An exploration of a weight management programme for pregnant women living with obesity

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This thesis is entirely the candidate's own work. No part of this degree has been submitted previously for a degree or any other qualification at any university

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Abstract

Introduction: Pregnancy is a time of both transformation and adaptation within the human body. Entering pregnancy with a body mass index (BMI) above the healthy range of 18.5-24.9kg/m^2 increases a range of health risks for both the mother and baby and so is a targeted area for weight management. This thesis aims to evaluate a weight management programme (Bumps and Beyond) developed for pregnant women with a high BMI and delivered in two geographic areas in the UK. **Methods**: Service evaluation was based on audit sheets completed by staff at the two locations. Data from anonymised records were statistically analysed to see if the intervention reduced gestational weight gain, and complications in pregnancy and labour. Intervention fidelity was reviewed via transcripts of staff delivering the intervention in Lincolnshire. Hermeneutic phenomenological analysis (HPA) was undertaken on transcripts of staff delivering the sessions within the intervention at one site. The HPA used the novel approach of utilising the Roles of 'Sarah the Mother', 'Sarah the Dietitian', and 'Sarah the Researcher' to find the essence within the texts of the transcripts. **Results**: Intervention fidelity was good, and staff were responsive to participants' needs. Full attendance at Lincolnshire Bumps and Beyond showed a positive impact on gestational weight gain, total pregnancy complications, pre-eclampsia, preterm birth, low birth weight and breastfeeding initiation. Full attendance at Nottinghamshire Bumps and Beyond did not show the same benefits and was associated with greater risk of instrumental delivery and lower breastfeeding initiation. HPA of transcripts brought out several essences for each role that indicated possible pathways for development of the programme in the future. **Discussion**: The contrasting efficacy of Bumps and Beyond at the two locations gives a clear indication that just transferring a programme from one setting to another is not

enough to ensure it will be successful. Despite being geographically close, the two locations had different populations which may in part explain the lack of success in Nottinghamshire. In addition to this, the type of staff may have had some effect in how the programme was delivered in each location. Use of the HPA output allowed insight into possible areas that could be further developed or adapted for the population the intervention is to serve. The Bumps and Beyond programme is similar to other small-scale midwife-led interventions that report positive outcomes in one local area. Larger trials have been less successful overall. **Conclusion**: Small local interventions to control gestational weight gain in women living with obesity can be effective when adapted to suit the needs of the population.

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And finally, to my Granny and Grandad, always in my heart. I wish you were here to see this. I miss you so very much.

Abbreviations

4P	Prevalence and Predictors of Pelvic floor dysfunction in Primips
AOR	Adjusted Odds Ratio
BDA	British Dietetic Association
B&B	Bumps and Beyond
BCTs	Behaviour change techniques
BM	Boehringer Mannheim
BMI	Body Mass Index
CEMACH	Confidential Enquiry into Maternal and Child Health
CCG	Clinical Commissioning Group
CHD	congenital heart defects
CI	Confidence Interval
CMACE	The Centre for Maternal and Child Enquiries
COMA	Committee on Medical Aspects of Food and Nutrition
CRF	Case Report Form
dp	decimal place
DM	diabetes mellitus
FeLIPO	Feasibility of a Lifestyle-Intervention in Pregnancy to optimise maternal weight
GCP	Good Clinical Practice
GDM	Gestational diabetes mellitus
GER	gastro-esophageal reflux
GERD	gastro-esophageal reflux disease
GHT	Gestational hypertension

GWG	Gestational Weight Gain
HELP	Healthy Eating and Lifestyle in Pregnancy
HEN	Home Enteral Nutrition
HPA	hermeneutic phenomenological analysis
HR	Hazard Ratio
hCG	human chorionic gonadotrophin
hPL	human placental lactogen
HSE	Health Survey for England
IoD	Index of Deprivation
IOM	Institute of Medicine
IPA	Interpretative phenomenological analysis
ITT	Intention-to-treat analysis
kg	kilograms
LAR	Local Area report
LA	Local Authority
LBW	low birth weight
LGA	Large-for-Gestational age
LIMIT	Limiting Weight Gain in Pregnancy trial
LMP	Lifestyle Modification Program
LRNI	Lower Reference Nutrient Intake
MBRRACE-UK	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK
MMR	maternal mortality ratio
MRC	Medical Research Council
MSDS	Maternity Services dataset

NDNS	National Diet and Nutrition Survey
NELIP	Nutrition and Exercise Lifestyle Intervention Program’
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMPA	National Maternity and Perinatal Audit
NTD	neural tube defects
NUH	Nottingham University Hospitals
OASIS	obstetric anal sphincter injury
OBPI	obstetric brachial plexus injury
OECD	The Organisation for Economic Cooperation and Development
ONS	Office for National Statistics
OR	Odds Ratio
PP	Per-protocol
PH	Public Health (guidance)
PHE	Public Health England
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PFD	Pelvic floor dysfunction/ disorders
PPGP	Pregnancy-related pelvic girdle pain
PPH	Post-partum haemorrhage
PPI	Patient and Public Involvement
PRAMS	Pregnancy Risk Assessment Monitoring System
PVR	peripheral vascular resistance
RAS	renin-angiotensin-aldosterone system

RBC	red blood cells
RCT	Randomised controlled trials
RCOG	Royal College of Obstetricians and Gynaecologists
REC	Research Ethics Committee
R&D	Research and Development department
RR	relative risk
SAB	spontaneous abortion
SACN	Scientific Advisory Committee on Nutrition
SD	standard deviation
SGA	Small-for-Gestational age
SPD	Symphysis dysfunction
SUV	suboptimal ultrasound visualisation
TM	teachable moment
UK	United Kingdom
UKOSS	UK-wide Obstetric Surveillance System
UNICEF	United Nations International Children's Emergency Fund
UPBEAT	UK Pregnancies Better Eating and Activity trial
UoN	University of Nottingham
UOR	Unadjusted Odds Ratio
US	United States (of America)
WC	waist circumference
WHR	waist-to-hip ratio
WHO	World Health Organisation

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Prologue

This PhD journey has taken nearly a decade. It started in 2013 when the researcher was offered a PhD placement to investigate maternal weight management by the University of Nottingham initially funded part-time for two years by The Revere Charitable Trust. The funding allowed two days per week for the PhD work. Within the funding the researcher was responsible for data management for the Managing Weight in Pregnancy (MAGIC) study alongside a colleague within the University (Dr Jo Pearce) whilst writing up the protocol for data collection for the Bumps and Beyond antenatal weight management Lincolnshire service evaluation.

The funding ended in May 2015 and as no further funding pots were available the PhD then became self-funded with bench fees covered by the University. The researcher was able to take up a teaching assistant position in the School of Biosciences in 2016, a post that subsequently became a permanent and substantive (0.9 fte) role. The initial phase of the project was focused on the qualitative evaluation of Lincolnshire Bumps and Beyond service. The author then designed the protocol and sought ethical approval for a qualitative study to evaluate the delivery of the Bumps and Beyond service in Lincolnshire, with a view to determining some of the factors which may explain its efficacy. The data collection period for the Bumps and Beyond Lincolnshire qualitative study ran from June 2015 to August 2015. Transcripts from this data collection period were reviewed and triple-checked by the researcher during 2016.

A further opportunity for data collection came about in 2016 when Bumps and Beyond was commissioned to run in Nottinghamshire. The NHS Trust running this programme requested UoN to evaluate the service on an ongoing basis via the internal

audit sheets that would be completed and anonymised by their staff. The researcher was responsible for overseeing the data input and analysis from that service evaluation. A timeline for the project is shown in Figure P1.

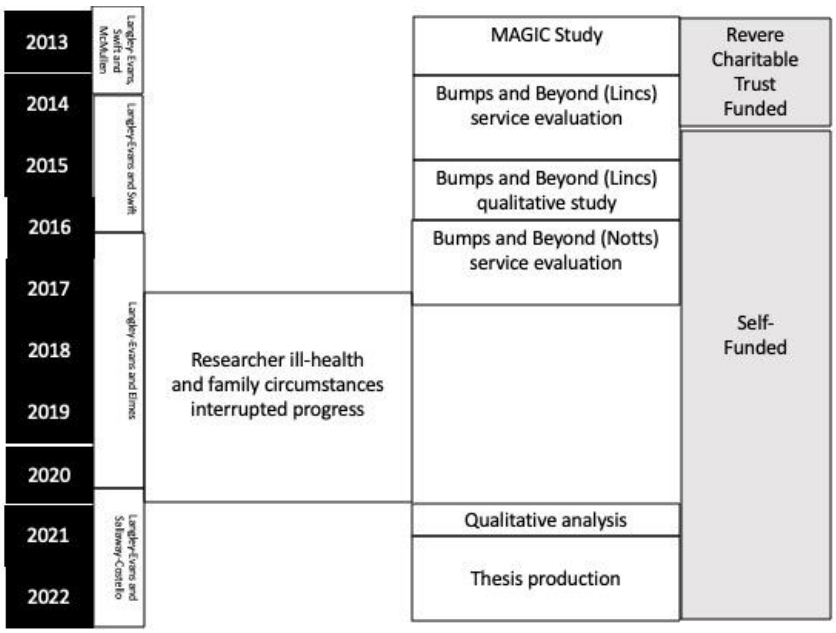


Figure P1. Timeline for the PhD project described in this thesis, showing timing of supervisory team changes (supervisory team on left), interruption due to health issues, project funding and main activities on project.

From 2017 and on an ongoing basis, the health of the researcher declined dramatically leading to a brain operation in 2020. Work on the PhD was minimal during this time period and had to be undertaken on a very stop-start approach. Immediately following the researcher's operation, her son was diagnosed with Hodgkin's lymphoma and received treatment during 2021. In addition, two of the supervisory team who were closely involved in the MAGIC study and establishing the protocols for the qualitative study (Dr Sarah McMullen and Dr Judy Swift) left the University of Nottingham.

Changes to the supervisory team further disrupted the project and also led to a rethink on the way in which the qualitative data should be analysed. These issues are the reason that the PhD work was not restarted until 2022 which has led to a large time gap from initial data collection to final analysis and write up.

It is also important to acknowledge that the terminology around obesity used within this thesis reflects that of the time and may have changed to become more inclusive.

Chapter 1. Introduction

1.1 The Bumps and Beyond antenatal weight management intervention

The work presented in this thesis is focused upon an investigation of the Bumps and Beyond antenatal weight management intervention. Three chapters are presented, two of which are quantitative analyses of service evaluation data from the clinical services providing the Bumps and Beyond intervention. A qualitative study utilised a hermeneutic phenomenological approach to evaluate the service. A fourth chapter evaluates the intervention against the Template for Intervention Description and Replication (TIDieR) checklist (Hoffman *et al.,* 2014), which seeks to fully report details of the intervention elements of a study. This TIDieR element will be presented ahead of the qualitative data in order to comprehensively set the scene for that investigation. The following sections will introduce Bumps and Beyond, before the main literature review chapter provides a broader context as to why the intervention was required.

1.2 The history of Bumps and Beyond

Bumps and Beyond was a small scale, midwife-led weight management intervention programme originally run in Lincolnshire and then expanded to Nottinghamshire. The main aims of the intervention were to keep Gestational Weight Gain (GWG) within the Institute of Medicine guidance range of 5-9 kg (IOM, 2009), increase physical activity levels, increase uptake of Healthy Start vitamins and secondary outcomes to decrease pregnancy-related risks and increase rates of breastfeeding in women with obesity.

After the service was initially commissioned, the service lead (Ailsa McGiveron) contacted Professor Simon Langley-Evans at the University of Nottingham to explore the possibility of analysing early findings to establish the efficacy of the intervention, as the local team were unsure of how to carry out a complex statistical analysis. This preliminary analysis led by Langley-Evans and Jo Pearce in 2013/14, indicated that the Lincolnshire Bumps and Beyond weight management in pregnancy intervention was able to limit GWG and was efficacious in reducing the risk of pregnancy complications. The initial evaluation of the programme was based on the first 89 participants (BMI $\geq$35 kg/m^2) with singleton pregnancies, compared to a similar number of women who were eligible for, but declined the service, and was undertaken by analysing data from audit sheets completed by the staff at two NHS Trusts involved with the intervention. The evaluation was focused on women attending for antenatal care in the city of Lincoln. Results showed that taking part in the intervention led to reduced weight gain in pregnancy, reduced risk of hypertension in pregnancy, and an overall reduced risk in general pregnancy complications. In addition, no adverse outcomes of the intervention were reported, despite some of the women losing weight during the pregnancy (McGiveron *et al.*,2015). Based on this evaluation, the service was recommissioned by the local Clinical Commissioning Group. The programme eventually closed in 2017 likely due to changes in funding, but since the work reported in this thesis was completed, has been revived in a new format. The current work reports analysis carried out following the 2014 recommissioning of the service and the data reported is an entirely new and enlarged set collected after publication of the initial evaluation.

The existence of a successful and relatively low-cost intervention to limit GWG with additional benefits in terms of maternal complications of pregnancy caught the

interest of an obstetrician at Nottingham University Hospitals Trust and the programme was commissioned to run for an initial period in the Trust in 2016. Whilst the basic design of the programme was the same as the original Lincolnshire version, the eligibility criteria were slightly different for the Nottinghamshire version of the intervention. The Nottinghamshire intervention was short-lived, ending in 2016 due to the lack of impact demonstrated by the analysis presented later in this thesis (Chapter 6).

1.3 Principles of Bumps and Beyond

The aims of the Bumps and Beyond intervention can be seen in Figure 1.1. The underlying principle was that a series of one-to-one, face-to-face appointments held between healthcare staff trained in behaviour-change techniques would have the power to deliver small but significant changes to the behaviour of pregnant women living with obesity. The sessions with healthcare staff would explore subjects such as food intake, healthy vs unhealthy foods and the value of physical activity, along with some of the risks associated with having excessive gestational weight gain. Avoiding a rigidly structured and didactic approach was recognised as one of the methods that could build rapport with a hard-to-reach group of severely obese women.

- To support pregnant women who wish to adopt positive lifestyle changes.
- To give consistent advice on achieving a healthy balanced diet.
- To encourage physical activity on a level appropriate to the individual.
- To encourage weight gain to within the recommended guidelines for obese women (5-9kg)*
- To assess the woman's readiness to change by using a model of attitudinal and behavioural change adapted from Prochaska and DiClemente's model of change#
- To increase uptake of Healthy Start Vitamins in low-income and disadvantaged families.

*The Institute of Medicine (Ed. Rasmussen and Yaktine, 2009) weight gain in pregnancy guidelines based on initial BMI. # Transtheoretical Model of Change, Prochaska and DiClemente (1983)

Figure 1.1 Lincolnshire Bumps and Beyond aims taken from original protocol.

1.4 Bumps and Beyond Lincolnshire

In the previous evaluation of the service (McGiveron *et al.*, 2015), records were only available for women in the city of Lincoln. At the time of the follow-up described in chapter 5, data via audit sheets was available from four centres (Lincoln, Gainsborough, Boston and Grantham).

The Lincolnshire-based 'Bumps and Beyond' programme was a weight management intervention programme aimed at pregnant women with a BMI>35kg/m^2. All women with BMI ≥35kg/m^2 at the first trimester dating scan were eligible to participate (no exclusions). BMI in this range triggered a referral to the programme and women could also self-refer. In this NHS Trust, as is typical for the UK, most women were initially booked for antenatal care at around 11 weeks gestation. This meant that

eligibility for participation in Bumps and Beyond could not be determined until most women were in their second trimester.

Bumps and Beyond was delivered in primary and secondary care settings by midwives and healthy lifestyle advisors on a one-to-one basis. The programme comprised seven sessions in total which covered healthy eating, physical activity, identification of triggers that lead to unhealthy lifestyle behaviours, and relapse to old behaviours around eating and physical activity. Participants of the programme had their first session at around 16-weeks gestation and were seen every two to three weeks up until around 36 weeks gestation.

1.4.1 Session outline

The delivery of the intervention was intended to be flexible and varied according to the needs of each individual participant. As the staff involved were not following a script for the delivery, to some extent the participant women received a bespoke service. Staff built rapport and used features of each woman's life as levers to bring about behaviour change. The overall design of the intervention and detailed session content is shown in Appendix 1, but the content of each session is described in brief below. Women were weighed at the sessions if they wished to be. During the sessions, the delivery team would consider referring women to external providers for additional activities including cooking lessons or exercise sessions, to support the intervention sessions.

- Session one (16 weeks gestation) covered: Motivation to change behaviour; current lifestyle, beliefs and habits; food diary use; goal setting.

- Session two covered: The Eatwell plate as a model of healthy eating (see Langley-Evans 2021); energy balance concepts; goal setting.
- Session three covered: Physical activity; pedometer use; goal setting.
- Session four covered: Food labelling; shopping; cooking; goal setting.
- Session five covered: Emotional eating; portion control; maintaining positive changes; goal setting.
- Session six covered: Progress and encouragement to maintain changes; how to handle lapses in behaviour.
- Session seven (36 weeks gestation) covered: Support to maintain changes; benefits of breastfeeding; nutrient supplements.

1.5 Bumps and Beyond Nottinghamshire

Bumps and Beyond in Nottinghamshire was delivered in a manner that mirrored the Lincolnshire intervention in all respects apart from the following:

1. The eligibility criteria were modified so that all women with a $\geq 30 kg/m^2$ were invited to participate in the intervention.
2. Delivery of the programme was midwife-led but the team comprised advisors with nutrition degrees. In contrast the Lincolnshire team were not nutrition trained but had a background in behaviour change focused on smoking cessation in pregnancy, or breastfeeding advisor.

1.6 The role of the author

This author joined the evaluation of the Bumps and Beyond programme after the initial evaluation published by McGiveron *et al.*, (2015) and was responsible for the following elements of the work described in this thesis:

1) Lincolnshire service evaluation

   Bumps and Beyond Lincolnshire was led by Ailsa McGiveron (midwife) and delivered by Ms McGiveron alongside three other staff members; Sally Foster (midwife); Jean Rickells (Healthy Lifestyle Advisor) and; Linsey Robinson (Healthy Lifestyle Advisor). This author joined the evaluation team when the intervention was already in operation. She worked with Ms McGiveron to redesign the service evaluation audit sheets, carried out all data entry, transferring data from the service audit sheets to SPSS and the analysis of the data

2) Nottinghamshire service evaluation

   The Nottinghamshire Bumps and Beyond intervention was led by consultant obstetrician Dr Lucy Kean, Claire O'Callaghan (lead midwife for the Trust) and initially Ailsa McGiveron (midwife) as the programme lead. McGiveron was later replaced by Sally Anderson (midwife). The programme was delivered by four healthy lifestyle trainers, all of whom had degree level nutrition qualifications. The author of this thesis was responsible for data entry, transferring data from the service audit sheets to SPSS and the analysis of the data. She initially liaised with Dr Keen on the design of the service evaluation.

3) Lincolnshire qualitative study

> The author was responsible for the design of this study and explored the ethical approval requirements, see appendix 2. She carried out all data collection, transcription of audio recorded data and analysis of the data.

It is important to appreciate that the Bumps and Beyond intervention in both locations was a clinical programme, led by clinicians and commissioned by the local Clinical Commissioning Groups. Bumps and Beyond was not a research-led intervention and the data presented in Chapters 5 and 6 of this thesis are service evaluations designed to explore the impact and efficacy of the intervention at each site.

1.5 Main aim of thesis

The main aim of the work presented in this thesis was to further evaluate the intervention. A mixed-methods approach was designed to first determine whether the benefits noted in the preliminary analysis were maintained with a larger sample size and then whether the intervention could be replicated by a different hospital trust. Intervention fidelity was explored via transcripts and field notes for Bumps and Beyond Lincolnshire. Finally, a novel hermeneutic phenomenological approach (HPA) was used to explore transcripts and find the essence through the lens of three Roles of Sarah, the Mother, the Dietitian, and the Researcher. These used transcripts of staff delivering the Lincolnshire B&B intervention sessions.

1.5.1 Objectives

- To quantitatively evaluate the service called Lincolnshire Bumps and Beyond with GWG and pregnancy complications as the primary outcomes.
- To quantitatively evaluate the service called Nottinghamshire Bumps and Beyond with GWG and pregnancy complications as the primary outcomes.
- To assess and report intervention fidelity via transcripts and field notes for Bumps and Beyond Lincolnshire using the template for intervention description and replication (TIDieR) tool.
- To use a hermeneutic phenomenological approach to review transcripts from sessions delivered by staff from Lincolnshire Bumps and Beyond to explore the essences within the text using the distinct roles of Sarah the Mother; Sarah the Dietitian; Sarah the Researcher.

Chapter 2. Pregnancy and possible risks

2.1 Pregnancy nutrition

Human pregnancy has been referred to as a state where a female supports a parasite for nine months (Naismith, 1969). The female grows an entirely new organ, the placenta, in order to pass nutrients and oxygen to the fetus and remove waste products. The use of the term parasite is considered controversial and outdated, but it does emphasize that it is not a mutualistic relationship between mother and the embryo/fetus as long as the mother is reasonably well nourished (King, 2003). For the mother to maintain the fetus through the nine months of pregnancy there is a requirement for an appropriate intake of nutrients. Over the first two trimesters, where embryogenesis, placentation and organogenesis are the predominant processes, this need is quite small but once the third, and final, trimester is reached the requirements increase in order to allow the fetus to gain weight.

2.1.1 Anatomical, physiological, endocrinological, and metabolic response to pregnancy

There are a range of physical responses within the female body which maintain the pregnancy and support the growing embryo/fetus. These changes are principally, but not only, driven by the hormones oestrogen and progesterone and prepare the body for the pregnancy, labour and breastfeeding after birth. The physical changes to the mother start once the embryo has implanted into the uterine wall and triggered the hormonal response. Every organ system in the body will be affected, and an entirely

new organ is grown (placenta). The uterus grows as the fetus develops, and the breasts enlarge as they are prepared for feeding post-partum (Coad et al., 2020).

In addition to changes in the mother's body proportions there are functional changes to her physiology. The release of progesterone will relax the smooth muscle within the body. One effect of this is a reduction in peripheral vascular resistance through vasodilation of the capillaries. Lower peripheral vascular resistance is required due to the increase in cardiac output linked to the increase in blood volume needed to support the pregnant state. There is an increase in blood volume due to a combination of hydraemia – excess fluid volume caused by an increase in plasma – linked to increased activation of the renin-angiotensin-aldosterone system and increase in red blood cells due to erythropoiesis. Cardiac output increases due to an increase in heart rate and stroke volume, both of which require anatomical changes in the heart itself (Sanghavi and Rutherford, 2014). In addition to this blood pressure decreases due to the vasodilation.

The renal system also undergoes change. Anatomically the kidneys increase in size to accommodate the increase in blood volume. The renin-angiotensin-aldosterone system is activated early in the first trimester which increases the blood volume by retaining salt and water. The overall increase in plasma causes haemodilution which can lead to physiological anaemia, which is seen as a normal response to pregnancy. Overall blood volume increases by around 45% (Sanghavi and Rutherford, 2014). Progesterone and relaxin affect the smooth muscle of the ureter and bladder and lead to an increase in urination. Later in pregnancy this may increase further due to the combined weight of the fetus, placenta and amniotic fluid.

The respiratory system must increase oxygen intake which is achieved through the effect of progesterone which combines to act as a respiratory stimulant to increase breathing rate and allows muscles within the chest to relax. In early pregnancy a flaring of the ribs and an increase in the range of diaphragmatic movement increases tidal volume of each breath. To combat the pressure and upward movement of the growing fetus later in pregnancy on the diaphragm there is an increase in breathing frequency (LoMauro & Aliverti, 2015).

The gastrointestinal tract comprises smooth muscle, which is relaxed by elevated concentrations of progesterone, and so motility decreases during pregnancy to allow for improved absorption of nutrients. Delayed gastric emptying serves to enhance micronutrient bioavailability. The relaxation of the intestinal wall can also cause unpleasant symptoms for the mother (Magowan, 2023), discussed later in the chapter.

The overall effect of all these physiological changes in a well-nourished mother is that she will increase in size. This change can be observed by outsiders.

An array of hormones is required in order for the pregnancy to be maintained. Initially these are mostly produced by the mother alone but as the pregnancy progresses the fetus also releases them. As the placenta develops it becomes the main endocrine organ controlling pregnancy and parturition (Magowan, 2023). During early pregnancy human chorionic gonadotrophin (hCG) is secreted by the embryonic tissue in order to increase production of steroid hormones – oestrogen and progesterone from the corpeus luteum. hCG is the hormone detected in pregnancy tests. hCG has a range of metabolic effects including increasing the cellular response to insulin and so increasing the amount of glucose that is uploaded into cells and increasing appetite

via thyroid activity. These have the effect of increasing the delivery of substrates for the mother in order for the organ growth needed to sustain the pregnancy (Coad *et al.*, 2020). Relaxin is also released by the corpeus luteum and is responsible for 'relaxing' muscle and ligament tissue within the pelvis. Relaxin also works alongside progesterone and so is responsible for the muscles in the body relaxing to accommodate the other anatomical and physiological changes needed for the birth process (Magowan, 2023; Coad *et al.*, 2020).

As the placenta matures, hCG levels decline, and the placenta starts to produce steroid hormones and human placental lactogen (hPL). hPL has a diabetogenic effect due to being an antagonist of insulin. This reduces the amount of glucose available to the mother but increases availability for use by the fetus, later in the pregnancy. hPL also acts by increasing availability of fatty acids for use by the mother (Magowan, 2023). Progesterone and oestrogen have multiple effects around the body of the mother. In early pregnancy oestrogen increases the cell size and number of the beta-cells of the pancreas for more insulin to be produced. Insulin sensitivity initially increases only to then taper off later in the pregnancy as the mother's body becomes insulin resistant increasing the mother's blood glucose levels (Magowan, 2023; Coad *et al.*, 2020). This increased sensitivity to insulin and the hCG effect of making cells more responsive, means overall glucose levels in the mothers' blood will be maintained whilst allowing enough glucose to be available for the fetus. Alongside the insulin response, progesterone and cortisol increase lipogenesis and so more fat is stored (Magowan, 2023; Coad *et al.*, 2020). This is an adaptation that enables the deposition of reserves that will be used later during lactation.

2.1.2 Energy requirements

The mother's body requires an increase in nutrient availability to make these anatomical and physiological changes, although the consensus is that in well-nourished women, dietary increases are only critical during the final trimester. Estimates of the amount of additional energy required to support a healthy pregnancy are between 70 000 and 80 000 kcal for the whole of gestation (Hytten and Leitch, 1971). Reflecting these estimates, the UK dietary reference values suggest that there is an additional increment of 250 kcal/d across the whole of pregnancy (a simple division of 80 000 kcal by the 280 days of gestation; COMA 1991). The energy increase required for a healthy weight mother is minimal 200 kcal/day, equivalent to two slices of bread (National Institute for Health and Care Excellence (NICE), 2010). The US dietary reference intake recommendations are similar with an increment of 300 kcal/d targeted at the second and third trimesters.

Whilst the dietary reference values suggest a moderate intake of energy intake may be necessary to support pregnancy, it is well-documented that most women are able to have a normal pregnancy without any increase in intake and this appears to be due to metabolic adaptations and reductions in physical activity (King 2000). Durnin (1991) suggested that the true additional requirement for pregnancy is as little as 100 kcal/d, and that only applies in the third trimester. Recent literature reports that in the first trimester energy needs do not increase and are accommodated by the mother's usual intake (Most *et al.,* 2019).

A range of studies appear to suggest that the reductions in physical activity during pregnancy are trivial, accounting for as little as a 5% change in energy requirements (Most *et al.,* 2019). However, whilst activity changes may be small, women become

more efficient in their movements, for example through changes in gait whilst walking, which offsets the greater respiratory burden of having a larger body (Davenport *et al.*,2009). Most *et al.,* (2019) reviewed papers which estimated energy expenditure in pregnancy and determined that between 13- and 36-weeks gestation there was an additional requirement of 420 kcal/d, with no additional requirement in the first trimester. Energy requirement was directly proportional to weight gain and after adjustment for this they estimated that in non-obese women the additional requirements for pregnancy were similar to the estimate of Durnin (1991) at 110 kcal/d. For obese women it was as low as 45 kcal/d.

2.1.3 Protein requirements

Protein is needed by the fetus, placenta, breast tissue, blood, and uterus in order to grow and sustain the pregnancy. The United Kingdom's Recommended Nutritional Intake (RNI) for adult women aged 19-50 years is 45g/day (Committee on Medical Aspects of Food and Nutrition (COMA), 1991). An increment of 6g protein per day is required during pregnancy in addition to the RNI; 11g per day during the first four months of lactation, and 8g per day for the remainder of lactation. The rolling programme of the National Nutrition and Diet Survey (NDNS) has been run in the UK since 2008. Data from this rolling programme shows that women aged 19-64 years have a mean intake of protein of around 65g/day, with the lowest figure for 2019 being recorded as 31g per day, and the highest being over 140g/day (Public Health England (PHE), (PHE, 2020).

2.1.4 Micronutrient requirements

2.1.4.1 General

Pregnancy is also a time where there is an increased need for micronutrients. Overall, the mother's body can adapt very well to the pregnant state as long as she is well-nourished herself, however for certain micronutrients the increase demand must be met from the diet or supplementation. In high-income countries where populations are mostly well nourished, the biggest increase in demand is for folate/folic acid (Scientific Advisory Committee on Nutrition (SACN) 2017), followed by vitamin D, and so current advice in the UK is to supplement these (COMA 1991, SACN 2007). Other vitamins that have an increased need in pregnancy include thiamine, riboflavin, vitamin A, and vitamin C all of which should be able to be obtained from the diet. There is no increased need beyond the standard female reference ranges for minerals currently recommended in the UK (COMA 1991).

The latest UK National Diet and Nutrition Survey has highlighted that many women of childbearing age are not consuming the recommended levels of micronutrients prior to conception and so place themselves and their fetus at risk of deficiency (PHE, 2019). Low-income/ less financially secure households are reporting micronutrient intake from food at levels lower than the Lower Reference Nutrient Intake (LRNI) (PHE, 2020), again suggesting that mothers and babies could be at risk of undernutrition.

2.1.4.2 Folic acid

B-vitamins are vital for the regulation of energy metabolism. The B-vitamin folate family (natural form), or folic acid (synthetic form) acts as a co-enzyme within the folate-methionine cycles and is required by all cells for nucleotide synthesis. An

inadequate intake of folic acid in pregnancy is linked to several serious health issues both short-and-long term, the most studied being neural tube defects (NTD) in the fetus. NTDs are characterised by the neural tube failing to close around the brain or spinal cord in weeks 4-5 of development. NTDs are one of the most common birth defects worldwide (World Health Organisation (WHO), 2022), therefore additional folate intake in prior to, and in the first trimester, is essential.

Whilst there has been an awareness of the link between folic acid and NTDs for some time, it was the Medical Research Council (MRC) Vitamin Study that established the positive impact of supplementation. This study looked at women who were at high risk of having a child with an NTD due to previous pregnancy having been affected (MRC Vitamin Study Group, 1991). Women were allocated to one of four groups, two of which had folic acid within the supplement offered, the other two having no folic acid. Participants were asked to take the supplement once randomisation to a group had been made until 12 weeks gestation. The study was suspended when it became clear that the benefit of folic acid supplementation was so great that it was not ethical to continue with the unsupplemented controls. Supplementing with folic acid with or without additional vitamins decreased the risk of NTDs by 72%, RR 0.28, 95% CI 0.12-0.71. Despite this and high awareness of the guidance to do so, many women still do not take folic acid supplementation before pregnancy (Morris *et al.,* 2016; Bestwick *et al.,* 2014). NDNS data for red blood cell folate results showed that 75% of all women in the UK aged between 18-49 years were folate deficient enough to be at risk of NTD in pregnancy (PHE, 2017).

Bestwick *et al.,* (2014) undertook an audit of records from a screening programme from 1998 to 2012 and found that the number of women taking folic acid supplementation according to UK guidelines, dropped from 35% between 1999-2001,

to 31% between 2011-2012. Further analysis indicated that ethnicity had an impact on supplementation numbers with the lowest being women who identified as Afro-Caribbean with just 17% taking folic acid.

Over 80 countries have implemented folate fortification of staple foods to prevent NTDs, of which the largest is the US. Morris *et al.*, (2016) reviewed figures for NTDs recorded on the country registers of the UK and US. They reported that the prevalence of NTD per 1000 births was 1.3 over the period reviewed with 81% of pregnancies being terminated due to the NTD. When they then estimated the effect of folic acid fortification of UK staples to the level of the US during the audit period of 1998 – 2012, they predicted a reduction of around 2000 fewer affected UK pregnancies. By 2017 eighty-one countries had introduced folic acid fortification of flour specifically to reduce the incidence of NTDs (Wald *et al.*, 2018). The UK government has approved fortification of flour but this has still not been implemented as of May 2023.

In those countries where folate fortification has not been adopted, current advice on folic acid supplementation varies globally with a range from 300mcg to 600mcg pre-conceptually up to the start of the 13th week of pregnancy (World Health Organisation, 2016). If the woman is classed as high risk due to a previous pregnancy affected with an NTD, has obesity, takes certain medications that interfere with folate metabolism, sickle-cell disease, or has existing diabetes mellitus (DM) then they need a higher dose of 5mg (SACN, 2017; NICE, 2015; NICE 2022).

2.1.4.3 Vitamin D

Vitamin D is essential for the maintenance of healthy bones and to support calcium metabolism. Even if there is a deficiency in the mother during pregnancy the fetus

will take priority over the mother as she can mobilise skeletal calcium, which will be replaced through renal adaptations that persist beyond lactation. The UK government advise a daily dose of 10mcg throughout pregnancy and lactation in order to meet the needs of both mother and child (NICE, 2008; SACN, 2007), whereas the WHO recommendations are to not supplement with vitamin D as it will not improve health outcomes (WHO, 2017) The UK NDNS data shows that most women between the ages of 19 to 64 years are not getting the vitamin D they need from all sources (arithmetic mean of 5.5mcg/d) (PHE, 2019), with even fewer managing this during the Covid-19 pandemic years (arithmetic mean of 2.3mcg/d from all sources) (PHE, 2021). Lactation is a metabolic burden to the mother and vitamin D deficiency in a lactating mother has been linked to neonatal rickets, poor mineralisation in teeth, and low bone mass during childhood (SACN, 2007).

Obesity is linked to low circulating vitamin D concentrations, although there is still debate as to the exact reasons. Karampela *et al* (2021) undertook a review of the latest meta-analyses around obesity and vitamin D. The review found that low concentrations of vitamin D were commonly seen with a higher body mass index (BMI), and that weight loss appeared to be linked to an increase in vitamin D concentrations. Bodnar *et al* (2007) measured vitamin D concentrations from antenatal booking-in appointment to the birth of the baby. Results showed that of the women who had a pre-pregnancy BMI between 25-29.9kg/m^2, 48.3% were vitamin D insufficient at booking, along with 45% of the neonates (using cord serum levels as a proxy). If the women had a BMI ≥ 30kg/m^2 then 61% were classed as vitamin D insufficient at booking, with nearly 59% of neonates insufficient using cord serum vitamin D levels.

Vitamin D deficiency in pregnancy can lead to poor health outcomes for the mother, neonate, and longer-term for the child (Palacios *et al.,* 2019; SACN, 2007). Despite the quality of research with regards supplementation being variable, the latest Cochrane Review of evidence (2019) concluded that it can reduce risks of adverse outcomes. Palacio *et al* (2019) concluded that vitamin D supplementation can reduce the risk of pre-eclampsia by 52%, GDM by 49%, low birth weight (LBW) by 45%, all classed as having moderate levels of evidence to support these figures. When the supplement contained both calcium and vitamin D, the risk reduction was 50% for pre-eclampsia with moderate evidence. All other adverse outcomes had low or very low levels of evidence and so firm conclusions for use of supplementation in those cases is unproven (Palacio *et al.,* 2019).

As obesity is linked to poor vitamin D status and there is evidence for a beneficial effect of taking a supplement it is wise to conclude that women with obesity should take a vitamin D supplement prior and during pregnancy and lactation.

2.1.4.4 Calcium

The foetus accumulates large quantities of minerals including calcium, magnesium and phosphorus to support the development, growth and mineralisation of the skeleton. Most of this occurs in the final trimester of pregnancy. Although there is a significant demand, in the UK there is no requirement for increased maternal intake during pregnancy (COMA 1991). This is because the typical diet already includes calcium at a level that meets demand and is also due to maternal adaptations which improve absorption of minerals from the gut, and limit urinary excretion (Langley-Evans, 2021). Chief among these adaptations include a slowing of gastrointestinal

transit, permitting more time for absorption. Detailed balance studies by Ritchie *et al.,* (1998) showed that whilst pre-pregnancy calcium bioavailability was 32.9% of the calcium in the diet, this increased to 49.9% in the second trimester and 53.8% in the third. The maternal skeleton will also release stores of all minerals to meet the fetal demand for skeletal growth, and the released stores are replaced in the post-partum period- potentially after the cessation of lactation (Langley-Evans 2021). Whilst calcium bioavailability falls to pre-pregnancy levels during lactation, urinary losses fall markedly, demonstrating that different mechanisms maintain calcium demand in pregnancy and lactation (Ritchie *et al.,* 1998).

2.1.5 Physical activity in pregnancy

The UK recommendation for physical activity in pregnancy is the same as for the adult population at 150 minutes of moderate activity every week (Department of Health and Social Care (DHSC), 2019). This advice has not changed since 2011 but has been updated to assimilate the latest evidence base (DHSC, 2019). Moderate activity is regarded as anything physical, including daily activities like shopping and cleaning, that makes an individual slightly out of breath but still able to hold a conversation (DHSC, 2019). Where there are no complications with the pregnancy, then being physical active throughout is known to support ongoing physical and mental health, reduce complications, and positively benefit the baby (DHSC, 2019; Collings *et al.,* 2019; Wadsworth, 2007). Whilst this is the general advice it should be tailored to the individual woman, so someone who has not been previously active should start slowly with low intensity activities whereas a woman who has had previous high activity levels can continue but avoid contact sports “don’t bump the

bump" (DHSC, 2019). Infographics are now available specifically for pregnancy and postpartum physical activity guidance in the UK (DHSC, 2019). There are known factors where the physical activity guidance does not apply as it is too risky for the woman and fetus (Evenson et al., 2013; Wadsworth 2007). This means that advice should be individually tailored to the woman's needs based on her health.

Despite guidance being in place, many women do not meet the recommendations for activity in pregnancy (Collings *et al.,* 2020). Analysis of a cohort of mother-child pairs from the Born in Bradford Study reported that three-quarters of those who were of Pakistani-origin classed themselves as inactive during their second trimester, with 39% of white British women reporting the same (Collings *et al.,* 2020). Even small amounts of activity in women of Pakistani-origin helped reduce blood lipid and glucose levels, blood pressure and their offspring had lower levels of adipose tissue (Collings *et al.,* 2020). Daly *et al.,* (2016) looked at a cohort of women to see whether there was any link between BMI and self-reported physical activity levels. Women who were in the obese BMI category of >29.9kg/m^2, reported lower levels of activity prenatally and antenatally and these levels reduced further as the pregnancy progressed (Daly *et al.,* 2016). The mean gestation at which activity levels dropped was 29 weeks irrespective of start BMI category (Daly *et al.,* 2016). Wojtyla *et al.,* (2020) looked at self-reported activity in the final trimester and found that 75% of women had reduced their levels to sedentary or light activities with 50% reported as being from household or caregiving. This study also reported that nearly two-thirds of women felt they had to restrict their activity levels in case it affected fetal development however as very few had appropriate advice with regards physical

activity levels by healthcare providers this figure could have been much worse (Wojtyla *et al.*, 2020).

Becoming and staying physically active during pregnancy is important for both maternal and fetal health and yet it is apparent that women are not fully aware of the benefits. In the context of weight management during pregnancy physical activity can play an important role as the energy expenditure associated with activity increases as gestation proceeds. Whilst there are adaptations which make movement more efficient (Forczek and Staszkiewicz, 2012) the respiratory work and metabolic response to weight-bearing exercise increases (Davenport et al., 2009). For women living with obesity or overweight in pregnancy, weight-bearing activity could play a key role in avoidance of excessive gestational weight gain. However, most women are largely inactive by the end of the second trimester (Swift et al., 2017) or engage in activities which support their greater weight such as low intensity swimming (Catov et al., 2018). Early cessation of physical activity has been associated with complications of pregnancy, including gestational diabetes (Catov et al., 2018).

2.1.6 Weight gain recommendations

Weight gain is a normal and expected feature of pregnancy. In addition to the weight of the fetus, placenta and amniotic fluid, deposition of fat stores, plasma volume increase and breast changes would be expected to increase maternal weight by at least 7-8 kg (Langley-Evans, 2022). There are no specific weight gain recommendations in the UK. Instead, the United States Institute of Medicine (IOM) recommendations are generally used as a reference by researchers (Table 2.1; Rasmussen, Yaktine & IOM, 2009). These were updated in 2009 and focussed on reducing five adverse maternal or

neonatal outcomes. These outcomes included; lowest level of caesarean deliveries; reduction in postpartum weight retention; reduction in preterm birth; reduced numbers of large-for-gestational age (LGA) or small-for-gestational age (SGA) babies; reduced levels of childhood obesity. By including a wider range of ethnicities and acknowledging the increase in levels of obesity, the IOM can be more certain that the figures given are more appropriate for the United State (US) current population (at that time. Using these figures for the UK could be problematic however as there are differences in the ethnicities with Hispanics not being a separate ethnic group option in the UK (GOV.UK site List of ethnic groups, 2022). However, excessive weight gain in studies in all countries take on board the IOM concept of grading weight gain requirements by maternal BMI and the ranges indicated.

Table 2.1 Institute of Medicine figures for weight gain in pregnancy to produce a healthy baby, singleton figures only (Rasmussen, Yaktine & IOM, 2009)

Prepregnancy BMI (kg/m^2)	**Optimal mean weight gain range (kg)**
<18.5 (underweight)	13-18
18.5-24.9 (normal/healthy)	11-16
25.0-29.9 (overweight)	7-11
>30 (obese) *	5-9

* BMI over 35 kg/m^2 is generally referred to as severe obesity. It is now common for BMI over 50 kg/m^2 to be termed super-obesity.

2.2 Obesity rates

2.2.1 Obesity prevalence

Obesity prevalence around the world is rising rapidly and is reported to have tripled from 1971 – 2016 (WHO, 2019). The Organisation for Economic Cooperation and Development (OECD) countries report average obesity rates in females over the age of 15 years of 23.1%, with the highest figure being 42.3% for Saudi Arabia, and the lowest Japan at 3.7% (OECD, 2017). According to the OECD report '*The Heavy Burden of Obesity; The Economics of Prevention'* (2019), in the UK, over two-thirds of women are within the overweight or obese BMI categories. When the figures for the UK are broken down further it becomes clear that the country has a significant problem with overweight and obesity in women of child-bearing age, taken as age 16-44 years. Data for England shows obesity/overweight from 34.9% in the 16–24-year range to 61.3% in the 35–44-year range (Conolly & Craig, 2019). Scotland's figures are higher for the 16–24-year range at 43%, but the same as England for the 35–44-year range (Scottish Health Survey, 2020). Wales figures are 34.1% for 16–24-year-olds, and 49% for 35–44-year-olds (Public Health Wales NHS (National Health Service) Trust, 2019). Northern Ireland does not break the figures down for male and female but combined overweight and obesity figures are similar to other countries of the UK (Health Survey Northern Ireland, 2019).

In the PHE (Public Health England) report '*Health of women before and during pregnancy: health behaviours, risk factors and inequalities*' (2019), analysis of the Maternity Services Dataset showed that at booking appointment 27% of women were recorded as overweight, 18% as obese, and 3% as severely obese. Women in the

overweight/obese BMI categories were more likely to be over the age of 40, in areas with high deprivation, and more likely to be black.

Jardine *et al.,* (2021) looked at birth records from between 2015 and 2017 and found that over 28% of women had a BMI in the overweight category at the start of the pregnancy with over 21% in the obese categories. They found that adverse birth outcomes were more common in women from the highest deprivation quintile when compared to the lowest, and non-White women were at higher risk of adverse birth outcomes compared to White women even after adjustment for BMI.

Pregnant women living with overweight or obese are known to be at increased risk of poor health for both themselves and their child, with excess weight being associated with poor outcomes in both the short and long-term (McCall *et al.,* 2019; Marchi *et al.,* 2015; Gaillard *et al.,* 2013; Siega-Riz *et al.,* 2009; Heslehurst *et al.,* 2008, Langley-Evans *et al* 2022, Langley-Evans 2022). These risks can be divided between those for the mother (Saranvanakumar *et al.,* 2006; Weiss *et al.,* 2004), and those for the child (Rankin *et al.,* 2010; Tennant *et al.,* 2011; Cedergren & Källèn, 2003; Watkins *et al.,* 2003); although they may ultimately affect both.

In the UK, The Centre for Maternal and Child Enquiries (CMACE) released a report on maternal obesity in 2010. This showed the prevalence of severe obesity in pregnant women, (classed as a body mass index greater than 35kg/m^2), at nearly 5%, 2% of women with a BMI ≥40kg/m^2 (morbidly obese – a level where ill health is likely), and 0.19% of women with a BMI ≥50kg/m^2 (super-obesity) (CMACE, 2010). Figures for the most recent data set for England reported half of all women were within the BMI overweight or obesity range at their booking appointment, constituting over 230,000 pregnancies per year (Gair, 2019) Recent statistics for hospital admissions in England,

where obesity is directly linked to that episode of care, list four pregnancy issues within the top ten – maternal care: other known or suspected fetal problems, labour and delivery complicated by fetal stress, perineal laceration during delivery, maternal care; known or suspected abnormality of pelvic organs (NHS Digital, 2021).

2.2.2 Financial impact of obesity

Obesity in pregnancy has a financial cost to health services. In order to ensure a safe and comfortable experience for mother and baby it is essential that the appropriate equipment is available to support them, that they have experienced clinicians around them, and that any risk assessments needed are completed (Denison *et al.,* 2018; Kean *et al.,* 2015). When pre-pregnancy BMI is considered, it is apparent that care costs increase as BMI increases (Kuhle *et al.,* 2018; Solmi & Morris, 2018; Watson *et al.,* 2013). Watson *et al.,* (2013) looked at the costs associated with hospital admission episodes for pregnant women from Queensland, Australia to assess the influence of maternal BMI. They found that for women with a BMI $\geq 30 kg/m^2$ there was more likely to be a hospitalisation prior to birth, and increased costs linked to the birth episode (Watson *et al.,* 2013). More recently Solmi & Morris, (2018), looked at costs to the NHS in the UK linked to women with either an overweight or obese classification BMI. They used data from the Millennium Cohort Study and found that most women who had a pre-pregnancy BMI in the overweight or obese categories were non-White, older, had lower levels of education and were single. They reported that being in the overweight or obese BMI category increased costs involved due to the type of delivery method needed, babies being born pre-term, and longer hospital stay.

Morgan *et al* (2014) undertook a retrospective prevalence-based study in Wales to look at cost of obesity in pregnancy to the local NHS. They used data from 484 pregnancies and categorised these by maternal BMI – healthy weight, or overweight/obese. They reported that the estimated cost of pregnancy, excluding infant costs, increases with increased BMI with a difference of over £1000 between a healthy BMI, and one in the obese range. This additional cost came from greater use of hospital care (inpatient and outpatient), GP care, and need for certain medications.

Costs associated with specific morbidity or labour interventions have also been considered. Herbst (2005) undertook a cost-effectiveness analysis for fetal macrosomia, which is described a fetus that is suspected to weigh >4.5kg at birth. Their modelling indicated that allowing a vaginal birth but with close monitoring was the preferred option due to the lower cost ($4014) whereas an elective caesarean cost an additional $1000. Whilst obesity alone is not directly linked to macrosomia, gestational diabetes mellitus (GDM) is, and is more likely to occur in women with a higher BMI (NICE, 2015). Dall *et al* (2019) looked specifically at all types of diabetes mellitus including gestational and estimated health costs for these conditions. When taking GDM alone they calculated additional costs of $5800 per mother and child with the bulk of that figure being for the mother's care, medication, and regular check-ups.

In terms of costs for infant care from a mother with a higher BMI, there is also an extra need for healthcare compared to infants from a mother with a BMI from the healthy range (Kuhle *et al.,* 2018; Morgan *et al.,* 2015). Morgan *et al* (2015) reviewed

609 records from the ‘Growing up in Wales: Environments for Healthy Living’ study. They found that there was additional cost linked to longer stays in hospital (over two-and-a-half times more likely), and more general practitioner visits (13% increase), (Morgan *et al.*, 2015). This gave a mean increase of around 70% on costs for an infant born to a mother with obesity when compared to a mother with a healthy weight BMI (Morgan *et al.*, 2015). Kuhle *et al* (2018) looked at data from the Nova Scotia Perinatal Database to see whether there were additional costs associated for children up to the age of 18 years with a mother with a higher pre-pregnancy BMI. They reported that these children were more likely to visit their physician, more likely to need admission to hospital and require a longer stay whilst there with increased associated costs.

2.3 Risks of obesity to the woman and baby

Weight gained in pregnancy is often seen as a catalyst for future weight problems for the mother and the child (Rooney & Schauberger, 2002, Langley-Evans *et al.*,2022; Langley-Evans 2022) and may increase the risk of adverse pregnancy outcomes with subsequent pregnancies (Villamor & Cnattingius, 2006). Of the women observed in the Centre for Maternal and Child Enquiries (CMACE) 2010 study, 38% had a co-morbidity diagnosed prior to, or during, their pregnancy. The most frequently diagnosed conditions were pregnancy-induced hypertension, and gestational diabetes (CMACE, 2010).

2.3.1 Obesity in pregnancy risks

2.3.1.1 Heartburn/ dyspepsia

The relaxation of smooth muscle due to the hormonal changes within the body may lead to an increase in dyspepsia, a group of symptoms that includes heartburn and acid reflux, also called gastro-esophageal reflux. The oesophageal sphincter sits at the bottom of the oesophagus and through opening and closing it allows the food/drink bolus into the stomach. Stomach acid has a very low pH and is normally contained within the stomach. If it can exit the stomach into the oesophagus it will lead to a 'burning' pain as the oesophagus is less protected than the stomach wall. In addition to the relaxation of the muscle there is the increased pressure from the uterus as the fetus grows and pushes organs out of the way (Coad *et al.*, 2020). As the stomach is squashed the effectiveness of gastric emptying is altered and becomes slower. Women

who are carrying excessive weight already have additional pressure from the weight of the adipose tissue on their internal organs so the added load of pregnancy can make this worse. The condition is likely to worsen as the pregnancy progresses. Ramu *et al* (2010) undertook a case-control study in India to see if they could determine the risk factors for an increase in dyspepsia symptoms that lead to gastro-esophageal reflux disease. They found that 19.3 % of the pregnant women had reflux and heartburn, as well as 12.8% having combined symptoms of reflux plus heartburn and regurgitation. Dennison *et al.,* (2009) reviewed the increased risk of minor complications during pregnancy. They found that once adjusted for parity, deprivations, age and smoking status, women with a BMI $\geq 30 kg/m^2$ were nearly three times more likely to suffer with heartburn than women with a BMI $< 25 kg/m^2$.

According to the NHS, lifestyle changes may help the symptoms, and these include eating smaller meals through the day, eating a healthy diet, eating in an upright position, raising the head of the bed, not eating just before bed, and reducing the amount of coffee and fatty foods. There is little quality evidence to support this but it still remains the primary approach (Vazquez, 2015; Phupong,and Hanprasertpong, 2015; NICE, 2008). The 2015 Cochrane Review by Phupong and Hanprasertpong reported that full relief from symptoms of heartburn could only be achieved with pharmacological intervention, RR 1.85 CI 95% 1.36-2.50. It should be pointed out however that only two, relatively old studies were included in the review although they were regarded as being of moderate quality. A clinical evidence review by Vazquez (2015) looked at more up to date data and concluded that antacids with or without alginates were effective at dealing with heartburn symptoms when compared to placebo but also reported the studies included in their review were of low quality.

Maternal obesity is a risk factor for heartburn with women with pre-pregnancy BMI over 30 kg/m^2, being more than twice as likely to suffer symptoms that those with BMI under 25 kg/m^2 (Denison *et al.*, 2009).

2.3.1.2 Pregnancy-related pelvic Girdle Pain (PPGP) / Symphysis Pubic Dysfunction (SPD)

Pelvic girdle pain, also known as symphysis pubis dysfunction, is a known complication of pregnancy (NHS, 2019). The muscles relax to accommodate the anatomical changes needed for the pregnancy which can cause the pelvic girdle to become unstable and then cause pain. Denison *et al.*, 2009 reported that there was a four-fold increased risk of pregnancy related pelvic girdle pain in women with a BMI $\geq$ 30kg/m^2 when compared to those classed as having a healthy BMI. A 2020 scoping review was able to identify several risk factors relating to pregnancy related pelvic girdle pain including high BMI, whilst acknowledging the evidence base is still limited (Wuytak *et al.*, 2020). Unfortunately, pregnancy related pelvic girdle pain and symphysis pubis dysfunction may not settle once the baby is born with women continuing to suffer with pain for time afterwards (Wuytak *et al.*, 2018). Wuytak *et al.*, (2018) undertook a systematic review of the literature to try and identify prognostic factors that would indicate high risk of pregnancy related pelvic girdle pain and symphysis pubis dysfunction post-partum. Despite limited research within the area, the papers included in the review showed that a BMI $\geq$ 25kg/m^2 was linked to an increased risk of pregnancy related pelvic girdle pain and symphysis pubis dysfunction beyond 12 weeks post-partum.

2.3.1.3 Fetal abnormalities

In the UK pregnant women are routinely offered a minimum of two ultrasound scans to monitor the fetus' growth and to check for anomalies (NHS England and Office for Health Improvement and Disparities, 2022). Women with obesity have been repeatedly reported as being at higher risk of having a fetus with certain structural and congenital anomalies (Persson *et al.,* 2017; Marchi *et al.,* 2015; Davies *et al.,* 2010; Fitszimons *et al.,* 2009), and should be offered additional scans throughout pregnancy (Denison *et al.,* 2018; NHS East Midlands Strategic Clinical Networks, 2015). The state of obesity itself appears to be a factor in causing these anomalies but specific mechanisms are not yet fully understood (Persson *et al.,* 2017; Marchi *et al.,* 2015; Davies *et al.,* 2010; Fitszimons *et al.,* 2009). There may be difficulties in detecting problems via ultrasound due to the excess adipose tissue and additional counselling with regards these difficulties is recommended as the anomalies may not be apparent until after birth (Denison *et al.,* 2018).

