this risk in that codes and concepts were applied to the whole observed dataset, allowing for unexpected information to be recognised rather than '*a priori*' coding according to theoretical considerations and pre-specified codes.(403, 404)

5.5.4 Data saturation and information power

'Data saturation' is a concept widely used in qualitative reporting to explain how a given study sample size was determined. This concept, proposed by Glaser and Strauss (1999) (403) in relation to 'grounded theory' methods, describes the point at which no new themes or ideas relevant to the topic of interest emerge with further data collection, indicating that adding more participants to the sample size will fail to provide new information. The concept has frequently been applied within other analytic methods without clear guidelines for identifying 'data saturation' or indication that it is an appropriate concept to apply. Reaching the point of 'saturation' will depend on the topic and the research questions, as well as other factors inevitably influencing the scope of the study, such as project timelines.(403) Explicit reporting of how sample size was determined is important.(399)

To determine sample size for the HELP 24m study qualitative phase, 'data saturation' was used as follows. The data analysis, which is discussed further in section 5.6, adopted an iterative approach in that analysis started after the first interview was completed and transcribed, and continued alongside the remaining data collection. Within this analysis process, coding of the data allowed the student to identify themes and list these themes into a coding frame. When two interviews in a row had been coded without producing any new

themes to be added to this frame, the research team agreed that the data had reached a reasonable point at which the research questions could be answered, and, therefore, the achieved sample size was adequate and data collection was stopped. However, to declare that the data was 'saturated' in that nothing else of interest could be collected would be inaccurate. This research explored individuals' experiences on a well-studied topic, and each individual is likely to bring different experiences in relation to the research questions. The decision to accept the achieved sample size and data was also made under other project constraints, including time and funding.

Malterud and colleagues (2016) (399) proposed an alternative concept of 'information power' for determining a study sample size. This follows the idea that the more information the sample holds, relevant for the actual study, the lower number of participants is needed. A retrospective appraisal of this concept led to the conclusion that 'information power' was a more appropriate way to think about how the sample size was determined here.(399)

The sample size required to provide sufficient 'information power' depends on the: 1) aim of the study; 2) sample specificity; 3) use of established theory; 4) quality of dialogue; and, 5) analysis strategy.(399) The aim of this study was to gather the views of women with obesity in pregnancy, who had taken part in the HELP trial, and had preschool children; to understand these experiences. This high sample specificity limited the pool of women from which participants could be recruited, but it also meant that a smaller sample size was sufficient to achieve varied views. Using the sampling matrix to help target women for recruitment ensured that contrasting experiences were included in the data. Therefore, it was determined that the sample size had been sufficient to achieve variation in relation to the study aims. The purpose of the study was not to establish theory, as the theoretical foundations of weight and health behaviours in pregnancy and parenting have been documented, as described in Chapters 1 and 2. Rather, the data collected from the recruited sample was considered to be sufficient to shed light on the usefulness of the existing theory, to inform future research. 'Information power' is further determined by the quality of the dialogue achieved in the research. Interviews with strong and clear communication provide more 'information power' requiring a smaller sample size. The experience and skills of the student meant that the dialogue was focused and flowed easily which allowed her to gather rich data from each participant. Alongside this, the participants were describing experiences within their everyday lives, which made it easy for them to talk about the topics. Therefore, the quality of the collected data was deemed sufficient to provide in-depth insights. The final consideration in achieving 'information power' is the analysis strategy used. A cross-case analysis looks for patterns in the data and requires an adequate sample size to be able to

compare accounts in order to present these patterns relevant to the study aims.(399) The analysis used for this study adopted a constant comparative method across participants' accounts, and the production of a coding frame evidenced that patterns in the data, relevant to the research questions, had been achieved by the recruited sample. In conclusion, the sample size recruited was thought to provide sufficient 'information power' to offer insights that contribute to or challenge current understandings.(399)

5.5.5 Data collection and handling

The interviews were audio recorded using a speaker phone and portable recording device to provide an objective record of the data. This equipment was tested before each interview. During the interviews, distractions or factors which impacted on the data quality were noted to allow the student to reflect on these issues during analysis and reporting. After the interviews, the audio recordings were transferred to networked folders on the CU secure password protected computer system and checked. The recordings were deleted from the recording device using an electronic file shredding system.

The interview audio recordings were transcribed verbatim. Transcription was completed by a professional company external to CU, ensuring speed of transcription so that the completed interviews could inform further data collection. A confidentiality agreement was established with this company, and participants had consented to allow their data to be handled in this way. Audio files were electronically uploaded to the company's password protected file sharing system. Completed transcripts were returned to the student through the CU secure file sharing system and saved to CU networked folders, separated from the audio files.

During the first reading of a transcript, the student 'anonymised' the data by removing any identifiable participant information, such as names of family members, or location; and replacing these with descriptive words, such as partner or town. The transcripts were subsequently imported to the Nvivo software package,(405) which was used to support the data analysis.

5.6 Data analysis

5.6.1 Thematic analysis

Thematic analysis is a broad term used to describe analytic methods which seek to identify and classify the content of qualitative data, to explore patterns and differences across accounts in order to describe the relationships between different parts of the data, with the aim of providing explanatory conclusions clustered around themes.(406) Thematic analysis was used in this study to explore themes across participants' accounts relevant to the research questions. Braun and Clarke's (2006) method of conducting thematic analysis was followed, as will now be described.(407)

The first step in the analytic process was that the student read and re-read each transcript, when they were available, to familiarise herself with the data and to note concepts of interest within the data. This familiarisation stage particularly focused on topics of importance raised by the participants, and deviations from the pre-conceived question schedule; within the data. Completion of this stage of analysis supported iterative interviewing, where the information noted during data familiarisation, was used to guide further data collection by modification of the interview schedule. Field notes were examined alongside the reading of the interview to which the notes applied, to help explain the context of the transcript, for example where interruptions had impacted on the flow of the dialogue. This stage of analysis continued throughout data collection, to allow the student to develop a detailed knowledge of the data.

After data familiarisation, initial codes were assigned; that is, to apply a descriptive or conceptual label to selected data excerpts to define the content. The coding procedure outlined that all data were to be covered by a code to retain all data in the analysis, that more than one code could be assigned to a data excerpt, and, that the questioning needed to be retained in the selected data. For this stage of analysis, the student and research supervisor, LBH, discussed the first two interview transcripts together and manually applied initial codes generated during this discussion. Moving forward, and using Nvivo 11,(405) the student collated these initial codes according to conceptual similarity, to look for repeated patterns across the data. This stage of analysis continued throughout data collection.

The student started to think about how the conceptually grouped codes fitted together into overarching themes and sub-themes, and electronic memos were recorded to account any

thoughts or initial observations she had about the data. A thematic map was drawn to assist in this process, to visually map out how the grouped codes may link together, to aid the progression of the analysis. When initial themes and sub-themes had been conceived, a coding frame was produced which provided a hierarchical structure of these themes and sub-themes, along with their content descriptions. This coding frame was used to support the coding of new interview data. It continued to be refined as further coding and re-mapping of the themes occurred, through further analysis or following discussions and reflections with the researcher supervisors. The coding frame was continuously reviewed to check that the coded data matched the code definitions, and were, in turn, a good fit within the overarching theme. Where required, the coding of extracts was changed or sub-themes merged into existing themes. Amended versions of the coding frame were retained throughout the analysis, to allow reflection on the progression of the analysis and to check that the correct meaning was retained while refining themes. When all data had been coded and allocated into themes, a review of the entire dataset was conducted to assess whether the final themes accurately reflected the dataset as a whole, and to check that themes were coherent, distinct and internally consistent.

When the resulting concepts were accepted by the student and research supervisors as accurately fitting together and incorporating the essence of the dataset, the themes were named to reflect the meaning of the content. The final coding frame was produced and a final thematic map was developed to summarise the results, providing a tool to visualise how the identified themes may fit together to inform the research questions.

The resulting themes and sub-themes, coding frame and thematic map are outlined in Chapter 6. The interpretation of women's experiences is presented alongside direct participant quotes, so that the reader may have a lens through which they may view the participants' worlds and be able to verify the resulting themes. Women were given pseudonyms which were used to attribute quotes.

5.6.2 Ensuring an 'inductive' approach in the thematic analysis

It was clearly acknowledged that the student entered into the research process with knowledge of the phenomenon. This knowledge influenced the interviews in that the question schedule was developed based on the literature review and previous research within this population. Furthermore, analysis of the initial interviews identified themes which closely followed this interview schedule, with sub-themes coded under these topics. However, during the analysis process the student remained cognisant of these pre-conceptions and employed techniques to allow a more emergent investigation to inductively

develop a pattern of meaning in the data.(331) As introduced in section 5.5.3, an emergent 'open coding' process was applied to the data, allowing for the discovery of unexpected concepts in participants' accounts so that the resulting themes were data driven rather than informed by theoretical assumptions.(403) Furthermore, by completing analysis alongside data collection, the identification of topics not fitting with the pre-conceived schedule allowed these topics to be added in subsequent interviews in an attempt to understand them in relation to the research questions. This ensured that further data was driven by the perspectives of the participants.(331) As the analysis progressed, and an inductive approach was applied, themes started to fit together under overarching themes related to women's attitudes and beliefs. Data were recoded under these overarching themes and new sub-themes were identified.

5.6.3 Using the HELP intervention theory as an analytical lens

After initial coding of the interview transcripts had been completed, it was determined that using the HELP intervention theory, based on Control Theory and Social Cognitive Theory, would be useful as an analytical lens to organise some of the women's accounts. Relevant concepts were mapped on to the theoretical mediators of change, namely social support, motivation, self-regulation and self-efficacy, and associated BCTs of monitoring and goal setting. Although this specifically evaluated the usefulness of the applied theory from the women's perspectives, these concepts often overlapped with main themes interpreted from the data but did not emerge as strong sub-themes. Furthermore, the analysis used existing theory to organise the data, rather than the inductive approach taken to arrange themes. Therefore, this was conducted as a separate analysis and was not presented with the main themes. It was determined that this analysis would be best merged with the HELP trial process evaluation interview data. A matrix incorporating examples of women's accounts mapped to theoretical concepts is presented in Appendix Q but will not be discussed within the scope of this thesis.

5.7 Study rigour

Throughout this Chapter, the aim has been transparency with regards to how the methods used yielded rich, valid and informative findings. The student undoubtedly influenced the interpretation and conclusions drawn from the data. However, by reflecting on her role and background, and on how this might bias the study findings, an awareness of this issue was created and considered throughout the research. The participant sampling and iterative interviewing sought to include opposing views that did not support majority themes or conclusions. Furthermore, all aspects of the study were subject to scrutiny by a team of research supervisors, and the systematic methods of data analysis were overseen by an experienced qualitative supervisor, LBH. Together, LBH and the student initially coded the first two transcripts, to ensure differing perspectives informed the analysis from the beginning. This initiated a more valid and rich pathway for the analysis to progress. To validate the final coding frame, 15% of the interview data were independently double coded by LBH using this coding frame. Any issues with the coding frame were discussed between the student and LBH and, where disagreements occurred, these were discussed until a required change to the coding frame was agreed upon. The aim here was not necessarily to achieve agreement, but to encourage reflexivity by challenging each other's interpretations, so that multiple and alternative explanations were considered and incorporated, to produce complex, rich and layered insights.(408) The proposed changes to the coding frame mainly related to overlap across the themes, and the naming of themes. These issues were discussed, along with options for dealing with identified discrepancies, such as merging sub-themes together or recoding some of the content. In the detailed reporting of the methods employed (Chapter 5), and the findings of the study, including data extracts (Chapter 6), the journey from data to conclusions was transparent and results remained reflective of the collected data. This aimed to increase the external validity of the research by allowing the reader to be able to compare both the methods and findings to their own research.(331)

There are other methods that have regularly been used in qualitative research with the intention of achieving rigour. Two such methods are 'respondent validation' and 'inter-rater reliability statistics'. However, more recently there have been criticisms of these techniques with regards to their capacity to add credibility to the research findings.(408, 409) 'Respondent validation', where respondents are asked to confirm and validate the accuracy of the study findings to their experiences,(408) is said to provide 'co-constructed' findings, thus adding validation to the researcher's interpretation of the data.(334) However, it is argued that this concept is an ineffective method for the purposes of verification as it goes against the philosophical stance of qualitative research; that knowledge is socially

constructed and, therefore, cannot be theory free.(408) Respondents, just like researchers, are unable to separate their interpretation from their previous assumptions, values and commitments.(408) The topics discussed in the present study, weight and health behaviours, are central to a respondent's identity and can be seen as 'moral' issues as well as health-related issues.(410, 411) The concept that respondents would be able to provide an objective and independent check of the study findings, thereby adding trustworthiness and credibility to the study, is therefore unfounded. Furthermore, there are practical problems of how to resolve disagreements and of the time taken for respondent validation.(408) As such, respondent validation was not used and the findings were the interpretation of the researchers.

Inter-rater reliability statistics is the technique of assigning a numerical value to the level of agreement between those independently coding the research data.(412) However, the issue with using these statistics is that there is no established level of what counts as 'good' and 'reliable' agreement and there are difficulties in establishing an appropriate unit of analysis.(408) Furthermore, assessing reliability goes against the assumptions underlying the use of qualitative research methods. The data collected is not intended to be reproducible, rather, the intention is to collect personally meaningful information. By aiming to achieve agreement, one might risk producing a less insightful interpretation.(408) In the present study, the research team involved in the interpretation of interview data had different backgrounds and knowledge. The aim was to bring these differing interpretations together to produce more in-depth insights, by incorporating 'disagreements' rather than discarding them to achieve what is deemed to be a reliable statistic. Therefore, inter-rater reliability statistics were not reported.

5.8 Software

NVivo qualitative data analysis Software for Windows; Version 11.(405)

5.9 Summary

This Chapter has described the qualitative methods used to address the research questions presented in section 5.1. The next Chapter will present the results of this exploration.

6 Qualitative phase: results

6.1 Introduction

This Chapter presents the findings of the qualitative exploration into participants' experiences, as described in the methodology presented in Chapter 5. The aim of this Chapter is to address the following research questions:

For women who participated in the HELP trial, what are:

- their experiences, attitudes and beliefs surrounding issues related to their weight, 24 months after birth?
- what are their experiences, attitudes and beliefs surrounding their child's weight and health behaviours, 24 months after birth?

This chapter was written in line with the COREQ checklist for the high quality reporting of interview studies (Appendix R).(391) It describes the sample of participants recruited to the study, along with an appraisal of the quality of the interviews, then the final themes and sub-themes are presented.

6.2 Descriptive results of the interviews

6.2.1 Participants

A total of 241 women took part in the quantitative phase of the HELP 24m study (Chapter 4), making them eligible to be approached for this second qualitative phase. Although there were no pre-planned grounds for excluding any woman from taking part, there were two safeguarding issues in the follow-up appointments, described in Chapter 4 (section 4.3.3). In these cases, the student and research supervisors agreed that it would be inappropriate to contact these women. Therefore, 239 women were eligible to be approached for interview.

The student started to approach women in August 2015, and recruitment of participants and data collection was completed between September and October 2015. Women were

selected using the sampling matrix, which defined the 239 eligible women according to the sampling criteria set out in Chapter 5 (section 5.4.1). Women were targeted according to similarities or differences of trial group, weight change, and intervention adherence, to those already recruited. The sampling particularly focused on including some women in the control group who had lost weight, and those in the intervention group who had not lost weight. A total of 18 women consented to take part and were interviewed. All women who were contactable on the day of their arranged telephone interview went on to provide their informed consent and complete the interview. There were no participant withdrawals from the study. Eight women who were invited for interview declined, due to a lack of time or interest. Two women arranged an interview but were unable to be contacted at the scheduled time. One of these women later decided she did not want to proceed with taking part due to conflicting demands, and the other was recruited.

An acceptable sampling spread was achieved based on the sampling criteria (Table 48). Of the 18 women who were interviewed (intervention: 11, control: 7), four women had gained weight, five women had a minimum change in weight, and nine women had lost weight, from baseline. In the intervention group, two women had attended zero intervention sessions, two women had attended one to six (minimum), and seven women had attended seven or more (high). Other characteristics of these women demonstrated diversity within the group. Eight women had been first time mothers at baseline, the other 10 women already had children. The age range of women was 25 to 42 years. Ten women had children categorised as healthy weight, six had children categorised as overweight, and two had children with obesity. Women were interviewed between 39 to 49 months postpartum, with a mean time point of 43 months postpartum (i.e. child age: 3 years and 7 months).

Table 48: Characteristics of the interview participants

	Pseudonym	Group	Intervention adherence[a] (N)	Weight change[b]	Age	Parity[c]	Timing of interview[d]	Child BMI threshold[e]
1	Ava	Control	-	9.7 kg gain	34	Multiparous	41	Healthy
2	Bev	Control	-	0.9 kg m/c	34	Multiparous	41	Obese
3	Clara	Control	-	1.6 kg m/c	32	Multiparous	45	Healthy
4	Debby	Control	-	5.8 kg loss	41	Multiparous	47	Overweight
5	Emma	Control	-	5.6 kg loss	34	Multiparous	45	Healthy
6	Fiona	Control	-	10.1 kg loss	26	Nulliparous	41	Overweight
7	Grace	Control	-	37.4 kg loss	34	Multiparous	43	Healthy
8	Hanna	Intervention	0	8.9 kg gain	30	Nulliparous	40	Overweight
9	Isabel	Intervention	0	4.7 kg loss	29	Multiparous	44	Overweight
10	Julie	Intervention	1	11 kg gain	36	Multiparous	39	Overweight
11	Kate	Intervention	6	-2.3 kg m/c	33	Nulliparous	45	Obese
12	Lou	Intervention	12	4.1 kg gain	32	Nulliparous	44	Healthy
13	Mabel	Intervention	12	5.5 kg loss	33	Nulliparous	44	Overweight
14	Nancy	Intervention	12	5.3 kg loss	42	Nulliparous	39	Healthy
15	Olive	Intervention	15	2.9 kg m/c	42	Multiparous	46	Healthy
16	Pam	Intervention	15	4.2 kg loss	39	Multiparous	49	Healthy
17	Rachel	Intervention	21	8.9 kg loss	25	Nulliparous	48	Healthy
18	Sara	Intervention	25	0.3 kg m/c	38	Nulliparous	45	Healthy

a Seven sessions or more considered 'dosage'
b Change between baseline and 24 months postpartum (m/c = minimum change, participant had lost or gained <3kg)
c At baseline
d Timing of interview completion in months postpartum, also reflecting child age at that time
e At 24 months postpartum follow-up

It was assumed that the resulting spread in participant characteristics had allowed the collection of contrasting views and experiences. These characteristics were not always explored in the interviews. For example, reasons for low or non-attendance at intervention group sessions was not asked about, as this had been covered within process evaluation interviews in the HELP trial. Where women reflected on how their characteristics were influential to their thoughts, beliefs and attitudes, e.g. age influencing how they perceived their health, this was intended to be drawn out in the analysis. Also, as the results of the quantitative phase did not provide evidence of a difference in maternal and child outcomes between the trial groups, the objective of this study was to identify what might be the common attitudes held by women, that may have led to these findings.

6.2.2 Interview details

The duration of the interviews ranged from 28 to 89 minutes, with longer interviews completed with women from the intervention group (mean: 51 minutes) compared with control (mean: 39 minutes). This was likely due to the additional discussion and evaluation of the intervention content. Furthermore, the longest interview was with a participant in the intervention group who became upset and distressed by the topics raised but expressed a wish to continue with the interview. Understandably, this disrupted the flow of the interview, and much of the interview content was not directly related to the research questions. Due to the student's concern for the participant's wellbeing and following study processes outlined in Chapter 5 (section 5.5.2), this information was passed to the participant's GP.

Overall, the quality of the remaining interviews was generally good and free flowing, and participants appeared to find it easy to talk about their experiences without excessive input from the student. Often, questions on the interview schedule were bypassed as respondents had raised these topics independently, and prompts were not required, although probes were used regularly to encourage expansion of women's responses. There were interruptions during a few of the interviews, often by young children. This sometimes led to difficulties in re-establishing the flow of women's accounts.

6.3 Results

From the interview data, there were two distinct groups of themes identified related to 'mother' and 'child' which remained throughout the analysis. Mothers' thoughts, beliefs and attitudes influencing weight management behaviours before, during and after pregnancy, as well as those influencing weight and health behaviours for their young children, were described in three themes: 1) pregnancy specific attitudes and behaviours; 2) wider weight control attitudes and experiences; and, 3) maternal perceptions and influences on children's weight, diet and activity. The final coding frame is available in Appendix S, and the final thematic map is shown in Figure 14.

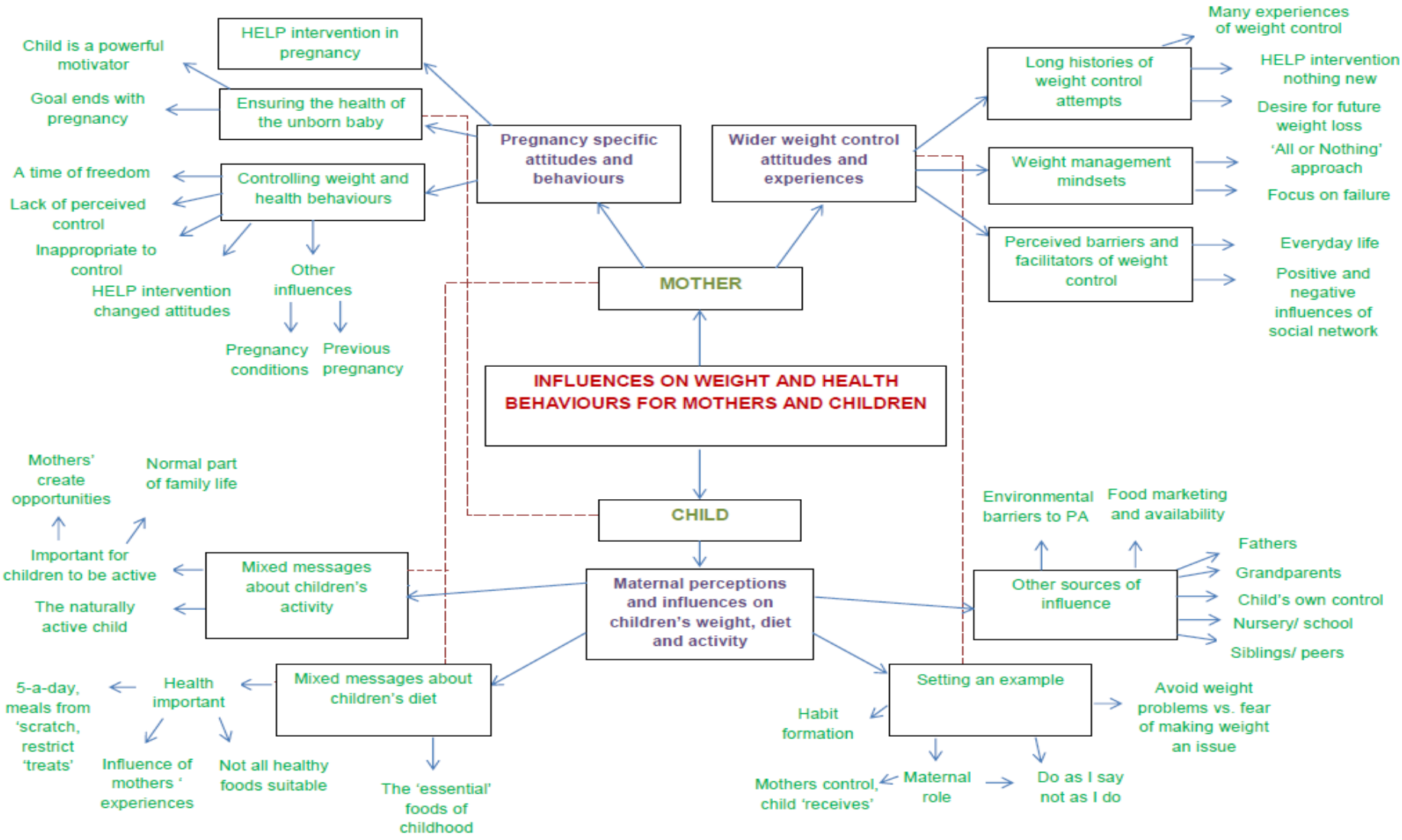

Figure 14: Thematic map displaying the themes and sub-themes resulting from the interview data analysis

6.3.1 Theme 1: Pregnancy specific attitudes and behaviours

Controlling weight and health behaviours in pregnancy

Pregnancy triggers specific thoughts and actions related to weight management and health behaviours. For some, pregnancy carries connotations of liberation, it is a time to relax and over-indulge in desired foods, a time during which the normal rules do not apply. There were contrasting views on how concerned women were about controlling their weight during pregnancy. Some women believed that their weight gain was not something to be concerned about, or something that was not appropriate to be concerned about, as getting bigger was a normal part of pregnancy. As such, excessive weight gain was often seen as a likely consequence of pregnancy, and some women simply embraced what they saw as the inevitable by allowing themselves to engage in less healthy behaviours. There were other women who felt that they would prefer to avoid excessive weight gain. However, they were not always sure about what they could do to control weight in pregnancy or if it could be controlled.

> *"The first thing you think is yay, I'm pregnant, I can eat what I want for however long I want and I'll just lose it after and you don't"* (Mabel, Intervention)

> *"I thought it was a bit of a free pass, a sort of free pass to eat what I like for nine months and obviously deal with the consequences afterwards"* (Debby, Control)

> *"I wasn't bothered about getting big in pregnancy or anything like that, you know about size because I know some people think oh I'm going to get fat and it's not fat, it's healthy isn't it to grow when you are pregnant and to have a bigger belly and to put some weight on to help the baby grow. I wouldn't say I was worrying about being pregnant and putting weight on, I was just thinking if there was something out there, you know, I could do while I was pregnant that wouldn't harm the baby because a lot of diets sort of cut back on a lot of calcium and things don't they and I was worrying about that"* (Olive, Intervention)

Women who had attended a high number of HELP intervention sessions reflected on how they may have entered pregnancy perceiving it as a time of behavioural freedom, but attending the intervention had changed their attitudes and, in turn, their behaviours during that time. The intervention advice had clarified what weight management behaviours could be adopted in pregnancy, and many believed they would have gained more weight had they not taken part as they would have been less likely to attempt to control their weight. A few of

these women emphasised how these changed attitudes would support them in a future pregnancy. They felt their experiences of the HELP intervention would encourage them to manage their weight and lifestyle during pregnancy, as it had given them the belief that it was possible to adopt a healthy lifestyle and to control weight during this time. Although women felt their own attitudes had changed, a few reported how other people had commented on being surprised about their weight management efforts in pregnancy. The general message received was that this seemed inappropriate, and women felt this was a widely held perspective.

> *"I didn't care what I looked like, well obviously you care to some extent, but cause I was pregnant I was like "I'm going to get fat anyway aren't I, so I might as well just scoff my face". But then when I got offered to do this class and I read all the books for Slimming World I realised well I can eat what I want but in a smaller size and then I wouldn't be the size of a house basically. It's definitely something I'd do if I had another child because I wouldn't want to get to be the size that I could've been without, I know that I would've put loads of weight on, I would've just ate what I wanted and not thought what other people thought. But knowing that I've done it and there are people that I know and they've been like "oh you did Slimming World when you were pregnant" I said "yeah" and they look at you to say like "you're mad"""* (Rachel, Intervention)

> *"I only put a stone on which was fantastic for, I think the average is probably about three or four stone when I speak to most ladies that didn't do that [intervention], so it must have some health benefit surely"* (Nancy, Intervention)

Interestingly, there were three women who had attended few or no intervention sessions and five women in the control group, who felt taking part in the HELP trial had increased their motivation and awareness of the importance of adopting healthy behaviours during and after pregnancy. The extent to which this led to changes in behaviours was not always clear.

> *"I suppose it gave me a little bit of motivation after I'd had the baby. When the lady came round and I was weighed and stuff, erm and she gave me some good advice, so I suppose yeah it motivated me a little bit"* (Clara, Control)

Experiences of pregnancy before the study were influential in how women approached their pregnancies during the study. Those who had gained excessive weight in previous pregnancies, and sometimes retained this weight, felt they wanted to try to manage their

weight better. A few women who had not experienced weight gain in previous pregnancies felt they were fortunate to have avoided this and identified themselves as someone who was not prone to weight gain in pregnancy. A few women who had experienced pregnancy specific conditions, such as tiredness and mobility issues, felt that these were powerful forces which had taken away their control to follow advice and engage in healthy behaviours. For example, their inability to avoid surrendering to cravings for unhealthy foods, or not being able to exercise due to pregnancy-related pain.

> *"I was trying to eat the things that midwife said, the healthy stuff, but you know there are cravings. So that's the thing that lost me... because my first pregnancy I had heartburn all the time, so I was eating a bit differently with things that didn't cause the heartburn. And my second [during study], I was eating a bit healthier than the first one. Because in my first I was eating everything I wanted. In my second I was, I think eating less fat. I didn't want to put as much on as my first"* (Ava, Control)

> *"My first pregnancy I just felt ill the whole time, so my diet was just eat whatever doesn't make me feel sick, my second pregnancy I just felt amazing, I felt really good, I don't think I really pigged out, but with my third, I had pelvis symphysis disorder with him and I was really fed up and I was on crutches and I didn't move a great deal, and I was eating because I wanted to eat that, because I was pregnant and why not because "don't you know how much pain I'm in?" sort of attitude, really felt sorry for myself. But then with [child] I had it again the SPD, but I had it a lot earlier on and I was in a wheelchair and I thought I can't be like I was when I was with [older child], I can't put more weight on"* (Pam, Intervention)

Ensuring the health of the unborn baby

The unborn child was a powerful motivator for adopting a healthy lifestyle in pregnancy. The majority of women, in both groups, discussed how they had become consciously aware, during pregnancy, of how their choices would have a direct impact on their unborn baby. This sense of responsibility and the desire to do the best for their baby, made it easier for women to adopt healthier behaviours in pregnancy, although this was usually limited to healthy dietary behaviours. Kate described her motivation as akin to women with a smoking addiction quitting the habit in pregnancy, the importance of her child's health created an external motivational force which made her successful in making healthy changes. This was compared to when women were not pregnant, their own health was not prioritised in the same way.

"Being more conscious that anything that you put into your body is going to directly or indirectly impact on that unborn child. I think the sense of responsibility around that is maybe, whereas, it's not as important to you when you're not pregnant, it suddenly becomes very important when you know that you're giving life to somebody else" (Bev, Control)

"It made [me think], not about my weight, but about not wanting to eat unhealthy, obviously I didn't want anything to go wrong or anything bad to happen to [study child], like if people smoked they might give up when they're pregnant, I thought I've got to eat healthy now and I did and it was easy at the time because I was pregnant, it wasn't just me that I was focusing on, I had to think I'm pregnant I've got to, I've got to do this for my child and her future in a way" (Kate, Intervention)

Women emphasised that their goals to ensure the health of their unborn baby were focused on health rather than weight. They believed that eating fresh and nutrient rich foods would be beneficial for their baby. However, in contrast to this common view, Hanna, in the following extract, expressed her belief that her dietary behaviours did not control outcomes for her baby.

"You are going to have a big baby whether you are big or small, if you're going to have a big baby you'll have a big baby, that's genetics, it is not down to how much you are eating" (Hanna, Intervention)

HELP intervention in pregnancy

Most women talked about their clear objective of a healthy pregnancy, and framed pregnancy as a distinct time period for the adoption of healthy behaviours. Attending the HELP intervention was valued as a source of support in helping women to achieve this objective. It reassured them about how to go about the safe adoption of healthy behaviours in pregnancy. The trusting and non-judgmental relationships that women had established with the intervention facilitators were important, particularly the midwife, who could relieve any concerns. This was often compared to negative and stigmatising experiences with other health professionals. Having their weight measured during the intervention sessions, was instrumental in motivating women to maintain healthier behaviours. The shared experiences and mutual understanding with other women in the group was also emphasised as a positive aspect of the intervention. However, there were differing views on the long-term impact of the intervention. A few of the women highlighted how being successful in managing their weight during pregnancy, as a result of the HELP intervention, had given them more belief in

their ability to manage weight outside of pregnancy. They described maintaining some healthy behaviours and attitudes over the long-term, such as portion control, regular fruit and vegetable intake, and trying to be active. On the other hand, most of those who attended the intervention felt that the influential motivations to adopt healthier behaviours in pregnancy ended with the birth of their baby, as this was perceived as the end goal. Three of the women in the intervention group emphasised that they would have preferred more support after pregnancy to help them maintain changes, or not relapse back into old habits in the early postpartum period. They felt that the six intervention sessions offered postpartum were badly timed. There were barriers to attending during this time, such as experiencing caesarean section meaning they were unable to drive or being overwhelmed with the new-born baby.

"Because I was seeing the Midwife weekly at the hospital, there was that closeness and I felt able to ask more questions and had more trust in the answers I was getting because, I felt that she was more, more interested in me really. I had a lot of blood tests and the GP Midwives weren't really getting back to me with answers… because it was the same Midwife seeing me, she had that consistent approach but, like I say when, the GP Midwives were different every time I went there. So, I think they didn't really understand me, as a person" (Sara, Intervention)

"That's the sort of thing that works for me, going somewhere every week and having to get on the scales. It keeps you motivated doesn't it? It is being part of a class and having the support of, you know, going and getting on the scales every week and giving you that motivation" (Olive, Intervention)

"I didn't eat healthy food every day before definitely not, I don't do a day now without eating fruit whereas before I would go days without having any fruit, and I'd think I'll have an apple one day, you know, but now I probably have about three or four pieces of fruit a day" (Nancy, Intervention)

"I think it was positive at the time, the support in the hospital, so that was, that was positive the support while I was pregnant but I think regarding my weight it hasn't made much difference" (Kate, Intervention)

6.3.2 Theme 2: Wider weight control attitudes and experiences

Long histories of weight control attempts

All but one of the women described having a long history of being concerned about their weight, struggling to control their weight, and of making attempts to lose weight. Some women traced their awareness of being overweight back to childhood, they felt they had always been prone to being bigger. Others pinpointed lifestyle changes caused by milestone events as responsible for their weight gain, such as getting married or having children. Many of the women spoke about having repeated experiences of attending commercial weight loss groups and following a variety of diet and activity programmes. Dietary behaviours were emphasised as being important for weight loss more often than exercise. These groups and programmes offered structure, a set way to behave, which women felt was important for keeping them focused to successfully adopt healthier behaviours and lose weight. Some women also felt that following a weight loss programme had a benefit for their family, as it influenced the foods they offered their family. Fiona was the one participant who did not describe a long history of weight control attempts. It was having a child which made her think about losing weight.

> *"I remember being on a diet when I was nine. My mum's always struggled with her weight, and I think she was worried that I was going to be a fat child. I remember being on this diet, although I don't remember the specifics about it, that if I lost, how much weight, I could have a pair of new shoes I wanted. I don't think it ever went away from there, so I recall through my teens I was conscious that I was bigger than my friends"* (Bev, Control)

> *"I mean what I've been doing for the last year is flitting between different, just eating healthy myself, or Slimming World. I've now gone back to Weight Watchers. My weight stays the same for a while, so I think I need to do something different, that's why I've gone to Weight Watchers last week. I think your body possibly gets used to what you're doing, then you just need a boost or mentally you need something different"* (Lou, Intervention)

> *"Your past really colours your future, no matter how hard you try. I can see it now looking back, all my eating habits I can trail it all the way back, and, at points where I added to those bad eating habits. I've got so much bad habits and portion control which was not there, and I've just added my own little twist on it as I've gone along. And it just, it's a lot of habits to break and reel myself in"* (Julie, Intervention)

In light of these long histories of weight control attempts, although the intervention was useful as it provided a structured programme to retain women's focus on weight control during pregnancy, most of the women who attended the intervention groups felt that they had the knowledge of how to manage their weight before taking part. A few spoke about how they felt they had continued to engage in a number of behaviours which they changed as a result of the intervention, but for most it was viewed as another period of attempting to control their weight within a history of such attempts.

> *"I was doing it anyway, or I was trying to do it anyway, you know, so I don't think it did that much, it wasn't like I was never eating healthy and I went there and that taught me all the correct, educated me in a way, I already knew but I just wasn't doing it"* (Kate, Intervention)

All of the women reported that they engaged in some sort of lifestyle behaviours for the purpose of weight loss or health. Many spoke about long-term habits which they maintained in an effort to be healthy. These included planning and providing healthy, home-cooked meals for their families, avoiding high fat foods, monitoring portions, regularly eating fruits and vegetables, family activities, weighing themselves, and reading food labels to ensure healthier food choices. However, many also felt they had unhealthy habits, such as regular consumption of sweet foods, which impacted their success in losing weight. Most of the women had a desire to lose weight. Many of the women spoke about their children as their main motivation for wanting to lose weight, the desire was fuelled by wanting to be fitter and healthier for their children, so they could actively engage with them, and, in the long-term, be around to see them grow up. This was emphasised by older mothers in particular, their age made them reflect on their health and longevity. Women spoke about their current weight as temporary, they visualised a time where they would manage to be successful in losing weight. However, they were unsure as to how exactly weight loss would be achieved or felt that the efforts that would be required would be an impossible task.

> *"I'm getting older now, I'm thinking I want to be thin, I want to be fit and I think I've got to achieve that, I've got to do something, I've got to make the changes"* (Pam, Intervention)

> *"I hate it [body], it's a prison. I really, I just want to get rid of the weight, I want to not be this way but I, I just feel like sometimes everything's just hopeless, this hopeless feeling... it's like there's this humungous mountain and I know I'm not going to bloody*

climb up there, you know, I'm not getting to the top of that one. There's no rope to help me up, there's no hand holds, there's just this big sheer up... I want to lose the weight, I want to be able to, I mean, I can't even chase [child] around and he knows it, because he runs off and he knows I can't catch him. I would love to surprise him one day and actually "gotcha"" (Julie, Intervention)

Weight management mindsets

All of the women believed it was important to be healthy and reported engaging in some form of healthy dietary or activity behaviours. Despite these positive behaviours, most of the women perceived their approach to weight management as *"all or nothing*". The majority of women talked about having two distinct periods of behaviour. The first women described as when their minds were extremely focused on controlling weight. They used language such as *'into it', 'head in the game', 'retraining my brain', 'kick start'* or *'started afresh'* to describe these times. This focus was associated with success in managing their dietary and activity behaviours, and in losing weight. Commercial weight loss groups were often used to achieve this focus, women felt they needed external monitoring to oversee their weight loss. Life events also acted as timed goals for achieving weight loss, such as getting married or going on holiday. The HELP intervention, and changes that women made during pregnancy, were viewed as a period of achieving great focus on controlling weight and being healthy. In contrast, these women also described periods of time where they went *'off*', *"forgot"* or *'quit'* weight management, and let it *'go by the wayside'* or *'out the window'*. During these times they felt they reverted back to bad habits and, as a result, gained weight. This often coincided with dropout from commercial weight loss groups.

"When I was pregnant I was, that was the last time I done it really well, but that wasn't about losing weight then that was just about being healthy for you and the baby, that was completely different, whereas this time it's definitely trying to get my target, get back to what I should be" (Nancy, Intervention)

"It just creeps back up. It wasn't one thing where, I put on three stone in a month or anything, it was just gradual over a year, over a few years. I don't know, I think I must have just lost focus because, I had focus for the wedding and then I was focusing to try and conceive and then, yeah you just a relax a little bit. I'm mentally trying not to leave this time, you know, trying to keep it going" (Lou, Intervention)

Being *'on'* weight management, was characterised as being in a *'bubble'* of focus and commitment to weight loss, it was all-encompassing and strict in terms of behavioural

control. Women were more likely to use the word 'diet' to describe their eating behaviours during this time. Some women tried to avoid social situations where foods might be available to avoid temptation. They felt they had an inability to eat unhealthy foods in moderation and would rather adopt a strict approach to diet and avoid foods completely. However, women struggled to sustain these efforts, and breaking the strict rules and eating forbidden foods, or not managing to do intense exercise, triggered feelings of guilt and failure, of being *'rubbish'* and could lead to relapse of bad habits. Times of focusing on weight control were perceived as boring and restrictive. On the other hand, times *'off'* were described as enjoyable, positive and easier, when women allowed themselves to eat what they wanted and give themselves a 'break'. However, these periods were also associated with a sense of failure. Viewing weight management in this way meant that achieving weight loss seemed like an immense task which required this all-encompassing effort to be successful, and women failed to acknowledge the achievement of maintaining some healthy behaviours over the long-term.

> *"It's hard when you go round someone else's and they've got a buffet or something. When I'm being really strict I'll just not eat anything from the buffet, I'll just go and try and not touch anything, but it's quite tempting"* (Nancy, Intervention)

> *"I'm rubbish... because I'm overweight and I want to lose weight, but it just never happens because I just don't manage enough time to apply a diet, do a diet and do the exercise with it"* (Isabel, Intervention)

Women who had been successful in losing weight or maintaining healthy behaviours, emphasised how important changing their mindset was. They felt it was important to move away from the *'all or nothing'* and *"quick fix"* approach, to thinking about long-term health and accepting that managing weight and behaviours did require constant attention. They pinpointed setting achievable goals and not aiming to have too many goals at one time, rethinking barriers, focusing on the positive aspects of a healthy lifestyle, and moderation rather than restriction, as important. For Mabel, it was the HELP intervention which had changed her attitude about being able to achieve balance in her weight management.

> *"Don't cut everything out, still give yourself that treat, not everything's as bad as you think it is, and like the bacon, I thought, you're going to diet you've got to give up a full English breakfast, but you actually go through the thing and it's like, well no actually you don't have to give it up, just don't cook it this way, cook it that way, do it this way"* (Mabel, Intervention)

"I do shift work so I've always been last minute on the go, and I've always lived behind that as an excuse, you know, I'm tired after a late shift to make something to eat, I'll do it in the morning and I get up in the morning and think "oh I can't be bothered". For me it's been preparation, eating healthy and exercise, I've done no quick fixes, *you've got to think about it all the time"* (Grace, Control)

Perceived barriers and facilitators of weight control

There were many perceived barriers to women achieving and maintaining weight control and lifestyle goals. There were a few unexpected events which led to women having a lack of control over their behaviours, such as unexpected health issues. However, the majority of women perceived set-backs or "*trigger moments"* within everyday life, which they did not have the ability to cope with, and which negatively impacted their behaviours. Many women felt their lifestyle did not allow them to dedicate the perceived effort required to lose weight. Regular exercise, in particular, was something they felt was not achievable as the demands of family life and job roles meant a lack of time for this. In addition, women felt their roles as mothers was to prioritise the needs of their children and encourage their health; rather than prioritising their own weight loss. Mood and emotions were implicated in the adoption of unhealthy behaviours, this could be women's inability to cope with stress or worries in their lives, but it could also be happiness leading them to be complacent about their weight. School holidays and bad weather were mentioned by a few women as barriers to maintaining dietary and exercise behaviours.

"I think it's all down to having the children, the initial weight gain from having babies, the restrictions that you have when you've got children, there's timing everything, when everybody's got things on and you, your needs come last, everybody else's needs come first, so if your exercise class clashes with their music class, they go to their music class and you skip it... your needs are always at the bottom of the pile" (Emma, Control)

"I know what triggers me to reach for something naughty. I am aware in my head that… what works and what doesn't. And that's why I'm nagging with myself when I do let myself down because I know I can do a lot better. If I didn't have these trigger moments, which I know they're coming but it's life unfortunately" (Sara, Intervention)

"It could be anything; it could be something to do with a relationship or finance, anything that will set my anxiety off but normally it is something to do with my self-confidence" (Clara, Control)

Family and friends hugely impacted the extent to which women were able to adopt or maintain healthy behaviours, both positively and negatively. Willingness by family and friends to participate in healthy behaviours, such as eating the same foods or joint exercise, was important in motivating women to maintain healthy behaviours. However, women did not necessarily expect that family members should be willing to eat the same foods as them, especially if they perceived their partner or children as having no need to lose weight. Having someone to exercise with, the commitment to keep to a schedule of exercising with friends, or the support from family for childcare; were factors that women felt helped them to engage in exercise behaviours. In contrast, women felt that those around them often brought temptations into their environment that they were trying to avoid, such as unhealthy foods. This made it difficult for them to stick to eating healthier foods. Mothers felt tempted by unhealthy foods that they made available in the home for their children, which they had not bought before having children, but felt that they could not avoid doing so. Family and friends tried to be supportive by telling women they did not need to lose weight, which they found unhelpful. A few women felt alone in their weight management attempts and not supported by others, which made them feel like there was no point in trying.

"If you've got the support behind you, it motivates you, it's like a snowball effect. When we do go to group [slimming world], my mum comes with me, we do it together. My husband follows the plan, he won't come to group but he does follow the plan. When we go to friend's houses, they have been known to make separate dishes or make things in a different way so that, that it's healthy enough for me not to worry about eating it. The husband still thinks that bringing me a bar of chocolate is a lovely treat or a nice bottle of wine or a cocktail, when, whereas it is a loveable gesture, but not when you're trying to be good" (Emma, Control)

"Since having the children, there's things that I have in the house that I wouldn't have had in the house before so those temptations that I would never have brought into my own home, like six packets of crisps or a packet of biscuits, are there so that the children can have treats" (Olive, Intervention)

"My husband fetching chocolate home when I've told him I want to diet, I want to do this, I want to lose the weight, he still fetches it home, and my dad will always fetch me chocolate and biscuits and stuff. My dad always takes the mick out of me for trying to eat healthily, and he says I stress about it too much, because "I turned out alright" and what not, but I didn't turn out alright because I'm overweight" (Isabel, Intervention)

"The stuff that I wouldn't particularly want to eat is the stuff that appeals to him [husband] and he doesn't need to manage his weight" (Debby, Control)

"All my close friends and family know I'm trying to be good, so they won't go and offer me a cream cake if I went round there, they say to me "is there anything you'd like" if they're all eating something. Most of the time he [partner] knows, we go out sometimes and he will have a pizza and I'm sitting there with a healthy option so I get a little bit annoyed, but obviously he wants his pizza, he's not trying to lose weight" (Nancy, Intervention)

"If it's [physical activity] something that's not solitary, something that you're not on your own with. Something that keeps it, it keeps it fun, it keeps it something that you're actually looking forward to doing. You've got a commitment with somebody else to go and do it, yeah, I find that helps" (Emma, Control)

6.3.3 Theme 3: Maternal perceptions and influences on children's weight, diet and activity

Mixed messages about children's diet

Mothers wanted their children to have a healthy and 'balanced' diet and most seemed to be aware of prolific public health campaigns, such as '5-a-day'. Women included encouraging their children to consume fruit and vegetables, and dairy, making fresh foods available in the home, restricting consumption of 'junk' foods, cooking family meals "*from scratch"*, and avoiding processed foods, as the methods they used to try to achieve this for their children.

"cooking from scratch, basically, not eating the high processed foods, making sure that the children are getting a balanced diet, making they're five a day mainly, more fresh fruit and veg, or frozen fruit and veg actually, just making sure that they're getting a good balanced diet" (Emma, Control)

Although health was important, this was sometimes confused with being a 'good eater', a child who was willing to eat a wide variety of foods, without fuss. Perceived child preferences often took precedence over health in mothers' food choices for their children; women avoided making something healthy if they thought their child was unlikely to eat it. When children refused foods, most of the mothers opted to offer them something else, often a less

healthy but more convenient option that they thought their child would eat. Mothers were more concerned that their children were eating 'something', regardless of how healthy the food was.

> *"He eats all sorts of weird and wonderful things. He eats like really, really healthy but that's like down to my mum. She, he has brioche and things like that"* (Fiona, Control)

A few mothers felt that making a big deal out of food and pressuring children to eat a particular food would lead to them being less likely to accept the food in the future.

> *"I would've done him fattening foods, food that isn't probably good for him like I'd do him chicken nuggets and chips or I'd do him pizza, things that he shouldn't be eating probably or I'd go for the easy option of just taking him McDonald's or go chippy. I think if you force someone to eat it, it puts you off wanting to eat it for the rest of your life"* (Rachel, Intervention)

Many of the women who had attended the HELP intervention, or who were following commercial weight loss programme, felt that these experiences had benefitted their children's diet. Slimming World was considered to be 'family friendly' and provided mothers with tips on healthy foods they could make for their children. Interestingly, Isabel, who had not attended any of the intervention sessions, felt she had received good advice from the local researcher who completed her follow-up visits, about how to encourage a healthy lifestyle for her child. However, women's choice of healthy food options for themselves, was not always viewed as appropriate or acceptable for their children, and they would offer them something different. The two quotes from Pam below show how there could be contradictions in mothers' accounts. Although she felt her attending the HELP intervention had encouraged her to offer her children healthier foods, there continued to be practices which suggested that the same healthy behaviours were not considered necessary for her children.

> *"Diets in the past it would be kids are eating one thing and mum's eating something else, that's too much, you've got to be eating as a family. It's made me look at recipes different and, trying to cook them more healthily or making little swaps. You know, going to the HELP group that made it, made me realise that"* (Pam, Intervention)

> *"He [husband] may cook sausage and chips for the kids, but then he'll do me a chicken breast with some pasta. I think it's probably through all my moaning like "why have you*

cooked that for me? You know I'm on a diet"... and the kids are eating their chocolate muffins and say "are you on a diet today mum?" (Pam, Intervention)

In addition to achieving a healthy diet for their children, certain foods were perceived as the typical 'norm' for children to have. Examples included sausages, chips, beans, chicken nuggets, fish fingers, and burgers/ McDonald's. Mothers also emphasised allowing their children 'treats' which were mainly snack foods, such as chocolate, jellies and crisps. Their child's consumption of these foods was perceived as an essential part of childhood. To be a child meant to have an automatic preference for unhealthy 'junk' foods. Although these foods were unhealthy, most mothers felt that they should provide them for their children, and that doing so would be harmless. In relation to this practice, quite a few mothers spoke about how providing 'treat' foods for their children in the home, acted as a barrier to their own weight management. However, they still felt they were obligated to make these 'treats' available. Similar to how mothers talked about their own on/off cycles of eating healthy foods, children's 'treats' were special, fun, relaxed and "*leeway"* from the boring rules. A few felt that denying these foods would make children want to consume them more.

"I try to not give him too many sweets, but I remember growing up having a few treats, you know, little sweets and stuff they didn't do me any harm, so I think it's nice for children to have a few little treats" (Nancy, Intervention)

"It's hard to stick to a diet when your family's eating sausage and chips, you know, we try and keep that sort of food down to a minimum but they're kids and they do need to have their sausages now and again, and a burger or whatever" (Pam, Intervention)

Mixed messages about children's activity

Despite not prioritising these behaviours for themselves, mothers placed emphasis on ensuring their children were active. The HELP intervention made a few mothers more aware of how important activity was for their children. Mothers created opportunities for their children's activity, including taking them to the park, swimming or soft play, letting them play in the garden, or walking places. Although the health benefits of exercise were acknowledged, this was often to keep children entertained or for energy exertion. It could be seen as a way to reduce sedentary behaviours, but it could also be seen as making up for sedentary behaviours, rather than replacing them. Also, children's requests to be taken places or their enjoyment of a particular activity encouraged mothers to create these opportunities. Engaging in activities as a family, which allowed children to be active, was

seen as a normal part of family life. Providing these activity opportunities for children positively increased mothers' own activity levels, although mothers did not acknowledge this.

> *"I don't specifically do any exercise anymore. I used to do Zumba and swimming, I don't do that anymore, so it's just quite literally running around for the kids, and on a Sunday, we normally go out for a walk around the local lake and that's about it really. We like to get out with the children at the weekend to give them fresh air and give them exercise instead of sitting in and watching telly... just normal life really, just go in the park with the children getting them out running around after them"* (Isabel, Intervention)

Although mothers spoke about the opportunities they created for their children to be active, at the same time most of the women perceived children of this age as needing no encouragement to be active. They described their children as *'constantly on the move', "running around all the time"*, and "*never sits still",* without the need for their input in promoting these behaviours. This concept of the 'active child' could influence mothers' food choices for their children, in that a few mothers justified allowing their children to consume less healthy food options, because they thought they would burn it off through exercise.

> *"He plays in the garden so he's always running around the house. He's not a sitter downer. When I think okay, we've been in front of the telly all day, I will take him to the park just to sort of burn off some steam. Erm, but I think we are only going to school and back, it is not going to kill you to walk. Sort of that is as much conscious effort as I put into it but he is very active himself. Doesn't need much help"* (Hanna, Intervention)

Setting an example

A few mothers mentioned the importance of establishing a 'norm' for healthy behaviours at an early age, in terms of habit formation in the long-term. Although most did not reflect on how unhealthy behaviours in childhood might lead to lifelong behaviours. Preschool children were not thought to be mature enough to make informed decisions for themselves, rather, they were perceived as passive 'receivers' of mothers' choices. It was a central part of the maternal role, to monitor and control their children's behaviours. By encouraging healthy options and restricting unhealthy options, mothers believed this would lead to their children learning to follow a healthy lifestyle.

> *"It's all down to the mother isn't it? What the child does and really you should be letting your children run around and be active and do stuff rather than sitting them at a telly all*

day letting them eat junk food. It's a way of life isn't it, so if they're brought up eating healthy and exercising that's what they know, if they're brought up on junk food and sitting at a computer they'll grow up eating junk food sitting at a computer, so it's what you put into them at a young age" (Grace, Control)

Some viewed themselves as role models for their children and felt that it was important to demonstrate healthy behaviours, believing that this would encourage children to engage in the same behaviours. However, many of the mothers prioritised and promoted healthy behaviours for their children that they acknowledged they did not adopt themselves. They took a 'do as I say not as I do' attitude and felt it was important for their children to adopt healthy behaviours that they did not achieve, because they did not want their children to experience the same weight problems that they had themselves. A few mothers hid their consumption of unhealthy foods from their children, as they recognised that their children would want to consume those foods if they did not. Mothers talked about how their children could have knowledge of the weight control strategies that they used, such as attending a commercial weight loss programme. However, they felt that children had little understanding of what this meant or paid much attention to what they were doing.

"I really try and, don't let the children see. I will gorge on it [cake and chocolate], it is disgusting and I know I'm doing it and I know it's wrong yet I still do it. I don't want them to be as unhealthy as I am and overweight as I am" (Isabel, Intervention)

"My attitude is very much it's alright for me… it's up to me what I do and what I eat and how fat I get, but certainly not for the kids…. I'd be quite upset if they were too big" (Debby, Control)

"My kids are aware that we go to this Slimming World and we eat salads and things like that you know. They don't really understand it but you know they don't offer me chocolates and things" (Hanna, Intervention)

Some of the mothers' reflected on how their own upbringing had guided the decisions they made for their children. They wanted to promote healthier habits for their children, than they had been taught, to help them avoid weight-related issues.

"I am determined none of my kids are going to be like me. When I was younger, it was like, here's a carrier bag of sweets, have fun, you know. I do not do that with my kids, I got fruit, vegetables, everything in this house, I cook, and not with a deep fat fryer...

and it's all about, you will not be like me, one of my biggest fears is that they will end up fat like me and hating themselves like I do" (Julie, Intervention)

Although women wanted their children to avoid weight problems, on the other hand, there was some hesitancy for mothers to focus on the weight of their children at this age. Mothers avoided discussing anything weight-related with their children, for fear of making an 'issue of weight'. They were often hesitant about how to explain their own weight management behaviours to their children. They believed that to make children aware of the concept of controlling weight, would make them worried, concerned or trigger an eating disorder. They did not want their children to have the same negative relationship with their weight, or particular foods, as mothers themselves had. In addition, many of the mothers believed that the concept of weight management was not relevant for their children because they perceived them as not having a 'problem' with their weight. Most mothers felt their children were of healthy weight, and they expressed more concern about underweight than overweight children. However, maternal perceptions of children's weight, and the presence or absence of perceived 'overweight', could be influential in mothers' decisions in relation to their children's behaviours. Children who were perceived as lower weight could 'get away' with eating more unhealthy foods, whereas if mothers thought their child was overweight, they believed they would take action to address this. The absence of any overweight concerns justified children's consumption of unhealthy foods.

"Because he's like a rake and he eats rubbish. I worry that maybe he's underweight but he's certainly not overweight. I try and give them healthy meals as much as possible but he won't eat a lot of stuff. So, I think well at least you are eating something. I just remember being, when I was a teenager and my mum trying to put me on diets and things like that and what effect that had on me and I don't want them to feel like that. Because when I think oh I am on a diet it makes you feel quite sad. I don't want him to have that with food, you know, there's nothing wrong with his weight so it's not really anything that I am worried about" (Hanna, Intervention)

"They see me standing on the scales and they ask me, "Why are you standing on the scales, mummy?" And I, the answer to that's really difficult. I don't, you know, "why am I standing on the scales"? "I'm standing on the scale to check my weight", but then I don't want them checking their weight all the time, I just want them to be healthy... I'll try and be positive about it, I don't say, "Oh, I'm standing on these scales to see if I've lost any weight", I would say something like, "I'm standing on here to check that I'm still fit and healthy" (Bev, Control)

Other sources of influence

Mothers discussed many ways in which their children exerted power over their own food choices. Mothers' decisions on what to feed their children were often based on children's preferences, and what they would be willing to eat. The potential for food refusal could discourage mothers from preparing or offering their children a particular option, and often food choices were negotiated between mothers and children. Children could also exert their influence over food availability through pestering mothers for particular foods.

> *"I have fruit every morning for breakfast, I try and get him to have some of that thinking that he might have it if it's mine, and he's "no I don't like fruit", I know he does because he has it at school. I try to cook him things like same as us, and it's just hit and miss as to whether he'll have it or not. I've tried making shapes with different foods and, oh all sorts, he'll just eat what he wants when he wants"* (Lou, Intervention)

Mothers perceived external challenges in achieving a healthy diet for their children, such as the marketing and promotion of some foods as child-friendly healthy options, when they were not. Ava spoke about the *'nightmare'* of eating out and being limited to unhealthy choices on children's menus.

> *"There is so much food considered healthy for kids but it is very calorific and it is basically not good for kids, even if it said it is good for them"* (Ava, Control)

Fathers shared a role in making decisions for children and, for a few of the women, their partners were solely responsible for buying and preparing meals for their children so these decisions were out of their control. Men, in general, were seen as less likely to think about children's health in the decisions that they made. In two separated households, these mothers talked about the difficulties in having joint responsibility for making choices for their children. Often, they felt their child was offered less healthy options at their father's home, which they had no control over. This, in turn, made it more difficult for them to persuade their children to accept healthy foods.

> *"He's with his dad three days of the week and I know that his dad doesn't do healthy eating whatsoever"* (Rachel, Intervention)

Grandparents were widely acknowledged as influential. Although some of the women spoke about grandparents as a positive influence, in that they encouraged their child to try new

foods and created opportunities for activity, the majority of women perceived grandparents as more lenient in allowing children to have unhealthy foods. For some, this was considered problematic, in that it thwarted their efforts to encourage their children to be healthy. For others, it was acceptable as they felt the role of grandparents was to spoil their grandchildren. Even when concerns were communicated to grandparents, by mothers, their wishes could be ignored.

> *"If they go to my mum's they can have whatever they want, they can sit with a cookie jar I have to argue with her. And they can keep going back to the cookie jar she wouldn't question it"* (Grace, Control)

The presence of older siblings in the home influenced children's food intake, in that younger children were offered and exposed to unhealthy foods at an earlier age, and food neophobia in older children was likely to influence whether the younger children would eat a particular food.

> *"It's second child syndrome, [older child] only drank water from weaning to being about 18 months. [Older child] was two and a bit when [child] comes along, by the time she gets to about 12 months, she's probably having juice instead of water"* (Bev, Control)

Nurseries and playschools were generally considered to be a positive influence in encouraging and offering healthy food options and allowing children the opportunity for activity. They also played an educational role in teaching children about healthy behaviours. However, for Rachel, healthy eating policies were viewed as restrictive as she was concerned her child would not eat the healthy foods she was limited to providing in his packed lunch. Without these policies, she felt she would be likely to include less healthy options that she knew her child liked. One mother considered her son to be influenced by peers in nursery, and that he was more likely to try new foods in that setting as a result of observing other children eating those foods.

> *"They eat healthy in the nursery, eating a range of different foods, they do cooking as well, so I think they talk about healthy eating and ways to eat healthy, so that has an impact on her too. They do activities in nursery... PE groups and they do dance groups and they make exercise fun in the nursery"* (Kate, Intervention)

Barriers to achieving activity for children at this age included bad weather and children being limited in their freedom for independent play as a result of safety concerns.

6.4 Discussion

6.4.1 Summary of findings

In this Chapter, the experiences of women who had taken part in the HELP 24m study quantitative phase, in relation to their weight before, during and after pregnancy, and the weight and health behaviours of their children, have been presented. Women's accounts were summarised into three themes: 1) pregnancy specific attitudes and behaviours, 2) wider weight control experiences and attitudes, and 3) maternal perceptions and influences on children's weight, diet and activity.

Specific beliefs about weight management are attached to pregnancy. Pregnancy is tied up with notions of overindulging, weight gain and retention, and relaxation of behavioural control. These can be seen as concepts that are central to pregnancy and unavoidable consequences of the experience. These views are considered to be widespread culturally held beliefs, and women had experiences of other people's input on what their weight and lifestyle behaviours in pregnancy should be. Weight management could be perceived as a selfish and trivial pursuit, that women's own weight control should not take precedence over gaining weight for the health of their baby. Attending the HELP intervention had addressed pregnancy specific attitudes. It changed women's beliefs about their ability to control weight in pregnancy and the appropriateness of doing so. It had shown these women that excessive weight gain in pregnancy was not an inevitable outcome. Rather, appropriate health-promoting behaviours could be initiated to control weight, while still ensuring the health of their baby. Having previously believed there was no way to control weight in pregnancy, there was a self-efficacy achieved by being successful in managing weight specifically in pregnancy. Experiences of the HELP intervention also led some women to believe that this would change the approach that they might take in a future pregnancy, as it had changed their attitudes about what pregnancy means in terms of weight and behaviours. However, women did not necessarily have a goal of using this to change long-term weight.

For multiparous women, previous experiences of excessive GWG may have motivated them to avoid doing the same in this pregnancy. Although, those who had not retained pregnancy weight may not have seen themselves at risk of doing so this time. Women felt that particular illnesses or conditions of pregnancy which they had experienced, such as pelvic pain or cravings for unhealthy foods, reduced their personal control in following health-promoting behaviours. For most women, an awareness that their behaviours would have a direct impact on the development of their foetus became salient in pregnancy. They felt they had a

moral responsibility to ignore their own desires and prioritise the needs of their unborn baby. This motivated them and made it easier to engage in healthier behaviours. For those who attended the HELP intervention, this was seen as supportive in helping them to achieve their goal of having a healthy baby. The non-judgemental support they had received from the intervention facilitators in the group was important, particularly the involvement of the midwife, who was able to alleviate pregnancy-related concerns and advise on the appropriateness of behaviours, in terms of ensuring the safety of the unborn babies. This was compared to experiences with other healthcare professionals, where women had felt judged and stereotyped. They felt other healthcare professionals they had encountered did not have the appropriate skills to treat women with obesity during pregnancy in the same way as those who facilitated the HELP intervention did. Some of the women reported maintaining small behaviour changes from the HELP intervention. However, crucially, for most of these women, the motivation for adopting healthy behaviours in pregnancy to ensure the health of their baby, and therefore the purpose of engaging with the HELP intervention, ended with the birth of their baby. Some women would have valued more support postpartum, but ultimately women did not perceive the HELP intervention as having a long-term impact in light of their goal to use it as a tool for a healthy pregnancy. Women did not consider their own weight and health with the same sense of importance as the health of their baby.

The majority of women reflected on their many weight-related experiences before and after pregnancy, and weight-control attempts were traced as far back as childhood for some. Participants repeatedly spoke about being on and off diets, and a lot of the women described themselves as seasoned followers of one or another weight loss support programmes, such as commercial weight loss groups. Past success in losing weight was driven by attending such a group and their success being assessed by someone else, in addition to specific events that acted as short-term goals for weight loss achievement. The HELP intervention was not necessarily viewed as anything unique to these past experiences, except for it having been in pregnancy and having supported pregnancy related goals and motivations. Although some women believed they had maintained one or two small behaviour changes made as a result of the intervention, most said they continued to need additional support to monitor and motivate them. Women's motivation for behaviour change postpartum often continued to be their children, but this had shifted to wanting to be an energetic parent and to ensure long-term health and longevity, so they would to be around for their children.

Most women wanted to lose weight, they saw it as their responsibility to control, and many reported long-term habits that supported this ambition. However, women characterised their

weight management experiences as cycles of success followed by relapse. Periods of success involved rigid rule following, focus on the goal and allowing no room for flexibility. Women relied on external sources, such as weight management groups, to achieve this focus, and felt they were not capable of doing it alone. Not being able to conform to strict rules in the long-term led women to relapse into old behaviours and, with it, feelings of guilt, failure and personal criticism at not being able to maintain their weight control. 'Off' periods were perceived as easier and more fun as they did not require the same mental effort, and women felt they could do what they wanted and revert back to what was their 'norm' behaviour. Women rarely recognised the success that they did have in weight control or health behaviours in the long-term. Finding a way to achieve balance and accepting weight management as a way of life was likely to have helped those who were successful in losing weight. There were many barriers that women perceived to set them on the path to relapse, or prevented them from adopting healthier behaviours, such as the various demands on their time due to family life and work life, and their responsibility as mothers to prioritise their families' needs. Women's success or failure in weight control was greatly impacted by the support they received from family and friends for maintaining healthy behaviours.

Mothers expressed mixed messages about the decisions they made in relation to their children's diets. Mothers wanted their children to consume a healthy and balanced diet, and felt they provided healthy foods. However, their priority was to ensure their children ate something, and mothers described avoiding conflict in relation to foods by providing children with preferred foods. Women's experiences of following the HELP intervention, or another programme after pregnancy, could positively influence the foods they provided for their family, but at the same time women viewed this as a diet for weight loss and not something necessary for their children to follow. Certain eating habits were perceived to be a characteristic part of childhood. Although mothers wanted their children to be healthy, they also felt they should provide 'junk foods' and 'treats'.

There were also mixed messages about mothers' behaviours in relation to their children's activity. It was considered good for children to be active and most mothers said they created some opportunities to allow this. It was a big part of family life to take part in activities together. At the same time, mothers perceived their children to be full of energy and always active in whatever they were doing within the home environment, without the need for structured activities. The role of being a mother was seen to include decision making in relation to children's behaviours. Mothers considered themselves as being responsible and in control of their child's behaviours, and their choosing of healthier options for their children would result in these behaviours becoming the child's lifestyle. Mothers were confident that

they knew how to promote healthy behaviours to their children, despite many having low confidence in their ability to do this for themselves. Some mothers felt their own behaviours had an impact on their children, and in recognition of this, a few hid their unhealthy eating habits from their children. Many mothers felt it was more important to encourage behaviours for their children that they themselves did not engage in, such as PA. Mother's own weight management experiences influenced their choices in relation to their children. They wanted their children to be healthy and encouraged healthy behaviours so that their children might avoid developing weight problems. On the other hand, weight management was viewed as a way of treating a weight problem not a way of preventing one. Most mothers were not concerned about their children's weight, and level of concern was linked to the foods that mothers felt their children could 'get away' with eating. Mothers' own experiences of having to deny themselves certain foods, and the sad feelings which were attached to this, meant that they did not want their children to have the same anxieties about consuming foods. Mothers had a fear that their children might become 'aware' of the concept of weight, which would lead them to have the same negative relationship that they themselves had with their weight, and a few mothers avoided creating this awareness by avoiding discussions of weight.

Children themselves exerted control over their own behaviours in many ways, including food refusal and requests for particular activities. There were many other positive and negative sources of influence on children's diet and activity behaviours, including fathers, grandparents, nurseries, siblings, food marketing, and environmental barriers.

6.5 Conclusion

This Chapter has explored women's perspectives of weight management and health behaviours before, during and after pregnancy, for themselves and their children. In the next Chapter, the findings presented in this Chapter will be integrated with those presented in Chapter 4, and discussed in relation to informing this field of research.

7 Discussion

7.1 Introduction

This final Chapter of the thesis brings together the findings of the two sequential phases of quantitative and qualitative research conducted in this mixed methods thesis. The integration of study findings aims to explain how the context of women's lives and their experiences and attitudes, may have influenced their behaviours and the effectiveness of the HELP intervention. The purpose of this Chapter is to discuss how these findings, together, may give insights into what might be important in helping women achieve better outcomes for themselves and their children. This Chapter will consider these findings in relation to the current body of evidence in order to discuss what these results contribute to future research and practice moving forward.

7.2 Main study findings: integration of quantitative and qualitative results

The review of the literature (Chapter 2) determined that there was a need to identify effective interventions for improving short and long-term maternal and child outcomes associated with maternal obesity. There was also a need to evaluate such interventions, from the perspective of the women themselves, in order to establish the barriers and facilitators as well as the contextual factors that might impact effectiveness, and to identify the potential important components of interventions. The present study provides novel information about the effect of a group-based weight management intervention in pregnancy and postpartum, for women with obesity, on long-term lifestyle behaviours for women and their children.

In this thesis, two different methods were used to examine the same problem, to obtain a more complete picture. Quantitative research methods were used to examine the effectiveness of the HELP intervention using a cluster RCT study design (Chapters 3 and 4). Following this, qualitative research methods were used to explore participants' experiences, to consider how the HELP intervention was used in the real world during and beyond the end of the intervention, and to aid interpretation of the quantitative results (Chapters 5 and 6).

Triangulation protocols were followed to combine these findings at the interpretation stage, using a convergence coding matrix.(227, 335, 336) Key concepts from the quantitative findings were listed, then the student actively searched the qualitative findings for related data. Following this, the qualitative findings were searched for any additional concepts to add to the matrix, then the quantitative findings were reviewed to check for additional related data. The quantitative and qualitative findings in relation to key concepts were then compared and defined according to disagreement or agreement between findings. Integrated findings were defined in the following ways: 1) convergence: where there was direct agreement between findings, 2) complementarity: where one dataset offered complementary information to something found in the other dataset, 3) dissonance: where findings appear to contradict one another, and 4) silence: where concepts identified using one method were not found using the other.(335) The overall themes to which the integrated findings related were grouped into three meta-themes: 1) short-term impact of the HELP intervention for mothers, 2) long-term impact of the HELP intervention for mothers, and 3) children's weight and health behaviours. The convergence, complementarity, dissonance and silence of findings in relation to these meta-themes is presented below.

Short-term impact of the HELP intervention for mothers

The integrated quantitative and qualitative key findings in relation to this meta-theme are presented in Table 49. Silence was present with regards to the short-term impact of the HELP intervention, as only the qualitative phase of study could inform this theme. In general, pregnancy in our society is viewed as a time when women should be 'eating for two' and when weight management is not appropriate. On the other hand, women in both groups were often motivated to adopt healthier behaviours to ensure the health of their unborn babies. For those who attended the intervention, the support, behavioural advice and weight monitoring received from the intervention facilitators, along with the support from other women in the group, were seen as beneficial for the adoption of healthier behaviours and alleviating pregnancy concerns. This was compared positively to other maternity care experiences, when some women reported feeling judged negatively in relation to their weight, or unsupported in relation to their weight management. However, pregnancy conditions were seen as reducing women's personal control over adopting healthier behaviours. As a result of attending the intervention, women could have increased self-efficacy and changed attitudes about the appropriateness of weight control in pregnancy, which they believed would benefit them in a future pregnancy. However, the self-efficacy for controlling weight was mainly limited to pregnancy and not long-term weight. The intervention content was familiar to women in that many had experiences of trying to manage their weight previously therefore they had knowledge of appropriate dietary and

physical activity behaviours, and women tended to focus on goals and motivations related to pregnancy only.

Table 49: Convergence coding matrix showing integration of results for meta-theme 1

24m follow-up (quantitative)	Interviews with women (qualitative)	Convergence assessment
Not applicable	Theme 1: societal attitudes about weight management in pregnancy.	Silence
Not applicable	Theme 1: main motivation is safety and health of babies.	Silence
Not applicable	Theme 1: positive aspects of the intervention; non-judgmental support, reassurance from midwife, weight monitoring.	Silence
Not applicable	Theme 1: intervention changed attitudes.	Silence
Not applicable	Theme 1: short-term goals.	Silence
Not applicable	Theme 1: intervention 'nothing new'.	Silence

Long-term impact of the HELP intervention for mothers

The integrated quantitative and qualitative key findings in relation to this meta-theme are presented in Table 50. There was convergence, complementarity and dissonance between the qualitative and quantitative study findings related to the long-term impact of the intervention on maternal BMI, diet and activity behaviours. Agreement between the findings indicated that there was no evidence of a difference in maternal BMI between the trial groups at 24 months postpartum and most women did not feel the intervention had a long-term impact on their weight. Dissonance occurred where some women spoke about having maintained healthier behaviours in the long-term, but this was not reflected in the quantitative analyses of self-reported dietary and activity behaviours of the whole sample. Individual women may have improved their diet and increased their PA levels, but overall the findings did not reflect a significant change in either of these outcomes.

There was complementarity obtained from women's accounts in relation to the potential of the intervention to improve long-term outcomes. In the interviews, experiences of the intervention were placed within the context of women's lives and their many experiences of successful and unsuccessful weight management attempts, and the feelings of failure attached to those experiences. The HELP intervention was viewed as similar to these past experiences and another temporary time of being focused on weight management to achieve a short-term goal. Women reverted back to their 'norm' after pregnancy and would

have required more ongoing support to continue behaviours. This provided a complementary explanation to the lack of significant differences in the quantitative outcomes.

There was convergence in women's reporting of dietary behaviours, as they were generally healthy, except for the consumption of additional high fat and sugary foods. In the quantitative results, there was no difference found between the groups in their levels of activity. The findings of the interviews provided complementarity to this information in that, although a few women were very active, most women indicated that PA was not prioritised as much as dietary considerations for weight, and women perceived exercise as less achievable within their busy lifestyles. There was convergence between the quantitative and qualitative findings, as the subgroup analyses of maternal BMI suggested that the intervention could be more successful for multiparous women, and in the interviews, women supported this idea by suggesting they may be more motivated towards weight control based on past experiences of weight retention. On the other hand, there was dissonance in that multiparous mothers who had not experienced previous weight retention could perceive less risk for excess weight gain.

There was agreement between the findings indicating that women perceived both positive support and sabotage from friends and family for maintaining a healthy lifestyle. Complementarity of findings related to social support came from the interviews where women spoke about the important influence social support and sabotage had on their maintaining a healthy lifestyle. There was silence in women's motivations for weight management postpartum as this was not measured in the quantitative aspects of the follow-up study. The qualitative findings showed women wanted to be fit, healthy and present for their children. However, in comparison with pregnancy, weight management for themselves postpartum was not seen as important. There was convergence and complementarity between data sources with regards to women's self-regulation and intrinsic motivation for weight management and health. Both the quantitative and qualitative findings indicated that most women had low self-regulation and autonomy over their lifestyle behaviours. It was found, in the quantitative data, that the majority of women attempted to control their weight and used commercial weight loss groups to help them achieve this. There was complementarity from interviews in that women spoke about how they felt reliant on following programmes or attending commercial weight loss groups to oversee their weight management, and used short-term goals for motivation.

Table 50: Convergence coding matrix showing integration of results for meta-theme 2

24m follow-up (quantitative)	Interviews with women (qualitative)	Convergence assessment
Null effect on maternal BMI	Theme 1: women did not think the intervention had changed their weight.	Convergence
No effect on maternal BMI	Theme 2: many women went through cycles of weight management.	Complementarity
Subgroup analyses: positive effect for previous weight loss	Theme 1: women did not think the intervention had changed their weight.	Dissonance
Subgroup analyses: positive effect for multiparous women	Theme 1: previous pregnancy weight retention may have motivated women towards weight control in pregnancy.	Convergence
Subgroup analyses: positive effect for multiparous women	Theme 1: not gaining weight in previous pregnancy may have reduced women's perceived need for weight control in pregnancy.	Dissonance
Null effect on maternal diet	Theme 2: some women maintained behaviours long-term e.g. portion control.	Dissonance
Maternal diet- medium fibre & fat, high f&v, high unsaturated fat, >25% sweets weekly	Theme 2: mothers' felt they generally had healthy diets, especially meals, but had a few bad habits, such as sweet foods.	Convergence
Null effect on maternal PA	Theme 2: some women increased incidental activity over the long-term.	Dissonance
Null effect on maternal PA	Theme 2: a few women spoke about being very active.	Dissonance
Null effect on maternal PA	Theme 2: activity not considered as important as diet for weight control. Harder to fit into busy lives.	Complementarity
Both groups receive social support, sabotage & punishment for diet & exercise	Theme 2: friends and family can positively and negatively influence diet and exercise.	Convergence
Both groups receive social support, sabotage & punishment for diet & exercise	Theme 1 and 2: women perceived support from others as important in helping them maintain healthy behaviours.	Complementarity
Not applicable	Theme 2: women have a desire to lose weight to be fit and healthy for their children.	Silence
Not applicable	Theme 2: women's own health not prioritised postpartum in the same way as babies' health during pregnancy.	Silence
Both groups have low self-regulation for diet and exercise	Theme 2: women do not feel they can lose weight without additional support.	Convergence
Both groups have low intrinsic motivation for diet and exercise	Theme 2: women are motivated by the health of babies in pregnancy and their children postpartum- not for selves.	Convergence
60% women attempting to control weight and >75% using commercial weight loss groups	Theme 2: women doing many things to control weight, including commercial weight loss groups.	Convergence
60% women attempting to control weight and >75% using commercial weight loss groups	Theme 2: women do not feel they can lose weight without additional support and often use commercial weight loss groups or structured programmes.	Complementarity

Children's weight and health behaviours

The integrated quantitative and qualitative key findings in relation to this meta-theme are presented in Table 51. Complementarity was identified in the findings, where there was no intervention effect on child BMI at age 24 months and mothers' perceptions that their own weight management experiences after pregnancy were not necessarily influential on their children. However, dissonance occurred between the high levels of children measured as overweight and the low number of mothers who perceived their children to be overweight or who indicated concern for their children's weight. The findings of the qualitative study provided further insight into mothers' increased concern with underweight rather than overweight, their perceptions that weight management was not required for children of this age, and their belief that their level of concern and controlling of behaviours would be amended according to problematic child weight. Mothers' views on their children's weight was contextualised within women's own weight-related experiences, in that their own experiences could influence how they thought about their children's weight. For some of the mothers, they wanted their children to avoid overweight due to their experiences of unhappiness and worry linked to their weight. However, they also wanted to avoid making their children aware of weight as an issue given mothers' own pre-occupation with weight and how this was experienced negatively. This led mothers to believe it was up to them to monitor and control their children's behaviours.

There was complementarity and dissonance between the two data sources in relation to children's dietary behaviours. Dissonance in the findings was evident between mothers' talking about the importance of a healthy diet during the interviews along with their reporting of often encouraging balance and variety in the quantitative findings. This was compared with the high daily intakes of obesity-promoting foods and beverages reported for children in the quantitative findings and some of the mothers discussing how their own 'healthy' behaviours for weight control were not always suitable or necessary for their children in the interviews. Further dissonance was found between the quantitative and qualitative findings in that mothers emphasised 'treat' foods as occasional in their interviews and reported using restriction for health and covert control in the quantitative data. However, a high proportion of children were reported to consume unhealthy foods and beverages on a daily basis and mothers spoke about how they made these available within the home. Complementarity in understanding this contradiction came from the interviews, where mothers' spoke about their perceived obligation to make these options available for their children as they were viewed as the 'norm' preferred options for children, and harmless. There was agreement between the findings whereby mothers reported high responsibility for child feeding and the use of

covert and overt control in the measures of maternal feeding practices, and spoke about their responsibility for controlling their children's dietary behaviours in the interviews. However, dissonance between the findings was identified in that mothers reported that their children had low control over food choices in the quantitative data, but in the interviews discussed how children did influence food choices through negotiations and accommodations around fussiness, food neophobia and preferences.

There was agreement and complementarity between the datasets in relation to children's activity. Agreement was identified where mothers reported, both in the quantitative and the qualitative findings, that their children engaged in many activities and that most of the time this was in the home or family activities outdoors. Complementarity of information came from the interviews to further understand children's activity levels. Mothers' perceived that it was good for children to be active but they also viewed their children as highly active naturally, especially within the home. In relation to children's sedentary behaviours, complementarity was found in the high levels of reported daily screen time, and some mothers who perceived activity as a way of overcoming sedentary behaviours rather than replacing them. There was silence of quantitative findings indicating that 40% of children frequently watched television during mealtimes, this was not explored in the interviews.

There was agreement, dissonance and complementarity between the two datasets in relation to how mothers modelled healthy behaviours to their children. Agreement came from women reporting in both the quantitative and qualitative data that they often modelled healthy eating to their children. Complementarity of data on this issue came from the interviews where women spoke about hiding their unhealthy eating habits from their children as they recognised this would influence their children to want to consume the same foods. However, there was dissonance of interview findings in relation to women's reporting that they modelled healthy behaviours to their children, in that women often wanted their children to adopt healthy behaviours that they themselves did not adopt.

There was complementarity between the quantitative and qualitative findings, each providing different information about other sources of influence on their children's behaviours. In the quantitative data, it was found that a large proportion of children attended childcare and were provided with meals and snacks in this setting. In the interviews, women discussed how fathers, grandparents, siblings, schools, food marketing, limited opportunities for children's free play and the weather, all influenced their children's behaviours.

Table 51: Convergence coding matrix showing integration of results for meta-theme 3

24m follow-up (quantitative)	Interviews with women (qualitative)	Convergence assessment
Null effect on child BMI	Theme 3: mothers did not think their weight management impacts their children	Complementarity
Child BMI- higher than average, 59.2% (intervention) and 48.1% (control) overweight or obese	Theme 3: mothers did not think their children were overweight	Dissonance
2% of children perceived to be overweight	Theme 3: mothers did not think their children were overweight	Convergence
Both groups show low concern for child weight	Theme 3: mothers did not think their children had a problem with their weight	Convergence
Both groups show low concern for child weight	Theme 3: mothers more concerned with underweight than overweight	Complementarity
Both groups show low concern for child weight	Theme 3: weight management not considered relevant at this age	Complementarity
Both groups show low concern for child weight	Theme 3: mothers would do something about their child's weight if they felt there was a problem	Complementarity
Both groups show low concern for child weight	Theme 3: mothers did not want their children to be concerned about their weight like they were	Complementarity
Both groups show low concern for child weight	Theme 3: mothers did not want their children to develop overweight	Dissonance
Null effect on child diet, 45-79% children consume obesity-promoting foods or beverages daily	Theme 3: healthy eating important for children	Dissonance
Null effect on child diet, 45-79% children consume obesity-promoting foods or beverages daily	Theme 3: some mothers in the intervention group believed the intervention had a positive impact on the foods they provided for their children	Dissonance
Null effect on child diet, 45-79% children consume obesity-promoting foods or beverages daily	Theme 3: some mothers believed their own healthy dietary behaviours were not relevant or necessary for their children	Complementarity
Null effect on child diet, 45-79% children consume obesity-promoting foods or beverages daily	Theme 3: mothers restricted 'treat' foods for health	Dissonance
Null effect on child diet, 45-79% children consume obesity-promoting foods or beverages daily	Theme 3: mothers made 'treat' foods available in the home	Convergence
Null effect on child diet, >30% of children consume fast food once per week or more	Theme 3: healthy eating important for children	Dissonance
Higher covert control used by control group	Not applicable	Silence
Both groups report using overt and covert controlling strategies	Theme 3: mothers made 'treat foods' available in the home	Dissonance
Both groups report using overt and covert controlling strategies	Theme 3: mothers believed it was their responsibility to control children's behaviours	Convergence
Both groups report mostly or always encouraging balance	Theme 3: healthy eating important for children	Convergence

24m follow-up (quantitative)	Interviews with women (qualitative)	Convergence assessment
and variety in children's diet		
Both groups report mostly or always modelling healthy eating to children	Theme 3: mothers aware that children might copy their behaviours so modelled healthy behaviours in front of them	Convergence
Both groups report mostly or always modelling healthy eating to children	Theme 3: some mothers believed their own healthy dietary behaviours were not relevant or necessary for their children	Dissonance
Both groups report mostly or always modelling healthy eating to children	Theme 3: mothers hide their unhealthy habits from their children	Complementarity
Both groups report mostly or always modelling healthy eating to children	Theme 3: mothers felt it was more important for their children to be healthy and wanted their children to adopt behaviours they did not	Dissonance
Both groups report using quite high restriction for health	Theme 3: restriction of 'treat' foods	Convergence
Both groups report using quite high restriction for health	Theme 3: mothers made 'treat' foods available in the home	Dissonance
Both groups perceive high responsibility for child feeding	Theme 3: mothers believed it was their responsibility to control children's behaviours	Convergence
Both groups perceive low child control over their feeding	Theme 3: mothers make decisions according to child preferences and avoiding conflict over food refusal	Dissonance
Null effect on child PA, children engage in >1 hour and 35 minutes activity per day, >30% indoor play and >30% outdoor play	Theme 3: mothers talked about how active their children were, that they played a lot in the home and family activities outdoors	Convergence
Null effect on child PA, children engage in >1 hour and 35 minutes activity per day, >30% indoor play and >30% outdoor play	Theme 3: mothers felt it was good for children to be active	Complementarity
Null effect on child PA, children engage in >1 hour and 35 minutes activity per day, >30% indoor play and >30% outdoor play	Theme 3: mothers felt that their children were naturally very active with no need for encouragement	Complementarity
No group difference in sedentary behaviorus, children had two hours or more screen time per day	Theme 3: activity used as a way to make up for sedentary behaviours	Complementarity
40% children across groups watch TV with dinner every day	Not applicable	Silence
>70% attended childcare settings, 74.4% intervention and 53.3% control received all snacks and meals in childcare	Theme 3: other sources of influence on children's behaviours include father, grandparents, siblings, schools, media, environment, play spaces, the weather	Complementarity

7.3 Strengths and limitations of the study

The present study had a number of key strengths. Follow-up of women in the HELP trial provided a unique opportunity to conduct a detailed investigation of the relationships between maternal obesity, maternal weight management intervention in pregnancy, weight gain in pregnancy, and the development of childhood obesity. It allowed the evaluation of the effect of the HELP intervention, for pregnant women with obesity, on later maternal and early childhood health outcomes. Some of the outcomes measured at 24 months postpartum were not considered to be directly attributable to the HELP intervention, based on the intervention logic model (Appendix B). For example, it was unlikely that the intervention would directly impact maternal feeding practices. However, one strength of this study is the ability to explore these factors in relation to the hypothesised intervention mechanisms. To the best of the student's knowledge, this is the first follow-up of a cluster RCT with lifestyle intervention during pregnancy and postpartum, focusing on maternal and child outcomes, which has included behavioural outcomes such as diet and PA, and measures of maternal determinants of childhood obesity in the home environment. This investigation was further strengthened by observing and recording women's unique experiences and perspectives related to pregnancy, obesity, motherhood, and of participating in the HELP intervention. The study not only explored women's understandings of weight management in pregnancy but placed these understandings within the context of their experiences before and after pregnancy, including in their role as mothers. Women from the intervention and control groups were included to understand some of the common barriers which might be present for this population, and which may impact effectiveness of pregnancy weight management interventions. To the best of the student's knowledge, only one other study has explored how women reflect on their experiences of a weight management intervention in pregnancy, several years beyond the pregnancy, in order to understand the impact on long-term attitudes and behaviours.(327) Furthermore, this is the first study to explore women's attitudes with regards to their children's weight and health behaviours in the context of having taken part in an RCT of a weight management intervention in pregnancy and postpartum. This may provide valuable information about the important influences on maternal and child outcomes, from the perspective of women, and what this means for future research that tries to improve these outcomes.