A population-based study by Madsen *et al.,* (2013) looked at the impact of maternal pre-pregnancy BMI and risk of congenital heart defects (CHD). The researchers looked at records from between 1992 and 2007 to identify babies with a range of CHD and then reviewed the mother's pre-pregnancy BMI. In the US, the mother's weight has been recorded on the baby's birth certificate since 1992, and height on the driver's licence since 2003. Following statistical analysis, they found that both maternal obesity and CHD prevalence had increased during the study period however no link with overweight and overall CHD was observed. With obesity, they noted that only certain CHD were associated with an increased risk. These increases were atrial septal defects (by 17%), hypoplastic left heart syndrome (by 86%), pulmonary valve

anomaly (by 46%), pulmonary artery anomaly (by 39%), patent ductus arteriosus for term infants (by 44%), and unspecified CHD (by 75%) (Madsen *et al.,* 2013).

Persson *et al.,* (2017) considered records from over 1.2 million liveborn infants with regards to whether there was increased risk of congenital malformations in those whose mothers were overweight or obese. They reported that 3.5% of this population had been recorded with having some kind of malformation. The most common of these was congenital heart defects with 1.6% infants recorded as having one followed by several other organ and body system malformation. Statistical analysis shows that higher BMI (kg/m^2) was linked to an increased risk of a congenital defect; 5% increase in a BMI of 25<30, 12% increase in a BMI of 30<35, 23% in a BMI of 35<40, and 37% in a BMI >40. Male fetuses appeared to be at greater risk than females (Persson *et al.,* 2017).

Further reviews have shown the same picture regarding BMI and congenital heart defects (Helle *et al.,* 2020; Liu *et al.,* 2019; Zhu *et al.,* 2018; Cai *et al.,* 2014). Helle *et al.,* (2020) considered the impact of all forms of diabetes mellitus when combined with maternal obese status and have tried to elucidate the possible mechanisms of action that cause these anomalies. The heart is one of the first organs to fully develop within a fetus starting at week 3 and being fully formed by week 6 (Langley-Evans, 2021) so it is likely that losing weight prior to pregnancy is a sensible way to prevent this birth defect (NICE, 2010).

2.3.1.4 Gestational Diabetes Mellitus (GDM)

Gestational Diabetes Mellitus (GDM) is a form of diabetes mellitus that only develops in pregnancy and is due to maladaptation to the normal insulin resistance of

pregnancy. According to the International Diabetes Federation's 2021 report, 21.1 million women globally are affected by hyperglycaemia in pregnancy each year, and 80.3% of this was due to GDM. GDM can be managed in several ways using combinations of diet and lifestyle advice, oral anti-glycaemic drugs, and/or insulin (British National Formulary, 2022; NICE, 2015). NICE guidance is not specific on which diet but recommends all women diagnosed with GDM should be referred to a dietitian for dietary advice (NICE 2015). Han et al (2017) reviewed 19 studies looking at dietary treatment of GDM and reported that there was not strong evidence to recommend any specific diet. When Zhang et al (2018) undertook a meta-analysis of low-glycaemic-index diets in pregnancy they found that whilst these diets reduced fasting blood glucose levels and 2-hour postprandial glucose levels there was no strong evidence that other negative outcomes were reduced. The British Dietetic Association (BDA) recommends that to support healthy blood glucose levels half the plate should contain vegetables or salad; a quarter of the plate should be protein with the final quarter being carbohydrates (Beckwith et al., 2021). Choosing low-glycaemic index carbohydrate is recommended as these foods tend to release glucose more slowly (Beckwith et al., 2021).

There are known risk factors for a woman being more likely to develop GDM which include a BMI >30kg/m^2, family history of diabetes mellitus (DM), previous GDM, and a previous macrosomic baby (NICE, 2015). Certain ethnicities are at higher risk of developing GDM with high rates reported in indigenous populations worldwide (Reid *et al.*, (2018). In the UK greater risk is noted in South Asian, Chinese, Black African, African-Caribbean women (NICE, 2013). Ethnicities affected differ from country to country with the US having higher rates of GDM in Hispanic, non-Hispanic Asian and Pacific Islanders (Bardenheier *et al.*, 2015). In a study by

Ogunwale *et al.,* (2022) an increase in risk was recognised in women classed as being foreign-born and having lived in the US for at least ten years. Once a woman has had GDM she may go on to develop Type 2 diabetes post-partum (NICE, 2015). If GDM is well managed during pregnancy then the risks for mother and baby can be partially managed, however even with controlled GDM there is still an increase in risk of adverse pregnancy outcomes (Ye *et al.*, 2022; NICE, 2015).

These outcomes are most often separated between those that affect the mother and those that affect the fetus/neonate. The UK has guidelines for the care of women who have any type of diabetes going into their pregnancy, or develop GDM during pregnancy (NICE, 2015). The focus for all of these is to ensure that blood glucose levels are kept within a healthy range based on their capillary plasma glucose. In clinical settings the capillary plasma glucose is also known as a BM which stands for Boehringer Mannheim, the original test stick supplier, and will be the abbreviation used in this thesis (Grant, 2009). The range recommended is a fasting BM of 5.3mmol/litre, 7.8mmol/litre one hour after eating, and 6.4mmol/litre two hours after eating. Staying below these thresholds will avoid the risk of chronic hyperglycaemia (NICE, 2015). It is also vital to keep the BM above 4mmol/litre to avoid hypoglycaemia, colloquially known as ‘four is the floor’ by clinicians. NICE (2015) also advise an initial blood test which will look at glycated haemoglobin – HbA1c, a measure of how much excess glucose there has been in the blood in the previous two to three months. This monitoring is vital to avoid the adverse outcomes that can come with either hyperglycaemia or hypoglycaemia in both mother and child which are numerous.

Women with overweight and obesity are repeatedly reported as being at high risk of developing GDM irrespective of socioeconomic status, ethnicity, or global location

(Yen *et al.,* 2019; Domanski *et al.*, 2018; Rahman *et al.,* 2015; Catalano *et al.*, 2012; Guelinckx *et al.,* 2008; Sebire *et al.,* 2001). Yao *et al.*, (2020) undertook a meta-analysis looking at measures of central obesity and risk of GDM and found that there was a more than 3-fold increased risk with the highest measures of central adiposity.

2.3.1.4.1 Adverse outcomes for mother

The most common adverse outcomes for a mother following the development of GDM are an increase in risk of caesarean section (Domanski *et al.,* 2018; NICE, 2015), gestational hypertension (NICE, 2019) pre-eclampsia, birth trauma for the woman, and induced labour (NICE, 2019; NICE 2015).

2.3.1.4.2 Adverse outcomes for fetus, neonate, and childhood

GDM does not only impact the health of the mother. Both the fetus and neonate can be affected with complications that can include congenital malformations (NICE, 2015), macrosomia (Domanski *et al.,*2018), large-for-gestational age (LGA) babies (Catalano *et al.,*2012), preterm birth – possibly due to awareness of fetal size and issues with a vaginal delivery if baby is allowed to go to term, neonatal hypoglycaemia, and jaundice (NICE, 2015). Anderson *et al* (2005) undertook a case-control study in Texas to look at central nervous system defect rates within a population with GDM combined with a maternal BMI ≥30kg/m^2. They found that when compared to a healthy BMI group there was nearly a three-fold increased risk of neural tube defects, (AOR 2.6 CI 1.7-4.0). Results from two case-control longitudinal studies in Canada reported that there was a decrease in language development in infants of mothers who had had GDM (Dionne *et al.,*2008). This study looked at how

the children expressed themselves using a validated checklist, and how they understood others, again using a validated tool. The results showed that children born to mothers who had had GDM scored lower in these tests than children from mothers who did not develop GDM. This study did not look at the association with maternal obesity independently of GDM. A more recent systematic review and meta-analysis by Robles *et al.*,(2015) reported that when a mother has any type of diabetes mellitus during pregnancy there may be an impact on their child's future neurodevelopment. They found that diabetes mellitus in pregnancy may cause a significant reduction in both mental development scores, and psychomotor development at the age of between 1-2 years, and a reduction in intelligence scores in school age children. Again, the analysis did not consider association of these outcomes with maternal weight.

In addition to the impact of GDM on both mother and baby, the treatment options for GDM may also cause health issues. Ye *et al* (2022) focussed on the adverse outcomes of GDM by treatment type. This 2022 review and meta-analysis looked at three groupings for GDM and treatment regimen. These included non-insulin treated GDM versus no GDM; insulin treated GDM versus no GDM; and treatment not known GDM versus GDM. They found that in those women who had treatment with insulin, there was an increased risk for neonatal outcomes only (Large for Gestational Age OR 1.61 CI 1.09-2.37, respiratory distress syndrome OR 1.57 CI 1.19-2.08, neonatal jaundice OR 1.28 CI 1.02-1.62, and admission to neonate unit OR 2.29 CI 1.59-3.31). The non-insulin treated group showed only one outcome for the women of increased rate of caesarean section (OR1.16 CI 1.03-1.32), and several adverse effects with the neonate (preterm delivery increased by 51%, low 1-minute Apgar score increased by

43%, macrosomia was 70% more likely and LGA was 57% more likely; Ye *et al.,* 2022).

2.3.1.5 Gestational Hypertension (GHT)

Pregnancy itself is not a cause of hypertension despite the many changes to the cardiovascular system, and in fact many women find they struggle with low blood pressure in early pregnancy due to the vascular relaxation. A blood pressure reading below 90/60 mmHg is regarded as hypotension (low blood pressure). A healthy reading is regarded as between 90/60 and 120/80mmHg, between 120/80 and 140/90mmHg is classed as pre-hypertension, and above 140/90mmHg is classed as hypertension and will trigger interventions if needed. Once blood pressure reaches 160/110mmHg it is regarded as severe hypertension and becomes an obstetric emergency with imminent admission to hospital required to manage the condition (NICE, 2019). Hypertension in pregnancy is never seen as normal and requires investigation as it could be an early sign of pre-eclampsia.

The effect of going into pregnancy with a BMI over 25kg/m^2 means that there is a risk of pre-existing hypertension (chronic hypertension), and an increased risk of developing GHT. Baugh *et al* (2016) looked at women in the United States) to see what factors could affect poor pregnancy or neonate outcomes. BMI based on pre-pregnancy weight and height measurements and recorded as “higher pregnancy BMI” in the article was associated with a significantly greater risk of becoming hypertensive during the pregnancy. In addition to this finding, weight gain in excess of that recommended by the IOM guidelines was also a significant risk factor (Baugh *et al.,*

2016). Reviews of the literature show the same picture of an increased risk of GHT when a BMI above the healthy range is considered (Rahman *et al.,* 2015; Davies *et al.,* 2010; Fitzsimons *et al.,* 2009; Guelinckx *et al.,* 2008). A more recent review by Heslehurst *et al* (2022) looked at alternative measures as indicators of obesity. These included waist circumference and waist-to-hip ratio (Heslehurst *et al.,* 2022). This review found that both measures were associated with hypertensive disorders in pregnancy, however the authors included pre-eclampsia as an outcome which is discussed in more detail in subsection 3.3.1.6.

The evidence that obesity increases risk of GHT has been so overwhelming that NICE released a guideline in 2019 to specifically cover diagnosis and management of hypertension and hypertensive disorders in pregnancy (NICE, 2019). Although this is for all pregnant women, it does specify the greater risk associated with having a BMI ≥35kg/m^2 and that this is a factor that requires additional assessment and follow-up.

2.3.1.6 Pre-eclampsia (PE) and eclampsia

In the UK, NICE guideline 133, (2019) covers identification and treatment for pre-eclampsia and eclampsia. This guidance defines pre-eclampsia as a combination of GHT after 20 weeks gestation in addition to one of the following - proteinuria and/or maternal organ dysfunction and /or uteroplacental dysfunction. Of the risk factors known for these conditions only that of a BMI ≥30kg/m^2 is controllable with recommendations being to try and lose weight prior to pregnancy (NICE, 2010). Without treatment these conditions can be fatal to mother and baby (Langley-Evans *et al.,* 2022). The WHO include recommendations for identification and treatment of pre-eclampsia in their 2017 Guidelines for Maternal Health (WHO, 2017).

Sebire *et al.,* (2001) reported that the risk of proteinuric pre-eclampsia increased in women with a BMI between 25-30 kg/m^2 by 44%, and by over 200% with a BMI ≥ 30kg/m^2. A cohort study undertaken in Scotland by Doi *et al.,* (2020) compared three groupings of BMI and risk of adverse outcomes in pregnancy and delivery. They reported an increased risk of pre-eclampsia with both the overweight and obese group (1.46-fold and 2.07-fold respectively) when compared to the healthy BMI group. A population cohort study in 2004 looked at adverse pregnancy outcomes with women who had a BMI >40kg/m^2 (Cedergren, 2004). This study found that there was a nearly four times increased risk of pre-eclampsia in women with a BMI between 35-40kg/m^2, and nearly five times increased risk if the BMI >40kg/m^2, when compared with healthy weight women with a BMI between 19.8-26kg/m^2. With a BMI ≥50kg/m^2 compared to one between 30-49.9kg/m^2, Alanis *et al.,* (2010) found a two-times increase in risk for pre-eclampsia even when controlling for other factors. Marshall *et al.,* (2012) compared women with obesity, morbid obesity, and super-obesity to assess risk for a range of perinatal outcomes. They found that the risk for pre-eclampsia was increased when the super obese (BMI ≥50kg/m^2) and obese were compared (70% increased risk), and when the obese and morbid obese groups were compared (40% increased risk), but not when the super obese and morbid obese were compared (p=0.11.

2.3.1.7 Monitoring of fetus

Obesity in pregnancy may cause problems for practical reasons too. Excess abdominal fat makes it difficult for sonographers to acquire visualisation of the fetal organs. In a retrospective cohort study, comparison between healthy BMI women and those who were classed as morbidly obese (BMI ≥40kg/m^2) at a mean gestational age of 20.2 weeks (for both groups), results showed that visualisation of fetal cardiac features on

ultrasound examinations became more difficult the higher the BMI (Adekola *et al.,* 2015). The same picture was seen in a retrospective study by Hendler *et al* (2004) who reviewed records with regard to craniospinal features in addition to the cardiac ones. In this study it was found that there was an increase in suboptimal ultrasound visualisation of the fetal structures in women in the higher BMI category (>30kg/m^2) when compared to the healthy BMI women ($p<0.0001$ for both comparisons). Another prospective study run by Fuchs *et al* (2013), used a validated tool to score the ultrasound scan quality of 223 women with a BMI > 30kg/m^2, and 60 women with a BMI between 20-24.9kg/m^2. The ultrasound scan was done at a mean of 22.6 weeks gestation for both groups. Following multivariate analysis one of the factors affecting whether the scan could obtain all the images required was abdominal wall thickness, with an abdominal wall thickness of ≥35mm making it 50% more likely this would not be achieved – OR 1.5 CI 1.1-2.0 - the healthy range is <24.9mm (Fuchs *et al.,* 2013). The quality of the majority of the images was poorer in women with obesity. As gestational age increases these difficulties with the suboptimal ultrasound visualisations decrease however this means that options for action that could be taken with regards fetal anomalies is reduced.

2.3.1.8 Miscarriage/ Spontaneous abortion

Miscarriage occurs when there is loss of the embryo or fetus before 23 weeks gestation (NHS, 2022). The bulk of the evidence points towards obesity leading to an increased risk of miscarriage in the first trimester as well as recurrent miscarriage (reported in Fitzsimons *et al.,* 2009). A meta-analysis in 2008 by Metwally *et al.,* found that women with a BMI ≥25kg/m^2 were at higher risk of miscarriage before 20 weeks gestation irrespective of how they conceived, OR 1.67 95% CI 1.25-2.25). This same analysis reported that ovulation induction in women with a BMI ≥25kg/m^2 was

associated with a 5-fold increased risk of miscarriage when compared to the control group who were in the healthy BMI range. Hahn *et al.,* (2014) looked at a range of anthropometric measures including BMI, waist circumference (WC), waist-to-hip ratio (WHR) and height, and risk of spontaneous abortion (SAB) in a cohort of Danish women. The only measure that indicated a statistically significant increased risk of spontaneous abortion was a BMI ≥30kg/m^2, and only with early (before 8 weeks gestation) spontaneous abortion, once adjustment for WC was made in addition to maternal age, physical activity, caffeine consumption, parity, vocational training, alcohol consumption, and smoking this lost statistical significance (Hahn *et al.,* 2014).

2.3.1.9 Maternal death

Maternal mortality is any maternal death during pregnancy or within 42 days of birth, or for the class "late maternal death" within one year of loss of the pregnancy (WHO, 2022). In the UK, all maternal deaths are reviewed biannually via the Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK). This reporting allows recommendations about future care to be made to reduce the number of maternal deaths. The latest report was published in November 2021 and reviewed deaths from 2017-2019 (Knight *et al.,* 2021). During this period 191 women died out of over 2 million giving birth in the UK giving a maternal mortality ratio (MMR) rate of 8.8 women per 100,000. This figure is lower than the estimated MMR for Europe and the Northern America of 12 women per 100,000 (WHO, 2019).

It is difficult to specify that a death was directly caused by obesity, however known risks linked to having obesity should be considered with all pregnant women and are

highlighted within the MBRRACE-UK and Centre for Maternal and Child Enquiries (CMACE) reports (Knight *et al.,* 2021; Knight *et al.,* 2019; CMACE 2010). In 2007 the Confidential Enquiry into Maternal and Child Health (CEMACH), a precursor to MBRRACE-UK, reported that there where BMI was recorded, 52% women from all causes of death had a BMI ≥25kg/m^2 (Lewis, 2007). Following on from this, CEMACH (2010) looked specifically at maternal obesity and identified that women with obesity were more likely to live in deprived areas and be older mothers >40 years. This is still reflected today as seen in the report by PHE, (2019) where the most deprived areas and women that are older are more likely to be in, or above, the overweight BMI category at their booking appointment (PHE, 2019). The PHE report shows that Black women are also at higher risk of having obesity when they go for their booking appointment. These same groups are over-represented in the maternal mortality numbers (Knight *et al.,* 2019). Obesity is a known risk factor for increasing the likelihood of conditions within pregnancy that could lead to death including pre-eclampsia and eclampsia, hypertensive disorders, ischaemic heart disease, and thromboembolism (Knight *et al.,* 2021; Saucedo *et al.,* 2021; Knight *et al.,* 2019).

Saucedo *et al.,* (2021) looked at records of maternal death from 2007-2012 in France and then compared them to a representative population. They found that having a BMI above the healthy range increased risk of maternal death by 1.6-fold if a woman was overweight, 2.2-fold if they were classed as between 30-34.9 kg/m^2, and by 3.4-fold if they had a BMI ≥35kg/m^2. All of this evidence points towards supporting women to go into pregnancy with a healthy BMI.

2.3.2 Obesity and the birth process

2.3.2.1 Labour process

The birthing process can be compromised in women with obesity due to poor uterine contractility which leads to a slower labour progression (Bamgbade *et al.,* 2009; Fitzsimons *et al.,* 2009; Sheiner *et al.,* 2004) this, in turn, can lead to an increase in fetal distress which is likely to trigger the intervention of an instrumental or caesarean delivery (Dresner *et al.,* 2006; Dempsey *et al.,* 2005; Sheiner *et al.,* 2004). When compared to the healthy BMI maternity population in the UK, women with a BMI ≥35kg/m^2 are more likely to need to be induced, have an instrumental delivery, and require a caesarean section (CMACE 2010).

2.3.2.1.1 Instrumental delivery

Instrumental delivery, also known as assisted vaginal birth, involves the use of either forceps or the ventouse to aid the birth. The National Maternity and Perinatal Audit (NMPA) report that as maternal BMI increases the likelihood of an instrumental delivery decreases (Relph *et al.,* 2021). In England, the prevalence of assisted vaginal birth goes from 25.4% with a BMI <18.5kg/^{2}, to 15.4% for a BMI ≥40kg/m^2 (Relph *et al.,* 2021). For Scotland, the difference is even higher with 27.3% of women in the BMI category <18.5kg/m^2 requiring an assisted delivery to 12.3% for women with a BMI ≥40kg/m^2 (Relph *et al.,* 2021). Interestingly the NMPA asks for opinions by a lay advisory group, and reports that the threshold for intervention for a caesarean may be lower in women of higher BMI, and this could explain the reduction seen here for assisted vaginal delivery.

Hollowell *et al.,* (2014) reviewed data from the Birthplace national prospective cohort study. This secondary analysis of existing data to see if BMI had any effect on

maternal and fetal outcomes. Following adjustment, they found that there was not an increased risk for instrumental delivery for women classed as overweight, obese, or very obese when compared to healthy weight women.

Xu *et al.,* (2021) undertook a cohort study in Sweden with the aim of assessing any link between BMI, GWG z-score and adverse delivery outcomes. This study included over 175,000 singleton pregnancies between 2008 and 2014. They found that when comparing a z-score for GWG of -0.05 to 0.5 in the cohort of women classed as obese there was no significant difference in the likelihood for instrumental delivery irrespective of whether more-or-less weight by z-score had been. Parambi *et al.,* (2019) considered women with a BMI above 50kg/m^2 (super obesity) who gave birth at a hospital in Melbourne Australia, and their planned mode of delivery. They found that of those who requested a vaginal birth nearly 68% got this, with 12.6% requiring an instrumental birth. The remainder needed an emergency caesarean delivery, 29.7%.

2.3.2.1.2 Caesarean delivery

Caesarean delivery of any type – elective or emergency, is reported as more likely to occur with women who are classed as overweight or obese - or as described in the paper by Barau *et al* (2006), as having maternal corpulence - (Dresner *et al.,* 2006; Dempsey *et al.,* 2005; Sheiner *et al.,* 2004). However, both Dresner *et al* (2006), and Barau *et al* (2006) used a BMI measure of <20kg/m^2 as the comparison group which is not classed as healthy, and Sheiner *et al* (2004) just referred to non-obese women with no specific BMI reported, and so these choices could skew the results. Sebire *et al* (2001) undertook a retrospective review of maternity records to look at comparisons between BMI categories for a range of maternal and neonate outcomes. Multivariate logistic regression taking ethnicity, parity, age, history of hypertension, placental abruption, gestational diabetes, pre-eclampsia, placenta praevia, breech

presentation and pre-existing diabetes mellitus into account, showed an increase in risk of both emergency and elective caesarean with increasing BMI with a healthy BMI range used as the comparison, (Sebire *et al* (2001). A BMI of 25-30kg/m^2 increased the risk of an emergency caesarean by 30% relative to women of healthy weight, and an elective caesarean by 20%, and a BMI >30kg/m^2 increased the risk of emergency caesarean by 83% and 72% respectively. In 2007 Chu *et al* undertook a systematic review and meta-analysis of the literature to quantify the risk of any type of caesarean delivery with maternal obesity. Their analysis showed that the risk increased as the BMI increased when compared to 'normal' weight women– overweight OR 1.46, CI 1.34-1.60; obese OR 2.05, CI 1.86-2.27, severely obese OR 2.89, CI 2.28-3.79. Bamgbade *et al* 2009 found no statistical difference between BMI groups for either elective or emergency caesareans. Mothers with diabetes mellitus were more likely to have a caesarean regardless of birth weight when compared to those mothers without it (Nesbit *et al*., 1998).

A report by Relph and the NMPA Project Team (2021) audited maternity records in Scotland, England, and Wales for the period of 1st April 2015 to 31st March 2017. This audit found that the likelihood of any type of caesarean birth in nulliparous women increased as the maternal BMI increased (Relph and NMPA Project Team, 2021). Scotland had the highest figures for nulliparous caesarean birth which went from 25.9% for the healthy range BMI (18.5-24.9kg/m^2) to 54.5% in the ≥40kg/m^2. With women in Scotland who had had a previous caesarean of any type, the figures increase to 75.5% in the healthy weight range to 93.4% for the greatest. This increase was also seen in England and Wales but was not quite as high.

2.3.2.1.3 Anaesthesia risks

Anaesthesia-related complications are well documented for women living with obesity (Lamon and Habib 2016; Mace *et al.*, 2011; Gupta and Faber, 2011; CMACE, 2010; Davies *et al.*, 2010; Fitzsimons *et al.*, 2009). The physiological changes during pregnancy put stress on organ systems and when this is combined with the metabolic, anatomic, and physiological changes of obesity additional anaesthesia risks appear. An audit undertaken at Leeds General Infirmary in 2006 looked at the impact of higher maternal BMI on a number of factors around analgesia in labour including the resite rates of epidural analgesia (Dresner *et al.*, 2006). The authors found that where women were of higher BMI it was more likely that the epidural had to be resited. Bamgbade *et al* (2009) looked at similar outcomes as Dresner *et al* (2006) and concluded that when working with women who had obesity there was greater likelihood that there would be a need for more than one attempt at neuraxial anaesthesia.

2.3.2.2 Post-partum haemorrhage (PPH)

Primary post-partum haemorrhage (PPH) is defined as a loss of blood over, or equal to, 500ml in 24 hours (Magowan, 2023). If blood loss is in excess of 1000ml over 24 hours and continues or the mother shows signs of hypovolemia then this is classed as major and becomes an obstetric emergency. Risk factors for PPH include, but are not restricted to, women with a BMI >30kg/m^2 as well as having an instrumental birth, which makes women living with obesity who are pregnant high risk.

Knight *et al.*, (2019) reported a non-significant drop in the maternal mortality rate in the UK due to obstetric haemorrhage from 2011 to 2017. Relph *et al.*, (2021) reviewed the data for obstetric haemorrhage, classed as >1500ml, and BMI class in

England, Wales and Scotland and found a clear rise in the number of women affected when BMI was above the healthy range. Nulliparous women were most affected with a doubling of percentage affected between a healthy BMI and one ≥40kg/m^2. The figures for England showed an increased number across the BMI range from healthy to severe obesity for both nulliparous and multiparous women, for Ireland a similar picture can be seen except the highest number of women with a PPH are in the BMI category 35-39.9kg/m^2, for Scotland PPH is only recorded as greater than 500ml which makes the number of women affected look huge, however the same picture of increased numbers across the BMI ranges is seen.

Sebire *et al.,* (2001) reported a 16% increased risk of PPH with overweight, and a 39% increase with obesity when compared to healthy weight BMI. Heslehurst *et al's* meta-analysis in 2008 found a 20% increased risk of PPH in the obese range, and 43% in the morbidly obese range when compared to the healthy BMI range. Rahman *et al.,* (2015) found an even greater risk for PPH in the overweight BMI range (more than 3-fold greater than seen in the healthy BMI range), and 3.5-fold greater risk in the obese BMI range when they reviewed papers from low-to-middle income countries.

2.3.2.3 Macrosomia

Macrosomia refers to a fetal-or-birth weight of more than 4000g or 4500g with extreme macrosomia being a birth weight beyond 5000g (Beta *et al.,* 2019; Caughey, 2015; Hehir *et al.,* 2015). Modifiable risk factors for the condition include the mother's BMI and weight gain above recommendations during pregnancy (Goldstein *et al.,* 2017; Baugh *et al.,* 2016; Hehir *et al.,* 2015; Davies *et al.,* 2010; Fitzsimons *et al.,* 2009), and, as reported in a study by Nkwabong and Nzalli, (2014), the father's BMI.

Women who have hyperglycaemia due to uncontrolled diabetes mellitus of any form, can be at higher risk of producing a baby with macrosomia due to the high levels of glucose passing into the fetus which is then stored as adipose tissue (NICE, 2020; Kamana *et al.,* 2015). Gestational diabetes mellitus is linked to an increased risk of macrosomia when compared to those without (NICE, 2020; Kamana *et al.,* 2015). Esakoff *et al.,* (2009) looked at perinatal outcomes in women with and without GDM, who had delivered babies with macrosomia (birthweight >4000g). Results of this study showed that to have a macrosomic baby and GDM increased the risk of neonatal hypoglycaemia by 2.5-fold and tripled the risk of respiratory distress syndrome. The babies were 16-times more likely to suffer shoulder dystocia, and nearly 42-times more likely to have a brachial plexus injury than those born to women without GDM, and not having a macrosomic baby.

A recent review by Beta *et al.,* (2019) looked at complications for both the fetus and mother due to macrosomia classed here as a birth weight above 4000g, and severe macrosomia as a birth weight above 4500g and without reference to weight or BMI. They reported that in pregnancies with a birthweight >4000g certain maternal and neonatal complications increased when compared to a birthweight <4000g (Beta *et al.,* 2019). These included emergency caesarean, post-partum haemorrhage (PPH), and obstetric anal sphincter injury (OASIS) for the mother, and shoulder dystocia, obstetric brachial plexus injury (OBPI), and birth fractures for the neonate (Table 2.2).

Table 2.2 Results summarised from the Beta et al., (2019) paper to show the pooled analysis (random effects) odds ratio and 95% confidence intervals (CI) for adverse outcomes for mother and baby with macrosomia when compared to those without.

	Birthweight >4000g Odds ratio (95% CI)	**Birthweight >4500g** Odds ratio (95% CI)
Mother:		
Emergency caesarean	1.98 (1.80-2.18)	2.55 (2.33-2.78
PPH	2.05 (1.90-2.22)	3.15 (2.14-4.63)
OASIS	1.91 (1.56-2.33)	2.56 (1.97-3.32)
Neonate:		
Shoulder dystocia	9.54 (6.67-13.46)	15.64 (11.31-21.64)
OBPI (Obstetric Brachial Plexus Injury)	11.03 (7.06-17.23	19.87 (12.19-32.40)
Birth fractures	6.43 (3.67-313.33)	8.16 (2.75-24.23)

As the increased risks are so well reported, interventions to reduce macrosomia have been attempted. Walsh *et al.,* (2012) ran a randomised controlled trial (the ROLO study) that compared a dietary intervention of a low glycaemic index diet compared to no diet intervention with the main outcome measure being birthweight. The women within the study had previously had a macrosomic baby, had BMI>25kg/^{2}, and did not have GDM at recruitment. Their results showed no statistical difference between the groups for birthweight but a significant improvement in weight gain throughout pregnancy, and glucose tolerance for the intervention group (Walsh *et al.,* 2012).

2.3.2.4 Shoulder dystocia

Any baby can suffer from shoulder dystocia, a condition in which the shoulders are too large to move through the birth canal, however there are several factors that have been identified that appear to increase the risk for this condition. These include babies who have a birth weight above 4000g (Hansen and Chauhan, 2014; Gherman *et al.,* 2006), babies that are macrosomic (Gherman *et al.,* 2006), have a mother with

diabetes mellitus (Gherman *et al.,* 2006; Ehrenberg *et al.,* 2004; Nesbitt *et al.,* 1998), have a mother who is short (Dyachenko *et al.,* 2005), there has been a previous shoulder dystocia or a mother who has a BMI ≥30kg/m^2 (Crofts *et al.,* 2012; Ehrenberg *et al.,* 2004). Shoulder dystocia can lead to instrumental intervention, caesarean section, brachial plexus injury (Crofts *et al.,* 2012; Gherman *et al.,* 2006; Nesbitt *et al.,* 1998), bone fractures in the fetus (Crofts *et al.,* 2012; Gherman *et al.,* 2006), hypoxic brain injury (Crofts *et al.,* 2012; Gherman *et al.,* 2006; Nesbitt *et al.,* 1998), sudden cardiac arrest (Dajani and Magann, 2014), and perinatal mortality (Dajani and Magann, 2014; Nesbitt *et al.,* 1998). Maternal complications include a higher incidence of PPH, episiotomy and second- and third-degree tears (Crofts *et al.,* 2012; Gherman *et al.,* 2006), uterine rupture and psychological stress (Dajani and Magann, 2014). As the risks for this condition can be specifically linked to obesity and GDM is more likely in the obese population it is vital to try and reduce weight gain in pregnancy with the aim of reducing GDM.

2.3.2.5 Stillbirth

Stillbirth is defined as a baby that dies in utero after 24 weeks of pregnancy and is born dead (NHS, 2021). Numerous review papers report an increased risk of stillbirth in women with overweight or obesity (Davies *et al.,* 2010; Flenady *et al.,* 2011; Fitzsimons *et al.,* 2009). Specifically in the UK, CMACE (2010) reported a stillbirth rate of 8.6 per 1000 singleton pregnancies compared to the general population rate of 3.9 per 1000. More recently NMPA reviewed births in England, Wales and Scotland between 1st April 2015 and 31st March 2017 and found that as maternal BMI increased so did the rate of stillbirths, with the highest figure being for those with a

BMI ≥ 40kg/m^2, 0.6% of births compared to 0.3% in the healthy or underweight BMI range (Relph *et al.,* 2021).

Lindam *et al.,* (2016) undertook a case-control study in Sweden and found that a BMI ≥30kg/m^2 increased the risk of stillbirth, an effect also seen when the researchers looked at sister control analyses indicating that genetics or familial factors were not significant. Zhu *et al.,* (2021) did a nationwide survey in China to look at rates of stillbirth and factors that may increase risk. The BMI ranges used were those appropriate to the population therefore a pre-pregnancy BMI between 24-27.9kg/m^2 is classed as overweight, and a BMI ≥28kg/m^2 is classed as obesity (Zhu *et al.,* 2021). This survey found that a pre-pregnancy BMI in the obesity range increased risk of antepartum stillbirth only (Zhu *et al.,* 2021).

Yao *et al.,* (2017) carried out a retrospective cohort study which looked at gestational weight gain and risk of stillbirth using the US Institute of Medicine 2009 weight gain recommendations for singleton pregnancy (Rasmussen, Yaktine & IOM, 2009). Weight gain above the IOM recommendation increased the risk of stillbirth with morbid obesity to a ratio of 22.4 per 1000 births compared to the recommended weight gain where the ratio was 7.4 per 1000 births (Yao *et al.,* 2017). The ratio of stillbirths for healthy BMI and recommended and excessive weight gain was 1.2 per 1000 births. These figures are considerably higher than those in the recent UK report (Relph *et al.,* 2021). Interestingly, Davis *et al.,* (2014) used data from the Pregnancy Risk Assessment Monitoring System which runs in several US states and found that women of BMI ≥30kg/m^2 and who gained excessive weight based on the IOM 2009 recommendation were less likely to suffer a stillbirth, OR 0.51 95% CI 0.31-0.84.

2.3.3 Obesity and neonate

2.3.3.1 Preterm babies

A preterm baby is classed as one that is born alive before 37 weeks gestation. This is recognised as one of the main causes of death in neonates globally (March of Dimes, 2012; WHO, 2018). When overweight or obesity BMI class is compared to a healthy BMI class with regards to preterm birth <37 weeks gestation there is evidence that it acts as a protective factor (Sebire *et al.,* 2001), and this is also seen with GWG > IOM recommendations (Goldstein *et al.,* 2018; Goldstein *et al.,* 2017; Baugh *et al.,* 2016). This reduction in risk is even bigger when looking at preterm birth < 32 weeks gestation, by 27% in the overweight BMI category and 19% in the obesity BMI category (Sebire *et al.,* 2001). There is also evidence that overweight, obesity, or super-obesity has no impact on preterm birth when comparison is made to healthy weight women (Baugh *et al.,* 2016; Rahman *et al.,* 2015; Alanis *et al.,* 2010; Guelinckx *et al.,* 2008). However, despite this there is also a significant body of research that suggests the greater the BMI, or GWG the more likely it is that the pregnancy will end with preterm birth (Ram *et al.,* 2020; Marchi *et al.,* 2015; Shaw *et al.,* 2014).

The UK NMPA report (2021) clearly indicates that greater BMI is a risk factor for a preterm birth between 32-36 weeks with figures rising from 6.2% in healthy weight women, to 7.5% in women with a BMI ≥40kg/m^2 (Relph *et al.,* 2021). This increase was also reported in the research by Ram *et al.,* (2020) where singleton births < 32 weeks in women who were overweight, and all obese classifications (I, II, III), were more likely to occur preterm. However, they report this may be due to "provider-

initiated preterm birth" (Ram *et al.,* 2020). There is nothing recommended within either the Royal College of Obstetricians and Gynaecologists (RCOG) green-top guidance or NICE guidance with regards delivering the baby early when the woman has obesity (Denison *et al.*, 2018; NICE, 2019; NICE, 2021), but in pregnancies which are complicated by pre-eclampsia, preterm delivery is the only effective medical treatment.

Shaw *et al.,* (2014) looked at pre-pregnancy BMI and preterm birth in a cohort of women in the United States. They found that the greatest risk of birth <27 weeks was in primiparous women with a pre-pregnancy BMI of $\geq 30 kg/m^2$ irrespective of ethnicity – in this study non-Hispanic white, Hispanic, and non-Hispanic Black (Shaw *et al.,* 2014). Researchers in the UK used the Born in Bradford data to try and identify differences between perinatal outcomes for White British women and Pakistani women (Bryant *et al.,* 2014). They found that there was no significant difference in risk of preterm birth with Pakistani women even when using ethnicity-appropriate BMI cut-offs, and that a higher BMI was protective for White British women (Bryant *et al.,* 2014). A similar finding was made by Stacey *et al.,* (2016), although they also used the Born in Bradford data.

2.3.3.2 Small-for-gestational age (SGA) and Large-for-gestational age (LGA) infants

There are several different definitions used for a small-for-gestational age (SGA) infant however the RCOG green-top guideline for 'investigation and management of an SGA infant' use an estimated fetal weight below the 10th centile, or severe SGA as below the 3rd centile (Robson *et al.,* 2014). This guideline makes clear that there are two different centile charts that can be used to identify risks for the infant (Robson *et*

al., 2014), and that a customised centile chart is better able to identify high risk infants born SGA who could suffer more adverse events (Gardosi & Francis, 2009; Clausson *et al.,* 2001). The risk of having a SGA infant is increased with higher maternal BMI on the customised charts only with Clausson *et al.,* (2001) reporting a two-fold increased risk of SGA with a BMI of 25-29.9kg/m^2 and five-fold increased risk with a BMI >30kg/m^2 in a population of predominantly Nordic women. Gardosi & Francis (2009), using a different population of women, found the same outcomes. The Gestation Related Optimal Weight software can be used to produce an individualised growth chart although may not be used in all maternity settings (Gardosi *et al.,* 2018).

The main issue with a high maternal BMI is the difficulty in measuring symphysis fundal height which is used in primary care to identify an SGA baby (Robson *et al.,* 2014). A 2022 review found that maternal BMI ≥30kg/m^2 plus ethnicity being Black, Asian American or Hispanic increased the risk of a baby classed as SGA or low birthweight (<2500g; Fakhraei *et al.,* 2022). Rahman *et al.,* (2015) reviewed studies that looked at low-and-middle income countries and found the risk of SGA was increased in underweight women and this risk reduced as the BMI increased irrespective of the country the data was from. UK data from the NMPA showed a decreasing number of SGA babies as BMI increased moving from a figure of 15.6% in women with a BMI <18.5kg/m^2, to 5.1% in women with a BMI ≥40kg/m^2 (Relph *et al.,* 2021). When GWG is considered using the US IOM 2009 recommendations (Table 2.1), women with weight gain above the recommendations appear less likely to have an SGA baby (Goldstein *et al.,* 2018).

The bigger risk for women with a high BMI, is a baby that is classed as large-for-gestational age (LGA) defined as a baby >90th centile for gestational age (Copel *et al.,* 2017). In the UK, NICE NG121, although talking about LGA babies, relies on birthweights that come under the macrosomia definition, see section 1.3.2.3, rather than the LGA one above (NICE, 2019). The NMPA report showed that as maternal BMI increased across the categories the percentage number of LGA babies increased dramatically from 5% with a BMI < 18.5kg/m^2, to 22% in those with a BMI ≥40kg/m^2 (Relph *et al.,* 2021). Sebire *et al.,* (2001) noted the same outcome when comparison was made between a healthy BMI and either overweight or obesity with an AOR 1.57 CI 1.50-1.64, and AOR 2.36 CI 2.23-2.50 respectively. With super-obesity, Alanis *et al.,* (2010) reported an AOR 1.8 CI 1.34-2.32. A GWG above IOM recommendations has repeatedly been linked to an increased risk of an LGA infant when the evidence base is reviewed (Goldstein *et al.,* 2018; Goldstein *et al.,* 2017; Siega-Riz *et al.,* 2009). The risks associated with an LGA (or macrosomic infant) include maternal, labour and birth, and neonate adverse outcomes (Table 2.2, section 2.3.2.3).

2.3.3.3 Obesity and infant feeding

There is a global consensus that nutrition for a baby should exclusively be provided by breast milk for the six months of their life (UNICEF, 2018; Denison *et al.,* 2018; SACN, 2018; WHO, 2017; NICE, 2008). The Baby Friendly Initiative was launched in 1991 with the intention of supporting breastfeeding practices worldwide and has been adopted by many countries including the UK (United Nations International

Children's Emergency Fund (UNICEF), 2019; Rollins *et al.,* 2016; NICE, 2014; Entwistle, 2013)

Breastfeeding not only offers positive benefits for the child but also the mother (UNICEF (United Nations International Childrens Emergency Fund), 2018; SACN, 2018; Rollins *et al.,* 2016; McFadden *et al.,* 2017; Victora *et al.,* 2016; Horta & Victora, 2013; Kramer & Kakuma, 2012). Rollin *et al.,* (2016) also argue that breastfeeding is a healthier alternative for the environment than infant formula. Despite this, breastfeeding rates vary around the world with low-to-middle income countries having higher rates than high income countries (UNICEF, 2018; Victora *et al.,* 2016). UNICEFs report 'Breastfeeding. A Mother's gift, for every child' (2018) gives figures for the percentage women who have ever breastfed. In the UK this is 81%, for Ireland 55%. More recent figures from the Office for Health Improvement and Disparities (2021) collated for England only, report that the rate for breastfeeding at 6-8 weeks post-partum is 47.6%. Data from the 'Born in Bradford' study was analysed to see whether women were less likely to breastfeed if they were exposed to *"…harsh environments…"* (Brown & Sear, 2019). This study had many women that identified as being of Pakistani origin with White British being the second largest group in the dataset. Following analysis, Brown and Sear, (2019) found links between breastfeeding initiation and increased social-economic disadvantage with fewer White British starting breastfeeding, OR 0.77, 95% CI 0.71-0.84 than the Pakistani-origin women. Breastfeeding duration also reduced with socio-economic disadvantage in the White British women (HR 1.11, 95% CI 1.01-1.20) when compared to the women of Pakistani origin. Brown *et al.,* (2010) also found that deprivation was linked to a reduction in the length of breastfeeding in two populations of women based in

England and Wales. Their statistical model showed that use of the Indicators of Multiple Deprivation was a good predictor of breastfeeding duration.

The NMPA report showed women of higher BMI were less likely to breastfeed at the first feed especially if they were multiparous (Relph *et al.,* 2021). In England just under 72% of women with a BMI <18.5kg/m^2 breastfed at first feed with this figure dropping to 69.4% on discharge this compared to 60.8% of women with a BMI ≥ 40kg/m^2 breastfeeding at birth and 56.6% on discharge (figures for nulliparous only). The breastfeeding figures are lower for Scotland for all BMI categories and no figures are available for Wales.

The UKs Office for Health Improvement and Disparities published a report in 2022 which looked at a range of data to see if there was any link between obesity and breastfeeding and risk for future overweight or obesity for mother or child (at age 4-5). They found that where breastfeeding levels had been high then the risk for future overweight or obesity was reduced (Office for Health Improvement and Disparities, 2022). Where there were known risk factors for high levels of obesity in a population, for example deprivation, the risk of being overweight or obese at age 4-5 was increased if the child had not been breastfed up to 6-8 weeks of age. The same increased risk was seen for the mothers in this scenario.

A qualitative study undertaken by Claesson *et al.,* (2018) looked at breastfeeding experiences for a group of Swedish women living with obesity. They undertook interviews with 11 women that had breastfeeding experience and had given birth within the previous two to eighteen months. Following thematic analysis of the transcripts three main themes emerged – Breastfeeding, a part of motherhood, the

challenges of breastfeeding, and support for breastfeeding. In the main the feedback was positive, but it was also clear that there were both practical difficulties and challenges with regards the process of breastfeeding due to issues with the size of their breast and the baby being unable to latch on properly, positioning for breastfeeding, and levels of support.

As described in earlier sections, women who are living with obesity are more likely to have a preterm delivery due to pregnancy complications and are also more likely to require a cesarian section. Neither scenario has a major impact on their ability to breastfeed. When infants are born preterm the decision on whether to breastfeed is based on their health and ability to suckle. The placenta produces prolactin and human chorionic somatomammotropin from early in pregnancy, so the breasts are ready to lactate from mid-gestation. After delivery, once placentally-derived oestrogen and progesterone concentrations fall to a point where prolactin production from the anterior pituitary is no longer inhibited, full lactation will begin (Langley-Evans, 2021). If a preterm baby is too sick to suckle then the ideal approach to feeding is for the mother to express milk and this is used as the basis for enteral feeding (Elliot and Golombek, 2022).

2.3.4 Obesity and risks in later life

2.3.4.1 Risks to child

In addition to increasing risk of poor pregnancy outcomes, obesity has the capacity to programme fetuses to be at greater risk of cardiometabolic disorders later in life. An extensive body of evidence from prospective and retrospective cohorts, as well as record linkage studies, demonstrates associations of maternal obesity and/or

gestational diabetes with cardiovascular disease, as well as type-1 and type-2 diabetes (Langley-Evans, 2022). Follow-up of 2.23 million Swedish births between 1992 and 2016 found that diagnosis of cardiovascular disease between the ages of 1 and 25 years was more likely in those whose mothers had been obese in pregnancy than it was in those whose mothers had been of ideal weight (Razaz *et al.,* 2020). The risk was graded so that, although those whose mothers had BMI between 30 and 34.9 kg m–2 were 16% more likely to have cardiovascular disease, this increased to 2.51-fold if maternal BMI was over 40 kg m^2. The range of disorders related to maternal obesity include childhood obesity (Herring *et al.,* 2012). A longitudinal follow-up of the 1956 UK Birth Cohort found a J-shaped relationship between birthweight and BMI in 33-year-old men and this appeared to be heavily driven by maternal but not paternal weight (Parsons *et al.,* 2001). A Finnish study found that the risk of abdominal obesity was greater in young adults who had been born small-for-gestational age (Laitinen *et al.,* 2004). There is an increased risk of autism and neurodevelopmental disorders (Krakowiak *et al.,* 2012; Kolevzon *et al.,* 2007) and death from cardiovascular disease in adult offspring of an obese or overweight mother (Reynolds *et al.,* 2013). Studies in animals suggest that these associations are underpinned by adaptations that occur in foetal life, which remodel the structures of major organs, including the brain, kidney and pancreas (Langley-Evans, 2014; Langley-Evans, 2022).

2.3.4.2 Risks to mother

2.3.4.2.1 Pelvic floor dysfunction/disorders (PFD)

Pelvic floor dysfunction (PFD) is a condition where the muscles that support the pelvic floor weaken which leads to a range of unwelcome symptoms. These can include urinary incontinence and prolapse of the pelvic organs and if not dealt with can lead to a decrease in quality of life. Women with a BMI within the overweight or obese range are already dealing with excess pressure on their pelvic organs due to the weight. Pregnancy hormones will further relax the muscles and worsen any symptoms. If there is no weight loss post-pregnancy then these women may suffer with worsening PFD.

There are risk factors linked to pregnancy and birth which can increase the likelihood of future PFD (NICE, 2021), as well as direct links to overweight and obesity with pregnancy exacerbating the chance (Durnea *et al.*, 2017; Sangsawang, 2014) having an emergency caesarean or instrumental delivery is known risk factor that can lead to PFD symptoms (NICE, 2021; Durnea *et al.,* 2017). Durnea *et al* (2017) looked at data from the Screening for Pregnancy Endpoints for their own nested study Prevalence and Predictors of Pelvic floor dysfunction in Primips (4P). Analysis of the 'Australian Pelvic Floor Questionnaire' data which collected information pertaining to pre-pregnancy and one-year post-pregnancy. PFD symptoms are broken down into urinary dysfunction, urgency urinary incontinence, urinary urgency – combined as bladder score, fecal dysfunction, fecal urgency – combined as bowel score, sexual dysfunction, vaginal tightness/vaginismus, dyspareunia – combined as sexual score, pelvic organ prolapse, prolapse sensation – combined as prolapse score. In a

multivariate analysis high hip circumference (>95cm) was linked to a poor bladder section score (high number of symptoms), OR 1.5 CI 1.05-2.28 (Durnea *et al.*, 2017). High bowel score was linked to high hip circumference (>95cm) OR 1.4 CI 1.02-1.85, and high waist circumference (>95cm) OR 1.01 CI 1.001-1.03. Finally, a high prolapse section score was linked to vacuum delivery OR 6.4 CI 2.23-18.16, and forceps delivery OR 8.8 CI 3.05-25.23 both types of delivery that are likely to be more common in overweight and obese women (see section 2.3.2.1.1).

Whitcomb *et al.,* 2009 conducted a study that looked at prevalence of PFD in a population (n=1155) of women who were all above a BMI of 35kg/m^2. Multivariate analysis of the data adjusted for age, mode of delivery, and parity and using the BMI group 30-34.9kg/m^2 as reference showed there was no link to an increase in PFD.

2.4 Teachable moment

The term 'Teachable moment' is based on a theory by Robert Havighurst in which he recognised that there are certain periods within an individual's life where they could perform a developmental task with greater success than at a different period in time (Havighurst, 1948). Ongoing development of this idea eventually led to the recognition of these points in time being teachable moments specifically if they included a cueing event, for example pregnancy, which incorporated the three elements of; levels of emotion being increased, awareness of risks and opportunity to improve positive outcomes, and that the individual's role within society has changed due to the cueing event (McBride *et al.,* 2003). Within the last two years alone the concept of a teachable moment has been used for reducing parental smoking (Mahabee-Gittens *et al.,* 2020), addressing biased patient behaviour (Sheffield *et al.,*

2021), preventing opioid-induced constipation by increasing awareness of side effects for this medication in prescribers (Saha *et al.,* 2020), reducing behavioural risk factors in those hospitalised with cardiovascular disease (Siewart-Markus *et al.,* 2022), and increasing adherence to physical activity guidance in people with chronic disease or who are classed as older adults (Collado-Mateo *et al.,* 2021).

Pregnancy itself meets the three elements suggested as a teachable moment (McBride *et al.,* 2003), and as such many interventions have been suggested for this period to improve outcomes for the mother and child, both in the present and future (Kebbe *et al.,* 2021; Phelan, 2010).

Lorenz *et al.,* (2022) undertook a qualitative study which looked at feedback from pregnant women and healthcare providers (gynaecologist, assistant, or midwife). They found that women in their first pregnancy felt a need for more information than those who already had children, and that this was recognised by the healthcare provider. All the pregnant women reported taking more care of themselves due to the motivation of being healthy for their unborn child however the providers felt that the women needed more education and health literacy was low. An interpretative phenomenological analysis of two women in their first pregnancy found that they had made all the healthy changes themselves and did not need further input from health professionals making the idea of their pregnancy being a teachable moment by external support unnecessary (Atkinson *et al.,* 2016). This makes the need for training of the individual supporting the pregnant woman important to ensure they are giving the support that is wanted and not just seen as needed.

If pregnancy is a teachable moment, then effective exploitation of that moment requires somebody to do the teaching effectively (Langley-Evans et al., 2022).

Obesity can be a difficult subject for health professionals to discuss with patients. There is evidence that, in primary care, both patients and healthcare professionals may be reluctant to raise the issue of body weight and therefore find it difficult to exploit the opportunity of having a more receptive patient. Midwives often bear the responsibility for delivering health education and promoting a healthier lifestyle in pregnancy. Although being in regular contact with women and carrying a high level of trust as a source of information, they are not well equipped for dealing with conversations about overweight (Soltani *et al*., 2017; Heslehurst *et al*. 2007) Midwives may lack the confidence to raise the issue of obesity and fear a hostile response from women that they are trying to develop professional rapport (Mulherin et al., 2013). With high workloads and time pressure, it can be difficult to maintain an awareness of unconscious bias around obese women and implement personal strategies to overcome that bias (McCann et al. 2018). Atkinson and colleagues reported that midwives may choose not to refer women with obesity to antenatal weight management services if they fear a hostile response, or if they perceive that a women may not be interested (Atkinson et al. 2017). Fear of hostility is not unreasonable as women who find the process of referring to a weight management service insensitive do report being offended by conversations with health professionals about their weight. Poor communication between midwives and women living with obesity may be a barrier to accessing relevant services (Atkinson et al. 2013) and may explain why uptake of weight management services is poor. Women want honest and respectful communication that provides personalised information about risk and facilitates informed lifestyle choices without scaremongering, and without proportioning blame about the causes of overweight (Furber *et al.,* 2011).

Midwives attitudes may result in inequality among women with high-risk pregnancies (Atkinson et al., 2017).

Chapter 3 Antenatal weight management for women living with obesity

3.1 Weight management

As discussed above, excess weight prior to, and during pregnancy markedly increases risks to both mother and baby, with short- and longer-term consequences become more likely. Current clinical and public health guidelines in the UK stress the importance of women trying to reduce weight before becoming pregnant or managing their weight gain during pregnancy.

3.1.1 NICE guidance

The National Institute for Health and Care Excellence, or NICE (National Institute of Clinical Excellence), produces guidance for a range of health and social care conditions. A number of these cover pregnancy (Table 3.1) and include recommendations for weight management for healthy outcomes. The advantage of using NICE guidance to support an intervention, is that it is based on not only the latest research, but it also has input from those stakeholders that will be affected by the final guidance. Stakeholders include a range of people from commissioners for services to those who will use that service. In addition to this, these guidelines also highlight the gaps within the research base, which are often vast, and make recommendations for future research. Many NICE guidelines have only limited reference to pregnancy and overweight/ obesity but when linked to the other, more specific ones, can create an overall care package for women during pregnancy.

Table 3.1 NICE guidance available between 2006 and 2015 that include reference to weight management in pregnancy or discuss behaviour change in interventions that include weight management in pregnancy.

Title	Guidance number	Guidance type	Year produced
Weight management before, during, and after pregnancy	27	Public Health	2010 Due to be updated 2023
Diabetes in pregnancy: management from preconception to the postnatal period	3	NICE guideline	2015
Obesity Prevention	43	Clinical guideline	2006
Maternal and child nutrition	11	Public health	2008 Due to be updated 2023
Behaviour change: individual approaches	49	Public health	2014
Behaviour change: general approaches	6	Public health	2007
Hypertension in pregnancy: diagnosis and management	133	NICE guideline	2019
Inducing labour	207	NICE guideline	2021
Intrapartum care for healthy women and babies	190	Clinical guideline	2014
Intrapartum care for women with existing medical conditions or obstetric complications and their babies	121	NICE guideline	2019
Antenatal care	201	NICE Guideline	2021

Arguably, the most relevant sources of information for health professionals dealing with pregnant women who are overweight or obese, are guidance PH27, ‘Weight management before, during, and after pregnancy’ (2010), and PH49 ‘Behaviour

change: individual approaches'. NICE PH27 (2010) is due to be updated in 2023. The emphasis of the PH27 guidance is the prevention of excessive weight gain during pregnancy (NICE, 2010), and how to support an individual to make the changes in their behaviour that will achieve this (NICE, 2014).

Whilst NICE PH27 (2010) focuses on guidance for all pregnant women, the main emphasis is on those with a BMI $\geq$30kg/m^2. It does not cover women classed as underweight (BMI <18kg/m^2). Advice is centred around being a healthy weight prior to pregnancy, not gaining too much during pregnancy, and losing any excess weight post-pregnancy. The way to do this, according to this guidance, is to follow the dietary guidelines, and stay active. No weight loss is recommended during the pregnancy or breastfeeding periods. Emphasis is on support via community-based services that incorporate behaviour change techniques.

Using behaviour change techniques to support people with choosing a healthier lifestyle has become more popular and NICE released two specific public health guidance for this in 2007 – Behaviour change: general approaches (NICE, 2007), and in 2014 – Behaviour change: individual approaches (NICE, 2014). Both guidelines are geared towards professionals that have public health involvement in behaviour change towards a healthier lifestyle rather than the public. This guidance sets out the best way to commission services whether they are for individuals or populations (NICE, 2014). The detail in this guidance allows a range of organisations to follow an evidence-based approach when putting interventions together so that they empower the individual/population to make healthy changes to their life (NICE, 2014). The NICE PH6 (2007) guidance is non-specific on which behaviour change model to use

within an intervention, this is because, at that time, there was little evidence to support a particular technique. It does, however, go into more detail about concepts within human psychology that are known to be effective in supporting behaviour change (NICE, 2007). There are some similarities in the recommendations in that both see goal setting and planning as vital parts of any intervention (NICE, 2014; NICE, 2007). The 2014 guidance has more detail on how to manage behaviour change interventions but used together all aspects from commissioning to delivery are covered.

Whilst the NICE guidelines can be a useful resource for the management of weight and weight gain during pregnancy, they are open to interpretation by individual clinicians and as a result there will be huge variation in how they are applied across the country and even within hospital trusts. The key feature of the NICE guidelines is that they indicate the requirement for behaviour change techniques to be used in managing weight gain, but do not specify how those techniques should be applied, consider their efficacy in large-scale primary care or advocate training in such techniques as a core element of the training of doctors and allied health professionals.

Across the world, researchers have recognised the need to develop effective interventions to target weight issues during pregnancy as well as in the pre-pregnancy period, as mandated by UK clinical guidance. There are many published interventions targeting women living with obesity, that have attempted to improve maternal diet and/or physical activity during pregnancy in order to prevent excessive weight gain and improve pregnancy outcomes. The following sections will first evaluate the outcomes of the most significant trials of weight management interventions (Simpson

et al., 2021; Poston *et al.,* 2015; Dodd *et al.,* 2014) and then consider some relatively small and pragmatic interventions, some of which have not been published.

3.1.2 Pregnancy intervention studies: Randomised controlled trials (RCTs)

There have been a number of weight management in pregnancy randomised controlled trials trialled around the UK for women of a range of BMI categories. The UK Pregnancies Better Eating and Activity trial (UPBEAT) aimed to positively change eating behaviours and increase physical activity levels in pregnant women with obesity. Content was delivered through a combination of a single one-to-one sessions with a health trainer followed by eight sessions in a group setting (Poston *et al.,* 2013). A pilot study ran between 2010 and 2011 across the UK with the primary outcome at that stage being to see a change in dietary and physical activity. Results at this stage indicated that the intervention group had a lower total energy intake, glycaemic load, lower fat /% energy intake, saturated fatty acid / % energy intake, and increased protein / % energy intake and higher fibre intake grams/ day. No treatment effect was seen between groups for any level of physical activity using accelerometer data but self-reported physical activity for the moderate-to-vigorous level showed an increase. This discrepancy may indicate an issue with hypothetical bias where participants are reporting what they feel they should be doing rather than what they are doing (Buckell *et al.*,2 020). No difference was seen between groups for GDM, LGA or birth weight above 4000g (Poston *et al.,* 2013). GWG was not initially reported as this was not an outcome of interest.

A larger trial was undertaken following the initial pilot with the primary outcome being to reduce the incidence of GDM in this population and secondary outcomes

including an improvement in diet quality improvement, level of physical activity, GWG, anthropometrics, biochemical findings, maternal outcomes – pregnancy and birth, and a range of neonate outcomes (Poston *et al.*, 2015). Results again showed that those in the intervention arm of the study had a better overall diet quality including a lower energy intake, decreased glycaemic load per day, lower carbohydrate/ % energy intake, and lower total fat and saturated fat intake and an increase in protein/% energy, and fibre intake than the non-intervention arm. However, no statistical comparison was run for the intervention group baseline data compared to the 27-28 weeks, so it is unclear if the intervention had a true effect in that group for these outcomes. There was no difference between physical activity levels between the two groups (Poston *et al.*, 2013). The positive changes in diet did not influence the incidence of GDM or LGA babies, the trial's primary outcome measures. However, GWG was reduced by a modest average 0.55 kg by the intervention.

The Healthy Eating and Lifestyle in Pregnancy (HELP) was a cluster randomised trial across England and Wales (John *et al.*, 2014). This used a group setting, with additional one-to-one sessions if requested, to deliver advice about healthy eating and physical activity throughout pregnancy and post-partum period. Advice was delivered by Slimming World consultants with additional support offered by the intervention midwives. Preliminary results from this study showed that there was no significant difference in BMI between the intervention and non-intervention groups at 12 months post-partum, which was the primary outcome for the trial (oral presentation at UKSBM 2014). These results were formalised in a paper in 2021 where no significance was seen in BMI 12 months post-partum. There were improved diet

quality scores with the intervention group having a healthier diet, eating more fibre, and lower levels of alcohol intake as per measures in the protocol (Simpson *et al.*, 2021; John *et al.*, 2014).

Daley et al., (2015) undertook a RCT feasibility study based on self-regulation theory. They recruited women within the healthy weight or overweight categories only and incorporated weighing as part of the self-regulation process using the US IOM categories for healthy weight gain as the target (Table 2.1). They found that nearly a quarter of those in the intervention group (23.5%) gained more than the IOM recommendations. As this was a feasibility trial no further statistical analysis was undertaken. The qualitative part of this RCT included semi-structured interviews with the midwives involved with delivery of the intervention and women that attended. Participants of the intervention reported that they were more active during their pregnancy and felt that the intervention was useful in keeping them motivated in monitoring their weight gain. Midwives reported that the intervention fitted well alongside standard antenatal care without adding too much time, a resource that is in short supply for clinicians. This feasibility study was deemed successful enough to run a much larger RCT (Daley et al., 2019). The outcome of this study was that the intervention was not successful in meeting its primary outcome of reducing excessive weight gain during pregnancy. They also found no difference between the intervention and control groups for the secondary outcomes of reduced anxiety and depression scores, or increased physical activity (Daley et al., 2019). This appears to indicate that the self-regulation approach to weight management in pregnancy is not a useful tool in promoting healthier behaviours that would reduce weight gain.

Similar lifestyle and healthy eating interventions have been trialled across the world. The Limiting Weight Gain in Pregnancy trial (LIMIT), was a multicentre randomised

trial in South Australia (Dodd *et al.,* 2014). The intervention consisted of dietary and physical activity advice delivered by a research dietitian and trained research assistants over six contacts, three by phone, for women with overweight or obesity. The primary outcome measure was the incidence of LGA with secondary outcomes linked to maternal and infant health. Intention-to-treat (ITT) analysis results showed that there was no difference in the rate of LGA births between the intervention and non-intervention groups and significance was only seen for a 18% reduction in risk of birth weight above 4000g between groups, and a reduction in antenatal length of hospital stay by 30%. Maternal mean weight gain was not impacted by the intervention. As LIMIT used ITT analysis they avoided attrition bias, however, the authors noted that attendance at the scheduled intervention appointments dropped from 87% at the first appointment to 77% at the second. This indicates a loss of compliance over time (Spencer & Heneghan, 2018).

The Feasibility of a Lifestyle-Intervention in Pregnancy to optimise maternal weight development (FeLIPO) cluster randomised control trial ran in Germany and also used lifestyle advice to promote changes in diet and physical activity to prevent excessive weight gain during pregnancy in a range of BMIs (Rauh *et al.,* 2013). Women received two one-to-one counselling sessions with a trained researcher and completed dietary records and the International Physical Activity Questionnaire long version for analysis. The primary outcome was whether women exceeded the weight gain recommendations of the US IOM, with secondary outcomes based on post-partum weight retention, and short-term obstetric and neonatal outcomes. Results of the FeLIPO trial showed that baseline characteristics of the intervention group were significantly different to those of the non-intervention arm. The intervention group

were older, had a lower pregravid and booking BMI, and later gestational age. The authors reported that most women approached wished to take part in the intervention arm (despite there being a randomisation process) and so the power calculation was re-run and more participants were enrolled in the study and a 2:1 ratio was used. This could indicate an element of volunteer bias (Brassey *et al.*,2017; Rauh *et al.,* 2013). Overall total weight gain was less in the intervention group but women in this group still gained more weight than the US IOM recommendations with a mean figure of 14.1±4.1kg. No breakdown between BMI categories was given (Rauh *et al.,* 2013). There were no significant differences between the groups for any of the pregnancy and birth outcome measures or physical activity. Energy intake stayed relatively static over the trimesters in the intervention group but increased in the control group and so was significant between the two.

Guelinckx *et al* (2010) undertook a randomised controlled trial which looked at the effect of a lifestyle intervention on dietary habits, physical activity levels and gestational weight gain – all primary outcomes - on obese pregnant women. The participants were split into 3 groups, the control group, a 'passive group' that only received written information used in the intervention, and the 'active' group who received the written information plus 3 group sessions with a trained nutritionist. The results of this RCT showed that there were no significant differences between the 3 groups for baseline characteristics or any of the secondary outcome measures which included gestational weight gain, and obstetric or neonatal complications. Physical activity levels dropped in all groups. GWG showed no statistical significance between any of the groups with a mean weight gain outside the US IOM guidance (Guelinckx *et al.,* 2010). Dietary intakes showed a reduced energy intake for active and passive

groups compared to the control, protein intake was significantly different between the control group compared to the other two, and also differed between trimesters with both the active and passive groups increasing their intake. Total fat intake showed no difference between groups, but a statistically significant change occurred over the trimesters with a decrease in both the active and passive groups. The change in total fat appeared to be a reduction in the saturated fat intake with a reduction through the trimesters for the passive and active groups, and between the passive and active and control group. Dietary fibre increased over the trimesters for the passive and active group and showed significance between the control group and two other groups, however mean intake was still below recommendation of 30g/d (Guelinckx *et al.*, 2010). Calcium intake increased over trimesters for all groups. Vegetable intake increased over trimesters in all groups but comparison between groups showed statistical significance in intake for the passive and active groups only. Whilst there was no difference between groups for both GWG and physical activity levels the results do show an impact on eating habits when information is given to the women, indicating that one element of the intervention showed promise.

The results from these large randomised controlled interventions show that there is no simple one-size-fits-all way to support overweight and obese women in managing their weight through their pregnancy. Meta-analyses and systematic reviews of weight management intervention programmes that use lifestyle and/or behaviour change show varying results, and further robust research in this area is recommended (Fair & Soltani, 2021; Yeo *et al.*, 2017; Thangaratinum *et al.*, 2012). Thangaratinam *et al.*, (2012) looked at randomised controlled trials) that involved dietary, physical activity or both in an intervention to limit GWG and reduce adverse outcomes for mother or

baby across all BMI categories. Overall, they found that any type of intervention had a positive impact on weight gain during pregnancy but were less effective at reducing adverse outcomes overall.

Yeo *et al.,* (2017) reviewed RCT interventions that targeted women who had overweight or obesity to see if they could identify what elements the intervention contained. Their analysis showed that the lowest GWG was achieved by clinician-led interventions (Yeo *et al.,* 2017). More recently a meta-review by Fair and Soltani, (2021) looked at 15 systematic reviews of interventions for the same population. This review reported that eight of the included papers had low or critically low confidence in the results following quality assessment, three were of moderate quality, and only three were of high quality. The certainly of the evidence provided overall for each outcome was classed as low or very low with serious risk of bias for all included reviews. Overall the evidence was not clear in terms of offering a benefit of undertaking a lifestyle intervention to reduce GWG and therefore risk of other adverse outcomes. There is, however, an interesting gap between the outcomes of large, highly controlled intervention trials and smaller, more pragmatic interventions in terms of outcome. In developing effective primary care approaches to managing maternal obesity, understanding the basis for this gap is of major interest.

3.1.3 Pregnancy intervention studies: Small interventions

There have been a number of relatively small-scale locally-based interventions around the globe each concentrating on limiting GWG for women living with obesity either as a primary or secondary outcome (Haby *et al.,* 2018; Robertson & Ladlow, 2018; Koleilat *et al.,* 2017; Opie *et al.,* 2016; Haby *et al.,* 2015; Raymond *et al.,* 2014;

Claesson *et al.,* 2014; de Keyser *et al.,* 2011; Mottola *et al.,* 2012; Shirazian *et al.,* 2010). The majority of these have used the US IOM guidance as a reference (Rasmussen, Yaktine & IOM, 2009), with the odd exception where an alternative figure of <7kg has been used (de Keyser *et al.,* 2011).

Shirazian *et al.,* (2010) compared a cohort of Latina /Black women (n=21) with a BMI >30kg/m^2 who had been enrolled in a lifestyle modification program with the aim of managing gestational weight gain within IOM guidance. This cohort was then matched to an historical cohort of women who had not been involved with the lifestyle modification program but delivered their baby within the same period. The programme focussed on eating a healthy diet and getting appropriate levels of exercise in order to prevent excessive GWG. Their results showed that the intervention did help to manage the GWG and keep it within the IOM guidance of between 5-9kg (IOM, 2009) however there was no difference in secondary outcomes linked to pregnancy, delivery, and fetal problems (Shirazian *et al.,* 2010). However, with such a small number of women involved these results, whilst encouraging, are not conclusive.

Robertson and Ladlow, (2018) undertook a pilot for a dietetic-led intervention to manage GWG in a town in the south-eastern Victoria region of Australia. They recruited 174 women with a BMI >35kg/m^2 of whom 87 were primiparous. The intervention offered dietetic counselling and goal setting support in order to achieve GWG within the IOM guidance (Robertson & Ladlow, 2018; Rasmussen, Yaktine & IOM, 2009). The authors reported that women who attended more than three of the intervention consultations gained significantly less weight than those who chose not

to attend ($p<0.05$) and, when compared to population figures for pregnant women with obesity, rates of caesarean delivery and macrosomia were lower. They also reported that there were 16% of participants (n=27) who lost weight during the intervention period but this was not linked to any harms to the baby. As a pilot study these results indicate that it would be worthwhile continuing this intervention with a larger population and more detailed analysis.

Mighty Mums was an intervention targeted at pregnant women who had a BMI $\geq 30/kg/m^2$ trialled in Sweden between 2011 and 2013 with the first results being published in 2015 (Haby *et al.,* 2015) and later results, after a larger cohort had completed the intervention in 2018 (Haby *et al.,* 2018). Mighty Mums was a midwife-led intervention with an emphasis on motivational interviewing as a style of making behaviours change in addition to making connections to the local community for further support for the women and access to a dietitian if needed (Haby *et al.,* 2018; Haby *et al.,* 2015). The intervention used a weight gain target of <7kg during pregnancy, a figure reported as being commonly used in antenatal healthcare setting in Sweden. The initial analysis showed promise with the women in the intervention group gaining less than the 7kg target compared to the control group (Haby *et al.,* 2015). In 2018, an intention-to-treat (ITT), and per-protocol (PP), analysis were undertaken which included a greater number of women from the Mighty Mums intervention, and compared these to a control group that included women from the same city's antenatal clinics plus a further number from a similar population elsewhere. The intervention appears to have developed from that which ran in 2015, as the later paper reports that participants could be offered additional individualised support from a range of healthcare practitioners dependant on their need (Haby *et al.,*

2018). With ITT analysis no significance was seen between groups for weight change throughout the pregnancy, whereas with PP analysis a significant difference was seen. The intervention population for ITT analysis was 438 participants whereas for PP analysis this dropped to 116 participants indicating the loss of participants did have an impact and so PP analysis alone would have had a high attrition bias. The ITT analysis also reduced the risk of compliance bias. Interestingly the ITT analysis showed a significance between the birth weights, and incidence of macrosomia with both being increased in the non-intervention control group.

These smaller local interventions do appear to have efficacy regarding weight gain during pregnancy and/or maternal, birth and neonate outcomes however there are also examples of trials like these that are less successful. Mottola *et al.,* (2010) ran an intervention to monitor weight gain throughout pregnancy, birth weight, and then weight retention over the following two months. The intervention entitled 'Nutrition and Exercise Lifestyle Intervention Program' (NELIP), ran in Canada, and recruited women at 16-20 weeks gestation who were classed as having overweight or obesity. This intervention was prescriptive and the participants were told exactly what their food intake should contain with regards total energy intake, % total carbohydrate of total energy, % total fat of total energy, and protein intake, all supported by a dietitian. A kinesiologist gave advice with regards specific exercise in the form of "mild walking" with the aim to get to 40 minutes three or four times each week until delivery. The results indicated that overall GWG was above the US IOM recommendations with the reason given by the researchers that the women had gained too much weight before entering the program (Mottola *et al.,* 2010). There was no difference between birth weights for any grouping, and no difference with weight

retention at two months between groups. In this case the intervention appears to have been started too late to have the desired outcome for weight gain.

Claesson *et al.,* (2014) considered pregnant women with obesity already enrolled on a weight management intervention to see if adding in a physical activity component could increase well-being as well as supporting minimal weight gain during pregnancy. They found that the physical activity group (n=74) reported better physical functioning at week 15, and 35 and at post-partum week 11 compared to the non-active group. Additionally, the active group reported better mental health at weeks 15 and 35 gestation but this effect had disappeared by week 11 post-partum. There was no difference between groups for weight gain during pregnancy or post-partum weight change. As no difference was found between the groups for a range of maternal morbidities and some positive outcomes with regards mental and physical health were found it is certainly worth considering a physical activity component within any intervention for this population.

Opie *et al.,* (2016) undertook a dietary intervention study delivered by a dietitian in Melbourne, Australia with pregnant women with a BMI $\geq 30 kg/m^2$ (or $\geq 26 kg/m^2$ if Asian), alongside standard antenatal care. Participants were given tailored diet and weight gain advice and were followed up by the dietitian to support ongoing goals with the main aim being to reduce GDM incidence, with the secondary outcomes of GWG to US IOM guidance, and reducing pregnancy and neonate complications. Irrespective of outcome studied there were no significant differences between the intervention and control group (Claesson *et al.,* 2014). The authors did report that diet quality improved with more fruit and vegetables being eaten, fewer ‘discretionary

items', healthier meat (e.g. trimming fat, or removing skin), and an increase in low glycaemic index foods (Claesson *et al.*, 2014).

These interventions appeared to have been well designed and were dietitian-led. The lack of efficacy raises the question of whether dietitians are the best people to deliver an intervention with this population, and if not which professionals might be better equipped.

3.1.4 Pregnancy intervention studies: case studies

In 2011, a care pathway with the overall aim of reducing childhood obesity was trialled in the West Midlands UK (United Kingdom) (Baker, 2011). One aspect of this was to limit weight gain in pregnancy to within 7-10kg in a population of women with a BMI above 30kg/m^2. Healthy weight advisors visited the homes of the participants as per the care pathway. Support was given to promote healthy behaviours including eating more fruit and vegetables and being more active with the subsequent effect being a healthy weight gain during the pregnancy. Mean weight gain at all sites was reported as 7.27kg, SD (Standard Deviation) 5.66kg. Whilst this was within the range required Baker (2011) reported that issues with data collection and recruitment at each site was low and so could not be fully analysed.

NICE holds a database of shared learning which is an opportunity for organisations to post case studies of their work. There are three case studies that showcase interventions for pregnant women who were overweight or obese to support them to make healthier life choices (NICE, 2022a,b,c).

‘The Monday Clinic’ was a midwife-led service which ran in Doncaster – year not stated but the case study was posted to the database in 2011 (NICE, 2022a). The service involved a community midwife referral to the programme based on woman’s BMI at booking. A BMI ≥30kg/m^2 would mean a referral to a healthy lifestyle midwife whereas a BMI ≥35kg/m^2 indicated a referral to the intervention. The Monday Clinic had some dietetic support, and there was the chance to use reduced price leisure activities. The main aim was to educate the women (and social support network) about obesity in pregnancy risks, and how to stay healthy and active as well as ensure the appropriate obstetric care during the pregnancy. The case study reported that the women who engaged in The Monday Clinic had an average weight gain of 7.65kg with 75% of the women not going on to develop and pregnancy related comorbidities. An attempt to offer an eight-week programme did not work as no women attended.

In 2009, Dartford and Gravesham NHS Trust community midwives set up and ran a 10-week programme for women with a BMI > 30kg/m^2 which aimed to educate them with regards risks of too much weight gain during pregnancy, become more active, and support lifestyle changes to achieve weight gain within the IOM guidance (NICE, 2022b). The programme, called Pregnancy Plus, included both antenatal and postnatal input and was supported by health visitors and local leisure facilities. The case study reported that data collection on outcomes was ongoing at the time, but early analysis showed that those women who attended stayed within the recommended US IOM weight gain guidance and were more likely to breast feed than those who did not attend.

Active Mothers was a programme run by Lewisham and Gravesend NHS (National Health Service) Trust with the case study posted in 2016 (NICE, 2022c). This was set up by a midwife involved with the above programme called Pregnancy Plus. By the time Active Mothers was set up Pregnancy Plus appears to have developed somewhat from the original. Referral to that programme was from a BMI >35kg/m^2 rather than the previous 30kg/m^2 reported in the case study posted in 2012. Active Mothers was developed after an audit of Pregnancy Plus and further research into what pregnant women wanted. Active Mothers consisted of an eight-week programme made available to all women but had a specific referral process from the Pregnancy Plus programme. It had input from a dietitian, physiotherapist, yoga teacher, hypnobirthing teacher, health visitor, health trainers, and breastfeeding lead for the Trust with additional support during school holidays so siblings could attend and from St John's Ambulance. Whilst the focus was on physical activity there was also discussion around changing behaviours with regards healthy eating and the clinical lead midwife was constantly adapting the programme based on the feedback. Outcome data was reported and showed the maximum number of women that attended a session was 11, and that 100% of the women breastfed.

These three local initiatives have not been reported in the peer reviewed scientific literature and so will not be available unless a grey literature search is undertaken or an individual is already aware of the NICE shared learning web pages. The Monday Clinic and the Pregnancy Plus programmes talk more of the need to educate the mothers to improve the weight management and pregnancy outcomes whilst the later Active Mothers programme is much more organic in its response to adaptation based on participant feedback and allowing the mums to be the lead (NICE, 2022a,b,c). There is no talk of educating the mums on the Active Mothers programme but it is

clear that sessions involved some taught elements (NICE, 2022c). In the years between these initiatives starting it would appear that there is a move from the idea that mums need education to one where this is available but the participants guide this. The costs reported for these initiatives were varied with The Monday Clinic costing £53,000 per annum, the Pregnancy Plus programme costing £10,000 per annum, and the Active Mothers programme costing £5,000, (NICE, 2022a,b,c).

The Bumps and Beyond weight management intervention that initially ran in Lincoln and Lincolnshire appears to fit very well alongside the above programmes for comparative purposes and has the advantage of being reported within the scientific literature (McGiveron *et al.*, 2015). A brief description was provided in Chapter 1. It is the focus of the work described in the rest of this thesis and the protocol will now be explored in full.

Chapter 4. Understanding the Bumps and Beyond intervention

A significant proportion of publications published in the health sciences report evaluations of the outcomes of intervention studies in humans. In nutrition and dietetics these may be reports of trials in which supplements are administered, or in which lifestyle interventions attempt to address body weight or metabolic disorders. The latter can be particularly challenging to report on since working with free living human subjects to change a quality such as ‘diet’ or ‘activity’ can never have the same precision as an experimental study or a pharmacological intervention.

Whilst understanding study methodology in detail is critical to interpretation of outcomes and the design of future interventions, many publications fail to report intervention methodology in sufficient detail (Hoffman *et al.,* 2014). Without sufficient detail, the capacity for trials that appear to be efficacious to be used in clinical practice is greatly reduced (Glasziou *et al.,* 2008). Hoffman and Glasziou (2013) reported that in a consecutive series of 170 trial and intervention reports of non-pharmacological randomized trials in leading medical journals, only 39% adequately described the intervention methodology. This proportion rose to more than 80% when authors were directly approached for more information.

To some extent the lack of detail in published work this is the fault of journal editors who insist on keeping the methods sections of papers as succinct as possible and as far as possible provide references to previously used methodology. Many authors also are not aware that providing more than the minimum information required to allow replication is critical for replication. For this reason, Hoffman and colleagues (2014) designed a reporting checklist to enable researchers to provide detailed accounts of

intervention methodologies and increase the quality of reporting. Prior to the introduction and growing uptake of their Template for Intervention Description and Replication (TIDieR) reporting checklist, it was often difficult to replicate all parts of an intervention in the main due to a lack of information in the public arena (Hoffmann et al., 2014). Glasziou *et al.,* (2008) identified a range of issues from lack of detail about staff training methods, to no description of equipment required. Hazy descriptions of interventions as a "behavioural intervention", for example, do not permit any replication or meaningful understanding of what an intervention comprised.

Treatment fidelity is an important concept in this regard. High treatment fidelity means that the intervention in a research study is conducted consistently and reliably. So, for example, a study would have low fidelity if nutritional supplements were taken by subjects only on the days that they remembered to do so, rather than following the schedule set out in the protocol. Treatment fidelity is often not monitored or reported in papers but can be enhanced at the point of study design by, for example, providing staff training on how to apply the protocol and observing intervention consultations (Belg *et al.,* 2004; Spillane *et al.,* 2007).

Chapters 5, 6 and 7 of this thesis describe evaluations of the Bumps and Beyond intervention, including quantitative analysis of the intervention in Lincolnshire and Nottinghamshire and a qualitative analysis of the Lincolnshire programme. The aim of the work described in the current chapter is to provide a detailed description of the intervention using the TIDieR checklist of Hoffman *et al*. (2014). This is in line with the National Institute for Health & Care Excellence [NICE] guidance with regards public health interventions and the use of behaviour change (NICE PH49, 2014; NICE PH 27 2010; NICE PH6 2007). This is an essential first step in understanding

how the intervention was delivered and making use of the findings for replication of Bumps and Beyond in other settings.

4.1 Methods

The TIDieR checklist is a useful tool to delve into the components of Bumps and Beyond Lincolnshire both via associated documents and real-life delivery of the intervention (Hoffmann *et al.,* 2014). Some of this detail has already been described in the general introduction (Chapter 1) but to allow for completeness will be expanded in this chapter as per the TIDieR tool (Hoffmann *et al.,* 2014).4.2.1 Data collection

To obtain the required information all documents used within the Bump and Beyond Lincolnshire intervention were collected and photographed or transcribed. Recordings of staff delivery of sessions were made and transcribed (see Chapter 7) which allowed for intervention fidelity compared to the protocol to be assessed.

This work was classed as an evaluation of the existing service and so covered by the ethical approval seen in Appendix 2. Both staff and participant consent were obtained prior to the recording being made via the appropriate consent forms, see Appendices 4 and 5. Where consent was not obtained then no recording was made. All recordings were destroyed once the transcripts had been thoroughly reviewed by the researcher.

4.1.1 Data presentation

4.1.1.1 TIDieR checklist

All data collected will be reported as per the TIDieR checklist (Hoffmann et al., 2014; Appendix 9). Where there are associated documents then this will be presented as an

Appendix due to both the length and number of these documents. The analysis in this chapter relates to the Lincolnshire Bumps and Beyond information. Similar information about Nottinghamshire was largely lacking. However, the aim of the Nottinghamshire team was to closely replicate the Lincolnshire programme and initially had the same intervention leader.

4.1.1.2 Intervention fidelity

To assess the intervention fidelity, recordings of staff delivering the intervention were checked by the researcher and compared to the Bumps and Beyond protocol (Appendix 1). This has been achieved by reading through the transcripts of the sessions as well as using keyword searches within the transcript documents and then comparing this to the session content in the guideline (Appendix 1). The Bumps and Beyond booklet (Appendix 6), was used alongside the transcripts to see if intervention fidelity was achieved through reference to it. Assessment grids (Appendix 8) were compiled to score the delivery of each session by staff. If the stated aims of the sessions were delivered then it was marked as yes, if not delivered it was marked as no, if that part of the session was not applicable or appropriate then it was marked as n/a. The update of the patient records via Systmone (the record system for the NHS Trust) could not be captured via the transcripts and so has been left out of the intervention fidelity results.

4.2 Results

Results are presented below as per the TIDieR checklist item titles and description (Hoffman et al., 2014; Appendix 9).

4.2.1 Brief name

The intervention is officially known as the Phoenix Antenatal Weight Management intervention service and more commonly known as Bumps and Beyond.

4.2.2 Why?

The protocol document reports an ethos that is "*to promote a healthier approach to eating and physical exercise*".

The main objective of the service is "*to establish a protocol whereby the information and support given to obese, pregnant women who wish to make positive lifestyle changes, is positive, consistent and evidence-based*".

The aims of the service can be seen in Figure 1.1 (Chapter 1).

The referral criteria as reported in the protocol is to be "*applied to all pregnant women with a BMI ≥35kg [sic] who are motivated to make positive lifestyle changes. Referral..via the Antenatal clinic at the initial dating scan*".

In addition, "*women who have a BMI 30-34.9 [sic] will be seen..if they request an appointment*".

Participants received their standard care alongside the intervention.

4.2.3 What?

A range of support material was provided to intervention participants during the intervention sessions (Appendix 7) in addition to the Bumps and Beyond session booklet, (Appendix 6). In session 1 the main Bumps and Beyond information pack

was given to the participant. Contents of this can be seen in Figure 4.1 with a written list in Appendix 7.

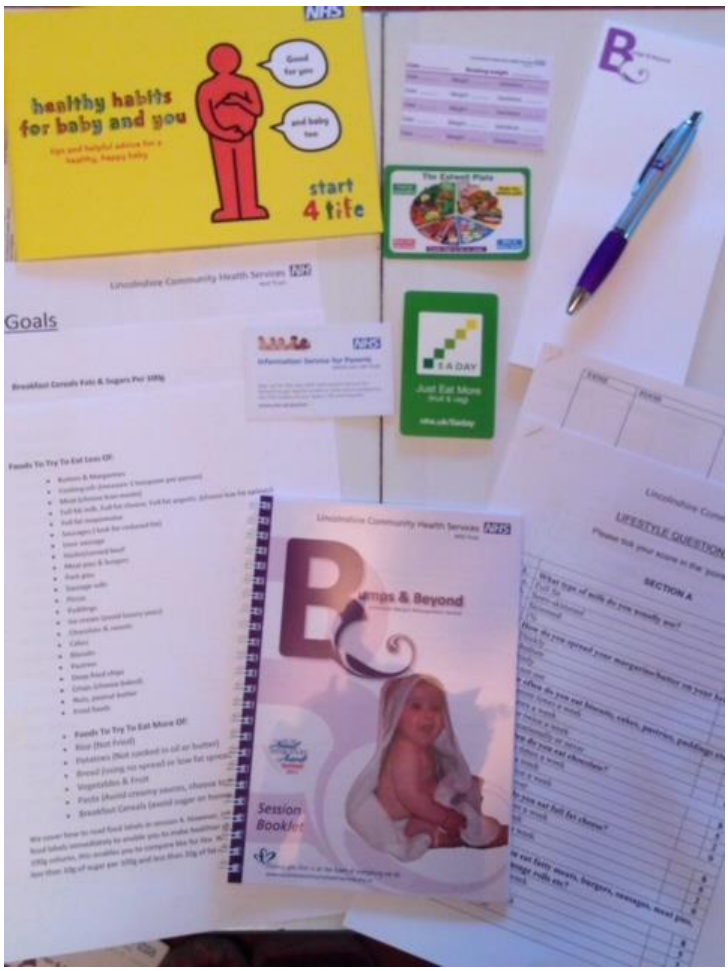


Figure 4.1 Contents of Bumps and Beyond information pack given in session 1. Photo ©Sarah Ellis

4.2.3.1 Materials

In addition to the main information pack staff gave participants other written material and take-away items, a full list of what was given at each session and by which staff member can be seen in Appendix 7. Where more than one session was delivered during the time allocated the material for that session was also given. A clear example

of this was a session at Gainsborough where the participant received content from session 2,3 & 4 and the support material for each of those sessions (Appendix 7).

4.2.3.2 Procedures

All pregnant women with a BMI above or equal to 35kg/m^2 were offered access to the intervention when they attended their booking in appointment with a midwife. Midwives had been briefed with regards to the intervention by the Lead Midwife Ailsa McGiveron. If a woman agreed to be involved, they were then contacted by a member of the Bumps and Beyond team to make an appointment for their first session. All staff involved in delivery of the intervention were trained by the Lead Midwife prior to the start of the programme. Further information about this was unavailable.

The content should have followed the protocol (Appendix 1) combined with the information in the Bumps and Beyond booklet (Appendix 6) with the use of support material as per Appendix 7. If consent was given then a text message would be sent the day before the appointment to act as a reminder. This was not written into the protocol but was found to be a useful tool in reducing non-attendance. All sessions were delivered on a one-to-one basis by either a Midwife or Healthy Lifestyle Advisor in a range of locations. Participants were asked if they wished to be weighed at all appointments so calibrated scales were required.

4.2.4 Who provided?

The intervention was provided via the Phoenix Weight Management Service which came under the umbrella of Lincolnshire Community Health Services NHS Trust. The

Lead Midwife for the programme had an undergraduate nutrition degree and had then trained as a midwife.

Other staff members included an experienced midwife, and two Healthy Lifestyle Advisors (HLA). One of the HLAs was a qualified Mental Health Nurse who had then moved into public health and worked on a smoking cessation intervention. The other HLA had a background as a breastfeeding support worker and had then moved into the intervention team. All staff had received training on the programme content and delivery by Ailsa McGiveron who was also their manager and so responsible for ongoing training needs. Staff wore uniforms provided by the Trust as per their staff grade.

4.2.5 How?

The intervention was delivered face-to-face, on a one-to-one basis. Participants were able to bring along their support network of family or friends and their children if they felt they wanted to. With consent, text messages were sent to the participant prior to appointments to act as a reminder. Staff were able to provide a letter for participants that could be given to an employer with regards to this intervention being part of their ante-natal care and so covered by law as requiring time off from work.

4.2.6 Where?

The intervention was delivered in several locations around Lincoln City and Lincolnshire. These included both the acute hospital setting (an acute hospital has facilities to provide acute, short-term care), community hospitals (hospitals that

provide longer term care and are used as an extension of Primary Care), and community locations like pharmacies or GP clinics. All facilities used had NHS links. Figure 4.2 shows an example of a community clinic room used for delivery of the programme.

Figure 4.1 Photo of clinic room where Bumps and Beyond was delivered. Also shows uniform of Healthy Lifestyle Advisor.
Permission obtained to take photo. ©Sarah Ellis

4.2.7 When and how much?

The first session should have taken place around week 16 gestation. Sessions were then scheduled approximately every four weeks apart, with the final session taking place at week 36 gestation. Session 1 was the longest session as it described the intervention as well as starting the content delivery and so was scheduled in a 60-minute appointment. Sessions 2-7 were shorter and are scheduled within a 30-minute appointment. Flexibility in timings and content delivery was written into the programme.

4.2.8 Tailoring

The intervention protocol explicitly refers to the option of each session being flexible for the staff to keep a "client-centered" approach. In addition, within each session certain elements were allowed to be disregarded if not appropriate at that time (Appendix 1). Sessions could be amalgamated to work around the participants' needs, for example allowing for holidays or missed appointments.

4.2.9 Modification

Not applicable for this process

4.2.10 How well?

4.2.10.1 Planned

Not applicable to this thesis

4.2.10.2 Actual

To assess intervention fidelity within the service evaluation the methods described in section 4.2.1 were used to collect data. All staff consented to the recordings, and recordings were made of staff delivering at least one of each of the sessions within the intervention. Locations for these recordings was dependent on what clinics were available during the data collection period and covered six locations – Lincoln Community in a pharmacist shop, Gainsborough in a Health Centre, Pilgrim Hospital Boston, Skegness in a Health Centre, Lincoln County Hospital – classed as Lincoln acute, and Grantham and District Hospital – all hospitals are part of the United

Lincolnshire Hospitals NHS Trust. Pilgrim Hospital Boston, and Lincoln County Hospital have inpatient maternity services.

Fidelity was assessed through the transcripts and additional notes made at the time of delivery which included comparison to the protocol elements as listed in Appendix 1, content analysis compared to the Bumps and Beyond booklet (Appendix 6) and variations in handouts (Appendix 7).

Two participants declined to be recorded but verbally agreed for the researcher to observe the staff member delivery of the session.

4.2.10.2.1 Session 1 intervention fidelity

There were recordings (n=5) of all staff delivering session 1. All locations were community-based rather than the acute hospital setting. All participants received the Bumps and Beyond pack as per Figure 4.1. Women were between 18 weeks and 19+4 weeks gestation. The sessions lasted between 49 minutes (Jean), and 29 minutes (Linsey), however for the shorter session 1, attendee had been on the programme before. No staff checked the baseline data at the time the recording was made (content point 4) however this is possible to do via SystmOne later point. All staff weighed the participants. Linsey offered free swimming sessions to two participants (a local supplementary option) but only one woman consented to the referral.

4.2.10.2.2 Sessions 2 & 3 intervention fidelity

There were recordings (n=7) of all staff delivering these sessions. All staff combined sessions 2 & 3 into a single session. There was a combination of acute and community settings however, all acute sessions were delivered by the midwife. The timing of

these sessions was often alongside standard obstetric appointments (scans, etc.). Participants were from 22 weeks' gestation to 25 weeks. The shortest session lasted 21 minutes and was delivered by Sally, the longest was 33 minutes and delivered by Jean. As these sessions were delivered at the same time some of the content points were duplicated and so this could explain how two sessions could be delivered in a relatively short period of time (around 30 minutes). All women consented to be weighed. Review of food diary sheets only occurred once, however most women did not complete them, n=5. When the option of keeping a food dairy was discussed with the women only one woman was given further food diary sheets with the others not requiring them or being given them. Fidelity was very good for session 2, with the bulk of the content being delivered.

With session 3 (appendix 8), content fidelity for points 1-5 was 100% for all staff in all locations. This was mostly with regards physical activity and all staff gave a pedometer and explained how to use it as well as discussing the benefits of being active within the participants' limits. However, two members of staff failed to investigate barriers to achieving healthy physical activity levels (Appendix 8). Most staff helped the participants set relevant goals.

All staff gave additional material to support the sessions which included information about the 5-a-day message, fruit and vegetable portion sizes and the pedometer. One staff member also gave a step count sheet (Jean; Appendix 7). All staff referred to the appropriate session material in the Bumps and Beyond booklet (Appendix 6).

4.2.10.2.3 Session 4 intervention fidelity

There were recordings (n=3) of two staff members delivering session 4 only. These were in both acute and community settings. Participants ranged from 28 weeks' gestation to 34 weeks. Verbal screening of problems did not appear to happen for two of these recordings. However, this was Sally the midwife and she often had conversations outside the clinic room which did not get recorded and it was clear that these covered the screening process in an informal way. The rest of the content was delivered as per the protocol except for the goal setting which was unclear in two of the sessions and so recorded as not covered. The sessions lasted from 18 minutes (Linsey) to 32 minutes (Sally). Food diary sheets were not required by any participant. Staff referred to the booklet (Appendix 6). Additional material was given by Sally as per Appendix 7.

4.2.10.2.4 Session 5 intervention fidelity (single session delivery)

All observed single session 5 deliveries were by Linsey, Healthy Lifestyle Advisor. There were five sessions recorded at two locations (Skegness and Boston). Participants were from 26 weeks' gestation to 36+5 weeks. Fidelity was 100% for all content except point 4, which covered portion control and was not explicitly mentioned during three of the sessions. Additionally, goal setting was only covered 50% of the time with one session being classed as not appropriate to cover (the 36+5 week gestation participant). Additional material was given in two of the sessions and consisted of recipe books as seen below in Figure 4.3. The sessions lasted from 18 minutes (the participant who was 36+5 weeks gestation) to just under 33 minutes.

Figure 4.2 Additional material given at session 5 consisting of two recipe books. ©Photo by Sarah Ellis

4.2.10.2.5 Combined sessions 5 & 6 intervention fidelity

One session was delivered by Jean as a combined 5 & 6 content for a participant who was 30 weeks' gestation. This took place in the Lincoln community setting (pharmacy). Content delivery was almost 100% for the combined sessions with only future goal setting being missed. No additional material was offered at this session, which lasted just under 28 minutes (Appendix 8).

4.2.10.2.6 Combined sessions 6 & 7 intervention fidelity

Linsey delivered two combined 6 & 7 sessions, one in Boston and one in Skegness. One lasted just under 13 minutes, and the other lasted 23 minutes. Both participants were 35 weeks' gestation which may explain the combined delivery. Point 5 in session 6, which covers lapse management, was not discussed with either participant. No review appointment was made as per the protocol as Linsey went on to cover the final session and so this has been recorded as not applicable with regards intervention fidelity. For session 7 the transcript is unclear as to whether a BMI was recorded at the appointment and so point 2, record weight and BMI, has been classed as partially completed. Point 6 was not covered with either participant and refers to the need for higher dose folic acid and 10mcg vitamin D for future pregnancies if the BMI stays above 30kg/m2. One participant received the Bumps and Beyond towel as well as the Start 4 Life breastfeeding leaflet (Figure 4.4). One only received the leaflet. The intervention fidelity table can be seen in Appendix 8

Figure 4.3 Photos of the Bumps and Beyond towel and start 4 life breastfeeding leaflet. ©Photo by Sarah Ellis

4.2.10.2.7 Session 7 intervention fidelity

There were two session seven-only sessions delivered by two staff members, (Appendix 8). One was in the acute setting in Lincoln County hospital - Sally Midwife, and one in a community setting in Boston - Linsey. Both hospitals have maternity services. The participants were 36 weeks' gestation as per the recommendation on the protocol. One session was delivered in 17 minutes (Linsey), and the other in 20 minutes (Sally). Fidelity was 100% for all points except number 6, future need for vitamin supplementation, which neither staff member discussed. Both participants received a weaning recipe book (Figure 4.5), with the Boston participant also receiving the Bumps and Beyond towel and Start 4 Life leaflet (Figure 4.4). This participant was also offered local postpartum support options like free gym and swim, free Weight Watchers, and free Health Trainer at home. The participant at the acute setting in Lincoln city would not have been able to access the Lincolnshire postpartum support but was given the British Heart Foundation recipe book (Figure 4.5).

Figure 4.4 Weaning recipe book and British Heart Foundation booklet given as handouts to participants. ©Photo by Sarah Ellis

4.2.10.2.8 Combined sessions

In addition to the above there were four recordings that captured combined multiple sessions delivery in one appointment slot. These have not been reviewed for intervention fidelity due to the contents being client-responsive and therefore tailored to their individual needs. All staff did this at some point during the data collection period. Reasons for these included participants having holidays booked, missing appointments, or by request from the participant. Additional material was given as per Appendix 7 and varied, again due to the flexibility around participant needs.

4.3 Discussion

In the main, intervention fidelity was good in all locations and for all staff. It was clear that staff responded to the needs of the individual at that particular time and place, hence e number of sessions that were combined and not all content being

delivered every time (Sections 4.3.10.2.2, 4.3.10.2.5, 4.3.10.2.6, and 4.3.10.2.8). Flexibility in delivery was critical as it allows the participant to receive sessions at times that suit them. It was built into the protocol to allow for issues with attendance as well as other life events such as holidays. This does mean, however, that some content did not obviously get covered and so had to be recorded as not showing intervention fidelity. These findings typify the difficulty in describing a client-focused and often bespoke intervention in the format required by a scientific publication. The level of detail captured through the use of TIDieR was not reported in the earlier work of McGiveron et al., (2015).

Vieten et al., (2018) undertook a facilitator fidelity check for the Maternal Adiposity, Metabolism and Stress (MAMAS) intervention. Sessions were recorded then assessed by trained staff using a manual that covered content for each session. The content fidelity could be marked as "No, not at all", "Yes, but not completely", and "Yes, complete information provided" and also had a free text box (the manual is in their supplementary material). They reported that facilitator fidelity was good with content being covered "mostly" or "completely" between 69.2% and 93% of the time. Bumps and Beyond Lincolnshire appears to have much better intervention fidelity than this study, as the content was classed as being explicitly mentioned within the text or not, giving no space for variation.

Wilcox *et al.,* (2022) undertook a process evaluation for the Health in Pregnancy and Postpartum (HIPP) RCT. This was an intervention that delivered very similar content to Bumps and Beyond but incorporated both social media and podcasts to support participants. The study did not use the TIDieR template to assess the intervention fidelity but instead used a combination of participant feedback and staff reporting. This is an interesting approach as it acknowledges that whilst staff may deliver

content this does not mean that the participant has taken it on board. By questioning the participants, Wilcox *et al.*, (2022) were able to report which behaviour strategies were seen as most useful in helping women to meet the desired outcomes of the trial.

All clients consented to be weighed at every appointment attended by the researcher and staff were very good at explaining the results and then discussing future ways to support any changes that were needed. This is an interesting finding as it is clear that randomised controlled trials have not been successful when weighing and feedback is part of the intervention (Daley *et al.*, 2019; Brownfoot *et al.*, 2015). A feasibility study by Allen-Walker *et al.*, (2020) found that weighing was a useful tool to promote healthy weight gain in pregnancy with most women feeling positive about its use during their antenatal care. Weighing during pregnancy to monitor weight gain is useful for the woman and clinician but only when used with appropriate support and explanation. Current guidance in UK obstetric practice does not require regular weighing, but our previous work from the MAGIC study suggests that pregnant women would very much welcome it (Swift et al., 2016),

All staff gave handouts to support the delivery of the intervention, appendix 7. These were mostly the same however it was clear that for one geographic area there was more postpartum support available via other agencies. This is likely due to local authorities funding specific public health areas that will not be seen as priorities in other locations. Staff had agency to assess what else was available locally for participants and so could be offered but this does mean a variation with additional support for participants often referred to as ‘postcode lottery’.

Locations for delivery of the intervention were clinic type settings (Figure 4.2). Field notes taken at the time report that many rooms were small and had no air-conditioning. This may seem like a small issue however many participants brought other children in pushchairs and so more space was needed. Additionally, many rooms were very warm alongside it being in the middle of a heatwave when the recordings were made. This made rooms without air-conditioning stifling at times with participants commenting about the temperature, and so the minimum of a fan is needed. Thought about the warmth of the room in winter is also necessary.

There are a number of limitations within this exploration of intervention fidelity. No training protocol or manual was available and so this is an unknown factor within the intervention delivery. It was clear that the staff member who was the qualified midwife often got asked specific questions around pregnancy which means that the participant would be receiving more than just the intervention material on top of their standard ante-natal care. Due to time and staff constraints, internal validity of the intervention fidelity results for Bumps and Beyond has not been undertaken. A further and important limitation is that the same analysis of the intervention fidelity and delivery for Nottinghamshire could not be conducted. This was due to circumstances beyond the control of the researcher and the early withdrawal of the service.

The intervention fidelity for Bumps and Beyond Lincolnshire indicates that staff followed the intervention protocol in a supportive and responsive manner. This chapter has provided the full context and description of the Bumps and Beyond

intervention. This provides a detailed platform for understanding the data which is presented in the next three chapters.

Chapter 5. A service evaluation of the Lincolnshire Bumps and Beyond intervention to manage pregnancy weight gain in women with severe obesity

5.1 Introduction

The concern about obesity and, in particular, excessive weight gain in pregnancy, and subsequent negative impacts on maternal and fetal/neonate outcomes, has led to numerous lifestyle intervention programmes being trialled in attempts to combat the issue. These range from large randomised controlled trials (RCTs) (Herring *et al.*,2017; Rauh *et al.*,2013; Renault *et al.*,2014; Phelan *et al.*,2011; Quinlivan *et al.*,2011; Vinter *et al.*,2011) to pragmatic local interventions (Robertson & Ladlow, 2018; Haby *et al.*,2018; Koleilat *et al.*,2017; Haby *et al.*,2015; Mottola *et al.*,2010; Shirazian *et al.*,2010), as discussed in Chapter 2. The outcomes of these interventions have been mixed. Some research has shown a positive effect of interventions when a reduction in gestational weight gain (GWG) is the target outcome, at all body mass indices. Impacts are less consistent for women with overweight or obesity when analysed alone, and there are varied outcomes in terms of other maternal and fetal outcomes (The International Weight Management in Pregnancy Collaborative Group, 2017; Muktabhant *et al.*,2015).

The Lincolnshire Bumps and Beyond project, described in Chapter 1, has shown promise as an intervention programme. Initial evaluation of the service showed that this intervention was highly successful in reducing certain health risks in this population (McGiveron *et al.*,2015). However, that evaluation was limited in terms of

sample size and only considered outcomes for women at one of the four healthcare settings at which the programme was delivered. In order to validate the original findings, a further service evaluation was undertaken with a larger number of participants and data from all four sites. The primary aim was to evaluate whether the findings identified in the initial phases of the intervention were maintained when a larger and county-wide population was investigated. The inclusion of data from four sites enabled the secondary aim of establishing whether the intervention had equal efficacy at all locations.

5.2 Methods

5.2.1 Data collection:

Data was obtained for all women eligible to take part in the Bumps and Beyond intervention in the county of Lincolnshire, regardless of whether they opted to attend sessions or not. As described in Chapter 1, this study was a service evaluation of an existing intervention. Audit sheets containing data taken from the medical records of the women, were collected by the intervention team post-partum, and then anonymised for analysis (Appendix 1). These audit sheets had been updated, in consultation with this researcher, following the original evaluation (McGiveron *et al.*, 2015) to become more pertinent to the clinical picture seen locally. Completion of the audit sheets was started at the booking-in appointment with further information being added post-partum. The audit sheets were completed by Bumps and Beyond staff only and were part of the standard workflow for women with a BMI in excess of 35 kg/m^2, within the NHS Trusts involved. The audit sheets included sections for a range of

outcomes. For the purpose, of this analysis, these were sorted into the following groups: pregnancy outcomes; labour and delivery outcomes, and birth outcomes.

The women who declined the offer of the intervention programme were classed as non-attenders, the women who attended all sessions of the intervention were classed as attenders. For this evaluation, another group was added which was those women who attended between 1 and 6 sessions (partial attenders). Women who attended the full programme (attenders) engaged with 7 sessions. All women were invited to take part from around 16-weeks gestation.

5.2.2 Ethical approval:

This service evaluation was approved and registered with the Research and Development Department of the United Lincolnshire Hospital NHS Trust. No ethical approval was required as this work was classed as a service evaluation. The anonymised outcome data taken from the internal audit sheets were supplied by members of the Bumps and Beyond team (Ailsa McGiveron, Sally Foster, Jean Rickells, and Linsey Robinson).

5.2.3 Statistical analysis:

Data were input into SPSS version 26, and then double-checked for accuracy. There were 641 records available. For analysis purposes, 15 twin pregnancies were excluded. In addition, two records were excluded due to lack of complete data (< 5 complete data points). The women were divided into three groups dependent on how many sessions of Bumps and Beyond they attended. Non-attenders (0 sessions), partial attenders (1-6 sessions), attenders (all 7 sessions). Age of mother at birth was

calculated based on their date of birth to delivery date of baby. A normal distribution was assumed for all continuous data. The alpha value was set at 0.05.

Socioeconomic status was derived from the postcode of the address recorded on the audit sheet which was then entered into a government index of deprivation calculator found at https://imd-by-postcode.opendatacommunities.org/imd/2019. The 'English Indices of Deprivation 2019' are a measure used by the UK government which incorporates seven domains recognised as affecting standards of living. These domains are income; employment; education, skills and training; health and disability; crime; barriers to housing and services; living environment. There is a further split into specific indicators within each domain which allows local authorities or councils to see where financial support may be needed (Noble *et al.*,2019).

Frequency statistics were analysed for intervention location attended (Lincoln, Boston, Grantham and Gainsborough), and attender/non-attender/partial attender groups. Comparison of means with standard deviations (SD) was performed using One-way Analysis of Variance (ANOVA) followed by a Least Statistical Difference (LSD) post hoc test, to provide descriptive information about participants in each group. ANOVA with LSD was applied to booking weight; booking height; booking BMI; number of weeks gestation at booking; gravida; parity; and mother's age.

A Pearson Chi^2 test to indicate independence with Phi and Cramers V tests for effect size was used to analyse; smoking during pregnancy; drinking alcohol during pregnancy; homeowner status; whether subjects took folic acid supplements at 400mcg; whether subjects took folic acid supplements at 5mg; whether subjects took vitamin D supplements; and ethnicity. The same tests were used for overall pregnancy complication; gestational diabetes; gestational hypertension; pre-eclampsia; mode of

delivery; gestation less than 37 weeks; gestation more than 37 weeks; birthweight more than 4kg; birthweight less than 2.5kg; feeding practice at birth. An independent T-test was used to evaluate some of the possible points of bias in the study, as described in the text.

To assess the impact of Bumps and Beyond attendance on pregnancy complications, labour complications and birth outcomes, odds ratios and 95% confidence intervals were determined using the Odds Ratio calculator tool at https://www.medcalc.org/calc/odds_ratio.php. Further analysis to determine odds ratios for these outcomes adjusted for confounding factors was performed using binary logistic regression, utilising a forward stepwise method.

5.3 Results:

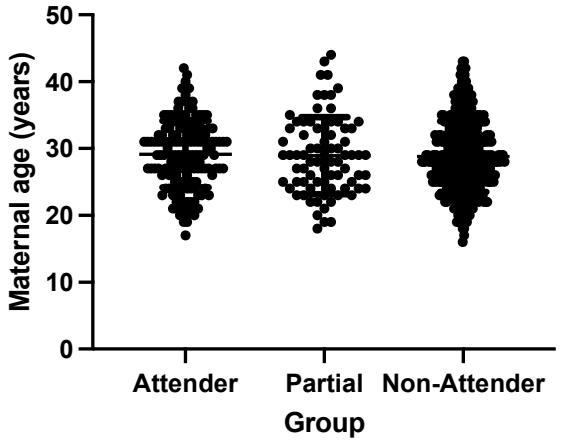
5.3.1 General

In total, after exclusions, 624 audit sheets were used for analysis. There were 156 attenders (25%), 390 non-attenders (62.5%), and 78 partial attenders (12.5%) of the Bumps and Beyond programme. The majority of attenders and partial attenders attended the programme in Lincoln (49%), Boston had 32.5% of the attenders and partial attenders, with Grantham and Gainsborough with the smallest numbers (12.7% and 5.8% respectively).