As with all research methodologies, the quantitative and qualitative phases of the present study each had its limitations, these are described below. However, by using a mixed methods approach and integrating the findings from each phase, the limitations impacting the findings of one method could potentially be diminished by the findings of the other.

Furthermore, each of the methodologies were carefully considered to achieve rigour, and best practice guidelines (CONSORT and COREQ) were followed to provide clarity and transparency in the reporting of the study.

The complexity of factors influencing obesity in adults and children is clear, as described in Chapter 1. Therefore, in the quantitative phase of study, it was challenging to decide what child outcomes might be important to measure, and how they might be measured. Where possible, validated scales were used and additional questions were adopted from other similar studies to allow comparison. The primary outcomes were calculated using measurements taken by trained researchers, to reduce error in these outcomes. However, most of the secondary outcomes were measured using participant self-report, which may not provide as accurate information as using more objective measures. The accurate measurement of diet and PA is particularly difficult. As described in the selection of measures (Appendix H), the use of dietary biomarkers and accelerometery could have provided more accurate information.(413, 414) However, the feasibility of taking these measures was unrealistic alongside the consideration of study sample size, participant retention, participant burden, cost, and researcher training. Mothers' reporting of their own and their children's behaviours, particularly food intakes and PA levels, may be prone to recall errors, underreporting or overreporting of behaviours, and social desirability biases.(164, 414-421) However, it would be expected that these reporting biases would be similar between the two groups. There may have been other factors impacting the primary outcomes that were not measured, such as sleep duration in children, which has been shown to be influential on adiposity.(422) Also, due to time limitations, the study did not explore how higher rates of subsequent births in the intervention group, intervention adherence, or childcare usage may have impacted the primary outcomes, despite the latter being influential on child adiposity.(423) An a priori statistical plan was developed to specify study outcomes prior to analyses. This is important when assessing multiple dependent variables with multiple independent tests, as the likelihood of finding significant effects due to chance increases based on the number of analyses conducted.(424) Specifying primary outcomes, and a conservative alpha level, reduced the risk of bias in the interpretation of results. Furthermore, the qualitative methods were conducted according to a qualitative analysis plan developed prior to the analysis of data. This ensured that the selected methods had been thought out and justified. By using an inductive approach to explore the experiences of women in the qualitative work, then bringing these findings together with outcomes from the quantitative phase, the study was strengthened, as both sets of findings could contribute different information to the same phenomena. The interviews also relied on mothers' reporting of their beliefs and behaviours, which may have encouraged socially

desirable responses from women reporting what they thought the interviewer wanted to hear, or what they thought they 'should' do in relation to their own and their children's behaviours, rather than what they actually do. However, on examining the findings there was nothing to indicate that women had not been honest in their opinions, especially in relation to their perceived benefit of the HELP intervention. Furthermore, within the phenomenological approach taken, the critical appraisal of the study should focus on the findings being more or less meaningful to the research questions, rather than being true or false. Women's perceptions, regardless of accuracy, can act as valid motivators or barriers to behaviour change.(203)

The HELP 24m study was given ethical approval as a separate study to the HELP trial, rather than an extension. As a result, unexpected challenges were encountered in re-recruiting sites. There were time pressures on recruiting clusters and local researchers, and obtaining appropriate approvals, as data collection was scheduled to take place between August 2013 and December 2014 based on when women reached the 24 months postpartum time point. The limited timeline between the student start date (July 2013) and reaching the 24 months postpartum time point of the HELP trial participants, was not sufficient for completing all the required steps prior to participant recruitment. Where local researchers involved in the HELP trial were not able to support the HELP 24m study, it was difficult to identify a suitable replacement, as these researchers were often the only ones supporting research within their departments. Identification but subsequent drop-out of a local researcher within one site caused significant delays where follow-up due dates had been missed and may have contributed to no participants being recruited within this cluster. Delays were also experienced where local researchers needed to complete GCP training. In applying for R&D approvals, different processes were used within different sites leading to uncertainty in the process requirements. This also had an impact on study timelines, where approvals within some sites were obtained after women within those sites had reached the 24 months postpartum time point. The timing of completion of the follow-ups was later than planned, later in the intervention group compared with control, and there was evident variation in the timing between sites. For example, the latest follow-up was completed at 1159 days postpartum (24 months plus 429 days). Within this site, the first follow-up was due in December 2013. An appropriate local researcher was only identified in November 2013. An application for R&D approval was submitted in December 2013, but due to confusion within the site about who was responsible for particular approval procedures, approval was only granted in July 2014. For women recruited and assessed by the student, there were logistical challenges of conducting home visits across four sites in northern and southern England. As such, follow-ups had to be grouped together to optimise resources

and allow several appointments to be completed during travel to each geographical location, rather than specifically according to the 24 months postpartum time point. This also led to delays in follow-up appointments. To account for this, the analysis of maternal BMI was adjusted for differences in timing, and this was accounted for by the consideration of age in the calculation of child BMI-for-age *z*-scores. However, there is a possibility that variability in timing of follow-up completion may have influenced other secondary outcomes, such as child PA which may be linked to stage of development.

In the HELP trial, participants were not initially asked if they would be willing to be contacted for future research, and the ethics committee considered the HELP 24m follow-up as a separate study. This contributed to loss to follow-up of participants. The National Institute of Health Research (NIHR) have recommended that permissions to approach participants for follow-up studies should be included in the initial study protocol and participant consent, so that long-term, unbiased follow-up evaluations are possible.(425) This is a lesson learned to consider at the planning stage of future studies. The loss to follow-up of women, from baseline, led to differences between clusters and individuals recruited in the HELP trial and the HELP 24m study. The sample of women recruited at 24 months postpartum were a population with lower BMI, more non-smokers, higher non-white ethnicity, more first-time mothers, higher SES and education, greater engagement with weight loss, and higher HELP intervention adherence. It is possible that these differences may have introduced systematic bias to this study as, based on the literature presented in Chapters 1 and 2, some of these characteristics may be more likely to support positive health outcomes. For example, women with higher SES and education are more likely to have better quality diets. In turn, this reduces the external validity of the study, in that the results obtained may not be reflective of the general population of mothers with obesity. However, the differences between responders and non-responders were small. For example, the difference in mean BMI between the samples (responders: 35.8 kg/m^2, non-responders: 36.2 kg/ m^2), was unlikely to have a clinically significant impact on health parameters,(4, 426) and the primary outcome was adjusted to account for lower baseline BMI in the recruited sample. A proportion of the resulting loss to follow-up was due to challenges associated with re-contacting participants, which is less likely to be due to any systematic bias. The follow-up rate of women and children was comparable with other studies (HELP 24m: 40.3%, ROLO trial: 35.1% (290), LiPO study: 43.6% (325)) reflecting difficulties in the retention and re-engagement of trial participants in the longer term. Furthermore, there was a null effect of the intervention in this advantageous population, so there is no suggestion that a different population would have had different outcomes. However, in terms of study power, the available pool of women for this study was limited to the number of women recruited to the HELP trial, who provided

agreement to be contacted. The sample size of children was further limited to only the women who consented for themselves and their children to take part in the HELP 24m study.

As described in Chapter 3 (section 3.6.2), it was estimated that in order to detect a medium effect size (0.5) of the intervention on primary outcomes, between the groups, 243 women and children (121 per group) would be required, allowing for 30% attrition and clustering. These numbers were almost achieved (N=241, intervention: 107, control: 134) and the estimated numbers were inflated for clustering based on a greater ICC (0.044) than what was actually found (ICC= 0.03), so there may have been an overestimation of the numbers required. However, robust multilevel modelling requires both sufficient clusters and sufficient numbers of participants available within each cluster.(338) There was variability in the numbers of participants recruited between groups and within clusters, including the dropout of one cluster. This is likely to have reduced the study power to detect a true effect on the primary outcomes, and increased the likelihood of Type II errors, reducing the reliability of the study findings and perhaps explaining the null results. Nevertheless, the study still involved a large cohort of women suitable for examining the study outcomes.

An intention to treat approach analysed participants' outcomes according to randomisation regardless of study compliance. In this case, the principle of intention to treat was challenged due to the lack of any statistical methods used to handle non-responders or empty clusters at the 24 months postpartum time point. Instead, these were discarded from the analyses. Imputation techniques could have been used to account for non-responders, but due to time limitations these were not employed. There are no statistical methods to handle the dropout out of randomised clusters. The ITT principle was violated in this case, reducing the internal validity of the study results, as systematic bias may have been introduced and no adjustment for this bias was made.

The women recruited to the qualitative phase were a sample of women who had taken part in the HELP trial and the HELP 24m study quantitative phase. As such, their views may not be generalisable to other women with obesity, other mothers, or other similar intervention studies. However, there was heterogeneity in many participant characteristics, and those who had experienced both the intervention and control groups were included, together with those who had low or no intervention adherence. As the themes and shared experiences were identified across these women's accounts, it suggested that these were common issues which makes them more likely to be relevant to other similar populations of women. Furthermore, comparison with similar research has shown comparable findings, as will be discussed below.

A thematic approach was selected to analyse the data as the gaps in the literature, that the present study addressed, were to understand women's views about weight management and health behaviours for themselves and their children, and to understand the common views which may have impacted on effectiveness of the HELP intervention. The approach looked for patterns across the accounts, so sometimes minority views may not have been well represented. Although contradictory views were sought, examined, and accounted for in the analysis, the selection of a different method of analysis may have better supported this. For example, framework analysis may have allowed clearer distinctions in conflicting attitudes to be drawn out of the data, such as between the intervention and control groups. It may also have allowed exploration of how participant characteristics, such as SES, might have impacted women's perspectives. However, many steps were taken to ensure that the study processes and results were unbiased, in-depth, valid and credible, as described in Chapter 5 (section 5.7). The data collection and analysis adopted a rigorous process. Each stage of this process was reflected on between the student and the research supervisors, including double coding of some of the data by LBH, and lengthy discussions with regards to how the study findings were interpreted by each person involved. Of particular note was that LBH was not involved in the design or evaluation of the HELP trial prior to this study. Her expertise was in qualitative research methods, rather than the study topic, meaning she was less invested in the outcomes of the trial and was less likely to have entered the analysis process with pre-conceived ideas of the important issues. Having this more independent oversight provided credibility to the research findings.

Although this study has presented some findings in relation to the HELP intervention components and the theoretical mediators of behaviour change that were hypothesised to improve outcomes, the findings were unable to fully address some of the current gaps in the literature. The HELP trial with embedded process evaluation focused on assessing the delivery and evaluation of the intervention content so it was not within the scope of this thesis to address this. Furthermore, only those women who remained enrolled in the study at 24 months postpartum were included. It is acknowledged, then, that the present study did not account for the barriers to participating and remaining in the HELP trial. Rather, it focused on the effect of the intervention and the experiences of those women who were retained. Relevant information collected at 24 months postpartum could be combined with process evaluation data, to provide a more complete picture of the barriers to participation, the intervention delivery and the usefulness of the HELP intervention theory for behaviour change in pregnancy.

Lastly, the HELP intervention was intended to target only a narrow range of influences on maternal and childhood obesity. In terms of the health of mothers and their children in pregnancy, this study focused on a population of women with obesity who had a high risk of pregnancy complications. However, a key issue is that many healthy weight women gain excess weight in pregnancy. This highlights pregnancy as a trigger for both the onset and exacerbation of obesity in many women, which will have worrying consequences for the health of these women, and their children, in later years. Interventions targeting all women, and their families, could be the key to changing the cultural norms and attitudes surrounding weight gain in pregnancy.(206) In addition, it is important to re-emphasise that many determinants play a role in the development and continuation of obesity, and it is likely that to tackle these issues, interventions will need to take account of broader contextual influences as well as intervening at different levels. The individual level factors influencing mothers and their children are only a small part of the change that is needed from the individual to broader societal levels.

7.4 Comparison with the literature

This discussion draws on existing research to understand where the findings of the HELP 24m study fit in to the current body of evidence. Two other trials of pregnancy weight management interventions, similar to the HELP trial, have conducted follow-up of women and children at two years postpartum (ROLO (290) and LiPO (324, 325) studies). Qualitative evaluations of comparable RCTs of lifestyle interventions in pregnancy are currently lacking. However, some of the findings of the HELP 24m study have been supported by other research that has documented the views of pregnant women in relation to behaviour change. These studies have explored women's views in the context of having taken part in a behaviour change lifestyle intervention in pregnancy, having experienced an adapted care pathway in the NHS, or their general experiences of pregnancy.(193, 203, 206, 227, 244, 327-329, 427) Other relevant research that may enhance understanding of the findings was also identified.

The women in the HELP 24m study reiterated some of the beliefs which previous research has identified as barriers to weight management in pregnancy. Women hold pre-conceived ideas about the concepts of weight management and health behaviours in pregnancy. Pregnancy can be perceived as a time of behavioural freedom when it is acceptable to abandon usual behaviours, including dietary restraint and PA.(206, 210) However, Dencker et *al.* (2016) found women viewed pregnancy as an opportunity for avoiding excessive weight gain.(327) In contrast, most of the women in the HELP 24m study said that they

perceived a lack of control over their weight in pregnancy. These findings have been supported by several other studies.(199, 206, 226, 428-430)

Other research has shown that women see it as a moral issue to be a good mother and adopt 'normative' behaviours during pregnancy and motherhood.(223, 431) Social and cultural attitudes are likely to influence the behaviours that women engage in. The foetus is seen as a precious body that pregnant women have a moral obligation to protect, to the exclusion of the women's own rights and needs.(411, 432) Pregnant women's lifestyle choices are 'policed' by others. Societally, women are expected to conform to what is considered to be acceptable behaviours of a 'good mother' and one that does not harm her baby in any way.(205, 411, 432, 433) The idea of limiting GWG can be viewed as a selfish and vain choice when the moral choice is to gain enough weight for the baby.(199, 434) The women in the present study described how other people had communicated this 'normative' belief that controlling gestational weight was not appropriate. This has been documented in other studies previously.(211, 435) Furness and colleagues (2011) found that women were socialised to 'eat for two'.(429) Other research has shown that women who continued PA in pregnancy can experience societal criticism as this is considered more high risk than being inactive.(223) Elsewhere, the incongruity of focusing on weight in pregnancy has been implicated as a reason why women may decline to take part in a pregnancy weight management intervention.(231) Other studies have concluded that women demonstrate a lack of understanding of how excessive GWG may impact the unborn foetus.(226) It needs to be recognised that weight management interventions and lifestyle advice from health professionals are not received in isolation and women will have pre-existing beliefs about what is 'normal' and 'appropriate' in pregnancy. These beliefs are likely to impact on their behaviours.

Nevertheless, the women described how their main priority in pregnancy is the health and safety of their unborn baby, and this is consistent with findings across studies.(193, 199, 232, 327, 430, 436) Pregnant women become conscious of how their own behaviours directly impact upon their unborn babies which acts as a strong motivation for adopting healthier behaviours for the benefit of the foetus.(193, 206, 227, 232, 327, 430, 436) In the present study, the women focused on the importance of healthy eating rather than PA for the health of their babies. This may be explained by their past beliefs about the importance of PA for weight management. Previous research by Smith and Lavender (2011) has suggested that women perceive nutrition as having a direct benefit for their unborn babies, whereas PA is for the benefit of the mother.(206) As was evident in the present study, women do not prioritise their own health in the same way they do for the health of their

babies. The benefits of PA for the foetus would need to be emphasised. However, other reasons have been identified to explain why women, despite being motivated, may fail to follow recommended behavioural advice in pregnancy. Women describe conflict in following recommended advice when experiencing other pregnancy conditions, such as tiredness and food cravings.(199, 209, 434) Furness and colleagues identified this as 'self-talk', where women with obesity experienced internal dialogues telling them they could excuse overeating as a result of pregnancy conditions.(429) They highlighted that healthcare professionals could help women recognise their unhelpful self-talk and provide support to make the necessary changes.

It is possible that the strong motivation to adopt healthier behaviours in pregnancy led women in the control group to change their behaviours resulting in no differences in outcomes between the groups in the long-term. However, the women described lacking confidence in their knowledge about the appropriateness of behaviours to achieve positive outcomes for their babies, and this has been supported elsewhere.(212-215) This can be explained by previous findings where women have reported that advice from midwives may be confusing and inconsistent.(226) This advice focused on the behaviours they should not do in pregnancy, rather than those that they should do in relation to diet and PA for weight management.(434) The long histories of weight management reflected on by the women in the present study and in other research,(201, 437) has been identified as a reason why women may be sensitive to communication by healthcare professionals during pregnancy in relation to weight.(438) A focus on weight, something women already hold a personal sense of failure at not being able to control, and something which they may not believe they have control over in pregnancy, may fail to acknowledge that mothers have a shared goal for ensuring the health of their babies. Other research has shown that women are not necessarily averse to receiving communication about their weight.(193) However, they wish to be seen as individuals, as pregnant and birthing women, not as a statistic of risk.(206, 327, 438)

The HELP intervention, and other similar weight management support services, have been considered beneficial for women as they offered non-judgmental and personalised advice that was consistent in helping them achieve their goals of health for their babies.(244, 327, 429, 437) The supportive and trusting relationships developed with specialist and trained intervention facilitators has repeatedly been compared positively with other maternity care experiences.(244, 429, 438, 439) The women described how this increased their confidence to change behaviours, indicating an increase in self-efficacy as theorised. In turn, this can alter misconceptions about the ability to manage weight in pregnancy and re-establish

women's sense of control. This is consistent with the findings that many pregnancy weight management interventions have led to modest reductions in GWG,(269, 288, 292, 293, 295, 300) including the HELP intervention.(Simpson et *al*. in draft)

The important aspects of the HELP intervention design, discussed by the women here and echoed in the HELP trial process evaluation interviews, was the involvement of a midwife, the group environment and weight monitoring. A midwife being involved in delivering the intervention provided the women with reassurance that the behaviour changes they were making were safe for their babies, but it also kept the focus on their pregnancy and meant they could discuss any pregnancy concerns they had. The importance of the midwife relationship during pregnancy has been identified in other studies.(244, 327, 440) The group environment and being with other women who had shared goals and an understanding of the challenges of obesity and behaviour change, was a valued part of the HELP intervention, and other interventions.(244, 277, 327, 427) Alongside group support, women in the study by Dencker et *al.* (2016) also highlighted the benefits of receiving individualised lifestyle advice. Furthermore, women felt having their weight monitored by the intervention facilitators was motivational, and this finding has been supported.(329, 441)

The present study has supported previous research indicating that in the longer-term, there is no evidence of a beneficial effect of pregnancy lifestyle interventions on maternal BMI, despite small reductions in GWG as a result of these interventions.(290) This previous intervention study, delivered in pregnancy only, also showed no group differences in smoking and many other detailed maternal anthropometric measurements.(290) The novel evidence provided by the present study is that the HELP intervention was specifically for women with obesity and continued into the postpartum period, and it found no impact on these and many other maternal outcomes that had not previously been measured, including maternal diet. Given the difficulties that women experienced in attending the six intervention sessions postpartum, it may have been ambitious to think this would have made a difference.

It was found that the HELP intervention may have had a more beneficial effect on maternal BMI for those who had lost weight within the two years prior to recruitment, along with those who were multiparous. No other quantitative evidence could be identified which concurred with these findings. However, other qualitative evidence has suggested that although women's ultimate goal was to ensure the health of their baby, multiparous women might have an additional focus on weight, based on their past pregnancy experiences.(227, 232) The women here indicated that this may only be the case for those who had previously

experienced pregnancy weight retention. Whereas, those who had not experienced this may be less susceptible to behaviour change advice focused on weight. In contrast, other research has shown that even mothers who have experienced weight retention from previous pregnancies may be unconcerned about GWG.(24) Heslehurst et *al.* (2013) additionally distinguished first time mothers as being more focused on nutritional benefits for the baby, which was not picked up in the accounts of women in the HELP 24m study. Regardless, these findings suggest that previous pregnancy experiences will influence women's individual goals for pregnancy behaviour change.

The lack of effectiveness of these pregnancy weight management interventions in the long-term contradicts evidence that suggests women are motivated to change behaviours and lose weight in the postpartum period.(193, 206) However, there has been limited examination of how women's views and behaviours after taking part in a weight management intervention in pregnancy transition within the postpartum period. The present study demonstrated that women perceive the purpose of such an intervention as short-term and no different from their past weight control experiences, and this is similar to what previous studies have found.(327, 436) In addition, it has supported the finding that women have a desire to be fitter and healthier for their children, however when the health-risks the foetus may be exposed to are no longer present, women's motivations and prioritisations for their own health are lessened.(327, 436) Combined with the many barriers identified to adopting healthy behaviours postpartum which have also previously been described, including busy lifestyles and prioritising children's needs,(79, 80) this explains why weight management advice may not continue to be followed postpartum and supports the finding that the value of these interventions cease when the intervention ends.(227)

A few studies have highlighted how women's lived experiences of obesity outside of pregnancy may impact the effectiveness of such an intervention.(67, 232, 327, 436) However, the present study has painted a more detailed picture of where a weight management intervention in pregnancy fits in within the context of women's experiences of obesity. The chronic and relapsing nature of obesity and its associated behaviours, which has been likened to drug and alcohol addictions, has been recognised.(442) The cycles of weight loss and weight regain experienced by women in the HELP 24m study are common. A systematic review and qualitative synthesis to explore the challenges of weight loss maintenance identified findings similar to the accounts of women in the present study. For those who are unsuccessful in maintaining weight loss, rigid and rule bound thinking is applied to the concept of weight management and attempts to control weight are seen as temporary and unnatural.(443) The required effort for sustaining this inflexible state is

mentally demanding and tiring, which leads to relapse perceived as a return to the 'norm'.(443) Environmental factors are likely to be influential on relapse, in particular the influence of family and friends. However, this is coupled with catastrophic thinking whereby behavioural relapse is seen as failure and undoing of previous efforts.(443)

The novel exploration of the theoretical mediators of behaviour change in the present study, indicated that there were no improvements in self-regulation, intrinsic motivation and self-efficacy at 24 months postpartum as a result of the intervention. Although the social support received was perceived to be a beneficial part of the intervention by the women, this was not sustained in the long-term. Women's ability to manage their weight is positively and negatively impacted by those around them.(436) Of particular interest in considering the effect of the HELP intervention, is that those who go through cycles of weight loss and regain are found to be less likely to self-regulate their behaviours and have a dependence on weight management groups.(443) The women's accounts described how they were reliant on external monitoring of their behaviours to help them achieve focus for weight loss. This was one of the most important aspects of the HELP intervention, and at 24 months postpartum many women reported attending commercial weight loss groups. However, placing this within the context of women's long histories of engaging in weight management attempts, women do not appear to have the self-efficacy to control their own weight. Although the HELP intervention may have supported women to manage their weight while attending, this type of intervention fed in to women's dependence on external regulation. A systematic review and meta-analysis explored the effectiveness of commercial weight-loss programmes, such as the SW programme used in the HELP intervention, for supporting people with obesity to achieve weight loss.(444) The authors concluded that these programmes were ineffective in leading to clinically meaningful weight loss in the longer term, and high attrition rates suggested that the programmes were unsustainable.(444) However, the impact that attitudes of women embarking on such a programme might have on sustainability is clear within the findings of the present study. Women are likely to initiate such a programme with a short-term goal that they want to achieve. Furthermore, women's perceptions of weight management as strict and inflexible makes it more likely that they will focus on failure rather than success.

Overall, understanding this context helps to identify that intervention in pregnancy and the early postpartum period only, is unlikely to be enough to lead to long-term behaviour change for this population of women. Women have different goals, motivations and barriers to behaviour change during pregnancy and postpartum, and the same advice is unlikely to be

able to help women change behaviours during these different times. Furthermore, women do not feel equipped to sustain behaviour changes postpartum.

There were two ways in which the HELP intervention was hypothesised to improve long-term health outcomes for children. The first was by improving the intrauterine environment through better maternal nutrition and increased PA, thereby controlling GWG, which would reduce the risk of overweight in the offspring. The second was by improving long-term lifestyle behaviours for mothers and increasing their ability to make healthier choices, this may improve the diet and activity behaviours they promote for their children and the food and activity environment of the children. The present study supports previous evidence gathered in the ROLO and LiPO RCTs that indicated that there was no positive effect of these pregnancy weight management interventions on child BMI at 24 months postpartum, despite small reductions in GWG in each of these trials.(290, 324, 325) The ROLO and LiPO trials also showed no evidence of differences in many other child body composition measurements. Related intervention studies, which examined the effectiveness of dietary behaviour change to reduce the impact of GDM on child outcomes, have shown that despite successful reductions in GDM (445) and macrosomia (446) in the intervention groups, no significant intervention effects were found on children's weight gain or body composition at age 12 months, or age four to five years.(445, 446) The ROLO study assessed breastfeeding behaviours and weaning behaviours, and similarly found no differences between the groups. However, no other RCTs of pregnancy lifestyle interventions could be identified that had examined child dietary and activity behaviours, or environmental determinants of child BMI, at this longer-term time point.

The HELP 24m study provides novel information in relation to explaining how environmental factors may overshadow the effects of any improvements in the intrauterine environment on child outcomes. The present study found that the HELP intervention did not lead to sustained improvements in maternal diet, PA, or psychological factors related to making healthier choices at 24 months postpartum. Given this finding, it is unsurprising that the intervention did not reduce the obesogenic nature of the home environment for children of mothers in the intervention group. Some mothers in the intervention group said that attending the intervention had helped them make positive choices for children's lifestyles. However, there were several other key findings in relation to the potential of pregnancy weight management interventions delivered to mothers to improve the health behaviours of their children. Despite health being important, mothers have perceptions about their children's weight and health behaviours that are likely to influence how much they prioritise health. Mothers think differently about their children's behaviours than they do their own, and

do not necessarily perceive that the behaviours they themselves adopt for weight control are relevant for their children. Mothers do not necessarily recognise problematic lifestyle behaviours in childhood as long-term habits. Women may not always identify themselves as role models of healthy behaviours for their children. Furthermore, women's long histories of weight management will impact how they think about their children's weight and behaviours.

Mothers perceive children's weight management as within their responsibility and under their control.(447, 448) However, in the present study mothers do not seem to believe that their children's weight and health behaviours are something to be concerned about at a young age. Other research has supported this finding and suggested parents largely see overweight or obesity as an issue for the future,(448, 449) and rarely prioritise weight in their choices.(450) Mothers, especially those with obesity, tend to misclassify their children's weight status so that children who are overweight are perceived as a healthy weight.(448, 449, 451-455) Also, mothers show more concern for risk of their children being underweight than overweight and would prefer their children to be in a higher weight percentile.(454) Gender differences also appear to influence these perceptions, in that lower concern in relation to excess weight is shown for boys.(453) This was not explored in the HELP 24m study. There may be a normalisation of obesity or denial or lack of awareness among parents.(452) For the mothers in the present study, their own experiences of weight management were likely to have influenced their view of health behaviours as important for the treatment of overweight rather than as a preventative measure. In turn, this may have reduced their perceived importance of health behaviours for their children indicated by the fact that they did not always see their own 'healthy' behaviours as relevant for their children, and they felt they could justify their children eating certain foods as they did not have a 'problem' with their weight.

Mothers further described how their own weight-related experiences influenced their attitudes in relation to their children's behaviours. They wanted to ensure that their children did not develop a weight problem but they also did not want their children developing anxieties over food or weight, like they themselves had. Fear of inducing eating disorders or negatively impacting child self-esteem have previously been identified to explain why parents may avoid talking about weight or health behaviours to their children.(448, 456) However, mothers' attitudes may encourage particular practices that, based on previous research, may have unintended consequences. Mothers spoke about the importance of health in their children's food choices and reported that they used restrictive practices to reduce their children's consumption of unhealthy foods identifying these as 'treats'. However, a causal relationship has been shown between restriction and childhood overweight in that

restricting access to palatable foods makes these foods more desirable and, as a result, increases children's consumption.(147, 457, 458) In addition, research has shown that when older children made food choices, special value was assigned to unhealthy snacks and fast foods as these were viewed as 'rewards' and 'treats'.(459) Restrictive practices may serve to communicate healthy eating as the 'socially responsible' option, hence the 'boring' and 'less pleasurable' way of life.(460) At the same time, to avoid making their children see certain foods as problematic, mothers felt they should provide 'treat' foods in the home. Furthermore, this was influenced by mothers' perceptions that these foods were a normal part of childhood. Provision of unhealthy foods in the home is shown to increase their consumption, and toddlers with obesity are more likely to have ready access to energy dense foods at home.(102) Other studies have supported the finding that young children are regularly consuming sugary snacks and sweetened beverages.(461, 462) Learning a liking for these foods and consuming them in childhood, is likely to lead to a lifelong preference for them.(137, 447)

The practices identified by women in the present study fall within overt and covert controlling practices. Overt control includes explicit restriction of unhealthy foods. Covert feeding strategies are those which control the food environment, and have been associated with better dietary quality in preschool children, including lower consumption of unhealthy snacks and greater fruit and vegetable intake.(463) The results of the HELP 24m follow-up indicated that women in the control group were significantly more likely to use covert control over snacks and meals, compared with women in the intervention group. It is possible that the intervention may have led mothers to be more vigilant over the health content of the foods their children consumed, which led them to use more overt control to monitor and restrict these foods. However, mothers in both groups reported similar levels of overt control and discussed making 'treat' foods available for their children, and the consumption of obesity-promoting snack foods was comparable between the groups. Women may need to be educated to increase their awareness of how controlling the environment and using covert feeding strategies might be more effective in supporting a healthy diet for children.

Research has suggested that parents show more concern for a healthy diet compared with an active lifestyle.(448) Mothers in the present study thought it was good for children to be active, but did not indicate concerns about whether their children were active enough as they perceived them to be constantly active without encouragement. Other research has also found mothers to perceive their young children to be very active.(464, 465) However, evidence has indicated that when preschool children are active, they tend to engage in brief spells of movement with the majority of time spent sitting still, with little

vigorous activity beneficial for health during these times.(157, 466) In addition, the average levels of children's activity that mothers reported in the HELP 24m follow-up, were less than the daily recommendations of three hours.(155) Furthermore, the main type of activity children engaged in was indoor play which has been linked to increased television viewing,(467) and mothers may not show concern for sedentary behaviours if they perceive their children to be active. These beliefs would need to be addressed if an intervention were to impact on mothers' encouraging their children to be active.

Maternal role modelling of healthy dietary and activity behaviours is shown to be important for encouraging children to adopt healthier behaviours.(97, 122, 130, 131, 146, 147, 158-160, 468, 469) Mothers in the HELP 24m follow-up reported that they modelled healthy eating to their children, but in their interviews they indicated that they considered health as more important for their children than for themselves. In particular, mothers may encourage their children to be active without being active themselves.(448) Mothers could recognise the influence that their own behaviour had on their children, such as bingeing on unhealthy foods, but felt that this would not impact them if hidden. They also believed that their children paid little attention to their behaviours and that their own approaches to weight management did not necessarily influence their children. Yet children are shown to mimic the behaviours of their mothers,(122, 124, 130-135) and mothers discussed in the interviews how their children were aware of their weight control efforts. Other studies have suggested that when parents display high levels of disinhibited eating together with high dietary restraint, as described by mothers in the present study, this may adversely impact body fat in their children.(470) Alternating patterns of restraint and disinhibition, may lead children to mimic that eating style rather than focusing on internal regulatory cues.(470) An intervention would need to empower mothers to positively model healthy behaviours to their children, and in how to educate their children to make healthy choices.

The HELP intervention delivered nutrition and PA advice but did not specifically aim to increase awareness of the problematic parental behaviours that contribute to childhood obesity. This is likely to have limited its effectiveness in using parents as the agents of change for childhood obesity.(131) Furthermore, despite mothers believing they are responsible for their children's weight and health behaviours, it is shown that there are many other influences which impact the extent to which mothers can achieve this, including children themselves, societal attitudes about child appropriate foods, food advertising, other family members including fathers, grandparents and siblings, childcare, schools, and the wider environment.(89, 447, 448, 471, 472)

7.5 Implications of main findings for maternity care services

The findings of this thesis have indicated that the idea of pregnancy as a 'window of opportunity' is important, if it is perceived as a unique time point in which women may have a strong motivation for short-term behaviour change. Even for those who have struggled with weight management in the past, the desire to preserve the health of their unborn baby can be powerful encouragement for adopting healthier behaviours. Some of the findings of this study have demonstrated the value to women of delivering person-centred care. When health professionals receive sufficient training, they are able to offer women personalised, non-judgmental and appropriate advice on adopting healthier behaviours in pregnancy. This can support women with obesity to make positive choices in pregnancy, which, in turn, may have a positive impact on GWG. Furthermore, this has the potential to correct some of the beliefs and misperceptions women have about their ability to control weight in pregnancy. Women enter pregnancy with previous knowledge and attitudes with regards to their weight and health behaviours. These attitudes would need to be addressed in discussion with health professionals.

It is clear from previous research that health professionals want to do the best thing for the women under their care, and are often concerned about how weight-related discussions might negatively impact the patient-carer relationship.(196, 198-202) Women understand the need for discussions of their weight, but in delivering person-centred care, the present study demonstrates that it is essential to recognise the complexity of weight management in pregnancy. Exploring women's past experiences of weight control or of previous pregnancies, may help health professionals appreciate the complex nature of women's lives, the reasons for weight gain and the beliefs, experiences and sensitivities women have in relation to their weight. Further, recognising that often women have knowledge of healthy behaviours, but how they behave in pregnancy is subject to widely held cultural beliefs and pressures from other people. This approach could help to move communication away from blame and guilt, by acknowledging and correcting misperceptions, and empowering women to make changes. Failure to address pre-existing beliefs makes any advice given less likely to be effective and means women may be less likely to engage with weight management services or more generally with lifestyle behaviours.(26, 223) Women need empathy in healthcare communication that recognises the barriers to weight management that an individual might have experienced, so that women do not feel like the sole blame and responsibility is placed on them. This would allow individual plans of behaviour change to be developed between health professionals and women, which fit with women's situations, motivations and goals. Furthermore, only targeting women for behavioural advice fails to

recognise the influence family and friends have over women's behaviours. Involving families in weight management support services and educating them on how they may support better outcomes is likely to be important.(199, 226, 232) Finally, healthcare professionals may need to show that they understand that women are likely to want to do the best thing for their babies, but are not always sure of what that is. A focus only on women's weight is unlikely to be effective in motivating women to change. However, providing communication about the risks of excessive weight, but empowering women to make healthier and safer choices, around diet and PA, for the sake of their baby is more consistent with women's motivations. Furthermore, health professionals may need to demonstrate their belief in women's ability to control their weight and behaviours in pregnancy, even in the face of experiencing the physical and psychological conditions that may come with being pregnant. This, in turn, may help women to see pregnancy as an opportunity for behaviour change and increase women's self-efficacy to control their weight gain.

At a minimum, providing communication skills training to students and practicing health professionals to allow them to adequately care for pregnant women with obesity is required. However, the barrier of how health professionals can feasibly deliver person-centred care within the current constraints of the NHS health system remains. The present study supports previous research in suggesting that additional referral options and behaviour change support services for this population are needed. Identifying weight risks and concerns, without offering appropriate support services, will only serve to increase women's sense of personal failure if they are unable to control their weight.

The findings of this thesis, however, also show that intervening in pregnancy and the early postpartum period alone, has not led to clinically important reductions in GWG or postpartum weight loss, that might positively improve short and long-term maternal and child outcomes. There are many explanations as to why these interventions have not been successful, including some of the findings of this study around women's pre-existing attitudes, their short-term goals focussed only on the baby, their past experiences of weight control or pregnancy and the negative influence they may sometimes receive from those around them. However, it may also be that pregnancy is too short a window in terms of its capacity for reducing the risk of pre-existing obesity on maternal and child outcomes. Currently, pregnancy weight management services are only able to engage women at their earliest antenatal appointment, usually between eight and 12 weeks gestation. The influential beliefs and attitudes women may have about weight and health behaviours in pregnancy will already have had an impact on behaviours during the first trimester of pregnancy. In addition, these pre-existing attitudes make it harder to engage women with weight

management services. Even for those who do engage, the duration of pregnancy that remains is unlikely to be enough to lead to meaningful change, especially as women themselves may not be focused on weight control. Furthermore, women have very different motivations, intentions and goals for adopting behaviours during pregnancy than they do postpartum. To impact long-term change, continuity and the transitioning of support further into the postpartum period is likely important. Currently, this a neglected part of services but one that this particular population of women are likely to need.(193, 203, 206)

7.6 Future research

Given the lack of effect (and potential lack of power) of the HELP intervention on outcomes in the HELP 24m follow-up, and the general lack of impact of other interventions on child outcomes, the results of two ongoing projects planning to combine data on child outcomes from similar trials, and including diet and PA, will be eagerly awaited. The i-WiP collaboration intend to use individual patient data meta-analysis, to examine the effectiveness of RCTs of diet and activity interventions for pregnant mothers who are overweight or obese, on child outcomes at three to five years.(74, 298) A similar initiative in the U.S, the Lifestyle Interventions For Expectant Moms Consortium, is a collaboration of seven studies which aims to identify effective behavioural interventions to improve weight and pregnancy outcomes in pregnant women who are overweight or obese, and determine whether these interventions reduce obesity and metabolic abnormalities in their children at one year postpartum.(473) By pooling the data from the included trials in a meta-analysis, these projects may provide more robust evaluations of the impact of interventions on long-term child outcomes. As far as the student is aware, results from these projects are yet to be reported.

The findings of this thesis support previous findings in suggesting that delivering weight management interventions during pregnancy and/or the early postpartum period alone, to improve short and long-term outcomes related to maternal obesity, is not effective. Pregnancy may still be a window of opportunity for weight management intervention, but so far there have been disappointing outcomes associated with pregnancy lifestyle interventions for women with obesity. The present study suggests that this approach ignores many women's long-term difficulties in controlling their weight, and overlooks the social context in which pregnancy occurs, as well as broader contextual influences. Future research now needs to move towards utilising women's motivation surrounding pregnancy to target interventions across reproductive ages.

Pre-conception health is becoming ever more important as a key determinant of pregnancy success and next generation health.(474) The findings of this thesis indicate that the minimal weight control that women can achieve in pregnancy as a result of weight management interventions is not shown to lead to improved outcomes. Furthermore, the pre-existing expectations that women may have in relation to their behaviours in pregnancy would be better addressed before they enter pregnancy to encourage women to engage with weight control and healthy lifestyle prior to conception. More opportunities for pre-conception intervention are being identified and, even before pregnancy, women may be motivated by the idea of ensuring their future child's health.(474) We need to increase the evidence on the feasibility of recruiting and identifying women before pregnancy, and on the effectiveness of pre-conception weight loss interventions.(219, 220, 474) A recent NIHR funding opportunity proposing interventions that might target women with obesity who attend healthcare services to have their long-acting contraception removed,(475) will hopefully lead to quality research that adds to the current paucity of evidence. Based on the findings of this thesis, pre-conception interventions might be most effective by aiming to support women to achieve substantial weight loss prior to becoming pregnant, in addition to targeting communities to address societal attitudes about weight and health behaviours in pregnancy and increasing general awareness of the importance of nutrition, PA and weight control for the health of unborn babies. Encouraging women to adopt healthier behaviours from the start of pregnancy to achieve better outcomes for their unborn babies, then combining this with continued support during pregnancy focusing on person-centred care, reassuring women, and increasing their self-efficacy for weight control, may be more beneficial.

Furthermore, the findings of this thesis emphasise that pregnancy will not be perceived as a time for women to make drastic changes and they are likely to set short-term goals related to their unborn babies. For this particular population of women, support needs to continue much further into the postpartum period to help women set long-term goals and find new motivations for improving long-term weight and health outcomes for themselves. Such an intervention would be different from that delivered in pregnancy, it would need to be less intensive, potentially harnessing the supportive and trusting relationships developed during pregnancy, but providing this in a way that is convenient to women's busy lifestyles.(476) E-technologies have been found to be effective for behaviour change in the postpartum period (477) and offer an easy way to transition support from an intervention in pregnancy.(478) More work would need to be done to determine what intervention components might be effective in shifting women's beliefs and skills towards self-management of weight and behavioural sustainability, by improving self-regulation, autonomous motivation, self-monitoring, and self-efficacy. Postpartum interventions would need to encourage women to

perceive weight management as the norm by encouraging flexible levels of restraint, avoiding unrealistically rigid rules, reducing perceived relapse severity, and increasing coping skills.(443, 479, 480) Furthermore, it is important to encourage social support for behaviour changes from family and friends.

With regards to improving child outcomes associated with maternal obesity, improving the intrauterine environment continues to be important and combining pre-conception intervention with pregnancy intervention is likely to better support this. However, the findings of this thesis indicate that a weight management intervention delivered to mothers, with the intention of preventing childhood obesity, would need to specifically address maternal attitudes and practices that may serve as determinants of obesity in the home environment. Increasing maternal knowledge on nutrition and PA is unlikely to be enough, as women hold many perceptions in relation to their children's weight and health behaviours that will impact how much they encourage healthy eating and PA. Future interventions would need to incorporate the perspectives of mothers in relation to their children's behaviours, in order to address problematic practices.(481) Recognising that mothers have the best intentions for their children's health but may not always be aware of the impact that their behaviours might have is important. A behavioural intervention for children is unlikely to be successful if it does not improve the behaviours of the adults around them. Both during and after pregnancy, women's motivations for their own health are driven by their children rather than their own personal sense of wellbeing. Utilising these motivations along with mothers' desires for their children to be healthy, and emphasising how important role modelling may be in directly impacting their children's behaviours, might motivate women more than a focus on their own weight. This could be a positive strategy in tackling maternal and childhood obesity.(130, 146, 147, 319) Furthermore, an intervention to improve child outcomes would need to target feeding practices and the messages mothers communicate to their children, by encouraging mothers to adopt responsive child feeding practices, covert rather than overt controlling strategies, and division of responsibility whereby parents provide healthy options and children choose what and how much they eat.(482) It would need to target mothers' awareness and behaviour change to reduce energy dense foods in the home, reduce sedentary behaviours and encourage opportunities for play.(483, 484) Such an intervention would also need to give mothers the skills to positively communicate with their children about healthy behaviours, and help them view behaviours in childhood as the establishment of behaviours for life. Future research would need to explore how this might be delivered alongside women's behaviour change, and how to involve fathers and grandparents in early childhood health promotion.(436, 485) In addition, all these changes would need to be

supported within an environment that promotes the same messages, including schools, nurseries, communities, governments, media, and public spaces.