5.3.2 Participant characteristics

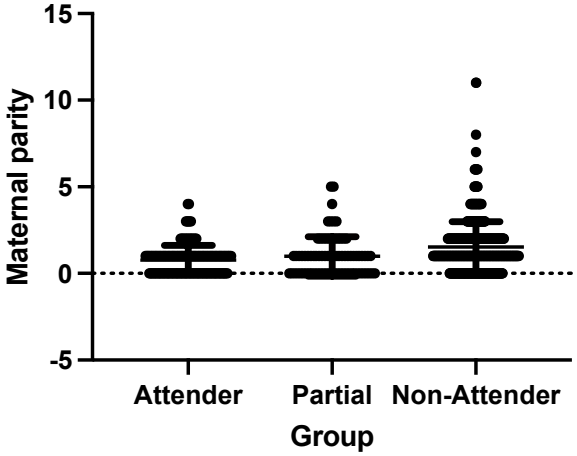
As can be seen in Table 5.1, attenders, partial attenders and non-attenders were well matched for age of mother at delivery (all means rounded to whole number - 29 years, between group p=0.374, n=619), and booking body mass index [BMI] 39.7kg/m^2,

39.7kg/m^2, and 39.5kg/m^2 respectively (between group p=0.874). There were no statistically significant differences between the groups for either characteristic. Mean booking weight was slightly higher in the partial attender group at 110.7kg, with attender and non-attender mean weights of 107.8kg and 107.4kg, respectively however this was not statistically significant (between group p = 0.182). The number of weeks pregnant at the booking appointment was not different between any of the group with a mean figure of 11 weeks (p=0.292). Attenders and partial attenders had fewer previous pregnancies (gravida) than non-attenders with the mean number of pregnancies = 2 for both attenders/ partial attenders, and 3 for non-attenders (p<0.001 between attenders and non-attenders, and p=0.001 between partial attenders and non-attenders). Previous birth rate above 20 weeks gestation (parity) was significantly different between the non-attenders (2), and both the attenders (1, p<0.001) and partial attenders (1, p=0.002), but not between the attenders and partial attenders (p=0.245). Figure 5.1 emphasises that there were no differences in maternal age between the three groups of women. There was a significant trend for women in the non-attender group to be of higher parity, but this was skewed by a relatively small number of women having had >5 live births (Figure 5.2).



Error bars indicate mean and standard deviation.

Figure 5.1 Maternal age for individual women in each of the three groups.



Error bars indicate mean and standard deviation.

Figure 5.2 Maternal parity for individual women in each of the three groups.

The majority of the women classed their ethnicity as White British, 90.8% of total number of participants whose ethnicity was recorded (n=598). There were other ethnicities, but all were below 2% of the total number of completed records (Lithuanian/Latvian/Estonian 1.5%; White Polish 2.0%; White other 3.8%, Black other 0.6%; Mixed British 0.4%; South Asian 0.7%; Middle East 0.2%).

Lifestyle factors included on the audit sheets were drinking alcohol during pregnancy, smoking during pregnancy, homeownership, taking folic acid supplements (400mcg/5mg) during pregnancy, and vitamin D supplement (10mcg) during pregnancy. Only 260 records were completed for drinking alcohol in pregnancy. These showed that the bulk of the women reported they did not drink alcohol n=256, compared to those who reported they did n=4. Too few drank alcohol to run comparison statistics with the Chi^2 test reporting the results as violated.

With regards smoking in pregnancy, 263 records were completed. For attenders and partial attenders of Bumps and Beyond only 7 in each group reported they were smokers. Of the non-attenders 35 recorded smoking during pregnancy. The Chi^2 test showed no significance between all groups (p=0.462).

There were 610 completed records for homeownership. Of these, 140 women recorded that they did regard themselves as being a homeowner, and 470 regarded themselves as non-homeowners. A Chi^2 test showed no significance between the groups (p=0.106).

There were 614 records for supplementation with folic acid. Most of the women took folic acid during pregnancy n=593, however only 11.1% took the higher dose of 5mg which is the recommendation for women with a BMI of $30kg/m^2$ (Denison *et al.*,2018). The Chi^2 was violated due to few women reporting not taking folic acid.

There were 613 records available for analysis of vitamin D use. There was no difference between the three groups with regards the use of vitamin D supplementation during pregnancy (p=0.203).

In summary, women who attended the Bumps and Beyond intervention either in full or in part, were more likely than those who did not to be first time mothers but there were no other significant differences between the three groups.

Table 5.1 Characteristics of the women

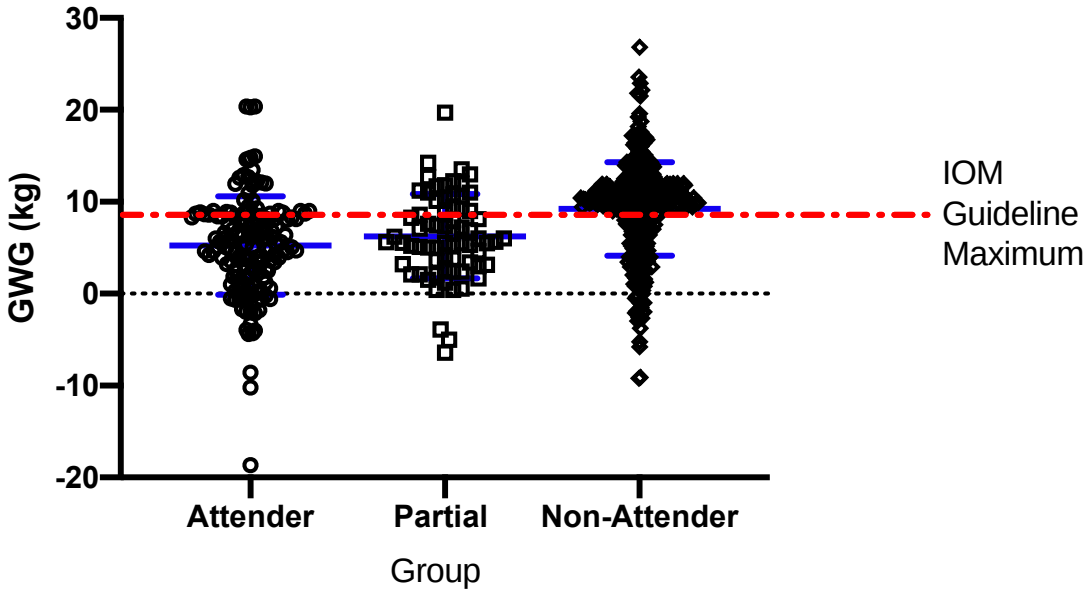
Characteristic	Non-attenders (n=390)	Attenders (n=156)	Partial attenders (n=78)	All groups N=624	Between group p value
Age at delivery					
Age (years) mean, SD (Standard Deviation), n	29.0 (5.3) n=385	29.2 (5.0) n=156	29.0 (5.8) n= 78	29.0 (5.3) n=619	0.734
Booking BMI					
BMI (kg/m2) mean, SD, n	39.5 (4.1) n=390	39.7 (4.2) n=156	39.7 (4.5) n=78	39.6 (4.2) n=624	0.874
Weight at booking					
Weight (kg) mean, SD, n	107.4 (14.4), n=390	107.8 (13.9), n=156	110.7 (15.7), n=78	107.9 (14.5) n= 624	0.182
Weeks pregnant at booking in appointment					
Weeks at booking to whole number, SD, n	11, (4), n=351	11, (2), n=144	11, (4), n=65	11, (4), n=560	0.292
Gravida (number of previous pregnancies)					
Gravida to whole number, SD, n	3, (2), n=386	2, (1)† , n=155	2, (2) †, n=77	3,2, n=618	<0.001
Parity (previous birth rate above 20 weeks gestation)					
Parity to whole number, SD, n	2,(1), n=386	1, (1)†, n=155	1,(1)†, n=77	1, (1), n=618	<0.001
Ethnicity n=598, 95.8 % of total audit sheet records					
White British	333, 55.7%	140, 23.4%	70, 11.7%	543, 90.8%	
Lithuanian/ Latvian/ Estonian	6, 1.0%	3, 0.5%	0	9, 1.5%	
White Polish	8, 1.3%	3, 0.5%	1, 0.2%	12, 2.0%	
White Other	17, 2.8%	5, 0.8%	1, 0.2%	23, 3.8%	
Black Other	2, 0.3%	0, 0%	2, 0.3%	4, 0.6%	
Mixed British	1, 0.2%	0, 0%	1, 0.2%	2, 0.4%	
South Asian	4, 0.7%	0, 0%	0, 0%	4, 0.7%	
Middle East	1, 0.2%	0, 0%	0, 0%	1, 0.2%	
Lifestyle					
Drinking in pregnancy n=260	2, 0.8%	2, 0.8%	0, 0%	4, 1.6%	
Smoking in pregnancy N=263	35, 13.3%	7, 2.7%	7, 2.7%	49, 18.7%	0.462
Homeowners N= 610	77, 12.6%	44, 7.2%	19, 3.1%	140, 23.0%	
Folic acid supplement - 400mcg	323, 52.6%	136, 22.1%	66, 10.7%	525, 85.5%	
5mg*	42, 6.8%	16, 2.6%	10, 1.6%	68, 11.1%	
Vitamin D 10mcg	336, 54.8%	145, 23.7%	70, 11.4%	551, 89.9%	0.203

*recommended dose for BMI >30kg/m^2. † indicates significantly different to non-attenders, P<0.05. ‡ indicates significantly different to attenders, P<0.05.

5.3.3 Impact of Bumps and Beyond attendance on weight change over pregnancy

There were 582 audit sheets available where both booking appointment weight, and 36 weeks gestation maternal weight were all recorded. Of these, 156 were attenders (27%), 357 were non-attenders (61%), and 69 were partial attenders (12%). Mean weight change from booking appointment to week 36 gestation for the attenders was 5.25kg (SD 5.35kg), for non-attenders 9.22kg (SD 5.09kg), and the partial attenders 6.24kg (SD 4.60kg). The data indicated that attenders and partial attenders stayed within the IOM recommended weight gain (Rasmussen, Yaktine & IOM, 2009) for pregnant women with obesity, a specific aim of this intervention. The non-attenders had a mean weight gain of 9.23kg (SD 5.09kg), just outside the IOM recommendations. All groups included women that lost weight over the pregnancy with the greatest individual loss being within the attender group (-18.65kg). The non-attenders group had the woman with the greatest weight gain (26.8kg). Weight gain was significantly greater in non-attenders than in attenders ($P<0.001$) and partial attenders ($P<0.001$). Individual women's weight change for each group can be seen in Figure 5.3. In order to see whether there was an effect related to number of sessions attended in the partial attenders group, a Pearson's correlation test was performed. The result of this showed that attending more sessions was associated with lower weight gain (Pearson's correlation $r=-0.214$, $P=0.039$). To see if this was an issue with any bias between attenders and non-attenders an independent T-test was run on the non-attender group with using booking BMI against having complete weight gain record compared to non-attender without weight gain record. No statistical differences were found between the groups indicating that the observed excessive weight gain in the non-attender group was not a result of systematic bias in record-keeping.

The primary aim of the intervention was to reduce GWG, and this was achieved even in women who failed to complete the programme (partial attenders).



Error bars indicate mean and standard deviation.

Figure 5.3 Gestational weight gain for individual women in each of the three groups.

Lincolnshire Bumps and Beyond ran in a number of locations throughout the county. When comparison was made between attenders and non-attenders, or partial attenders and non-attenders at each location a beneficial effect on attendance on GWG was observed at all sites (Table 5.3). The lowest GWG was seen with attenders at each location, with weight gain well within the 2009 IOM guidance (Table 5.2). There was also a statistically significant difference between partial attenders and non-attenders for each site, with the exception of Boston. To assess whether there was any bias introduced through missing data points an independent T-test was run on the non-

attender group – nonattender with weight gain record compared to non-attender without weight gain record. No statistical differences were found between the groups.

Table 5.2 Comparison between sites for GWG

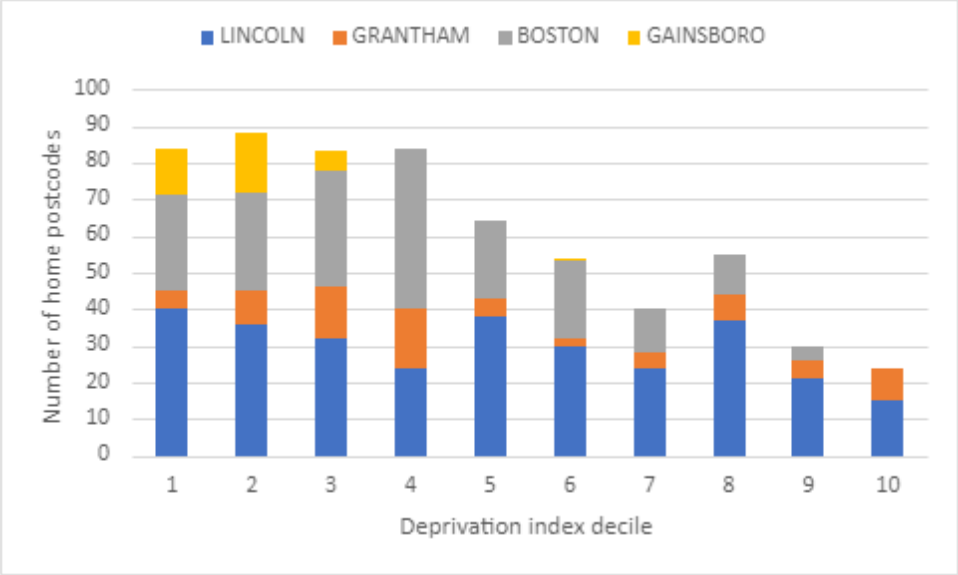
	Lincoln	**Grantham**	**Boston**	**Gainsborough**
Non-attenders	9.27±4.58	10.49±4.71	8.68±6.06	9.53±2.88
Partial attenders	**7.04±4.08 ***	**4.26±3.19 ***	6.59±5.19	**6.24±6.18 ***
Attenders	**5.27±5.72 ***	**4.94±6.82 ***	**5.70±4.08 ***	**2.08±4.31 ***

Weight gain kg. Data and mean ±SD. *P<0.05 vs non-attend.

Lincoln Non-attenders n=173; partial attenders n=26; attenders n=90 Grantham Non-attenders n=42; partial attenders n=14; attenders n=14. Boston Non-attenders n=122; partial attenders n=20; attenders n=46. Gainsborough Non-attenders n=20; partial attenders n=9; attenders n=14.

5.3.4 Postcode analysis as a deprivation indicator

In order to understand more about the socioeconomic background of the individuals offered Bumps and Beyond, postcodes were analysed against a number of factors to produce the overall multiple index of deprivation decile. Postcodes were analysed by location of booking appointment as can be seen in Figure 5.4. Most of the women offered the Bumps and Beyond intervention had a completed postcode on the audit form, however only 606 were available for analysis. Reasons for the postcode not being included were postcode not recognised; postcode written incorrectly (o instead of 0); and postcode terminated (Post Office terminology).



Decile 1 represents the most deprived postcode areas, whilst Decile 10 represents the most affluent.

Figure 5.4 Deprivation index decile by location of booking appointment.

The decile totals were combined to make approximate groups for a level of deprivation - high (deciles 1-3), medium (deciles 4-7) or low (deciles 8-10). Totals showed 109 women in low deprivation areas, 242 women in medium deprivation areas, and 255 women in high deprivation areas. The majority of the women offered the Bumps and Beyond intervention attended a booking-in clinic at a Lincoln location, (n=297), Boston had a total of 198 women offered the intervention, then Grantham (n=76), and finally Gainsborough (n=35). Figure 5.4 shows that the majority of the women offered the programme, regardless of booking appointment location, lived in areas classed as the most deprived within Lincolnshire. All but one Gainsborough subject resided in high deprivation postcodes. None of the Boston subjects resided in a decile 10 postcode.

Further analysis considered the attendance groupings in terms of deprivation, as can be seen in Figure 5.5. For those that lived in a high deprivation area 54 women

attended Bumps and Beyond, 167 women did not attend Bumps and Beyond, and 34 women partially attended Bumps and Beyond. For those that lived in medium areas of deprivation, 57 women attended Bumps and Beyond, 159 women did not attend Bumps and Beyond, and 26 women partially attended. For those that lived in low deprivation areas, 38 women attended the intervention, 59 women did not attend, and 12 women partially attended. These figures indicate that the majority of the women who were offered the Bumps and Beyond intervention, regardless of attendance status, were classed as living in deprived areas. A greater proportion of women who attended the intervention were from low deprivation areas. For this reason, deprivation index was regarded as an important potential confounding factor in subsequent analyses of the impact of the intervention.

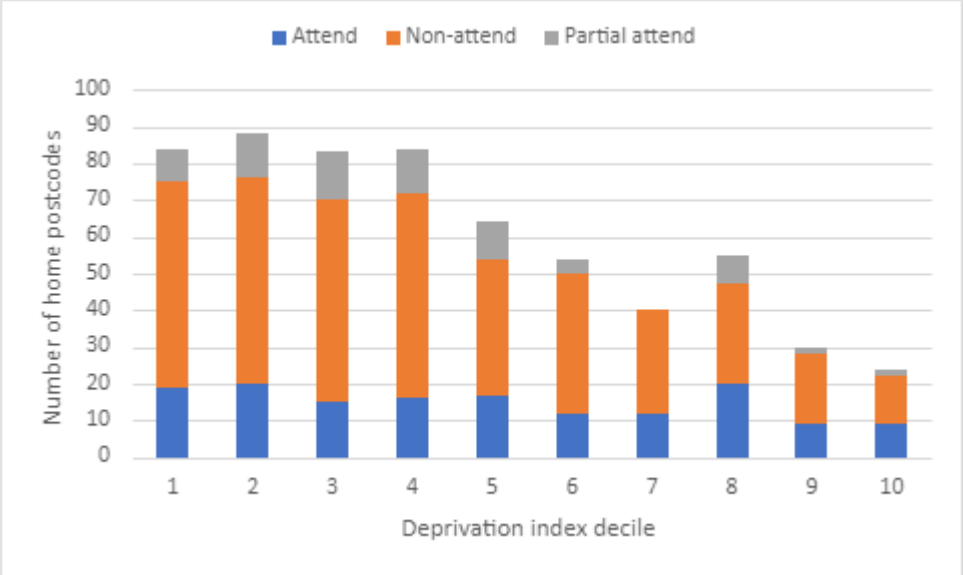


Figure 5.5 Deprivation index based on postcode for attenders, non-attenders, and partial attenders.

5.3.5 Impact of Bumps and Beyond attendance on pregnancy conditions

Pregnancy conditions logged on the audit sheet included gestational diabetes, gestational hypertension, and pre-eclampsia. These were later grouped together to pool all pregnancy complications for analysis.

Table 5.3 All outcomes recorded on the audit sheet for each group with numbers and percentage of the total number of women in that group

	Non-Attenders (n=390)	**Partial Attenders (n=78)**	**Attenders (n=156)**
All pregnancy complications (n=137, 22.1)	96, 24.8%	16, 20.5%	25, 16.0%
GDM (n=58, 9.4%%)	45, 11.6%	6, 7.7%	7, 4.5%
GHT (n=58, 9.3%)	37, 9.6%	6, 7.7%	15, 9.6%
PE (n=20, 3.2%)	16, 4.1%	3,3.8%	1, 0.6%
PPH (n=228, 36.7%)	128, 33.1%	33, 42.3%	67, 42.9%
Vaginal delivery (n=348, 56.1%)	226, 58.5%	40, 51.3%	82, 52.6%
Instrumental delivery (n=46, 7.4%)	24, 6.2%	5, 6.4%	17, 10.9%
Elective CS (n=107, 17.3%)	75, 19.4%	9, 11.5%	23, 14.7%
Emergency CS (n=119, 7.4%)	61, 15.8%	24, 30.8	34, 21.8%
LBW <2500g (n=20, 4.0%)	13, 4.1%	6, 9.1%	1, 0.8%
Macrosomia >4000g (n=100, 19.8%)	65, 20.7%	9, 13.6%	26, 20.8%
Preterm <37weeks (n=36, 6.1%)	21, 5.7%	14, 18.2%	1, 0.7%
Breastfed at birth (341, 55.4%)	187, 49.0%	48, 62.3%	106, 67.9%
Any other combination of feeding at birth (n=274, 44.6%)	195, 51.1%	29, 37.7%	50, 32.0%

5.3.5.1 All pregnancy complications

There were 621 records available for analysis. Pregnancy complications of any sort were more common among non-attenders (n=96, 24.8%) than for attenders (n=25, 16.0%) and partial attenders (n=16, 20.5%; Table 5.3). For overall pregnancy complications there was no statistically significant difference seen between the partial attenders and non-attenders (p=0.435). There was a statistically significant difference between the attenders and non-attenders (p=0.026). As shown in Table 5.4 the risk of complications was reduced by 42% in attenders and 74% in partial attenders

(unadjusted odds ratios). After adjustment for maternal age, folate supplementation, vitamin D supplementation, ethnicity, gravida, deprivation index the impact of partial attendance was no longer significant but there was a reduced risk in all pregnancy complications when attending Bumps and Beyond versus not attending with an adjusted odds ratio (AOR) of 0.53, CI 0.31-0.91, (Table 5.4).

Table 5.4 Impact of the intervention upon complications during pregnancy when comparing attenders v non-attenders, or non-attenders v partial attenders.

	UOR	**CI (Confidence Interval)**	**AOR***	**95% CI**
Attenders v non-attenders				
Total Pregnancy comp	**0.58^**	**0.36 - 0.94**	**0.53^**	**0.31-0.91**
GDM (Gestational Diabetes Mellitus)	0.36	0.16 - 0.82	ns	
GHT (Gestational hypertension)	1.01	0.54 - 1.89	ns	
PE (Pre-eclampsia)	**0.15^**	**0.02 - 1.14**	**0.05^**	**0.003-0.642**
Partial-attenders v non-attenders				
Total Pregnancy comp	0.26	0.14-0.48	ns	
GDM (Gestational Diabetes Mellitus)	0.63	0.26-1.54	**0.39∞**	**0.16-0.93**
GHT (Gestational hypertension)	0.79	0.32-1.94	ns	
PE (Pre-eclampsia)	0.93	0.26-3.26	**0.095∞**	**0.009-0.959**

Data are shown as odds ratios and 95% confidence intervals. UOR- unadjusted odds ratio, AOR- adjusted odds ratio. All to 2 d.p except PE which is to 3 d.p. due to small numbers. Ns = not significant.

*Adjusted for maternal age, folate supplementation, vitamin D supplementation, ethnicity, gravida, deprivation index. ^ Attendance reduced risk of total complications and PE. ∞Partial attendance reduced risk of GDM and PE.

5.3.5.2 Gestational Diabetes (GDM)

Fifty-eight women were diagnosed with GDM (Table 5.3). There were forty-five non-attenders (11.6%), six partial attenders (7.7%), and seven attenders (4.5%; Table 5.3). Whilst the unadjusted odds ratio indicated a reduction in risk of GDM in women who fully attended the intervention compared to non-attenders, no significance was found between these two groups after adjustment through binary logistic regression (AOR 0.61, CI 0.18-2.02, see Table 5.3). Conversely, no significance was seen between the partial attenders and any other group in unadjusted analysis, but partial attenders had a 61% reduced risk of GDM when compared to the non-attenders in the adjusted model. Together these data suggest that attending Bumps and Beyond was associated with lower risk of GDM.

5.3.5.3 Gestational Hypertension (GHT)

There were fifty-eight women that were diagnosed with GHT (Table 5.3). The split was 37 women did not attend (9.6%), 6 women partially attended (7.7%), and 15 did attend (9.6%), table 2.2. Attendance at Bumps and Beyond either in full or partially had no significant impact on occurrence of GHT in this population (Table 5.4).

5.3.5.4 Pre-eclampsia (PE)

The number of women diagnosed with PE was 20 (3.2%) with a split of 16 women were non-attenders (4.1%), 3 were partial attenders (3.8%), and 1 was an attender (0.6%; Table 5.3). In unadjusted analysis full attendance at Bumps and Beyond reduced risk of PE by 85% and after adjustment this effect strengthened with AOR 0.05, (CI 0.003-0.642). For partial attenders there was also a significant reduction in PE risk after adjustment (AOR 0.095, CI 0.009-0.959; Table 5.4) These results

indicate that both full attendance and partial attendance dramatically reduced risk of pre-eclampsia by up to 95%.

5.3.6 Impact of Bumps and Beyond attendance on labour and delivery

5.3.6.1 Post-partum haemorrhage (PPH)

Two hundred and twenty-eight women had a diagnosis of PPH (volume not recorded; Table 5.3). Unadjusted analysis suggested an increase in risk of PPH associated with Bumps and Beyond attendance (Table 5.5). The binary logistic regression was adjusted for maternal age, deprivation index, ethnicity, gravida, folate supplementation, vitamin D supplementation, mode of delivery and baby weight. After adjustment no significant differences were found between any groups.

Table 5.4 Impact of the intervention on labour complications and mode of delivery when comparing attenders v non-attenders, or non-attenders v partial attenders.

	UOR	CI	AOR*	CI
ǂ**PPH (attend v non-attend)**	**1.52**	**1.04 - 2.23**	ns	
ǂ**PPH (non- attend v part-attend)**	1.48	0.90-2.44	ns	
Mode of delivery (attend v non-attend)				
Instrumental	1.95	1.00 - 3.81	ns	
Emergency caesarean	1.54	0.94 - 2.51	ns	
Elective caesarean	0.85	0.50 - 1.44	ns	
Mode of delivery (non-attend v part-attend)				
Instrumental	1.18	0.42 - 3.27	ns	
Emergency caesarean	**2.22**	**1.25 - 3.97**	ns	
Elective caesarean	0.68	0.31 - 1.46	ns	

Data are shown as odds ratios and 95% confidence intervals. UOR- unadjusted odds ratio, AOR- adjusted odds ratio. Figures to 2 d.p. *Adjusted for maternal age, deprivation index, ethnicity, gravida, folate, and vitamin D supplementation. ǂPPH additionally adjusted for mode of delivery and baby weight. No significance (ns) is seen for any outcome once adjusted for confounders.

5.3.6.2 Mode of delivery

Mode of delivery included normal vaginal, instrumental, emergency caesarean, and elective caesarean. Six-hundred and twenty records were available for analysis. For those that attended all sessions of Bumps and Beyond (n=156), 52.6% had a normal delivery (n=82), 10.9% had an instrumental delivery (n=17), 21.8% had an emergency caesarean (n=34), and 14.7% had an elective caesarean (n=23). For partial attenders (n=78), 51.3% had a normal delivery (n=40), 6.4% had an instrumental delivery (n=5), 30.8% had an emergency caesarean (n=24), and 11.5% had an elective caesarean (n=9). For non-attenders (n=386), 58.5% had a normal delivery (n=226), 6.2% had an instrumental delivery (n=24), 15.8% had an emergency caesarean (61), and 9.4% had an elective caesarean (n=75; Table 5.3).

Simple Chi-square analysis showed a significant difference between the groups for mode of delivery, (p=0.014), suggesting that women who had attended the intervention were more likely to have a labour intervention. Binary logistic regression was adjusted for maternal age, deprivation index, ethnicity, gravida, folate supplementation and vitamin D supplementation and indicated no significant differences in likelihood of any mode of delivery between either non-attenders and attenders, or non-attenders and partial attenders (Table 5.5). This would indicate that Bumps and Beyond attendance did not significantly affect mode of delivery in these groups of women.

5.3.7 Impact of Bumps and Beyond attendance on birth outcomes

5.3.7.1 Gestation

Gestation at birth was recorded on the audit sheets as above 37 weeks and classed as full term, or below 36+6 weeks (classed as premature). A total of 595 audit sheets had these data recorded with 29 missing cases (total records n= 624). A Chi^2 test was run on this data and showed a significant difference between groups ($p<0.01$), suggesting that full attendance reduced the risk of prematurity and that risk was higher in the partial attendance group. The majority of babies were born after 37 weeks gestation in all groups (n=559). The number of premature babies was 1 in the attenders group, 14 in the partial attenders group, and 21 in the non-attenders group (Table 5.3). In order to find the direction of significance both unadjusted, and adjusted odds ratios were calculated, these can be seen in Table 5.6. Attendance at all sessions of Bumps and Beyond was associated with a marked decrease (98%) in the likelihood of a gestation before 37 weeks. There was no effect seen when comparing the partial attenders and non-attenders.

Table 5.5 Impact of intervention on birth and feeding outcomes when comparing attenders v non-attenders, or non-attenders v partial attenders.

	UOR	CI	AOR*	CI
Gestation (attend v non-attend)				
<37 weeks	**0.11[a]**	**0.01 - 0.83**	**0.02[a]**	**0.02-0.17**
Gestation (part-attend v non-attend)				
<37 weeks	3.67	1.77 - 7.60	ns	
Birth weight (attend v non-attend)				
Low Birth Weight <2500g	0.19	0.02 - 1.44	**0.08[b]**	**0.01-0.78**
Macrosomia >4000g	1.01	0.60 - 1.68	ns	
Birth weight (part-attend v non-attend)				
Low birth weight <2500g	2.32	0.85 - 6.33	ns	
Macrosomia >4000g	0.60	0.28 - 1.30	ns	
~Feeding choice at birth (attend v non-attend)				
Breastfeeding	**2.21[c]**	**1.50-3.27**	**1.68[c]**	**1.09-2.60**
Other method of feeding	**0.45[d]**	**0.31-0.67**	**0.59[d]**	**0.39-0.92**
Feeding choice at birth (non-attend v part-attend)				
Breastfeeding	**1.73[e]**	**1.04-2.85**	ns	
Other method of feeding	**0.58[e]**	**0.35-0.96**	ns	

Data are shown as odds ratios and 95% confidence intervals. UOR- unadjusted odds ratio, AOR- adjusted odds ratio. All figures to 2 d.p. *Adjusted for maternal age, deprivation index, ethnicity, gravida, folate, and vitamin D supplementation. ~Feeding choice additionally adjusted for pregnancy complications and delivery type. [ab]Attendance reduced risk. [c]Attendance increased the likelihood of breastfeeding as the first feed. [d]Attendance reduced the likelihood of other types of feeding (bottle or combination) as first feed. [e]Partial attendance reduced the likelihood of other feeding but not once adjustments were made.

5.3.7.2 Birth weight.

A total of 508 audit sheets recorded the birth weight of the baby. Birth weights were recorded in grams, and for the results of this analysis have been rounded to whole figures. Mean birth weight for babies born to attenders (n=125) was 3616g (minimum 2360g, maximum 4950g), mean birth weight for non-attenders (n=317) was 3541g (minimum 905g, maximum 5090g), and for partial attenders (n=66) mean birth weight was 3381g (minimum 1350g, maximum 4950g). ANOVA (Analysis of Variance) with LSD (Least Statistical Difference) post-hoc comparison showed a significant difference between attenders and partial attenders, with partial attender's

babies being born significantly smaller than in the other groups (p=0.007), and between partial attenders and non-attenders, (p=0.040). There was no significant difference between attenders and non-attenders, (p=0.215).

Further analysis of birth weights was undertaken to see whether there was any impact of the intervention on occurrence of either macrosomia or low birth weight (LBW) deliveries. Macrosomia is classed as a weight above 4000g regardless of gestational age, and LBW is classed as a birth weight below 2500g regardless of gestational age. One hundred babies were classed as having macrosomia, (non-attenders group n=65, 20.7%; partial attenders group n=9, 13.6%; attenders group n=26, 20.8%; Table 5.3). Twenty babies were born at LBW (non-attenders n=13, 4.1%; partial attenders n=6, 9.1%; n=1, 0.8%; Table 5.3). Binary logistic regression adjusted for maternal age, deprivation index, ethnicity, gravida, folate, and vitamin D supplementation was run for both categories with the group comparisons of non-attenders and attenders, and non-attenders and partial attenders. This showed that attenders were 92% less likely to have an LBW baby, AOR (Adjusted Odds Ratio) 0.08, CI 0.01-0.78; Table 5.6). Partial attendance had no impact on LBW and there was no significant effect of attendance on occurrence of macrosomia.

5.3.7.3 Feeding practice

Feeding practice at birth was logged on the audit sheet and indicated the mode of feeding from delivery to discharge from hospital. Feeding practices included breast feeding, artificial feeding (formula milk), or combination feeding (breast and

formula). A total of 615 records were included in the analysis (attenders n=156, partial attenders n=77, non-attenders n=382). Nine records had missing data. Three hundred and forty-one babies were breast-fed at birth. Breastfeeding was recorded for 67.9% of attenders (n=106), 49.0% of non-attenders (187), and 62.3% of partial attenders (n=48). For artificial feeding (n=268), 18% were attenders (n=49), 72% were non-attenders (n=192), and 10% were partial attenders (n=27). Finally, for mixed feeding (n=6), 17% were attenders (n=1), 50% were non-attenders (n=3), and 33% were partial attenders (n=2). Table 5.6 shows that whilst partial attenders were not significantly more likely to breastfeed than non-attenders (after adjustment for confounders), full Bumps and Beyond attendance was associated with a 68% increase in likelihood of breastfeeding (AOR 1.68, 95% CI 1.09-2.60). The attendees were also 41% (AOR 0.59, 95% CI 0.39-0.91) less likely to use any other form of feeding at birth (Table 5.6).

5.4 Discussion

The results of this service evaluation are very encouraging with regards to this intervention programme with this specific population, particularly when looking at the primary outcome measure (overall GWG). Both the previous and current evaluations indicated high efficacy of the intervention, as women who attended Bumps and Beyond had lower GWG and were less likely to have weight gain in excess of the IOM recommendations (McGiveron *et al.*,2015). In the present study whilst 67% of non-attenders gained more than the maximum recommended 9kg, only 14% of attenders and 26% of partial attenders did so. A number of non-RCT weight management intervention programmes also showed a positive impact on gestational weight gain when they compared the controls to the intervention group (Robertson & Ladlow, 2018; Haby *et al.*,2018; Koleilat *et al.*,2017; Haby *et al.*,2015; Mottola *et*

al.,2010; Shirazian *et al.*,2010). There are mixed results with RCTs with very few showing significant effect on reducing GWG (Herring *et al.*,2017; Rauh *et al.*,2013; Renault *et al.*,2014; Phelan *et al.*,2011; Quinlivan *et al.*,2011; Vinter *et al.*,2011).

The aim of keeping GWG down is to reduce the overall complications for both mother and foetus with the latest MBRRACE-UK report indicating that a BMI > 30kg/m^2 and excess GWG was a direct cause of death for 29% of those women that died either during or up to six weeks post-pregnancy over a two-year period (Knight *et al.*,2020). Due to a high BMI being such a risk factor, enabling women to keep their weight gain within the IOM range should improve outcomes for both mother and child (IOM 2009). Lincolnshire Bumps and Beyond demonstrates that a local, pragmatic approach was highly effective in limiting GWG, performing better than many large RCTs (Herring *et al.*,2017; Rauh *et al.*,2013; Renault *et al.*,2014; McGiveron *et al.*,2015; Phelan *et al.*,2011; Quinlivan *et al.*,2011; Vinter *et al.*,2011).

5.4.1 Results of previous service evaluation

Results of the initial service evaluation by McGiveron *et al* (2015) compared maternal, obstetric and neonatal outcomes between those women who attended the programme (intervention group) and those that declined (non-intervention group). This showed that mean weight gain was less in the intervention group n=89 [4.5(4.6) kg] than the non-intervention group n=89 [10.3(4.4) kg] between dating scan and 36 weeks gestation ($p<0.001$) (McGiveron *et al.*,2015). Weight loss was observed in 21% of women in the intervention group. The intervention was associated with a significant reduction in gestational hypertension (OR 0.05, 95% CI 0.01-0.22), and in post-partum haemorrhage (OR 0.45, 95% CI 0.21-0.96) when compared to the non-intervention group). No effect was seen on other complications of pregnancy or

labour, birth weight or length of hospital stay. No adverse effects were seen, even though a number of the women lost weight during pregnancy.

5.4.2 Comparison of the two service evaluations

The current service evaluation was completed in order to reassess the McGiveron *et al* (2015) findings. The current evaluation had access to 624 audit sheets which allowed for more comprehensive analysis of data. There was also the capacity to determine whether partial attendance of the programme had an impact on outcomes, and whether there were any influences of the location at which the intervention was delivered. The patient group in this evaluation was very similar to the original group in terms of age and booking weight and had a similar booking BMI.

When comparison of weight gain through pregnancy from booking appointment to week 36 of gestation was made, the McGiveron *et al* (2015) evaluation findings were similar to the present analysis when comparing the attenders/intervention, and non-attenders/non-intervention groups. Attenders/intervention groups gained less weight through the pregnancy, (mean (SD) in kg 5.25 (5.35)/ 4.5 (4.6)) whilst the non-attenders/ non-intervention groups gained more than the Institute of Medicine recommendation (mean (SD) in kg 9.22 (5.09)/10.3 (4.4)). The partial attenders also stayed within the IOM range with a weight gain of 6.24kg SD 4.60kg. It must be remembered though that this is weight gain from around week 11 gestation to week 36 and so does not include the entire pregnancy. As both attenders/intervention, and partial attenders were all at the lower end of the IOM range we can infer that these women did stay within the 5-9kg recommendation (Rasmussen, Yaktine & IOM, 2009).

The US (United States) Institute of Medicine recommends that pregnant women with a pre-pregnancy BMI >30 kg/m^2 gain between 5 and 9 kg across their pregnancy (Rasmussen, Yaktine & IOM, 2009). This recommendation is largely followed by clinicians in the UK, in the absence of UK-specific recommendations. There are no specific recommendations for women living with more profound obesity, and the 5-9 kg recommendation is equally applied to women with BMI >35 and women of BMI 30-35 kg/m^2. In the present study, as in the McGiveron *et al* report, there were women who lost weight (see Figure 5.3), and on average women who were partial or full attenders at the Grantham site and full attenders at Gainsborough had a gestational weight gain below 5kg. It is generally assumed that weight loss in pregnancy should be avoided as there may be adverse consequences for fetal development (Langley-Evans 2014). This study could only consider whether there were short-term impacts of weight gain below the Institute of Medicine recommendation. No differences in Apgar scores at 1 and 5 minutes after birth, or birthweight were seen when comparing women who gained less than 5kg with those who gained more than 5 kg, and low weight gain was not associated with adverse pregnancy outcomes.

Little is actually known about the effect of weight loss in pregnancy on fetal development and it is recognised that it is relatively common during the first trimester given the impact of nausea and vomiting of pregnancy. The latter condition has been associated with improved pregnancy outcomes (Furneaux *et al.*, 2001; Koren *et al* 2014) There is some concern that weight loss may have a longer-term programming effect on disease risk in the impacted babies, but this has not been specifically investigated in human pregnancy (Langley-Evans, 2014; 2022). Weight loss in a

severely obese woman would have very different basis and consequences compared to a woman who is underweight. In the latter case this would indicate undernutrition (with both short and long-term consequences for the baby), whilst for the obese woman it could indicate a relatively minor shift in body fatness with no consequences. Research shows that normal pregnancy is associated with a redistribution of body fat (Langley-Evans 2021).

This evaluation of the Bumps and Beyond intervention showed a significant success in reducing risks of total pregnancy complications by 47%, and pre-eclampsia by 95% in the group that had attended all sessions of Bumps and Beyond when compared to the non-attenders. When partial attenders were compared to non-attenders the findings were a reduction in risk for gestational diabetes mellitus of 61%, and pre-eclampsia 9%. These findings differ from McGiveron *et al* (2015) who found a reduction in risk of gestational hypertension by 95% for the attenders only when looking at pregnancy complications. It is most likely that the difference in outcomes may be due to the smaller sample size within the original evaluation. With a low sample size and pregnancy outcomes which are relatively uncommon even among women with BMI >35 kg/m2, the likelihood of missing a benefit of the intervention is greater. The current study was better powered statistically. The results of the current larger analysis verify that Bumps and Beyond reduced risk for some pregnancy complications and so was an effective intervention for women with severe obesity (BMI > 35kg/m^2).

No reduction in risk was seen for any element of labour or delivery in this evaluation, again a difference to the results seen in the original service evaluation where

attendance at the Bumps and Beyond programme was associated with a reduction of post-partum haemorrhage (McGiveron *et al.*,2015). Assessment of post-partum haemorrhage is quite subjective and so this could have played a part with the difference in results seen here.

When looking at birth and post-partum related factors this evaluation found a reduced risk of premature birth of 98% (OR 0.02, 95% CI 0.02-0.17), and low birth weight babies 92% (OR 0.08, 95% CI 0.01-0.78) among the attenders versus the non-attenders. These results differ from the original evaluation where no difference was seen (McGiveron *et al.*,2015). Again, this disagreement will be attributable to the greater statistical power of the current study. Both of these factors can lead to poor outcomes in a neonate and so any reduction in the risk associated with them is positive. The major cause of premature birth is pre-eclampsia which is treated by early caesarean delivery, so it is unsurprising that an intervention that would reduce risk of PE would have a knock-on effect on gestation length. Similarly, as birthweights were not adjusted for gestation length, a reduction in risk of LBW birth would be expected.

Both evaluations found a large increase in women initiating breast feeding following attendance of Bumps and Beyond sessions, with a 75% increase for the 2015 McGiveron *et al.*, evaluation, and 68% increase for the current analysis. This level of increased initiation sits very firmly within the UNICEF ideal that women breastfeed wherever possible due to the positive impact on both mum and baby (UNICEF UK, 2021). Unfortunately, these figures were still lower than that reported by the last UKs Infant Feeding Survey in 2010, with breast feeding initiation rates of

81% (McAndrew *et al.*,2012). This may reflect the fact that the majority of subjects lived in deprived areas. Deprivation is one factor which predicts low breastfeeding initiation (Brown and Sear, 2019; Brown *et al.*,2010). All of the women had an initial BMI $\geq$35kg/m^2 and severe obesity is also associated with lower uptake of breastfeeding.

5.4.3 Comparison to similar interventions

For this evaluation, only papers from the last ten years have been included for comparison purposes. There are a multitude of interventions that have taken place over that period which use GWG within the IOM weight gain recommendations in pregnancy (for a BMI above 35kg/m^2) as a primary or secondary outcome (Aung *et al.*,2021; Hutchesson *et al.*,2020; Rasmussen, Yaktine & IOM, 2009). One intervention 'Mighty Mums' based in Sweden used a GWG figure based on a national recommendation used within antenatal settings of 7kg (Haby *et al.*,2015; Haby *et al.*,2018). Many of these studies are randomised controlled trials (RCT) which makes direct comparison to this intervention difficult due to the differing methods used, however, their results are still useful as they use GWG within IOM guidelines, or health outcomes for mother and baby, as primary outcomes and the research population are women with obesity (Liu *et al.*,. 2021; Downs *et al.*,. 2021; Okesene-Gafa *et al.*,. 2019; Peccei *et al.*,. 2017; Poston *et al.*,. 2015; Dodd *et al.*,. 2014; Poston *et al.*,. 2013; Bogaerts *et al.*,. 2013; Guelinckx *et al.*,. 2010).

The largest of these RCTs (Randomised Controlled Trials) (UPBEAT (UK Pregnancies Better Eating and Activity Trial) and LIMIT) recruited 2202 participants,

and 1555 participants respectively (Poston *et al.,*. 2015; Dodd *et al.,*. 2014) however the primary outcomes for both of these RCTs were maternal and baby outcomes rather than weight gain specifically. In the LIMIT trial conducted in Australia, Dodd *et al* (2014) found that a diet and lifestyle intervention reduced the risk of a birth weight above 4000g by 18% (RR 0.82, CI 0.68 to 0.99, p=0.04), a different result to the Lincolnshire Bumps and Beyond intervention. The results for maternal weight gain showed no significance for the intervention group with any of the categories analysed – below/within/above – IOM recommendations (Dodd *et al.,*. 2014). The UK Pregnancies Better Eating and Activity Trial (UPBEAT) had a primary outcome of a reduction in GDM with a number of secondary maternal outcomes including managing GWG (Poston *et al.,*. 2015). No effect of the intervention was seen with the majority of outcomes reported although total weight gain over the pregnancy was on average 0.55kg less in the intervention group, p=0.041 (Poston *et al.,*. 2015). This contrasts to the 4kg difference noted in the current analysis.

Smaller RCTs had mixed outcomes (Liu *et al.,*. 2021; Downs *et al.,*. 2021; Okesene-Gafa *et al.,*. 2019; Peccei *et al.,*. 2017; Bogaerts *et al.,*. 2013; Guelinckx *et al.,*. 2010). All of these were looking at the effect of the intervention on GWG as a primary outcome with a range of secondary outcomes dependent on style of intervention (Liu *et al.,*. 2021; Downs *et al.,*. 2021; Okesene-Gafa *et al.,*. 2019; Peccei *et al.,*. 2017; Bogaerts *et al.,*. 2013; Guelinckx *et al.,*. 2010). Of these RCTs, results for all bar one showed no significant impact of intervention on GWG (Liu *et al.,*. 2021; Downs *et al.,*. 2021; Okesene-Gafa *et al.,*. 2019; Peccei *et al.,*. 2017; Guelinckx *et al.,*. 2010). Bogaerts et al (2013) ran an RCT (Randomised Controlled Trials) that used three groups, a control group that had standard ante-natal care, a brochure group that

received standard care plus a brochure that contained information on nutrition and physical activity and how to keep GWG within appropriate limits, and an intervention group. Results reported were that both the intervention and brochure groups gained less weight throughout the pregnancy, p=0.007 but the brochure group actually had a lower weight gain overall (9.5kg SD 6.8kg v 10.6kg SD 7kg). No group stayed within the IOM guidance (Bogaerts *et al.,*. 2013).

There are also a small number of cohort, case-control or pilot studies that more closely resemble the Bumps and Beyond approach and so some parallels can be made (Robertson & Ladlow, 2018; Haby *et al.*,2018; Koleilat *et al.*,2017; Opie *et al.*,2016; Haby *et al.*,2015; Mottola *et al.*,2010; Shirazian *et al.*,2010). All of the cohort studies directly recruited women to the intervention and then made comparison to an historical matched cohort (Koleilat *et al.*,2017; Mottola *et al.*,2010; Shirazian *et al.*,2010). Each of these studies had overall GWG compared to IOM recommendations as the primary outcome, with secondary outcomes including reductions in pregnancy and birth complications (Koleilat *et al.*,2017; Mottola *et al.*,2010; Shirazian *et al.*,2010; Rasmussen, Yaktine & IOM, 2009). Reporting methods for GWG were slightly different for each study, however only the Lifestyle Modification Program (LMP) (Shirazian *et al.*,2010), and the Nutrition and Exercise Intervention Program (NELIP) (Mottola *et al.*,2010) reported a significant reduction in GWG in the intervention groups. Both of these interventions contained nutrition and exercise advice for the participants with delivery by a range of personnel (Shirazian *et al.*,2010; Mottola *et al* 2010). No difference was seen between groups for secondary outcomes related to pregnancy, birth, or baby in the LMP intervention (Shirazian *et al.*,2010). The NELIP intervention reported that women with overweight, and women with obesity, in the intervention group had fewer babies

weighing between 4-4.5kg, p=0.048 and p=0.071 respectively when compared to the historical cohort, with no difference seen for babies weighing over 4.5kg between any grouping (Mottola *et al.*,2010). This differs from the findings from this evaluation where the results were non-significant between any of the groups for weight over 4kg. No other significant findings were reported from the NELIP study (Mottola *et al.*,2010).

A number of case-control intervention studies have been carried out since 2010 which are also comparable to the Bumps and Beyond intervention (Haby *et al.*,2018; Opie *et al.*,2016; Haby *et al.*,2015). The Mighty Mums very closes matched the Bumps and Beyond intervention in that it covered lifestyle advice (healthy eating and physical activity), and was based on local needs (Haby *et al.*,2015; Haby *et al.*,2018). The initial findings for the first 100 women (50 in each group) reported a statistically significant difference between the two groups for total weight gain with the intervention group gaining 8.6kg SD ±4.9kg compared to the control group 12.5kg SD ±5.1, p<0.001 (Haby *et al.*,2015). Analysis was both intention-to-treat (ITT), and per-protocol (PP) which more closely matches the analysis used within this evaluation (Haby *et al.*,2018). For the final analysis the team also included a secondary aim of the interventions effect on maternal and perinatal health (Haby *et al.*,2018). Haby et al (2018) reported with the PP analysis a statistically significant reduction in GWG for the intervention group, 8.9kg ±6kg compared to the control group, 11.2kg ±6.9kg, p=0.031. These overall weight gain figures are higher than those recorded with the current evaluation when comparing the attenders (5.25kg SD ±5.35kg) or partial attenders (6.24kg SD ±4.60kg) to the non-attenders (9.22kg SD ±5.09kg), p<0.00 for both comparisons. Haby *et al* (2018) reported no significances for any maternal or perinatal outcomes between the two groups, very different to this evaluation of

Bumps and Beyond in which a reduction of total pregnancy complications was seen within the attenders group, a reduction of PE seen in both attenders (95%) and partial attenders (91%), and also a of reduction of risk of premature delivery for both of these groups.

Opie *et al* (2016) ran an intervention that focussed on culturally appropriate dietary advice given by dietitians and used a range of behaviour change techniques to enable the participants to have the confidence to make changes. Their primary outcome was to limit GWG, set a weight gain target within the IOM guidance, and also to reduce maternal, fetal and ante-natal complications (Opie *et al.*,2016). They reported no significant differences for any of the outcomes set (Opie *et al.*,2016).

The final intervention used for comparison to this evaluation also looked at dietetic intervention and was a pilot study looking to optimise GWG in pregnancy for women with a BMI >35kg/m^2 (Robertson and Ladlow, 2018). Results of this study showed GWGs (Gestational Weight Gain) that fell within the IOM guidance of 5-9kg for 63% of participants however the study also reported that GDM was more frequent in participants than figures recorded by the hospital where the intervention took place, 18.4% compared to 15.1%. The more appointments the participants attended, the lower their GWG, a finding which mirrors the current evaluation's findings.

5.4.4 Limitations

Whilst this service evaluation shows a number of positive outcomes for the women that either completed the programme or attended at least one session there are

limitations with the data analysis which need to be considered. The audit forms were completed by staff during the scheduled maternity appointments but not by researchers who can ensure that all of the appropriate data is captured. This meant that a number of forms had incomplete information which reduced the statistical power for those areas or meant that some aspects of the data cannot be analysed. As the health professionals delivering the intervention will have used different sets of scales for weighing women and babies some variation in data quality may have been possible, but this would be unlikely to have been of a magnitude to impact the overall analysis.

Selection of participants was governed by the enthusiasm of the individual women to attend the Bumps and Beyond intervention once offered. There is no doubt that this will lead to selection bias and may skew the results towards a positive impact of the intervention due to high levels of motivation. That said, the women who did attend came from a range of backgrounds and socioeconomic bands. The aims of the Bumps and Beyond programme (Figure 1.1), included a number of goals that were not recorded on the audit sheets which means that this evaluation is not able to show if any impact of the intervention has been made in those areas. There was no investigation into the reasons why women declined this intervention and further research around this is vital to aid understanding of the needs of these women. The intervention worked well in this geographical location but it cannot be said with certainty that it could transfer this success elsewhere. Lincolnshire has a largely white population with the 2011 census reporting 93% of the overall population being White British, and 4% White Other (NHS Clinical Commissioning Group, 2021). The 4% were mostly of an Eastern European background (NHS Clinical Commissioning

Group, 2021). This mirrors the results seen in Table 5.1 for this service evaluation. There also needs to be consideration with regard to the staff that delivered the intervention in this location. All were from the local area and had an extensive knowledge of services available for the participants that could support a reduction in weight gain and complications. The staff were able to offer tailored advice and give information about those services to fit the attenders needs based on the aims set and material covered in the session, examples of these can be seen in Appendix 2

A lack of standardised equipment is always an issue for studies of this nature. With women being weighed at multiple centres in quite informal settings an element of measurement error may have been present as weighing scales were not standardised and randomly checked. However, this is unlikely to have had a major impact on the findings of the study for several reasons. Firstly, the error factor would be random as each centre would have weighed a mixture of attenders, partial attenders and non-attenders, thereby not introducing systematic bias to any one group. It was also the case that all weighing was carried out on NHS sites and the scales would have been considered accurate enough for clinical use. Finally, the difference in weight gain seen between attenders and non-attenders was of the order of 4 to 5 kg, whilst variability between weighing scales would be unlikely to be more than 1kg.

In determining adjusted odds ratios for the impact of intervention on pregnancy, labour and birth outcomes, binary logistic regression models were able to make adjustment for a number of potential confounding factors. It is possible that other unrecorded confounders were at play in this study, but there is a high level of confidence that most known confounders identified elsewhere in the literature were

included in the analysis. In some of the analyses the difference between unadjusted and adjusted outcomes were stark (for example the risk of PE in partial attenders vs non-attenders was 0.93 in unadjusted analysis and 0.095 after adjustment). There were powerful effects of deprivation, and parity in many of the analyses as women attending the intervention were more likely to be first time mothers and to live in a less deprived area. The population overall is predominantly White British with less diversity than other nearby counties and all staff members delivering the intervention were also White British. However, the staff were local to the area, had worked in behaviour change around health previously and had an excellent understanding of the needs of the participants and what was available for them locally to support the healthier behaviours wanted.

5.5 Conclusion

This service evaluation adds evidence to the fact that local interventions targeting GWG appear to have a better outcome than large RCTs. The reasons for this are multifactorial but likely, in part, because they are run at easy to reach locations by local people who understand the issues within the area. The intervention can be more adaptive and show flexibility within the content delivery whilst still ensuring high quality.

Chapter 6. A service evaluation of the Nottingham City and Nottinghamshire County Bumps and Beyond intervention to manage pregnancy weight gain in women with moderate to severe obesity

6.1 Introduction

6.1.1 Lincolnshire Bumps and Beyond results

As described in the previous chapter, Lincolnshire Bumps and Beyond was highly effective in keeping weight gain within the IOM guidance (Rasmussen, Yaktine & IOM 2009) for both attenders ($p<0.001$) and partial attenders ($p<0.001$). The Lincolnshire programme had a huge impact on reduction of risk for pre-eclampsia (PE) for both attenders (AOR 0.05 CI 0.003-0.642) and partial attenders (AOR 0.39 CI 0.16-0.93) when compared to the non-attenders. Partial attenders risk of gestational diabetes (GDM) was reduced compared to the non-attenders too (AOR 0.39 CI0.16-0.93), a similar effect was seen in the attenders but once adjustment for maternal age, folate supplementation, vitamin D supplementation, ethnicity, gravida, and deprivation index this disappeared. Attenders were less likely to have premature (<37 weeks gestation) (AOR 0.02 CI 0.02-0.17) and low birthweight (LBW) babies (AOR 0.08 CI 0.01-0.78) than the non-attenders. Breastfeeding as the first form of nutrition was more likely in the attender group than either the partial or non-attenders but only before adjustment as listed above plus pregnancy complications and delivery type was made. The data presented in Chapter 5 largely agreed with the preliminary study

published by McGiveron *et al.*,(2015) but the bigger sample size gave greater confidence and demonstrated the possible benefits in relation to GDM.