7.7 Conclusions

The findings of the present study found no evidence that the HELP intervention, a group-based weight management intervention delivered during pregnancy and to six weeks postpartum, to women with obesity, led to significant improvements in maternal and child outcomes for the included sample of women at 24 months postpartum. It may have benefitted some women to adopt and maintain some healthier behaviours for themselves and their families. However, offering women this type of personalised and non-judgmental support during pregnancy may have a benefit for short-term outcomes and attitude change.

The results presented in this thesis have suggested that pregnancy should be viewed as a uniquely motivating period that could be built upon by engaging women in interventions during pre-conception, pregnancy and postpartum. It is important to incorporate the perspectives and understandings of women into the development of maternity care services and weight management interventions. A consideration of women's motivations, past experiences and goals at each stage, may lead to the encouragement of meaningful change, consistent with women's motivations and lived realities, hopefully leading to better outcomes. Furthermore, to encourage a healthy environment for their children, such an intervention would need to directly target maternal attitudes and practices in relation to their children's weight and behaviours. Involving the wider family and social network to improve outcomes for both women and children is important, alongside societal change. Although it is recognised that this is challenging to achieve.

Above all, what is clear from the present study is that, in modern society, mothers, both during and after pregnancy, have many demands and expectations placed upon them. They face moral judgement by others and are considered accountable for their own and their children's health. For mothers with obesity, their own sense of responsibility may be positioned within personas of failure and lack of control. Alongside this, women face many other demands on their time in trying to balance their weight management and the needs of their families, and other demands such as employment. Furthermore, attempts to choose healthier options for themselves and their children are done so within a context that does not always support these choices. We need to continue to find ways to better support women before, during and after pregnancy to ensure positive short- and long-

term outcomes for mothers and babies, while considering the wider societal changes that are needed to support the treatment and prevention of obesity.

8 Appendices

Appendix A: Literature Search Strategy

Aim

This review aimed to provide a systematic, explicit and reproducible examination of the literature related to maternal obesity: It specifically aimed to answer the following questions:

- What is the current health care pathway for women with obesity in pregnancy?
- What is the current evidence base surrounding interventions to improve outcomes associated with obesity in pregnancy?
- Are there gaps in our knowledge from the current evidence base? If so, what are they and how can they be addressed?

This document is intended to outline a systematic plan for searching for relevant literature to provide a comprehensive overview of our current knowledge;(331) however, a systematic review of the literature was not conducted as part of this study.

Method

Training and advice on how to plan a comprehensive search of the literature was received from Cardiff University's Specialist Unit for Review Evidence (http://www.cardiff.ac.uk/specialist-unit-for-review-evidence). An initial step was to identify key words which could be used to identify relevant papers. As this was a follow-up study to the HELP trial, previous literature searching had been conducted by the trial team, including the student. Therefore, the student initially used this literature to identify key words and search terms, to allow a more thorough search of electronic databases. The databases MEDLINE, PsycINFO, EMBASE and the Cochrane Library (Cochrane Controlled Trials Register and the Health Technology Assessment) were used to carry out this literature search. The key words and MeSH terms (below) were used, results from each combination of search terms were combined and duplicates removed.

Search terms

Obesity AND pregnan*
+ a combination of the following terms:
Risk
Gestational weight gain
Weight retention
Postpartum
Lifestyle Intervention
Behaviour change
Behaviour change theory
Diet
Nutrition
Exercise
Physical Activity
Randomis(z)ed trial
Neonatal
Childhood obesity
Infant obesity
Foetal programming
Family environment
Infant feeding
Feeding practices
Child diet
Child activity

The determinants of child weight status within the levels of child characteristics and parent and family characteristics in Davison and Birch,(95) were used to search for relevant articles related to childhood obesity in relation to maternal obesity. Age of the infant was not included as a search term to avoid exclusion of evidence; however, many papers were removed from the identified literature if they were not relevant to a preschool/ toddler age group.

When reviewing relevant articles, a snowballing technique was used where bibliographies were searched for additional publications of interest. Google Scholar (http://scholar.google.co.uk/) was used to find specific papers as part of this snowballing technique using author names:

Search terms were also used to identify relevant publications from the following organisations:

- National Institute of Health and Care Excellence https://www.nice.org.uk/
- UK government and the Department of Health https://www.gov.uk/government/policies, https://www.gov.uk/government/publications, https://www.gov.uk/government/organisations/department-of-health
- World Health Organization http://www.who.int/publications/guidelines/en/
- Royal College of Obstetricians and Gynaecologists https://www.rcog.org.uk/
- Royal College of Paediatrics and Child Health http://www.rcpch.ac.uk/
- Institute of Medicine http://iom.nationalacademies.org/
- The American College of Obstetricians and Gynecologists http://www.acog.org/
- Medical Research Council http://www.mrc.ac.uk/publications/browse/
- Welsh Government http://gov.wales/?lang=en

*Royal College of Midwives https://www.rcm.org.uk/ had to be excluded from the search for policy and practice literature, as college membership was required to access publications.

Methods to assess relevant literature:

To manage the large volume of publications found by this review, the title and abstract was read, and publications were categorised as 'relevant', 'potentially relevant', or 'irrelevant', prioritising systematic review and meta-analysis evidence into the relevant category. Literature that was classified as relevant was read in full and used to write the initial literature review. The title and abstract of 'potentially relevant' publications was reviewed again, and publications read in full when they added something new to the draft literature review. The reference lists of relevant papers were also used to search for more relevant literature.

Critical Appraisal of Literature

To assess the quality of the literature, the Critical Appraisal Skills Programme checklists (www.casp-uk.net) were used to assess the quality of different types of evidence, which were adopted to encourage a critical approach to be taken when reading the literature. The tools utilised for this review were the Randomised Controlled Trials, Systematic Reviews, Qualitative Studies, Cohort Studies and Case Control Studies checklists. Publications were not excluded on the basis of their quality assessments.

Outlining the literature review

As papers were deemed relevant, that they made a useful contribution to the student understanding the literature, publications were grouped into key concepts. This allowed the literature review to be structured according to these key concepts, which made up the final presentation of the review in Chapter 2.

Keeping up to date

To keep up to date with new findings in the literature, citation and key word alerts were used. Searches within the electronic databases were saved and alerts set up to notify the student monthly of publications related to the keywords of each saved search. 'Key' papers were identified which relate to

the findings of other RCTs within a pregnant population with obesity. Monthly email notifications were set up to notify the student of any published articles which had cited these 'key' papers. These notifications were renewed every 12 months to ensure the up-to-date relevance of 'key' papers guiding notifications. Search results were sorted by date to make it easier to repeat searches and identify which papers had been published since the last search date. Another literature search was conducted before the end of the study but searching only for papers published from the date of the original searches and excluding any which had been retrieved through citation and key word alert.

Appendix B: HELP Trial Protocol Paper

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http://www.biomedcentral.com/1471-2458/14/439

BMC Public Health

STUDY PROTOCOL Open Access

Healthy eating and lifestyle in pregnancy (HELP): a protocol for a cluster randomised trial to evaluate the effectiveness of a weight management intervention in pregnancy

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Abstract

Background: Approximately 1 in 5 pregnant women in the United Kingdom are obese. In addition to being associated generally with poor health, obesity is known to be a contributing factor to pregnancy and birth complications and the retention of gestational weight can lead to long term obesity.
This paper describes the protocol for a cluster randomised trial to evaluate whether a weight management intervention for obese pregnant women is effective in reducing women's Body Mass Index at 12 months following birth.

Methods/design: The study is a cluster randomised controlled trial involving 20 maternity units across England and Wales. The units will be randomised, 10 to the intervention group and 10 to the control group. 570 pregnant women aged 18 years or over, with a Body Mass Index of +/=30 (kg/m^2) and between 12 and 20 weeks gestation will be recruited. Women allocated to the control group will receive usual care and two leaflets giving advice on diet and physical activity. In addition to their usual care and the leaflets, women allocated to the intervention group will be offered to attend a weekly 1.5 hour weight management group, which combines expertise from Slimming World with clinical advice and supervision from National Health Service midwives, until 6 weeks postpartum. Participants will be followed up at 36 weeks gestation and at 6 weeks, 6 months and 12 months postpartum. Body Mass Index at 12 months postpartum is the primary outcome. Secondary outcomes include pregnancy weight gain, quality of life, mental health, waist-hip ratio, child weight centile, admission to neonatal unit, diet, physical activity levels, pregnancy and birth complications, social support, self-regulation and self-efficacy. A cost effectiveness analysis and process evaluation will also be conducted.

Discussion: This study will evaluate the effectiveness of a theory-based intervention developed for obese pregnant women. If successful the intervention will equip women with the necessary knowledge and skills to enable them to make healthier choices for themselves and their unborn child.

Trial registration: Current Controlled Trials: ISRCTN25260464
Date of registration: 16th April 2010.

Keywords: Study protocol, Pregnancy, Obesity, Complex intervention, Randomised controlled trial, Diet, Physical activity

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Background

Obesity: the problem

The Foresight Report (2007) estimates by 2050, 50% of women could be obese and National Health Service (NHS) costs associated with obesity could be £10 billion per annum [1]. Approximately 1 in 5 women attending antenatal care in the United Kingdom (UK) are obese [2,3] and this figure is likely to increase. In Europe and the United States of America (US) between 20 and 40% of women gain more weight during pregnancy than is routinely advised [4]. Pregnancy is a significant factor in the development of obesity in women. Many women retain cumulative weight gained over several pregnancies and women with high weight gain during pregnancy retain more weight at follow-up [5-7]. Excess maternal weight gain during pregnancy is also associated with child obesity at 3 years and in adolescence [8,9]. This suggests there is potential for influencing the mother's lifestyle and weight as well as the child's weight.

Obesity has been linked to an increased risk of complications during pregnancy and birth including pregnancy-induced hypertension [2,10], gestational diabetes mellitus [2,11], increased emergency and elective caesarean section rates [2,10], increased induction of labour rates [2,11], venous thromboembolism [12] and increased postpartum haemorrhage [2,13]. There are also increased risks for the child including pre-term birth [2,11], shoulder dystocia [14], admission to a neonatal unit [2,13], birth defects (e.g. spina bifida, omphalocele) [14], still birth [2,13], macrosomia [2,15], fetal and neo-natal death and poor Apgar scores [16]. Consequently, the NHS costs are significantly higher in overweight and obese pregnant women compared to women in the normal weight range. Antenatal care costs may be 5–16 times higher in overweight and obese women [2,17].

Obesity interventions

Clinicians are often uncomfortable dealing with their patients' obesity [18,19], referral options are limited and few evidence based interventions to tackle obesity during pregnancy exist. In addition, although the Institute of Medicine (IOM) in the US has produced guidance on appropriate pregnancy weight gain for obese or overweight women this remains somewhat controversial as research evidence is limited and the guidance is based on observational data [20,21]. UK guidance is also lacking [22].

In the wider population there is evidence that lifestyle or behavioural interventions including modifications of diet and/or physical activity can help with weight loss even in the longer term [23-27]. However, interventions often have limited effectiveness, are costly and weight regain is common [23,27,28]. In the UK, the National Institute for Health and Care Excellence (NICE) has suggested that commercial weight management groups are a treatment option for obese patients [29]. Trials of commercial weight management groups have shown these approaches to be effective in the short term [30,31]. However, evidence for longer term effectiveness is lacking.

With regard to pregnant obese or overweight women, a recent large randomised controlled trial (RCT) found no impact of a lifestyle intervention on gestational weight gain (GWG) or on the proportion of women whose weight gain was below or within IOM guidance [32]. The intervention did not reduce the risk of large for gestational age infants nor did it improve maternal outcomes. However, the intervention was associated with a reduction in the risk of birth weight above 4000 g. A recent high quality meta-analysis of RCTs of interventions of diet and physical activity, alone or in combination, which included studies where women were obese, overweight and normal weight, found an overall 1.42 kg difference between intervention and control participants in GWG (in favour of the intervention group) [33]. For diet alone the difference was 3.84 kg. For interventions targeting obese or overweight women only the reduction in GWG was 2.1 kg. This review also found that reductions in pregnancy weight gain were not associated with an increased rate of small for gestational age babies. Interventions were associated with a lower risk of pre-eclampsia and shoulder dystocia and there was a trend towards a reduction in gestational diabetes, gestational hypertension and pre-term birth. However, the quality of the evidence was low for clinical outcomes as there was evidence of significant heterogeneity in the effect size, study level biases including issues with randomisation, incomplete outcome data, blinding, as well as risk of publication bias [33]. Other systematic reviews and meta-analyses have also found lower GWG from diet and physical activity interventions, but included studies often had methodological limitations including high loss to follow-up, small sample sizes and problems with blinding [34-38]. A Cochrane review of interventions to prevent excessive weight gain during pregnancy concluded that due to small effect sizes and methodological limitations of studies no intervention could be recommended for limiting excessive GWG [39].

With regards to postpartum weight loss, a recent systematic review including 12 trials indicated that a combination of diet and exercise or diet alone can help women lose weight in the postpartum period [40]. In addition, women in intervention groups were more likely to achieve a healthy weight. The authors did not find a difference between the amount of weight lost between the diet alone or diet and physical activity together. They caution that weight loss was moderate and that there were a number of methodological shortcomings in some trials. They also noted that there was much variation in

the type, intensity and duration of interventions. Another systematic review also found that diet and supervised physical activity based interventions could lead to greater postpartum weight loss of 1.5 kg in the intervention compared to control group [41].

Diet and physical activity changes are key to weight loss but trials usually include other behavioural components as part of the intervention. The NICE guidance on obesity [29] and the new draft guidance on behaviour change [42,43] recommend self-monitoring and feedback, goal setting, planning and social support. Self-monitoring is important for successful behaviour change for weight loss [44]. In a meta-analysis of behaviour change interventions of physical activity and healthy eating, more effective interventions were shown to combine self-monitoring with at least one other technique derived from Control Theory (e.g. intention formation, specific goal setting) [45]. Social support is associated with improved weight loss as well as an increase in people completing treatment and maintaining weight loss [46,47]. Social support may offer benefits such as encouragement, feedback, and role modelling or peer pressure for healthy behaviours.

With regards to interventions to limit GWG, a recent meta-analysis identified that behavioural intervention components including providing information, motivational approaches, self-monitoring and rewards contingent on success were important, and using these alongside dietary interventions could be more effective [48]. Authors of this review suggest that further research is needed to identify the most effective behavioural components for limiting GWG. Another systematic review exploring lifestyle interventions which utilised goal setting approaches found that successful interventions included personalised goal setting for diet and physical activity, self-monitoring and feedback [49]. However, the authors highlighted a lack of theory in the design and evaluation and methodological problems with many studies including issues around blinding, high drop out and lack of information on intervention fidelity. Finally, a meta-analysis examining characteristics of successful interventions to reduce GWG found that diet and physical activity interventions were effective in limiting GWG. However, the authors identified that developing an understanding of the processes that lead to behaviour change and determining key behaviour change techniques is difficult because of poor reporting of the content of interventions, alongside lack of measurement of psychological determinants or behavioural outcomes. They suggest that better description of theory and the behavioural components of interventions, as well as assessing behavioural outcomes and theorised mechanisms of the effect of interventions is required [50].

The intervention being tested in this trial is a complex intervention which includes many of the effective components described above [51]. The proposed intervention is based on Social Cognitive Theory [52] and Control Theory [53] and includes techniques associated with these theories that have shown to be efficacious in changing weight related behaviours in systematic reviews and meta-analyses [26,44,45,54,55]. These include boosting self-efficacy, goal setting, modelling, encouragement, feedback and self-monitoring. Other elements of effective behaviour change such as action planning, problem solving, tailoring and social support are also central to the intervention.

Rationale

Pregnancy is a time of change in women's lives and is a potentially important point at which to influence women's health behaviours as well as those of other family members [56]. Weight loss interventions with one individual can have spin-off effects on other family members [57]. Therefore, intervening with pregnant women and equipping them with the skills, knowledge and support necessary to manage their weight effectively, both during their pregnancy as well as after (thereby preventing excessive weight gain during pregnancy and retention of weight), is an important step in tackling obesity in this group.

An effective intervention would decrease obesity-related health risks for the women, reduce the risk of complications for mother and baby during childbirth and reduce health service costs. This could have a long term impact on not only the mother, but the child and other family members, resulting in far reaching public health benefits [56,57]. Although trials targeting GWG or weight loss postpartum by using advice on diet and/or physical activity have had some success [58,59], many studies have methodological problems including issues with randomisation and blinding, poor retention, incomplete follow-up data, small sample sizes, issues relating to intervention fidelity, poor description of the intervention and lack of a theoretical basis [58,60]. As such, more evidence is required. This trial seeks to address some of these methodological shortcomings, in that: it is adequately powered; it is theory-based; moderators of intervention effect are being measured; there are a number of different strategies in place to retain participants; there is a detailed process evaluation assessing issues like fidelity; and, there is a cost effectiveness analysis. As far as we are aware no RCTs of pregnancy or postpartum interventions have included an assessment of cost effectiveness. This trial will test a theory-based intervention targeting longer term postpartum weight control as well as weight gain during pregnancy.

Aim of the study

The primary aim is to assess whether a weight management intervention for obese pregnant women is

effective in reducing the women's Body Mass Index (BMI) 12 months after giving birth.

Secondary aims include:

- to examine whether the intervention leads to lower weight gain during pregnancy;
- to assess whether the intervention leads to fewer complications during pregnancy, at birth and postnatally;
- to examine the impact of the intervention on diet, physical activity levels, health related quality of life, mental health, self-efficacy, social support and breast feeding;
- to examine the child's weight gain;
- to examine mediators and moderators of change;
- to conduct a cost effectiveness analysis;
- to conduct a process evaluation to examine participant views, drop out, fidelity, duration of participation in the intervention and associated factors.

Methods/design

Ethical approval

The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The study has been approved by the Research Ethics Committee for Wales (Reference number 09/MRE09/58).

Design

The study is a cluster randomised controlled trial; the maternity units, rather than individual participants, are the units of randomisation. This is to minimise risk of contamination of control participants through two potential mechanisms. Firstly, the use of aspects of the intervention with control participants by site midwives who have been trained in study procedures and secondly, the passage of information regarding the intervention between intervention and control participants who are acquainted and attend the same maternity unit.

In addition to receiving usual NHS care, all study participants will be provided with 2 study leaflets: 1) a Food Standards Association eating during pregnancy leaflet detailing foods which should be avoided during pregnancy and 2) an exercise during pregnancy leaflet detailing recommended physical activity during pregnancy and warning signs for when to stop exercise and seek medical attention. Participants attending intervention sites will also receive the HELP Study intervention which is described below. Participants attending control sites will only receive usual care and the leaflets.

Study intervention

A logic model (shown in Figure 1) describing the theory of the intervention was developed. This illustrates the key inputs, outputs/behaviours and outcomes of the intervention. Participants attending intervention sites will have the opportunity to attend free, weekly, 1.5 hour weight management group sessions from the point of recruitment (between 12 and 20 weeks gestation) up until 6 weeks postpartum. At this time point they will receive one voucher for a free Slimming World session at a 'normal' community group. They will also receive two intervention phone calls from the Intervention Midwife at 3 and 6 months postpartum in order to provide longer term support and encouragement. Long term intervention contact helps sustain weight loss [61] and telephone support can be effective in weight loss interventions [62]. Assuming normal gestation of between 37 and 42 weeks and depending on when women were recruited, the intervention period will be up to 56 weeks in total.

The intervention sessions will be held in NHS Antenatal Clinics and will be run jointly by an NHS midwife and a Slimming World consultant. There are four main components of the intervention group sessions: 1) healthy eating, 2) physical activity, 3) midwifery advice and 4) behavioural component.

1) The healthy eating component

Slimming World, a major UK based commercial slimming organisation has developed a flexible weight management and healthy eating programme called "Extra Easy", which follows current UK government recommendations for a healthy diet including the "Eat Well Plate". The diet consists of a combination of different food types: approximately 80% combined from fruit, vegetables, carbohydrates and protein; a smaller section for milk and dairy; and an allowance for foods high in fat or sugar. Other than limiting the intake of high fat or high sugar foods, it is not a 'restrictive' diet. Pregnant women are offered advice to encourage them to eat additional healthy extras to ensure they have adequate calcium and fibre intake. The programme utilises a "food optimising system" to encourage adherence to the healthy eating plan by considering and modifying energy density and satiety, complemented by flexibility of food options.

2) The physical activity component

An individualised physical activity programme for obese pregnant women was developed, based on The Royal College of Obstetricians and Gynaecologists guidelines for exercise in pregnancy [63]. Due to its flexibility, ease and cost effectiveness, walking is the primary focus of the programme. Women will be provided

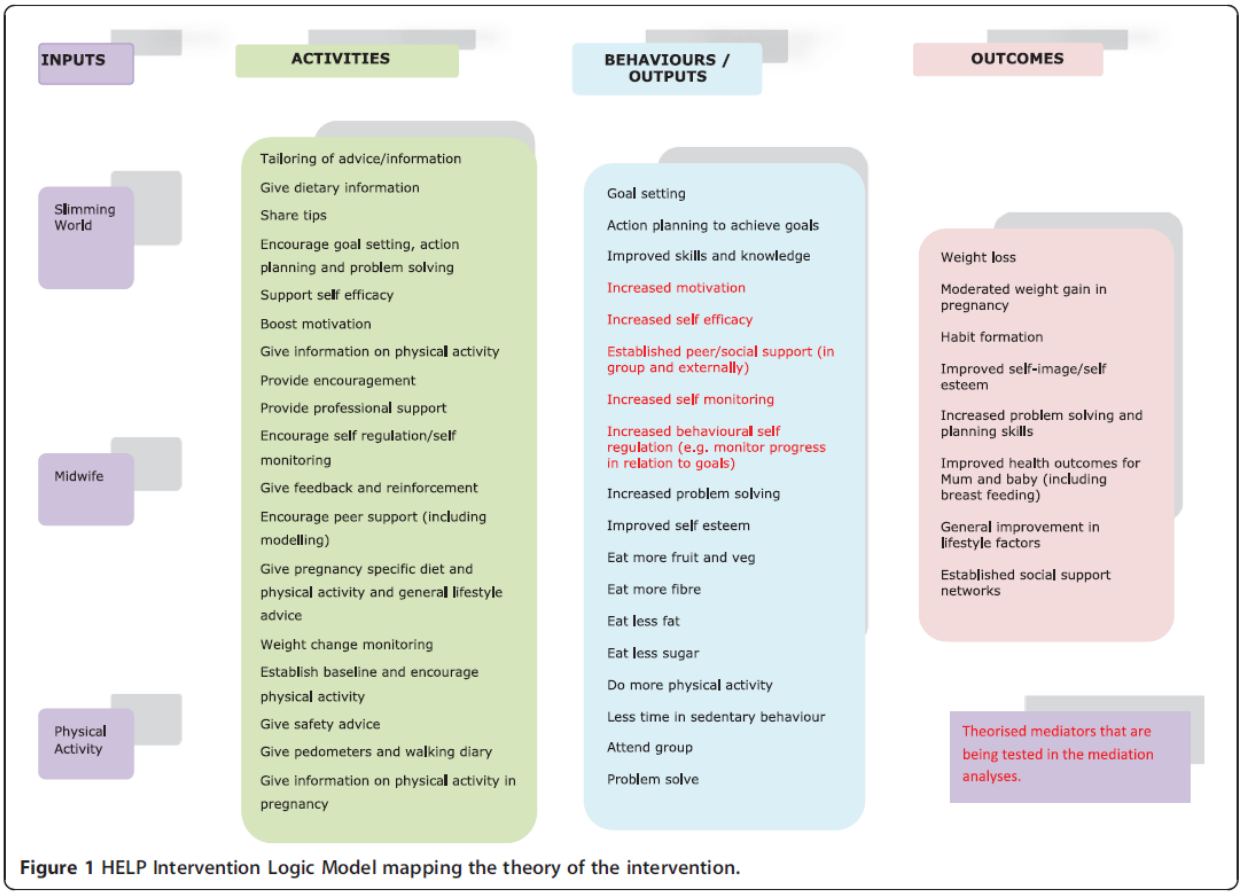

Figure 1 HELP Intervention Logic Model mapping the theory of the intervention.

with a pedometer and walking diary in order to record daily step counts for up to seven consecutive days at various time points (baseline, 36 weeks gestation, 6 weeks postpartum, 6 months postpartum and 12 months postpartum). Women's physical activity tends to decline as pregnancy progresses and therefore the use of pedometers is intended to act both as a motivational tool to encourage physical activity but also as a device to facilitate self-monitoring of physical activity [64]. Step count targets will be individually agreed as part of the walking intervention based on the following four study recommendations and taking into consideration government recommendations of 30 minutes of physical activity five days a week which equates to 10000 steps per day [65]. All women will be encouraged to increase their step counts gradually and as they feel able, as follows:

1 If previously sedentary, women will be advised to aim to walk for 15 minutes, three times per week, gradually increasing to 30 minutes, five times per week.
2 If previously moderately physically active, a maintenance activity plan will be negotiated based on current step counts.
3 If current step counts are greater than 10000 per day, women will be advised to continue as able within limits of comfort but not to start new modalities of physical activity.
4 Following birth, women will be encouraged to restart walking by gradually increasing daily step counts as soon as they feel able. If delivery was complicated, consultation with the women's general practitioner (GP) or midwife will be advised prior to restarting the walking programme.

Women who are unable to complete the walking programme will be encouraged to undertake alternative recommended physical activity including swimming, aquanatal and prenatal exercise classes, as appropriate.

In order to prevent over-exertion, women will be advised to only partake in moderate physical activity and they will be asked to utilise the Borg Scale of Perceived Exertion [66] each time they do any physical activity to monitor levels of exertion. The Borg scale runs from 6 (no exertion) to 20 (maximum exertion), women will be asked to engage in activity that is 'somewhat hard' (around 12-14 on the scale). Information regarding warning signs to terminate exercise and when medical

advice should be sought will be provided. However, for the majority of women, exercise is safe for both mother and foetus throughout pregnancy and initiating moderate exercise or continuing exercise is recommended in most pregnancies [63].

3) The Midwife component

In addition to the usual NHS midwifery care, the Intervention Midwife will be available to provide advice regarding pregnancy and lifestyle, as well as provide additional support in topics that women may be anxious about like labour choices and breast feeding. Evidence indicates that obese women are less likely than their non-obese counterparts to breast feed [67] and breast feeding is associated with reduced postpartum weight retention [68]. The study is recommending a healthy, balanced and unrestricted diet in pregnancy and therefore foetal weight should not be impaired. Any woman in the intervention group who loses a cumulative 3 kg over the pregnancy will be reviewed by the Intervention Midwife and asked to complete a 7-day food diary to confirm that she is eating a healthy amount of food. If necessary, the Intervention Midwife will refer the participant to their obstetrician. Participant safety will be the responsibility of the Intervention Midwife and any concerns will be referred to an appropriate medical practitioner as per normal protocol within the health care service.

Each session will include the following:

- The weighing session where each woman attending will be weighed.
- New members will be welcomed and achievements of the group reviewed.
- Nutritional advice will be given and the group will discuss topics such as foods to avoid in pregnancy, sharing ideas, recipes, eating out ideas. The women will also be given access to Slimming World resources such as recipe books and magazines.
- Physical activity advice will be given and the group will review progress, share experiences, hints and tips, and discuss local activities like aquanatal. All participants will have their step targets reviewed monthly.
- Advice will be given on ailments during pregnancy such as symphysis pubis dysfunction and sciatica.
- Discussion of a 'Topic of the week' such as 'eating for two', nausea and breast feeding.
- Opportunities for one-to-one advice with the Intervention Midwife or Slimming World consultant.

4) Behavioural component

Practical skills and strategies for managing behaviour change will be discussed in the groups. The Slimming World approach (http://www.slimmingworld.com/health/how-sw-works/image-therapy.aspx) provides motivational support and aims to raise self-esteem and empower members. It involves aspects of Transactional Analysis [69], Motivational Interviewing [70] and Compassionate Mind Theory [71]. The approach taken within the groups is similar to Motivational Interviewing, as it is collaborative and seeks to strengthen motivation for change, while avoiding judgment or criticism. It uses empathy, acceptance and compassion to help individuals to overcome barriers and identify goals and their own reasons or motivators to change.

In the groups there will be a level of tailoring to individuals in terms of the diet and physical activity advice and as described above, the participants will have the opportunity to discuss these as well as plans and goals individually with the Slimming World consultant or Intervention Midwife, as well as within the wider group. A number of behavioural strategies will be discussed and encouraged during the group sessions these include; self-monitoring, self-regulation, goal setting, problem solving and action planning. Within the groups different behaviours will be modelled both by the intervention staff but also by other women in the group e.g. where they have started aquanatal classes or started cooking with fresh vegetables. The intervention staff will give encouragement and feedback to the women not only on their weight but also diet and physical activity and other issues.

The key aims of the groups are to encourage goal setting, self-monitoring and behavioural self-regulation, improve motivation and boost self-efficacy and social support. These are addressed directly by the Slimming World approach. Intervention staff will also be trained by the study team on the importance of encouraging and supporting women with respect to these aims. Women will be encouraged to weigh at least weekly and to monitor and, if necessary, alter their eating and physical activity behaviours in relation to their goals. The groups seek to enhance women's motivation by providing positive feedback and by helping them set realistic goals, problem solve and manage lapses or setbacks appropriately. It is intended that the groups will improve women's self-efficacy by providing them with useful information and by helping them develop the necessary skills for a healthy lifestyle, but also by helping them build on success and by giving them opportunities for observing similar others succeeding (modelling) as well as providing positive feedback on progress [72]. Social support will be provided by other women within the groups as the setting facilitates sharing experiences and information, giving feedback, empathy and encouragement as well as reinforcement of behaviours which may help increase motivation. It also provides opportunities

for role modelling, improved self-efficacy, instrumental support (help), appraisal (e.g. affirmation) and peer pressure for healthy behaviours.

Regular attendance at the groups will be encouraged and participants will be contacted if they miss two or more consecutive intervention group sessions, to try to foster future attendance. Intervention group sessions will be held at a convenient time to enhance attendance, usually early evening.

The Intervention Midwives and Slimming World consultants will attend a one day training workshop delivered by the study team and will receive a study manual detailing all aspects of the intervention, in order to ensure consistency in the delivery of the intervention across all sites. In addition, intervention group sessions will be observed by study team members to examine intervention fidelity across sites.

Sample size

At the time we were developing the study we could find no systematic reviews of lifestyle interventions in pregnant women, so we based our sample size on a systematic review of interventions with obese adults, which found a mean weight loss of 7.9 kg (8.5%) during the first 6 months of interventions involving diet and exercise, after which weight was gradually regained, by 48 months a mean weight loss of 3.9 kg (4%) was maintained [28]. Results for trials which included only obese women (mean BMI+/=30 at baseline) demonstrated weight loss of a similar magnitude at 12 months [28]. In order for an individually randomised trial to have 80% power to detect a moderate effect size of 0.333 for a difference in BMI at 12 month follow-up of 1.5 kg/m^2 (SD = 4.5), at a 5% significance level, 143 women per group would be required. Little pertinent data are available for the estimation of the intra-cluster correlation coefficient (ICC). Assuming an ICC of 0.02, if 20 maternity units were recruited across England and Wales, a variance inflation factor of 1.4 would result, so the total sample size is therefore inflated to 400 to detect the difference stated above and we would require an average of 20 women per unit. This would allow for a variance inflation factor of 1.4 (ICC = 0.02) [73]. In trials investigating weight management interventions in pregnant women, losses to follow-up range considerably from 5% to 38% [58,59,74-76], therefore we have allowed for a drop out of 30% and intend to recruit 570 women.

Centre recruitment

Twenty maternity units across England and Wales will be recruited, ensuring a spread of different demographic areas, e.g. areas of high minority populations and low socio-economic status. All units will use electronic maternity information systems, in order to facilitate collection of outcome data and will have at least 1500 births per year. We will exclude any centre currently running a service similar to the HELP intervention.

Participant recruitment

570 pregnant women with a Body Mass Index (BMI) of +/=30 aged 18 years or older and between 12 and 20 weeks gestation will be recruited. Potentially eligible participants will be approached at their earliest antenatal appointment by NHS midwives or researchers, who will provide an information sheet and briefly describe the study. The decision to approach women will not be made by the midwife delivering the intervention. If women are eligible and interested in participating, they will be contacted by the research midwife (local Principal Investigator (PI)) to discuss the study in greater detail and arrange a baseline home visit where informed consent and baseline measures will be taken.

The approaching midwife/researcher will provide the women with a comprehensive information sheet prior to the baseline visit and adequate time will be given for them to read the material and to ask any questions they have about the study. Women will be reminded that they retain the right to withdraw consent for participation in any aspect of the trial at any time without their routinely available NHS care being affected. Midwives/researchers will be trained in Good Clinical Practice and all study procedures. The participant's GP, named midwife and obstetrician, if applicable, will be informed that she is taking part in the study.

A screening form will be completed to record the number of women approached about the study, eligibility, and at what stage women declined to take part in the study (e.g. when first approached or at the consent stage).

Exclusion criteria

Women will be excluded from being recruited into the study if they:

1) are unable to understand the intervention, e.g. have insufficient understanding of spoken English;
2) have any detected pregnancy related complications e.g. multiple pregnancy, foetal anomaly, current antenatal, maternal or foetal complications, recurrent miscarriage (three or more) or previous pre-eclampsia;
3) have any previous medical complications e.g. cardiac disease, serious respiratory disease including severe asthma, diabetes mellitus, serious mental illness/ psychological illness, epilepsy requiring anticonvulsant therapy or hypertension requiring treatment;
4) have nutritional complications e.g. serious physical or psychological disorders (eating disorders) or previous surgery for weight problems;

5) are involved in any other research that may affect any of the outcome measures that are being investigated in this study.

This list is not considered exhaustive. If the midwife considers that the woman has other serious complications that would affect her suitability to participate in the study, the midwife may at her discretion exclude the woman from recruitment noting on the recruitment form the reason why the woman has been excluded. If medical or obstetric complications arise while a participant is involved in the study advice will be taken from the woman's lead obstetrician on whether she should withdraw from the intervention. If a woman is withdrawn on clinical grounds the study team will still complete follow-up if the woman is willing.

Site randomisation

Sites will be randomised when all necessary approvals are obtained. Randomisation will be completed to give optimal balance for geographic region, maternity unit size, ethnic mix and the proportion of the maternity unit pregnant patient population with a BMI +/=30 [77-81]. A process of optimal allocation will be undertaken [79-81]. This will involve calculation of all possible allocations and a balance statistic for each one. A proportion of all allocations with the greatest degree of balance will be identified and passed to the independent statistician on the Trial Steering Committee (TSC) blinded to unit. He will randomly select a single allocation. This will then be returned to the trial statistician. The process of optimal allocation will be carried out in two blocks of ten sites with each block allocation being chosen by the independent statistician from the 25% most optimal allocations in each case. A statistician independent of the study but within the South East Wales Trials Unit will create random numbers for intervention/control arm allocation. The rest of the trial team and the clinics themselves will be informed of allocation after site recruitment.

In the event of delayed approvals for the maternity units such that it is not possible to randomise the second block of 10 sites together, minimisation will be used. A random component will be added to the minimisation algorithm using an 80% weighted randomisation. The allocations of the first block will be used to balance the remaining sites [77,78].

Outcomes

All outcome measures are listed in Table 1 and mediator measures in Table 2. Measures were selected following a comprehensive literature search and consultation with experts in diet and physical activity. Evidence of reliability, validity and sensitivity to change were considered in the selection process. An important issue was completion time to avoid excessive respondent burden as this could affect follow-up rates. For most of the outcomes and for the mediators there was a limited choice of measures and the final choice was inevitably a compromise between evidence of good psychometric properties and the resources and time available to complete the assessments.

The primary outcome is maternal BMI at 12 months postpartum. Secondary outcomes will include investigation into the impact of the intervention on gestational weight gain, the child's weight gain, complications during pregnancy, at birth and postnatally, diet, physical activity levels, health related quality of life, mental health and breast feeding intentions. All staff collecting data will be trained in administering the different outcome measures as well as accurately measuring weight, height and waist and hip circumference. Height will be measured once at baseline and used for all BMI calculations.

Information on both adverse events (AE) and serious adverse events (SAE) will be collected in the study. Trial sites, participants' GPs and intervention staff are responsible for reporting AEs and SAEs. They may also be reported by participants and by staff completing follow-up. In this trial cohort the following are expected to occur: hospitalisation for normal birth or any antenatal, perinatal or postnatal complications, termination of pregnancy for foetal anomaly and hospitalisation for postnatal depression. Rates of AEs and SAEs are likely to be higher in this group of obese women than the normal population of pregnant women. There are no SAEs expected to be related to the study intervention.

Follow-up & drop out

Baseline data will be collected by local PIs. Follow-up data will be collected by local PIs or research staff in each centre, or network research staff. For units in Wales this will be the Clinical Studies Officers employed by National Institute for Social Care and Health Research Clinical Research Collaboration (NISCHR CRC), in England the research nurses employed by the Comprehensive Local Research Networks (CLRN). The follow-up visits will be completed in the participants' home or at a location of the participants' choice. The follow-up appointments are timed to occur at important milestones both pre and postnatally: 36 weeks gestation, 6 weeks postpartum, 6 months postpartum and 12 months postpartum.

Every effort will be made to reduce loss to follow-up: women will be visited at a convenient location of their choice for all follow-up appointments. In order to improve response rates, participants will be contacted to rearrange any missed follow-up appointments, participant-nominated contacts will be collected at baseline in order to facilitate contact at follow-up appointments, participants will be posted study updates in the form of newsletters and follow-up calendars, and each participant will be provided with a

Table 1 Measurement of Outcomes

Outcomes	Measure	When*
Primary outcome		
Maternal weight expressed as BMI relative to height measured at baseline	Calibrated adult scales & stadiometer	B, 36w, 6p, 6 m, 12 m
Secondary outcomes		
Antenatal and birth complications**	Routinely collected data held in patient records	Birth
Pregnancy weight gain	Calibrated adult scales	B, 36w
Waist circumference and waist-hip ratio	Measuring tape	12 m
Child weight centile (adjusted for birth weight and age)	Calibrated baby scales and measuring tape	Birth, 6p, 6 m, 12 m
Admission to neonatal unit	Patient records	Birth
General mental health	General Health Questionnaire (GHQ) 12 [82]	B, 36w, 6p, 6 m, 12 m
Breast feeding intentions	Study-developed questions	36w
Breast feeding behaviour and weaning	Study-developed questions	6p, 6 m, 12 m
Self-reported physical activity	7 Day Physical Activity Recall (7 Day PAR) [83-85]	B, 36w, 6p, 6 m, 12 m
Diet	Dietary Instrument for Nutrition Education (DINE) [86] (plus additional questions on fruit and vegetables, sugar, sweets)	B, 36w, 6p, 6 m, 12 m
Alcohol	Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) [87]	B, 36w, 6p, 6 m, 12 m
Smoking	Study-developed questions	B, 36w, 6p, 6 m, 12 m
Costs	Participant resource use	B, 36w, 6p, 6 m, 12 m
Health related quality of life	EQ-5D (including visual analogue scale) [88]	B, 36w, 6p, 6 m, 12 m

*B = baseline; 36w = 36 weeks gestation; 6p = 6 weeks postpartum; 6 m = 6 months postpartum; 12 m =12 months postpartum.
**gestational diabetes; pre-eclampsia; thrombosis; proportion staying within IOM guidance on weight gain in pregnancy [20]; form of pain relief; birth delivery mode; gestation at delivery; induction of labour; shoulder dystocia, 3rd/4th degree perineal tear; postpartum bleeding or thrombosis; Apgar scores.

£10 high street voucher as a thank you for completing each follow-up. A HELP study website will be used to provide study updates (http://medicine.cf.ac.uk/help-study/), and a minimum dataset will be developed to collect follow-up data by telephone for those participants who are unwilling or unable to meet with the researcher.

In order to prevent resentful demoralisation in the control group, each of these women will be offered 12 weeks normal community-based Slimming World sessions free of charge after her 12 month follow-up is complete. Any woman who undergoes a miscarriage, stillbirth, neonatal death or termination of pregnancy will be given an open option whether or not they wish to continue participation in the study.

All site study staff including the Intervention Midwife and Slimming World consultant will be visited by the research team and updated via regular contact and newsletters in order to encourage continued enthusiasm. In addition, to prevent disappointment following randomisation in the control sites, if results from the study prove positive units allocated to the control group will then be offered training for their midwives in the intervention.

Process evaluation

A process evaluation will be conducted in line with the framework suggested by Steckler and Linnan [95]. This evaluation will utilise both qualitative and quantitative data including data taken from focus groups, interviews, site intervention group observations, session summaries. The process evaluation model will include assessment of eight components; these are context, reach, exposure, fidelity, recruitment, retention, contamination and theory testing. The definition of some of these elements is less

Table 2 Measurement of Mediators

Mediators	Measure	When
Social support	Social Support Exercise and Eating Habits Scales [89] (plus intervention specific social support questions)	B, 36w, 6 m, 12 m
Self-efficacy	Weight Efficacy Lifestyle Scale [90] and Multidimensional Self efficacy for Exercise Scale [91,92]	B, 36w, 6 m, 12 m
Self-regulation	Shortened Self-Regulation Questionnaire [93]	B, 36w, 6 m, 12 m
Motivation	Treatment Self-Regulation Questionnaire (for diet and physical activity) [94]	B, 36w, 6 m, 12 m

(B = baseline; 36w = 36 weeks gestation; 6 m = 6 months postpartum; 12 m =12 months postpartum).

clear than others and there is some overlap between concepts, so these are defined here as used in this study. "Context" includes information relating to different aspects of the context that the intervention was delivered in. This was explored by addressing who delivered the intervention and where it was delivered. The broader context was considered in the qualitative work and includes data on circumstances, skills, resources and attitudes that may influence intervention effectiveness. "Reach" is defined as the extent to which the target audience is reached by the intervention as well as whether the intervention had 'spillover' effects on other people not recruited in the trial. We were interested in exploring whether it had any impact on the family and friends of the participants. "Exposure" is defined as whether the participants received the different elements of the intervention and whether the participants implemented the different elements as intended. "Fidelity" is defined as the degree to which the Intervention Midwives and Slimming World consultants delivered the intervention as intended.

We will assess study attrition by intervention or control group as well as by site. We will compare those dropping out with those remaining in the trial in terms of demographics. We will attempt to obtain reasons for dropout where possible and record these. Finally, we will assess potential contamination between groups through the interviews and focus groups as well as by obtaining details of all other services or interventions that control group participants accessed. Table 3 shows the key sources of information used to explore the eight components of the process evaluation.