6.1.2 The wider picture

The evaluation results of the Lincolnshire Bumps and Beyond intervention showed that small community focused programmes can have great success in reducing pregnancy weight gain as well as multiple other positive outcomes for baby and mother in contrast to generously funded RCTs (Symons Downs *et al.*,2021; Liu *et al.*,2021; Peccei *et al.*,2017; Dodd *et al.*,2014; Bogaerts *et al.*,2013; Guelinckx *et al.*,2010). There is now acknowledgement from health agencies that a community approach with weight intervention programmes is appropriate for obtaining the best outcomes for not only maternal and fetal health but also in prevention of serious health problems later in life (Davidson *et al.*,2021; PHE (Public Health England) 2020; WHO 2016; NICE 2010).

Obesity continues to be a major health risk factor for poor pregnancy outcomes. The UK Confidential Enquiries into Maternal Deaths and Morbidity (MBRACCE-UK) repeatedly finds that maternal obesity was both a direct, and indirect, cause of maternal death (Knight *et al.*,2017; Knight *et al.*,2016; Knight *et al.*,2016). Obesity does not just happen to women, there are multiple factors that create an environment that encourages obesity. These include socio-economic issues that must be considered when delivering any type of intervention. The capacity for small-scale, locally controlled interventions to be built around community needs, taking into account local circumstances, is vital to their success. Following initial reports of the efficacy of the Lincolnshire B&B intervention programme in reducing GWG in severely obese

women, great interest was shown by Nottingham University Hospitals NHS Trust (NUH NHS Trust) to introduce it to women attending maternity services within the areas they covered. This chapter describes the evaluation of the Bumps and Beyond service delivery in Nottinghamshire.

6.2 Methods

6.2.1 Intervention delivery

As described in Chapter 1, the intervention programme ran in a similar format as Lincolnshire B&B with a midwife, initially Mrs. Ailsa McGiveron and later Ms. Sally Anderson, having overall responsibility. Dr Lucy Kean, Consultant Obstetrician, was the lead for the programme within NUH NHS Trust, and health workers with degree level qualifications delivered the programme at sites across both Nottingham City and Nottinghamshire County. Bumps and Beyond Nottinghamshire began in 2016 and was open to women who came under the maternity care of NUH NHS Trust and had a BMI >30kg/m^2. This was a significant change to the protocol followed in Lincolnshire where only women with BMI >35kg/m^2 were invited to participate. Otherwise the intervention ran on the same principle, including seven sessions and recruiting women from approximately 16-weeks gestation.

6.2.2 Data collection

Data for the evaluation of the new service was collected via audit sheets completed by staff at the Nottingham University Hospitals (NUH) NHS Trust. These records were started at the woman's booking in appointment and completed post-partum. The audit sheets had been adapted to suit local maternity care needs and differed from slightly

from the Lincolnshire Bumps and Beyond version. Data were collected for all women eligible for the Nottinghamshire Bumps and Beyond weight management in pregnancy intervention regardless of whether they chose to attend. The intervention was run at different sites across the Nottingham area. As per the Lincolnshire audit sheets there were a number of pregnancy and labour outcomes recorded. Overall, these included the same groupings as Lincolnshire B&B however Nottingham had separated PPH to light (500-1000ml) or heavy (>1000ml). Nottingham had removed reference to vitamin supplementation and extended fetal outcomes to include reference to live birth, miscarriage, intra-uterine death (IUD), and stillborn. Analysis was not undertaken on this additional classification as there was nothing to compare within the Lincolnshire Bumps and Beyond data, and too few of these adverse outcomes occurred to make for a meaningful assessment.

6.2.3 Ethical approval

No ethical approval was required due to this being a service evaluation. This was logged within NUH NHS Trust by the staff involved with the intervention programme.

6.2.4 Statistical analysis

Data were input into SPSS version 26 and double-checked for accuracy. There were 681 records available. For analysis purposes 15 twin pregnancies were excluded. In addition to this, three records were removed due to lack of complete data (<5 complete data points). This left 663 records available for analysis. As per the Lincolnshire B&B analysis, women were grouped according to the number of B&B sessions attended; non-attenders (0 sessions), partial attenders (1-6 sessions), full attenders (7 sessions). Age of mother was calculated based on their date of birth and

the delivery date of their baby. For example if a mother was born on 1st July 1998 and gave birth on 14th August 2017, it is straightforward to determine that her age would be 19 years, 1 month and 1 days. This is a simple function in SPSS and there are also several web-based age calculation tools available (see https://www.calculator.net/age-calculator.html?today=07%2F01%2F1998&ageat=08%2F14%2F2017&x=92&y=19). A normal distribution was assumed for all data. The alpha value was set at 0.05.

No home postcodes were available for this cohort, so approximate socioeconomic status was calculated based on the location the women attended for their booking in appointment and data taken from from https://fryford.github.io/imdmap/. This is an interactive tool provided by the Ministry of Housing, Communities & Local Government. The areas are classed as Lower Super Output Areas and are used by local government to make economic decisions. Category one is least deprived and ten is most deprived. The decile totals were combined to make groups for a level of high (group 1-3), medium (groups 4-7) or low (8-10) deprivation index.

ANOVA was used to compare means and SD for; age, BMI at booking, weight in kg at booking, height in cm at booking, number of weeks pregnant at booking, gravida, and parity between the three groups, using LSD as a post-hoc analysis. A Pearson Chi^2 test was used to indicate independence with Phi and Cramers V tests for effect size was used to analyse; drinking alcohol during pregnancy, smoking during pregnancy, and homeowner status. The data collected on the audit sheets only noted any consumption of alcohol and any maternal smoking, so it was not possible to determine levels of consumption. No data was collected on exposure to other smokers

in the household or the use of illegal substances. The same tests were used for overall pregnancy complications; gestational diabetes; gestational hypertension; pre-eclampsia; mode of delivery; gestation less than 37 weeks; gestation more than 37 weeks; birthweight more than 4kg (macrosomia); birthweight less than 2.5kg; feeding practice at birth. As specified in the text, an independent T-test was used for some analysis within the non-attender group.

To assess the impact of Bumps and Beyond attendance on pregnancy complications, labour complications and birth outcomes, unadjusted odds ratios and 95% confidence intervals were determined using the Odds Ratio calculator tool at https://www.medcalc.org/calc/odds_ratio.php. Further analysis to determine odds ratios for these outcomes adjusted for confounding factors was performed using binary logistic regression, utilising a forward stepwise method.

6.3 Results

6.3.1 General

There were 663 records available for analysis. There were 470 non-attenders (70%), 143 partial attenders (22%), and 50 attenders (8%). There were 33 locations used for booking-in appointments within either the Nottingham City or Nottinghamshire County area (Figure 6.1 shows booking-in locations for attenders, partial attenders and non-attenders separately). Two hundred and ten records had no location recorded. Strelley (high deprivation) was the next highest attendance, constituting 8% of the total population, then Wollaton (low-to-middle deprivation; 6.3% of the population, and Clifton (high deprivation; 6.2%). All other locations accessed less than 6% of the population at booking-in. For some locations (Carlton, Keyworth, West Bridgford,

Valleys, Basford, Bingham and Aspley), none of the women engaged with the Bumps and Beyond service. There was no clear demographic difference between areas with no attendance and those from which Bumps and Beyond recruited. For example West Bridgford is the most affluent area of Nottingham, whilst Carlton is among the most deprived.

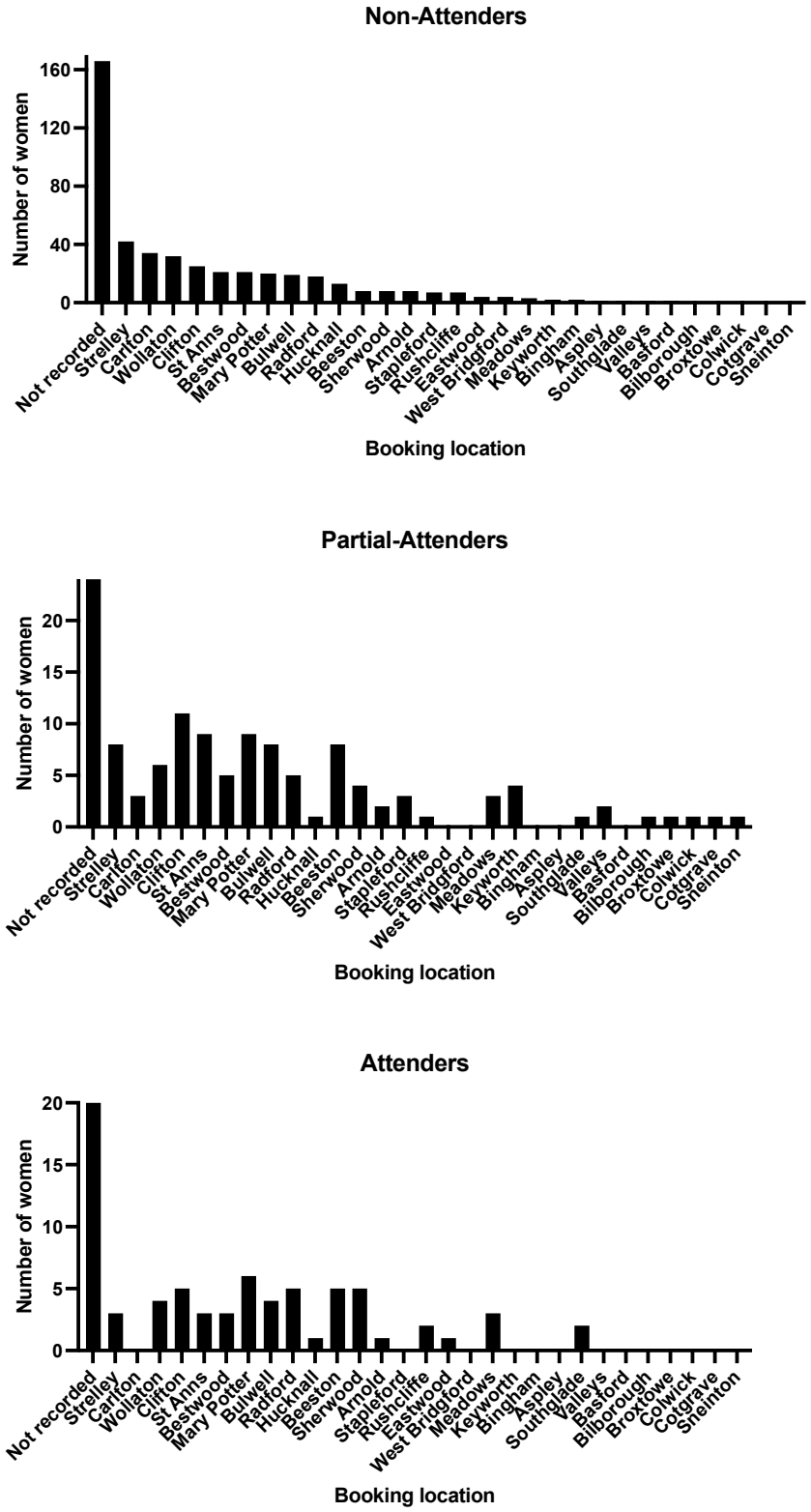


Figure 6.1 Individual locations used for booking in appointments as recorded on the audit sheets, ranked by number of women booked at each location. Non-attenders n=; partial attenders n=; attenders n=.

6.3.2 Descriptive data

As can be seen in Table 6.1, maternal age at delivery differed significantly between the three groups (p=0.047). Women who attended the Bumps and Beyond programme were significantly older than non-attenders (p=0.020), and partial attenders (p=0.026). Booking BMI also differed between the three groups (p=0.011). Post-hoc analysis showed this statistically significant difference was between non-attenders and partial attenders, who tended to have more serious obesity (p=0.006). Weight at booking in showed no difference between the groups. No statistical difference was seen between the groups for, gestation at booking in appointment (12 weeks SD 4weeks p=0.804), gravida (3± 2 p=0.928), and parity (1±1 p=0.834).

When drinking alcohol in pregnancy was reviewed, there were 653 records completed, of these only a total of 38 women reported that they drank alcohol in pregnancy - non-attenders n=29 (4.4%), and partial attenders n=9 (1.4%). All attenders reported that they did not drink alcohol (n=50). There were too few records completed to run comparison statistics. Six-hundred and sixty records were completed with data for smoking during pregnancy. Of these, 126 reported that they were smoking during their pregnancy - non-attenders n=102 (16%), partial attenders n=22 (3%), attenders n=2 (0.3%). Again, there were too few records completed to run comparison statistics. There were only 131 (20%) records completed with homeowner status. Seventy-three of these were partial attenders, 37 were attenders, and 21 were non-attenders.

Table 6.1. Characteristics of the women

Characteristic	Non-attenders N=470	Partial attenders N=143	Attenders N=50	All groups N=663	Between group p value
General					
Age (years) mean, SD, n	30.0 (5.3), n=127	29.2 (4.4), n=18	33.3 (4.7), n=15	30.2 (5.2), n=160	**0.047***
BMI (kg/m^2) mean, SD, n	35.3 (4.5), n=470	36.5 (4.8), n=143	36.4 (5.6), n=50	35.6 (4.7), n=663	**0.011**$^{\#}$
Weight (kg) mean, SD, n	95.0 (14.3), n=469	98.0 (16.3), n=143	98.2 (17.9), n=50	95.9 (15.1), n=662	0.069
Pregnancy					
Weeks at booking to whole number, SD, n	12 (5), n=440	12 (4), n=136	12 (3), n=49	12 (4), n=625	0.804
Gravida to whole number, SD, n	3 (2), n=470	3 (2), n=143	3 (2), n=50	3 (2), n=663	0.928
Parity to whole number, SD, n	1 (1), n=470	1 (1), n=143	1 (2), n=50	1 (1), n=663	0.834
Lifestyle					
Drinking in pregnancy - yes, %	29 (4.4%)	9 (1.4%)	0 (0%)	38 (5.8%), n=653	
Smoking in pregnancy - yes, %	102 (16%)	22 (3%)	2 (0.3%)	126 (19%), n=660	
Homeowners – yes, %	21 (16%)	73 (56%)	37 (28%)	131 (20%)	

SD (standard deviation). *indicates significantly different to non-attenders, $p<0.05$ and non-attenders and partial attenders ($p=0.26$). #indicates a significance was found with the post-hoc LSD test between non-attenders and partial attenders ($p=0.006$)

6.3.3 Weight change over pregnancy

There were 324 audit sheets available for analysis where both booking in weight and weight at 36 weeks gestation were recorded. Of these, 189 were non-attenders (58%), 85 were partial attenders (26%), and 50 were attenders (15%). Mean weight change from booking appointment to 36 weeks gestation was; non-attenders 7.3kg (SD 7.4kg), partial attenders 8.2kg (SD 5.4kg), and attenders 5.9kg (SD 5.6kg). These mean weight gains showed that the women stayed within the limits set by the IOM for weight gain in pregnancy for women with obesity of 5-9kg (Rasmussen, Yaktine & IOM, 2009). Figure 6.2 shows the weight gain for each individual woman within their grouping. All groups had women who lost weight during their pregnancy. The greatest loss of weight was in the non-attenders group (-11kg). This group also had the greatest weight gain (43kg). No statistical difference in GWG was found between the groups on further analysis. Weights were available for all attenders of the intervention (n=50), therefore it can be said with confidence that the intervention supported the aim of staying within the IOM guidance for weight gain. However, as 60% of non-attenders had incomplete data, the possibility that their gain was greater cannot be excluded. To see if this was an issue an independent T-test was run on the non-attender group – non-attender with using booking BMI against weight gain record compared to non-attender without weight gain record. No statistical differences were found between the groups.

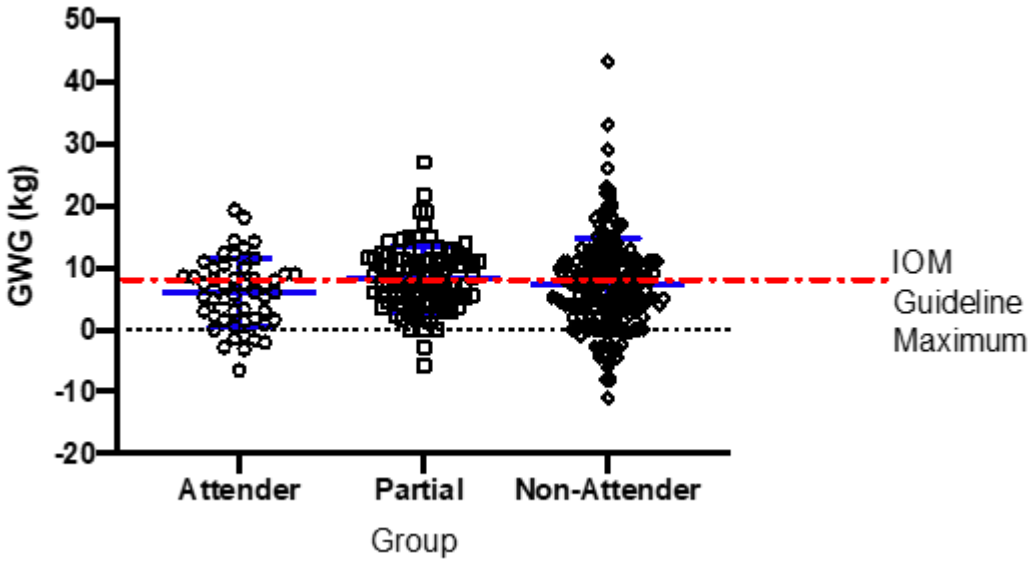


Figure 6.1 Data shown as gestational weight gain for individual women in each of the three groups. Error bars indicate mean and standard deviation.

6.3.4 Booking-in location analysis as deprivation indicator

As describer in the methods section, deprivation index was calculated by using the booking-in appointment location and then grouping these to calculate an approximate indicator of the women's socioeconomic status. Analysis of these postcode deprivation indicator and attendance status of the intervention can be seen in Figure 6.3. The greater prevalence of missing data for non-attenders made it difficult to determine whether there was any systematic difference in socioeconomic status between the groups.

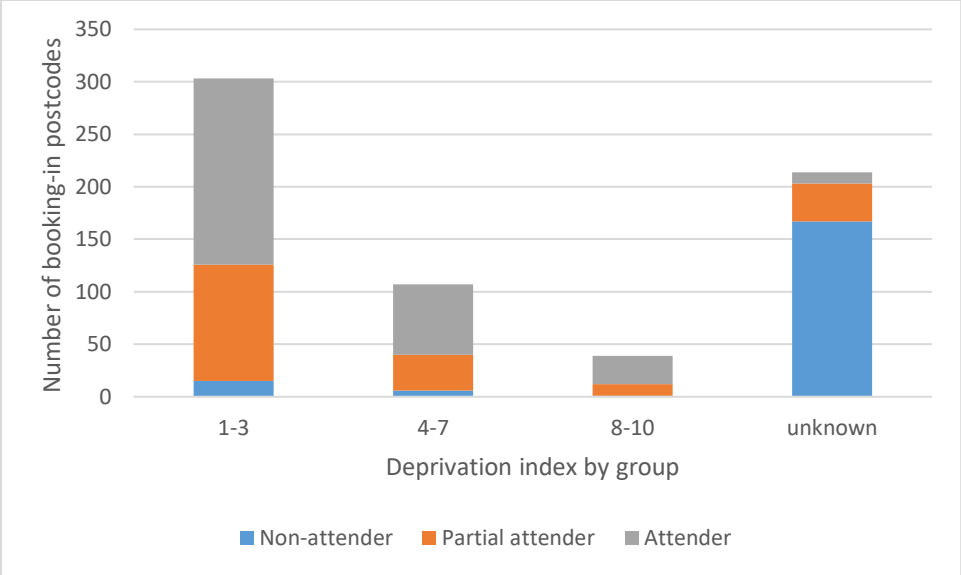


Figure 6.2 Deprivation index based on booking-in postcode and attendance status for non-attenders, partial attenders and attenders

Table 6.2 All outcomes recorded on the audit sheet for each group with numbers and percentage of the total number for that group

	Non-Attenders (n=470)	**Partial-Attenders (n=143)**	**Attenders (n=50)**
All pregnancy complications (n=132, 20.8%)	83,18.7 %	38, 27.0%	11, 22.0%
GDM (n=93, 14.7%)	54,12.2 %	30, 21.3%	9, 18.0 %
GHT (n=45, 7.1%)	34, 7.7%	8, 5.7%	3, 6.0%%
PE (n=14, 2.2%)	9, 2.0%	4, 2.8%	1, 2.0%
PPH Heavy (n=77, 12.2%)	41, 9.3%	27, 19.1%	9, 18.0%
Vaginal delivery (n=414, 65.7%)	299, 68.0%	82, 58.6%	33, 66.0%
Instrumental delivery (n=31, 4.9%)	20, 4.5%	7, 5.0%	4, 8.0%
Elective CS (n=78, 12.4%)	49, 11.1%	24, 17.1%	5, 10.0%
Emergency CS (n=108, 17.1%)	73, 16.6%	27, 19.3%	8, 16.0%
LBW <2500g (n=32, 5.1%)	24, 5.5%	7, 5.1%	1, 2.0%
Macrosomia >4000g (n=93, 14.9%)	64, 14.6%	19, 13.8%	10, 20.0%
Preterm <38weeks (57, 9.1%)	37, 8.4%	17, 12.4%	3, 6.1%
Breastfed at birth (389, 62.6%)	259, 59.7%	91, 66.4%	39, 78.0%
Any other combination of feeding at birth (232, 37.4%)	175, 40.3%	46, 33.6%	11, 22.0%

6.3.5 Pregnancy complications

6.3.5.1 All pregnancy complications

Recorded pregnancy complications were complete for 634 of the women in the analysis. One hundred and thirty-two women had one or more pregnancy complications (20.8% of all women in the study; Table 6.2). This split into 18.7%

(n=83) of non-attenders, 27% (n=38) of partial attenders, and 22% (n=11) of attenders (Table 6.2). Comparison between non-attenders and attenders for combined overall pregnancy complications showed no statistical significance (p=0.58). When adjustment was made for maternal age, gravida and deprivation index there was still no significance between these two groups (Table 6.3). A significant difference was found between non-attenders and partial attenders before adjustment (p=0.037) (Table 6.2). The risk of total complications increased by 60% in the partial attenders group (UOR 1.60 CI 1.03-2.49) compared to non-attenders, but this association disappeared once adjusted for maternal age, gravida, and deprivation index (Table 6.3).

Table 6.3 Impact of the intervention upon complications during pregnancy when comparing attenders v non-attenders, or non-attenders v partial attenders.

	UOR	**CI (Confidence Interval)**	**AOR***	**95% CI**
Attenders v non-attenders				
Total pregnancy complications	1.22	0.60 to 2.49	ns	
GDM (Gestational Diabetes Mellitus)	1.58	0.73 to 3.43	ns	
GHT (Gestational hypertension)	0.77	0.23 to 2.60	ns	
Pre-eclampsia	0.98	0.12 to 7.91	ns	
Partial-attenders v non-attenders				
Total pregnancy complications	1.60	1.03 to 2.49	ns	
GDM (Gestational Diabetes Mellitus)	**[#]1.95**	**1.19 to 3.19**	**[#]4.18**	**1.18 to 14.74**
GHT (Gestational hypertension)	0.72	0.33 to 1.60	ns	
Pre-eclampsia	1.40	0.43 to 4.63	ns	

Data are shown as odds ratios and 95% confidence intervals. UOR- unadjusted odds ratio, AOR- adjusted odds ratio, ns – non-significant. All data shown to 2 d.p.

*Adjusted for maternal age, gravida, deprivation index. [#] Partial attendance increased risk of GDM.

6.3.5.2 Gestational Diabetes (GDM)

Analysis of the effect of the intervention on risk of GDM showed that there was no effect of the intervention when comparing the non-attenders to the attenders (p=0.25). There were 93 (14.7%) women that were diagnosed with GDM, of which 54 (12.2%) were non-attenders, 30 (21.3%) were partial attenders and 9 (18.0%) were attenders (Table 6.2). Both UOR and significant AOR results can be seen in Table 6.3. Comparison of non-attenders and partial attenders showed GDM was twice as likely to occur in the partial attenders versus the non-attenders (UOR 1.95, CI 1.19-3.19), but once adjustment was made this increase in risk leapt to greater than 4-fold higher (p= 0.026, AOR 4.18, CI 1.18-14.74; Table 3.3).

6.3.5.3 Gestational Hypertension (GHT)

Forty-five women were diagnosed with GHT and this split into 34 (7.7%) non-attenders, 8 (5.7%) partial attenders, and 3 (6%) attenders, Table 6.2. Neither attendance nor partial attendance had any impact on the risk of GHT in this population, relative to women who did not attend any sessions (Table 6.3).

6.3.5.4 Pre-Eclampsia (PE)

Pre-eclampsia was diagnosed in 14 women. Of these, nine (2%) were non-attenders, four (2.8%) were partial attenders, and one (2%) was an attender (Table 6.2). Neither attendance, nor partial attendance had any impact on the risk of PE in this population, when compared to non-attending women (Table 6.3).

6.3.6 Labour and delivery

6.3.6.1 Labour complications

When considering heavy PPH (blood loss >1000 mL), B&B attendance status appeared to have some impact on risk. Seventy-seven women had heavy PPH (12.2%). Forty-one of these were from the non-attender group (9.3%), 27 were from the partial attenders group (19.1%), and 9 were from the attenders group (18%; Table 6.4). Whilst there was no difference in risk between attenders and non-attenders, unadjusted risk was significantly greater in women who were partial attenders (p=0.0082, UOR 2.31, 95% CI 1.36-3.92). This association disappeared after adjustment for confounding factors (Table 6.4).

6.3.6.2 Mode of delivery

As per the Lincolnshire audit sheets (Chapter 5), mode of delivery included vaginal, instrumental, emergency caesarean, and elective caesarean. All comparisons were made against vaginal delivery as this is regarded as the least dangerous for mother and baby. There were 630 audit sheets available for analysis. There were 440 non-attenders (70%), 140 partial attenders (22%), and 50 attenders (8%) records available for analysis. Most of the women had a vaginal delivery regardless of whether they had attended (66%), partially attended (58.6%) or did not attend any sessions of the intervention (non-attenders 68%; Table 6.2).

When comparing non-attenders with attenders for instrumental delivery it was apparent that attendance at B&B sessions was associated with greater risk of intervention during delivery (Table 6.4). Only 31 women required an instrumental delivery (Table 6.2). Of these 20 were non-attenders (4.5%), 7 were partial attenders (5%), and 4 were attenders (8%). After adjustment for maternal age, gravida and

deprivation index women who attended all sessions were 10-fold more likely to have an instrumentally assisted (forceps or ventouse) delivery than women who did not attend Bumps and Beyond (AOR 10.33 CI 1.88-56.9). Partial attendance at the sessions was not associated with risk of having an instrumentally assisted delivery (Table 6.4). However, partial attendance increased the likelihood of elective caesarean by 5-fold (p=0.007, AOR 5.55 95% CI 1.91-16.14) (Table 6.4). There was no statistically significant difference seen between groups for emergency caesarean (Table 6.4).

Table 6.4 Impact of the intervention on labour complications and mode of delivery when comparing attenders v non-attenders, or non-attenders v partial attenders.

	UOR	**CI**	**AOR***	**CI**
Heavy PPH >1000ml˜				
Attenders v Non-attenders	2.14	0.97 - 4.72	ns	
Partial Attenders vs Non-Attenders	2.31	1.36 - 3.92	ns	
Mode of delivery (Attenders v Non-attenders)				
Instrumental	**1.81**	**0.58 - 5.62**	**$10.33**	**1.88 - 56.9**
Emergency caesarean	0.99	0.44 - 2.24	ns	
Elective caesarean	0.94	0.35 - 2.54	ns	
Mode of delivery (Partial Attenders vs Non-Attenders)				
Instrumental	1.28	0.52 - 3.12	ns	
Emergency caesarean	1.35	0.81 - 2.23	ns	
Elective caesarean	**1.82**	**1.05 - 3.15**	**# 5.55**	**1.91 -16.14**

Data are shown as odds ratios and 95% confidence intervals. UOR- unadjusted odds ratio, AOR-adjusted odds ratio, ns – non-significant. Mode of delivery compared to vaginal (OR=1).

*Adjusted for maternal age, gravida, deprivation index. ~PPH additionally adjusted for mode of delivery and baby weight. $Attendance increased risk of instrumental delivery. # Partial attendance increased risk of elective caesarean

6.3.7 Birth and feeding

6.3.7.1 Gestation

The audit form collected data with regards the number of weeks gestation the infant was when born. This was split between before 38 weeks, which is one week beyond the worldwide classification of prematurity, and above 38 weeks which is classed as term. Infants born after 38 weeks have a better chance of survival. There were 625 records available for analysis. Eight percent of non-attenders had an infant born before 38 weeks (n=37), 12% of the partial attenders had an infant born early (n=17), and 6% of the attenders had an infant born before 38 weeks gestation (n=3; Table 6.2). No statistically significant difference was seen between any of the groups in terms of premature delivery (Table 6.5).

6.3.7.2 Birth weight

The audit sheets recorded birth weights for 626 infants. These data were then classed as weights below 2500g, referred to as low birth weight (LBW), or above 4000g, referred to as macrosomia. With regards LBW infants, prevalence was 5.5% in the non-attender group (n=24), 5% in the partial attender group (n=7), and 2% in the attender group (n=1; Table 3.2). There were no statistical significances seen between any of the groups in the adjusted regression analysis (Table 6.5).

When looking at the macrosomic infants, the prevalence was 14.6% in the non-attender group (n=64), compared to 13.8% in the partial attender group (n=19), and 20% in the attender group (n=10; (Table 6.2). No significant difference was seen between any of the groups after adjustment (Table 6.5).

6.3.7.3 Feeding Practice

Feeding practice at birth compared breastfeeding with any other form of feeding (formula, or breast-and-formula). There were 621 audit sheets available for analysis. Overall, most mothers, regardless of group, chose to breastfeed their infant at the time of birth. Sixty percent of non-attenders (n=259), 66% of partial attenders (n=91), and 78% of the attenders (n=39; Table 6.2) chose to breastfeed after giving birth. For other forms of feeding, 40.3% of non-attenders (n=175), 33.6% of partial attenders (n=46), and 22% of attenders (n=11) chose this method (Table 6.2).

Comparison suggested that women who attended B&B sessions were 66% less likely than those who were non-attenders to choose a feeding method other than breastfeeding at birth (UOR 0.34 CI 0.17-0.69). However, after adjustment for confounding factors this difference in behaviour was no longer statistically significant (Table 6.5). Partial attendance did not impact upon the feeding choices of the women.

Table 6.5 Impact of intervention on birth and feeding outcomes when comparing attenders v non-attenders, or non-attenders v partial attenders.

	UOR	CI	AOR*	CI
Gestation length (Attenders v Non-Attenders)				
<38 weeks	0.71	0.21 to 2.39	ns	
Gestation (part-attend v non-attend)				
<38 weeks	1.54	0.84 to 2.83	ns	
Birth weight (Attenders v Non-Attenders)				
Low birth weight <2500g	0.35	0.05 to 2.66	ns	
Macrosomia >4000g	1.46	0.70 to 3.07	ns	
Birth weight (Partial Attenders v Non-Attenders)				
Low birth weight <2500g	0.92	0.39 to 2.19	ns	
Macrosomia >4000g	0.93	0.54 to 1.62	ns	
Feeding choice at birth (Attenders v Non-Attenders)˜				
Other than breastfeeding	**#0.34**	**0.17 to 0.69**	ns	
Feeding choice at birth (Partial Attenders v Non-Attenders)˜				
Other than breastfeeding	0.70	0.48 to 1.03	ns	

Data are shown as odds ratios and 95% confidence intervals. UOR- unadjusted odds ratio, AOR- adjusted odds ratio. Choice of feeding compared to breastfeeding OR=1. All figures to 2 d.p.

*Adjusted for maternal age, gravida, deprivation index. ~Feeding choice additionally adjusted for pregnancy complications and delivery type.

[#] Attendance decreased the likelihood of other types of feeding (bottle or combination) but not once adjustments were made.

6.3.8 Comparison of the Nottingham and Lincolnshire interventions

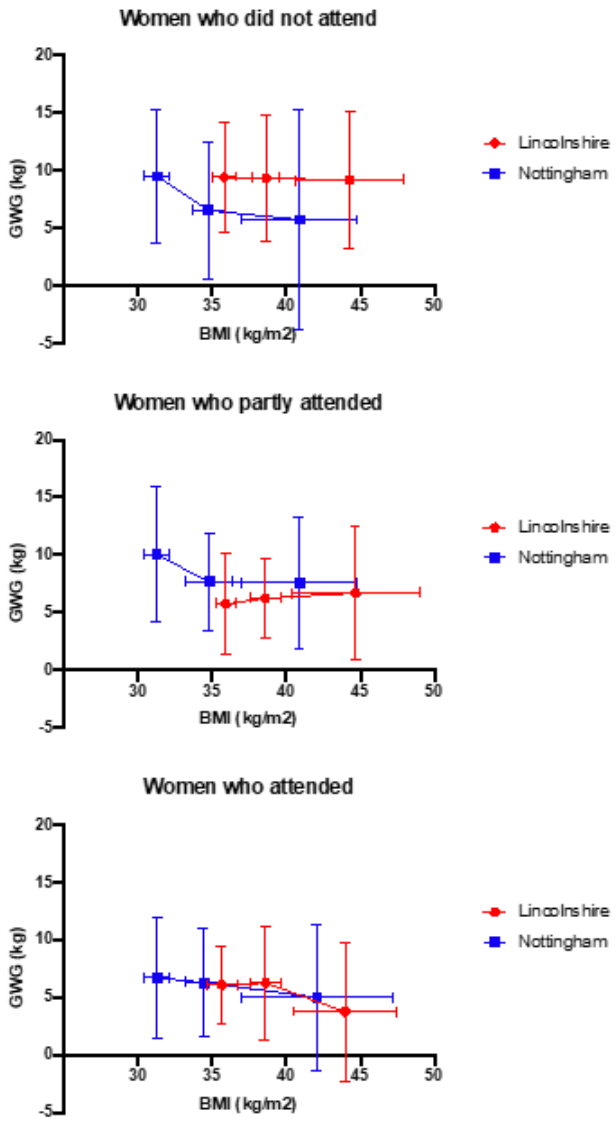
The low weight gain throughout the pregnancy period with attendance of the programme in both Lincolnshire and Nottinghamshire seems to indicate that this programme is successful in both locations in meeting their desired outcome of weight gain within the 2009 IOM guidance (Rasmussen, Yaktine & IOM, 2009). However, when these results are looked at in more detail, it is clear that the two populations were very different in terms of obesity profiles.

Table 6.5 Comparison by tertile of the Lincolnshire booking BMI and weight gain through pregnancy, and the Nottinghamshire booking BMI, and weight gain.

Attendance status	**Lincolnshire**		**Nottinghamshire**	
	Tertiles of booking BMI (kg/m^2)	Weight gain (kg)	Tertiles of booking BMI (kg/m^2)	Weight gain (kg)
Non-attenders	1 (<37.03)	9.41±4.85	1 (<32.79)	9.49±5.78
	2 (37.03-40.46)	9.34±5.51	2 (32.80-36.59)	6.54±5.93
	3 (>40.46)	9.16±5.88	3 (>36.59)	5.73±9.55
Partial attenders	1 (<37.03)	**5.76±4.38***	1 (<32.79)	10.04±5.87
	2 (37.03-40.46)	**6.26±3.38***	2 (32.80-36.59)	7.67±4.29
	3 (>40.46)	**6.70±5.84***	3 (>36.59)	7.57±5.77
Attended	1 (<37.03)	**6.07±3.36***	1 (<32.79)	6.69±5.19
	2 (37.03-40.46)	**6.20±4.96***	2 (32.80-36.59)	6.28±4.75
	3 (>40.46)	**3.74±6.06***†	3 (>36.59)	4.98±6.33

Data are shown as mean±SD. * indicates significantly different to non-attenders (P<0.01). † indicates significantly different to partial attenders (P<0.05).

When results are split by tertile of booking BMI, (Table 6.6), it becomes apparent that the booking BMI ranges were very different between the Lincolnshire B&B intervention and the Nottinghamshire B&B intervention. The booking BMI for all of the Lincolnshire group tertiles was greater than that of the Nottinghamshire groups which resulted from the differences to the inclusion criteria between Lincolnshire Bumps and Beyond (BMI $\geq 35 kg/m^2$) and Nottinghamshire Bumps and Beyond (BMI $\geq 30 kg/m^2$). Weight gain (kg) throughout pregnancy was significantly lower between attenders and partial attenders in the Lincolnshire B&B groups compared to non-attenders ($p<0.01$) although all groups, regardless of tertile, kept within the IOM (Institute of Medicine) guidance for maternal weight gain (Rasmussen, Yaktine & IOM 2009; Table 6.6). The most severely obese women that attended the Lincolnshire B&B programme had the lowest weight gain through their pregnancies when compared to both the non-attenders ($p<0.01$) and partial attenders ($p<0.05$; Table 6.6). A different picture was seen in the Nottinghamshire B&B. Whilst those women in tertile 3 were the ones that gained the least weight throughout their pregnancy when compared to the other tertiles in their group, no statistical significance was found (Table 6.6).



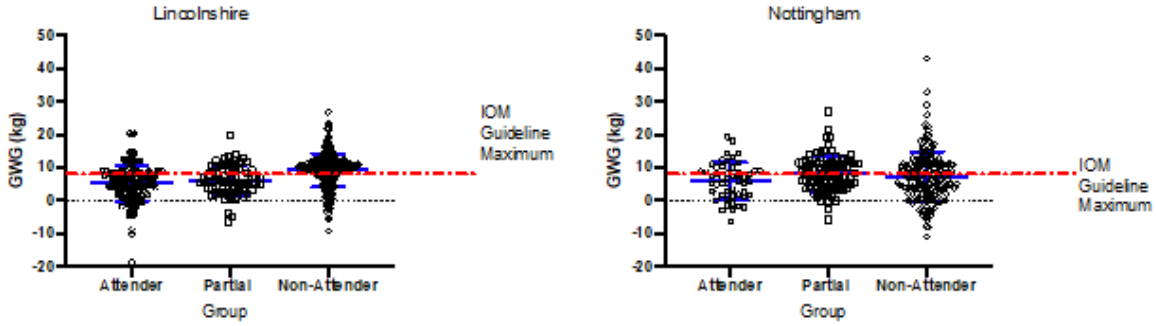
Data are shown as mean and SD for both booking BMI and GWG.

Figure 6.3 Relationship between booking BMI and Gestational Weight Gain in Lincolnshire and Nottinghamshire women.

Figure 6.3 shows the relationship between booking BMI and weight gain for both Lincolnshire Bumps and Beyond and Nottinghamshire Bumps and Beyond across the tertiles. This emphasizes that in Lincolnshire full attendance was associated with the greatest impact on GWG in those women who were most severely obese at recruitment, which among partial attenders and attenders GWG was largely unrelated

by booking BMI. When looking at the Nottinghamshire B&B, all groups showed a downward trend for weight gain regardless of attendance (Figure 6.3) and among the non-attenders. Thus, in Nottinghamshire more severely obese women (tertile 3) gained less weight than those in tertile 1, regardless of attendance at B&B. This could indicate that other factors were influencing weight gain among the Nottinghamshire women.

When weight changes throughout pregnancy in the two groups of women are compared further findings of interest are seen (Figure 6.5).



Error bars indicate mean and standard deviation.

Figure 6.4 Data shown as comparison between Lincolnshire B&B and Nottinghamshire B&B gestational weight gain for individual women in each of the three groups.

The Nottinghamshire B&B non-attenders had the greatest individual weight gains and also appeared to have the higher number of women who lost weight. This more extreme range of outcomes relative to the women in Lincolnshire, again, begs the question as to what was happening within this group of women that may have helped some control their weight gain. It is also clear that more women were below the IOM

maximum weight gain figure of 9kg within the Lincolnshire B&B group than the Nottinghamshire Bumps and Beyond group (Figure 6.4).

Comparison of other outcomes between the sites when compared to non-attenders can be seen in Table 6.7. The Nottinghamshire B&B attenders had increased risks for GDM, Instrumental delivery and, for partial attenders, an increased number of elective caesareans (Table 6.7). There were no decreases in risk seen for any other outcome in contrast to the overwhelmingly beneficial effects of Lincolnshire B&B on GWG, GDM, PE for both groups, and reduced risk for preterm birth and LBW (Table 6.7). Whilst attenders were more likely to breastfeed than non-attenders in the crude analysis, this was not significant after adjustment for confounders (Table 6.7). Overall it is very apparent that the intervention was far more successful in Lincolnshire than in Nottingham/Nottinghamshire.

Table 6.6 Comparison of all outcomes between the Nottinghamshire B&B, and the Lincolnshire B&B when compared to the non-attending groups.

	Nottingham		**Lincolnshire**	
	Attended	Partially attended	Attended	Partially attended
Gestational weight gain	↔	↔	↓	↓
Total pregnancy complications	↔	↔	↓	↓
GDM	↔	↑	↓	↓
GHT	↔	↔	↔	↔
PE	↔	↔	↓	↓
PPH	↔	↔	↔	↔
Instrumented delivery	↑	↔	↔	↔
Elective CS	↔	↑	↔	↔
Emergency CS	↔	↔	↔	↔
Preterm birth	↔	↔	↓	↔
Low birth weight	↔	↔	↓	↔
Macrosomia	↔	↔	↔	↔
Breastfed at birth	↔	↔	↑	↔

↑ indicates increased likelihood/risk compared to non-attenders.

↓ indicates decreased likelihood/risk compared to non-attenders.

↔ indicates no impact of intervention attendance.

6.4 Discussion

The results obtained from the service evaluation of the Nottinghamshire B&B are in stark contrast to those showing the efficacy of the Lincolnshire intervention, in relation to GWG and complications of pregnancy. It is vital to understand what differences there were between the two interventions as not only may this explain the lack of positive outcomes in Nottinghamshire, but also give clues to how best to design future antenatal weight management programmes.

The two areas where B&B were implemented have very different populations. No direct data for ethnicity was available for Nottinghamshire Bumps and Beyond but based on the areas that the intervention was run it may be assumed that there were a range of ethnicities attending the programme. In the Lincolnshire county area 2011 census data (the latest available at the time of writing), it was reported that 97.6% of the population classed themselves as White (White British 93%), with the remaining population being a mix of ethnic groups (Lincolnshire County Local Area Report (LAR), accessed online 19/11/21, ONS). Of the 543 records that reported ethnicity for Lincolnshire Bumps and Beyond, 90.8% classed themselves as White British, which indicates that the sample largely reflected the demographic of the area. In Nottingham City the 2011 census data reports that 84.6% of people classed themselves as White (White British 80.5%), 7.3% classed themselves as Asian/Asian British (Nottingham Built-up area, LAR accessed online 19/11/21, ONS). The difference in the ethnic mix in the two areas could mean that directly lifting a model that worked with a mostly White population in one area, may not have been culturally appropriate for another. This factor may have contributed to the lack of efficacy in the Nottinghamshire programme.

The latest MBRRACE-UK report (Knight *et al.*,2021) describes the huge disparities between ethnicities with regards maternal morbidity and mortality, and it is clear that this has been an issue over many years with reporting showing very little improvement in this area (Knight *et al.*,2021; Knight *et al.*,2019; Knight *et al.*,2018). A 2018 systematic review and meta-analysis by Goldstein *et al* (2018) looked at observational studies and specific maternal and neonate outcomes for over 1 million women across the world and the effect of ethnicity. This review identified that over 60% of women in the overweight or obese BMI categories used in the study gained more than the IOM (Rasmussen, Yaktine & IOM 2009) recommended amount for that BMI class (Goldstein *et al.*,2018). When ethnicity was taken into account by splitting into continent of origin of the study (Europe, Asia, USA), weight gain above the IOM figures showed significant differences between both Europe and Asia, and USA and Asia but not between Europe and USA.

One key difference between Nottinghamshire and Lincolnshire was the BMI threshold at which women were invited to participate in B&B. There is increased awareness that the standard BMI classes are not appropriate for certain ethnicities due to increased risk of pathologies at a lower BMI class and so Nottinghamshire B&B including women from a BMI $\geq 30 kg/m^2$ would make clinical sense based on their population base (NICE Pathway, 2021; NICE, 2013). In the Goldstein et al (2018) review some of the Asian countries used population specific BMI categories which had a lower figure for the overweight and obese categories. These alternative BMI figures have not been used within the B&B interventions but could have a place in identifying ethnic backgrounds that may have a higher or lower risk than when using the standard charts.

In addition to differences in population diversity, there are interesting socioeconomic differences between the two locations in which the programme was implemented. The Local Authority Rank (LAR) considers all of the Index of Deprivation (IoD) classes to give a geographical area a rank which can then be compared to other LARs which will have a similar population figure (Ministry of Housing, Communities & Local Government, IoD Interactive Dashboard – Local Authority Focus, ©Crown 2019). It is clear to see that Lincoln and Lincolnshire boroughs have higher levels of deprivation overall when compared to Nottingham and Nottinghamshire (Ministry of Housing, Communities & Local Government, IoD Interactive Dashboard – Local Authority Focus, ©Crown 2019). This may also have influenced the outcomes of B&B in the two locations as there is a firm association between deprivation, obesity and reproductive history.

Walker and Cresswell (2019) looked at records of a population of women in Portsmouth and surrounding areas who had given birth between April 2013 and March 2014 to assess whether those that lived in very deprived areas were more likely to have obesity than those in less deprived areas (Walker and Cresswell, 2019). They found that women in the most deprived areas were one and a half times more likely to have obesity than those who were in less deprived areas, AOR (Adjusted Odds Ratio) 1.60 CI 1.13-2.26 (Walker and Cresswell, 2019). They also found that women were more likely to have had three or more previous pregnancies and obesity, AOR 1.65 CI 1.26 to 2.16 - a higher figure than that seen in both the Lincolnshire Bumps and Beyond and Nottinghamshire Bumps and Beyond populations (Walker and Cresswell, 2019). Heslehurst *at el* (2007) looked at a population from Middlesbrough and had similar findings where those women with obesity were 2.5 times more likely to reside in areas of high deprivation (AOR 2.42 CI 1.96 to 2.98) and have had higher parity

(AOR 1.17 CI 1.13 to 1.22). Fraser *et al* (2012), although looking at the influence of food outlet availability on obesity levels in pregnant women, also considered the impact of deprivation. Interestingly they found a link between deprivation and obesity within the non-South Asian women for one of their statistical models which included the number of retail outlets per Super Output Area (SOA) – a term no longer used in IoD (Index of Deprivation) – (AOR 1.01 CI 1.00 to 1.03) but not for the South Asian women (Fraser *et al.*,2012).

Sutherland et al (2013) looked at a population of pregnant women in Victoria and South Australia to see whether socioeconomic factors (household incomes, educational level, admitted to public hospital or had money problems in the past twelve months) between women with overweight and obesity were linked to their weight. They found strong evidence of an association between high-levels of obesity at the start of pregnancy and low household income (AOR 2.31 CI 1.6 to 3.2), low educational level (AOR 1.71 CI 1.2 to 2.2), have had financial stress (AOR 1.63 CI 1.2 to 2.1) and a parity of three or more (AOR 1.43 CI 1.0 to 1.8) (Sutherland *et al.*,2013). These studies would seem to indicate that despite Lincolnshire B&B being run in an area of high deprivation it was still able to achieve the positive outcomes seen in Chapter 5. Whilst this might suggest that the programme is better suited to women who live in deprivation, it is important to remember that women from more affluent areas were over-represented in the group of attenders and that the effects of the programme on the measured outcome were robust after adjustment for deprivation.

Based on the latter observation, the contribution of deprivation to determining whether B&B might be successful is likely to be small. Similarly, the anticipated ethnic mix of the two populations (95% White British in Lincolnshire compared to

80.5% in Nottinghamshire) are not likely to be different enough to explain such divergence in the outcomes associated with the intervention. One result that stands out in this context is that whilst Lincolnshire B&B attendance was associated with a greatly enhanced rate breastfeeding at birth, in Nottinghamshire there was no significant difference in breastfeeding initiation after adjustment for confounding factors. Women with more severe obesity tend to be less receptive to interventions to promote healthy eating and exercise, so the lack of impact of B&B in the leaner Nottinghamshire population compared to the Lincolnshire population where all women were in the severely obese category is, again, striking.

Consideration of participation rates in the intervention make a strong argument for it being the case that the way in which staff delivered the programme in Nottinghamshire was the main driver for the differences in outcome. In Lincolnshire 37.5% of women who were approached to participate in B&B attended at least one session and 66.7% of those attended the full programme. In contrast 29% of the Nottinghamshire women attended a session and only 26% of those completed the programme. The high drop-out rate (74% in Nottinghamshire vs 33% in Lincolnshire) suggests that the Nottinghamshire programme was not meeting the needs of the participants and this in itself could be the main factor leading to a lack of positive outcomes. An element of this may have been the type of staff used for delivery. In Nottinghamshire B&B the programme was delivered by clinical staff, whilst in Lincolnshire the team came from a background of promoting behaviour change in relation to smoking cessation. The observation that in Nottinghamshire the more severely obese women, including those who did not attend the programme, gained less weight regardless of the intervention suggests that other aspects of their routine antenatal care were influencing behaviours in relation to diet and/or physical activity.

6.4.1 Limitations

There are a number of limitations to this specific service evaluation which must be considered in reviewing the results. Data was collected using audit sheets for completion by the clinical staff. Once data had been collected it was apparent that this was often done very poorly, resulting in large gaps in the data set. A lack of completeness may have reduced the power of the study to detect any impact of the intervention, although it is clear from the most basic comparisons of outcome frequency that there were no positive effects. The use of the location recorded for attendance at clinics did not differentiate between whether this is the area that the woman lived or accessed maternity services and so was only an approximate measure of the level of deprivation. For some areas of the analysis there were very low numbers of records available which reduced the chance of identifying any statistical difference. It was not possible to obtain data of a higher standard as the intervention was closed-down very quickly when it became apparent that it was not delivering the expected benefits.

6.4.2 Conclusion

The two service evaluations described in the current and previous chapters, have allowed a deeper delve into why the intervention was more successful in one area compared to another despite the same programme being delivered. It can be postulated that the main factors that determine the efficacy of Bumps and Beyond include ensuring cultural appropriateness of the intervention delivery, taking into account those factors that are out of the individual's hands but contribute to

socioeconomic status and, ensuring that participants become engaged with the process once recruited. In order to identify further reasons that could actively increase the positive outcomes seen in Lincolnshire Bumps and Beyond, a qualitative study was undertaken which looked at the direct delivery of the programme in Lincolnshire. The early closure of the Nottinghamshire intervention meant that a similar process could not be followed in that location.

Chapter 7. A hermeneutic phenomenological analysis of Lincolnshire Bumps and Beyond

Having observed stark differences in the outcomes of the Bumps and Beyond intervention at the Lincolnshire and Nottinghamshire sites, it was of interest to investigate the programme using qualitative methods, in order to determine whether features of the delivery could explain the efficacy of the original Lincolnshire team. For the service evaluation of the Lincolnshire B&B programme permission was obtained for qualitative data to be collected, but unfortunately this was not possible in Nottinghamshire. A novel hermeneutic phenomenological analysis (HPA) was taken to produce essences from the text using the three roles of "Sarah – Mother", "Sarah-the Dietitian", and "Sarah the Researcher".

7.1 Qualitative research in healthcare

Healthcare research is notorious for being number output focused (Cruickshank, 2012). How many people became ill? How many people died/left the study/did not comply? Thankfully this quantitative approach now (in 2022) has been supported by a wealth of qualitative research which is able to look into depth at why humans do what they do. The lived experience of an individual is dependent on both internal and external influences and those same elements may have different meaning to another person. Using qualitative methods allows the researcher to explore those factors and the impact they may have in the healthcare setting, and potentially answer the questions 'why do humans do what they do?'

Qualitative research has a range of methods available to explore an area of interest (WHO, 1994). These differ from the quantitative approach, although certain methods could be analysed in a statistical manner and so be regarded as such (WHO, 1994).

The advantage of qualitative research is that the researcher is able to make inquiry into personal issues for the participant in a depth that number-focused research does not (Hudson *et al.*,2015; Phiri *et al.*,2015; Martins, 2008). The use of qualitative research in healthcare allows for a more personalized approach to delivery of services as long as it is used in a meaningful way, and it should be part of the care commissioning and development process (Barker, 2015; Peckham *et al.*,2014).

7.1.1 Qualitative approaches in health research

The approach taken for a piece of research has depended on the branch of healthcare involved. In some disciplines the use of qualitative methods has been road-tested for a range of needs (Wertz, 2014; Seale *et al.*,2012). Nursing and midwifery have been disciplines that have embraced qualitative research and this is unsurprising given the caring nature of their work (Sundler *et al.*,2019). In nutrition there is evidence of qualitative work undertaken during the colonial era. Although the specifics of data collection are not mentioned there is reference to anthropological study (Culwick, 1944). Nutrition science now produces a range of research that has championed the qualitative approach for the usefulness of the findings in order to support service users and staff in the discipline (Joy *et al.*,2019; Jager *et al.*,2019; Hancock *et al.*,2012).

Methods differ depending on the desired outcome for the piece of research. Working on a one-to-one basis with an individual as is the case with interviews can allow the researcher to explore an issue of interest in depth (WHO, 1994). The type of interview, structured/ semi-structured/ unstructured should be chosen with regard to the research question (Bowleg, 2017). With any interview it is vital that the interviewer is fully conversant with how to undertake this process (Roulston *et al.*,2003). In healthcare these interviews can take place in a range of locations some of

which are clinical and could affect how the participant responses due to the way these areas are perceived. For example, someone of an older generation will have grown up with the paternalistic approach of the early NHS and this could colour their response to questions (MacGregor, 1998). In addition, a reflexive approach is needed as the lived experience of the researcher can influence the research process and so acknowledgement of this through reflexivity allows the researcher to check-in on themselves and produce a more transparent approach with the analysis (Sundler *et al.*,2019).

7.1.2 Qualitative research in dietetic practice

Dietetic practice uses qualitative research in order to try and understand the dietary behaviour of both individuals and populations (King *et al.*,2019; Jager *et al.*,2019; Hancock *et al.*,2012), as well as for investigating the dietitians', or dietetic students', thoughts and feelings about a subject (O'Shea *et al.*,2022; Morgan *et al.*,2019; Joy *et al.*,2019; Students are expected to produce case studies for their portfolio in order to pass their placements (personal communication) which would involve interrogation of medical records and talking to the individual (if possible). A dietitian must work within their own competencies and has to base their advice on the evidence available or they risk losing their professional registration (British Dietetic Association, 2017; Health and Care Professions Council, 2013). Many papers are now published using this approach with both the study of an individual (Shwide-Slavin, 2003), and groups/populations (Young *et al.*,2021; Yona *et al.*,2020).

Within the subject area of maternal weight management for women living with overweight or obesity there is now a wealth of papers that have used some form of qualitative approach to gather and analyse data (Thorbjörnsdottir *et al.*,2020; Norris *et*

al.,2020; Dinsdale *et al.*,2016; Lavender & Smith, 2016; Arden *et al.*,2014; Olander *et al.*, 2011; Weir *et al.*,2010; Nyman *et al.*,2010; Claesson *et al.*,2008). A range of data collection methods have been used, ranging from semi-structured interviews (Thorbjörnsdottir *et al.*,2020; Norris *et al.*,2020; Dinsdale *et al.*,2016; Weir *et al.*,2010; Nyman *et al.*,2010), structured interviews with questionnaires (Shub *et al.*,2013; Claesson *et al.*,2008), questionnaires with open comment boxes (Swift *et al.*,2016) focus groups (Olander *et al.*,2011), focus group or semi-structured interviews (Lavender & Smith, 2016), to use of online forum comments (Arden *et al.*,2014). Despite some similarities in the data collection method, the method for analysis of data varies across studies with variations of phenomenological approaches (Thorbjörnsdottir *et al.*,2020; Norris *et al.*,2020; Nyman *et al.*,2010), thematic analysis (Dinsdale *et al.*,2016; Lavender & Smith, 2016; Arden *et al.*,2014; Olander *et al.*, 2011), Framework Approach based on Subtle Realism theory and Theory of Planned Behaviour (Weir *et al.*,2010), and quantification (Swift *et al.*,2016; Shub *et al.*,2013; Claesson *et al.*,2008). The use of each method can be chosen to suit the subject being researched and findings can be combined for best effect.

7.1.3 Common methodological practices

Patient Public Involvement (PPI) has been an element of the NHS, and research & development of services for some time under different names (Ocloo *et al.*,2017). PPI should be at the heart of the decision making within health and incorporate the views of both service users and stakeholders (Smith *et al.*,2022; Crocker *et al.*,2019). PPI can take the form of focus groups (Crocker *et al.*,2019), interviews (Locock *et al.*,2019), and combinations of quantitative and qualitative data collection (Smith *et al.*,2022). There has also been research looking at those who use PPI and their

thoughts about the usefulness of the process (Bergerum *et al.*,2022; Boylan *et al.*,2019).

The Friends and Family Test is now used in the NHS to find out if people would be happy to recommend the service to a member of their family or a friend and uses a rank order from 'Extremely likely' to 'Extremely unlikely (NHS England, 2014). The FFT was introduced in 2013 for patients who attended A&E or required in-patient care in the NHS with the intention of improving patient care (NHS England, 2014). This type of qualitative research is then transformed into numerical data for analysis.

Semi-structured interviews are often used in healthcare in order to try and understand the best way to support people from specific populations (Dennison *et al.*,2022; Donnelly *et al.*,2018; Locock *et al.*,2019). A set of open-ended questions are used that allow the participant to chat about their experience in a way that is partially directed and recorded, and then analysis of the transcripts and/or review of video footage allow ideas and themes to be identified (Dennison *et al.*,2022; Donnelly *et al.*,2018). The interviews can take place in a setting that is most suitable for the interviewee and may be face to face or online/telephone. Healthcare-based interviews may be given a time limit due to the fact clinicians are often time poor (personal experience).

Focus groups are group settings where questions can be asked to a group of people to enable conversations around a subject in order to try and elucidate answers that can feed into a decision around healthcare support. They can be used as part of the PPI process (Crocker *et al.*,2019), as a tool with the aim of answering specific questions

(Ferrari *et al.*,2013), and alongside other methods like semi-structure interviews (Nicklas *et al.*,2011). The use of a lay advisory group in the NMPA report is a form of focus group where the participants were responding to outcomes with regards pregnancy and giving feedback (Relph et al., 2021).

7.2 Phenomenological health research

7.2.1 Characteristics of phenomenological inquiry

Phenomenology has its origins in philosophy and was first mentioned in the 18th Century (Dowling, 2007). It is based on the idea that phenomena, defined as "something… that can be observed and studied and …unusual or difficult to understand or explain fully (Britannica online, 2022), can be explored in a way that fully exposes the true 'essence' of the thing being observed (Merriam & Tisdell, 2015).

This researcher has no belief in this concept so has to put their conscious attitudes aside completely in order to actually use this as a tool for analysis. In order to be able to see through a phenomenological perspective the researcher needs to suspend judgement – epoché - of their natural attitude. If all belief, preconceived notions, and scientific theories about what the researcher is viewing are contrary, it does not change the fact that there is something to be viewed. This is the first step in undertaking Husserlian phenomenological analysis, the 'bracketing' of own preconceived beliefs in order to view the object/subject afresh (Gallagher, 2012).

Husserl's approach would then use Phenomenological Reduction (PR) – to now view the phenomena and describe it from anew. The researcher can only describe how what is being experienced with regards this object/subject, and not anything theoretical. However, this researcher cannot totally remove herself through epoché. There will always be a level of lived experience, of their own 'lifeworld', which will impinge on

the view of the phenomena (Svenaeus, 2012). To remove all prejudgement is impossible, but it can be harnessed in order to look for meaning in the text. The researcher can bring their 'lifeworld' to the phenomena they are viewing which in this case is that of Mother, a healthcare professional (Dietitian), or Researcher, and that in itself will change the starting point of the essence within the text.

For this researcher to do this they begin to move into the phenomenology of Heidegger. I recognise that whilst the ideal is to have no preconceptions I cannot remove all my own lived experience, my *Dasein* or 'being-in-the-world' (Rolfe, 2015; Dowling, 2007). As I look for the essence in the text I can also look for the meaning as it fits into the world using my lived experience as a basis of understanding (Dowling, 2007). Heidegger's approach was the basis for Gadamer's development of the Human Sciences (Rolfe, 2015).

Gadamer focussed on language and its importance in understanding of a subject within the text (Rolfe, 2015). He moved away from the idea of Social Science to that of Human Science, the individual, in that a lived experience is only lived in that specific way by that specific individual, we can only try and understand the subject that person is talking about not their lived experience of it (Rolfe, 2015).

My lifeworld roles are numerous but there are three that can be used to view the transcripts of the B&B sessions in order to place the subjects described into those specific roles. The roles of Mother, Dietitian, and Researcher have been chosen as most appropriate for this piece of research and by using these roles I can accept the 'prejudices' each may bring to the text and see through the lens of that role.

7.2.2 Phenomenology in health research

Areas in health that have made good use of phenomenological research are midwifery (Thorbjörnsdottir *et al.*,2020; Nyman *et al.*,2010) and nursing (Hudson *et al.*,2015).

Nyman *et al.*,(2010) undertook a qualitative study which looked at women living with obesity and their encounters with staff during their pregnancy and subsequent birth of the baby. They used an approach which is described as an "empirical phenomenological psychological method" (Nyman *et al.*,2010). They combined philosophies of Hesserl, Heidegger and Gadamer and then went on to analyse the data using a five-step approach by Karlsson which produced both subjective and objective results (Nyman *et al.*,2010). More recently, Thorbjörnsdottir *et al.*,(2020) aimed to investigate the birth experience of women living with obesity and used a 'descriptive phenomenological' approach. This method is based around the Husserl approach to phenomenological research as it requires the researcher to find the 'essence' of the phenomena and then combined this with that of Merleau-Ponty's version of phenomenology (Thorbjörnsdottir *et al.*,2020; Dowling, 2007). Both of these papers utilized interviews with participants in order to explore the subject matter, and then analysed according to the phenomenological approach taken – the five step Karlsson approach in Nyman *et al.*, (2010), and a "disciplined empathic stance" in Thorbjörnsdottir *et al.*,(2020).

In the paper by Hudson *et al.*,(2015), the participants were staff members (nurses and medics) and the approach used was interpretative phenomenological analysis (IPA).

Staff were interviewed by the researcher on a one-to-one basis following an acute life-threatening event in order to try and get an understanding of what support and training could be developed (Hudson *et al.*,2015). The analytical approach taken was both idiographic and inductive with the researcher reviewing the data to try and make sense of what the participant was saying about their perception of the event (Hudson *et al.*,2015). Each of these studies used a style of phenomenological analysis suited to the clinical situation with the aim of getting output that could go on to inform practice.

7.2.3 The broad range of phenomenological practice

The most common use of phenomenology in research is Interpretative Phenomenological Analysis (IPA). IPA is a phenomological approach which looks at both the lived experience of the participant and how they make sense of it and how the researcher makes sense of the lived experience of the participant in a reflexive way (Roberts, 2013; Reid *et al.*,2005). Participants are chosen based on the fact they have had the lived experience that the researcher is interested in (Roberts, 2013; Reid *et al.*,2005). This approach allows a researcher to focus on the individual's lived experience but also to try and identify if there is a shared experience that can be used to support a need with this population (Roberts, 2013; Reid *et al.*,2005). Data is most often collected via interviews with the participants on an individual basis but there can also be triangulation of data sources with the use of focus groups or other data collection tool (Roberts, 2013; Reid *et al.*,2005). It is vital that the researcher uses a reflexive approach throughout the process in order to appreciate the impact of their own subjectivity as they go through the analysis (Olmos-Vega *et al.*,2022). For this piece of research the methodology used by Sundler *et al.*,(2019) paper will be used however as they report stopping at the descriptive phenomenology, this thesis will

also take an hermeneutic approach to go on to interpret the phenomena in light of what the staff member was aiming to achieve.

7.3 Positionality

Over time I have moved from realism to relativism (most probably bounded relativism; Moon & Blackman, 2014) as I have aged (in all areas). This is due to the accumulation of lived experiences. Over time I've become aware that an individual will see the world around them based on their experiences whether from nurture or other factors. I can use a dog as an example. I see a dog as a pet to be loved and cared for. Someone else may see a dog as a status symbol in their life (Maher & Pierpoint, 2011), whilst someone from South Korea may see a dog as food (Dugnoille, 2018). The difference between each of us is based on our social and cultural upbringing and lived experiences and so our perception of what a dog is to us differs.

7.3.1 Sarah the Dietitian

I completed my training as a dietitian in 2009 and went straight into clinical practice in a small hospital in Nottinghamshire. This post included both acute and community care and covered all ages. I progressed into a specialist position with paediatrics where I supported children with feeding tubes who lived in the community and was part of the Home Enteral Nutrition (HEN) team. To further my experience, I moved into Primary care for two years which covered a range of health issues in children in a community clinic setting. Alongside these positions I undertook an MSc in Advanced Dietetic Practice and was then offered a PhD opportunity. I moved back to the HEN team before then moving into academia.

My clinical experience is in paediatrics with weight loss being only a small part. Due to the fact that losing excess weight is so much more than just eating less, I found that I had very little impact on the situation. Nearly all cases became Child in Need or

similar due to perceived or real neglect by the parent/ carer which then involved horrendous meetings where you had to say if a child could stay with their parent. Often not being able to control the weight gain was seen as failure by the authorities surrounding the child (police, social care, education system, healthcare).

I have limited experience with GDM and talking to newly diagnosed women. This was early in my career and, at the time, involved a single session with the dietitian and a leaflet of information. I can look back and be disappointed with that approach now.

Being able to talk to people about their experiences, beliefs, knowledge and wants, I may be able to develop a service that addresses their needs rather than what I think they need. This is not dissimilar to a booked clinical consultation in that frequently in clinical practice the 'patient' actually wanted and needed something different to what was described on a referral letter. They may have a disease or need for clinical input but this could not be addressed until the other need was. This may involve contacting other service providers on behalf of the 'patient'.

Sarah the Dietitian can use the theory-based evidence in practice but can only truly make a difference with service users/ patients when this is combined with the human I-Thou relationship (Rolfe, 2015). This moves ontological positioning from realist to relativist with bounded relativism being the most comfortable fit.

7.3.2 Sarah the Mother

I retrained as a dietitian in 2009 as feeding my children had increased my interest in nutrition. So, I did not have professional knowledge at the time they were born, 2001 and 2004.

I did not enjoy being pregnant. It was a time of high anxiety as so many people blurt out about early pregnancy loss and I knew I was pregnant very early. In my first pregnancy I weighed myself weekly as the midwife did not weigh me at all. When I got to a 3 stone gain I stopped weighing myself, this was around the seven-month pregnant mark. I did accept that the weight gain had gone on over nine months and it made sense to expect it to be lost in a similar amount of time which it was. I did not worry about weight during my second pregnancy as I knew I could lose it post-partum.

Personally, it was a time to do everything as best I could. I wanted to make sure this baby had the best nutrition via me as they could. I was more relaxed the second time and allowed myself a sip of prosecco at birthdays but overall my diet was never better than when I was pregnant. This was reflected in the biochemical measures taken at the time for example, my iron levels were excellent.

An area of confusion at the time was around drinking alcohol with advice differing between pregnancies from the odd glass being alright to total abstention. Advice with regards eating peanuts was to avoid not only during pregnancy but not to give to children under five. This changed following research into the impact on nut allergies. I also gave my children rice milk if they were ill and could not tolerate normal milk. The advice with regards rice milk now is to avoid until after the age of five due to possible arsenic exposure. Advice appeared to change regularly but my sources at the time would have been mostly anecdotal rather than evidence based. This was also in the early internet which meant policing around dangerous advice was non-existent. No information was given about weight gain even though I would have been classed as having an underweight BMI at the time. When I was given professional advice this was followed to the letter.

With regard Sarah the Mother the relationship of between realist and relativist was developed over time and lived experience within the role. There is a definite leaning more towards a relativist role as life goes on however it is difficult to remove the Sarah the Dietitian role from the Mother role now as I am very aware of what the science tells me around nutrition and so it takes some effort to focus only as a Mother.

7.3.3 Sarah the Researcher

I have a question that I'm trying to answer. In order to do this, I want to understand the experiences of the people involved. I may be looking at an area where there is little research already and trying to add to what research there is (by answering a question). Working as an academic means research output is an expectation particularly if promotion is sought.

I am a teaching academic who brings practical experience to the teaching content delivered. I sprinkle anecdotes into my teaching with the aim of showing how you can have research and evidence-base but how in the 'real world' people may not follow this as it does not suit them or their lifestyle. So many factors intertwine with real world nutrition that being an academic without outside life experiences is not useful. People do not follow advice even when they are aware that it is useful to them. This is their choice and a clinician would aim to work with them to support small changes if appropriate.

I have not been involved with qualitative output to this level before and am wary of it. I know, with my clinician head, that it is a powerful tool but I have been taught that hard evidence involved numbers (quantitative research). When confronted with the need to undertake qualitative research I had to drop any pre-conceived idea that it is a

woolly science. In fact, the qualitative work has been the most exacting, but also enlightening, piece of work.

At the time of data collection the staff members delivering the intervention were aware of my background as a dietitian and did comment on how this impacted on their delivery. In a couple of the sessions my background was referred to and I was asked to offer an opinion of the information being given. This was difficult to negotiate through as I was supposed to be an observer only.

It is clear that within Sarah the Researcher there is life experience that colours the meaning of text. It is no longer possible to just be a realist with this as my own lived experiences mean I am acutely aware of the factors that impinge on knowledge and this moves my ontological position to that of bounded relativist.

7.4 Data collection

It was confirmed by both Trusts that were involved with the Lincolnshire Bumps and Beyond intervention that this data collection was regarded as a service evaluation, appendix ??? Only the data collected for the staff members could be analysed.

Bumps and Beyond had seven sessions and there were four staff members. The researcher aimed to record each staff member delivering each of the sessions making a minimum of 28 recordings being sought from the data collection period.

All staff members of the Bumps & Beyond team were eligible to be participants of the service evaluation data collection. The researcher met with all staff to explain the purpose of the study and how it fitted into an evaluation of the service. A consent form (Appendix 3) was given to the staff at the meeting with contact details of the co-investigators should they have wished to talk in more detail about the study. The meeting took place one week prior to the start of the data collection. Further verbal consent was sought prior to each data collection period and recorded on the original consent form. All data collection took place in June, July and August 2016.

Each location had a different member of staff delivering the intervention. Each member of staff delivered at least one of each of the seven sessions to a participant however there was no chance to follow an individual participant through the intervention process due to a lack of time available. This lack of time was due to the intervention no longer being funded and so not running anymore.

All participants were asked whether they consented to the consultation being recorded and it was explained why this was happening and they were then asked to sign a

consent form for this (Appendix 4). If both participant and staff member gave consent then the consultation was recorded on a Dictaphone.

At the end of the day all recordings were downloaded onto a laptop. And then uploaded to the University of Nottingham's server (R-drive), which was password protected. The recording was given a coded filename so could not be identified by anyone other than the research team. The original recordings on the Dictaphone were deleted.

Recordings were sent to an NHS approved transcription company and transcribed and then returned to the researcher. The transcripts were double-checked for accuracy and amended where necessary. Any identifiable data was removed from the transcript. Transcripts were saved onto the university system using the coded filename.

The protocol for the Bumps and Beyond intervention is available in Appendix 2

7.5 Phenomenological thematical analysis

7.5.1 Analytical praxis

I will look at the transcripts and aim to identify the essence in the text but bring my own lived experience of mother, dietitian, and researcher in order to explore meaning. This utilizes the apparent weakness of preconception and uses it as a way to look at the text and give it meaning within a specific context.

7.5.2 Analytical process

7.5.2.1 Familiarising

The transcripts were read through during the data check and reread in order to refamiliarize the researcher with the data. Following this a decision was made to focus on the transcripts that delivered a recognisable session as per protocol (Appendix 2) rather than those that delivered numerous sessions within the appointment (n=5). This choice was made to be clear about which message was vital to that session. As the transcripts were being read it was clear that there were instinctive areas of interest within the text. Anything that aroused interest was highlighted based on the three roles of the reader – dietitian, researcher and mother – in addition where text showed promise but did not seem to quite fit into these roles it was also highlighted to review it again alongside the other areas. Additional points of interest that were felt to have a connection with one of the roles were logged. Each session of the intervention had specific messages that needed to be delivered to the participant and these were very clear within the text which almost felt scripted at times. Finding lived experiences was quite difficult due to this however reading the transcripts several times allowed

pictures to develop and start to shape areas of interest. Where the meaning within the text reflected the aims of the actual Bumps and Beyond intervention they were also marked. By moving from the ‘whole’ to the ‘parts’ of the transcripts it was possible to begin to see patterns and meanings within the text. Once the transcripts had been read numerous times the coding process began.

7.5.2.2 Coding for themes and meanings

The transcripts were highlighted in four different colours to indicate which role the text fitted into or where some level of meaning could be derived that did not fit into the roles at first review. It was clear that often there was more than one role linked to the same piece of text. The coding process involved physically going back through the transcripts and cutting them up into approximate themes and meanings. These are listed below as the first pass theming for each session.

7.5.2.2.1 Session 1

There were five session 1 transcripts available. Following the highlighting sessions, the transcripts were reread and then a possible theme linked to it. At the first pass thirteen possible themes or meanings were identified within session 1 of Bumps and Beyond.

- Not saying never.
- Family support
- Social comparison
- Professional advice
- Physical activity
- Misinformation
- Staff personal stories
- Weighing
- Pregnancy risks
- Food diary
- “lots of ladies”
- Pedometer
- Miscarriage

Following review of this first pass it seemed clear that some of these linked together within the actual session coding.

7.5.2.2.2 Sessions 2 & 3

Area of interest within the seven available transcripts were reread and then categorized. Nine possible themes were found as follows:

- Goal setting
- Something interesting/ not sure
- Weight loss in pregnancy
- Language used by staff member
- Family support both positive and negative
- Staff (and sonographer) story
- Advice around nutrition
- Weighing
- Pedometer 'script'

7.5.2.2.3 Session 4

Three transcripts from session four were reread and notes and highlights collected. Six themes were found through this process. These were:

- Language around nutrition
- Weighing
- Pedometer
- Social influences
- Staff stories
- Partner support

7.5.2.2.4 Sessions 5

Five transcripts for sessions 5 were reviewed and areas of interest were highlighted. From these eleven potential themes were identified as follows:

- Family support (positive or negative)
- Praise language
- Interesting factual?
- Language used for praise
- Nutrition advice
- "a lot of ladies…" language
- Role model
- Weight loss in pregnancy conversations
- Weighing process
- Practical support post-partum
- Conversation around weight gain
-

7.5.2.2.5 Sessions 6 & 7

There were two combined session 6 & 7 transcripts, and two session 7 transcripts. Session 7 was the last delivered session for the intervention and so covered post-partum issues as well as current ones. Three possible themes were identified within this text.

- Post-partum support
- Weight loss and weighing
- Language used around breastfeeding

7.5.2.3 Patterns within the data

Once all transcripts for individual sessions had been reviewed and possible areas of interest found these were further examined to see if they overlapped between sessions. Could the initial theme be linked to those identified elsewhere? Was there a pattern beginning to develop?

The highlighted texts were reread and it was clear that there were similarities between sessions for some experiences. By looking at the individual session text and comparing to other sessions as well as considering the whole picture as to the aim of that specific session as per the protocol, individual parts could be identified. At this stage it was possible to reduce the overall 'themes' to the following; physical activity and pedometer; personal stories; weight; post-partum support; social/ family support; language around nutrition; pregnancy risks; never say never; professional advice; interesting language used not for nutrition.

It was at this stage that the analysis really felt like it was getting to the essence of these experiences. Rereading the text again it became much more apparent what the meaning was behind the words and patterns developed that stepped away from the previous suspected ones. Taking time to absorb the content and consider its context within the bigger picture of a weight management programme allowed meanings to appear that were unexpected but were much more linked to the essence of the experience. This was eye-opening as the themes developed around the experiences as seen through the different roles but also within the larger context of weight management in pregnancy. Final themes emerged and were decided upon by the researcher.

Themes chosen were; ‘Oh dear’, support is key; staff as cheerleaders; never say never; post-partum support; scare tactics and risks; weight loss in pregnancy; time for weigh-in; forbidden food; importance of physical activity; pedometer means motivation; living with kids, living with pregnancy; practical nutrition advice. 'Oh dear' has been used as it was the visceral response from the researcher in dietitian role as the text was read.

After further consideration it was clear that even some of these themes could absorb other themes identified as they often showed the different side (role) of the experience being looked at. Because of this ‘'Oh dear' and practical nutrition advice’ became ‘ **“you need to be taught a lesson about …” food’**. This section includes nutrition misinformation given during the session. Practical nutrition advice was as it says, and this was interesting in itself from a number of perspectives/ roles.

‘Support is key’ is used where experiences around social support whether positive or negative have been identified. A separate theme had appeared around staff using positive language about behaviours which on rereading really became a perspective within social support therefore ‘support is key and staff as cheerleaders’ were combined to become **‘support is key’**.

Both ‘importance of physical activity’ and ‘pedometer means motivation’ clearly showed experiences within each role and so were combined to become **‘physical activity in pregnancy’**. The theme ‘post-partum support’ was considered within this grouping as from a content perspective it mostly covers physical activity support

however after some thought it was left as a separate theme that was specific to post-partum as this is really important in itself.

With regard to weight, this is a critical element of the overall intervention. The Bumps and Beyond protocol is very clear as to the expectation for weight gain during the pregnancy being within the IOM guidance (Rasmussen, Yaktine & IOM, 2009). Reviewing the two themes around weight, 'time for the weigh-in' and 'weight loss in pregnancy' the researcher felt that these showed meaning from differing perspectives/ roles and so these were combined to become **'"…on the scales then"'**.

Two themes that initially seemed very different become two sides of the same coin when looked at again. These were 'forbidden food' and 'never say never'. These are interesting as lived experiences as they so sharply contradict each other. The new theme became **'never say never except when we do'** as it seems to cover both categories.

7.5.2.4 Theming

The final themes chosen were:

1. “You need to be taught a lesson about…” food
2. Support is key
3. “…On the scales then”
4. “After baby is born”
5. Don’t worry about the risks but…
6. Physical activity in pregnancy
7. Never say never except when we do
8. Living with kids, living with pregnancy

7.6 Thematic outputs

7.6.1 General feedback

There was a very clear separation on style of delivery between staff members which most likely reflects their personal employment background (one was a midwife, one was an ex-breastfeeding counsellor, and one was an ex-mental health nurse). Each session needed to cover specific material as per the Bumps and Beyond protocol (Appendix 2) and all staff members did this, which was demonstrated by the 'scripted' approach taken at times. There was an overlap of planned sessions within some appointments due to the personal approach needed for the participant. This showed that the staff were responsive, flexible and tailoring the programme for the needs of individuals.

7.6.2 Theme 1 "You need to be taught a lesson about…" food

This theme came about due to the way nutrition was discussed by the staff. This swayed between scientifically factual information and very poor advice. As this is delivered within the intervention it immediately caught the attention of both the Sarah the Dietitian and Sarah the Mother roles.

Sarah the Dietitian shuddered at the following comments due to the inaccuracy of what was said…

S2 *"Lemon is cleansing isn't it. It's cleansing and my mum once told me I'd get stomach ulcers if I ate too much."*

And these where the language used was unpleasant and non-inclusive and really made Sarah the Dietitian scream.

S1 *"You need to be taught a lesson about frozen fruit and vegetables…"*

S2 *"I am not very good with dyslexia as I don't know anything about it."*

However, the following nutrition advice was practical and interesting from both Sarah the Dietitian and Sarah the Mother perspective. The first quote is about increasing fruit and vegetable intake which is useful to know as a mother but also as a learning experience for a dietitian to include similar information in sessions or consultations.

S3 *"A way of increasing that…casseroles, pasta dishes, bolognaise, anything, double up the amount of vegetables that you're putting in it. So, if you put a tin of tomatoes in, open two tins of tomatoes and put it in. if you're cooking one onion, double up to two."*

And this quote about the change in size of plates and therefore the portion size for meals today. Sarah the Dietitian knows that many people are unaware of how large their portion size is and the practical implications of this to weight management.

S3 *"…when you look at an old tea set, let's say from back in the 1930s…and you look how small those plates were in comparison to ours."*

Sarah the Mother finds this a fascinating piece of historical information with a practical use.

7.6.3 Theme 2 Support is key

This theme covers both upbeat language given by the staff member around changes in behaviour already made by the participant, and also the importance of family support in making positive changes that can be more healthful for the participant.

Staff used motivational language numerous times within the sessions but often as single words or short phrases – see section 4.6.10.2. A couple of longer sections show how agreeable this appears especially when looked at through Sarah the Mother's eyes. The following refers to how a participant has managed their own depression through action.

S3 *"And I mean, that's remarkable that you've been able to do that and do that yourself."*

And continues…

S3 *"And you've taken control of that and that then helped you with the depression because you've taken control of something and you've moved forward and you're thinking, 'yeah, I can do it'."*

After a participant talks about wanting to be healthy and keep up with all the healthier lifestyle changes they have made in order to avoid their child becoming overweight, the staff member responds with this which speaks to Sarah the Mother both in a supportive way but also in that it puts pressure on and is scary.

S1 *"You're the role model, so he will have whatever you provide him with for these first few, you know, years. So, if you can do that for him, you're doing it for yourself, then you'll be fit and healthy."*

And a gentle reminder from the staff member about looking after yourself during pregnancy is not just about baby which really resounded with Sarah the Mother.

S1 *"But you are so important. So, and so is your baby."*

Support and motivation may not be just from staff. Family members are able to help too. The following is an excerpt from a session 5 transcript where the participants partner attends the sessions and is enthusiastic about supporting the changes suggested. Both Sarah the Dietitian and Sarah the Researcher knows that support is key in making and sustaining changes to improve health. Sarah the Mother knows that support from key people in life is needed and how hard it is when this is not forthcoming.

S3 *"Because the third session you came as a couple didn't you?..And last time you came together didn't you?..he takes it all on board as well, didn't he?..It's really good. Because it does help when you have that support."*

Support can be from other family members in this case the mum of the participant who attended the session too.

S3 *"...and I think also getting mum on board and giving you information to mum as well if she's doing meals, that will definitely help. Because it's healthy, so it's not specific to you, it can be used for the whole family*."

Not everyone does offer support whether family, friends or colleagues. A good example of a 'guilt trip' is seen in the comment below which was made as part of a conversation about biscuits and cake at the workplace. This spoke to all three roles as an actual lived experience and shows how hard making changes can be when peer pressure is there.

S2 *"It's hard because people do come around and offer you stuff don't they? And you're like, I want to say no…and if you say no, people don't like it. So they're a bit like, oh go on, I'm having one and it makes them feel better if you're having one and that's not really…not really what you want*."

And when it is the partner that is the issue it is even harder to make the healthy changes needed. This participants partner did not have a weight issue and so bought crisps and chocolate in bulk when they were on offer.

S3 *"…try and tell your partner to avoid the B&M specials when they're on there…that way then they're not so readily available in your cupboard."*

Sarah the Mother regards not having partner support as daunting.

7.6.4 Theme 3 "…On the scales then"

Participants were weighed at every session and so any language around weighing was put into this theme. This included the practical need to get onto scales and the feedback given once the weight was known. This theme also includes specific talk around weight loss in pregnancy.

There was always conversation around weight prior to the weigh-in and often the participants reported having had a bad week with regards their eating. Responses to this from staff varied and spoke in particular to Sarah the Dietitian due to the lack of non-judgmental language.

This is following a conversation with regards a birthday week and impact of food.

S3 "*Let's get you on the scales then, and we'll talk about your…you were 104.6 (kg)…f'woah! It's quite a bit, that is quite a bit…"*

The conversation continues later in the session referring to the 3kg weight gain seen.

S3 "*So what progressively will happen if you continue on that scale, you will gain another three if you carry on eating the way that you, that you're doin' at the moment."*

Going on holiday was a worry for one participant with regards weight gain and the staff response again shows accusative language which does not sit well with Sarah the Dietitian.

S1 *"...shall we weigh you then and see what damage the holiday did?"*

A more encouraging response was given in the next example when the participant expressed concern over celebrations and impact on their weight. Sarah the Mother would hope to experience this more supportive language, and Sarah the Dietitian

would aim to respond like this as it uses much more compassionate and motivational language.

S2 *"And you're doing incredibly well, I mean your weight says that. So don't worry about it. Just go forward from here and you will be absolutely fine…"*

Constructive language is used here following a weigh-in and speaks to Sarah the Mother specifically as it is a more supportive approach and acknowledges the work already done by the participant prior to the intervention starting.

S1 "*So you're nearly halfway there (through pregnancy) so you could easily be able to stay within these guidelines of 5-9 kg because you're only 2.3 (kg weight gain) now."*

S1 *"So you're going away from here feeling good."*

S1 "*That's really good so once you start to make these few changes, it will help you manage your weight. So obviously you're already 20 weeks and you haven't had any of this input, any of this support, so now you've been, it will help you to make a few changes which will help so much."*

The following is the staff response to hearing a participant's story about how she had seen that a sonographer had written in her notes that her weight was affecting the ability of the sonographer to see baby on the scan. The participant was angry that this hadn't been explained at the time. Sarah the Researcher remembers this from the actual session as it was recorded and was so upset for the participant and also shocked that someone in a caring role could be so inconsiderate. From a professional perspective as Sarah the Dietitian this is not acceptable language or transparent practice.

S2 *"I've had another lady maybe a year or so ago and she was really upset that they (the sonographers) had not said it verbally to her but then she'd read it in her notes. And she said the same thing as you. She said, 'I'm not stupid, but they didn't say that that was the reason.'"*

The way staff talked about weight loss during pregnancy and whilst on the programme was fascinating as whilst this is not recommended by the NHS (NICE, 2010), it was seen during the intervention. This is an important area for research and thus reaches out to Sarah the Researcher. The staff are also clear that as long as mother and baby are progressing then weight loss is not an area for concern which is an important message for Sarah the Mother to hear.

S3 *"…it's quite normal for there to be a weight gain, but provided you're fit, well, and healthy, if there isn't up to 5kg, we're not necessarily unduly worried but we're not putting you on this programme to lose weight, alright?"*

When weight loss is recorded, and the participant asks if this is a concern a staff member responds as below which is very soothing to Sarah the Mother reducing feelings of anxiety.

S3 *"…we're not expecting you to lose weight but…any weight loss that happens, because sometimes it does because it can be you're changing what you're eating and everything, providing you're well, baby's well, you're attending regular appointments with your midwife, then that's absolutely fine. We go by how you are not what you are."*

One staff member often talked about weight loss once baby is born due to the combination of low weight gain in pregnancy and the combined weight of baby, placenta etc. being lost at birth, and what this could mean for the future. This grabbed

the attention of both Sarah the Dietitian and Sarah the Researcher. From Sarah the Dietitian's perspective it felt like this should not have been said to the participant despite being factually correct.

S3 *"…that will mean that once you have a baby, that you would have lost quite a considerable amount of weight so that will give you a really good start to be able to continue with that if you wanted to. Is that something you want to continue with working at, losing weight after baby is born?"*

Sarah the Researcher felt it was thought provoking in that, could this be a motivational way of speaking to participants as it is so specific about losing weight post-partum, a time often acknowledged as a difficult one to do this.

7.6.5 Theme 4 Don't worry about the risks but…

Sarah the Researcher found the way in which known risks linked to high BMI in pregnancy were underplayed by staff members fascinating. Sarah the Dietitian noticed the language used around certain diet behaviours that were almost like a scare tactic to make the participant change in some way.

Pregnancy itself can suffer with serious complications which can be more likely with a raised BMI above the healthy range ≥24.9kg/m^2 (NICE, 2010). The Bumps and Beyond (B&B) booklet lists these in an explicit way as they are so important. Despite this all staff members appear to downplay these risks by the language they used about them which is interesting for all roles.

One staff member referred to the page of risks in the B&B booklet. The truth is that the list is scary particularly when viewed as Sarah the Mother, seeing what can go wrong with the pregnancy. As Sarah the Dietitian it is important that these risks are known as this allows awareness of symptoms that could indicate a problem and treatment can be sought. As Sarah the Researcher the contrast between reference to risk and then the direction to not worry is interesting as it is downplaying true risk.

S1 *"…it gives you a long list of those risks and complications, don't let this list worry you because it is a long list…it is a long scary list. So don't let it worry you…"*

A staff member to a participant who has been through the programme before does not reiterate these risks despite this participant having had a tough time with the previous pregnancy.

S3 *"…if you can cast your mind back to before what we said was, you're part of the service to avoid certain risk factors to you and your baby…"*

In other areas of the session staff use language that could be interpreted as a scary in order to change the behaviour. Sarah the Dietitian knows that the language used to describe foods should be non-judgmental and non-threatening and so word choice is important around food. A range of examples where language choice could be a perceived threat to health are given below.

The staff member below is referring to the ingredients on a food label as having chemicals in them without any reassurance that everything has chemicals, and if it is in food it has been well-tested.

S2 "*and obviously as well the more kind of ingredients that is in something probably the worse it is because they start getting all chemically named don't they and you start not really knowing what it is that is in there so that obviously means they're highly processed and had bits taken out and bits put in…"*

This staff member is talking about food choices and how food choice could be detrimental to health.

S1 *"Is it going to enhance my health or is it going to take away from it?"*

And the same staff member talking about what the food can offer an individual using language that insinuates one food is bad for you compared to the other.

S1 "*…bear in mind, 'is this going to offer me some nutrients or is it going to offer me a bowl of sugar?*""

In conversation about breastfeeding post-partum to a woman who has breastfed a previous baby.

S3 *"no matter what start you have whether it be, you have a section or a normal birth, there's nothing that should prohibit you from breastfeeding."*

Two Sarah's felt a response to the word 'prohibit'. Sarah the Mother feels it implies that should breastfeeding be difficult the second time around it will be a failure on her part. Sarah the Dietitian finds the language chose as weighted and could make a participant feel pressurized around an already high-pressure life stage. Careful word choice around breastfeeding is needed to ensure that the process does not become more stressful to the mother.

7.6.6 Theme 5 Physical activity in pregnancy

This theme covers both practical advice around where and how to be active as well as the health benefits in being active within pregnancy, an interesting theme for both Sarah the Mother, and Sarah the Researcher. Sarah the Dietitian needs to be aware of physical activity recommendations but must make sure not to step out of their scope of practice. Being physically active during pregnancy is first mentioned in session 1 and then session 3 is specifically about activity and a free pedometer is given to each participant.

The importance of physical activity, what is meant by moderate activity and types of physical activity are all discussed. Sarah the Mother is hungry for any information that supports making healthier choices, so this is extremely useful to know for this role.

S1 *"Physical activity is really important for us all and it's important when you're pregnant but it's important for us all. What we should all be doing, government recommendations are, thirty minutes of moderate activity five time a week."*

Sarah the Mother then asks herself what does moderate activity mean though? Thankfully the staff member explains as below.

S1 *"Moderate activity is the kind that makes you feel slightly out of breath and slightly warm (laughs)…it's so important. It's important for our physical health. It's useful for our mental health…so useful so never underestimate the value of it…"*

The same staff member later continues…

S1 "*Any activity counts, doing the housework counts because if you really put effort into housework, you feel slightly warm and slightly out of breath and that's what you're aiming for."*

One staff member had useful insight into an activity that was pleasant for pregnant women as they moved through the pregnancy. The extra weight carried becomes cumbersome so being guided towards an activity that reduces this is so appreciated by Sarah the Mother.

S2 "*And swimming is brilliant because obviously you become weightless and once you've got that little bump there and maybe your hips are hurting and things, it's nice to get in the water and kind of have a little relief for your back…"*

For Sarah the Mother, when a first-time mother, a big fear was the birth so linking physical activity and how it is helpful for labour is reassuring and motivational.

S2 *"…it's about staying healthy once you're pregnant. Because when you go into labour…you're body is used to be as active as it is then it will be…cope a lot better with labour…"*

Sarah the Mother knows it is difficult to comprehend what life will be like with a baby so knowing that you can do something that will impact health in a positive way is heartening.

S2 *"It helps you get your body back sooner after you've had a baby because you're more active and you're more likely to carry on being active."*

All participants received a pedometer in order to record how many steps they took and see if they could increase the amount (if necessary). The staff equate the 10,000 steps

each day message to the equivalent of walking 5 miles. This is fascinating for Sarah the Researcher and Sarah the Mother (who likes free stuff). Equating the steps message to an actual distance is useful and easier for Sarah the Mother to picture and then setting up a competition with herself in order to increase activity levels is a clever strategy for change.

S2 *"You just kind of do what you, what you can do but you have a little competition with yourself. You write down what you did in one day and then you think, 'Right tomorrow I'm going to add 50 (steps) to that.'"*

Sarah the Researcher is curious about the motivational aspect of using a pedometer.

S3 *"Pedometers are motivational tools really, that's why we give them to people just so people are aware of how little or how much they're actually walking in a day, because walking is an absolutely great exercise…"*

Staff told anecdotes about wearing the pedometers which were endearing and encouraging to Sarah the Mother.

S1 *" We can always tell at work who's wearing a pedometer and who isn't in the office because when people have got a pedometer on, they offer to go and make a drink, they walk the long way around to the photocopier and all things like that."*

Sarah the Researcher feels that there could be scope for using anecdotes and stories in this way to support behaviour change through shared experiences.

S2 *"…that's what me and my colleagues is when we put them on, we were like, 'I'll go down the kitchen and, I'll do this and I'll take that to the postal libraries', because when it's on you're very motivated to move."*

7.6.7 Theme 6 Never say never, except when we do.

This theme includes content around the fact that no food should be denied but then the same staff member uses language that indicates some food is taboo and should be avoided. This does not cover foods that the NHS advises pregnant women to avoid.

Sarah the Dietitian found it interesting to hear staff members refer to not denying self when it comes to healthier habits. Depriving self of something is a disordered style of eating which is not conducive to weight management (or weight loss post-partum) so staff explicitly saying this is not what is wanted is so important.

S1 *"People think that weight management is about deprivation and starving and not being able to eat anything you like."*

And another example

S1 *"But don't feel at all that you've got to go and put yourself on a diet or anything like that."*

Staff used interesting language around not denying self when it comes to eating and that we do not have to be faultless with food choices. In effect, we are human and that is alright. This is very reassuring for Sarah the Mother as this can help stop self-criticism around certain behaviours.

S1 *"Living a healthy lifestyle just means most of the time; make healthy choices but not being this perfect individual."*

And then following a conversation about not denying self from having chocolate,

S2 "*I just think it makes it harder for you because if you…can't have chocolate, it makes you want chocolate."*

When staff offered advice around shopping and how to support a healthier lifestyle, they tumbled into exactly the sort of language that is so often used within dieting and could drum up feelings of guilt or shame around a food choice. Sarah the Dietitian me screamed at the screen when reading this.

S2 *"Don't go (to the supermarket) with anyone who's going to fill your trolley with naughty things."*

Staff also referred to their own eating habits especially with sweet foods in a way that clearly indicates that these foods are taboo,

S1 *"I had a custard cream problem many years ago…"*

Another staff member also feels that biscuits are a problem. Sarah the Dietitian does not like this at all.

S2 *"I don't have biscuits in my house because I know that I'll eat them."*

But Sarah the Mother likes to hear a member of staff say something around attempting a behaviour and failing is reassuring, and then further anecdotes that show it can support the children to be healthy is actually useful.

S2 "*I'm not here to say that it's not right because it's just me and hypocritical as well because I'm not going to say that I don't eat chocolate…"*

And this staff member talking about not having biscuits in the house.

S2 "*So I stop buying them and my kids just know not to ask (for) biscuits in my house…But it's that habit while your little ones are little, you can get them out of habits very easy and it helps to motivate you because you think, I'm not getting it, the kids don't have it so I'm not having it too*."

7.6.8 Theme 7 Living with kids, living with pregnancy

This theme is around the acknowledgement that being pregnant is hard and being pregnant alongside already having a child or children can be even harder. For Sarah the Mother this is important as it validates her own feelings.

Staff acknowledged nausea and vomiting in pregnancy. One of whom used an informal colloquialism which appeared to be a local term referring to nausea.

S3 *"…when you're pregnant you're kind of a bit more likely to, a little gimpy about things aren't you."*

Another member of staff talks about loss of interest in certain foods during pregnancy which, again, reflects the lived experience of Sarah the Mother.

S2 "*Yeah it's weird. When you think to yourself, I really want that, but I don't…I can't stomach it so, yeah, that is pregnancy for you*."

These comments felt like they showed a shared experience between the staff member and Sarah the Mother.

Some of the women in the intervention already had children and one staff member had a conversation with a woman about how hard it is to deal with tiredness in pregnancy with children. This was very meaningful to Sarah the Mother as it is unbelievably hard to look after children and having this acknowledged by a professional is validating.

S2 *"…your second pregnancy is a lot different isn't it because you have a toddler. So, you're like, 'I used to rest when I was pregnant last time, but now I don't."*

The staff member continues in response to the participant…

S2 "*There was no little person going, 'Mummy, mummy, open your eyes.' My little lad used to do that. 'Mummy open your eyes.' And I'll be like, 'I'm just resting my eyes, I'm not actually asleep.*'"

Later in the session the same staff member talks about the difficulty of going out to eat with a toddler and new baby but how this improves with time.

S2 *"…we kind of got to the point where our eldest was three and we said, 'Right, we're not eating out anymore.' Because we wanted to, but it was just too difficult with the baby and the little one that just wanted to run around all day."*

Sarah the Mother groaned at the remembrance of this. The staff member then continues…

S2 "*Now, we've kind of gone full circle and they can vaguely behave themselves now, we're like, 'Yeah, let's just go out.*'"

Sarah the Mother is given light at the end of the tunnel.

7.6.9 Theme 8 "After baby is born"

This theme is around practical advice offered for after the baby had been born. The phrase 'after baby is born' is used repeatedly within the final session with reference to the support (practical) that could be offered. Sarah the Mother adores free things and the idea that something is being offered for free that could help with weight management after the birth is ideal. Practical resources like those mentioned are perfect. This also spoke to Sarah the Researcher as they could not help but wonder that if there were more of these types of free social and practical support opportunities available could weight management programmes be more successful? Examples of what was available in and around Lincolnshire are given with these quotes.

S3 *"…we can offer you is 12 weeks of Weight Watchers and it's free of charge…I don't know if that would suit you for after the baby is born*."

S3 "*…I can refer you for 12 weeks swimming and gym membership if you want to after baby is born."*

With a one-to-one option with a health trainer also being available.

S3 "*So the other thing is something like a health trainer might work. A health trainer is basically somebody very similar to myself but she would be looking at your family as a whole…."*

All of these came from the same staff member although in different locations. This is interesting for Sarah the Dietitian and Sarah the Researcher as there seems to be a clear indication that either there is an unequal availability of support across the region, or that this staff member goes above and beyond to find the post-partum support available.

7.6.10 Subordinate themes

During the reading of the transcripts there were also a number of noteworthy findings that seem valuable to include.

7.6.10.1 Free stuff

Throughout the sessions the staff used a range of support material to back up the key messages they were trying to get across. It is tricky to find text to show any depth to this as often the language used was very practical and literally refers to the visual aid. In addition to reference material, staff gave a number of freebies to participants. These included the pedometer as mentioned in 4.6.6 as well as recipe books, a baby towel, pen, pad etc. Sarah the Mother loves free stuff.

7.6.10.2 “Brilliant”

Another area which was very apparent within the text was the number of times a staff member used praise language in response to the participant as can be seen in section 4.6.3. Often these were single words or short phrases and so were difficult to show as anything meaningful as standalone comments. However, when taken within the conversation they were clearly used to congratulate and motivate the participant and could be seen as improving rapport.

7.6.10.3 How long is too long?

It was apparent within the transcripts that staff members talked for much more of the session time than the participant. In one example the staff member talked for over eight minutes without stopping and delivers a huge amount of information. This

approach seemed to hark back to a more paternalistic style of delivery that grates with both the dietitian and mother role. It is also not how motivational interviewing is expected to be delivered.

7.7. Discussion

In order to make full sense of the findings these have been split into the different roles taken with the analysis. In some cases, examples used have spoken to a number of the roles in a way that the essence differs, in itself interesting when viewing the wider picture. By stepping out of each role and looking back into it a perspective on what was the true essence is more easily seen so this section is written in the third person. Figure 4.1 shows a summary of the essences and each role it came from.

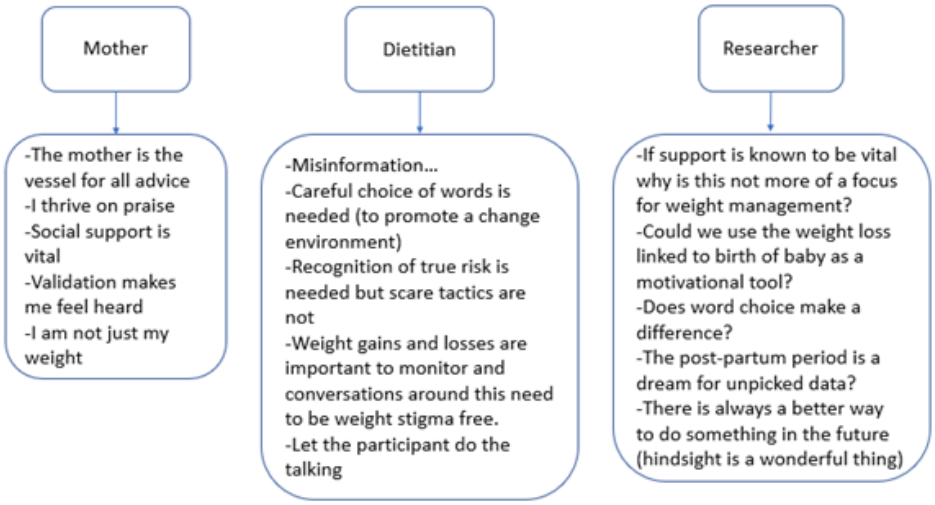


Figure 7.1 Hermeneutic phenomenological analysis of transcripts using the roles of Sarah the Mother, Sarah the Dietitian, and Sarah the Researcher

7.7.1 Sarah the Mother

7.7.1.1 Information and advice

Sarah the Mother wanted (and still wants) to gather as much information as she can to make informed decisions. Sections 4.6.2., and 4.6.6 contain interesting and useful information that can be utilized by the Mother.

The two quotes used within section 4.6.2 that were practical advice from the staff member were genuinely useful. The first enabled the Mother to see where small changes could be made to support a healthier way of eating by increasing fruit and vegetable intake. The ideas given are actual very simple, doubling the tinned tomatoes or using two onions, and would not be too expensive. The second comment used is appealing as it is educational and eye-opening. It is a piece of advice that can be tested by going away and looking at differences between plate sizes. When trying to make healthy food choices becoming aware that a simple choice around plate size could help better control the portion size.

Section 4.6.6. covers physical activity in pregnancy. The advice from staff is clear about what is the healthiest choice for physical activity in pregnancy regardless of size. They cover how long, types, and describe what is meant by 'moderate activity' in the guidelines of that time (Varney *et al.*,2014). The advice given also explained about how swimming can help make a mother more comfortable whilst being active. During the latter stages of pregnancy, the extra weight can be very uncomfortable and being in water completely removes this feeling. Sarah the Mother remembers vividly how lovely and relaxing this was and being given this piece of information when new to being pregnant is not only useful but allows a mother to try something which is beneficial. The Bumps and Beyond programme always offered mothers a pedometer and staff talked about the benefit of walking for health. Staff mentioned "*competition with yourself*" by trying to increase the number of steps each day even if this was by a small amount. Being a competitive person, this absolutely spoke to Sarah the Mother.

Later, staff gave anecdotes about their use of the pedometers which were amusing and reiterated the competitive element. The idea of staff using the pedometers also felt inclusive, like this was not a 'special measure' but normal and fun.

ESSENCE – THE MOTHER IS A VESSEL FOR ALL ADVICE.

7.7.1.2 Praise

As Sarah the Mother there is a constant need for praise that advice is being followed or that actions and behaviours are acknowledged as positive. Within the sections 4.6.3, and 4.6.10.2 the language used by staff was very motivating for this role with words like "*brilliant*", "*remarkable*", and "*taken control*". What is not captured by the text alone is how genuine this praise was and that the staff member was not being patronizing.

ESSENCE – I THRIVE ON PRAISE.

7.7.1.3 Support

The need for support from others was also a presence within the text and spoke to Sarah the Mother. Family support was the main component with both positive and negative being apparent, section 4.6.3. Where the support was positive it was clear that close family members were on board (partner, mother). This support was shown by attendance at appointments,

"…you came as a couple…"

and also changing behaviours in the home and wider environment alongside a participant,

"…giving information to mum if she's doing meals…".

Examples found within the text show how difficult change can be when those around the individual are not supportive,

"*…people come around and offer you stuff…and it makes them feel better…",*

or a partner who is not on board with the healthy changes needed,

"…try and tell your partner to avoid the B&M specials…"

Lack of social support is a known risk factor for mental health problems for pregnant women which in the worst cases can end with death by suicide (Bedaso *et al.*,2021; Knight *et al.*,2019). The thought of no support whilst pregnant is frightening to Sarah the Mother. Pregnancy is a time of change and the need to share the 'burden' of this is crucial. Not having family around at this time can be hard and being supported by others both friends and professionals was a critical need.

In the final session staff talked about "*after the baby is born*", section 4.6.9. Sarah the Mother knows that being a first-time mother can be very difficult as it is hard to know what is to come after the birth. Having someone offer support via other services is both practical and useful, and crucially, allows mum to get out and be social. All support offered by staff at this stage was from third parties and does not last indefinitely however it lasts long enough to get baby to a few months old. Sarah the Mother enjoys receiving free things too, and everything offered here is free.

ESSENCE – SOCIAL SUPPORT IS VITAL.

7.7.1.4 Validation

The need for validation is so important for Sarah the Mother, whether as praise see 4.6.10.2, or in itself through confirmation of lived experience, section 4.6.8. Acknowledgement of what a pregnant woman has to go through whether checking baby is fine through ultrasound and regular measurements, that they themselves are well via blood and urine tests and regular ante-natal appointments, or simply how difficult this time in life can be is so very important. Section 4.6.8 is very specific with this and was probably the section that spoke most to Sarah the Mother. It is all about validation of how difficult life can be as a mother. Sarah the Mother's lifeworld includes children and recognition of this by staff was so affirming. Staff were brilliant at acknowledging the life difficulties of the mother role and sharing their own experiences within the Mother role.

ESSENCE – VALIDATION MAKES ME FEEL HEARD

7.7.1.5 Weight

Bumps and Beyond operated specifically to support women with a high BMI to not gain too much weight. This made language around weight and other associated subjects really important, but this importance spoke to each Role in very different ways. A high BMI during pregnancy increases the chance of serious health issues occurring, however hearing these as Sarah the Mother is terrifying especially as it is too late to really do much once pregnant. All staff downplayed the long list of known risks by referring to them but in a lowkey way,

"…don't let this list worry you because it is a long list…it is a long scary list…".

This approach is very much appreciated by Sarah the Mother. The anxiety even seeing the list can cause is high so staff downplaying in this way is encouraging and even motivating as they go on to give ways to help prevent bad things from happening.

Every participant was weighed at every appointment on Bumps and Beyond. Preventing excess weight gain being the main point of the programme. There was very matter-of-fact language used with this, literally,

> *"…on the scales then…"*

This spoke to Sarah the Mother as it was so down-to-earth and factual. That said sometimes the language used after the weigh-in was not supportive at times despite concern being shown. Sarah the Mother cannot think of a time when weight and thoughts about weight were not an issue. Support around weight gain or loss becomes important and positive and acceptable language is needed for this. When used it produces a feeling of comfort for the Mother role.

ESSENCE – I AM NOT JUST MY WEIGHT

7.7.2 Sarah the Dietitian

Sarah the Dietitian has a very specific way of looking at things in part through the training and clinical experience for becoming a dietitian. This means that in many cases what has been picked up through the transcripts are areas where there have been mistakes with language use, information given, or style of consultation. This felt like quite a harsh look at what was said, but it resonated so much with what has been taught about being a good dietitian that the essence of these points is so deep and meaningful in this role.

7.7.2.1 Misinformation

There is nothing that speaks louder to Sarah the Dietitian than people giving really bad nutrition advice. Unfortunately, there were times that this was apparent within the transcripts with incorrect nutrition advice. Some examples are given in section 5.6.2. with this one being interesting as it is a very old-fashioned piece of advice.

> "*lemon is cleansing isn't it…?"*

ESSENCE – MISINFORMATION..

7.7.2.2 Language

Sarah the Dietitian found the language use particularly interesting. The staff swayed between very supportive language to very negative language both around behaviour and food. Personal experience within the dietitian role has shown that language can be damaging when used at the wrong time for an individual. Even with the use of words that can seem innocuous. Examples within the text around weight gain included words like, "*f'woah*!", and "*damage*" when the participant has been worried about gaining too much weight. Sarah the Dietitian finds these words judgmental and would never recommend using them especially around something as sensitive as weight gain. Later, staff talked about diet changes to help with weight management, and again negative and judgmental words are used like, "*naughty*", and "*problem*". These conjure up a barrier with those foods referred to which is best avoided when aiming to support weight change.