A key method for assessing these components is via the qualitative data collection i.e. qualitative interviews with participants and focus groups with the staff delivering the intervention. Semi-structured interviews will be completed with approximately 30 participants from the intervention group, purposively sampled across sites according to attendance levels at the intervention group sessions and whether they lost weight or not. The interviews will be carried out at the end of the intervention period (at approximately 6 months postpartum) and at the end of the study (at approximately 12 months postpartum). We will explore the participants' views of the intervention, barriers and facilitators, the impact of life events on adherence to the intervention, importance of social support, strategies, coping mechanisms and responses to relapses. We will interview a small sample of participants who drop out of the intervention but who are willing to be interviewed, to establish their views of the intervention and reasons for discontinuing. We will also conduct brief interviews with a sample of around 15 women from the control group about taking part in the study and any lifestyle changes they made both during and after pregnancy. The interviews will continue until data saturation is reached.

Three intervention staff focus groups will be completed and will explore the intervention components, the delivery of the intervention, intervention fidelity, participant adherence to the intervention, the recruitment process, perceived challenges or barriers in implementing the intervention and potential improvements to the intervention or the training.

With regards to theory testing we developed a logic model (this is shown in Figure 1) to explain the processes by which the intervention brings about change and we plan to test the theory of our intervention via mediation analyses as well as through other aspects of the process evaluation including participant interviews. Potential mediators including self-regulation, intrinsic motivation, self-efficacy and social support will be assessed. The analyses will identify both the extent to which the intervention was successful at changing these mediators and the extent to which mediator change was associated with change in BMI. Potential moderators of intervention effect will be examined including demographics, ethnicity, parity, mental health (also an outcome), smoking status and weight loss history.

Economic evaluation

The main evaluation will be a cost utility analysis assessing between group differences in total costs against differences in Quality Adjusted Life Years (QALY) derived from the EQ-5D quality of life instrument [88]. This approach is preferred by the National Institute for Health and Care Excellence (NICE) for the economic evaluation of NHS interventions as resulting cost utility estimates can be compared across unrelated health care interventions (www.NICE.org.uk). However, as a generic measure, EQ-5D may not be sufficiently sensitive to capture small changes in health-related quality of life in essentially healthy participants. A secondary cost effectiveness analysis will therefore be undertaken with BMI as the effectiveness measure. Both analyses will be done from an NHS perspective but as the HELP intervention might substitute for other weight control interventions, patient borne costs will also be assessed but will be reported separately.

Resources for training intervention midwives and delivery of the intervention will be recorded prospectively in relevant units and valued using standard methods [96]. Participants' use of NHS resources will be collected by questionnaire from women in both arms of the trial at baseline and all follow-up points specified above and similarly valued. The questionnaire will also record payments for non-NHS weight loss/maintenance activities and will include the EQ-5D questionnaire [88].

Table 3 Process Evaluation Elements

Process evaluation component	Assessment
Context	• Data collected on a site proforma detailing site demographics, ethnicity, size, services delivered etc.
	• Data on those delivering the intervention
	• Data from two site observations completed at different time points in the intervention delivery period using a structured observation guide.
	• Contextual issues explored in the staff focus groups and participant interviews
Reach	• Attendance at the group sessions
	• Comparison of characteristics of those attending the intervention with those not attending
	• Reach explored in the staff focus groups and participant interviews
Exposure	• Number of group sessions delivered
	• Data from group session summary forms which describe those attending and the content/timings of sessions
	• Data from site observations (two per site)
	• Attendance at group sessions
	• Exposure and attendance explored in the staff focus groups and participant interviews
	• Data gathered on use of pedometers, step targets and walking diary completion
Fidelity	• Data from site observations (two per site)
	• Data from group session summary forms which describes how the intervention was implemented at each session
	• Fidelity explored in the staff focus groups and participant interviews
Recruitment	• Comparison of demographics of sites recruited
	• Recruitment rates compared across sites in terms of how many recruited, who is recruited and also how quickly people are recruited
	• Comparison of potentially eligible women with those recruited using data from case report forms and screening forms
	• Recruitment issues explored in the staff focus groups and participant interviews
Retention	• Dropout by trial arm
	• Dropout by site
	• Comparison of demographics of those dropping out with those remaining
Contamination	• Participants asked what other services control group utilised in case report forms
	• Contamination explored in the staff focus groups and participant interviews
Theory testing	• Mediation analyses using questionnaire data
	• Theoretical mediators explored in the staff focus groups and participant interviews

Analysis

Quantitative analysis

The main analysis will be by intention to treat and will compare the primary outcome of BMI at 12 months postpartum in the intervention and control groups. Multilevel modelling will be used to account for clustering within antenatal unit and individual effects. A two level linear regression model will include baseline BMI (measured at recruitment) as a covariate. Both levels will be considered 'random effects' i.e. patients and units are drawn randomly from a larger population of patients and units. Cluster level variables include those used to balance the randomisation: antenatal unit size; proportion of women with BMI +/=30, geographic location and ethnic mix.

For the BMI data, positively skew distributed form is anticipated and will be checked prior to analysis. Log transformation will be considered, not only to deal with the non-normality but to allow interpretation of differences between arms in percentage terms. To further aid clinical interpretation of the intervention effect, analysis of log transformed weight at 12 months postpartum will also be considered, with baseline log weight and log height as covariates. The results can then be expressed in terms of BMI or weight along with a 95% confidence interval. The intra-cluster correlation (ICC) for the primary outcome will be calculated and reported.

Intention to treat analysis will be used for all secondary outcomes. Analysis of secondary outcomes will also use multilevel modelling incorporating baseline scores as covariates where appropriate. Two level linear regression models will be used for outcomes such as pregnancy weight gain and waist-to hip ratio and validated questionnaire scores, while logistic models will be used for clinical event outcomes. 95% confidence intervals for the intervention effect will be calculated. The ICC for each secondary outcome will be calculated and reported.

The impact of individual demographic factors as well as theoretical mediators (self-efficacy, social support, intrinsic motivation and self-regulation) on the intervention effect using interaction terms included in the main analysis models will be examined. Individual demographic variables include age, ethnicity, smoking status, previous weight loss history, psychological wellbeing and social class. We also intend to carry out tests for mediator variables [97].

As well as examining number of sessions attended, patterns of missed sessions and compliance with the intervention will also be explored. A complier average causal effect (CACE) analysis will be carried out for the primary outcome to assess the effect of the intervention in those who complied [97,98]. An investigation of required minimum dose of intervention will be carried out. A per- protocol analysis will include only those

participants in each arm that received treatment as randomised excluding those in the control arm attending weight loss groups.

No formal subgroup analyses are planned. However, exploratory analyses of the impact of social class, parity, ethnicity (if numbers permit), smoking status and initial BMI on the effect of the intervention will be carried out. This will be achieved by fitting a subgroup by randomised group interaction term to the multilevel model.

If the proportion of missing primary data is substantial (more than 10%) a series of sensitivity analyses will be carried out to determine the likely effects of missing data [99-101]. The intention is to use multiple imputation to generate complete datasets for analysis. Imputation models will include those variables in the analytic model plus any additional variables associated with missingness and outcome. Self-reported weight (from the minimum dataset) and Slimming World session weight data may be used to replace missing weights where appropriate in secondary analyses. Further sensitivity analyses may be carried out to examine the effects of removing women who are known to be pregnant at the 12 month postpartum follow-up, as well as those who have recently given birth to a second baby. The assumptions of all models used for primary and secondary analysis will be checked.

Short and long term effects of the intervention can be examined using repeated measures analysis of intermediate weight measurements. The difference in weight at 6 months postpartum will also be examined. The proportion of participants who lost 5% of their weight (weight at 6 months postpartum compared to baseline) will be calculated for each arm. The difference between groups will be examined to identify if they maintained that loss. The association between subsets of clinical outcomes will also be investigated and a total count of all clinical outcome events will be calculated and compared between trial arms. Individuals lost to follow-up will be compared to those who complete follow-up to identify potential sample bias.

Qualitative analysis

Interviews and focus groups will be audio recorded, transcribed and checked by the researcher. Standard thematic analysis techniques will be employed. Transcripts will be closely examined to identify themes and categories [102]. Codes will be applied to these broad themes which will then be broken down further into sub-codes. Agreement on concepts and coding will be sought between members of the research team to ensure reliability. Commonly expressed themes will be identified as well as unusual cases. 20% of the data will be coded separately by two team members to check reliability of the coding process. Interviewing will be iterative; where new themes emerge they will be incorporated into the interviews and focus groups. Thematic analysis will be supported by qualitative analysis software (NVIVO).

Economic analysis

As training can be regarded as an investment producing a flow of benefits over time, training costs will be amortised and expressed in equivalent annual cost terms. Costs of delivering the intervention, including an element for training, will be apportioned to the intervention group. Mean differential costs between intervention and control groups will be estimated. As cost data are often skewed, tests for normality will be carried out and if data are not normally distributed non-parametric analyses will be used to carry out the comparison of costs between the two arms of the trial. Economic comparisons between the two study arms will take account of the cluster nature of the data.

Results of the cost utility analysis will be reported in the form of an incremental cost utility ratio (incremental cost/QALY). A series of one-way sensitivity analyses will assess how sensitive results are to changes in key assumptions. Probabilistic sensitivity analyses will be used to quantify uncertainty around the estimates and cost effectiveness acceptability curves will show the probability of the intervention having an incremental cost utility ratio below a range of acceptability thresholds [103].

In the secondary analysis, cost effectiveness will be assessed using BMI as the effectiveness measure. Unless the intervention is shown to be dominant (lower costs greater effect) the resulting incremental cost effectiveness ratio (incremental cost per unit difference in BMI) can be compared with that of other weight management programmes delivered to pregnant women.

Exploratory work will be carried out to model the medium term effect of the intervention bearing in mind the high degree of uncertainty in long term weight patterns particularly among the obese [104].

Discussion

This trial will evaluate the effectiveness of a theory-based intervention for obese pregnant women, which combines dietary expertise from Slimming World, physical activity, and clinical advice and supervision from midwives. The intervention aims to provide support to enhance motivation and equip women with the necessary knowledge and skills to enable them to make healthier choices and control their weight gain during pregnancy as well as maintain a healthy lifestyle postpartum through healthy eating and physical activity.

The study is novel as, to our knowledge, no RCTs of pregnancy or postpartum weight control interventions have included an assessment of cost effectiveness and there are no published trials of diet and physical activity interventions that run through pregnancy and into the

postpartum period [34]. In addition, few trials have explicitly described the theoretical basis of the intervention or measured the psychological mediators of the effect.

The cluster design was chosen to avoid the risk of contamination, because midwives trained in the use of the intervention could potentially use aspects with control participants and pregnant women resident in the same area often know one other and could share study information. Also in order to run effective groups the cluster design is superior in terms of recruiting sufficient numbers to ensure sessions can be delivered locally.

The study incorporates economic and process evaluations as well as explicit testing of the theory of the intervention. The process evaluation will allow us to explore the impact of different aspects of the intervention and if the trial does not show an effect it will allow us to explore possible reasons for this.

Protecting against bias

Staff in maternity units who volunteer for the study are likely to be motivated in favour of the intervention, which may result in disappointment in those subsequently allocated to the control group. In order to avoid differential dropout between the experimental and control groups, we will offer the maternity units in the control group the opportunity to complete the training programme after the follow-up period, should the intervention prove to be successful. Careful characterisation of the participating sites, clinicians and patients will be undertaken to judge the external validity of the study findings.

Outcome data will be collected by PIs or trained researchers allied to the project. Due to the nature of the study, it will be difficult for researchers collecting outcome data to be blinded to the allocation of the women; however no staff involved in delivering the intervention will collect follow-up data.

The findings of this study will advance current knowledge in this field, both in terms of weight management interventions for obese pregnant women as well as behaviour change theory. If the trial is successful, this could alter the management of obese pregnant women within the NHS. Potential outcomes of the intervention may include fewer complications in pregnancy and postpartum for both mother and baby as well as less traumatic deliveries. Improvements in the women's physical and psychological health and self-esteem may also result from attendance at the intervention group sessions, and from the physical activity aspect of the intervention, independent of any weight loss. Benefits to the women may be long lasting. There is evidence that many women retain weight gained during pregnancy. If this intervention is successful this may impact on cumulative obesity developing over several pregnancies. Women will also benefit from expanded healthcare choices (e.g. midwife as opposed to consultant led care) in subsequent pregnancies, if a healthy lifestyle leads to a BMI within normal limits.

Conclusions

Obesity in pregnancy is linked to poor health and increased NHS costs. This intervention could potentially have an impact on the women taking part during their current pregnancy but it could also equip them with weight management and healthy lifestyle skills they can use in the future. Benefits to public health could be far reaching; pregnancy is a time of significant change within a family at which women who could benefit from weight control are accessible and may be readily motivated, and any change to lifestyle could influence families' behaviour in the longer term.

Abbreviations

AE: Adverse event; BMI: Body mass index; CACE: Complier average causal effect; CLRN: Comprehensive local research networks; DINE: Dietary instrument for nutrition education; GP: General practitioner; GHQ: General Health questionnaire; GWG: Gestational weight gain; HELP: Healthy eating and lifestyle in pregnancy; ICC: Intra-cluster correlation; IOM: Institute of medicine; NHS: National Health service; NICE: National Institute for Health and Care Excellence; NISCHR CRC: National Institute for Social Care and Health Research Clinical Research Collaboration; 7 Day PAR: 7 Day Physical Activity Recall; PI: Principal investigator; QALY: Quality adjusted life years; RCT: Randomised controlled trial; SAE: Serious adverse event; TSC: Trial steering committee; UK: United Kingdom; US: United States of America.

Competing interests

Amanda Avery has an academic post at the University of Nottingham but also works part-time for Slimming World. Slimming World have provided some of the intervention costs for the study, however neither Amanda Avery or Slimming World will have access to the study data or will be involved in the data collection or analyses of the study. The other authors declare that they have no competing interests in relation to this study.

Authors' contributions

Dr. EJ led the writing of this manuscript, contributed to the protocol and intervention development and managed the trial. Dr SAS is the Chief Investigator she led the study design, wrote the original protocol and led the trial implementation. DMC completed the qualitative aspects of the trial as well as the data management. KJ led the pilot study, assisted with study design and advised on the clinical aspects of the study. Professor DC contributed to study design and led the health economics component and Dr ML assisted with the health economics component. DD assisted with study design and advised on the dietary component of the intervention. Dr RP assisted with study design and led the statistical component of the study. Professor RN assisted with study design and advised on the statistical component of the study. Dr MB assisted with study design and the design of the physical activity component of the intervention. Dr EO-J assisted with study design and advised on trial management procedures of the study. Dr NW advised on the clinical and scientific aspects of the study design. AA contributed to intervention design and advised on different aspects of the protocol. All authors contributed to and commented on the different versions of this paper. All authors read and approved the final manuscript.

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Appendix C: Ethical approval- substantial amendments

Substantial amendment	Brief description of amendment	Date submitted to REC	Date approved by REC
1	Child outcomes and additional measures at 24 months postpartum had not approved in initial ethics submission. Protocol was updated with child outcomes and data collection forms submitted with added scales to measure child outcomes.	20/11/2013	13/12/2013
2	Initial consent process for qualitative interviews was to post a written consent form to participants' homes and await the return of this form before proceeding with the interview. This process was changed to taking verbal consent to increase recruitment. The interview topic guide and schedule were also submitted for approval.	26/11/2014	18/12/2014

Appendix D: Appointment letter for follow-up

South East Wales Trials Unit (SEWTU),
Department of Primary Care & Public Health,
Cardiff University,
7th Floor Neuadd Meirionnydd,
Heath Park,
Cardiff,
Wales
CF14 4YS

Date:

Dear

Re: **Healthy Eating and Lifestyle in Pregnancy (HELP) PhD Study**

Thank you for agreeing to help us with our research study. I recently spoke to you to arrange an appointment to meet up with you to discuss this study. You have already taken part in the main HELP study which is looking at whether an intervention for overweight pregnant women, that includes healthy eating and mild physical activity, can help control weight in pregnancy and after child birth. This follow-up will form part of a PhD study, which is a study coordinated by a student researcher in order to gain a Doctorate of Philosophy qualification. The study will look at the effects of the HELP intervention on you and your family at 2 years after you have given birth.

Please find enclosed an information sheet with further information about the study.

Your appointment with myself is on the at

During this appointment I will explain the study to you by going through the Information Sheet (enclosed with this letter). You will have the chance to ask any questions you may have about the study.

If you are happy to take part I will request your written consent to join the study. I will then weigh you and your baby, measure your height and ask you to complete a questionnaire which includes questions about physical activity, eating habits and your and your family's general health. This will take about 40 minutes. If you are unable to make the meeting please let me know by calling the number below.

All information collected about you and your baby during the course of the study will be kept strictly confidential.

Thank you for your interest. We hope that you will help us with our study, but if you are not able to do so, this will not affect your or your baby's care in any way.

Yours sincerely,

Tel:
Email:

Appendix E: Participant information sheet for follow-up

South East Wales Trials Unit (SEWTU),
Department of Primary Care & Public Health,
7th Floor Neuadd Meirionnydd,
Heath Park,
Cardiff, CF14 4YS

Participant Information Sheet: HELP PhD Study- 2 Year Follow-up

Study title: Healthy Eating and Lifestyle in Pregnancy (HELP) PhD Study

Part 1 of the Information Sheet

You may remember that you kindly took part in the HELP study and we would like to thank for your support with this study. We would now like to invite you to take part in this extension to the HELP research study. Before you decide if you would like to take part, you need to understand why the research is being done and what taking part in the extension study would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish, such as members of your family or friends.

The HELP study is being run by Cardiff University and is funded by the National Prevention Research Initiative. The extension to the HELP Study forms part of a PhD study, which is a study coordinated by a student researcher in order to gain a Doctorate of Philosophy qualification. This extension is funded by Slimming World via an unrestricted grant, which means that Slimming World have no control over the research. All research will be under the control of staff at Cardiff University. As a participant of the HELP Study, you will remember that the study evaluates an intervention for overweight pregnant women, which focuses on healthy eating and mild physical activity.

Part 1 tells you the purpose of the extension to the HELP study and what will happen to you if you take part. Part 2 gives more detailed information about how the study extension will be organised. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

You have already taken part in the main HELP study and have been visited by a researcher to collect information from you up to 1 year after you have given birth.

The purpose of this extension to the main HELP Study is to follow up women for a longer period in order to see if being in the HELP study:

helps reduce a woman's BMI (body mass index) at **2 years** after giving birth?
has an impact on women's eating habits, physical activity and wellbeing?
has an impact on your baby's weight gain, diet, physical activity and wellbeing at **2 years** after giving birth?

Why have I been approached?

You have been invited to take part in this study as you have already taken part in the main HELP study up to 1 year after giving birth. We would like you to take part in the study extension if you were recruited at either an intervention or a control site, so even if you didn't receive the intervention or attend the group, we would still like to follow you up. The purpose of this longer-term follow-up is to look at the longer-term impact of taking part in the HELP Study on both women and their babies.

Do I have to take part?

No. You do not have to take part in the HELP study extension. If you are willing to take part, the researcher will ask you to sign a consent form to show you have agreed. You are free to withdraw at any time, without giving a reason.

This would not affect the standard of care you or your child receives. Your usual NHS care will not be affected at any time. Your consent will allow the study researchers to access your medical notes and to look at the results of tests or check-ups in relation to your pregnancy and baby.

What will happen to me if I agree to take part?

If you agree to take part then the researcher will contact you when the 2-year follow-up is due (2 years after you have given birth) to arrange to visit you at your home at a time convenient to you. The researcher will be a Cardiff University researcher, a member of staff from the Maternity Department in your local hospital or, if you are based in Wales, a researcher from the National Institute for Social Care & Health Research. At the visit, the researcher will weigh you and ask you to complete a questionnaire which includes questions about physical activity, your eating habits, your general health and questions regarding your baby. We will also weigh your baby. This will take about 45 minutes. We may also contact you to see if you are willing to do a short telephone interview about your health and wellbeing and that of your baby. We will use data collected about you and your child during the main HELP study.

What will I have to do?

We will need to take up some of your time to ask certain questions at 2 years after you have given birth to your baby. For some of you, we will also take up some of your time to complete a short telephone interview.

What are the possible benefits of taking part?

There may be no direct benefits to anyone taking part in the extension to the HELP study. The study is being undertaken to find out whether or not the intervention is beneficial to women and their babies in

the longer term. This is important as it could influence whether this group intervention could become a service for overweight pregnant women in the future. The results of the study may benefit other mothers and their babies in the future.

What are the possible disadvantages and risks of taking part?

You will be asked to spare some time to fill out questionnaires and for some of you to do a short telephone interview. However, should you have any concerns, please contact the PhD Researcher, Dunla Cassidy, on the number at the end of this information sheet. Should you consider that you or your baby have been harmed in any way by participating in the study the usual NHS complaints and legal system will be available to you. Also, it is possible that some people may find it upsetting talking about their experience if they feel that they had a bad experience. The researcher that visits you is not in a position to advise you about your care and works independently from those involved in your care. However, if the researcher feels that you are distressed about something raised in the course of the interview, or has concerns about your health and wellbeing, they will offer to contact your health visitor or GP to address as part of your ongoing care.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Information Sheet

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time, without giving a reason. If you withdraw at any time, or decide not to take part, it will not affect the standard of care you or your child receives now or in the future. If you do decide to withdraw from the study, we will use the data collected up to that point but we will collect no more data. We will tell you if the study is stopped for any other reason, and your care will continue as usual. Also, if someone who has given informed consent loses capacity to consent during the study, the person would be withdrawn and we would use the data collected up to that point but we would not collect any more data.

What if there is a problem?
If you have a concern about any aspect of this study, you can speak to the researchers at Cardiff University who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this through Cardiff University.

Mr Chris Shaw
Research Governance Coordinator
Cardiff University Research and Commercial Division
30-36 Newport Road, Cardiff, CF24 0DE Tel: 029 2087 9130 or 029 2087 9277

Harm
In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University but you may have to pay your legal costs.

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. All information which is collected about you during the course of the research will be kept confidential and will only be seen by the research team. Study data stored at the University will be kept separate from personal information (names and addresses). Only members of the research team will have access to view identifiable data. However, in some instances, official people from regulatory authorities may need to access data for checking the quality of the research. All members of the research team and regulatory bodies are trained in data protection issues and bound by the terms of the Data Protection Act 1998. Once the study is complete and it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information. Other information will be kept securely for up to 15 years in line with Cardiff University's policies.
As is usual, if during your meetings with anyone involved with the study (the midwives or researchers) somebody is concerned that you or a child may be at risk, we will contact the relevant authorities.

Expenses and payments
We cannot pay you directly to take part in this study but will send you a £10 voucher following completion of the 2-year follow-up visit to thank you for taking part and if you do the telephone interview we will send you an additional £10 voucher.

What will happen to the results of the research study?
A report of the research results will be completed. Results will be published in scientific journals and presented at scientific meetings. You or your child will not be identified in any report, publication or presentation. Once the research study is complete the results will be posted on the South East Wales Trials Unit website (http://www.cardiff.ac.uk/medic/subsites/sewtu/whatwedo/fully-coordinated-trials-studies.html). If you would like the results sent to you please contact the PhD Researcher.

Who is organising and funding the research?

This study is being organised by the South East Wales Trials Unit, Cardiff University. The extension to the HELP Study is being paid for by Slimming World via an unrestricted grant.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee for Wales.

Contact for Further Information

Dunla Cassidy (PhD Researcher) Tel: 029 20687602

Thank you for considering taking part in this study

Appendix F: Consent form for follow-up

PATIENT CONSENT FORM: Study Extension 2 Year Follow-up

CID ☐☐ **PID** ☐☐☐

Study Title: ***Healthy Eating and Lifestyle in Pregnancy (HELP) PhD Study***

Name of Researcher:

Please initial box

1. I confirm that I have read and understood the Participant Information Sheet Extension / 2 Year Follow-up dated 5th November 2013 (Version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered to my satisfaction. ☐☐☐☐

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

3. I understand that information about me and my child needed for the study (including personally identifiable information) may be collected from us and from our medical records and looked at by the research team during the study. It may also be looked at by regulatory authorities supervising the study, and the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records. ☐☐☐☐

4. I give permission for data collected about me and my child during the main HELP Study to be used by the PhD Researcher ☐☐☐☐

5. I agree to take part in the above study ☐☐☐☐

Name of Participant	Date	Signature of Participant
Name of Researcher	Date	Signature of Researcher

2 Year Follow-up Decline Form

Date: ☐☐/☐☐/☐☐☐☐

Form Completed by: _____

CID: ☐☐☐☐ **PID:** ☐☐☐☐ **Initials:** ☐☐☐ **DOB:** ☐☐/☐☐/☐☐☐☐

Has the woman declined to take part? ☐ Yes ☐ No

If yes, please complete the questions below

Time point of decline

Declined when contacted for follow-up ☐

Declined at home visit before consent ☐

Declined at home visit after consent ☐

If the participant provided a reason why they did not want to participate in the study, please write details of this below

_____

_____

_____

Please keep a copy for the site file and return the original to the HELP Study team in the provided envelope.

Appendix H: Measurement of maternal and child outcomes

Maternal body composition: BMI measured by weight and height, waist and hip circumferences and waist-hip ratios

BMI was used to establish maternal adiposity, as it is the most commonly applied measure of obesity, can be compared across the adult population, and is relatively cheap and non-invasive to measure.(5) BMI describes the relationship between a person's weight status and their health risk, with a higher BMI taken to indicate an increasing risk of ill-health; although the exact relationship between BMI and health risk is unclear.(4) There are criticisms of BMI as a measure of obesity, as it may not correspond to the same degree of adiposity in different individuals. Factors, such as ethnicity and muscle mass, can alter the relationship between BMI and body fat, but currently there is limited evidence to allow modification of classification thresholds according to these factors.(83) Maternal weight (kg) was measured by the researcher using calibrated scales. Maternal height (m) was taken from HELP trial baseline measurements. Maternal BMI was calculated during data processing, expressed as weight relative to height, and thresholds according to the WHO recommendations (5) applied, as described in Chapter 1 (section 1.2.1). Classification of BMI was further categorised into a binary variable, obesity or severe obesity and overweight or healthy weight.

Although other measures, such as bioelectrical impedance analysis, may be more accurate in measuring body fat, they are invasive and expensive to administer.(83) Proxy measures which give a better indication of fat distribution or central adiposity, such as skinfold thickness, are difficult to accurately measure and do not allow for population level comparison according to published thresholds.(4) Instead, waist and hip circumferences (cm), and waist-hip ratio (cm) were measured as indicators of central adiposity, as they offered good reliability, validity and low measurement error, although may be influenced by timing of measurement, and local researchers could be trained to take these measures.(371) Waist and hip circumferences (cm) were measured using a measuring tape (following the methods recommended by the WHO (371)). Waist-hip ratios (cm) were calculated during data processing and the WHO thresholds indicating health risk were applied to waist-hip ratios, so ≥ 0.85 cm for women was considered high risk.(371)

Maternal diet

The Dietary Instrument for Nutrition Education (DINE) Questionnaire is a 29-item scale which collects information on frequency intake of common foods. To support accurate and consistent reporting of intake, visual guidance on portion sizes was provided (see below). DINE has been validated against a reliable 4 day diary method and showed measurement correlation between the same aspects of dietary intake.(347) It was used to measure maternal diet as it could be assessed at one timepoint and but measure change over time points, and was less burdensome on participants in comparison to other measures of food frequency.

DINE was scored into dietary intakes of fibre, fat and unsaturated fat. By subtracting a respondent's fat intake from their fibre intake, a 'healthy eating' score was calculated.

The first part of DINE contains 3 questions relating to bread, cereal and vegetables. The score for each question is calculated by a summation of values in the boxes selected by the patient. In turn, the scores from these 3 questions are summed to create the **DINE Fibre** score.

1. About how many **pieces or slices per day** do you eat of the following types of bread, rolls, or chapattis? (Choose one answer on each line)

Breads & Rolls	None	Less than 1 a day	1 to 2 a day	3 to 4 a day	5 or more a day
White bread or rolls	0	1	4	9	13
Brown or granary bread or rolls	0	2	7	15	22
Wholemeal bread or rolls	0	3	8	18	26

2. About how many **servings per week** do you eat of the following types of breakfast cereal or porridge? (Choose one answer on each line)

Breakfast cereals	None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 or more a week
Sugared type: Frosties, Coco Pops, Ricicles Sugar Puffs Rice or Corn type: Corn Flakes, Rice Krispies, Special K	0	0	0	1	2
Porridge or Ready Brek Wheat type: Shredded Wheat, Start, Weetabix, Fruit 'n Fibre, Puffed Wheat Muesli type: Alpen, Jordan's	0	1	2	5	7
Bran type: All-Bran, Bran Flakes, Country Bran	0	2	5	12	18

Cereal	

3. About how many **servings per week** do you eat of the following foods? (Choose one answer on each line)

Vegetable foods	None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 to 7 a week	8 to 11 a week	12 or more a week

Pasta or rice	0	0	1	3	4	6	8
Potatoes	0	0	1	3	5	8	10
Peas	1	1	3	8	12	16	24
Beans (baked, tinned, or dried) or lentils	1	1	4	10	15	20	30
Other vegetables (any type)	0	0	1	2	3	5	6
Fruit (fresh, frozen, or canned)	0	0	1	3	5	8	10

Vegetables	

FIBRE = BREAD + CEREAL + VEGETABLES

The second part of DINE contains 3 questions relating to other foods, milk and spreads. The score for each question is calculated by a summation of values in the boxes selected by the patient. In turn, the scores from these 3 questions are summed to create the **DINE Fat** score.

4. About how many **servings per week** do you eat of the following foods? (Choose one answer on each line)

	None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 or more a week
Cheese (any except cottage)	1	1	2	6	9
Beefburgers or sausages	1	1	2	4	6
Beef, pork, or lamb (for vegetarians: nuts)	1	1	2	6	9
Bacon, meat pie, processed meat	1	1	2	5	8
Chicken or turkey	0	0	1	3	5
Fish (NOT fried fish)	0	0	0	1	2
ANY fried food: fried fish, chips, cooked breakfast, samosas	1	1	2	6	9
Cakes, pies, puddings, pastries	1	1	2	5	8
Biscuits, chocolate, or crisps	1	1	2	4	6

Other	

5. About how much of the following types of milk do you yourself use **per day**, for example in cereal, tea, or coffee? (Choose one answer on each line)

Milk	None	Less	About a	About	1 pint

		than a quarter pint	quarter pint	half a pint	or more
Full cream (silver top) or Channel Islands (gold top)	0	1	3	6	12
Semi-skimmed (red striped top)	0	0	1	3	6
Skimmed (blue checked top)	0	0	0	0	0

Milk	

6. About how many **rounded teaspoons per day** do you usually use of the following types of spreads, for example on bread, sandwiches, toast, potatoes, or vegetables? (Choose one answer on each line)

Spreads	None	1	2	3	4	5	6	7 or more
Regular margarine or butter or **Reduced fat spread** such as sunflower or olive spread, Flora, Vitalite, Clover, Olivio, Stork, Utterly Butterly	0	4	8	12	16	20	24	28
Low fat spread such as Flora Light, St. Ivel Gold, Half-fat butter, Olivite, Flora Pro-activ, Light spread	0	2	4	6	8	10	12	14

Spread	

FAT = OTHER + MILK + SPREAD

Using these two scores, a Healthy Eating score was calculated as the following:

HEALTHY EATING = FIBRE – FAT

An Unsaturated Fat score (**UFAT**) was also calculated. The score was calculated by a summation of values in the boxes selected by the patient.

7. What type of fat do you usually use for the following purposes?
(Choose one answer on each line)

	Butter, lard, or dripping	**Solid cooking fat** (White Flora, Cookeen) **Half-fat butter** **Hard margarine** (Stork)	**Soft margarine** (sunflower, soya) **Reduced fat spread** (olive, Flora Buttery, Olivio)	**Vegetable oil** or **Low-fat spread** (Flora Light, Olivite, St. Ivel Gold)	**No fat used**

On bread and vegetables	1	2	3	4	3
For frying	1	2	3	4	3
For baking or cooking	1	2	3	4	3

In addition to the DINE-related scores, fruit and vegetable consumption scores was calculated. The score (**FV**) was calculated by a summation of values in the boxes selected by the patient.

How many pieces of fruit and vegetables (excluding potatoes) do you eat, of any sort, on a typical day?

	None	1	2	3	4	5	6	7	8 or more
Fruit	0	1	2	3	4	5	6	7	8
Vegetable	0	1	2	3	4	5	6	7	8

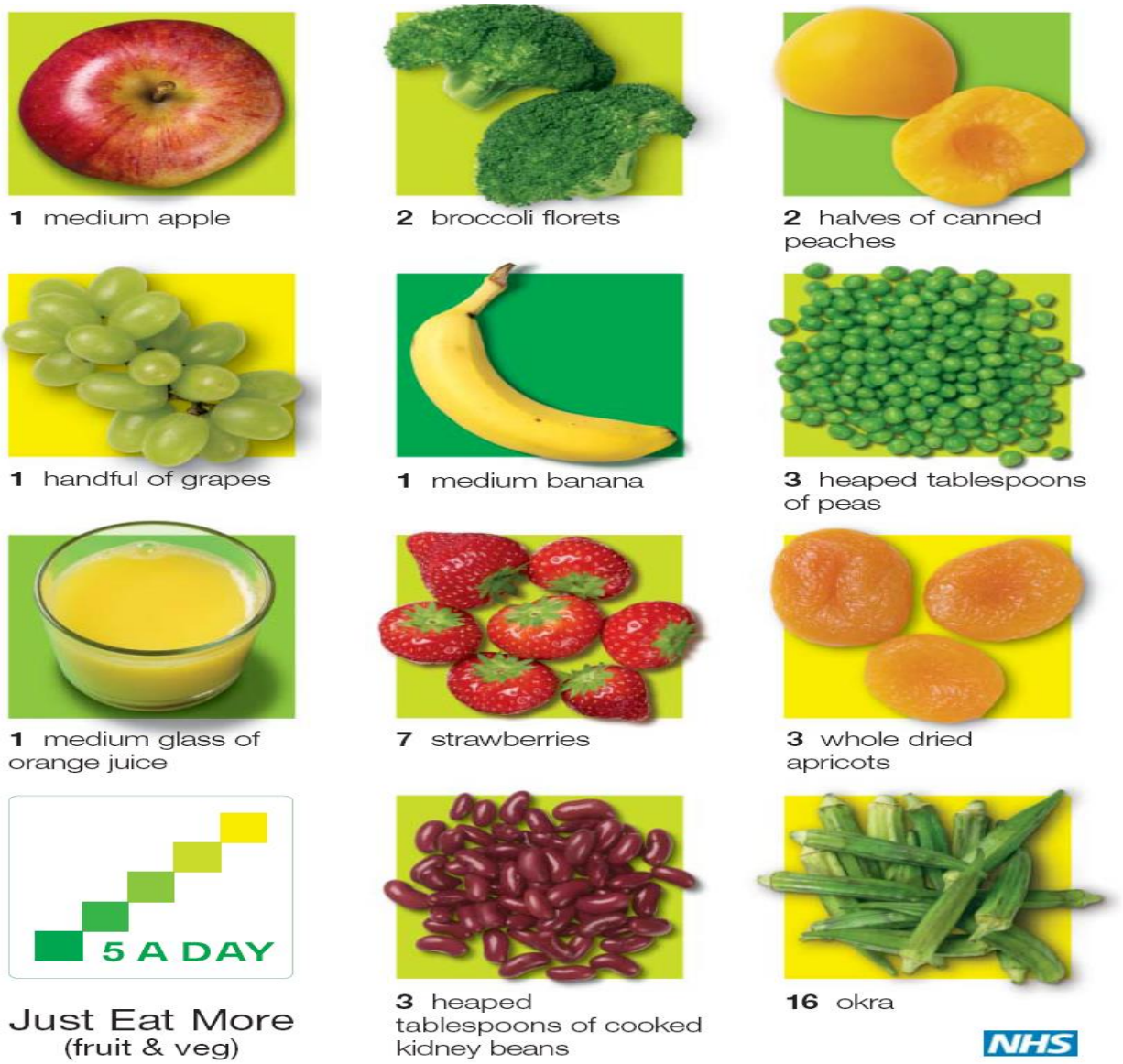
FV = FRUIT + VEGETABLE

Three additional diet questions ask values for the following
Number of cans of pop per day
Teaspoons of sugar per day
How often do you eat sweets (other than chocolate) per day?

These were analysed separately to DINE FIBRE, DINE FAT, DINE HEALTHY EATING and DINE UFAT.

In the HELP trial, there were high volumes of missing responses for DINE which were attributed to participants leaving blank responses rather than selecting zero. As such, missing data for DINE and additional study questions related to dietary intake were assumed to be zero for primary analysis and assumed to be missing for secondary analyses. The same method of dealing with missing data was adopted at 24 months postpartum, although during researcher training, this issue was highlighted to local researchers so that they could guide women in completing the questionnaire correctly to try to reduce the levels of missing data.

Adult's food portion guidance



Maternal PA

The 7-day PAR collects participant recall of time spent in bed, doing physical activities or strength and flexibility activities, in the seven days prior to the measurement being administered by a researcher.(348, 349) It is intended to capture any activities lasting ≥ 10 minutes, of moderate or greater intensity. Across the seven days, total hours spent in sleep and total minutes of moderate, hard and very hard intensity activities, were multiplied by 1, 4, 6 and 10 metabolic values respectively. This yields total weekly energy expenditure, measured as kilocalories (kcal)/kg/week. Subsequently dividing this by seven yields total daily energy expenditure, measured as kcal/kg/day. Finally, multiplying this by the individual's weight provides the 'PAR

score' indicating total individual energy expenditure in kcal/kg/day. The PAR score was categorised into a binary outcome of low and high energy expenditure using the median value as the cut-off.

The 7 Day PAR was used in the HELP trial as it accurately measures changes in PA over time (349) and had been used to measure PA in a pregnant population.(486) As it captures information on intensity of PA it also gives a better idea of energy expenditure related to health benefits.(349) However, recall of PA can be problematic in that people tend to over-estimate the intensity of the PA they have completed, a problem commonly found with any PA self-report measure.(487)

There was unlikely to be high levels of missing data as this measure was researcher administered, but where weight data or 7 Day PAR data was missing, a total score was also missing.

DAYS

		SLEEP	1 _____	2 _____	3 _____	4 _____	5 _____	6 _____	7 ___
MORNING	Moderate								
	Hard								
	Very Hard								
AFTERNOON	Moderate								
	Hard								
	Very Hard								
EVENING	Moderate								
	Hard								
	Very Hard								
Total min per day	Strength:		_____	_____	_____	_____	_____	_____	_____
	Flexibility:		_	_	_	_	_	_	_

Alcohol consumption

There may be co-morbidities in health behaviours in that those with obesity may adopt other less health favouring behaviours.(235) The HELP intervention was a complex intervention aimed at improving diet and PA behaviours; spill over effects were examined for alcohol and smoking behaviours. The AUDIT-C is a three-item scale used to measure levels of risk in relation to frequency and quantity of drinking alcohol. In the HELP trial an error was made in the scale wording, which invalidated the scoring system. However, this error was retained at follow-up to allow a comparison of repeated measures. Rather than summation of the three items into a total risky drinking score, as per AUDIT-C scoring; items were scored separately and compared between groups. The items were scored and converted to binary outcomes indicating risk as follows:

- item 1 asks how often the person drinks alcohol, ≥ four days a week was coded as high risk and ≤ two to three times a week was coded as low risk; as UK guidance recommends three non-drinking days a week.(488)
- item 2 asks how many units of alcohol a person drinks on a typical drinking occasion, ≥ three units was coded as high risk and ≤ two units was coded as low risk; as women are recommended to have 14 units per week spread across four drinking days.(488)
- item 3 asks a person how often they have six drinks or more on a single occasion, ≥ 1 times a month was coded as high risk and <1 occasion a month coded as low risk, as binge drinking ≥ four drinks on one occasion is associated with poorer health outcomes.(488)

The validity of the AUDIT-C measure was compromised due to wording error. However, the items in this scale are shown to be valid for detecting risky alcohol consumption, and when sex specific thresholds for risky drinking are applied, as they have been in this study, this improves the sensitivity and specificity of the measure.(489) It was used in the HELP trial as it was practical and easy to complete,(490) and had been validated in a pregnant population,(491) a consideration which may also be applicable at 24 months postpartum follow-up.

How often do you have a drink containing alcohol?

Never	Monthly or less	2-4 times a month	2-3 times a week	4 times a week or more
0	1	2	3	4

How many drinks containing alcohol do you have on a typical day when you were drinking?

n/a	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
	0	1	2	3	4

How often do you have six or more drinks on one occasion?

Never	Less than monthly	Monthly	Weekly	Daily or almos daily
0	1	2	3	4

Smoking behaviours

Questions were developed by the HELP trial team and used at follow-up. Women were asked the following questions:

Are you a current smoker?

___ Yes

___ No

If yes, how many cigarettes or roll-ups do you smoke per day? _____

Smoking was scored as yes/ no for current smoker and mean number of cigarettes per day for those that smoked. For women who indicated they were not current smokers, responses for cigarettes per day were scored as missing. A binary variable indicating smokers and non-smokers was created; and, for smokers, quantity of cigarettes per day was scored as a continuous outcome.