Despite the use of negative language within the transcripts, Sarah the Dietitian also noticed many examples of very supportive and inclusive words. These include

examples such as, "*that's remarkable*", "*feeling good*", and those seen in section 4.6.10.2. Careful use of this type of language can help an individual make changes in their lifestyle, a tool that can be used with motivational interviewing (Smith *et al.*,2021) also noted by Sarah the Mother as it made her feel good about herself, section 4.7.1.3.

ESSENCE – CAREFUL CHOICE OF WORDS IS NEEDED (TO PROMOTE A CHANGE ENVIRONMENT)

7.7.2.3 Risky

Pregnancy is risky life stage for women even in modern times. A range of pregnancy risks were described in Chapter 1, and in low-income countries many of these risks still result in the premature death of mothers and their unborn child, hence WHO making the reduction of these risks and maternal mortality part of the Sustainable Development Goal 3 (WHO, 2022). The Bumps and Beyond support booklet has a page of these risks which the staff referred to but downplayed, and this was seen in all transcripts from session 1. Language used includes, *"…don't let it worry you…".* This appears to be supportive and make the risks less scary but it could also lead to an individual not being aware of the type of symptom that should trigger a check-up by a midwife or medic. Sarah the Dietitian feels this should have been more explicit for this reason. Brushing over these does not make clinical sense.

Conversely the same staff make 'monsters' where there do not need to be any, in particular around food and diet choice. One staff member repeatedly talked about processed foods as "*chemically*" which is often seen as a bad thing due to lack of awareness of what processed means and what these chemicals are. Another staff

member used ‘scare tactics’ by saying that food could “*take away from it (health)*”, or *“offer a bowl of sugar*”. Neither of these are useful terms. Sarah the Dietitian is acutely aware that these types of terms are often used in the media and show a lack of knowledge around food and food production. This does not mean an expectation that everyone has to know the chemical content of their food but making food scary is not appropriate.

ESSENCE – RECOGNITION OF TRUE RISK IS NEEDED BUT SCARE TACTICS ARE NOT.

7.7.2.4 Weight

Bumps and Beyond was first and foremost a programme aimed at preventing excessive weight gain in pregnancy. This meant that being weighed was an integral part of each session and was written into the protocol (weigh with consent). This means that all staff did this task. Every staff member was very practical and factual with the weighing process and then reporting back the weight and any change, section 4.6.4. All participants appeared to want to know the result.

An interesting story was picked up via the transcripts where a participant had something written by a sonographer in her handheld maternity notes but which had not been discussed with her at the time. The participant was very upset and the staff member, who was a midwife, talked about hearing this having happened before and mentions that it could be due to other staff not feeling comfortable talking about weight. This speaks to Sarah the Dietitian in a couple of ways. First, the lack of transparency by the sonographer, and secondly, the thought that is this lack of training around weight stigma? Both of these are unacceptable to the Dietitian role. If

something is to be written in handheld notes then it is polite to discuss this with the individual. Weight stigma in pregnancy from healthcare professionals is a known problem and has and is being studied (Jensen *et al.*,2022; Incollingo Rodriguez *et al.*,2020). Sarah the Dietitian has become more aware of this as an issue during her own professional life and to hear of it via these stories is upsetting.

One of the surprising findings in both evaluations of Bumps and Beyond Lincolnshire was how many participants lost weight during the programme with no ill effect reported, see Chapter 2, section 2.3.3, and McGiveron *et al.*,(2015). In the transcripts the staff referred to small weight gains or losses as not being critical as long as both mum and baby are well. One staff member repeatedly mentioned post-partum weight loss due to small weight gain and subsequent birth meaning overall there will be a weight loss,

"*…once you've had the baby, you'll have lost…a considerable amount of weight*".

This speaks to Sarah the Dietitian as whilst true, it seems to endorse small weight gain in pregnancy.

ESSENCE – WEIGHT GAINS AND LOSSES ARE IMPORTANT TO MONITOR AND CONVERSATIONS AROUND THIS NEED TO BE WEIGHT STIGMA FREE.

7.7.2.5 Stop talking

A subordinate theme that is important to Sarah the Dietitian is that of the staff member talking for extended periods of time, section 4.6.10.3. A key area of

communication skills training for a dietitian is how to discuss issues with participants so that they are the ones doing the bulk of the talking. The clinician should be actively listening in order to support the client/ participant with whatever behaviour change they are working towards. At times within the transcripts the staff member spoke for such extended periods and gave so much information it was difficult to difficult to see how the participant could be actively involved.

ESSENCE – LET THE PARTICIPANT DO THE TALKING

7.7.3 Sarah the Researcher

7.7.3.1 Social support

The need for positive social support was clear to Sarah the Researcher. There is evidence available to say that not having enough social support during and after pregnancy increases the risk of severe mental health issues (Bedaso *et al.*,2021; Knight *et al.*,2019) and could prevent post-partum weight loss (Dinsdale *et al.*,2016). Bumps and Beyond did not itself continue after birth but did signpost women to practical support. Support from family or the workplace was both positive and negative and ways in which to improve this are important. An article by Montgomery *et al.*,(2012) reported the main theme from interviews with male partners of women whom had given birth within the past five years was the negative perception of pregnancy weight gain but that the male partners also wanted to be supportive. Partner support can help women to lose weight and, when missing, the absence can be very damaging (Montgomery *et al.*,2010). Sarah the Researcher read the text and felt that this area is so critical in weight management that interventions should take this on board when being put together.

ESSENCE – IF SUPPORT IS KNOWN TO BE VITAL WHY IS THIS NOT FOCUSED ON BETTER IN WEIGHT MANAGEMENT?

7.7.3.2 Weight loss

Weight loss during pregnancy is never encouraged as the possible impact on the fetus is not fully understood (NICE, 2010). In the Bumps and Beyond programme a number of women did lose weight with the greatest weight loss being 18.65kg however no adverse effect was associated with this or in the others with weight loss. Staff were clear within the transcripts that as long as mum and baby are doing well then weight loss or low weight gain is not a cause for concern, "… *we go by how you are not what you are.",* section 4.6.4. Staff also talked about weight loss or low weight gain and how, once baby is born and the weight associated with that is lost, the woman will have lost weight overall and this is a great start to the post-partum weight loss journey. As Sarah the Researcher this was really fascinating to read. There is truth in what is said however is it appropriate to talk about weight loss in this way? It leads to an interesting research question around whether weight loss linked to baby, placenta and associated products of pregnancy could be a motivational tool in some way? Or is it a dangerous place to go?

ESSENCE – COULD WE USE THE WEIGHT LOSS LINKED TO BIRTH OF BABY AS A MOTIVATIONAL TOOL?

7.7.3.3 Tab'ood (taboo food)

Sarah the Researcher found that section 4.6.7 was particularly interesting as it looked at the language used around food. Staff talked about not going on a diet or depriving oneself of foods as well as pointing out everyone is human and so cannot be perfect all of the time. However, later in the text they used words that were very negative, discussed in section 4.6.7. Word choice around food and diet could alter the perception of that food and make it taboo. Zhou & Tse, (2020) undertook research looking at word association and emotion. They found that when people were asked to associate emotion words to the five human tastes (except umami) only sweet brought up positive words (Zhou & Tse., 2020). Whilst not a direct comparison to this text it does show that humans put emotions onto words around food and taste. Sarah the Researcher is fascinated about what the end result could be with the use of 'positive' and 'negative' words in weight management.

ESSENCE – DOES WORD CHOICE MAKE A DIFFERENCE?

7.7.3.4 Post-partum

One area that shines out to Sarah the Researcher is that of available support post-partum. The transcripts show this came in a number of forms from free access to swimming pools for the whole family to a Health Trainer offering support in the home. The post-partum period comes with a range of issues linked to pregnancy not least juggling life with a new baby. Dinsdale *et al.*,(2016) captured the reflections of women around the post-partum period with one commenting about specific classes for those who need to lose baby weight. None of the services offered with Bumps and Beyond did this. What is lost with Bumps and Beyond Lincolnshire is the knowledge around whether these services were used and the impact of them on the women and

their families. Being able to follow up on this for a meaningful period of time would be such a useful piece of research.

ESSENCE – POST-PARTUM PERIOD IS A DREAM FOR DATA

7.7.3.5 Further reflections

Sarah the Researcher also felt that there were areas of interest about the consultations that were not captured well within the transcripts. Sarah the Researcher was responsible for gathering the data and so observed the body language of the staff members. At the time the research was put together no written data tool for observing body language could be found and so this part of the consultation was mostly missed. Notes were taken at the time, and a short course about body language had been attended. Following the analysis of the text Sarah the Researcher feels that the best way of being able to combine spoken word and body language would be to video the consultations in any future research. One without the other loses much of the communication but would change the type of analysis needed.

In addition, more use of modern technology could be incorporated. There was little use of technology within the B&B programme, but women did receive a phone text prior to their appointment to remind them about it but also as an opportunity to reschedule if they needed to. There was limited additional technical support via text which was not measured in anyway and so not captured as data.

ESSENCE – THERE IS ALWAYS A BETTER WAY TO DO SOMETHING IN THE FUTURE (HINDSIGHT IS A WONDERFUL THING).

Chapter 8. General Discussion

The work presented in this thesis has been focused on addressing the stated aim to evaluate the Bumps and Beyond (B&B) programmes through a mixed-methods approach. In so doing, two quantitative studies and one qualitative study have considered the efficacy of Bumps and Beyond, an intervention designed by clinicians with the primary target being control over gestational weight gain in pregnant women with obesity.

The literature reviewed in chapter 3 of this thesis has established that obesity and excessive gestational weight gain are risk factors for a range of complications in pregnancy and labour, poor pregnancy outcomes and a failure to initiate breastfeeding (Langley-Evans et al., 2022). Both are also associated with greater post-partum weight retention, increasing risk to further pregnancies and longer-term maternal health. There is some debate about whether the risk associated with excessive gestational weight gain is independent of obesity itself, since women with a pre-pregnancy BMI in the healthy range exhibit greater risk of outcomes such as gestational diabetes and hypertension (Lewandowska et al., 2020; Yong et al., 2020) when weight gain is high. However, in the context of this thesis where all records obtained were from women living with obesity and, in the case of the Lincolnshire participants, severe obesity this point is not of great importance. Pregnancies complicated by obesity are already high risk and the aim of controlling weight gain was to ameliorate the associated risk. Intervening to promote the attainment of a healthy weight gain was also a very challenging prospect. For women with obesity, the US Institute of Medicine guidelines suggest optimal weight gain is between 5 and 9 kg (Rasmussen, Yaktine & IOM, 2009). Given that the weight of the baby placenta,

amniotic fluid, uterine and breast adaptations will be 6-7kg (Langley-Evans, 2021), there is little capacity for controlling weight gain.

8.1 Summary of findings

8.1.1 Objective 1

The first objective for the thesis was to further evaluate the Lincolnshire Bumps and Beyond weight management in pregnancy programme using a larger data set in order to compare to the preliminary findings as reported in McGiveron *et al.*,(2015) that showed a reduction in GWG and overall reduction in pregnancy complications.

Findings from the analysis of 624 audit sheets showed that full attendance of the Lincolnshire B&B programme led to a reduction in GWG (Figure 5.2), total pregnancy complications, PE, number of preterm births, LBW, and an increase in breastfeeding at first feed when compared to non-attendance (Chapter 5, Tables 5.4, 5.5, and 5.6). Partial attendance of Lincolnshire B&B intervention led to a reduction in GWG (Figure 5.2), total pregnancy complications, GDM, and PE when compared to non-attendance (Chapter 5, Tables 5.4, 5.5 and 5.6). This confirmed the initial analysis of McGiveron *et al.*,(2015) and provided the first evidence that GDM could be ameliorated by the intervention. The findings were in keeping with reports from other small-scale, patient-centred interventions (Shirazian et al., 2010; Haby et al., 2015) and at least one randomized controlled trial (Daley et al., 2015). The findings add further weight to systematic review outcomes which suggest combined diet and exercise interventions are effective in preventing excessive GWG and pregnancy complications (Fair & Soltani, 2021; Yeo *et al.*, 2017; Thangaratinum *et al.*, 2012).

8.1.2 Objective 2

The second objective was to evaluate the service called Bumps and Beyond Nottinghamshire which ran at NUH NHS Trust.

In Nottinghamshire analysis of 663 audit records showed full attendance on the Nottinghamshire version of Bumps and Beyond compared to non-attendance had no benefit for any of the outcomes reviewed plus was associated with an increased risk of instrumental delivery (Chapter 6, Tables 6.3, 6.4, and 6.5). Partial attendance of the Nottinghamshire B&B intervention showed no benefit and led to an increase in GDM, and elective caesarean risk (Chapter 6, Tables 6.3, 6.4 and 6.5). These findings prompted the discontinuation of the intervention and raised interesting questions for this thesis in terms of the differences in outcome between two similar protocols.

8.1.3 Objective 3

The third objective was to use transcripts taken from recordings of sessions delivered by staff in the Bumps and Beyond Lincolnshire team, and field notes taken at the time to assess and report intervention fidelity. This used the template for intervention description and replication (TIDieR) tool (Hoffman et al., 2013). Overall staff adhered to the Bumps and Beyond protocol but what was also apparent was how they adapted material to the needs of the participant (Chapter 4, section 4.3.10.2). This was written into the original protocol and utilising this approach allowed the personalisation of the programme for the women participating. Field notes allowed for identification of additional material handed to the participants within the sessions, (Figures 4.3, 4.4, & 4.5). The field notes also identified additional needs for delivery of this type of programme including appropriately sized rooms and a temperature of a comfortable

level (Chapter 4, section 4.4). The use of the TIDieR tool (Hoffman et al., 2013) allows for future replication of the programme as delivered by the Bumps and Beyond Lincolnshire team.

8.1.4 Objective 4

The final objective for this thesis was to explore transcripts of sessions delivered by staff within Lincolnshire B&B using a hermeneutic phenomenological approach that utilised three roles of Sarah to find essences within the text.

This analysis of transcripts allowed each Sarah Role (Mother, Dietitian or Researcher) to pull out a range of lifeworld essences from the text. These showed that there were both similarities and differences for each Role and combining these could be a useful tool for shaping interventions in the future. Following analysis of the text 14 lifeworld essences were identified (Figure 7.1). This analysis provided an additional layer to the work of the thesis and gave insights into what made the Lincolnshire programme effective. Again this is useful for organisations that may consider attempting to replicate the service.

8.2 Critical analysis

8.2.1 Service evaluations

The results from these services evaluation (Chapters 5 and 6) showed that the Bumps and Beyond Programme could be effective and that results seen in earlier analysis were replicated on a larger scale but only in the original location. There was a profound difference between the two locations where the intervention ran, with

respect to outcomes. As a service evaluation no additional data other than that provided by the clinical team was able to be collected. Analysis of the audit sheets allowed a level of insight into the outcomes seen at the two sites and was able to identify key differences between them.

Lincolnshire B&B clearly had a positive impact on pregnancy and birth outcomes, with a reduction in GWG, decrease in pregnancy complications and increase in breastfeeding (Section 5.3.7.3). Similar low-key programmes have been reported on the NICE Shared Learning Database, see section 3.5.2. The specific outcomes of the Lincolnshire B&B programme (Figure 5.1) have many direct comparisons to these small midwife-led programmes with education around diet and physical activity to reduce pregnancy weight gain being the main focus (NICE 2022a; NICE 2022b; NICE 2022c). As there is no published data in the literature about these other programmes only the information on the NICE Shared Learning Database can be used (NICE 2022a; NICE 2022b; NICE 2022c). None of these interventions still run (checked October 2022) despite reports of positive outcomes. The Lincolnshire B&B programme has an advantage in that results are reported in the literature and available for anyone to see (Langley-Evans *et al.*,2022; McGiveron *et al.*,2015) and learn from. Nottinghamshire B&B was unable to replicate the positive results seen in the Lincolnshire B&B programme and was halted. Data from Nottinghamshire B&B has not been published as of October 2022. The lack of published data on small, local, pragmatic interventions to promote healthy weight gain in pregnancy makes it difficult for other researchers and clinical teams to pick up and attempt to replicate or evaluate successful programmes.

In addition to the small scale locally run interventions mentioned above, the Bumps and Beyond programme can be compared to interventions like NELIP (Mottola *et*

al.,2010) and the LMP by Shirazian *et al.*,(2010). These two programmes had similar content with nutrition, exercise and support (Mottola *et al.*,2010; Shirazian *et al.*,2010). NELIP reported lower GWG during the actual programme with the bulk of the weight being gained prior to women attending the intervention (Mottola *et al.*,2010). The LMP reported a weight gain by attendees that was only half that of the matched control group, but no difference between secondary outcomes which included GDM, PE, caesarean delivery, and infant birth weight (Shirazian *et al.*,2010). These programmes differed in that they were only partially successful when looking at all outcomes compared to Lincolnshire B&B, which appears to be one of the most effective interventions reported in the literature. The current observation that the efficacy remains with a much bigger data set is therefore an important start point for the design of future interventions.

The key outcome for the B&B intervention was to keep weight gain within the IOM guidelines (Rasmussen, Yaktine & IOM, 2009). Lincolnshire B&B attenders and partial attenders were very successful in achieving this outcome when compared to non-attenders (Chapter 5, section 5.3.3), whereas Nottinghamshire B&B results showed no significant difference between groups (Chapter 6, section 6.3.3). The lack of significance between the groups as seen in Nottingham indicates that the intervention does not appear to be the reason for these differences. One thing of note is that referral to the Nottinghamshire B&B programme was from a BMI 30kg/m^2, whereas the Lincolnshire B&B programme was from a BMI of 35kg/m^2. When GWG was compared as booking BMI tertiles for the Lincolnshire B&B programme (Chapter 6 Table 6.6), there was a significant difference between attenders and partial attenders compared to non-attenders. The same pattern was not seen in the Nottinghamshire B&B programme (Chapter 6 Table 6.6). It was interesting to note

that non-attenders in Nottinghamshire were able to attain healthy GWG, which may indicate that routine care practices might have been effective, rendering the B&B programme ineffectual against the clinical background. Uncovering differences in the way in which the intervention was delivered can lead to insight into possible factors which led to success in one location, and a lack of impact in another location just 25 miles away, and for this qualitative approaches would be appropriate.

8.2.2 Qualitative study

The qualitative element of this thesis was undertaken to advance knowledge around the way in which the Lincolnshire B&B programme was delivered using a novel approach based on hermeneutic phenomenological analysis (HPA) of text. HPA is often used in nursing to try and find, and better understand, the lived experiences of both staff (Santiago *et al.*,2020) and patients (Nielsen *et al.*,2019; Cypress, 2013). The current study is novel in that HPA has not been undertaken in this manner with this type of source text (recordings of B&B staff and clients) before, and uses three Roles of Sarah the Mother, Sarah the Dietitian, and Sarah the Researcher. By looking at the text and utilising the lived experience of each Role it has been possible to find the essence, the subjective understanding of for each role. Drilling down into the interactions of the staff and clients with each role, threw up differing areas of importance which could go on to be considered when developing similar interventions. Using Roles to extract the essence from text worked well for this thesis and researcher however it may be a style that some researchers find more difficult to utilize. Personal ontology and epistemology will impact how an individual approaches this style of research and it is likely to be unsuitable for a realist positivist.

8.3 Drawing together quantitative findings and textual essences

8.3.1 Weight

The analysis of the transcripts was able to find essences that are linked to weight irrespective of the Role taken (Figure 7.1). As Sarah the Mother, weight is seen as one aspect of the whole person (Section 7.7.1.5). Sarah the Dietitian is more practical, and the essence speaks of this with reiterating the importance of monitoring weight but also that conversations with regards weight are stigma-free (Section 7.7.2.4). Finally, Sarah the Researcher (Section 7.7.3.2) is more forward-thinking and the essence is about future possibility; could the inevitable weight loss due to baby being born be used as a motivational tool for post-partum weight management? Each essence can provide a picture as to how conversations about weight could be undertaken by staff. The staff delivering the programme would not have the luxury of the bigger picture produced by this analysis and so this output could be used as a basis for future programme development. In addition, the essence from Sarah the Researcher around use of the initial post-partum weight loss being a motivational tool for future weight loss has not been looked at before and so may offer a missed opportunity for weight loss at this stage (Section 7.7.3.2).

The fact that weight management in the periconceptual and antenatal period is a key area of care cannot be understated. The risks involved with excess weight and pregnancy are well known (Section 3.3). Whilst the qualitative analysis for the Lincolnshire B&B programme gave some clues as the why the delivery there was effective, the fact that the same analysis could not be conducted with data from the Nottinghamshire B&B means that full understanding of why the B&B programme worked in one location but not another remains unclear. Despite occasionally

stigmatizing language about weight and some misinformation, the praise, validation of the mothers and flagging of social support may have contributed to the observed successful outcomes.

8.3.2 Staffing

One of the differences between the two intervention programmes were the staff delivering the sessions. In Lincolnshire, the Bumps and Beyond staff consisted of a lead midwife and a midwife and two healthy lifestyle advisors with previous health behaviour change experience. The behaviour change practical experience was apparent in the session delivery. The Nottinghamshire B&B programme had a lead midwife and then four healthy lifestyle advisors with nutrition degrees. The HPA did not bring up specific essences around staffing, rather it emphasized possible training gaps.

In the NICE Shared Database, the three similar interventions used a variety of different staff to deliver the programmes although the service was always midwife-led (NICE, 2022). The use of healthy lifestyle advisors or health trainers is common in interventions aimed at improving health (Visram *et al.*,2014; Jennings *et al.*,2013). The staff are often recruited from the area that the intervention is due to run, and this has the benefit that they can understand local issues that may impact on behaviour change (Visram *et al.* 2014). Van der Pligt *et al.* (2013) reviewed a range of interventions for limiting post-partum weight retention. In this review they considered who delivered the programmes and reported a wide range of staff including dietitians but not midwives, who would no longer be involved at the post-partum stage, and not healthy lifestyle advisors (Van der Pligt *et al.*,2013). Only seven of the eleven studies in the review showed successful outcomes of reducing post-partum weight retention

or promoting weight loss (Van der Pligt *et al.*,2013). It is difficult to say for certainty that there is a staff affect but it should be flagged as a possible difference between the two interventions and consideration made about this for future programmes. It is also important that the training and professional background of whoever delivers the intervention is fully reported within any research publications in order for comparisons to be made.

8.3.3 Language

The HPA of the transcripts allowed a number of essences to be identified with each Role of Sarah that fit into an overall grouping of language and the giving of information to aid knowledge (Sections 7.7.1.1, 7.7.1.2, 7.7.2.1, 7.7.2.2, and 7.7.3.3).

Staff from the Lincolnshire B&B programme subjectively used both judgmental and non-judgmental language during the sessions. It appeared that the judgmental language may have been used in an unconscious way, or if conscious then it was quickly changed to more positive language, (Sections 7.6.2, 7.6.3, 7.6.4, 7.6.5, 7.6.7 and 7.6.10.2).

Each role perceived the language use slightly differently. Sarah the Mother felt the need for information (section 7.7.1.1), wanted praise and validation for behaviours (sections 7.7.1.2 and 7.7.1.4), and was very conscious of language use around weight (section 7.7.1.5). Sarah the Dietitian was more aware of giving incorrect advice and information (section 7.7.2.1), the use of judgmental or scaremongering language (section 7.7.2.2 and 7.7.2.3) and allowing the participant to do most of the talking (a subordinate theme, section 7.7.2.5). Finally, Sarah the Researcher reflected on the use of word choice when referring to foods which sparked the thought around how

language with food can tap into negative emotions for an individual and so make that food taboo, and if this could be an area for further research (section 7.7.3.3).

The choice of words used around weight and food needs to be careful as they can trigger strong emotions (Zhou & Tse, 2020) and feelings of shame (Meadows & Danielsdóttir, 2016).

Unconscious (or conscious) bias around weight and stigmatization of women living with obesity is something that has been reported in the literature (Johnson *et al.*,2013; Mulherin *et al.*,2013). Midwives are a particular group of clinicians identified as being poorly equipped to tackle weight issues sensitively (McCann *et al.*,2018). It is impossible to exclude that this was a factor at work in the Nottinghamshire B&B programme where the staff did not have the behaviour change experience.

Overall this could be a strong indicator that training for staff around language use and unconscious bias with weight should be a critical element of all intervention programmes.

8.3.4 Engagement

The participation rate for Nottinghamshire B&B was poor, with only 8% of women offered the programme accepting and attending all sessions. In contrast Lincolnshire B&B achieved a participation rate of 25%. Within the analysis partial attendance status could not differentiate between attrition due to no longer wishing to engage with the programme or due to other reasons. For Lincolnshire B&B partial attendance was 12.5%, almost half that seen in Nottinghamshire B&B at 22%. There were large numbers of women who declined the programmes, 62.5% in Lincolnshire, and 70% in Nottinghamshire. Overall recruitment and retention were markedly higher for the Lincolnshire programme. This may be a driver of the success of the intervention or

may indicate that the way in which the programme was initially promoted and subsequently delivered, was more engaging for the women.

A review by Miller and Brennan, (2015) discussed attrition in obesity treatment programmes for non-pregnant participants and found figures ranging from 13.4% to 80% although there is differentiation within reporting of early and late drop-out rates in some of the studies reviewed. A review by Mutsaerts *et al.*, (2013), looked at dropout rates for lifestyle intervention programmes for women who had obesity and were infertile and found a median dropout rate of 24%. Understanding predictors as to why someone may drop out of a programme is a useful tool for shaping interventions. Where work has been done around this for weight loss programmes it has been found that depressive symptoms, high stress levels, body shape concern, unemployment, lack of parental support, and being disorganized were all given as reasons for not attending the intervention offered (Moran *et al.*,2019; Sawamoto *et al.*,2016; Chang *et al.*,2009). Miller and Brennan's 2015 review also looked at this and broke attrition into pre-treatment and post-treatment. They reported that it is difficult to specify pre-treatment issues but with post-treatment there seems to be three overarching themes which are practical/physical, programme/treatment specific, and psychological factors (Miller & Brennan, 2015). Atkinson and colleagues (2013) reported that inadequate explanations of what services would provide and negative perceptions of services are a key factor driving low uptake of antenatal weight management programmes. The reasoning behind attrition for B&B in either location was not examined, so it is somewhat speculative to say it would have been for similar issues. The low engagement of women living with obesity, with the programme at both locations, casts doubt on the notion that pregnancy is a teachable moment that could be exploited.

8.3.5 Support

The importance of support both from family, staff and those around the women came over as a vital element of the programme in Lincolnshire. This was captured from the transcripts within both Sarah the Mother and Sarah the Researcher roles (sections 7.7.1.3 and 7.7.3.1, and Figure 7.1).

When pregnant women were asked about social support (family, friends or special person) with regards both health and non-healthy behaviours, Mitchell *et al.*,(2022) reported that women who rated their social support higher than those who did not undertook fewer of the health-impairing behaviours during their pregnancy. In the review by Sutcliffe *et al.*,(2018) that looked at non-pregnant users of weight management programmes, the aim was to determine what service-users felt was most important in supporting their weight loss. They found that the combination of support from staff and peers was the biggest factor to aid weight loss by providing motivation to attend, to make changes to behaviours, and to support maintenance of weight loss (Sutcliffe *et al.*,2018).

In research undertaken in Brazil looking at breastfeeding initiation in a hospital setting, social support was classed as having a companion "at any or all moments" whilst at the hospital (Pujól von Seehausen *et al.*,2020). They found that women who were described as Class I or II Obese (>30kg/m^2) were less likely to initiate breastfeeding when they had no companion with them in that first hour after birth (after adjusting for confounders), (Pujól von Seehausen *et al.*,2020).

The support element of any weight management intervention is critical whether from family, staff or the wider social circle. The HPA of the Lincolnshire B&B transcripts

also identified this as an important factor so ensuring this is recognized and utilized within any intervention is vital.

8.3.6 Breastfeeding

Breastfeeding is the optimal form of nutrition for an infant. The NMPA (2021) report which covers England and Scotland showed that children whose mothers had a high BMI were less likely to have been breastfed at first feed. Those most likely to start breastfeeding were nulliparous women for all BMI groups with multiparous women least likely especially if they gave birth via caesarian section (Relph *et al.*,2021). In B&B the breastfeeding initiation rate for the Lincolnshire intervention participants was 68% and significantly greater than in non-participants at 49%. In Nottinghamshire, women that attended B&B were twice as likely to breastfeed at birth compared to non-attenders but once confounders were taken into account no difference was seen between groups. Relph et al.,(2021) reported that in England breastfeeding initiation for women with a BMI 35-39.9kg/m^2 was between 60.8-67.2% dependent on parity and whether there had been a previous caesarean section. It could be that the Lincolnshire B&B attenders who were recruited from a BMI >35kg/m^2 felt more confident in initiating breastfeeding than their non attending peers as a result of the support from the programme.

Pre-pregnancy body mass appears to impact breastfeeding initiation and duration (Winkvist *et al.*,2015; Campbell & Shackleton, 2018; Huang *et al.*,2019). Winkvist *et al.*,(2015) evaluated data from the Norwegian Mother and Child Cohort Study (MoBa) to assess factors linked to breastfeeding. They found that a BMI > 25kg/m^2 prior to pregnancy had a huge effect on whether a mother would initiate breastfeeding

with the effect size varying dependent on GWG (Winkvist *et al.*,2015). Campbell and Shackleton's (2018) analysis of data from the UK Millennium Cohort Study (MCS) showed that being in the overweight BMI category appears to decrease the likelihood of breastfeeding initiation, and that both early cessation and longevity are impacted by a BMI >25kg/m^2 when compared to a healthy BMI. The systematic review and meta-analysis of cohort studies by Huang *et al.*,(2019), which includes the Winkvist *et al.*,(2015) paper, found that being in the overweight or obese BMI categories pre-pregnancy meant a lower breastfeeding initiation rate compared to a healthy BMI.

When talking with women who had overweight or obesity about their breastfeeding experiences, a review by Chang *et al.*,(2020) found that there were a number of barriers that impacted on the issue. These included physical anatomical issues i.e. bigger breasts, psychological factors like low confidence in ability to breastfeed, and level of social support (Change *et al.*,2018). These factors are recognized within the Relph *et al.*,(2021) report as areas that need assistance.

It is particularly important to note that one of the staff members from B&B Lincs was an ex-breastfeeding peer support worker. This staff member was also very knowledgeable around post-partum practical support, see section 4.6.9. Bringing this level of experience and support to the programme allowed women to feel confident in asking questions and the staff member also had the ability to answer.

8.3.7 Funding

The Health and Social Care Bill 2012 was a major shake-up in the provision of health services for England (DH, 2011). Primary Care Trusts (PCTs) became Clinical Commissioning Groups (CCGs) and were overseen by NHS England (Nuffield Trust, 2022a). Strategic Health Authorities were abolished, and public health tasks were

given to Local Authorities (LA) and overseen by Public Health England (PHE) (Nuffield Trust, 2022a). Funding for interventions like B&B Lincolnshire came from both local authorities and Clinical Commissioning Groups (Figure 8.1, © Nuffield Trust, 2022b).

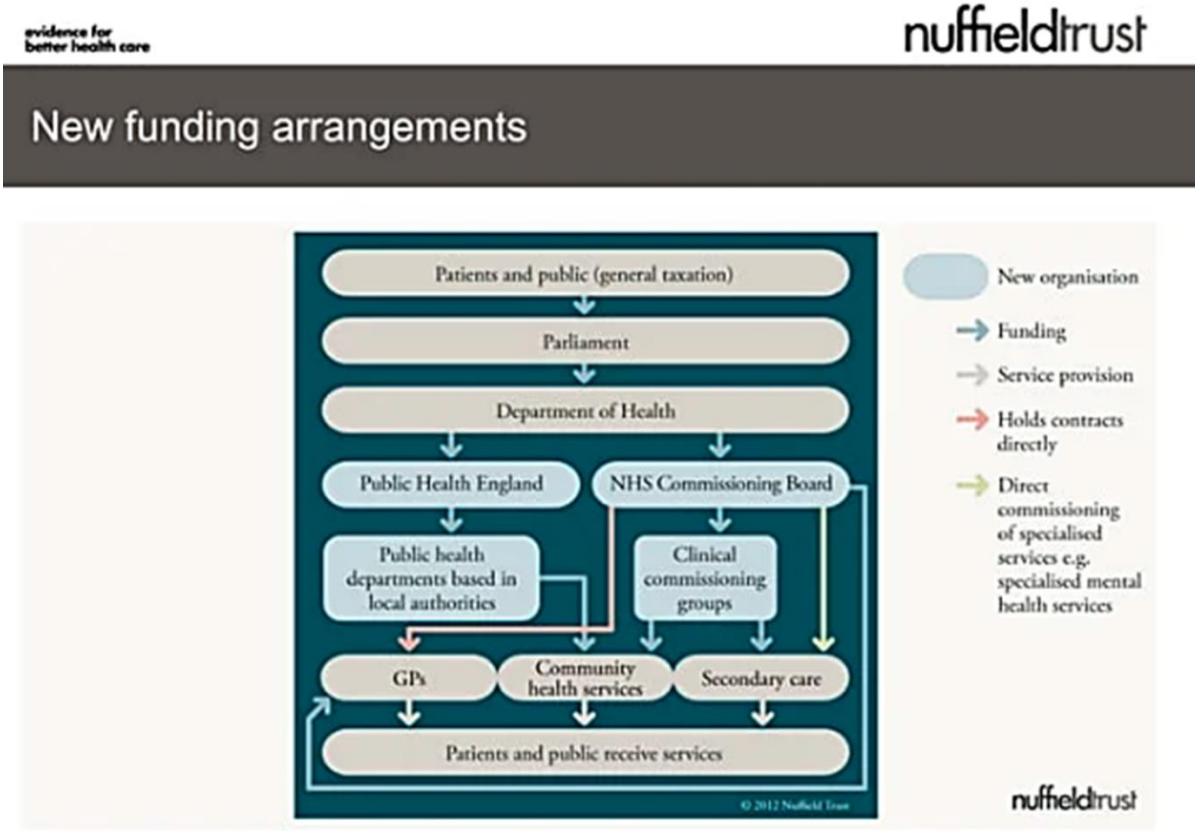


Figure 8.1. Funding arrangements following the Health and Social Care Bill 2012. © Nuffield Trust 2022

These changes meant that funding to LAs (Local Authorities) via PHE was cut and redirected to the NHS with the knock-on effect of other public health or social issues becoming a higher priority than that of maternal weight management (Nuffield Trust, 2022). Funding is likely to change again following the introduction of the Health and Care Act 2022 in England (Department of Health and Social Care, 2022; Nuffield

Trust, 2022). Public Health England has been abolished and the functions it carries out incorporated into new bodies including the Office for Health Improvement and Disparities. In practice the 2015 changes (which ultimately impacted on delivery of the B&B programmes) resulted in public health nutrition interventions becoming the responsibility of LAs which led to the loss of whole departments of nutritionists and dietitians working in this area but under Clinical Commissioning Group funding. In part, changes in funding meant that the Lincolnshire B&B programme closed despite the positive outcomes from the programme. In contrast the Nottinghamshire programme was abandoned at an early stage due to the lack of efficacy, demonstrated by analysis in Chapter 6.

8.4 Limitations of the work presented in this thesis

The main limitation of the work presented in the thesis was that the research team had no control over the design of the interventions, the recruitment of the participants, or the quality of the data collection for the quantitative elements. This is an inevitable feature of the team being brought in to evaluate the existing clinical services. For this reason the analyses presented in this thesis have had to adapt to issues of missing or incomplete data and have suffered from a lack of key information. For example, it is noted that women in Lincolnshire were given food diaries to complete early in the programme, but these were not retained by the intervention team thus making it impossible to determine whether attendance brought about dietary change or to perform analysis to assess what had changed. Similarly, many women were given pedometers which could have been a tool for assessing changes in physical activity, but that data was not collected by the programme team. Our role was to observe the clinical service, record the outcomes and not interfere.

MacAulay and colleagues (2019) carried out a mixed-methods study to consider the key components of antenatal weight management programmes. They noted that a high proportion of the 68 programmes followed up in the UK, there were many issues associated with inclusion criteria, staff training, data collection and recording and how programmes were communicated to participants, which undermined efficacy. It is clear that these same limitations applied to Bumps and Beyond in both of the settings in which it was deployed. The planning of an intervention is a key stage and needs to consider how data will be collected to ensure meaningful monitoring and evaluation. In the planning of Bumps and Beyond this was very much an afterthought and as a result this researcher has had to work with datasets that had missing data and where key information (e.g. dietary intakes, physical activity levels, alcohol consumption

and smoking habit) was not quantified. If the research team had been involved in the initial planning and design the utility of the data generated would have been greatly enhanced.

Better planning to optimise communication with participants, as advocated by MacAulay *et al.,* (2019) would also enhance participation rates and retention on women on the programmes. In Lincolnshire we noted that only 25% of women completed the whole programme and in Nottinghamshire this was only 8%. Inadequate explanations and negative perceptions of services are a key factor driving low uptake of services (Atkinson *et al.,* 2013). The fact that Bumps and Beyond was one-to-one may have been a factor impacting recruitment and retention as some women prefer group support.

Bumps and Beyond had a physical activity component within the protocol (session 3, see Appendix 1). The intervention fidelity showed that staff for Bumps and Beyond Lincolnshire delivered this session and offered support material however, there was no data collected on actual physical activity levels which means it is not possible to see whether there is an impact on adverse outcomes. Since the Cochrane Review by Muktabhant *et al.,* (2015), evidence has grown that physical activity within pregnancy can reduce adverse outcomes and improve the long-term health of both mother and baby (Teede *et al.,* 2022; Collings *et al.,* 2019; DHSC, 2019; Russo *et al.,* 2015). For physical activity interventions alone there appears to be a reduction in GWG, GHT, GDM, maternal blood lipid levels and macrosomia (Teede *et al.,* 2022; Collings *et al.,* 2019; DHSC, 2019; Russo *et al.,* 2015; Muktabhant *et al.,* 2015). Combined physical activity and diet interventions do not show quite the same success but still reduce adverse outcomes. Due to the lack of specific data for the Bumps and Beyond

programme it is not possible to see if there is an effect of the physical activity component.

The Bumps and Beyond programmes no longer run as per the protocol in either location and so adapting methodology to improve service user outcomes based on the findings within this thesis is not possible. It was also not possible to return to Nottinghamshire and explore the delivery of the programme using qualitative methodology. The audit sheets used for analysis for the Lincolnshire B&B and Nottinghamshire B&B were not exactly the same so direct comparisons of certain data points was not possible. The researcher having more input with this could have prevented the loss of information. As the data comprised service evaluations there was a reliance on staff collecting the data which led to some incomplete data sheets and no knowledge of whether this was a staff error, or the information was not available to be collected. Data protection issues were handled differently between the two NHS trusts that ran the B&B programmes and so certain data points had no direct comparison.

Limitations of the qualitative study are partially linked to the fact that the Lincolnshire B&B was due to close down whilst the data was being collected which meant the researcher had to rush to collect what was possible. Following up the data collection of the staff delivery of sessions with interviews with those same staff and participants would have been a useful tool to identify factors around the programme that were important and could have shaped future interventions. Undertaking the same process with the Nottinghamshire B&B could have allowed a comparison to the

results from chapter 4. Capturing the same data in both sites could have facilitated insight into why one was so beneficial compared to the other.

Finally, it would have been useful to try and work with those women who turned down the programmes to see if the reasons given could be solved in some way to enable access. This is of course a considerable research challenge as their lack of receptivity to a health intervention makes this group unlikely to participate in research. Tactics used with known hard to reach populations could be utilized, examples being online survey recruitment platforms (Ibarra *et al.*,2018), community-immersion and trust-building (Linders & Chifos, 2018), or social media advertisements and in-person intercept (Guillory *et al.*,2018).

8.5 Further work and recommendations

The work reported in this thesis has clearly shown that with appropriate patient-centred design a programme to manage antenatal weight gain that targets women with severe obesity can be highly effective. There are major challenges in terms of recruiting women to take part and in trying to replicate the programme in a new setting, but much can be learned from the experience of Lincolnshire Bumps and Beyond. Ideally this experience should have impact upon a range of stakeholders in this field. The following sections will consider those stakeholders in turn:

1. Policymakers- organisations at various levels from national government to local care commissioning groups.
2. Practitioners- individuals responsible for delivery of commissioned services or managing individual women who live with obesity.
3. Researchers- groups considering the key steps in advancing understanding of obesity in pregnancy and how it may be managed.

8.5.1 For policymakers

Policy around the management of obesity in pregnancy in the UK comes from the Department of Health, and Social Care which publishes overarching policy which is then translated into clinical practice guidelines through the National Institute for Health and Care Excellence (NICE) and the Royal Colleges. In 2020 the Department of Health and Social Care published "*Tackling obesity: empowering adults and children to live healthier lives*", constituting a national strategy for the prevention and management of obesity. Disappointingly this national strategy failed to mention pregnancy and the very clear risks associated with obesity in the antenatal period (Department of Health and Social Care, 2020).

Guidelines from NICE that consider obesity in pregnancy have not been significantly updated since 2010, when the emphasis was very much placed on managing maternal weight prior to conception (NICE 2010). It has already been demonstrated in the field of antenatal supplementation with folic acid, that such a strategy is inadequate due to low compliance in the population and the fact that 4 in 10 pregnancies are not planned (Langley-Evans and Langley-Evans 2002). The existence of a global epidemic of obesity is more than sufficient evidence to demonstrate that managing weight is not something that people are able to choose to do as and when they deem it necessary. Putting the onus on women to manage their weight before they become pregnant is therefore not realistic and does nothing to reduce the impact of pre-existing obesity or excessive gestational weight gain on the pregnancies of women who are unable to manage their weight pre-conception.

Public Health England (2020) also place emphasis on supporting healthy weight before and between pregnancies, in their maternity high impact area support documents which are used to assist local maternity systems to embed prevention approaches to support women in preparation for pregnancy. Whilst the Public Health England impact document recognises the importance of interventions around antenatal obesity and the fact that the Covid-19 pandemic may have worsened the problem, the suggested outcomes are focused on skills such as motivational interviewing which most clinicians who come into contact with women before pregnancy do not possess and will, again miss the 40% of women who do not plan their pregnancies. However, their recommendations around making service delivery more effective and enhancing commissioning of services are realistic, timely and welcome.

The Royal College of Obstetricians and Gynaecologists play a key role in the translation of policy into clinical practice in this field. In 2019 they published a green top guidance paper on the care of women with obesity in pregnancy (Denison et al., 2019), which was developed around a systematic review of evidence leading to development of clinical guidelines. The Denison et al., professional guidelines are disappointingly cautious and conservative, and are hampered by the viewpoint that published evidence does not achieve a high enough quality threshold to merit firm guidelines. Insistence on basing guidelines on large randomised controlled trials is unhelpful as patient-centred general lifestyle interventions do not lend themselves to the rigidity of the double-blind randomised trial design. Such studies are also hugely expensive to run, and it will take decades for a sufficient number to be run and generate the wealth of data demanded. For an example, the UPBEAT trial was funded by grants from the UK National Institute of Health Research (£2.2 million), the Medical Research Council (£842000) and the British Heart Foundation (£217000).

Like the 2010 NICE guidelines there is no call from the Royal College of Obstetricians and Gynaecologists to even do basic monitoring such as regular weighing of women (beyond the initial booking appointment and a late gestation weighing that is specifically to determine whether bariatric equipment might be needed for the delivery). If excessive GWG is seen as a major risk factor for poor pregnancy outcomes, then a failure to recommend that clinicians attempt to detect it is a remarkable oversight. It has been demonstrated that pregnant women of all pre-pregnancy BMI classes would actually welcome regular weight checks (Swift et al., 2016). The Denison et al. (2020) guidelines still appear to be focused on raising awareness that antenatal obesity makes pregnancy high risk and offers nothing around interventions to limit gestational weight gain. Across all UK policy documents there

is still no agreement on what optimal weight gain should be across all classes of pre-pregnancy BMI, which is a remarkable oversight given that most clinicians and all researchers now work from the US guidelines.

It is imperative that policymakers engage with the wealth of data that already exists to demonstrate that obesity in pregnancy and excessive gestational weight gain increase the risk of pregnancy complications and adverse outcomes, and establish more rigorous policies and practice guidelines for reducing that risk as an element of antenatal care. The research reported in this thesis and in the wider literature (Langley-Evans et al. 2022) show that this can be done effectively and safely. The current position does not provide any assistance for the estimated 300000 women who go into pregnancy with overweight and obesity and will therefore continue to leave their health and wellbeing at risk. Restricting interventions to pre-pregnancy also fails to make use of the teachable moment that pregnancy offers. Maintaining the status quo is insufficient. In developing a more ambitious policy the following points should be considered.

It is impossible to have the same lived experience as another person. This means it is critical that input from those who will be going through an intervention is sought. Talking to women about what they actually need rather than making assumptions is always going to be helpful when putting an intervention of this nature together. An example of this can be seen in the paper by Sutcliffe *et al.*,(2018), where they reviewed qualitative studies looking for service-users' perspectives on the intervention. They found that feeling supported by the service provider or their peers within the programme was one of the main motivators for success (Sutcliffe *et al.*,2018). Critically, the service-users felt that this support was what gave them the external motivation to stay on the programme (Sutcliffe *et al.*,2018). Co-design of

nutrition interventions is a relatively new area and equal partnerships between those responsible for interventions and the consumers of the interventions are rare (Meloncelli *et al.*,2023).

- Co-development of programmes is a must

Strategies to increase participation and reduce attrition would be useful tools in moving forward with any similar programme. A review by Pirotta *et al.*,(2019) looking at ways to reduce attrition in weight loss intervention, found a number of useful measures that could be implemented in future. These included financial incentives, self-monitoring technology, and multi-component interventions (Pirotta *et al.*,2019). All of these need to be funded in some way, so shifts in the way public health is planned, funded and monitored represent a challenge for the future.

- Understanding attrition is necessary

Previous versions of the Lincolnshire B&B programme allowed time for a post-partum visit which was able to support both breastfeeding and post-partum weight loss however changes in funding meant this session was lost. The evidence is clear that breastfeeding has a positive impact on mother and baby and so having antenatal and post-partum support for this is so important and not valued enough by funding bodies. Cook *et al*. (2021) undertook a qualitative study talking with a population of mothers in a deprived community about their experiences of breastfeeding were. This research showed that the mothers perceived a range of barriers and facilitators for breastfeeding (Cook *et al.*,2021). Overcoming the first and supporting the second is crucial to better support this population. Including post-partum visits as part of interventions could do this.

- Post-partum visits should be an element of antenatal interventions.

8.5.2 For practitioners

Practitioners on the ground may struggle to balance the clinical guidelines with what they experience in their day-to-day interactions with pregnant women who are obese. This is partly due to a disconnect between policy and service delivery and partly due to a lack of training in how to manage the emotive issue of obesity. These factors can result in inappropriate practice or inaccuracy. Sarah the Mother was eager for information however Sarah the Dietitian quickly spotted incorrect advice (Figure 7.1). It is essential that any information whether verbal or written that is given to participants is factually correct and appropriate. This means that those who are to deliver the intervention need to be trained, understand their scope of practice, and stay up to date with weight management research. Training was unrecorded within the B&B programmes although is known to have taken place.

Basu *et al.*,(2014) undertook a feasibility study around delivery of a training package which was delivered by a dietitian in a 3.5-hour session to midwives. This covered evidence-based nutrition, physical activity and weight management issues and was found to be acceptable in terms of content and time taken out of clinical practice to attend (Basu *et al.*,2014). The Royal Society for Public Health (2014) issued a governance framework for health trainers services which specifies ongoing training as part of not only the service management but also to develop trainers and keep their skills current. An old, but useful, publication is the NHS Health Trainer Handbook (Michie *et al.*,2008) which is a best practice guidance for Health Trainers and includes information on how to have conversations with the service-user/ participant to promote changes in behaviour and is an appropriate tool for current use.

- For future programmes integration and recording of training for the staff on an ongoing basis is vital.

Language and word choice are important. Whilst there were many examples of positive and motivating language that Sarah the Mother appreciated, Sarah the Dietitian picked out areas of concern within the language used at times by the staff. Sarah the Researcher coined an entire new word around taboos in food, "tab'ood". The staff within Lincolnshire B&B were mostly proficient in dealing with weight conversations with a few exceptions with language use but did downplay the risks involved with a high BMI and pregnancy.

Christensen *et al.*,(2018) found that due to the fact that midwives tend to have high levels of empathy they then found conversations around health risks and weight difficult. Walker and Kang, (2021) looked at terminology about weight and how acceptable it was to the individual. They summarized three papers results and found that certain words were perceived as more agreeable than others for example, 'weight' or 'BMI' rather than 'fat' or 'obesity' (Walker & Kang, 2021). A scoping review by Dieterich and Demirci, (2020) looked at research around communications around overweight and obesity in pregnant women. Their findings were split between how the women themselves perceived communication, and how the staff felt about it and clearly showed that there is a gap between the two (Dieterich and Demirci, 2020). Women did not feel supported and staff felt conversations with regards weight were difficult (Dieterich and Demirci, 2020). These outcomes clearly drive women's disengagement from services (Atkinson et al., 2013).

- Improving awareness of the impact of language and word choice on self-esteem and motivations should be an area of training for all staff involved with a service for weight management in pregnancy.

8.5.3 For researchers

Sarah the Researcher had the opportunity to read the texts and find the essences that could link to future research. Social support has been discussed previously in this section however Sarah the Researcher is more interested in how this could be embedded into the programmes in the future and be part of the ongoing evaluation.

- Utilize social support as a tool for improving weight management

The essence discussed in section 7.7.3.2, 'could we use weight loss linked to birth of the baby as a motivational tool', is interesting as this is appears to be an unresearched area within weight management. There is plenty of research to show that weight gained during pregnancy is most often retained afterwards and that support at this life stage can aid continuing weight loss (NICE, 2010). This means that the use of this initial weight loss could be an internal motivator for a woman if handled well.

- Use weight loss linked to birth of the baby as a motivational tool.

Further work around the impact of giving away free gifts could be useful as this may be a way of increasing the feeling of support and giving of information. Linking into local health initiatives for post-partum practical support can aid this as per recommendations in the NHS (National Health Service) Health Trainer Handbook (Michie *et al.*,2008). Ongoing review of this availability would be needed and so requires thought at the development and funding stages. Appropriate free support material that has been properly curated or developed could be used as additional motivation. In addition, as much of the free practical support offered in Lincolnshire B&B (section 7.7.3.4) ran in the post-partum period it is vital to acknowledge that this is a challenging life stage due to the commitments of being a mother (McKinley *et al.*,2018). McKinley *et al.*,(2018) have summarized a range of systematic reviews

looking at post-partum weight loss. In this review of reviews, it is clear that the programmes with measurable success have some kind of freebie attached whether this is technology, or supervision as part of the intervention (McKinley *et al.*,2018). As technology has improved there is also the use of this as a motivator in achieving behaviour change around weight loss and then maintenance (Stubbs *et al.*,2021). The use of phone apps could be promoted as long as there is recognition that they need to be appropriate and evidence-based (Walker & Kang, 2021). Appropriate evaluation of use of freebies is necessary both qualitative and quantitative.

- Exploit the motivational element of free gifts for post-partum weight loss?
- Post-partum data linked to usefulness and use of freebies is essential for evaluation of effectiveness.

8.6 Conclusion

Bumps and Beyond Lincolnshire was an impactful and effective maternal weight management programme. Transplanting the concept to a different geographic location lost nearly all of the positive outcomes seen in Lincolnshire. Bumps and Beyond Lincolnshire was comparable to a number of small midwife-led programmes that have repeatedly been shown to be more impactful than large Randomised Control Trials without the same levels of funding. Differences between the programmes are clearly a part of the explanation that the concept did not travel well, however it is clear that Bumps and Beyond is a suitable intervention for weight management in pregnancy when adapted appropriately to the community it is to serve.

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Appendices

Appendix 1 – Bumps and Beyond Lincolnshire Protocol

Guidelines for delivering antenatal weight management advice – session content.

The Antenatal Weight Management Service will be delivered by Phoenix Healthy Lifestyle Midwives/Advisors in the community or hospital setting.

The service will provide 7 individual sessions from 16 weeks to 36 weeks.

The appointments will be as follows:

Session 1

Around 16 weeks gestation

1. Screen for contraindications or possible problems verbally and by checking the client's hand held pregnancy records.
2. Establish motivation to make changes.
3. Discuss the aims of the service focusing on the benefits of adopting a healthy lifestyle in pregnancy.
4. Check baseline data; height, weight and BMI has been taken and recorded and is correct.
5. Discuss current lifestyle, beliefs and habits to identify any problems or barriers.
6. Encourage discussion about initial changes best suited to the client.
7. Explain the use of the daily food diary if appropriate.
8. Encourage the client to consider positive changes (goals) that could be set and maintained.
9. Make exercise referral if client agrees.
10. Record the appointment on SystmOne.

Session 2

1. Verbally screen for any problems.
2. Record weight if client wishes to be weighed.
3. Review food diary if completed.
4. Discuss client's positive changes.
5. Identify 'high-risk' triggers or barriers to change and advise accordingly.
6. Give information on the Eat Well plate and discuss energy balance.
7. Give advice on portion size and daily requirements.
8. Discuss client's aims – set goals for next appointment (for example eating two portions of vegetables five times per week).
9. Give further food diaries if required.
10. Record the appointment on SystmOne.

Session 3

1. Verbally screen for any problems.
2. Record weight if client wishes to be weighed.
3. Discuss progress and success with goals and food diary since last appointment.

4. Discuss current levels of physical activity and ways of incorporating activity into lifestyle.
5. Give pedometer to client.
6. Discuss barriers or preferences and give tailored advice accordingly.
7. Low intensity physical activity should be encouraged (for example walking, swimming).
8. Give appropriate advice on high impact or contact sports in pregnancy to reduce risk of fetal trauma.
9. If goal setting approach has been successful, ask the client to set their own goals for the next session.
10. Give further food diaries as required.
11. Record the appointment on SystmOne.

Session 4

1. Verbally screen for any problems.
2. Record client weight if client wishes to be weighed.
3. Discuss progress and success with goals and food diaries since last appointment.
4. Discuss client's feelings so far and give advice on areas highlighted as difficult.
5. Discuss food labelling, shopping, cooking and eating out.
6. Again, encourage client's to set further goals for the next session.
7. Issue food diaries if required.
8. Record the appointment in SystmOne.