Mental health-General Health Questionnaire (GHQ)

The GHQ-12 measures mental health to identify minor psychiatric disorders.(384) It asks respondents to score 12 items related to their ability to carry out normal functions and the presence of sources of distress, rating statements on a four point scoring system ranging from better/ healthier than normal through to much worse/ more problems than usual, the wording dependent on the statement. The GHQ scoring method, recommended by the author of the measure, was used.(376)

Responses were scored as 0-0-1-1 to make a distinction between no- minor distress- some distress- much more distress. The 12 items were summed, and the total score categorised by thresholds to identify 'caseness', where ≥ two was taken to indicate the presence of psychological distress, and < two indicated no distress.(376)
GHQ-12 is useful as a short screening tool in the general population to detect cases of psychological distress and has shown good validity in different applications.(384)

1. Been able to concentrate on whatever you're doing?			
Better than usual ☐	Same as usual ☐	Less than usual ☐	Much less than usual ☐
2. Lost much sleep over worry?			
Not at all ☐	No more than usual ☐	Rather more than usual ☐	Much more than usual ☐
3. Felt that you were playing a useful part in things?			
More so than usual ☐	Same as usual ☐	Less useful than usual ☐	Much less useful ☐
4. Felt capable of making decisions about things?			
More so than usual ☐	Same as usual ☐	Less so than usual ☐	Much less capable ☐
5. Felt constantly under strain?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
6. Felt you couldn't overcome your difficulties?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
7. Been able to enjoy your normal day-to-day activities?			
More so than usual ☐	Same as usual ☐	Less so than usual ☐	Much less than usual ☐
8. Been able to face up to your problems?			
More so than usual ☐	Same as usual ☐	Less able than usual ☐	Much less able ☐
9. Been feeling unhappy and depressed?			
Not at all ☐	No more than usual ☐	Rather more than usual ☐	Much more than usual ☐
10. Been losing confidence in yourself?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
11. Been thinking of yourself as a worthless person?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
12. Been feeling reasonably happy, all things considered?			
More so than usual ☐	About same as usual ☐	Less so than usual ☐	Much less than usual ☐

HRQoL

EQ-5D is a standardised non-disease-specific instrument for measuring HRQoL.(352) It captures a respondent's current HRQoL and consists of two components. The first asked respondents how their health was 'today' in relation to five dimensions of HRQoL: mobility, self-care, usual activities, pain/ discomfort and anxiety/depression; and response levels for these five items were 1) No problems, 2) Some problems, 3) Severe problems. The responses were combined into a five-digit number which represents that person's health state e.g. 13121, which was transformed into an EQ-5D index score reflecting the person's HRQoL. Index scores were calculated using time trade off value sets elicited from a UK general population,(492) and index scores correspond to HRQoL as follows: 1= perfect health, < 1 indicates a deterioration in HRQoL, and minus values indicate HRQoL worse than death. Where any of the five responses were missing, the five-digit number was also missing. The second component of the EQ-5D measure was a visual analogue scale (VAS) which asked respondents to self-rate their health 'today' by drawing a line from a central point, to cross an illustrated vertical scale with endpoints labelled 'Best Imaginable Health State' (value of 100) and 'Worst Imaginable Health State', (value of 0). The value at which a respondent's line crossed the VAS was used as a score of HRQoL. EQ-5D is recommended by NICE to measure HRQoL in adults.(493) It was used in the HELP trial to allow an economic evaluation to be completed, and the inclusion of it at 24 months postpartum follow-up allowed for the possibility of an economic evaluation. However, this was not completed as part of the thesis due to time constraints and lack of expert input. HRQoL was compared between the groups.

1. Mobility Score

I have no problems in walking about 1

I have some problems in walking about 2

I am confined to bed 3

2. Self-Care

I have no problems with self-care 1

I have some problems washing or dressing myself 2

I am unable to wash or dress myself 3

3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities 1

I have some problems with performing my usual activities 2

I am unable to perform my usual activities 3

4. Pain/Discomfort

I have no pain or discomfort 1

I have moderate pain or discomfort 2

I have extreme pain or discomfort 3

5. Anxiety/Depression

I am not anxious or depressed 1

I am moderately anxious or depressed 2

I am extremely anxious or depressed 3

Social support for diet and PA

Social support was one of the theorised mediators of intervention effect on behaviour change in the HELP trial. The SSEH scale measures respondents' perceived friends and family support for eating habits. It asks respondents to rate how often they receive positive comments, negative comments, encouragement (e.g. to avoid unhealthy food) and sabotage (e.g. offers them food they are trying to avoid) from friends and family.(353) This scale is comprised of 23 items which was abbreviated to two 'sabotage' questions (2 and 3) and one 'encouragement' question (1) in the HELP trial. The scores were summed, first by separating sabotage and encouragement from family or friends, then by combining sabotage and encouragement from family and friends. Six variables were calculated for secondary analysis: family sabotage, friends' sabotage, combined sabotage, family encouragement, friends' encouragement, and combined encouragement. The higher the score, the greater the encouragement (positive social support) or sabotage (negative social support).(353)

The scores were calculated as:

SSEH family sabotage = Q2+Q3 (family)

SSEH family encouragement = Q1 (family)

SSEH friends sabotage = Q2+Q3 (friends)

SSEH friends encouragement = Q1 (friends)

SSEH combined sabotage = Q2+Q3 (family+friends)

SSEH combined encouragement = Q1 (family+friends)

1. Discouraged me from eating "unhealthy foods'' when I'm tempted to do so	**none**	**rarely**	**a few times**	**often**	**very often**	**not apply**
Family	**0**	**1**	**2**	**3**	**4**	
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	
2. Refused to eat the same foods I eat	**none**	**rarely**	**a few times**	**often**	**very often**	**not apply**
Family	**0**	**1**	**2**	**3**	**4**	
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	
3. Offered me food I'm trying to avoid	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	

The SSEX scale measures respondents' perceived friends and family support for PA. It asks respondents to rate how often they receive 1) support for exercising, 2) participation and involvement (from others), and 3) rewards and punishments.(353) This scale is comprised of 18 items which was abbreviated to three questions, one from each category, in the HELP trial. The scores were summed, first by separating support, punishment and participation from family or friends, then by combining support, punishment and participation from family and friends. Nine variables were calculated for secondary analysis: family support, friend support, total support, combined punishment, friend punishment, combined punishment, family participation, friend participation, and combined participation. The higher the score, the greater the support and participation (positive social support) or punishment (negative social support).

The scores were calculated as:

SSEX family participation = Q1 (family) SSEX friends participation = Q1 (friends)

SSEX family punishment = Q3 (family) SSEX friends punishment = Q3 (friends)

SSEX family support = Q2 (family) SSEX friends support = Q2 (friends)

SSEX combined participation = Q1 (family+friends) SSEX combined support = Q2 (family+friends) SSEX combined punishment = Q3 (family+friends)

1. Exercised with me or offered to exercise with me	**none**	**rarely**	**a few times**	**often**	**very often**	**not apply**
Family	**0**	**1**	**2**	**3**	**4**	
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	
2. Gave me encouragement to stick with my exercise program	**none**	**rarely**	**a few times**	**often**	**very often**	**not apply**
Family	**0**	**1**	**2**	**3**	**4**	
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	
3. Criticised me or complained about the amount of time I spend exercising	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	

Confirmatory factor analysis of subscales, acceptable test-retest reliability and internal consistency, of the SSEH and SSEX scales, has been reported.(353) Social support, measured by SSEH and SSEX, was found to be related to dietary intake and levels of PA, (353) so it was used in the HELP trial to measure social support as a theoretical mediator of these behaviours.

Motivation for diet and PA

The TSRD and TSRE scales measure motivation/ self-determination for diet and PA respectively.(354) The extent to which individuals regulate their own behaviours is important for behaviour change, and intrinsic motivation was theorised to be a mediator of the HELP intervention effect on behaviours.(494) Participants were asked to rate motivations for diet and PA according to how true they felt a given statement was in relation to the health behaviour (e.g. it is consistent to my life goals). Both scales were comprised of 15 items measured on an ordinal scale from 1 (not at all true) to 7 (very true). Each scale measured three subscales of motivation, either for diet or PA: 1) Autonomous (six items); 2) Controlled (six items); and, 3) Amotivational (three items). A mean score was calculated for each subscale, then a 'relative autonomous motivation index' score calculated for each scale, by subtracting

mean controlled motivation from mean autonomous motivation.(354) These scales have been validated for use in various settings and shown to be consistent across different health behaviours.(354)

The Treatment Self-Regulation Questionnaire Concerning the Motivation for Eating a Healthy Diet (TSRD)

AUTONOMOUS REGULATION
I feel that I want to take responsibility for my own health
it is very important for being as healthy as possible
it is consistent with my life goals
it is an important choice I really want to make
I personally believe it is the best thing for my health
I have thought carefully about it and I believe it is very important for many aspects of my life

CONTROLLED REGULATION
others would be upset with me if I did not
I feel pressure from others to do so
I want others to approve of me
I want others to see I can do it
I would feel guilty or ashamed of myself if I did not eat a healthy diet
I would feel bad about myself if I did not eat a healthy diet

AMOTIVATIONAL
it is easier to do what I am told than think about it
I really don't think about it
I don't really know why

The Treatment Self-Regulation Questionnaire Concerning the Motivation for Exercising Regularly (TSRE)

AUTONOMOUS REGULATION
I feel that I want to take responsibility for my own health
it is very important for being as healthy as possible
it is consistent with my life goals
it is an important choice I really want to make
I personally believe it is the best thing for my health
I have thought carefully about it and I believe it is very important for many aspects of my life

CONTROLLED REGULATION
others would be upset with me if I did not
I feel pressure from others to do so
I want others to approve of me
I want others to see I can do it
I would feel guilty or ashamed of myself if I did not eat exercise regularly
I would feel bad about myself if I did not exercise regularly

AMOTIVATIONAL
it is easier to do what I am told than think about it
I really don't think about it
I don't really know why

Self-regulation for health

The SRQ measures a respondent's ability to self-regulate behaviour to achieve desired future health outcomes, in the face of challenges to this behaviour,(355, 356) which was one of the theorised mediators of intervention effect on behaviour change in the HELP trial. This scale is comprised of 63 items which was abbreviated to eight items,(356) measuring positive and negative aspects of self-control in relation to health (e.g. I am able to accomplish goals I set for myself). Participants were asked to rate items on a 5-point Likert scale where 1= strongly disagree and 5= strongly agree. Some items were negatively worded and reverse scored for analysis. Scores for the eight items were summed to create a total self-regulation score. The 63 item scale has shown good internal consistency and test-retest reliability.(355) For the purposes of SRQ total score calculation, the scales of the negative items (questions 1, 4, 5, 6 and 8) are reversed and the responses to the 8 questions are simply summed.

In relation to my health……..					
	Strongly Disagree	Disagree	Uncertain/ unsure	Agree	Strongly agree
1. I don't notice the effects of my actions until it's too late	5	4	3	2	1
2. I am able to accomplish goals I set for myself	1	2	3	4	5
3. I have personal standards, and try to live up to them	1	2	3	4	5
4. I tend to keep doing the same thing even when it doesn't work	5	4	3	2	1
5. I have a hard time setting goals for myself	5	4	3	2	1
6. I have trouble making plans to help me reach my goals	5	4	3	2	1
7. I set goals for myself and keep track of my progress	1	2	3	4	5
8. I give up quickly	5	4	3	2	1

Self-efficacy for diet and PA

Self-efficacy is a mechanism of behaviour change for weight management,(249) and was a theorised mediator of the HELP intervention effect. The WEL scale comprises 20 items to assess self-efficacy for eating habits, specifically in a population with obesity.(357) It asks respondents to rate their confidence to resist eating in different situations, on a 10 point Likert scale ranging from 0= not at all confident to 9= very confident. Five subscales of self-efficacy to maintain a healthy diet were calculated,

by summing four relevant items within each: 1) Negative Emotions, 2) Availability (of unhealthy foods), 3) Social Pressure, 4) Physical Discomfort, 5) Positive Activities.(357) A total 'global score' was calculated by summing the subscales.(357) WEL has shown good psychometric properties, sensitivity to change, and test-retest reliability.(357)

Weight Efficacy Lifestyle Questionnaire (WEL)

AVAILABILITY
when there are many different kinds of foods available
even when I am at a party
even when high calorie foods are available
I can control my eating on the weekend

NEGATIVE EMOTIONS
when I am anxious (nervous)
when I am depressed (or down)
when I am angry (or irritable)
when I have experienced failure

SOCIAL PRESSURE
even when I have to say 'no' to others
even when I feel it's impolite to refuse a second helping
even when others are pressuring me to eat
even when I think others will be upset if I don't

PHYSICAL DISCOMFORT
when I feel physically run down or unwell
even when I have a headache
when I am in pain
when I feel uncomfortable

POSITIVE ACTIVITIES
when I am watching TV
when I am reading
just before going to bed
when I am happy

The Multi-dimensional self-efficacy for exercise scale (MSES)

The MSES comprises 10 items to assess self-efficacy for PA, which is found to be important in the uptake and maintenance of PA.(359) It measures three aspects of self-efficacy: 1) task, 2) scheduling, 3) coping; these skills, along with a person's confidence, are needed to carry out PA behaviours in different situations and when presented with barriers.(358) MSES asks respondents to rate their confidence to exercise within three subscales: 1) three items related to 'task' (performing elemental aspects of PA), 2) four items related to 'coping' (exercising under challenging circumstances), 3) three items related to 'scheduling' (exercising regularly in spite of

other time demands). Items are rated on an ordinal scale ranging from 1 'No confidence' to 10 'Complete confidence', with an option for a 'not applicable' response. Three subscales of self-efficacy to exercise were calculated, along with a total 'global score'. Confirmatory factor analysis has supported the three dimensions of self-efficacy for PA, and MSES scores have been shown to correlate with PA levels in regular exercisers.(359)

How confident are you that you can exercise when you……		
	No Confidence **Complete Confidence**	**N/A**
4. are tired?	**1 2 3 4 5 6 7 8 9 10**	
5. are in a bad mood?	**1 2 3 4 5 6 7 8 9 10**	
6. feel you don't have the time?	**1 2 3 4 5 6 7 8 9 10**	

These next questions are about exercise itself; that is, engaging in the activity of your choice, assuming you were able to get to the place to exercise and that you have all the necessary equipment. How confident are you that you can do the following?		
	No Confidence **Complete Confidence**	**N/A**
7.Follow directions from an Instructor (if applicable)?	**1 2 3 4 5 6 7 8 9 10**	
8.Pace yourself during the activity to avoid overexertion?	**1 2 3 4 5 6 7 8 9 10**	
9.Perform the required movements?	**1 2 3 4 5 6 7 8 9 10**	
10.Check how hard the activity is making you work?	**1 2 3 4 5 6 7 8 9 10**	

The next questions are about scheduling time for exercise. How confident are you that you can do the following?		
	No Confidence **Complete Confidence**	**N/A**
11. Arrange your schedule to exercise regularly no matter what.	**1 2 3 4 5 6 7 8 9 10**	
12. Overcome obstacles that prevent you from participating regularly.	**1 2 3 4 5 6 7 8 9 10**	
13. Make up times when you missed your regular exercise session.	**1 2 3 4 5 6 7 8 9 10**	

The score for each section is calculated by taking the mean of the three items which comprise each subscale. Low scores are interpreted as low self-efficacy and high scores as high self-efficacy. MSES TASK = mean of items 4-6 MSES COPING = mean of items 7-10 MSES SCHEDULING = mean of items 11-13

Self-monitoring

Behavioural self-monitoring is associated with self-regulation, and is shown to be important in controlling GWG.(255) The HELP intervention aimed to increase self-monitoring behaviours. Questions were developed by the HELP trial team which asked women if they monitored their diet in the last four weeks, and responses scored as a binary variable indicating those that monitored diet and those that did not. Women were also asked how often they measured their weight, with responses ranging from 'daily' to 'never'. Responses were categorised into a binary variable indicating frequency of self-monitoring weight, those who weighed themselves weekly or more often and those who weighed themselves less frequently than weekly.

To assess diet self-monitoring, women were asked the following question:

Have you used any form of self-monitoring for your diet in the past 4 weeks?
___ Yes
___ No

Diet self-monitoring was scored as yes/ no for those that monitored and those that did not.

To assess self-monitoring of weight, women were asked the following question:

How often do you measure your own weight?
___ Daily
___ Weekly
___ Monthly
___ Less than monthly
___ Never

Responses were categorised into a binary variable indicating frequency of self-monitoring weight. 'Daily' and 'weekly' responses were combined into a 'weighs themselves weekly or more often' category, and 'monthly', 'less than monthly', and 'never' combined into a 'weighs themselves less frequently than weekly' category.

Weight control

The HELP intervention aimed to increase self-efficacy and motivation for weight management and health behaviours, to enable women to control their weight. As such, questions to measure aspects of weight control were developed by the trial team. Women were asked how important it was for them to control their weight, with responses ranging from 'very important' to 'I really do not want to at the moment'.

Responses were categorised into a binary variable indicating importance of weight control, those who rated weight control as important or higher and those who rated it as less than important. Similarly, women were asked how confident they were that they could control their weight, with responses ranging from 'very confident' to 'very unsure'. Responses were categorised into a binary variable indicating confidence to control weight, those who rated their themselves as confident or higher and those who rated themselves as less than confident.

For the HELP 24m study, a question first developed by the trial team asking women whether they engaged in weight control (yes/ no), was amended by the student to capture whether participants engaged in weight control activities and, if so, the types of weight control strategies they engaged in. Women were asked whether they had started any group, activity or programme for the purposes of weight control. Responses were yes/ no. Where a participant responded 'yes', they were then asked whether they used any of the following strategies: attend a commercial weight loss group face to face, follow a commercial weight loss group online, organised PA, individual PA, apps or online resources, technology devices or equipment. Responses for each were yes/ no. Strategies used were later combined into four binary variables 'commercial weight loss groups', 'physical activity', 'apps or online resources' and 'technology', and responses scored as 'yes' or 'no' to whether a respondent used a strategy or not.

To assess perceived importance of weight control, women were asked the following question:

Just at the moment, how important is it for you to control your weight?
___ Very important
___ Important
___ Not bothered either way
___ Not important
___ I really do not want to at this moment

Responses were categorised into a binary variable indicating importance of weight control. 'Very important' and 'important' responses were combined into a 'rated as important or higher' category, and 'not bothered either way', 'not important', and 'I really do not want to at this moment' combined into a 'rated as less than important' category.

To assess perceived confidence to control weight, women were asked the following question:

Right now, how confident are you that you can control your weight?

___ Very confident
___ Confident
___ Don't really know
___ Unsure
___ Very unsure

Responses were categorised into a binary variable indicating confidence for weight control. 'Very confident' and 'confident' responses were combined into a 'rated as confident or higher' category, and 'don't really know', 'unsure', and 'very unsure' combined into a 'rated as less than confident' category.

To assess whether women engaged in weight control, and what strategies they used to control their weight, they were asked the following questions:

Have you started or continued a slimming group or any other group, activity or programme for the purposes of weight control since we saw you at 1 year after the birth of your baby?
___ Yes
___ No

If yes, indicate any of these strategies that you use:
Attend slimming world or another weight management group face to face?
___ yes ___ no
Follow slimming world or another weight management programme online?
___ yes ___ no
Organised physical activity? e.g. zumba ___ yes ___ no
Individual physical activity? e.g. gym ___ yes ___ no
Use apps or online resources? e.g. myfitnessPAL ___ yes ___ no
Use technology devices or equipment? e.g. fitbit ___ yes ___ no

Please provide further details about the groups you have attended or activities/ resources used
_____
_____

Weight control engagement was scored as yes/ no for those that engaged in weight control activities and those that did not. Yes/ no scoring was also used for each of the strategies, but responses were recategorised into four binary variables. 'Attends group face to face' and 'follows programme online' responses were combined into a 'commercial weight loss groups' category with participants considered to be 'yes' if they used either strategy. 'Organised physical activity' and 'individual physical activity' were combined into a 'physical activity' category with participants considered to be 'yes' if they used either strategy. 'Apps or online resources' and 'technology devices or equipment' were as collected. For women who indicated they did not engage in any activity for the purposes of weight control, responses for all the strategies used variables were scored as missing.

Breastfeeding

Breastfeeding is lower in women with obesity, and a preventative factor for childhood obesity.(120) The HELP intervention aimed to improve breastfeeding outcomes. Questions were developed by the trial team to measure breastfeeding initiation rates which asked women whether they were currently breastfeeding, if no, had they ever breastfed, and if yes to this, how long had they breastfed in weeks. These questions were used at follow-up with reference to the child born during the HELP trial. For current breastfeeding, responses were scored as binary yes/ no to indicate women as either currently breastfeeding or not currently breastfeeding. For breastfeeding initiation, responses were scored as binary yes/ no to indicate women as having initiated breastfeeding or not initiated breastfeeding, and for those that had initiated breastfeeding, duration in weeks was used as a continuous outcome.

Subsequent pregnancies

Interpregnancy weight gain and the related increased risk in future pregnancies, are associated with maternal obesity. The HELP intervention aimed to reduce weight and, in doing so, decrease this risk. Questions were developed by the student, with guidance from a consultant midwife, to explore outcomes in subsequent pregnancies. First women were asked if they were pregnant or had baby since the HELP trial. Those who responded 'yes' to had another baby were asked for information on planned and actual delivery method (vaginal/ instrumental or caesarean), and breastfeeding (initiation and duration questions as above, with reference to a subsequent infant) for this baby. It was unlikely that there would be a high incidence rate of subsequent pregnancies to allow sufficient power to detect an intervention effect, but comparison between groups were made.

Women were asked the following questions to assess further pregnancies since the HELP trial:

Are you pregnant now? ___ yes ___ no
If so, how many weeks pregnant are you? _____ weeks

Have you given birth to another baby since you had your HELP child? ___ yes ___ no
If yes, how many weeks old is this baby? _____ weeks

If you had another baby since your HELP child:
What was the planned mode of birth for this child?
___ Spontaneous vaginal delivery
___ Elective caesarean section

What was the actual mode of delivery for this child?
___ Spontaneous vaginal delivery
___ Elective caesarean section
___ Emergency caesarean section
___ Ventouse
___ Forceps
___ Vaginal Breech

Responses for actual mode of delivery were categorised into a binary variable. 'Spontaneous vaginal delivery' was combined with 'ventouse', 'forceps' and 'vaginal breech' to make a 'vaginal/ instrumental' category, to compare with 'Elective' and 'emergency' caesarean sections. If a woman indicated 'no' to have you had another baby, the rest of the responses in relation to a subsequent baby were coded as missing.

To assess breastfeeding initiation and duration, women were asked the same questions as above, except with reference to the subsequent infant. Scoring was completed in the same way.

Are you breastfeeding your HELP child now? ___ yes ___ no
If no, have you ever breastfed your HELP child? ___ yes ___ no
If so, how long did you breastfeed your HELP child for? _____ weeks

Child body composition: BMI measured by weight and length

To assess childhood obesity as an outcome related to maternal obesity and GWG,(63-65) a measurement of child body composition was required. Although anthropometric measures, such as skinfold thickness, provide accuracy in measuring child obesity risk, studies similar to the HELP 24m study have experienced loss of children to follow-up where these measures have been used. This was due to the inconvenience of clinical examinations and mothers being unwilling for their children to go through such assessments;(324) as well as difficulties in obtaining trained staff to perform measures.(285) Instead BMI was used, as described below. Measuring BMI in children has been validated against other measures of adiposity as an acceptable way to define overweight and obesity.(82, 98) It is cheap and easy to measure, has good accuracy when measurements are taken by a trained person, and can be applied from age two years.(98).

For children, BMI is calculated using weight (kg) divided by recumbent length or standing height (m^2). However, as BMI in children changes substantially according to age and sex, assessment of BMI in children further involves the use of age and sex

related reference curves.(375) Growth standards and growth references, based on reference populations, are used to establish nutritional status and growth.(84)

A growth standard reflects optimal growth that all children should be capable of achieving under supportive conditions.(84) It allows for the calculation of BMI-for-age *z*-scores which are recognised as the best system for expressing child BMI assessment.(84, 375) *Z*-scores are the deviation of an individual's height and weight values from the median value of a reference population, divided by the standard deviation of the reference population. This gives a fixed interval by which to describe the weight and height of children of a given age, which is also sex-dependent, which means summary statistics can be used to make comparisons across age and sex. The WHO Child Growth Standards (2006) for children up to six years were used to determine BMI-for age *z*-scores.(375) Values are expected to fall between -3 and 3 (based on the reference population), with a median value of 0, and values above and below this interpreted as distance from the average.(495)

A growth reference provides distribution within a particular population,(84) and allows comparison of a child's height or weight with the heights and weights of a reference population, to evidence normality, or otherwise, of growth.(81) The UK90 growth references, which provide centile curves for BMI for British children aged 0 to 23 years,(373) were used to determine BMI percentiles. This allowed child growth to be expressed as an age and sex specific percentile (0- 100), in comparison with this growth within a UK reference population. The UK90 growth reference is recommended for population monitoring purposes, as it is applicable to children across SES and feeding history.(81, 496) Thresholds were applied to percentile values to indicate normality of growth expressed as 'underweight' (<2nd percentile), 'healthy weight' (≥2nd to ≤84th percentiles), 'overweight' (≥85th to ≤94th percentiles)', and 'very overweight' (≥95th percentile).(98) Classification of BMI percentile was further categorised into a binary variable, overweight or obesity and healthy weight or underweight. Obesity defined according to these thresholds is based on statistical distribution rather than health risk; however, it has clinical meaning in that it is associated with short and long-term morbidity.(82) A limitation of adopting a particular growth reference, is that study findings are only directly comparable to other studies that have adopted the same measure.

Weight (kg) and recumbent length (cm) were measured by the researcher. The use of baby scales was considered impractical and unreliable due to difficulties in

accurately measuring children of this age. Instead, measurements were taken using calibrated adult scales, by weighing the mother alone and then weighing her holding the child, and both values recorded. Child weight (kg) was calculated during data processing. The child was weighed in light, indoor clothing and no shoes.(98) Standing height is recommended for measuring children aged 731 days and over (>24 months), with recumbent length measured for children aged 730 days or under (≤ 24 months) as there are differences in stature, and length will be overestimated in children >730 days.(375) However, follow-up in this study was intended to be around the 24 months postpartum time point, which posed practical challenges for accurately establishing which children should have height or length measured. Instead, recumbent length was measured for all children, and accounted for in data processing, as described in Chapter 3 (section 3.7.4).

Child diet

Accurately measuring dietary intake in preschool children is challenging, as reported food intake is often overestimated, forgotten or subject to social desirability bias.(164, 345, 497) Purpose and practicality of the measure need to be considered.(164) Food diaries, which involve the weighing and recording of food preparation and consumption over a period of time, are considered the most accurate method of assessing food intake in preschool children. However, this method was too burdensome, and the method itself may change food intake.(164) Multiple pass 24 hour recalls ask respondents to report their child's food intake over the previous 24 hours across several occasions. 24 hour recall is acceptable to measure the dietary intake of young children and has been validated against observation of actual intake.(164) The multiple pass method recommends repeating the 24 hour recall on at least four occasions for improved accuracy.(498) Again, the burden for this method was too high, and required assessment beyond one appointment. A food frequency questionnaire was considered the best option for assessing child diet in this study, as they can be completed on a single occasion but reflect 'usual' dietary habits.

In selecting an appropriate measure, the focus was to assess diet as a determinant of child weight. Children with dietary intake consisting of high fat, energy-dense and sugary foods and drinks, are more at risk of developing obesity.(91) An Australian intervention study aimed at reducing obesity and promote healthy behaviours in young children, developed the EPAQ scale to measure parent reported food intake for children aged two to five years.(107, 360) The EPAQ focuses on intakes of obesity-promoting and obesity-protective foods (fruits, vegetables, packaged snacks,

chocolate and confectionery, cake and biscuits, and takeaway/ fast food), and beverages (fruit juice, sugar-sweetened drinks, water, plain milk, flavoured milk). As the focus of this measure was on obesity risk, and it was much shorter than other questionnaires which include extensive lists of foods, which may not be applicable across different populations,(164) the EPAQ questions were (used with the authors' permission).

The EPAQ asks parents to recall quantities or frequency of food or beverage consumption by their child, in general household measures, and the timeline refers to either the previous day or typical intake (e.g. 'Yesterday, how many servings of the following beverages did your child drink?). For beverages, seven responses range from 'none' to 'six', for foods, seven responses range from 'none' to 'five' (with a ½ measure possible), and for frequency of fast food intake, seven responses range from 'less than once per month' to 'two or more times per day'.(360) It also asks about portions of fruits and vegetables consumed on a typical day.

Assessment of habitual diet over a long period is difficult in preschool children as food habits change frequently.(164) Therefore, an additional question was added which asked parents whether the intake reported reflected their child's 'usual' intake. Use of the EPAQ has been validated against an interviewer administered 24-hour recall method and shown to correlate with intake for all items except water.(360) Portion size guidance is provided with the EPAQ, but this guidance was developed for an Australian population and includes foods uncommon in the UK. To aid standardised reporting of dietary intake, UK recommended age appropriate portion sizes were used,(499) to create a visual servings guide to give to mothers (see below). Each food or beverage was categorised into a binary variable of those that consumed (all responses > none) or did not consume (none). Frequency of takeaway consumption was categorised into a binary variable of those that consumed once a week or more often and those who consumed less than once a week. Fruit and vegetable consumption was scored as number of portions per day. Reflection of 'usual' intake was scored as binary variable yes/ no.

Drinks (servings)	Servings	None	1	2	3	4	5	6 or more	Don't know
Fruit Juice	One serving equals 105ml								
Cordial, Squash or Soft Drink	One serving equals 105ml								
Water	One serving equals 105ml								
Plain Milk (remember to include milk on cereal and in drinks)	One serving equals 165ml								
Flavoured Milk (including times that you have added flavour to milk)	One serving equals 165ml								

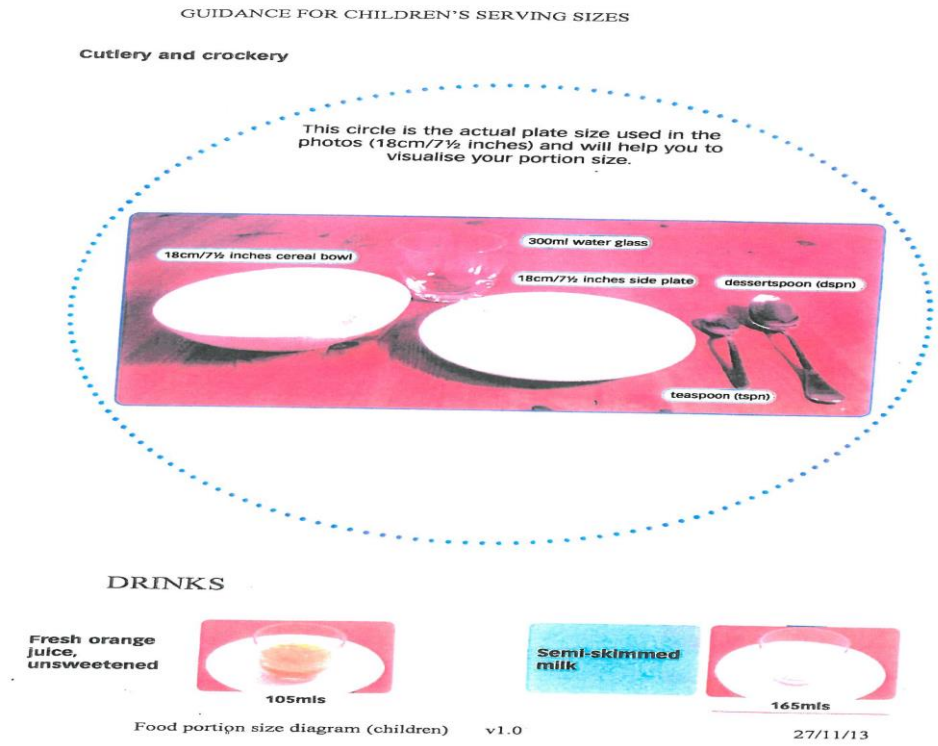
Foods (servings)	Servings (examples)	None	1/2	1	2	3	4	5 or more	Don't know
Vegetables (cooked & raw veg and baked beans)	Any amount of Broccoli, carrots or salad 1dspn peas/ sweetcorn 2dspn baked beans								
Packaged snacks (crisps, corn snacks, muesli bar)	20g packet of crisps or one muesli bar								
Fruit (fresh, dried and tinned)	½ apple or banana, 1 plum, 2 tbsp raisins, 2 pieces of tinned pears								
Confectionary and/ or chocolate	22g fun sized bar or a small handful of sweets								
Cake/ doughnuts, sweet biscuits and muffins	1 small slice cake, 1 rich tea, ¼ regular muffin								

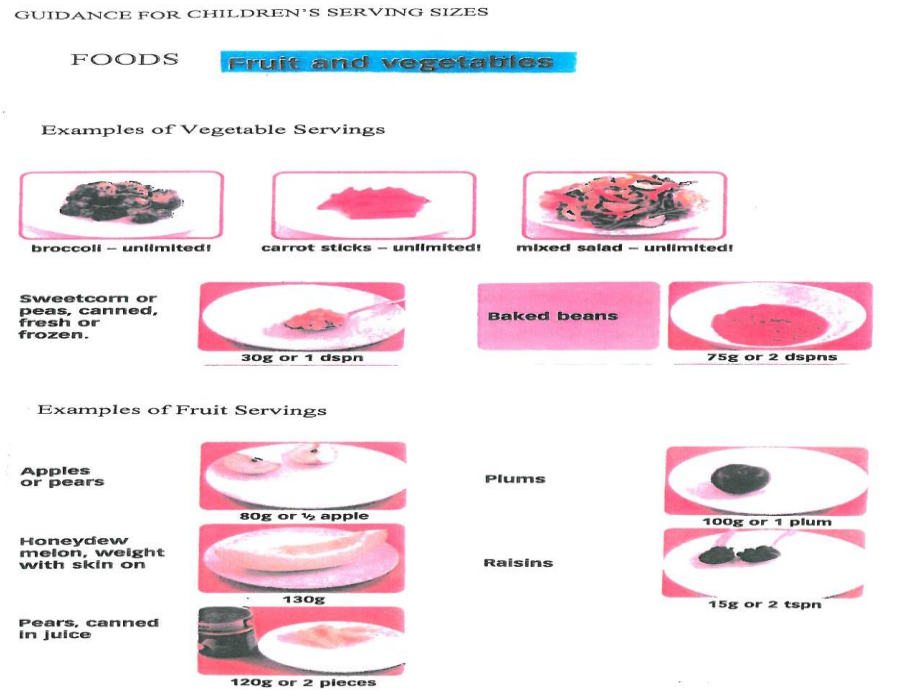
Takeaway/ fast food intake

How often does your child eat takeaway or fast-food? (e.g. Hot chips, hamburgers, chicken nuggets, sausage rolls, hot dogs, pizza- do not include when foods are homemade)

Less than once per month	1- 3 times per month	Once per week	2- 4 times per week	5- 6 times per week	Once per day	2 or more times per day

Children's food portion guidance





Child PA, sedentary behaviours and parent-child activities

The purpose of measuring PA, sedentary behaviours and parent-child activities, was part of identifying risk of an 'obesogenic' environment. Therefore, understanding levels of child PA and sedentary behaviours; that is, to what extent children were meeting guidelines for these behaviours, or parents were supporting the child to be active, was of interest. There was a paucity of standardised measures used to assess PA behaviours of toddlers.(500) Objectives measures, such as using accelerometery devices, may be reliable and valid methods.(500-502) However, these were not appropriate as this would require measurement over time. No validated parent-report measures of PA in children, aged 24 months, were identified. Researchers conducting similar studies were contacted for advice on measurement of PA in young children. Questions were adopted from the UPBEAT trial database (with permission), which were intended to be used for future follow-up of participants in this trial.(269) Adopting these questions would make findings from these studies comparable.

Women were asked to report the types of activities their child engaged in (e.g. 'does your child play active games and activities inside?), how many times per week and duration of each activity type. Frequency of parent/ child activities (e.g. 'how often does your child walk with you to do an errand?), were also collected, with four responses ranging from 'less than once a week' to 'more than four times a week'. Number of activities engaged in per week and duration of activity (minutes) were summed across the activity types to create 'number of activities completed' and 'minutes of activity' per week scores for each child. According to responses yes/ no for each type of activity engaged in, numbers engaging and total duration of each activity type were calculated. Frequency of parent/ child activities were categorised into binary variables: parent actively plays with child twice or more per week and less than twice per week; parent takes child for a walk once or more per week and less than once per week; and parent takes child to park/ playgroup once or more per week and less than once per week.

Activity during a typical week	Does this activity (tick 'yes' or 'no') Yes No	If yes, number of times per week (complete boxes)	If yes, average number of minutes each time (complete boxes)
None	☐		
Play outside at home in games and activities that involve exercising (e.g. running, jumping, playing with a ball)	☐ ☐	☐☐ week	☐☐☐ inutes
Play active games and activities inside?	☐ ☐	☐☐ r week	☐☐☐ inutes
Attend kinder gym or similar e.g. soft play, jump, indoor play area?	☐ ☐	☐☐ week	☐☐☐ inutes
Attend playgroup or other organised activity outside the home?	☐ ☐	☐☐ week	☐☐☐ inutes
Attend dance or music classes?	☐ ☐	☐☐ week	☐☐☐ inutes
Swim for fun?	☐ ☐	☐☐ week	☐☐☐ inutes
Attend swim lessons?	☐ ☐	☐☐ week	☐☐☐ inutes
If your child does any of these activities less often than once a week, please describe what they do and how often:	_____ _____		

	Less than once a week	Once a week	2-3 times a week	More than 4 times a week
On average, how many times in a usual week does your child play with their parent (one or both)? *(parent is actively engaged in play not just observing or taking child to play)*				
How often does your child walk with you to do an errand (e.g. to the local shops, to post a letter)?				
On average, how many times per week is your child taken to a playground/park outside the home?				

Questions to capture sedentary behaviours were taken from the EPAQ, which asked mothers to report 'yesterday, how long did your child watch TV/ videos/ DVDs or play computer or video games at home', in hours and minutes in the 'morning', 'afternoon' and 'evening'; and how children would prefer to spend free time, with three

responses ranging from ‘active pastimes’ to ‘inactive pastimes’.(360) Total minutes of sedentary behaviour per day was calculated, and children categorised as preferring to spend free time ‘being active’, ‘being inactive’ or ‘no preference’.

Yesterday, how long did your HELP child watch TV/ videos/ DVDs or play computer or video games at home (or a friend’s or relative’s home)? If you are not sure please state your ‘best guess’.		Don’t Know (tick)
Morning	☐☐ Hours **and** ☐☐ Minutes	
Afternoon	☐☐ Hours **and** ☐☐ Minutes	
Evening (after 6pm)	☐☐ Hours **and** ☐☐ Minutes	

What does your child usually do when he/ she has a choice about how to spend free time?

Usually chooses inactive pastimes (i.e. TV, computer, drawing or reading)	
Just as likely to choose inactive as active pastimes	
Usually chooses active pastimes (i.e. outdoor play, dancing, sports)	

Mealtime environment

Eating meals as a family at a table and away from the television is influential in achieving dietary quality and portion size control.(91, 124, 134, 141, 142) Positive role modelling by parents during mealtimes is also important to encourage healthy food intake in children.(122, 130-133) There were no validated measures identified to measure these aspects of mealtime environment. Researchers conducting work in this field were contacted. Questions from the UPBEAT trial resources were again used (with permission): 1) How often do you sit down for family meals together? 2) At mealtimes do the adults in the house have the same food as your child?; and, 3) How often does your child eat dinner in front of the television? For questions 1 and 2, five responses ranged from ‘never’ to ‘always’. For question 3, four responses ranged from ‘every day’ to ‘rarely/ never’, and additional numeric information on ‘times per week’ or ‘times per month’ was prompted for when these response options were selected. Responses for questions 1 and 2 were categorised into binary variables of ‘meals together’, mostly or always and some of the time or less often; and, ‘same foods’, mostly or always and some of the time or less often. For tv viewing, responses for ‘times per week’ and ‘times per month’ were combined into a

'sometimes' response, and responses scored as either 'every day', 'sometimes' or 'never'. Number of times per week was also calculated for the 'sometimes' option.

	Never	Rarely	Some of the time	Most of the time	Always	Don't know
How often do you sit down for family meals together?						
At mealtimes do the adults in the house have the same food as your **child?**						

How often does **your child** eat dinner in front of the television?

Every day	Times per week	Times per month	Rarely/ Never	Don't know
	☐☐	☐☐		

Maternal feeding practices

Maternal feeding practices may be influential on children's dietary behaviours, although the relationship is not straightforward, as discussed in Chapter 1. It was considered important to measure feeding practices as they may be influential on child diet and weight, particularly those practices which have been associated with obesity development. The selection of measures was limited by their applicability to this age group. However, several measures were identified and are discussed.

The CFQ is widely used to assess parental beliefs, attitudes and practices in relation to child feeding, with a focus on proneness for obesity. It measures parents' perceptions about their child's susceptibility to overweight, and the feeding strategies they employ. The CFQ has been validated for use in children aged two to 11 years.(143) Respondents were asked to rate 31 statements on a five point Likert scale, responses dependent on the statement (e.g. how concerned are you about your child eating too much when you are not around, responses range from unconcerned to very concerned). Seven subscales related to parental feeding were scored: 1) perceived responsibility, 2) perceived parent weight, 3) perceived child weight, 4) perceived concern for child weight, 5) restriction, 6) pressure to eat and 7) monitoring. Mean scores were calculated for each subscale of parental feeding to be used in the secondary analysis. Subscales 2 and 3 were categorised into binary variables to reflect maternal perceptions of their own and their child's weight into: perceived as overweight or higher and perceived as normal weight or lower. Differences between the groups, and how this may relate to child weight or diet, can be explored.

Subscale 1: Perceived Responsibility

	Never- 1	Seldom- 2	Half of the time- 3	Most of the time- 4	Always- 5
When your child is at home, how often are you responsible for feeding him/ her?					
How often are you responsible for deciding what your child's portion sizes are?					
How often are you responsible for deciding if your child has eaten the right kind of foods?					

Subscale 2: Perceived parent weight

	Markedly underweight- 1	Underweight- 2	Normal- 3	Overweight- 4	Markedly overweight- 5
Your childhood (5 to 10 years old)					
Your adolescence					
Your 20s					
At present					

Subscale 3: Perceived child weight

	Markedly underweight- 1	Underweight- 2	Normal- 3	Overweight- 4	Markedly overweight- 5
Your child during the first year of life					
Your child as a toddler					

Subscale 4: Concern about child weight

	Unconcerned- 1	A little concerned- 2	Concerned- 3	Fairly concerned- 4	Very concerned- 5
How concerned are you about your child eating too much when you are not around him/ her?					
How concerned are you about your child having to diet to maintain a desirable weight?					
How concerned are you about your child becoming over weight?					

Subscale 5: Restriction

	Disagree- 1	Slightly disagree- 2	Neutral- 3	Slightly agree- 4	Agree- 5
I have to be sure that my child does not eat too many sweets (candy, ice-cream, cake or pastries)					
I have to be sure that my child does not eat too many high- fat foods					
I have to be sure that my child does not eat too much of his/ her favourite foods					
I intentionally keep some foods out of my child's reach					
I offer sweets (candy, ice-cream, cake, pastries) to my child as a reward for good behaviour					
I withhold sweets/dessert from my child in response to bad behaviour					
I offer my child his/ her favourite foods in exchange for good behaviour					
If I did not guide or regulate my child's eating, he/ she would eat too many junk foods					
If I did not guide or regulate my child's eating, he/ she would eat too much of his/ her favourite foods					

Subscale 6: Pressure to Eat

	Disagree- 1	Slightly disagree- 2	Neutral- 3	Slightly agree- 4	Agree- 5
My child should always eat all of the food on his/ her plate					
I have to be especially careful to make sure my child eats enough					
If my child says "I'm not hungry", I try to get him/ her to eat anyway					
If I did not guide or regulate my child's eating, he/ she would eat much less than he/ she should					

Subscale 7: Monitoring

	Never- 1	Rarely- 2	Sometimes- 3	Mostly- 4	Always - 5
How much do you keep track of the sweets (candy, ice-cream, cake, pies, pastries) that your child eats?					
How much do you keep track of the snack food (potato chips, Doritos, cheese puffs) that your child eats?					
How much do you keep track of the high-fat foods that your child eats?					
Do you encourage this child to eat healthy foods before unhealthy ones?					

The parental overt and covert control over snacks and meals scale was developed as a complimentary measure to the CFQ, but differentiates between two types of control, overt and covert, which parents use in influencing their child's food environment and access to certain foods, such as unhealthy snacks.(153) These aspects of child feeding, although correlated to those measured by the CFQ, are shown to be conceptually and statistically different.(153) Parents were asked to rate 12 statements on a five point Likert scale ranging from 'never' to 'always', related to how often they employed behaviours reflective of overt or covert control. Four subscales of parental control were measured, these were: overt control over snacking, covert control over snacking, overt control over meals, covert control over meals. Mean scores were calculated for each subscale of parental feeding, to be used in the secondary analysis.