Session 5

1. Verbally screen for any problems.
2. Record weight if client wishes to be weighed.
3. Discuss progress and success with goals and food diaries since last appointment.
4. Revisit portion control.
5. Discuss emotional reasons for eating if this is an issue.
6. Discuss 'high risk triggers' to eating and eating behaviour and ways to minimise them.
7. Encourage maintenance of changes and physical activity.
8. Encourage client to set further goals for the next session.
9. Issue food diaries if required.
10. Record the appointment on SystmOne.

Session 6

1. Verbally screen for any problems.
2. Record weight if client wishes to be weighed.
3. Discuss progress and success with goals and food diaries since last appointment.
4. Congratulate client on changes made so far and reiterate the importance of continuing with changes.
5. Advise on lapse management strategies.
6. Make review appointment for when client is 36 weeks pregnant.
7. Record the appointment on SystmOne.

Session 7

At 36 weeks pregnant

1. Verbally screen for any problems.
2. Record weight and BMI.
3. Assess how positive changes have been maintained.
4. Give support and encouragement and discuss any issues on maintenance of changes if required.
5. Highlight benefits of breastfeeding.
6. The importance of taking 5mg Folic acid and 10mcg vitamin D in future pregnancies if their BMI remains >30 to be discussed.
7. Record appointment on SystmOne.

The outline of each session is flexible to enable them to be client-centred and tailored to suit individual needs.

Appendix 2 – Email with regards confirmation of Service Evaluation for Lincolnshire Bumps and Beyond

From: STEPHANIE.HEATHCOTE@lincs-chs.nhs.uk

[STEPHANIE.HEATHCOTE@lincs-chs.nhs.uk]

Sent: 02 February 2015 12:09

To: katy.ward1@nhs.net

Cc: Ellis Sarah; Rebecca.McConville@lincs-chs.nhs.uk; Ailsa.McGiveron@lincs-chs.nhs.uk

Subject: FW: Research within the trust

Dear Katy,

I am confirming our approval for Sarah Ellis to go ahead with a service evaluation of the LCHS Bumps and beyond service.

Kind regards

Stephanie Heathcote

Midwifery Liason Project lead

Lincolnshire Community Health Services NHS Trust

From: Ward Katy (LINCOLNSHIRE COMMUNITY HEALTH SERVICES NHS TRUST)

[katy.ward1@nhs.net]

Sent: 19 January 2015 13:02

To: Ellis Sarah

Subject: RE: Research within the trust

Yes, it's Service Evaluation, have just double-checked my table comparing Service Evaluation criteria against Research and it definitely fits more with that so let's go with that.

I would be grateful if you could please keep me updated and once you have Ailsa's Manager's I would be grateful if you could let me know and provide evidence of this to me, so this could be an e-mail from Ailsa's Manager confirming their approval. Also, once you have completed your protocol and supporting documents I would be grateful if these could be e-mailed to our e-mail address which is Research.Team@lincs-chs.nhs.uk and we'll just run it past our Data Protection department for their approval and add the study details to our database.

Is that ok?

Best wishes

Katy

Appendix 3 – Lincolnshire Bumps and Beyond audit sheet template

AUDIT

United Lincolnshire Hospitals NHS
NHS Trust

Lincolnshire Community Health Services NHS
NHS Trust

AUDIT TRAIL

PREGNANT WOMEN BMI ≥ 30

NHS Number: APPX LABEL HERE IF AVAILABLE

Surname:

Forename(s):

D.o.B:

Would like intervention [ ] **Declines intervention [ ]**

Telephone contact.....

Gravida..... **Parity** ..... **E.D.B**...../...../..... **Date of Delivery**...../...../.....

Booking weight.....**kg Booking height**.....**cms Booking BMI**.....

Date of booking..... **No. of weeks at booking**.....

Smoker? [ ] **Alcohol in pregnancy?** [ ]

Weight at 36 weeks .....kg Total weight gain/loss.....kg BMI at 36 weeks.....

Multiple birth pregnancy Yes ☐ No ☐ If 'yes' specify number .....

Date and time of Bumps & Beyond Session 1 appointment.....

Attended Bumps & Beyond Intervention Sessions: 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6 [ ] 7 [ ]

FTA 1st session [ ]

Centre attended .....

Conditions during this pregnancy:	Tick	**Apgar:** At 1 min:	
		At 5 mins:	
None		**Baby's Weight:**	
Gestational diabetes		**Feeding** (at birth) Breast	
Hypertension		Artificial	
Pre-eclampsia		**Self – efficacy score:**	
Labour complications:		First visit:	
PPH ≥ 500mls		Final visit	
Delivery gestation:		**Occupation:** **Client:**	
		Partner:	
36+6 and below (please state)		**Home Owner:** Yes	
37 and above (please state)		No	
Outcome- Mother – Type of birth:		**Marital status:** Single	
Normal		Cohabiting	
Instrumental		Married	
Elective Caesarean		Living with parents	
Emergency Caesarean		**400mcg Folic Acid:** Yes	
Outcomes – Baby:		No	
Live		**5mg Folic Acid** Yes	
Miscarriage <23+6/40		No	
IUD 24/40+		**10mcg Vitamin D** Yes	
Stillborn		No	
Neonatal death		**Ethnic Origin:**	

Appendix 4 – Consent form for recordings of staff

Consent form for Bumps & Beyond service evaluation - staff

Name of staff member:……

Name of person gaining consent:……

1. I confirm that the reasons for the service evaluation have been explained to me, and that I have had the chance to ask questions. ✓☐ ×☐

2. I understand why I have been asked to be involved. ✓☐ ×☐

Delete point 3 or 4 if appropriate:

3. I agree to take part in study 2 of the service evaluation which will involve the audio recording of the Bumps & Beyond session. ✓☐ ×☐

4. I agree to take part in study 4 of the service evaluation which will involve two audio-recorded focus groups with a member of the research team. ✓☐ ×☐

5. I give permission for my words to be used in reports but understand that my name will not be mentioned (anonymised). ✓☐ ×☐

6. I understand that the information (data) collected may be looked at by members of the research team. I understand that strict confidentiality will be maintained. I give consent for the research team to have access to the information. ✓☐ ×☐

7. I have been given the contact details of people who can help if I have any more questions about the service evaluation. ✓☐ ×☐

8. I understand that my involvement with this service evaluation can contribute to my CPD. ✓☐ ×☐

Signed…….(staff member)

Print name……..

Signed…….(researcher)

Print name……..
Date…….

Continued verbal consent (as necessary)

Signed……

Print name……..

Date…….

Further information and contact details

University of Nottingham team:

PhD researcher – Sarah Ellis

PhD supervising team – Professor Simon Langley-Evans, Dr Judy Swift. Dr Sarah McMullen.

Division of Nutritional Sciences, University of Nottingham, Sutton Bonington campus, Loughborough. LE12 5RD

Tel: 0115 951 6178 / Tel: 0115 951 6139

Appendix 5 – Participant consent form

Consent form for Bumps & Beyond service evaluation - participant

Name of participant:……

Name of person gaining consent:……

1. I confirm that I have read and understood the information sheet, and that I have had the chance to ask questions. ✓☐ ×☐

2. I understand the purpose of the evaluation and why I have been asked to be involved. ✓☐ ×☐

Delete point 3 or 4 if appropriate:

3. I agree to take part in study 2 of the service evaluation which will involve the audio recording of the Bumps & Beyond session. ✓☐ ×☐

4. I agree to take part in study 3 of the service evaluation which will involve an audio-recorded telephone interview with a member of the research team. ✓☐ ×☐

5. I understand that I can change my mind at any time and leave the service evaluation and this will have no effect on my routine ante-natal care. ✓☐ ×☐

6. I give permission for my words to be used in reports but understand that my name will not be mentioned (anonymised). ✓☐ ×☐

7. I understand that the information (data) collected may be looked at by members of the research team. I understand that strict confidentiality will be maintained. I give consent for the research team to have access to the information. ✓☐ ×☐

8. I have been given the contact details of people who can help if I have any more questions about the service evaluation. ✓☐ ×☐

9. I have been given the details of who I need to talk to if I have a complaint about my involvement with the service evaluation. ✓☐ ×☐

Signed…….(participant)

Print name……..

Signed…….(staff /researcher)

Print name……..

Date…….

Continued verbal consent (as necessary)

Signed……

Print name……..

Date…….

Further information and contact details

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Appendix 6 – Bumps and Beyond Lincolnshire session booklet

Title page

Contents page

Introduction – page 3 of booklet

Pregnancy is a time when looking after your own health is especially important, because it directly affects the health of your baby.

A healthy diet is very important whilst you are pregnant as it will help keep you fit and well and help your baby develop and grow.

You do not need to go on a special diet but there are foods that all women should avoid in pregnancy (see page 9).

You do not need to eat for two but you may find you are more hungry than normal.

You may have to change high fat/sugar snacks for healthier options and alter the amounts of different foods you eat.

Weight gain is inevitable during pregnancy and is quite normal!

Gaining weight at a steady pace will help your baby grow and develop and reduce the risk of complications during your pregnancy.

With support and advice from Bumps and Beyond, you can adopt a healthy lifestyle.

Bumps and Beyond is free and tailored to suit your needs.

The aim of the service is to provide you with information, advice and support to achieve a healthier lifestyle, which would in turn promote weight management.

This is NOT a weight loss programme – dieting during pregnancy is not recommended. We aim to help you develop a healthier approach to eating and physical exercise and manage your weight more effectively.

The programme – page 5 of the booklet

The programme consists of 7 sessions.

The first session will take place when you are approximately 16 weeks pregnant

You will have 6 more sessions up to 36 weeks pregnant at 2-4 weekly intervals.

Bumps and Beyond has been developed to give the extra help and support you need to make lifestyle changes to benefit both you and your baby

It is simple and easy to follow.

The booklet gives you information on each of the 7 sessions and it will only take a few minutes to read the help and tips each week.

The plan works by showing you how to make small but lasting changes to the way that you eat and how active you are – changes that you will be able to keep up for the rest of your life not just for the rest of your pregnancy!

“very good programme for those who struggle with their weight” – service user.

Please bring this booklet with you to each of the sessions.

Welcome to session 1 – starts page 6 of booklet

An introduction to lifestyle changes

“Thank you Bumps and Beyond, you made such a difference to my pregnancy” – a service user.

You are not alone!

Today, almost a quarter (22%) of pregnant women are excessively overweight (i.e. have a body mass index (BMI) >30) at the start of their pregnancy (1).

By aiming to gain only the recommended amount of weight in your pregnancy – 5-9kg (or 11-20kg for twins), you can help minimise the risks to yourself and your baby.

Why is it important to avoid excessive weight gain in pregnancy?

Research has shown that excessive weight gain in pregnant women with a BMI above 30 has been linked to the following risks (2,3,4):

Miscarriage

Premature labour

Abnormalities of the baby – particularly of the heart and spine

Abnormalities of the baby are more difficult to detect by ultrasound scan

High blood pressure

Increased risk of developing blood clots

Pre-eclampsia. If this is your first baby you have an 11.7% increased risk of developing this condition

Gestational diabetes – which can lead to large birth-weight babies and an increased risk of diabetes in later life

Stillbirth

Birth complications – Caesarean section and assisted birth/ shoulder dystocia

Failed epidural and an increased anaesthetic risk

Postnatal infections and poor recovery

Eat safely -page 8

There are some foods that you should avoid when you are pregnant because there is a risk of food poisoning or catching an infection that could harm your baby. See lists below (5,6,7)

FOODS TO AVOID	REASON FOR AVOIDING	FOOD TO EAT INSTEAD
Raw or undercooked meat – especially sausages, burgers and chicken.	Risk of toxoplasmosis – a tiny parasite that can live in raw meat and cat faeces and can harm baby.	Well-cooked meat.
Liver	Contains too much vitamin A. High levels of this can harm baby.	Any other well-cooked meats.
Pate	Risk of listeria – a bug that can harm your baby	Slices of cooked ham
Unpasteurised milk – all milk sold in shops, supermarkets and restaurants in the UK is pasteurised and safe to drink.	Risk of toxoplasmosis - a tiny parasite that can live in raw meat and cat faeces and can harm baby.	Pasteurised milk
Cheese with blue veins – (like Stilton or Danish Blue) or mould-ripened cheese (such as Brie or Camembert)	Risk of listeria – a bug that can harm baby	Hard cheeses such as cheddar and cheddar spreads (eg Philadelphia), cottage cheese, mozzarella
Undercooked ready meals	Risk of listeria – a bug that can harm your baby	Thoroughly cook meals until piping hot
More than two portions of oily fish a week (fresh tuna, mackerel, sardines or trout)	Risk of food poisoning. Tuna can be dangerous because of high levels of mercury in it which can harm baby's nervous system.	All other fish types and less than two tuna steaks or two medium cans of tuna a week. Tinned tuna doesn't count as oily fish!
Raw shellfish, shark, marlin, and swordfish	Shark, swordfish and marlin contain high levels of mercury in it which can harm baby's nervous system. Avoid raw shellfish because of the risk of food poisoning.	You can have other fish types – remembering to limit to oily fish to two portions a week.
Supplements with vitamin A	You need some vitamin A but too much means that the increased levels could harm your baby	Pregnancy-specific vitamins and folic acid (see www.healthystart.nhs.uk to see if your entitled to free Healthy Start vitamins)

Too much caffeine – you should limit your caffeine intake to 200mg a day (roughly two mugs of coffee, three mugs of tea or fice cans of cola)	Caffeine is a stimulant that increases your heart rate and metabolism, which in turn can affect your developing baby	Juice, milk or water, and tea/coffee under the advised limit
Raw eggs or cooked eggs with a runny yolk/white	Risk of salmonella, a common cause of food poisoning that can harm your baby	Hard boiled eggs (yolks should be cooked all the way through, eggs used in cooking)

Peanuts – the latest research has shown that there is no clear evidence showing that eating peanuts during pregnancy affects the chances of your baby developing a peanut allergy. So peanuts are safe in pregnancy unless YOU are allergic to them.

Here we go! In week one you will be making yourself more aware of your current eating, activity and thinking habits and learning ways of cutting down on the amount that you eat inbetween meals.

Making healthy lifestyle changes are the first steps to keeping your weight gain to within recommended guidelines.

To do this successfully it is important to consider the eating and physical activity habits you have now and look at ways that you could improve them.

So, let's think about

Your food shopping and eating habits

The amount and types of foods you eat

How you deal with the urge to eat

Why you eat and when you eat

Regular structured activity

Your barriers to more activity

Planning your day (8)

Take a minute or so to think about how maintaining your weight gain could improve your life.

It may help your confidence, improve your health and your baby's health and give you more energy so you can play with your baby or children.

Write a list here of how life would be better if your weight was maintained:

[Space to list 4 things]

EATING PATTERNS	RARELY	SOMETIMES	OFTEN
I eat when I'm hungry			
I eat when I'm bored			
I eat if others are eating			
I eat while I'm cooking			
I eat because it's mealtime			
I eat because I'm lonely, upset, or tired			
I eat if there are leftovers			
I eat to finish what is on my plate			
I eat because I need a treat			
I eat when food catches my eye			
I eat because I'm in the kitchen and food calls to me			
I eat sitting at the table			
I eat in front of the TV			
I eat whilst doing something else			
I eat on the run			
I stop eating when I'm full			
I stop eating when my plate is empty			
I eat 3 meals and 2 snacks a day			
I balance what I eat by thinking about portion sizes			
I eat not-so healthy snacks			
I eat healthy snacks			
I give others food as treats or rewards			
I'm tempted to buy extra treats when I'm shopping			
I enjoy cooking			

Starting to change – page 12 of booklet

You will be asked to keep a food diary over the course of the next two weeks. After you have kept it for seven days, ask yourself the following questions:

Do you eat breakfast?

Breakfast is the most important meal of the day! How many times have you heard this sentence? Well it's true! It is important to start the day with a healthy breakfast, ideally within two hours of waking. This is because it 'kickstarts' your metabolism.

Many people don't have breakfast because they say they are not hungry or because they don't have time. This could be one of the changes you make to your lifestyle that

will make a huge difference. If you don't eat breakfast you often find that you are snacking on high fat and sugar foods.

Often for pregnant women, eating breakfast can be difficult if they are suffering from morning sickness. This should improve when you are around twelve weeks pregnant.

Try small amounts of toast or cereal and work up from there.

Whole-wheat cereals, such as Weetabix, All bran and Shredded Wheat, and porridge are ideal. Add some fresh fruit and you have a filling start to the day that will keep the hunger pangs at bay all morning because of the fibre content of your breakfast. Try to replace full fat milk with semi skimmed or even skimmed milk.

For many of you, starting to have a healthy breakfast every day will be a big change. If you can do this in week one, you are proving to yourself that you can change your eating habits

Do you eat regularly over the day?

Regular meals are the key to success! If you don't eat regular meals, you will get hungry at certain times of the day and then eat too much to make up for it. Too many people either miss out a meal altogether or try to last as long as possible without eating. Unfortunately, they let themselves get too hungry and end up raiding the cupboards!

Do you only eat when you are hungry?

Many people eat for comfort or if they are bored. By cutting out eating at these times you can significantly reduce how much energy you take in. This could be one of only a few changes you need to make to stop you gaining weight.

Do you eat in-between meals?

Eating in-between meals can be a sign that you need to eat something a little more filling at mealtimes or that you are eating for reasons other than being hungry. If you do have snacks try to have healthy snacks such as fruit and avoid, sweets, chocolates, biscuits or cakes.

At what time of day do you eat the unhealthiest of food?

Are there times of the day when you eat high fat, high sugar foods? Look at your food diary to help you work this out. Some people find it most difficult to control what they eat during the day. Others find evenings their hardest time. If there is a particular time of day that is particularly unhealthy, you can concentrate your efforts on changing it.

Do you eat more on a certain day or maybe at weekends?

Some food diaries show a healthy eating pattern throughout the week but then an unhealthy one at the weekends. Are there days when you eat more? Think about the reasons why and what you can do to change this.

Where do you tend to eat most of your food?

Do you eat in the car, at your desk, on the move or watching TV? Making time to sit down and concentrate on what you are eating will help you enjoy your food and slow down your eating. If you eat quickly, you are more likely to eat too much.

“Bumps and Beyond are not pushy with their advice – but are always there to provide support” – service user.

Sarah Ellis

Ready, Steady, GO! (page 15 of booklet)

To help you get started we need to get the balance of your diet right.

Using the Eatwell plate will help to make healthy eating easier to understand. It shows the types and proportions of the foods we need to have a healthy diet.

The Eatwell plate shows how much of what you eat during the day should come from each food group.

[picture of Eatwell plate]

What's in a portion size?

FOOD	ONE PORTION EQUALS…	AND LOOKS LIKE…
vegetables	3 tablespoons	Half a tennis ball
salad	80g	Large cereal bowl
Fresh fruit	1 medium whole fruit	Whole tennis ball
Cooked rice	2-3 heaped tablespoons	Half a tea-cup
Peas, lentils, beans	2-3 heaped tablespoons cooked	Half a tennis ball
nuts	2 tablespoons	Small handful
cheese	30g	Small matchbox
Meat,fish, poultry	80g	Pack of cards

Is your plate too big?

Try this simple task to find out.

Place your outstretched hand in the centre of the plate you use to eat your meals from and draw an imaginary circle around it. When you remove your hand the imaginary circle is where you should be placing your food. [photo showing this]

If there is a big difference between the plate size and your imaginary circle you need to reduce your portion sizes! Try using a smaller plate for your meals.

How active are you at the moment?

As well as looking at your eating habits, Bumps and Beyond will help you to build more activity into your daily life. Being more active, even by just walking more, will help to adapt to your changing shape and help you cope with labour and get back into shape after the birth of your baby.

[photo of woman swimming]

You can also learn a lot about your activity levels by recording when you carry out planned activities such as swimming or a gentle exercise class. You can also record other activities including walking to the supermarket or taking the stairs instead of the lift.

Your food diary – page 18 of booklet

Keeping a food diary will make you think about what you are eating and by keeping a record of what you eat and how you feel you can learn a lot about your eating habits.

There will be high-fat foods that you avoid or eat less of as a result of keeping a diary. Writing everything down makes you think about your eating and can help you recognise that you are not always eating because you are genuinely hungry.

Your food diary can show you where you can make small but lasting changes to your eating habits and can gradually help you identify goals that you may wish to set both for your healthy eating and for physical activity.

DAY/TIME	FOOD/DRINK EATEN	WHERE?	THOUGHTS AND FEELINGS
Mon 7.30am	Cornflakes, 2 teaspoons of sugar, full fat milk, 2 slices of toast with butter spread medium, small glass of orange juice, tea with full fat milk	kitchen	Need to eat before work, really hungry

Setting Goals – page 19 of booklet

Choose goals that you feel are achievable. Remember small changes make a big difference!

Examples of small changes

Sarah Ellis

2 chocolate biscuits to 1 banana

[photos] saves 90 kcal

Chips to boiled or jacket potato

[photos] saves 370kcal

A whole Hawaiian pizza to one slice and salad

[photos] saves 2160 kcal

Start with three small changes. Write then down on this page and tick them off when you have achieved them.

For example:

I will grill or bake foods rather than fry

I will have breakfast three times this week

I will change from whole milk to semi skimmed milk

1.

2.

3

Try to think about some further changes you would like to make for your next session.

[graphic with word ‘changes’]

Welcome to session 2 – page 21

An [sic] Quick Nutrition Lesson !

Base your meals on starchy foods

(Throughout this booklet you will see the letter ‘g’ after fat/sugar/salt/fibre, this is an abbreviation for ‘grams’ the measurement of weight for these items)

Starchy foods should make up about a third of the food we eat. They should be your main source of energy because they contain vital sources of nutrients such as fibre, B vitamins, calcium and iron.

Most of us should eat more starchy foods and try to include starchy foods in each of our main meals. So for example, you could have a wholegrain cereal for breakfast, a sandwich for lunch and potatoes, rice or pasta with your evening meal.

If you can chose wholegrain foods rather than white or refined starchy foods it’s even better! These foods contain more fibre and nutrients and we digest wholegrain foods more slowly and so they can help us to feel full for longer.

The fibre found in;

Wholegrain bread

Brown rice

Wholegrain breakfast cereals

Fruit and vegetables

Cannot be digested by the body. So, it passes through the gut, it helps other food and waste products to pass more easily through the gut and so keeps your bowels healthy and prevents constipation.

The fibre found in;

Oats

Pulses (such as beans and lentils

Fibre is partially digested by the body and can help reduce the amount of cholesterol in the blood.

Top tips to help you eat more starchy foods and fibre

Potatoes are great! Jacket potatoes, new potatoes, boiled potatoes, steamed potatoes, sautéed potatoes or mashed potatoes! Try to keep the skins on as most of the nutrients are contained under the skin. [photo of potatoes in skins]

Use spray oil for roasting potatoes rather than pouring oil from the bottle.

Go without the fat spread onto a jacket potato. Why not have beans or chilli or cottage cheese?

Choose low fat oven chips rather than chips fried in oil.

Mash potatoes with milk only, rather than using butter or margarine.

Have more rice and pasta and less sauce.

Add beans or lentils to your stews, curries and casseroles – this will bump up the fibre content and you will need less meat, making the dish cheaper!

Try different breads such as seeded, wholemeal and granary and go for thick slices. Try and go without a fat spread on the bread or spread it very thinly.

Porridge with fruit makes a great breakfast.

Eat lots of fruit and vegetables!

Try to eat at least five portions of fruit and vegetables each day. It might be easier than you think!

Try:

A glass of fruit juice and a sliced banana with your cereal at breakfast.

A side salad at lunchtime.

An apple as an afternoon snack.

A portion of peas or other vegetable with your evening meal.

[photo of fruit salad and glass of OJ]

You can choose from fresh, frozen, tinned, dried or juiced fruit and vegetables. But remember potatoes count as a starchy food not as a portion of fruit or vegetable. Always wash your fruit and vegetables before use.

For more information and portion sizes, visit www.5aday.nhs.uk

Cut down on saturated fat.

To stay healthy we all need some fat in our diets. What is important is the kind of fat we are eating. There are two main types of fat:

Saturated fat – having too much of this type of fat can increase the amount of cholesterol in the blood, which increases the chance of developing heart disease.

Unsaturated fat – having unsaturated fat instead of saturated fat lowers blood cholesterol.

Try to cut out food that is high is saturated fat and have foods that are high in unsaturated fat instead.

These include vegetable oils (sunflower and olive oil), oily fish, avocados, nuts and seeds.

[photo of salmon in frying pan]

Foods high in saturated fat

Try to eat these foods less often or in small amounts;

Cakes

Biscuits

Pastries

Butter, margarine and lard

Meat pies, sausage rolls and meat with visible white fat

Burgers

Crisps and other savoury snacks

Chocolate

Hard cheese

Cream, soured cream and crème fraiche

Coconut oil, coconut cream or palm oil

Cut down on sugar

We all eat too much sugar. We should all be trying to eat and drink less of the foods and drinks that contain added sugar, such as sweets, cakes and biscuits, fizzy and sugary soft drinks.

Sugary foods are high in calories and eating or drinking them between meals can cause tooth decay.

Other words are often used to describe added sugar such as;

Sucrose

Glucose

Fructose

Maltose

Hydrolysed starch

Invert sugar

Honey

Corn syrup

Salt

Try to eat less salt – no more than 6g (about 1 teaspoon) a day.

Three quarters of the salt we eat is already in the foods we buy, such as soups, breakfast cereals, ready meals and sauces. So you could easily be eating too much salt without realising it – even if you don't add salt to your food.

Too much salt can cause your blood pressure to be raised. People with raised blood pressure are three times more likely to develop heart disease or have a stroke than people with normal blood pressure.

Try flavouring foods with herbs and spices rather than salt.

[photo of chives and oregano]

Snack attack!

We advise you to have two healthy snacks throughout the day. Try replacing your usual snacks with healthier options.

Sarah Ellis

Snacking on high fat/ high sugar foods such as crisps, chocolate, biscuits, cakes or sweets, will cause excessive weight gain. Try swapping them, for savoury or sweet alternatives such as:

[in table]

Savoury snacks

Bread sticks	5 sticks (15g)	70 calories
Bread/toast	1 slice	80 calories
Melba toast	4	60 calories
Raw carrots and celery sticks	100g	0 calories
Low calories soups	1 cup	40-60 calories
Oatcakes	2	90 calories
Pretzels	25g	100 calories

Sweet snacks [table]

Low calorie hot chocolate drink	1 mug	40 calories
Fruit	1 medium piece	60 calories
Low calorie breakfast/cereal bar	1	90-100 calories
Diet yogurt	125-150ml	65-80 calories
Scotch pancake	1	120 calories

Did you know?

A small packet of crisps contains about 160 calories

A small piece of hard cheese (30g) contains 125 calories

A banana instead of a packet of crisps will save 70 calories

2 chocolate biscuits contain 200 calories

Welcome to session 3 page 29 of booklet

Physical Activity

So far we have looked at healthy eating. Week three is very much about activity and ways of increasing this

If you were inactive before you were pregnant, don't suddenly take up strenuous exercise!

Being active is about getting the most out of life, enjoying yourself and improving your health. For the majority of mum's-to-be doing some kind of moderate exercise is beneficial.

This could be a leisurely swim or a walk in the park as long as it is comfortable for you. Thirty minutes of light exercise do both you and your baby the world of good! [photo of swimmer]

Keep up your normal daily physical exercise or activity (sports, dancing or just walking the dog) for as long as you feel comfortable. Don't exhaust yourself, and remember that you may need to slow down as your pregnancy progresses or if your midwife or doctor advises you to.

As a general rule you should be able to hold a conversation as you exercise. If you become breathless as you talk then you are probably exercising too strenuously (5).

If you were inactive before you became pregnant, don't suddenly take up strenuous exercise. If you start an aerobic exercise programme, start slowly with no more than 15 minutes continuous exercise, three times a week. Increase this gradually to a maximum of 30 minutes, five times a week and make sure you inform the instructor that you are pregnant (5).

Exercise doesn't have to be strenuous to be beneficial.

Try to keep active on a daily basis. Half an hour of walking each day can be enough. If you cannot manage that, any amount is better than nothing.

Your fitness level should be in tune with your lifestyle. You should have plenty of energy to climb the stairs or take a brisk walk, as well as performing everyday tasks without gasping for breath or becoming tired.

Being fit not only makes you look and feel better, it is beneficial to your health. It strengthens your heart and bones and improves your circulation. It can also help lower your blood pressure, blood cholesterol levels, control your weight and reduce your stress levels.

[photo of almonds in shape of a heart]

More benefits of exercise during pregnancy….

As well as increasing your energy levels, gentle exercise can also help:

Reduce discomforts such as constipation, cramps and backache.

Makes you feel stronger and more able to cope with everyday tasks.

Makes you sleep better.

Reduces stress and helps fend off pregnancy blues.

Exercise gets you out to meet other mums-to-be.

Get your body shape back faster after your baby is born.

It prepares you for labour.

Exercise safety tips

Make sure you warm up and cool down.

Drink plenty of water. [photo of someone drinking from bottle]

If you go to exercise classes make sure the instructor is properly qualified and knows that you are pregnant and how far your pregnancy has progressed.

Swimming is great because the water will support your increased weight.

Do not get overheated for prolonged periods.

Wear a sports bra and protective footwear.

Watch your balance (pregnancy alters your centre of gravity).

Avoid lying flat on your back – particularly after 16 weeks. Your ‘bump’ presses on the big blood vessels and can make you feel faint.

Avoid contact sports where there is a risk of being hit, such as kickboxing, judo or squash.

Avoid lifting weights above head height or over your abdomen. [photo of weights]

Avoid horse riding, downhill skiing, ice hockey and gymnastics as there is a risk of falling.

Avoid scuba diving as the baby has no protection against decompression sickness and gas embolism.

Avoid strenuous exercise in hot weather.

Sarah Ellis

Activity planner

Think about where you might be able to fit more activity into your life and start to plan extra activity (such as walking). People who are most successful at getting more active tend to be good at planning their activity into their everyday lives. It can be useful to sit down and plan your activity for the week ahead. You can use the activity planner to help you.

	PLANNED ACTIVITY	ACTUAL ACTIVITY
Example day	*Walking to the shops instead of driving*	*Bags were getting heavy so I came home on the bus*
MONDAY		
TUESDAY		
WEDNESDAY		
THURSDAY		
FRIDAY		
SATURDAY		
SUNDAY		

Excuse busters!

I don’t have time

Instead of watching television could you use some of the time to go for a walk?

Break the activity into smaller sessions and build up gradually.

Walk up the stairs instead of taking the lift.

Get off the bus one stop earlier.

What other ways can you think of to increase your activity?

I’m always too tired, I’d rather relax

Increasing your activity makes you less tired as you increase your heart and lung fitness.

Activity is a way of relaxing if you’ve had a stressful day.

I’m embarrassed because of my size

Find a friend to walk with or go to the pool with, that way you have support.

Regular activity can help you to feel better about yourself and boost your self-confidence.

Welcome to session 4 – Page 36

Food labelling, shopping and eating out.

Food labelling

If you want to eat a healthy diet, one of the main things you can do is to try to cut down on fat (especially saturated fat), sugar and salt.

When you are checking food labels to choose which products to buy, it can be very confusing – all those facts and figures! It can sometimes be hard to understand what the products we buy every day actually contain!

The big name and picture on the front of packs are there to persuade you to choose the product. But they don't tell you the whole story! The good news is that many retailers and manufacturers now provide 'at a glance' nutritional information on the front of packs.

Many are now using traffic light signposting to show you whether a food has high (red), medium (amber), or low (green) amounts of fat, saturated fat, sugar and salt in 100g of the food. In addition you can also see the amount of these nutrients that are present in a portion or serving of the food. [

Many foods with traffic light colours will have a mixture of greens, ambers and reds. So when you are choosing between similar products try and go for products with more greens and ambers, and fewer reds, for the healthier choice. Foods with a red light should only be eaten occasionally. [clip art of traffic lights] [

What do labels tell you?

Use by dates are often seen on foods that go off quickly, such as chilled meat, dairy products and ready meals. It is an offence for shops to sell food after their use by date. Don't buy it – it may make you ill!

Best before dates – there may be no immediate risk of food poisoning, but after this date the food will be going stale or losing flavour.

Allergy advice or intolerance can cause serious problems. New rules require that the main allergens are listed on the label, including nuts and shellfish.

Ingredients are listed in order of weight with the largest first. This list is useful to identify major sources of fat, sugar, and salt. But remember, they can all be listed under a variety of names!

Nutrition information can tell you how healthy a food is. But beware, some labels only show energy, protein, carbohydrate and fat. This may hide how much sugar, saturated fat and salt is in food.

[photo of tinned foods]

Fat

Some fats are easy to recognise others are hidden. Examples of foods with hidden fats include pastry, cakes, biscuits, crisps and other snack foods.

Here are some different names for fats: [photo of cream cakes]

Butter, butter fat, milk fat, lard, dripping, nut butter eg, peanut butter, coconut butter

Ghee, coconut cream, coconut milk, palm oil

Vegetable oil, hydrogenated vegetable fat/oil

Mono and polyunsaturated or saturated fat

Mono-,di-, and triglycerides

Total fat and saturated fat – what's high and what's low? How do I know?

Total fat

High = more than 20g of fat per 100g

Low = 3g or less per 100g

Saturated fat

High = more than 5g saturate per 100g

Low = less than 1.5g per 100g

To find an up-to-date list of the stores and food producers that are using traffic light colours, see the Food Standard Agency's eatwell website at www.eatwell.gov.uk/trafficlights

Sugar

Sugar also has many names. If sugar occurs in the first three ingredients then the food is high in sugar.

To recognise sugars look for the following:

Names ending in -'ose' e.g. glucose, dextrose, maltose, sucrose

Brown sugar, fruit sugar, cane sugar, or invert sugar [picture of sugar cubes]

Honey, molasses, treacle, syrup or invert syrup

Total sugar - what's high and what's low? How do I know?

Total Sugar

High = more than 15g sugars per 100g

Low = 5g sugars or less per 100g

Salt

Salt is the general term used for sodium chloride and also has many different names:

Sodium as any part of a chemical name e.g. monosodium glutamate, sodium chloride, sodium bicarbonate

Baking soda, baking powder

Sea salt, garlic salt, celery salt

The government recommendation for our daily salt intake is 6g or 1 teaspoon. This does not mean that we can add this much to our daily meals as most of the salt in our diet has already been provided in the processed foods we eat.

Total salt - what's high and what's low? How do I know?

Total salt

High = more than 1.5g salt per 100g (or 0.6g sodium)

Sarah Ellis

Low = 0.3g salt or less per 100g (or 0.1g sodium)

Fibre

Fibre in food comes from whole-meal or whole-grain cereals, pulses, fruit and vegetables. The nutrition label will tell you how many grammes of fibre are in the food. The recommended daily intake is 12g or more.

Nutrition claims

Not everything that looks like a health claim is necessarily a healthier choice! [picture of pasta]. For example a claim that a food is 85% fat free

In real terms this means that the food contains 15% fat.

There are 15g of fat per 100g of food (100g food minus 85g 'fat free' = 15g fat)

The food does not fall into the categories for a healthy eating food or low fat food

Low fat may still be high energy (calories) if there is lots of sugar added

Foods without a 'low fat' claim can have less fat than a food claiming to be 'low fat'

Ready made meals - a healthy ready-made meal has less than 20g fat and 10g sugar in the whole meal for 1 serving.

Shopping, cooking and eating out – page 42 of booklet

Shopping

Shopping for food can be a difficult time. There are lots of temptations about!

Stay in control with the following suggestions:

Avoid shopping when you are hungry, tired or stressed as these may lead to poor food choices

Make a shopping list of everything needed for the next day or week's menu and stick to it!

Plan ahead and choose foods low in fat for the whole family

Don't wander around the supermarket looking for extras or bargains

Check your usual food labels and compare them to the recommended levels of fat, sugar, salt and fibre

Choose seasonal fruits and vegetables or those on special offer as they will be the best value for money

Remember frozen foods are just healthy as the fresh options

Tinned foods tend to have added salt, when choosing these foods try those without added sugar or salt and drain off excess juice or brine

Cooking

Healthy meals can be quick meals! You can also make healthy versions of your family's current favourite foods – just remember the following tips:

Meat, chicken and fish

Remove skin from chicken and trim all visible fat from meat

Try grilling, poaching, microwaving or baking rather than frying

If you do shallow fry, use a non-stick pan and limit oil to 1 teaspoon per person or just enough to prevent sticking

Use mono or poly-unsaturated oils such as olive, rapeseed or sunflower oils

If making soup or casseroles, skim the fat off the top before serving

Bulk out stews and casseroles with plenty of vegetables and/or pulses

[Picture of roast chicken meal on plate]

Throw away that chip pan!! Use oven chips instead

If mashing potatoes use low-fat milk and/or a low-fat spread or natural yoghurt

Roast potatoes can be dry roasted in a non-stick pan

Add potatoes to soups to thicken them

Dressings and sauces

Avoid full fat mayonnaise and salad cream, try lower fat versions instead

Experiment and make your own salad dressings. Use natural yoghurt, herbs, spices, vinegars, lemon juice or tomato juice

Make gravy using gravy powder and water instead of juices from the meat

[photo of pasta with sauce]

Eating Out

Eating out includes any food eaten outside of the home. This may include lunch in the cafeteria at work, take-away lunches or dinners or food at a restaurant of café.

Eating out can be a real treat so if you rarely eat out (once a month or less), enjoy your favourite foods.

If you eat out regularly (once a week or more) consider what's available and try and choose the healthier options - which of course can also be delicious!

Making healthier choices;

Enjoy 2 courses rather than 3; a starter and a main or a main and a dessert

Choose broth rather than 'cream of' type soups

Examine the menu carefully

Avoid the bread basket before your meal especially if you add butter to your bread

Be assertive! Ask questions

Ask for dishes to be cooked and served how you want

Ask for no butter on potatoes or vegetables

Ask for extra vegetables

Share a dessert

Have a big bottle of mineral water to sip throughout your meal

Welcome to session 5 – page 46 booklet

Eating behaviour

“(Bumps and Beyond) gave me an element of control at a time when I had little control over my body and feelings” – service user

Eating is a very complex behaviour! It is often triggered by situations, emotions or feelings.

Understanding your personal triggers to eating can be very helpful when you are trying to change your eating habits.

Your daily food diary will often give you clues about your triggers to eating.

Look at the times when you have not stuck to your eating plan or goals and consider:

What time of day was it?

Where were you?

What was the occasion?

What were you doing?

What were your thoughts and feelings?

Eating is very personal to you and can be influenced by things around you, your feelings and emotions.

[photo of salmon, rice and salad]

Take a few minutes to write down your personal associations to eating in the boxes below.

[box] sound/sight/smell

[3 boxes] feelings/emotions, times, places

[2 boxes] events, activities

Triggers to eating

Once you become aware of your triggers and links to eating, you can learn strategies to help you avoid these triggers and break the links. This will help you to avoid unwanted or unplanned eating. [

Eating is often the result of a chain of events. If you want to change your eating behaviour you need to understand the chain of events and learn how to break links in the chain. Look at the example below.

[diagram of chain of events – Mary buys biscuits / leaves the biscuits on show / home along –high risk! / tired and bored / feels urge to eat / biscuits into lounge/ eats and watches TV / feels guilty / eats more biscuits /[back to] Mary buys biscuits]

Let's look at how the links could be broken.

Buying the biscuits:

Shop from a list and on a full stomach

Shop with a partner or friend who keeps you motivated [

Avoid the biscuit aisle

Buy something that needs preparation

Biscuits on the table:

Store in an opaque container

Store out of sight and reach

Home alone – high risk time tired and bored:

Do you something you enjoy – meet a friend, go for a walk [

Read a book

Do some exercise

Urge to eat:

Phone a friend!

Think of alternatives to eating

Learn to separate hunger from cravings

Biscuits into lounge:

Avoid going into kitchen except to prepare meals

Make sure a low fat/low sugar food is available

Only eat in kitchen

Eat away from distractions

Eats while watching TV:

Do nothing else while eating

Sarah Ellis

Only eat in kitchen

Feels guilty:

Think positively about achievements [

Review realistic goals

Plan how to limit the damage

Eats more biscuits:

Watch attitude traps

Examine behaviour chain

REMEMBER THE BEHAVIOUR CHAIN BECOMES MORE DIFFICULT TO BREAK THE FURTHER DOWN YOU GO.

Welcome to session 6 – page 52 of booklet

How to cope with lapses

There are many times in life when things don't go according to plan! When making healthy lifestyle changes it is perfectly normal to slip up occasionally.

There are different stages to slipping up!

Firstly, you may have a lapse, a one-off mistake on any given day. A relapse is a series of slip-ups where you begin to use fewer and fewer of the new habits and skills that you have developed. Finally you may have a collapse of your efforts and a complete return to your old lifestyle (8).

By this stage you will have experienced many highs as you feel in control, but also some lows as you suffer lapses and the occasional relapse. What you need to do is recognise what is happening and prevent collapse.

There are two ways of dealing with lapses. Firstly you can prepare and plan for the situations where you feel you may have a lapse. Secondly, you can learn from your lapses for next time.

[photo of chips]

How to recover after a lapse

The STOP and THINK technique

STOP – assess the problem

Remember, one slip is not the end of the world.

THINK – What was going on before the lapse?

What were the triggers?

As you analyse the situation, remember the 'behaviour chain' technique.

Regain control –do something else

Learn and plan – what can be done in the same situation to prevent another lapse?

Try to plan ahead for celebrations and holidays.

Plan ahead for times when you are feeling low and it seems more difficult to stick to your new lifestyle.

Planning will keep you on track. If you are staying with your new plans for 95% of the time then consider yourself a success!

Attitude traps

These are unhelpful thoughts and recognising then may help you become more positive in your thinking and help you achieve more realistic goals.

Are your thoughts blocking your progress?

Do you set yourself impossible goals?

Take a minute to think about whether your thoughts contain the words MUST, NEVER or ALWAYS.

If they do, try to rephrase them more realistically.

INSTEAD OF	USE
I must	My goal is to
I must not	I will attempt to
I will always	I will try to
I will never	I will try not to

[photo of salmon, rice and salad]

Sarah Ellis

Welcome to session 7 – page 56 of booklet

Maintenance

Well done on getting this far and making some really positive healthy lifestyle changes! You should be very proud that you have made these changes and hopefully will continue along this route and make a difference to your health, your baby's health and your family's health

With a bit of careful planning you can enjoy filling, tasty food that can have a big impact on your health – now and in the years to come. Not only will it help you to lose weight, which is good news because being overweight or obese means a higher risk of diabetes, high blood pressure, coronary heart disease and arthritis. Healthy eating, being more active and stopping smoking are the best opportunities you have of keeping disease at bay.

You will have noticed that at first eating healthily involved a lot of careful planning. It should now have become easier as you have become familiar with all the things that you can eat and enjoy – as well as the things to steer clear of. Your commitment to healthy eating and increased activity will probably get stronger as you start to feel the benefits of your changes.

Of course there will be times when it is very difficult to stay on track. Holidays and parties come round, family crises happen – or you just have a bad day! You can plan ahead for some of these things, but others will come out of the blue. Don't be too hard on yourself. If you break your healthy eating or activity plan for a few hours or days, it's not the end of the world. If it was unplanned, try to learn from what went wrong and get back on track as soon as you feel ready.

Sometimes you may need to revisit your food diaries if you find yourself eating the wrong things.

Keeping on track

People who maintain positive lifestyle changes and avoid weight regain tend to have the following in common;

Increased physical activity

Being physically active has been shown to be more important than anything else in preventing weight regain.

Eating reduced calorie, low fat, high, carbohydrate foods

Remember your portion sizes! Have regular meals and don’t skip breakfast.

Self monitoring

Keep a daily food/activity diary from time to time to monitor what you eat and how much physical activity you do

Social support

Try to obtain support from others. Try to identify key people among your family and friends who will support your continuing efforts to change your lifestyle.

Relapse prevention strategies

Prevent one-off lapses from becoming a complete return to your old habits by using some techniques you learnt over the last two sessions.

Breastfeeding

Now is the time to give some thought as to how you will feed your baby. Breast milk provides all the nutrients a baby needs for healthy development in the first six months of life and helps protect them from infection and diseases.

Every day that you breastfeed makes a difference to your baby’s health now and in the future.

Breastfeeding allows the bond between you and your baby to grow stronger as it allows you both to become physically and emotionally closer.

Breastfeeding is free, requires no preparation and may help you to lose some of the weight gained during pregnancy (10).

Bottle feeding does not give your baby the same ingredients as breast milk, which is designed to be easy for your baby to absorb and is perfect to help him grow and develop (11)[sic]. Bottle feeding doesn’t provide protection against infection and diseases.

Breastfeeding your baby helps against:

Ear infections

Gastro-intestinal infections

Chest infections

Urine infections

Childhood diabetes

Obesity

Eczema

Asthma

Breastfeeding also encourages better mouth formation and straighter teeth.

Breastfeeding helps protects mothers against:

Ovarian cancer [photo of woman holding baby]

Breast cancer

Weak bones in later life

Women who breastfeed return to their pre-pregnancy figure faster!

You do not need to follow a special diet when you are breastfeeding. But it's important for you and your baby that you eat a healthy balanced diet, as described throughout this book and also drink plenty of fluid – at least 6-8 glasses of fluid every day.

It's a good idea to have a drink by your side before you settle down to breastfeed. If you feel thirsty that means you are already dehydrated. If your urine is dark and has a strong smell this is a sign that you're not drinking enough.

It's not a good idea to try and lose weight while you're breastfeeding. This is because you need to keep up your energy levels and you might miss out on the nutrients that you and your baby need.

The good news is that the extra fat laid down in pregnancy is used to make breast milk (using up to 500kcals each day!), so breastfeeding will help you get in shape more quickly!

If you eat a healthy balanced diet, limit the amount of fat and sugar you eat and are physically active, this will help you to lose any extra weight you put on during pregnancy.

Remember to limit your intake of oily fish to two portions a week (as you were advised during pregnancy) and if you, your baby's father, brothers or sisters have a food allergy or other allergic condition such as hay-fever, asthma or eczema, your baby may be at higher risk of developing peanut allergy.

If this is the case, you should avoid eating peanuts and peanut products while you are breastfeeding and while you are introducing solid food.

"I cannot put into words the benefits I have gained from the programme" – service user

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www.counterweight.org

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Appendix 7 – Support material used within sessions in Lincolnshire

Code:	Location:	Staff member	Session number	Handout	Date of clinic
Not recorded	Lincoln community	Jean	3	5 a day foldout. Goal setting sheet. Pedometer. Steps record sheet	30.6.15
LC306/1	Lincoln community	Jean	3	5 a day foldout. Goal setting sheet. Pedometer. Steps record sheet	30.6.15
LC306/2	Lincoln community	Jean	5/6	None given	30.6.15
LC306/3	Lincoln community	Jean	1	Questionnaire. The following in the B&B pack: Food diary sheet, Appt. card, Foods to eat less/more sheet, Breakfast cereals sheet, Fats/oils/butter sheet, B&B booklet, 5 a day foldout leaflet, Eat well plate fridge magnet, B&B pen, B&B pad, Start4life leaflet, Info for parents card	30.6.15
LC306/4	Lincoln community	Jean	2/3	5 a day foldout. Goals sheet. Pedometer. Step count record sheet.	30.6.15
GA017/1	Gainsborough	Jean	2/3/4	5 a day foldout. Goals sheet. Pedometer. Step count record sheet. Understanding food labels leaflet (and card). 2 x Potatoes leaflets. Change4life taster recipes booklet. Change4life 'be food smart' recipe book. Magnifying card (Phoenix wt management service). Phoenix wt management recipe book.	1.7.15
B147/1	Boston hospital	Linsey	5	None given	14.7.15
B147/2	Boston hospital	Linsey	5	Change4life tasters recipe book. Phoenix wt management recipe book.	14.7.15
B147/3	Boston hospital	Linsey	1	B&B pack: Pad and pen, Appt card, Eat well plate fridge magnet, Start4life 'healthy habits for baby and you' booklet, B&B booklet, Lifestyle questionnaire,	14.7.15

				Food diary sheet, Goal setting sheet, Breakfast cereal list, Food to eat/food to eat more sheet. *free swimming sessions	
B147/4	Boston hospital	Linsey	5	None given	14.7.15
B147/5	Boston hospital	Linsey	2/3	5 a day foldout. 5 a day large leaflet. Pedometer	14.7.15
B118/1	Boston hospital	Linsey	7	Start4life breastfeeding leaflet. B&B towel. Satisfied Tummies recipe book. *post-partum options – free gym and swim, free Wt Watchers, free Health Trainer sessions (at home).	11.8.15
B118/2	Boston hospital	Linsey	4	? not recorded in written notes. Check audio recording.	11.8.15
B118/3	Boston hospital	Linsey	6/7	B&B towel. Start4life breastfeeding leaflet.	11.8.15
B118/4	Boston hospital	Linsey	2/3	Pedometer. 5 a day foldout.	11.8.15
SK128/1	Skegness HC	Linsey	5/6/7	Change4life taster recipes booklet. [agreed to leave B&B towel at the HC at a later date]	12.8.15
SK128/2	Skegness HC	Linsey	1	B&B starter pack but not gone through individually (as participant had been through programme before). *free swimming lessons	12.8.15
SK128/3	Skegness HC	Linsey	5	None given	12.8.15
SK128/4	Skegness HC	Linsey	6/7	Start4life breastfeeding leaflet.	12.8.15
SK128/5	Skegness HC	Linsey	5	Change4life taster recipe booklet. Phoenix wt management recipe book.	12.8.15
Not recorded	Lincoln hospital	Sally	5/6/7	BHF ‘So you want to lose weight for good’ booklet. B&B towel	17.6.15
LA176/2	Lincoln hospital	Sally	2/3	5 a day booklet. 5 a day foldout. Pedometer.	17.6.15
LA176/3	Lincoln hospital	Sally	7	Start4life breastfeeding leaflet. BHF ‘So you want to lose weight for good’ booklet. Weaning booklet.	17.6.15
GR236/1	Grantham	Sally	1	Questionnaire. Goal setting sheet. The following in the B&B pack: Food diary sheet, Appt. card, Foods to eat less/more sheet, Breakfast cereals sheet, Fats/oils/butter sheet, B&B booklet, 5 a day foldout leaflet, Eat well plate fridge magnet, B&B pen, B&B pad, Start4life leaflet,	23.6.15

				Info for parents card	
GR236/2	Grantham	Sally	1	Questionnaire. Goal setting sheet. The following in the B&B pack: Food diary sheet, Appt. card, Foods to eat less/more sheet, Breakfast cereals sheet, Fats/oils/butter sheet, B&B booklet, 5 a day foldout leaflet, Eat well plate fridge magnet, B&B pen, B&B pad, Start4life leaflet, Info for parents card	23.6.15
GR077/1	Grantham	Sally	4	Pedometer. Traffic light labelling card (Children's Food Trust version). Phoenix wt management recipe book. Change4life tasters recipe leaflet.	7.7.15
GR077/2	Grantham	Sally	5/6/7	Start4life breastfeeding booklet (Off to the best start). BHF 'So you want to lose wt for good' booklet. B&B towel. Satisfied tummies recipe book	7.7.15
GR077/3	Grantham	Sally	2/3	Pedometer. 5 a day large leaflet 'what's it all about'. 5 a day foldout.	7.7.15
LA087/1	Lincoln hospital	Sally	4/5	Traffic light labelling card (Children's Food trust version). Change4life tasters recipe booklet. Phoenix wt management recipe book.	8.7.15
LA087/2	Lincoln hospital	Sally	4	Traffic light labelling card (Children's Food trust version). Change4life tasters recipe booklet. Phoenix wt management recipe book.	8.7.15
LA087/3	Lincoln hospital	Sally	2/3	Pedometer. 5 a day large leaflet. 5 a day foldout	8.7.15

Appendix 8 – Tables for intervention fidelity

Location	**Lincoln community**	**Skegness**	**Boston**	**Grantham**	**Grantham**
Staff	**Jean**	**Linsey**	**Linsey**	**Sally**	**Sally**
Content Session 1					
1	**y**	**y**	**n**	**y**	**y**
2	n	y	n	y	y
3	y	y	y	y	y
4	n	n	n	n	n
5	y	y	y	y	y
6	y	y	y	y	y
7	y	n	y	y	y
8	y	y	y	y	y
9	n	y	refused	n/a	n

Location	**Boston**	**Lincoln Acute**	**Lincoln Acute**	**Lincoln Community**	**Boston**	**Lincoln Community**	**Grantham**
Staff	**Linsey**	**Sally**	**Sally**	**Jean**	**Linsey**	**Jean**	**Sally**
Session 2:							
1	y	y	y	Y	y	y	y
2	y	y	y	Y	y	y	y
3	n/a	n/a	y	n	n/a	n/a	n/a
4	y	y	y	y	y	y	y
5	y	y	y	y	y	y	y
6	y	y	y	y	y	y	y
7	y	y	y	y	y	y	y
8	y	y	y	n	y	y	y
9	n/a	y	n/a	n/a	n/a	n	n/a
Session 3:							
1	y	y	y	Y	y	y	y
2	y	y	y	Y	y	y	y
3	y	y	y	y	y	y	y
4	y	y	y	y	y	y	y
5	y	y	y	y	y	y	y
6	y	y	y	n	n	y	y
7	y	y	y	y	y	y	y
8	y	n/a	y	n	y	n/a	n
9	y	y	y	n	y	y	y
10	n/a	y	n/a	n	n/a	n	n/a

Location	Grantham	Boston	Lincoln Acute
Staff	Sally	Linsey	Sally
Session 4			
1	n	y	n
2	y	y	y
3	y	y	y
4	y	y	y
5	y	y	y
6	n	n	y
7	n	n/a	n/a

Location	Skegness	Boston	Boston	Skegness	Boston
Staff	Linsey	Linsey	Linsey	Linsey	Linsey
Session 5					
1	y	y	y	y	y
2	y	y	y	y	y
3	y	y	y	y	y
4	y	n	y	n	n
5	y	y	y	y	y
6	y	y	y	y	y
7	y	y	y	y	y
8	y	n	n/a	y	n
9	n/a	n/a	n/a	n/a	n/a

Location	Lincoln community		Lincoln community
Staff	Jean		Jean
sessions 5		session 6	
1	y	1	y
2	y	2	y
3	y	3	y
4	y	4	y
5	y	5	y
6	y	6	y
7	y	7	y
8	N		
9	n/a		

Location	**Boston**	**Skegness**
Staff	**Linsey**	**Linsey**
Session 6		
1	y	y
2	y	y
3	y	y
4	y	y
5	n	n
6	n/a	n/a
Session 7		
1	y	y
2	part	part
3	y	y
4	y	y
5	y	y
6	n	n

Location	**Boston**	**Lincoln Acute**
Staff	**Linsey**	**Sally**
Session 7		
1	y	y
2	y	y
3	y	y
4	y	y
5	y	y
6	n	n

Appendix 9 - TIDieR checklist (Hoffman et al., 2014).

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____

	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____

	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____ _	_____ _
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____ _	_____ _

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an

extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).