Subscale 1: Covert control over snacking

	Never-1	Rarely-2	Sometimes-3	Mostly-4	Always-5
How often do you avoid going to cafes or restaurants with your child which sell unhealthy snacks?					
How often do you avoid buying snack foods for your child, such as sweets?					
How often do you avoid having snack foods such as sweets and crisps in the house?					

Subscale 2: Overt control over snacking

	Never-1	Rarely-2	Sometimes-3	Mostly-4	Always-5
How often are you firm about what your child should eat as a snack?					
How often are you firm about when your child should eat a snack?					
How often are you firm about how much your child should eat as a snack?					

Subscale 3: Covert control over meals

	Never-1	Rarely-2	Sometimes-3	Mostly-4	Always-5
How often do you avoid going to cafes or restaurants with your child which sell unhealthy meals?					
How often do you avoid buying unhealthy foods for your child's meals?					
How often do you avoid having unhealthy foods in the house for your child's meals?					

Subscale 4: Overt control over meals

	Never-1	Rarely-2	Sometimes-3	Mostly-4	Always-5
How often are you firm about what your child should eat at mealtimes?					
How often are you firm about when your child should eat their meals?					
How often are you firm about how much your child should eat at mealtimes?					

The CFPQ was designed to measure the feeding practices of parents of children aged two to eight years, to better understand how parents feed their children.(362) This scale had not been used as widely as the CFQ in the literature, despite also measuring feeding related to obesity proneness; however factor analysis confirmed aspects of child feeding not already captured by the CFQ or parental overt and covert control scale; therefore, it was shortened and added as a complementary measure to obtain a wider understanding of maternal feeding.(362) The original scale measured 12 subscales of parental feeding practices, the following seven subscales were measured here, to complement the information already measured by the CFQ: 1) encourage balance and variety, 2) food as reward, 3) modelling, 4) restriction for health, 5) restriction for weight, 6) child control and 7) emotional regulation. Parents were asked to rate statements on a five-point Likert scale ranging from 'never' to 'always', or from 'disagree' to 'agree', dependent on the statement. All items included from the CFPQ are positively scored and mean scores were calculated for each subscale of parental feeding, to be used in the secondary analysis. Higher scores demonstrate a higher use or presence of the feeding practice.

Subscale: Restriction for weight control

*Question 1 from this scale repeated from CFQ subscale 5

	Disagree-1	Slightly disagree-2	Neutral-3	Slightly agree-4	Agree-5
*I have to be sure that my child does not eat too many high- fat foods					
I encourage my child to eat less so he/she won't get fat					
I give my child small helpings at meals to control his/her weight					
If my child eats more than usual at one meal, I try to restrict his/ her eating at the next meal					
I restrict the food my child eats that might make him/her fat					
There are certain foods my child shouldn't eat					

because they will make him/her fat					
I don't allow my child to eat between meals because I don't want him/her to get fat					
I often put my child on a diet to control his/her weight					

Subscale: Restriction for health

	Disagree-1	Slightly disagree-2	Neutral-3	Slightly agree-4	Agree-5
If I did not guide or regulate my child's eating, s/he would eat too much of his/her favourite foods.					
If I did not guide or regulate my child's eating, he/she would eat too many junk foods.					
I have to be sure that my child does not eat too much of his/her favourite foods.					
I have to be sure that my child does not eat too many sweets (candy, ice cream, cake, or pastries).					

Subscale: Child control

	Never-1	Rarely-2	Sometimes-3	Mostly-4	Always-5
Do you let your child eat whatever s/he wants?					
At dinner, do you let this child choose the foods s/he wants from what is served?					
If this child does not like what is being served, do you make something else?					
Do you allow this child to eat snacks whenever s/he wants?					
Do you allow this child to leave the table when s/he is full, even if your family is not done eating?					

Subscale: Emotion Regulation

	Never-1	Rarely-2	Sometimes-3	Mostly-4	Always-5
When this child gets fussy, is giving him/her something to eat or drink the *first* thing you do?					
Do you give this child something to eat or drink if s/he is bored even if you think s/he is not hungry?					
Do you give this child something to eat or drink if s/he is upset even if you think s/he is not hungry?					

Subscale: Encourage balance and variety

*Question 1 from this scale repeated from CFQ subscale 7

	Disagree-1	Slightly disagree-2	Neutral-3	Slightly agree-4	Agree-5
*Do you encourage this child to eat healthy foods before unhealthy ones?					
I encourage my child to try new foods					

I tell my child that healthy food tastes good					
I encourage my child to eat a variety of foods					

Subscale: Modelling

	Disagree-1	Slightly disagree-2	Neutral-3	Slightly agree-4	Agree-5
I model healthy eating for my child by eating healthy foods myself					
I try to eat healthy foods in front of my child, even if they are not my favourite					
I try to show enthusiasm about eating healthy foods					
I show my child how much I enjoy eating healthy foods					

Subscale: Food as a reward

	Disagree-1	Slightly disagree-2	Neutral-3	Slightly agree-4	Agree-5
I offer sweets (candy, ice cream, cake, pastries) to my child as a reward for good behaviour.					
I withhold sweets/dessert from my child in response to bad behaviour.					
I offer my child his/her favourite foods in exchange for good behaviour.					

Childcare

Childcare outside the home is likely to have an influence on children's dietary and PA behaviours,(165, 166) so it was important to assess the level of this influence. Women were asked if their child attended different types of childcare care settings attended (e.g. 'does your child attend 'group care'); if so, how many days/ half days, and frequency of food provision in childcare, with four responses ranging from 'yes, all meals and snacks' to 'no meals'. These questions were adopted from the UPBEAT study resources.(269) Numbers attending each childcare setting (yes/ no) and level of food provision in childcare was scored.

Which of the following best describes your most recent childcare?

Childcare Setting	Attends (tick) Yes	No	If he/ she attends, complete the number of days per week below	All Day	Mornings or afternoons only
None	☐				
Group Care e.g. crèche, nursery	☐	☐	☐	☐	☐
Childminder/ Nanny in your home	☐	☐	☐	☐	☐
Childminder/ Nanny in another home	☐	☐	☐	☐	☐
Relative in your home	☐	☐	☐	☐	☐
Relative in another home	☐	☐	☐	☐	☐
Other (please specify): _____	☐	☐	☐	☐	☐

Food provision in childcare

Does your current childcare provide food for your child?
___ Yes, all meals and snacks
___ Yes, main meals only
___ Yes, snacks only
___ No meals

Appendix I: CRF and Questionnaire

CID PID Participant initials

Participant DOB d d m m y y y y

F7 CASE REPORT FORM

CID

PID

Participant initials

Participant DOB

Date form completed

Form completed by (researcher)……

Date form received by SEWTU

Date entered onto database Data entered by

CID ☐☐ PID ☐☐☐ Participant initials ☐☐☐☐

Participant DOB ☐☐ ☐☐ ☐☐ d d m m y y y y

1. **Just at the moment how important is it for you to control your weight? (Please tick one box)**

Very important	Important	Not bothered either way	Not important	I really do not want to at this moment
☐	☐	☐	☐	☐

2. **Right now, how confident are you that you can control your weight (please tick one box)**

Very confident	Confident	Don't really know	Unsure	Very unsure
☐	☐	☐	☐	☐

3. **Have you used any form of self monitoring for your diet in the last 4 weeks e.g. diet diaries?**

☐ Yes ☐ No

4. **How often do you measure your own weight?**

☐ Daily
☐ Weekly
☐ Monthly
☐ Less than monthly
☐ Never

5. **Have you ever been diagnosed with any of the following health conditions? (please tick)**

Heart Disease	☐
Diabetes	☐
Depression	☐
Stroke	☐
Arthritis	☐
Hypertension	☐
High Cholesterol	☐
Asthma	☐
Chronic Obstructive Pulmonary Disease	☐
Chronic Backache Requiring Referral	☐
Postnatal depression	☐
Other	☐

If you answered 'Other' please write what the condition is._____

Date form received by SEWTU ☐☐☐☐☐☐☐☐

Date entered onto database ☐☐☐☐☐☐☐☐ Data entered by ☐☐

CID | | PID | | Participant initials | | | | |

Participant DOB | | | | | | | | | (d d m m y y y y)

6. Have you recently or are you currently involved in any other research studies? (please tick)

☐ Yes ☐ No

If so, can you give us the title of study and some brief details about the research?

.....

.....

7. Since we last saw you at 1 year after your HELP baby's birth, have you gained any of the following qualifications?

☐ A higher degree, like a master's degree, or a PhD
☐ A first degree, like a BA or BSc
☐ A certificate or diploma in higher education
☐ A or AS or S levels
☐ O levels or GCSE grades A-C
☐ Other qualifications (please write in

.....
☐ None of these qualifications

8. Are you a current smoker? (please tick)

☐ Yes ☐ No

If so, how many cigarettes or roll-ups do you smoke per day? .....

9. Are you breastfeeding your HELP baby now? (please tick)

☐ Yes ☐ No

If no, have you ever breast-fed your HELP baby?

☐ Yes ☐ No

If so, how long did you breast-feed your HELP baby for?.....weeks

10. Are you pregnant now?

☐ Yes ☐ No

If so, how many weeks pregnant are you? .....weeks

Date form received by SEWTU | | | | | | | | |

Date entered onto database | | | | | | | | | Data entered by | |

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

11. Have you given birth to another baby since you had your HELP baby?

☐ Yes ☐ No (if no, skip to question 14)

If yes, how many weeks old is this baby? .....weeks

12. a) If you have had another baby since your HELP baby, what was the planned mode of birth for this baby? (i.e. how you intended to give birth)

☐ Spontaneous Vaginal Delivery (normal birth)
☐ Elective Caesarian Section

b) And what was the actual mode of birth for this baby? (i.e. how your baby was delivered)

☐ Spontaneous Vaginal Delivery (normal birth)
☐ Elective Caesarian Section
☐ Emergency Caesarian Section
☐ Ventouse (suction)
☐ Forceps
☐ Vaginal Breech

c) If your planned mode of birth was different from your actual mode of birth, please explain the reason for this:

.....
.....
.....

13. If you have had another baby since your HELP baby, are you breastfeeding this baby now? (please tick)

☐ Yes ☐ No

If no, have you ever breast-fed the baby you had after your HELP baby?

☐ Yes ☐ No

If so, how long did you breast-feed this baby for? .....weeks

Date form received by SEWTU

Date entered onto database Data entered by

CID ☐☐ PID ☐☐☐ Participant initials ☐☐☐☐

Participant DOB ☐☐☐☐☐☐☐☐ (d d m m y y y y)

14. Have you started or continued a slimming group or any other group, activity or programme for the purposes of weight control since we saw you at 1 year after the birth of your HELP baby?

☐ Yes ☐ No

If so, please tick all that apply:

☐ Attend Slimming World or another Weight Management group **face to face**
☐ Follow Slimming World or another Weight Management programme **online** at home
☐ Organised physical activity groups e.g. Buggyfit or Zumba classes
☐ Individual physical activity e.g. gym or running
☐ Use apps or online resources e.g. myFitnessPAL, Weight Loss Wars, STICKK
☐ Use equipment to monitor and support diet/ physical activity e.g. FitBit, pedometers

If so, please provide further details about the groups you have attended or activities/ resources used:

_____
_____
_____

Please now weigh the participant first and record her weight; then weigh the participant with her HELP baby on the scales **together** to record the **combined weight** and complete the following information:

Mother's Weight ☐☐☐.☐ **kg**

Waist circumference ☐☐☐.☐ **cm** **Hip circumference** ☐☐☐.☐ **cm**

Mother & HELP Baby's Combined Weight: ☐☐☐.☐ **kg**

HELP Baby's height: ☐☐☐.☐ **cm**

Baby's Sex: male ☐ **female** ☐ **Baby's Age:** ☐☐ **months AND** ☐☐ **weeks**

SEWTU USE ONLY
THE FOLLOWING BOXES WILL BE COMPLETED IN SEWTU, PLEASE LEAVE BLANK

Baby Weight: ☐☐.☐ **kg** **Baby BMI:** ☐☐.☐

Date form received by SEWTU ☐☐☐☐☐☐☐☐

Date entered onto database ☐☐☐☐☐☐☐☐ Data entered by ☐☐

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

RESOURCE USE QUESTIONS

Ask respondent if they have seen any of the health professionals below in the last three months for any reason. Response should only include seen for the mother's care/ treatment. Visits for any children should not be recorded

1. In the past 3 months, did you see any health professional at your GP surgery?

☐ Yes ☐ No

If yes, how many times were you seen by:

Your own or another GP	…….. times
Midwife or Nurse	…….. times
Any other health professional (e.g. physiotherapist)	……..... times

2. In the past 3 months, were you visited at home by any health professional? (please tick)

☐ Yes ☐ No

If yes, how many times were you visited by:

Your own or another GP	…….. times
Midwife or Nurse	…….. times
Any other health professional (e.g. physiotherapist)	……..... times

3. In the past 3 months did you attend an Accident and Emergency (Casualty) department ? (please tick)

☐ Yes ☐ No

If yes, how many times ……

Date form received by SEWTU

Date entered onto database Data entered by

CID		PID		Participant initials				
Participant DOB	d	d	m	m	y	y	y	y

4. In the past 3 months were you admitted to hospital as an in-patient? (please tick)

☐ Yes ☐ No

If yes, how many nights did you spend in hospital?

…… nights

5. In the past 3 months did you receive any prescriptions for medicine? (please tick)

☐ Yes ☐ No

If yes, which drugs were you prescribed:

Drug Name	Strength

6. And finally, in the past 3 months did you pay for any services for the specific purpose of helping you with your weight control following pregnancy – for example slimming clubs, health clubs, gyms, swimming pools, exercise classes? (please tick)

☐ Yes ☐ No

If yes, approximately how much did you pay in total for all these services in the last 3 months?

£ ……..

Please thank the participant for answering these questions.

Once completed, please photocopy this form for your records and return this form to the study team in the provided envelope

Date form received by SEWTU									
Date entered onto database									Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

Healthy **E**ating and **L**ifestyle in **P**regnancy (HELP)

Your Questionnaire Booklet Q7
Follow-up Questionnaire
(2 years)

CID

PID

Participant initials

Participant DOB

Date form completed

Form completed by (researcher)……

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

The following two sections ask about your diet and physical activity. Some of the questions in these two sections may seem repetitive but we need to collect all this information so that we can score the questionnaires properly and complete the analyses. We understand that repetitive questions can be off-putting so your cooperation in completing all the questions is greatly appreciated.

Please feel free to ask the researcher any questions if there is anything you don't understand. This questionnaire should take around 40 minutes to complete but take as much time as you like.

Please turn over to begin the questionnaire

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

Part 1 —Your Diet

The questions in this section focus on the food you eat as well as your eating habits and patterns of eating.

The questions below ask about the different foods you eat. For guidance on portion size please see the pictures at the end of this questionnaire.
Some of the questions ask you what you eat in a normal *week* but others what you eat in a normal *day*.
Please tick only one box on each line

1. About how many pieces or slices of bread do you eat on a **usual day**?
(choose one answer on each line)

Bread	None	less than 1 **a day**	1 - 2 **a day**	3 - 4 **a day**	5 or more **a day**
White bread or soft rolls					
Brown or granary bread; Best of Both, soft grain					
Wholemeal bread or 2 slices crispbread or wholemeal scones					
Chapattis, wraps					
(Please write in) Other: ……..					

2. About how many **servings per week** do you eat of the following type of breakfast cereal or porridge?
(choose one answer on each line)

Breakfast Cereal	None	less than 1 **a week**	1 – 2 **a week**	3 - 5 **a week**	6 or more **a week**
Sugar type: Frosties, Coco Pops, Ricicles, Sugar puffs, **Rice/Corn type**: Corn flakes, Rice Krispies, Special K.					
Porridge or Ready Brek **Wheat type**: Shredded Wheat, Weetabix, Puffed Wheat, Fruit'n Fibre, Oat Krunchies, Start. **Muesli type**: Alpen, Jordan's					
Bran type: All-Bran, Bran Flakes, Sultana Bran					

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

3. About how many **servings per week** do you eat of the following foods?
(choose one answer on each line)

	None	less than 1 **a week**	1 – 2 **a week**	3 – 5 **a week**	6 – 7 **a week**	8 - 11 **a week**	12 or more **a week**
Pasta or rice							
Potatoes							
Peas							
Beans (baked, tinned, or dried) or lentils							
Other vegetables (any type)							
Fruit (fresh, frozen, canned)							

4. About how many **servings per week** do you eat of the following foods?
(choose one answer on each line)

	None	less than 1 **a week**	1 - 2 **a week**	3 - 5 **a week**	6 or more **a week**
Cheese (any except cottage)					
Beefburgers or sausages					
Beef, pork, or lamb (for vegetarians: nuts)					
Bacon, meat pie, processed meat					
Chicken or turkey					
Fish (NOT fried fish)					
ANY fried food: fried fish, chips, cooked breakfast, samosas					
Cakes, pies, puddings, pastries					
Biscuits, chocolate					
Crisps					

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

5. About how much of the following types of milk do you yourself use **per day**, for example in cereal, tea, or coffee?

(choose one answer on each line)

Milk	None	less than a quarter pint	about a quarter pint	about a half pint	1 pint or more
Full cream					
Semi-skimmed					
Skimmed					

6. About how many **rounded teaspoons** per day do you usually use of the following types of spreads, for example on bread, sandwiches, toast, potatoes or vegetables,

(choose one answer on each line)

Spreads	None	1 a day	2 a day	3 a day	4 a day	5 a day	6 a day	7 or more
Regular margarine or butter or reduced fat spread such as sunflower or olive spread, Flora, Vitalite, Clover, Olivio, Stork, Utterly Butterly								
Low fat spread such as Flora Light, Half-fat butter, Olivite, Flora Pro-activ, Light spread								

7. What sort of fat do you usually use for the following purposes?

(choose one answer on each line)

	Butter, lard or dripping	**Solid cooking fat** (White Flora, Cookeen) **Half-fat butter, Hard margarine** (Stork)	**Soft margarine** (sunflower, soya) **Reduced fat spread** (olive, Flora Buttery, Anchor Lighter, Olivio)	**Vegetable oil, Olive oil** or **Low fat spread** (Flora Light, Flora pro-active, Olivite)	**No fat used**
On bread and vegetables					
For frying					
For baking or cooking					

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

8. How many pieces of fruit and vegetables (excluding potatoes) do you eat, of any sort, on a typical day? (choose one on each line)

	None	1	2	3	4	5	6	7	8 or more
Fruit									
Vegetable									

Please note: Fruit and vegetable juice can count as **one** portion

9. How many cans of pop, flavoured water or a fizzy drink which isn't sugar free or diet do you drink on a usual day?
(NOTE: A 2 litre bottle = 6 cans)

_____cans

10. How many rounded teaspoons of sugar do you have on a usual day e.g. in tea or coffee or on cereals?

_____ rounded teaspoons

11. How often do you eat sweets **other than chocolate**, e.g. toffee, boiled sweets etc? (please tick under one column)

None	Less than monthly	Less than weekly	1-2 times a week	3-6 times a week	Once a day	Twice a day	More than twice a day

Consider a 'drink' to be: half a pint of average strength beer/lager OR a glass of wine OR one single measure of spirits.

12. How often do you have a drink containing alcohol?

Never	Monthly or less	2-4 times a month	2-3 times a week	4 times a week or more

13. How many drinks containing alcohol do you have on a typical day when you were drinking?

n/a	1 or 2	3 or 4	5 or 6	7 to 9	10 or more

14. How often do you have six or more drinks on one occasion?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

These questions below ask about how much social support you receive in relation to your eating habits? Below is a list of things people might do or say to someone who is trying to eat healthily. Please rate each question three times (***family, friends, Slimming World and midwifery group***) under each question by circling the number that applies to you. If the statement does not apply to you please tick the box under 'does not apply'.

During the past three months, my family (or members of my household) or my friends and colleagues at work have;

15. Discouraged me from eating "unhealthy foods" when I'm tempted to do so	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	☐
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	☐
16. Refused to eat the same foods I eat	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	☐
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	☐
17. Offered me food I'm trying to avoid	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	☐
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	☐

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

The questions below ask about why you choose to eat healthily. Please circle the appropriate number. For example, if you feel the statement is very true for you, you should circle '7'. If you feel the statement is not true for you, you should circle '1'. If the statement is somewhere in between you should place a circle between '2' to '6' depending on how true the statement is to you

The reason I would eat a healthy diet is because……	**Not at all true**			**Somewhat true**			**Very true**
18. …..I feel that I want to take responsibility for my own health	1	2	3	4	5	6	7
19. ……I would feel guilty or ashamed of myself if I did not eat a healthy diet	1	2	3	4	5	6	7
20. ……I personally believe it is the best thing for my health	1	2	3	4	5	6	7
21. ……others would be upset with me if I did not	1	2	3	4	5	6	7
22. I really don't think about it	1	2	3	4	5	6	7
23. ……I have thought carefully about it and I believe it is very important for many aspects of my life	1	2	3	4	5	6	7
24. ……I would feel bad about myself if I did not eat a healthy diet	1	2	3	4	5	6	7
25. ……it is an important choice I really want to make	1	2	3	4	5	6	7
26. ……I feel pressure from others to do so	1	2	3	4	5	6	7
27. ……it is easier to do what I am told than think about it	1	2	3	4	5	6	7
28. ……it is consistent with my life goals	1	2	3	4	5	6	7
29. …..I want others to approve of me	1	2	3	4	5	6	7
30. …..it is very important for being as healthy as possible	1	2	3	4	5	6	7
31. …..I want others to see I can do it	1	2	3	4	5	6	7
32. I don't really know why	1	2	3	4	5	6	7

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

These questions ask you about how much confidence you have in controlling your eating.
Please answer the following questions by circling the appropriate number. For example, if you have complete confidence that you can carry out the behaviour specified you should circle the number '9'. If you have no confidence you should circle the number '0'. If your confidence levels are somewhere in between you should circle between '1' to '8', depending on your level of confidence.

I can resist eating……	**No confidence**									**Complete confidence**
33. ……when I am anxious (nervous)	0	1	2	3	4	5	6	7	8	9
34. …….even when I have to say 'no' to others	0	1	2	3	4	5	6	7	8	9
35. ……when I feel physically run down or unwell	0	1	2	3	4	5	6	7	8	9
36. …….when I am watching TV	0	1	2	3	4	5	6	7	8	9
37. …….when I am depressed (or down)	0	1	2	3	4	5	6	7	8	9
38. …….when there are many different kinds of foods available	0	1	2	3	4	5	6	7	8	9
39. …….even when I feel it's impolite to refuse a second helping	0	1	2	3	4	5	6	7	8	9
40. ……..even when I have a headache	0	1	2	3	4	5	6	7	8	9
41. ……when I am reading.	0	1	2	3	4	5	6	7	8	9
42. ……..when I am angry (or irritable)	0	1	2	3	4	5	6	7	8	9
43. ……..even when I am at a party	0	1	2	3	4	5	6	7	8	9
44. ……..even when others are pressurising me to eat	0	1	2	3	4	5	6	7	8	9
45. ……..when I am in pain.	0	1	2	3	4	5	6	7	8	9
46. ……just before going to bed	0	1	2	3	4	5	6	7	8	9
47. ……when I have experienced failure	0	1	2	3	4	5	6	7	8	9
48. ……even when high calorie foods are available	0	1	2	3	4	5	6	7	8	9
49. ……..even when I think others will be upset if I don't eat	0	1	2	3	4	5	6	7	8	9
50. ……..when I feel uncomfortable	0	1	2	3	4	5	6	7	8	9
51. ……when I am happy	0	1	2	3	4	5	6	7	8	9
52. I can control my eating on the weekends	0	1	2	3	4	5	6	7	8	9

Date form received by SEWTU

Date entered onto database | Data entered by

CID ☐☐ PID ☐☐☐ Participant initials ☐☐☐☐

Participant DOB ☐☐☐☐☐☐☐☐ (d d m m y y y y)

Part 2—Your General Health

The questions in this section focus on your general physical and psychological health

We would like to know how your health has been in general over the last few weeks. Please read the questions below and each of the four possible answers. Please tick beside the response that best applies to you. Thank you for answering all the questions.

1. Been able to concentrate on whatever you're doing?			
Better than usual ☐	Same as usual ☐	Less than usual ☐	Much less than usual ☐
2. Lost much sleep over worry?			
Not at all ☐	No more than usual ☐	Rather more than usual ☐	Much more than usual ☐
3. Felt that you were playing a useful part in things?			
More so than usual ☐	Same as usual ☐	Less useful than usual ☐	Much less useful ☐
4. Felt capable of making decisions about things?			
More so than usual ☐	Same as usual ☐	Less so than usual ☐	Much less capable ☐
5. Felt constantly under strain?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
6. Felt you couldn't overcome your difficulties?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
7. Been able to enjoy your normal day-to-day activities?			
More so than usual ☐	Same as usual ☐	Less so than usual ☐	Much less than usual ☐
8. Been able to face up to your problems?			
More so than usual ☐	Same as usual ☐	Less able than usual ☐	Much less able ☐
9. Been feeling unhappy and depressed?			
Not at all ☐	No more than usual ☐	Rather more than usual ☐	Much more than usual ☐

Date form received by SEWTU ☐☐☐☐☐☐☐☐

Date entered onto database ☐☐☐☐☐☐☐☐ Data entered by ☐☐

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

10. Been losing confidence in yourself?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
11. Been thinking of yourself as a worthless person?			
Not at all ☐	No more Than usual ☐	Rather more than usual ☐	Much more than usual ☐
12. Been feeling reasonably happy, all things considered?			
More so than usual ☐	About same as usual ☐	Less so than usual ☐	Much less than usual ☐

Questions continue on the following page

Date form received by SEWTU

Date entered onto database | Data entered by

CID | PID | Participant initials

Participant DOB (d d m m y y y y)

By placing a tick in one box in each group below, please indicate which statements **best describe your own health state today.**

13. Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

14. Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

15. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

16. Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

17. Anxiety/Depression

I am not anxious or depressed ❑

I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

Date form received by SEWTU

Date entered onto database | Data entered by

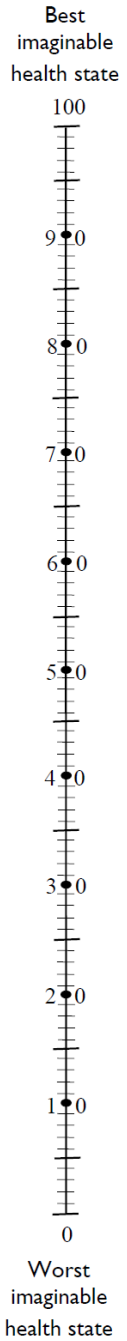
CID | PID | Participant initials

Participant DOB (d d m m y y y y)

18. To help people say how good or bad a health state is we have drawn a scale (rather like a thermometer) on which the best state you could imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today

Your own health today



CID | PID | Participant initials

Participant DOB (d d m m y y y y)

Part 3 — Self Regulation

This section focuses on how you manage your health e.g. how you manage your weight

Please answer the following questions by ticking the box that best describes how you are. If you STRONGLY DISAGREE with a statement, tick in the relevant box under "Stongly Disagree". If you DISAGREE, are UNCERTAIN or UNSURE, AGREE or STRONGLY AGREE tick in the relevant box under that statement. There are no right or wrong answers. **Work quickly and don't think too long about your answers**

In relation to my health……..	Strongly disagree	Disagree	Uncertain/ unsure	Agree	Strongly agree
1. ……...I don't notice the effects of my actions until it's too late					
2. …….. I am able to accomplish goals I set for myself					
3. ……I have personal standards, and try to live up to them					
4. ……I tend to keep doing the same thing even when it doesn't work					
5. ……I have a hard time setting goals for myself					
6. ……I have trouble making plans to help me reach my goals					
7. ……I set goals for myself and keep track of my progress					
8. ……I give up quickly					

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Part 4 —Physical Activity

The questions in this section ask you about the amount of physical activity you do, and when and why you choose to partake in it

These questions ask you about the social support you receive in relation to physical activity.
Below is a list of things people might do or say to someone who is trying to exercise regularly.
Please rate each question three times (family, friends, Slimming World and midwifery group) under each question by circling the number that applies to you. If the statement does not apply to you please tick the box under 'does not apply'.

During the past three months, my family (or members of my household) or my friends and colleagues at work have;

1. Exercised with me or offered to exercise with me	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	☐
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	☐
2. Gave me encouragement to stick with my exercise program	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	☐
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	☐
3. Criticised me or complained about the amount of time I spend exercising	**none**	**rarely**	**a few times**	**often**	**very often**	**does not apply**
Family	**0**	**1**	**2**	**3**	**4**	☐
Friends and colleagues at work	**0**	**1**	**2**	**3**	**4**	☐

Questions continue on the following page

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The questions below ask you about how much confidence you have in relation to exercise. Please answer the following questions by circling the appropriate number. For example, if you have complete confidence that you can carry out the behaviour specified you should circle the number '10'. If you have no confidence you should circle the number '1'. If your confidence levels are somewhere in between you should circle between '2' to '9', depending on the level of your confidence.

How confident are you that you can exercise when you……											
	No Confidence									**Complete Confidence**	**N/A**
4. …are tired?	1	2	3	4	5	6	7	8	9	10	☐
5 …are in a bad mood?	1	2	3	4	5	6	7	8	9	10	☐
6.…feel you don't have the time?	1	2	3	4	5	6	7	8	9	10	☐

These next questions are about exercise itself; that is, engaging in the activity of your choice, assuming you were able to get to the place to exercise and that you have all the necessary equipment. How confident are you that you can do the following?											
	No Confidence									**Complete Confidence**	**N/A**
7. Follow directions from an Instructor (if applicable)?.	1	2	3	4	5	6	7	8	9	10	☐
8. Pace yourself during the activity to avoid overexertion?	1	2	3	4	5	6	7	8	9	10	☐
9. Perform the required movements?	1	2	3	4	5	6	7	8	9	10	☐
10. Check how hard the activity is making you work?	1	2	3	4	5	6	7	8	9	10	☐

The next questions are about scheduling time for exercise. How confident are you that you can do the following?											
	No Confidence									**Complete Confidence**	**N/A**
11. Arrange your schedule to exercise regularly no matter what.	1	2	3	4	5	6	7	8	9	10	☐
12. Overcome obstacles that prevent you from participating regularly.	1	2	3	4	5	6	7	8	9	10	☐
13. Make up times when you missed your regular exercise session.	1	2	3	4	5	6	7	8	9	10	☐

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The questions below ask about why you choose to exercise. Please circle the appropriate numbers. For example, if you feel the statement is very true for you, you should circle '7'. If you feel the statement is not true for you, you should circle '1'. If the statement is somewhere in between you should place a circle between '2' to '6' depending how true the statement is to you

The reason I would exercise regularly is because…….	**Not at all true**			**Somewhat true**			**Very true**
14. ……I feel that I want to take responsibility for my own health	1	2	3	4	5	6	7
15. …….I would feel guilty or ashamed of myself if I did not exercise regularly	1	2	3	4	5	6	7
16. …….I personally believe it is the best thing for my health	1	2	3	4	5	6	7
17. ……..others would be upset with me if I did not	1	2	3	4	5	6	7
18. ……..I really don't think about it	1	2	3	4	5	6	7
19. …….I have thought carefully about it and I believe it is very important for many aspects of my life	1	2	3	4	5	6	7
20. ……. I would feel bad about myself if I did not exercise regularly	1	2	3	4	5	6	7
21. ……it is an important choice I really want to make	1	2	3	4	5	6	7
22. ……I feel pressure from others to do so	1	2	3	4	5	6	7
23. ……it is easier to do what I am told than think about it	1	2	3	4	5	6	7
24. ……it is consistent with my life goals	1	2	3	4	5	6	7
25. ……I want others to approve of me	1	2	3	4	5	6	7
26. ……it is very important for being as healthy as possible	1	2	3	4	5	6	7
27. ……I want others to see I can do it	1	2	3	4	5	6	7
28. I really don't know why	1	2	3	4	5	6	7

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Part 5 —Your child

The questions in this section ask you about your HELP child. This is **the child you had at the time you took part in the HELP study.** Please do not answer these questions for any other children that you may have.
We want to find out about where your HELP child spends time, the activities that he/ she does and the foods that he/ she eats.

The following questions ask you about where and with whom your HELP child spends his/ her day, and how often your child might take part in certain activities.

1. Which of the following best describes your most recent childcare?

Please tick which childcare settings your HELP child attends by selecting 'yes' or 'no' for each. For each childcare setting that is ticked 'yes' they attend, in the next column please complete the number of days per week they attend in the box AND in the last columns indicate if this is either 'all day' or 'morning or afternoons only' by ticking the relevant box.

Childcare Setting	Attends (tick) Yes	No	If he/ she attends, complete the number of days per week below	All Day	Mornings or afternoons only
None	☐				
Group Care e.g. crèche, nursery	☐	☐	☐	☐	☐
Childminder/ Nanny in your home	☐	☐	☐	☐	☐
Childminder/ Nanny in another home	☐	☐	☐	☐	☐
Relative in your home	☐	☐	☐	☐	☐
Relative in another home	☐	☐	☐	☐	☐
Other (please specify): _____	☐	☐	☐	☐	☐

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2. Does your current childcare provide food for your HELP child?
Please choose **one** answer by ticking the relevant box.

If you do not have childcare please tick N/A or if you are not sure you can tick 'Don't know'

Yes, all meals and snacks	Yes, main meals only	Yes, snacks only	No meals	Don't know	N/A

3. The next few questions are about your HELP child's activity levels **when NOT attending childcare**. During a typical week how much time does your child do the following activities? If you are not sure please state your 'best guess'.

Please tick which activities your HELP child does by selecting 'yes' or 'no' for each. For each activity ticked 'yes' 'they do', in the next column complete the number of times per week they do it AND in the last column indicate the average number of minutes they do the activity for each time.

Activity during a typical week	Does this activity (tick 'yes' or 'no') Yes	No	If yes, number of times per week (complete boxes)	If yes, average number of minutes each time (complete boxes)
None	☐			
Play outside at home in games and activities that involve exercising (e.g. running, jumping, playing with a ball)	☐	☐	☐☐ Per week	☐☐☐ Minutes
Play active games and activities inside?	☐	☐	☐☐ Per week	☐☐☐ Minutes
Attend kindergym or similar e.g. soft play, jump, indoor play area?	☐	☐	☐☐ Per week	☐☐☐ Minutes
Attend playgroup or other organised activity outside the home?	☐	☐	☐☐ Per week	☐☐☐ Minutes
Attend dance or music classes?	☐	☐	☐☐ Per week	☐☐☐ Minutes
Swim for fun?	☐	☐	☐☐ Per week	☐☐☐ Minutes
Attend swim lessons?	☐	☐	☐☐ Per week	☐☐☐ Minutes
If your child does any of these activities less often than once a week, please describe what they do and how often:				

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4. For these next questions please tell us about your **HELP** child's usual activity and play by ticking one answer on each line

(Please tick **one answer** on **each line**)

	Less than once a week	Once a week	2-3 times a week	More than 4 times a week
On average, how many times in a usual week does your child play with their parent (one or both)? *(parent is actively engaged in play not just observing or taking child to play)*				
How often does your child walk with you to do an errand (e.g. to the local shops, to post a letter)?				
On average, how many times per week is your child taken to a playground/park outside the home?				

5. a) Yesterday, how long did your **HELP** child watch TV/ videos/ DVDs or play computer or video games at home (or a friend's or relative's home)? If you are not sure please state your 'best guess'.

Please indicate the hours and minutes by completing the boxes for each time of day, morning, afternoon and evening.

		Don't Know (tick)
Morning	Hours **and** Minutes	
Afternoon	Hours **and** Minutes	
Evening (after 6pm)	Hours **and** Minutes	

b) Would you say yesterday represented a typical day for watching TV/ videos/ DVDs or playing computer or video games? Please tick **one** response from 'yes' or 'no', If no, please complete why you think this.

Typical day (tick yes or no)	Yes	No
If no, please specify in the box the reason for this:		

6. What does your **HELP** child usually do when he/ she has a choice about how to spend free time?

(Please tick **one answer only**)

Usually chooses inactive pastimes (i.e. TV, computer, drawing or reading)	
Just as likely to choose inactive as active pastimes	
Usually chooses active pastimes (i.e. outdoor play, dancing, sports)	

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The following questions ask you about your HELP child's eating behaviours focusing on the foods and drinks that your child consumes. For guidance on serving size please see the pictures at the end of this questionnaire. The questions ask you to rate how many servings of certain foods or drinks your child ate yesterday. Please tick the box which applies and only one box on each line. If they did not have any of the particular food/ drink tick 'none' or if you are not sure tick 'don't know'.

7. a) Yesterday, how many servings of the following beverages did **your HELP child** drink?

(Please tick **one answer** on **each line**)

Drinks (servings)	Servings	None	1	2	3	4	5	6 or more	Don't know
Fruit Juice	One serving equals 105ml								
Cordial, Squash or Soft Drink	One serving equals 105ml								
Water	One serving equals 105ml								
Plain Milk (remember to include milk on cereal and in drinks)	One serving equals 165ml								
Flavoured Milk (including times that you have added flavour to milk)	One serving equals 165ml								

b) Yesterday, how many servings of the following foods did **your HELP child** have?

(Please tick **one answer** on **each line**)

Foods (servings)	Servings (examples)	None	1/2	1	2	3	4	5 or more	Don't know
Vegetables (cooked & raw veg and baked beans)	Any amount of Broccoli, carrots or salad 1dspn peas/ sweetcorn 2dspn baked beans								
Packaged snacks (crisps, corn snacks, muesli bar)	20g packet of crisps or one muesli bar								
Fruit (fresh, dried and tinned)	½ apple or banana, 1 plum, 2 tbsp raisins, 2 pieces of tinned pears								
Confectionary and/ or chocolate	22g fun sized bar or a small handful of sweets								
Cake/ doughnuts, sweet biscuits and muffins	1 small slice cake, 1 rich tea, ¼ regular muffin								

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Participant DOB	d d m m y y y y				

c) Would you say yesterday represented a typical day for him/ her eating these foods and drinking these drinks?
Please tick **one** response from 'yes' or 'no' **and** If no, please complete why you think this.

Typical day (tick yes or no)	Yes	No
If no, please specify in the box the reason for this:		

d) On a typical day, how many portions of vegetables does **your HELP child** eat?

☐☐ servings **each day**

e) On a typical day, how many portions of fruit does **your HELP child** eat?

☐☐ servings **each day**

f) How often does **your HELP child** eat takeaway or fast-food? (e.g. Hot chips, hamburgers, chicken nuggets, sausage rolls, hot dogs, pizza- do not include when foods are homemade)

Less than once per month	1- 3 times per month	Once per week	2- 4 times per week	5- 6 times per week	Once per day	2 or more times per day

g) If you would like to add any other comments about how much of the foods/ drinks in Q7a-f **your HELP child** eats OR how much you know about what your child eats, please write your comments in the box.

Comments:	

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These questions ask you about your HELP child's habits and patterns of eating, and how you feed your child so please answer the questions in relation to when you are responsible for feeding your child. The questions ask you to rate things which are related to feeding your HELP child (make sure you answer these specifically about the child that you had when you took part in the HELP study). Please tick the box which applies and **only one box** on **each line.**

8. Please rate the level of responsibility you have in feeding **your HELP child** by ticking one box between 'never' and 'always' on each line.

(choose **one** answer on **each** line)

	Never	Seldom	Half of the time	Most of the time	Always
When your child is at home, how often are you responsible for feeding him/ her?					
How often are you responsible for deciding what your child's portion sizes are?					
How often are you responsible for deciding if your child has eaten the right kind of foods?					

9. Please rate for each question how you would think of **your own weight** at different stages in your life by ticking one box between 'markedly underweight' and 'markedly overweight' on each line.

(choose **one** answer on **each** line)

	Markedly underweight	Underweight	Normal	Overweight	Markedly overweight
Your childhood (5 to 10 years old)					
Your adolescence					
Your 20s					
At present					

10. Please rate for each question how you would think of **your HELP child's weight** at different stages in his/ her life by ticking one box between 'markedly underweight' and 'markedly overweight' on each line.

(choose **one** answer on **each** line)

	Markedly underweight	Underweight	Normal	Overweight	Markedly overweight
Your child during the first year of life					
Your child as a toddler					

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11. Please rate for each question the level of concern you have about **your HELP child's** weight by ticking one box between 'unconcerned' and 'very concerned' on each line.

(choose **one** answer on **each** line)

	Unconcerned	A little concerned	Concerned	Fairly concerned	Very concerned
How concerned are you about your child eating too much when you are not around him/ her?					
How concerned are you about your child having to diet to maintain a desirable weight?					
How concerned are you about your child becoming over weight?					

12. Please rate for each question the extent to which you control how much **your HELP child** eats by ticking one box between 'disagree' and 'agree' on each line.

(choose **one** answer on **each** line)

	Disagree	Slightly disagree	Neutral	Slightly agree	Agree
My child should always eat all of the food on his/ her plate					
I have to be especially careful to make sure my child eats enough					
If my child says "I'm not hungry", I try to get him/ her to eat anyway					
If I did not guide or regulate my child's eating, he/ she would eat much less than he/ she should					

13. Please rate for each question how much you keep track of **your HELP child's** eating by ticking one box between 'never' and 'always' on each line.

(choose **one** answer on **each** line)

	Never	Rarely	Sometimes	Mostly	Always
How much do you keep track of the sweets (candy, ice-cream, cake, pies, pastries) that your child eats?					
How much do you keep track of the snack food (potato chips, Doritos, cheese puffs) that your child eats?					
How much do you keep track of the high-fat foods that your child eats?					
Do you encourage this child to eat healthy foods before unhealthy ones?					

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14. Please rate for each question the extent to which you restrict **your HELP child** from eating certain foods by ticking one box between 'disagree' and 'agree' on each line.
(choose **one** answer on **each** line)

	Disagree	Slightly disagree	Neutral	Slightly agree	Agree
I have to be sure that my child does not eat too many sweets (candy, ice-cream, cake or pastries)					
I have to be sure that my child does not eat too many high- fat foods					
I have to be sure that my child does not eat too much of his/ her favourite foods					
I intentionally keep some foods out of my child's reach					
I offer sweets (candy, ice-cream, cake, pastries) to my child as a reward for good behaviour					
I withhold sweets/dessert from my child in response to bad behaviour					
I offer my child his/ her favourite foods in exchange for good behaviour					
If I did not guide or regulate my child's eating, he/ she would eat too many junk foods					
If I did not guide or regulate my child's eating, he/ she would eat too much of his/ her favourite foods					
I encourage my child to eat less so he/she won't get fat					
I give my child small helpings at meals to control his/her weight					
If my child eats more than usual at one meal, I try to restrict his/ her eating at the next meal					
I restrict the food my child eats that might make him/her fat					
There are certain foods my child shouldn't eat because they will make him/her fat					
I don't allow my child to eat between meals because I don't want him/her to get fat					
I often put my child on a diet to control his/her weight					

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15. Please answer this next question about **your HELP child's** snacking behaviour between meals by ticking one box between 'never' and 'always' on each line. (choose **one** answer on **each** line)

	Never	Rarely	Sometimes	Mostly	Always
How often are you firm about what your child should eat as a snack?					
How often are you firm about when your child should eat a snack?					
How often are you firm about how much your child should eat as a snack?					
How often do you avoid going to cafes or restaurants with your child which sell unhealthy snacks?					
How often do you avoid buying snack foods for your child, such as sweets?					
How often do you avoid having snack foods such as sweets and crisps in the house?					

16. Please now answer this similar question about **your HELP child's** meals (not including snacks in between meals) by ticking one box between 'never' and 'always' on each line.
(choose **one** answer on **each** line)

	Never	Rarely	Sometimes	Mostly	Always
How often are you firm about what your child should eat at mealtimes?					
How often are you firm about when your child should eat their meals?					
How often are you firm about how much your child should eat at mealtimes?					
How often do you avoid going to cafes or restaurants with your child which sell unhealthy meals?					
How often do you avoid buying unhealthy foods for your child's meals?					
How often do you avoid having unhealthy foods in the house for your child's meals?					

17. Please rate for each question how much you allow **your HELP** child to control his/ her eating behaviours by ticking one box between 'never' and 'always' on each line.
(choose **one** answer on **each** line)

	Never	Rarely	Sometimes	Mostly	Always
Do you let your child eat whatever s/he wants?					
At dinner, do you let this child choose the foods s/he wants from what is served?					
If this child does not like what is being served, do you make something else?					
Do you allow this child to eat snacks whenever s/he wants?					
Do you allow this child to leave the table when s/he is full, even if your family is not done eating?					

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18. Please rate for each question how you deal with **your HELP child's** emotional states by ticking one box between 'never' and 'always' on each line.

(choose **one** answer on **each** line)

	Never	Rarely	Sometimes	Mostly	Always
When this child gets fussy, is giving him/her something to eat or drink the *first* thing you do?					
Do you give this child something to eat or drink if s/he is bored even if you think s/he is not hungry?					
Do you give this child something to eat or drink if s/he is upset even if you think s/he is not hungry?					

19. Please rate for each question the extent to which you encourage **your HELP child** to make healthy food choices by ticking one box between 'disagree' and 'agree' on each line.

(choose **one** answer on **each** line)

	Disagree	Slightly disagree	Neutral	Slightly agree	Agree
I encourage my child to try new foods					
I tell my child that healthy food tastes good					
I encourage my child to eat a variety of foods					
I model healthy eating for my child by eating healthy foods myself					
I try to eat healthy foods in front of my child, even if they are not my favourite					
I try to show enthusiasm about eating healthy foods					
I show my child how much I enjoy eating healthy foods					

20. For these next questions please tell us about your family mealtimes when the family are home together by ticking one answer on each line.

(Please tick **one answer** on **each line**)

	Never	Rarely	Some of the time	Most of the time	Always	Don't know
How often do you sit down for family meals together?						
At mealtimes do the adults in the house have the same food as your **HELP child?**						

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21. How often does **your HELP child** eat dinner in front of the television?

Please tick **one** answer **only.** If this is a number of times per week or a number of times per month, please complete the relevant boxes with how many times this happens.

Every day	Times per week	Times per month	Rarely/ Never	Don't know

Please go back and check that you have completed all the questions in this section

Please hand the questionnaire back to the researcher

The researcher will now ask you some questions about the last seven days.
These questions will be completed by the researcher.

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NOTE: the Seven Day Recall table is on the following page

Part 6 —Researcher completed

The questions in this section should be completed by the researcher and continue to ask you about the amount of physical activity you do

1) Were you employed in the last seven days? **0. No** (Skip to question 4) **1.Yes**

2) How many days of the last seven did you work? _____ **days**

3) How many total hours did you work in the last seven days? _____ **hours**

4) What two days do you consider your weekend days? (please circle 2 days below)

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday

5) Compared to your physical activity over the past three months, was last week's physical activity more, less or about the same? **(Please tick the box that applies to you)**

1. More ☐

2. Less ☐

3. About the same ☐

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Days								
Sleep Times								
Sleep Hours								
Morning	Mod							
	Hard							
	V.Hard							
Afternoon	Mod							
	Hard							
	V.Hard							
Evening	Mod							
	Hard							
	V.Hard							
Total per day	Physical activity							
Total per day	Strength and Flexibility							

Rounding	
10-22 minutes	0.25
23-27 minutes	0.50
28-52 minutes	0.75
53-1.07 hr/ min.	1.0
1.08-1.22 hr/min.	1.25

Please ensure that the participant has completed the "health state thermometer" question on page 13 correctly (i.e. drawn a line from the centre box which crosses over the thermometer on the right hand side).

THE FOLLOWING RESPONSE BOX BELOW WILL BE COMPLETED IN SEWTU, PLEASE LEAVE BLANK:

What is the participant's percentage health state? ☐☐☐ %

END OF THE QUESTIONNAIRE

Please thank the participant for their time and effort

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Appendix J: Start Recruitment Letter

Dr Sharon Simpson
SEWTU

School of Medicine
Cardiff University
7th Floor Neuadd Meirionnydd
Heath Park
Cardiff University

Dear *INSERT NAME

Thank you for agreeing to take part in the HELP PhD Study and for your help in getting the study up and running in *INSERT SITE. Your Centre Identification number is *INSERT CID.

We have now received R&D approval and a signed agreement with Cardiff University. Therefore, I am happy to inform you that you are ready to commence participant recruitment after we complete the arranged training.

You will have received all HELP PhD Study documents. We will inform you of any updates to these documents. Please complete the delegation of responsibilities log and return a copy of this.
We wish you luck with recruitment and if you have any questions, please do not hesitate to call Dunla Cassidy.

Best wishes,

Sharon Simpson
HELP PhD Study Chief Investigator

Contacts

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Thank you

Appendix K: CONSORT checklist for reporting a cluster randomised controlled trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page (Pg) or Chapter (Ch) or Appendix (Ap)
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Pg i
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[i,ii]	See table 3	Pg viii
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Chs 1,2 and 3
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	Ch 2
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	Chs 2 and 3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Ap B
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Ap B and CH 3
	4b	Settings and locations where the data were collected		Ch 3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Ap B and Ch 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	Ch 3
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	Ch 3
	7b	When applicable, explanation of any interim analyses and		N/A

		stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Ap B
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Ap B
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Ap B and Ch 3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Ap B
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Ap B
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Ap B
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		Ap B and Ch 3
	11b	If relevant, description of the similarity of interventions		N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	Ch 3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Ch 3
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Ch 4
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Ch 4
Recruitment	14a	Dates defining the periods of		Ch 4

		recruitment and follow-up		
	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Ch 4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Ch 4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Ch 4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Ch 4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Ch 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[iii])		N/A
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Chs 4 and Ch 7
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Chs 4 and 7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Chs 4 and 7
Other information				
Registration	23	Registration number and name of trial registry		Ap B
Protocol	24	Where the full trial protocol can be accessed, if available		Ap B
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		Pg iii

Appendix L: Tables of results in Chapter 4

Maternal BMI adjusted for baseline variables of smoking, parity, ethnicity, SES and education, and 24 months postpartum variable of timing of follow-up

Adjusted primary outcome	Intervention N 107	Intervention Baseline mean (SD)	Intervention Follow-up mean (SD)	Control N 134	Control Baseline mean (SD)	Control Follow-up mean (SD)	ICC	Adjusted[a] intervention effect[b,c] (95% CI)	p-value
Smoking									
BMI (kg/m^2)	105	38.0 (6.2)	36.8 (7.3)	134	36.4 (4.8)	35.5 (5.9)	-	-0.01 (-0.04 to 0.02)	0.68
Parity									
BMI (kg/m^2)	105	38.0 (6.2)	36.8 (7.3)	134	36.4 (4.8)	35.5 (5.9)	-	-0.01 (-0.04 to 0.02)	0.52
Ethnicity									
BMI (kg/m^2)	105	38.0 (6.2)	36.8 (7.3)	134	36.4 (4.8)	35.5 (5.9)	-	-0.01 (-0.04 to 0.02)	0.69
SES									
BMI (kg/m^2)	105	38.0 (6.2)	36.8 (7.3)	134	36.4 (4.8)	35.5 (5.9)	-	-0.01 (-0.04 to 0.02)	0.48
Education[d]									
BMI (kg/m^2)	105	38.0 (6.2)	36.8 (7.3)	134	36.4 (4.8)	35.5 (5.9)	-	-0.01 (-0.04 to 0.03)	0.74
Time point									
BMI (kg/m^2)	105	38.0 (6.2)	36.8 (7.3)	134	36.4 (4.8)	35.5 (5.9)	-	-0.01 (-0.04 to 0.02)	0.62

a Adjusted for baseline BMI and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Baseline BMI used in the model was on the log scale.
c Intervention effect was interpreted as percentage difference (intervention minus control) due to log transformation.
d Education based on highest qualification achieved

Child BMI-for-age *z*-scores adjusted for maternal GWG

Adjusted primary outcome	Intervention N 107	Intervention Mean (SD)	Control N 134	Control Mean (SD)	ICC	Adjusted[a] intervention effect[b] (95% CI)	p-value
Maternal GWG	94	1.22 (1.5)	133	1.03 (1.5)	-	-0.30 (-0.13 to 0.72)	0.170

a Adjusted for birthweight and cluster level variables used to balance the randomisation: antenatal unit size, proportion of women with BMI ≥30, geographic location and ethnic mix.
b Intervention effect was interpreted as difference in means (intervention minus control).

Appendix M: Appointment letter for interview

South East Wales Trials Unit (SEWTU),
Cardiff University,
7th Floor Neuadd Meirionnydd,
Heath Park,
Cardiff, CF14 4YS

Appointment Letter to Participant

Date: _____

Dear _____

Re: **Healthy Eating and Lifestyle in Pregnancy (HELP) PhD Study**

Thank you for agreeing to help us with our research study. I recently spoke to you to arrange a telephone interview with you to discuss this study. Please find enclosed an information sheet with further information about the interview.

Your telephone interview is on _____.

You will have the chance to ask any questions you may have about the study before we start the interview. If you are happy to take part I will request your verbal consent. I will then ask you to talk about your experiences in relation to physical activity, eating habits and your and your family's general health. This will take about 40-60 minutes. If you are unable to make the arranged time please let me know by emailing me or calling the number below.

All information collected about you and your family during the course of the interview will be kept strictly confidential.

I look forward to speaking to you.

Yours sincerely,

Tel: 02920687602
Email: cassidyd@cardiff.ac.uk

Appendix N: Participant information sheet for interview

South East Wales Trials Unit (SEWTU),
Cardiff University,
7th Floor Neuadd Meirionnydd,
Heath Park,
Cardiff, CF14 4YS

Participant Information Sheet for 2 Year Interviews

Study title: Healthy Eating and Lifestyle in Pregnancy (HELP) PhD Study

Part 1 of the Information Sheet

This study is being run by Cardiff University and forms part of a PhD study, which is a study coordinated by a student researcher in order to gain a Doctorate of Philosophy qualification. It is funded by Slimming World, via an unrestricted grant, which means that Slimming World have no control over the research. All research is under the control of staff at Cardiff University. This extension study evaluates the longer-term impact of an intervention, for overweight pregnant women, which includes healthy eating and mild physical activity.

You have already very kindly helped us with the 2-year extension study. We would now like to invite you to take part in a telephone interview which is an important part of this research. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully.

Part 1 tells you the purpose of this part of the study and what will happen to you if you decide to take part. Part 2 gives more detailed information about how the study will be organised. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this part of the study?

The purpose of this part of the study is to discuss with you in a more in-depth way the experiences you have had in taking part in the HELP PhD study.

Why have I been approached?

We are inviting a sample of around 45 women who took part in the HELP PhD study.

Do I have to take part?

No, you do not need to take part. Your decision will not affect the valuable contribution you have already made to the study, and it will not affect the care you receive. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I agree to take part?

If you agree to take part then you will be contacted to complete a telephone interview with a Cardiff University researcher which will last between 45-60 minutes. You will have an opportunity to tell us about your experiences in more detail. We will ask you about the longer-term impact that taking part in the study has had on you, your child and your family. We will ask you about your behaviours in relation to healthy eating, physical activity and weight management, and whether you have made any changes to your behaviours. With your permission we will be recording the interview so that we do not miss what you say. After the interview, the recording will be typed up so that we can explore what you said in more detail and compare it to what others have said.

What will I have to do?
We will need to take up around 45-60 minutes of your time to conduct the interview by telephone.

What are the possible benefits of taking part?

You will have the opportunity to talk about your experiences of taking part in the study and what impact it has had on you since. Your valuable input will allow us to improve this intervention and this may benefit other mothers and their babies in the future.

What are the possible disadvantages and risks of taking part?

The only disadvantages to taking part are that we ask you to give up about 45-60 minutes of your time. Also, it is possible that some people may find it upsetting talking about their experience if they feel that they had a bad experience. The researcher is not in a position to advise you about your care and works independently from those involved in your care. However, if the researcher feels that you are distressed about something raised in the course of the interview, or has concerns about your health and wellbeing, they will offer to contact your health visitor or GP to address as part of your ongoing care.

Expenses and payments
We cannot pay you directly to complete the telephone interview. However, we will send you a £10 voucher to thank you for taking part.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Information Sheet

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time, without giving a reason. If you withdraw at any time, or decide not to take part, it will not affect the standard of care you or your child receives now or in the future.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers at Cardiff University who will do their best to answer your questions (contact details on the last page). If you remain unhappy and wish to complain formally, you can do this through Cardiff University.

Mr Chris Shaw
Research Governance Officer
Cardiff University Research and Commercial Division
30-36 Newport Road, Cardiff, CF24 0DE
Tel: 029 2087 9130 or 029 2087 9277

Harm
In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

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. Your personal information (name, address etc.) will continue to be kept confidential, the recording will be kept in a locked cabinet, and any information that we use from the interview will not have your name or anything else that would identify you attached to it.

As is usual, if during your meetings with anyone involved with the study (the midwives or researchers) somebody is concerned that you or a child may be at risk, we will contact the relevant authorities.

What will happen to the results of the research study?
A report of the research results will be completed. Results will be published in scientific journals and presented at scientific meetings. You or your child will not be identified in any report, publication or presentation. Once the research study is complete the results will be posted on the South East Wales Trials Unit website (http://www.cardiff.ac.uk/medic/subsites/sewtu/whatwedo/fully-coordinated-trials-studies.html). If you would like the results sent to you please contact the Trial Manager.

Who is organising and funding the research?

This study is being organised by the South East Wales Trials Unit, Cardiff University. The research is being paid for by Slimming World.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee for Wales.

Contact for Further Information

Dunla Gallagher (Researcher)
Tel: 029 20687602

Thank you for considering taking part in this study.

Appendix O: Verbal introduction to interview

Thank you for agreeing to speak to me today. In this interview I would like to find out how things have been for you since you had your baby two years ago. The interview will be in three sections. First, I will ask you about taking part in the HELP study and how things have been for you and your baby. Can I ask the name of your two-year-old child please- that is the child you were pregnant with when you took part in the HELP study?

Ok so we'll discuss how things have been for you and (study infant). In the next section I will ask you to talk about your weight management experiences and your attitudes and behaviours in relation to healthy eating, physical activity and your weight management. In the final section I will ask you about these things in relation to (study infant), and we will also chat about the other people around you and your influence on them.

The interview may take up to 1 hour, but if you want to take a break or stop at any time just let me know. You don't have to answer any question you don't want to. If that is the case, just say so and we can move on to something else. To emphasise, there are no right or wrong answers, I'm not trying to put you on the spot or test you. The questions are asked to find out your personal opinions and your experiences so don't worry if there is something you aren't sure about answering, just let me know and I will try and explain.

I'd like to reassure you of the confidential nature of this interview. Any information you give me will be used anonymously- the interview is recorded and only the people responsible for the research will have access to this recording. These people, including myself, are bound by the data protection act. The recording is transcribed into written form and this will be done by an external company. Again, those responsible for transcribing are bound by the data protection act. During transcription we will remove details which identify you or your family members and identifying details will not be included in any reports of our findings.

Please give as detailed a response to the questions as you can and add anything that you think is important but which I may not ask you about because, as it is your opinion, then it is all relevant and useful. It is only by asking people, such as yourself, in this way; that we can understand things from your perspective and others who are in a similar situation to you.

I'd like to make sure you have had an opportunity to read the information sheet which we sent out to you in the post and check whether you have any questions before we begin?

Can I confirm that you consent to take part in this interview?
Can I confirm that you are happy for me to record the interview?
And can I confirm that you consent for your interview to be transcribed by an external company who are bound to preserve the confidentiality of your interview?

Shall we begin?

Appendix P: Interview question schedule

Text in bold indicates the key questions that were to be asked to participants. Text not in bold were included as potential follow-up questions. Probes and prompts were only used when a more in-depth exploration of responses was required and were included in the interview schedule as suggestive reminders rather than as a prescriptive part of the schedule. The order of the schedule followed participants flow of responses, and bolded questions were not asked in cases where the participant had already discussed the issue without prompting. Text in italics was script used to move the interview from one section to another.

Ice Breaker-
Find out about their family and living situation. E.g. other children, partner etc.

SECTION 1: HELP Study Impact

Obviously, the background to today's interview is your participation in the HELP study and I want to discuss what impact taking part in this study may have had on you and on others around you. So, to give you a quick reminder, you were enrolled in this study in the early stages of your pregnancy with (study infant).

(If intervention) You were invited to take part in weekly groups in the hospital and we visited you at home every few months to ask you questions about your health and wellbeing.
(If control) We then visited you at home every few months to ask you questions about your health and wellbeing.

The original plan was to do this until (study infant) was aged 1 year. However, we asked if you were willing for us to visit you again when (study infant) turned 2 years which you have now completed.

- **So, thinking back, in what ways would you say the HELP study has impacted on your life, if at all?**
  - And in what ways would you say the HELP study has impacted on (study infant) life? *Prompt: feeding, physical activity.*
  - And how about the ways in which the HELP study has impacted on your wider family, if at all? *Prompt: family feeding, physical activity.*

SECTION 2: Weight Management

Moving on to the next section I want to ask you about your weight management in general to this point in your life.

- **Can you tell me about your experiences of trying to manage your weight?** Probe: what has helped you? What has hindered you? Have you been successful and why? Why have you struggled and why?

- **Thinking back to earlier in your life before you had (infant name), can you tell me about your weight experiences then?** Probe: when did you start experiencing issues with your weight? Why do you think this happened?

- **And thinking about where you are now, can you tell me what your current feelings are about your weight?**
  - How do you feel about your ability to manage your weight currently?
  - Have you managed to lose or maintain your weight over the last few years since you were part of the HELP study? Probe: How did you achieve that? What were the barriers? What helped you?

- **Can you tell me about anything you learnt from taking part in the HELP study which you think has helped you to manage your weight over the last couple of years?** Probe: are there any healthy behaviours you feel you have maintained over the long-term?
  - What factors are important for you, in helping you manage your weight?
  - What things get in your way and set you back in successfully managing your weight?

- **Can you tell me what you think about weight management during pregnancy specifically?** Prompt: What do you think about the appropriateness of weight management during pregnancy? Do you think your weight can be managed during pregnancy?
  - How did you feel about weight management while you were pregnant during the HELP study? Probe: why were you interested in joining the study? Did being pregnant make you to think differently about your weight, and why?

- **Do you think your attitude in terms of pregnancy and weight management changed as a result of being part of the HELP study?** Probe: In what ways?

I am going to ask you about plans in relation to future pregnancies. If you would rather not answer any question I ask, please just let me know and we can move on to the next section.

- **So, do you mind if I ask are you pregnant at the moment or are you thinking about having another child?**
  - (If pregnant) Can you tell me if you have made plans to manage your weight during this pregnancy? Probe: What do you plan to do? Prompt: In what ways does this differ from previous pregnancies?
  - Have you given birth to another baby since (2-year-old child name)? (If had another baby) Can you tell me about your experience of weight management during this pregnancy? Probe: What did you do? Did you manage your weight successfully? How did you do this? Prompt: In what ways does that differ from previous pregnancies?
  - (If pregnant or had another baby) How are / were things for you during this pregnancy? Prompt: How would you say this compared to your experience of pregnancy and your care when taking part in the HELP study?

Now I would like to discuss specific behaviours which are usually associated with weight management, the first of these is healthy eating.

- **First off, can you tell me what does 'healthy eating' mean to you**? Prompt: do you think of healthy eating as a diet? Is healthy eating something you go on and off?
- **Can you tell me about your approach to healthy eating at this stage in your life?** Prompts: what things are you trying to do in order to eat healthily, if any? Probe: When did you start this? Why did you start this? Prompt: Is there anything specifically you learnt from the HELP study that you have

continued to do in relation to healthy eating? Probe: Do you think you can continue to maintain these behaviours over the long-term? If so, why?

- Can you tell me what factors you find help you to follow a healthy eating lifestyle? Probe: what is important in helping you stick to a healthy eating plan? What motivates you to eat healthily?
- Can you tell me what you struggle with which stops you from following a healthy eating lifestyle? Prompt: what circumstances in your life hinder you from sticking to a healthy eating plan? Probes: What happens when you break from following your healthy diet i.e. have a bad day? How do you react? How does this impact your ongoing healthy eating? What do you think about that?
- In an ideal world, is there anything you would like to be doing in relation to healthy eating that you are not currently doing? Probes: What stops you? Do you intend to do this thing? Have you made any plans to do this thing?

Now I would like to discuss another behaviour associated with weight management which is physical activity. So, when I say physical activity I not only mean intentional or structured fitness exercise, such as going to the gym or going for a run, but any activity or movement which requires energy expenditure. We will discuss anything in relation to this you may do.

- **So, can you tell me about your approach to physical activity at this stage in your life?** Probe: what physical activity are you doing, if any? How often? Probe: When did you start this? Why did you start this? Prompt: is it for the purposes of weight control? Prompt: Is there anything specifically you learnt from the HELP study that you have continued to do in relation to physical activity? Probe: Do you think you can continue to maintain these behaviours over the long-term? If so, why?
  - Can you tell me what you find helps you to keep up a physically active lifestyle? Probe: what is important in helping you stick to doing physical activity? What motivates you to exercise?
  - Can you tell me what you struggle with which stops you from following a physically active lifestyle? Prompt: what circumstances in your life hinder you from following a physically active lifestyle? Probes: What happens when you break from exercising i.e. get out of the routine? How do you react? How does this impact your ongoing physical activity? What do you think about that?
  - In an ideal world, is there anything you would like to be doing in relation to physical activity that you are not currently doing? Probe: What stops you? Do you intend to do this thing? Have you made any plans to do this thing?

One thing people who are trying to manage their weight often struggle with over the long-term, is keeping up good habits in relation to healthy eating and physical activity which often means they put weight they have lost back on.

- **People often find that people or things around them influence whether they are able to stick to a healthy lifestyle. How do you think your environment affects you?** Prompt: does your environment help or hinder you in sticking to healthy behaviours? Can you think of an example? Prompt: for example, you try to eat healthily but there are always cakes in work to tempt you.
  - Can you tell me whether this is something you are aware of? Prompt: Is this something you have experienced? What can happen to make you break your good habits? What helps you maintain good habits i.e. what motivates you?

- **How important do you think the support from your family and friends is, in helping you to maintain a healthy lifestyle?** Probe: do you receive support from others around you? Can you give me some examples of how they support you / don't support you? How does this impact your behaviours? Prompt: Is there anything that you wish they would do to support you?

SECTION 3: Your two-year child and wider family

Moving on to the final section I want to ask you about (study infant) and your wider family (refer to the family members you found out about at the start of interview).

When we visited you recently we asked some questions about (study infant), about the foods that he / she eats and the activities he / she does. I would like to discuss this with you in more detail now. So specifically, we wanted to know about how eating and activity is managed in your family.

- **What do you think about the idea of weight management for (study infant)? *Probe: What makes you say this?***

- How do you encourage (study infant) to follow a healthy eating lifestyle? Probe: in what ways do you do this? Why do you do this / why do you avoid doing this?

- How do you encourage (study infant) to be physically active? Probe: in what ways do you do this? Why do you do this / why do you avoid doing this?

- **How do you think your own weight management influences (study infant)?** Prompt: How do you think it impacts what you do in relation to his or her weight management? Do you think he / she learns from you?
  - Do you think your experiences of weight related issues has influenced the way you manage (study infant) diet? Can you give some examples? Prompt: do you think what you learnt from taking part in the HELP study has influenced the way you manage (study infant) diet?
  - Do you think your experiences of weight related issues has influenced the way you manage (study infant) physical activity? Can you give some examples? Prompt: do you think what you learnt from taking part in the HELP study has influenced the way you manage (study infant) physical activity?
  - Is the way you feed (study infant) different from the way you were brought up? *Probe: In what ways? Why do you think this is?*
  - Is the activity you do together with (study infant) different from the way you were brought up? *Probe: In what ways? Why do you think this is?*

- **(If has older child(ren)) You said earlier that weight management is / is not relevant for (child's name). Is weight management something you think about for your older child(ren)?** Prompt: at what age is weight management appropriate?

- **How do you think you influence the eating behaviours of the rest of your family?** Probe: In what ways? Can you give some examples? Prompt: do you think what you learnt from taking part in the HELP study has influenced the diet of others in your family? Probe: in what ways?

  - How do you think you should be influencing your child(ren)'s eating behaviours? Probe: Is this what you do? What do you actually do?
  - Who else do you think has an influence on your child(ren)'s eating behaviours? Probe: What influence do they have? In what ways do they impact your children's behaviours? Prompt: is there anyone that goes against the rules that you try to set for your child(ren)?

- **How do you think you influence the physical activity of the rest of your family?** Probe: In what ways? Can you give some examples? Prompt: do you think what you learnt from taking part in the HELP study has influenced the activity levels of others in your family? Probe: in what ways?

- How do you think you should be influencing your child(ren)'s activity behaviours? Probe: Is this what you do? What do you actually do?
- Who else do you think has an influence on your child(ren)'s activity behaviours? Probe: What influence do they have? In what ways do they impact your children's behaviours? Prompt: is there anyone that goes against the rules that you try to set for your child(ren)?

- **Thinking about everything we've discussed in terms of your weight management experiences across your life, where would you say the HELP study fits in to this?** Probe: what significance does taking part have in terms of your weight and how you manage it?

- **Is there anything else you would like to add or discuss?**
- **Is there anything which you think has not been covered today which is important to you?**

Thank you for your time.

Appendix Q: Women's accounts mapped onto HELP intervention theory

Social Support	
The social support obtained during the intervention was emphasised as one of the most positive aspects of taking part, and different from other groups.	*"I have done Slimming World before but not I've never stuck to it as soon as I started to maintain or I'd put a pound on I'd quit but doing it when I was pregnant I stuck to it mostly because I knew that it was free but not only that because I was getting the support. I don't know whether it was because you had the midwife and there was [slimming world consultant] and a midwife, probably because you had the support, because when you go to a Slimming World class, you've just got the one person that weighs you in basically"* (Rachel, Intervention)
Trusting relationships established with the intervention facilitators. Involvement of the midwife especially important to reassure women.	*"Because I was seeing the Midwife weekly at the hospital, there was that closeness and I felt able to ask more questions and had more trust in the answers I was getting because, I felt that she was more, more interested in me really. I had a lot of blood tests and the GP Midwives weren't really getting back to me with answers… because it was the same Midwife seeing me, she had that consistent approach but, like I say when, the GP Midwives were different every time I went there. So, I think they didn't really understand me, as a person"* (Sara, Intervention) "*You learn so much from the midwives, it is quite daunting not really knowing what's going to happen and them, just there to answer any questions or give you advice is really good. I know you've got your local midwife to go and see, to get updates, but it's a little bit different"* (Nancy, Intervention)
Supportive relationships established with other women in the intervention groups, they had shared experiences, understanding and common goals.	*"Meeting the other people and they're all, sometimes you'd get some of the other girls going "oh we've had this this week", then they'd get on the scales and put on and then I'd be like, in the beginning I'd probably lose, like sometimes I'd lose two pounds. They're like "god how can you do that and eat and you're pregnant and lose it" and I'd say "well I'm not doing anything wrong like I'm just doing, following the Slimming World book". So, I think it gives that spur onto the other girls, that where they end up doing it and putting on, and they're thinking well if she can do it so can I"* (Rachel, Intervention) *"When I was in the group [intervention], all the ladies were big, we all knew what everyone was going through, we were all like, you know, common ground, then you gain strength from that, you know, you gain support from that, and then it's not there"* (Julie, Intervention)
Intervention social support was	*"Being an overweight woman when I was pregnant, the pressure gets put on you a bit more. It's not like you*

viewed positively compared with other healthcare experiences	*can wave a magic wand and be an ideal weight when it's just one of them things, you fall pregnant when you're overweight and you've just got to do your best to be healthy really, as much as you can. Every time you'd go, you'd have additional scans or every time you go to the midwife, and then obviously you are classed as high risk as well... I mean I didn't have any problems in any of my pregnancies, my weight didn't cause me any more difficulties than it would cause any other woman I felt. But you know there's all that, you're high risk, but there's, obviously they've got to do that because that is their job to make sure you are okay but they do drum it into you a bit that you're overweight. Your scans are difficult because of your body mass. Like they even put it on your letter when you have your scan done, they will put "difficult scan due to body mass"* (Hanna, Intervention) *"They don't have the knowledge of bigger women, they don't fully understand... like I'm seeing the nurse at the time, and she just didn't fathom everything and the wording she used was, she made me feel worse, she didn't give me any coping mechanisms to try and fight against that urge to, you know, munch when you're a bit upset or, and I, I generally came away wanting to cry. A lot of the health professionals they come across like, "oh, you're fat, you're going to have kidney failure, liver failure, you've got diabetes, you've got clots", and it's not like that. People with the HELP study in the hospital and that, they understood. I mean it, it just feels like a lot of the professionals outside the study were, had this stereotype thing in their head"* (Julie, Intervention)
More support needed beyond the intervention. Commercial weight loss groups sometimes used to replace this support, women felt they were unable to do it on their own.	*"It gives you a boost on what other people are doing at the same time, like because you'll get people going "I've lost this" and you think if they can lose it, what have they been doing to lose it and what have they changed and then you're interested then in what they're doing to lose their weight. So, then that gives you, you think "well I'm going to stay next week because I've listened to what they've ate and then hopefully I'll lose weight next week" and then when you lose weight you feel happy, you get back on that scale"* (Rachel, Intervention) *"I've bought an exercise bike which has helped me lose some weight but, it's not the same as a group of people, is it, it's not the same as having like-minded people who have got the same problem and, it's so nice to know that there's someone else the same as you fighting that fight and trying to win"* (Julie, Intervention)
Family and friends support hugely impacted the extent to which women were able to adopt or maintain healthy behaviours, both positively and negatively.	*"I've had my partner and he's pushed, we've done it together rather than on my own, it's just easier because your determination between you, there's somebody to keep you motivated and that's what you had at the groups. There's somebody with you, "oh, I can't really eat that because I'll know when it's wrong" or it's like, "oh come on, let's go for a walk", you know someone's with you, you know, it's quite important there's someone there, the support network's there for you… and you don't get disheartened and stop, "oh put it back on, what's the point""* (Mabel, Intervention)

	"I think it needs to be something that you all do together isn't it rather than, if you are with family and friends and they want to go out for fish and chips every night you meet up or whatever, you know unhealthy meetings. My mum doesn't live that far away and she's quite supportive as well of, you know, hiding any goodies that she's got when I am trying to be good and telling me off if she finds me with my hand in the biscuit tin" (Olive, Intervention) *"My husband fetching chocolate home when I've told him I want to diet, I want to do this, I want to lose the weight, he still fetches it home, and my dad will always fetch me chocolate and biscuits and stuff. My dad actually always takes the mick out of me for trying to eat healthily, and he says I stress about it too much, because "I turned out alright" and what not, but I didn't turn out alright because I'm overweight and what not, and he just thinks I'm stupid really sometimes"* (Isabel, Intervention) *"My partner he doesn't, I know he'll eat healthy but he doesn't eat as healthy, like I'll buy things and he'll say "you should've bought some oil" and I'm like "well it's not really healthy" but then in a way I think, well it's easy just buying something that we can all eat. Say if we went out for a meal and I look at what everyone else is eating, and I think well they're all eating that why can't I eat that"* (Rachel, Intervention) *"We'll not have treats so we'll not buy any chocolate, just things like that really or we'll, one of us might suggest, or I might suggest, a take-away or something and he'll [husband] be like, "do you really want to, just think about how you might feel tomorrow", and "you're right" because sometimes you feel rubbish the next day if you've had a take-away or whatever. So, it's just a sounding board"* (Lou, Intervention) *"It'd be nice if they didn't buy me any rubbish to be quite honest, if I feel low or whatever and start asking for chocolate bars or cake, then instead of buying me a cake, it would be nice if they just sat down with me and actually spoke to me and tried to understand where I was coming from… because of, oh God, I'm getting teary eyed for some reason. It just, it, it just, communication and the understanding... it would be good if people actually talked to me and tried to understand instead of rushing out and doing what I ask them to do. Or buying me a cake or a chocolate bar if they come round. But that's what they do, all, all of them do, they all do it, they see you're fat and they instantly connect it with, ooh, we'll get you some food"* (Julie, Intervention) *"All my close friends and family know I'm trying to be good, so they won't go and offer me a cream cake if I*

	went round there, they say to me "is there anything you'd like" if they're all eating something. Most of the time he [partner] knows, we go out sometimes and he will have a pizza and I'm sitting there with a healthy option so I get a little bit annoyed, but obviously he wants his pizza, he's not trying to lose weight" (Nancy, Intervention)
Motivation and self-regulation	
During pregnancy, the unborn baby acted as the main motivator for behaviour change	*"I didn't want anything to go wrong or anything bad to happen to [child], like if people smoked they might give up when they're pregnant, I thought I've got to eat healthy now and I did and it was easy at the time because I was pregnant, it wasn't just me that I was focusing on, I had to think I'm pregnant I've got to, I've got to do this for my child and her future"* (Kate, Intervention)
The HELP intervention supported women to adopt healthy behaviours to ensure the health of their baby	*"Because the motivation was ongoing, next week, I must make sure that I'm doing all these things right"* (Sara, Intervention)
Although the motivation of the unborn baby ended with pregnancy, women wanted to be able to engage with their children and be around for them, which fuelled a desire to lose weight	*"Probably having the children has made me feel a sense of mortality, I've got a responsibility to them being as fit and healthy as I can be, so that I'm around for them. I think when there's just you, it doesn't matter, well of course it matters, but you're only accountable to yourself, whereas when you've got a family, a husband and children, you're accountable to them"* (Bev, Control) *"Just past forty you know, I need to do it now or it'll never come off… I think it's more about being healthy now, than what you look like and fitting in clothes, it's thinking … you want to be around for your children for as long as you can"* (Debby, Control) *"I think because my age, I'm forty-two now, I'm an older mum and I feel like I just need to look after myself. I used to be a lot slimmer, I want to be more active and slimmer and look after myself now, and just be more active and, if I start putting on weight I don't want to start getting diabetes or anything you know. I want be healthy for him"* (Nancy, Intervention)
Intrinsic motivation more important than external policing from perspective of those who have lost weight	*"They've got to want to do it and that's what I would say to people now, that message about the weight I've lost, I said "you've got to want to do it, you've not got to do it because you've been told you've got to, otherwise you won't do it""* (Grace, Control) *"You feel happy, you feel like you've accomplished something, you feel like you're, I don't know, making a difference for yourself, it's something that nobody else can do for you"* (Emma, Control)

Self-efficacy	
Successful weight management in the intervention boosted women's self-efficacy for behaviour change. They felt if it was possible in pregnancy, it must be possible outside of pregnancy.	*"I think because I know I did it for that period of time, so I know it's something that works and that I was capable of doing it while I was pregnant, that there's no reason why I can't be doing it all the time. So that motivates me to continue the good work really"* (Sara, Intervention) *"If I hadn't have done this [intervention], I don't think that I would've been the way I am now like weight wise, and I wouldn't have had the confidence that I have got now with my body. Like now I go out and I don't care what people think about me, what I look like but I used to be like "god they're looking at me" so that also made me think well I've changed for the better... it just gives you that confidence which I wouldn't have had if I hadn't been doing the healthy eating... and I've got that confidence for me to do it which I never would've had before, losing weight gave me the confidence to do exercise"* (Rachel, Intervention) *"It sort of says to me "yes, I can do it" what I'm doing is working and, yeah, it does give you that buzz"* (Pam, Intervention)
The importance of health professionals' belief in women's ability to manage weight influenced their own confidence	*"The way they treat you, that's what brings stress on. It just, you're just stereotyped, all they see is the external, they don't see the internal... It makes me not want to try, it just makes it hopeless. What's the point? If a health professional doesn't think you're capable of losing weight, they can't be confident that you can manage your weight, that you can actually do what you need to do. You know? To get healthier, to get better, to be more active and, then you just think, well they know better than I do, so why should I bother?"* (Julie, Intervention)
Monitoring	
The intervention facilitators were overseers of women's behaviours by monitoring their weight. Knowing someone else would weigh them, motivated women to adopt healthier behaviours, to feel like they had passed the test.	*"That's the sort of thing that works for me, going somewhere every week and having to get on the scales. It keeps you motivated doesn't it? It is being part of a class and having the support of, you know, going and getting on the scales every week and giving you that motivation"* (Olive, Intervention) *"You've got that weigh-in at the end of the week, just knowing that somebody else is going to be weighing [you], I mean I am not bothered about what number is on that scale because I just tell myself it is going to be less, it is never going to be that number again because you are doing something about it"* (Hanna, Intervention) *"You want to get on the scales and you want to have lost that weight, and also if you have [gained weight]*

	they say "it's not a problem", you don't get defeated, they look on the bright side and say "well is there a reason why you've put it on" and you'll look back over the week and you think, oh, yeah I went to so and so's party and I just didn't really watch what I had and so, "well that's fair enough then" so then you can aim to lose it again the next week or you can do that little bit extra to compensate for it and you don't get disheartened and stop" (Mabel, Intervention)
Commercial weight loss groups were used to continue this. Women felt they needed someone external to police their behaviours.	*"I know full well if I don't go to a class to get weighed that I won't stick to it"* (Rachel, Intervention) *"I need somebody behind me saying "oh you've done this or you've done that" ... because otherwise it's just mill along and eat what you want and not think about it really isn't it"* (Olive, Intervention) *"I'm in Slimming World so I'm quite focussed on it. I have been losing weight steadily... it's having to be weighed every week, it's the constant maintenance, otherwise I'd just forget about it. If you're not getting weighed on a Monday then you sort of think, oh that doesn't matter"* (Debby, Control)

Appendix R: COREQ Checklist

Checklist Item	Reported (Page (Pg) or Chapter (Ch) or Appendix (Ap))
Research Team and Reflexivity	
Personal characteristics	
1. Interviewer/facilitator: Which author/s conducted the interview or focus group?	Ch 5
2. Credentials: What were the researcher's credentials? E.g. PhD, MD	Ch 5
3. Occupation: What was their occupation at the time of the study?	Ch 5
4. Gender: Was the researcher male or female?	Pg iii
5. Experience and training: What experience or training did the researcher have?	Ch 5
Relationship with participants	
6. Relationship established: Was a relationship established prior to study commencement?	Ch 5
7. Participant knowledge of the interviewer: What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Ch 5
8. Interviewer characteristics: What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Ch 5
Study Design	
Theoretical Framework	
9. Methodological orientation and Theory: What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Ch 5
Participant selection	
10. Sampling: How were participants selected? e.g. purposive, convenience, consecutive, snowball	Ch 5
11. Method of approach: How were participants approached? e.g. face-to-face, telephone, mail, email	Ch 5
12. Sample size: How many participants were in the study?	Chs 5 and 6
13. Non-participation: How many people refused to participate or dropped out? Reasons?	Ch 6
Setting	
14. Setting of data collection: Where was the data collected? e.g. home, clinic, workplace	Ch 5
15. Presence of non-participants: Was anyone else present besides the participants and researchers?	Chs 5 and 6
16. Description of sample: What are the important characteristics of the sample? e.g. demographic data, date	Chs 5 and 6
Data collection	
17. Interview guide: Were questions, prompts, guides provided by the authors? Was it pilot tested?	Ch 5 and Ap P
18. Repeat interviews: Were repeat interviews carried out? If yes, how many?	Ch 5
19. Audio/visual recording: Did the research use audio or visual recording to collect the data?	Ch 5
20. Field notes: Were field notes made during and/or after the interview or focus group?	Ch 5
21. Duration: What was the duration of the interviews or focus group?	Ch 6
22. Data saturation: Was data saturation discussed?	Ch 5

23. Transcripts returned: Were transcripts returned to participants for comment and/or correction?	Ch 5
Analysis and findings	
Data analysis	
24. Number of data coders: How many data coders coded the data?	Ch 5
25. Description of the coding tree: Did authors provide a description of the coding tree?	Ch 6 and Ap S
26. Derivation of themes: Were themes identified in advance or derived from the data?	Chs 5 and 6
27. Software: What software, if applicable, was used to manage the data?	Ch 5
28. Participant checking: Did participants provide feedback on the findings?	Ch 5
Reporting	
29. Quotations presented: Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Chs 5 and 6
30. Data and findings consistent: Was there consistency between the data presented and the findings?	Ch 6
31. Clarity of major themes: Were major themes clearly presented in the findings?	Ch 6
32. Clarity of minor themes: Is there a description of diverse cases discussion of minor themes?	Ch 6

Appendix S: Coding frame for summarising interview data

Theme/ Parent Code	Sub- Theme/ Child Codes	Description
1. Introduction	1.1 Introduction and attributes	E.g. number of children, age of children, mother's job, marital status
Mother		
2. Pregnancy specific attitudes and behaviours	2.1 Attitudes about weight and behaviours in pregnancy	How pregnancy makes women think and feel about weight and related behaviours
	2.2 Intervention in pregnancy	Women's experiences and evaluations of the HELP intervention and its impact in pregnancy
	2.3 Motivations for controlling weight in pregnancy	Reasons for adopting healthy behaviours in pregnancy
	2.4 Barriers to adopting healthy behaviours in pregnancy	Barriers impacting women's ability or desire to adopt a healthy lifestyle in pregnancy
3. Wider weight control attitudes and experiences	3.1 Weight control histories	Women's descriptions of their weight loss attempts and experiences, and the tools which helped them to be successful in weight loss
	3.2 Mindsets underlying weight control approaches	What women think about weight control, how they approach controlling their weight and maintaining health behaviours
	3.3 Barriers to weight management	Women's descriptions of obstacles in their lives which act as barriers to their successful weight control or health behaviours
Child		
4. Maternal perceptions and influences on children's weight, diet and activity	4.1 Child diet	Maternal attitudes and behaviours related to food choices for children
	4.2 Child activity	Maternal attitudes and behaviours related to activity behaviours for children
	4.3 Child weight	Maternal attitudes and behaviours related to perceptions of children's weight
	4.4 Role Modelling	Mothers' perceptions of their role in influencing their children
	4.5 Other sources of influence on children's behaviours	Other sources, perceived by mothers, as having an influence on their children's behaviours
5. Other		

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