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1 Limiting antenatal weight gain improves maternal health outcomes in 2 severely obese pregnant women: findings of a pragmatic evaluation of a 3 midwife-led intervention 4 5 Ailsa McGiveron², Sally Foster², Joanne Pearce¹, Moira A Taylor³, Sarah 6 McMullen^{1,4}, Simon C Langley-Evans^{1*}. 7 ¹ School of Biosciences, University of Nottingham, UK. 8 9 ² Lincolnshire Community Health Services NHS Trust, UK. 10 ³ School of Life Sciences, University of Nottingham, UK. 11 ⁴ National Childbirth Trust, London, UK. 12 13 * Corresponding author: Professor Simon Langley-Evans, School of Biosciences, 14 University of Nottingham, Sutton Bonington, Loughborough, LE12 5RD, UK.

Simon.Langley-Evans@Nottingham.ac.uk

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Abstract

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Background: Antenatal obesity in pregnancy is associated with complications of pregnancy and poor obstetric outcomes. Although most guidance on pregnancy weight is focused on the pre-pregnancy period, pregnancy is widely viewed as a period where women are open to lifestyle change to optimise their health. Method: The hospital-based Bumps and Beyond intervention invited all pregnant women with a BMI of over 35 kg/m² to take part in a programme of health education around diet and exercise, accompanied by one-to-one guidance and monitoring of dietary change. This service evaluation compares 89 women who completed at a programme of 7 sessions with healthy lifestyle midwives and advisors (intervention) with a group of 89 women who chose not to attend (nonintervention). **Results:** Weight gain in the intervention group (4.5±4.6 kg) was less than in the non-intervention group (10.3±4.4 kg) between antenatal booking and 36 weeks gestation (<0.001). This was associated with a 95% reduction in the risk of gestational hypertension during pregnancy and a general reduction in pregnancy complications. There was no effect of the intervention upon gestational diabetes or complications in labour other than post-partum haemorrhage (reduced 55%). The impact of the intervention on gestational weight gain was greater in women with BMI over 40 kg/m² at booking. There were no adverse effects of the intervention, even though 21% of the intervention group lost weight during their pregnancy. **Conclusion**: Intensive, personalised weight management intervention may be an effective strategy for prevention of hypertensive disorders during pregnancy.

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The worldwide increase in the prevalence of overweight and obesity is increasingly impacting across all age-groups in the population (Ogden et al., 2013; WHO 2013). As a result all developed countries are reporting high levels of obesity among women of childbearing age and this has important consequences for maternal and fetal health during pregnancy, and potentially for the longerterm health of the children of obese women (Normia et al., 2013; Langley-Evans 2014; Taylor et al., 2014). In the UK 13 % of 21- to 30-year-old and 22 % of 31to 40-year-old women were estimated to be obese in 2007, and this was expected to rise to 30 and 47 % respectively by 2050 (Foresight, 2007). 20% of UK women aged 16-44 were obese in 2010 (National Obesity Observatory, 2014) and in the USA (Ogden et al., 2013) this figure was approximately 32% in the 20-39 year old population. A dramatic increase in the prevalence of severe or morbid obesity has occurred alongside the increasing prevalence of obesity in young women and in 2009 approximately 5% of all pregnancies in England were associated with maternal BMI of over 35 kg/m², with approximately 2% of pregnant women having BMI in excess of 40 kg/m² (National Obesity Observatory 2014). Pregnancy is recognised as a period during which women are vulnerable to excessive weight gain that they may find difficult to reverse, thereby increasing risk for subsequent pregnancies and their longer-term health (Groth et al., 2013; Von Rueslen et al., 2014).

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Maternal obesity during pregnancy increases the risk of adverse pregnancy outcomes, including miscarriage, gestational diabetes and hypertensive disorders (Sebire *et al.*, 2001; Wang *et al.*, 2002; Jensen *et al.*, 2003; Maconochie

et al., 2007; Centre for Maternal and Child Enquiries 2010; Li et al., 2013; Sommer et al., 2014). Obesity is recognised as a significant risk factor for maternal and fetal death (Centre for Maternal and Child Enquiries 2010). The risks associated with maternal overweight and excessive weight gain are recognised by the US Institute of Medicine (2009), which has published guidance on optimal ranges of weight gain during pregnancy. These are based upon maternal weight prior to pregnancy, with obese mothers advised to gain 5-9 kg across pregnancy, compared to the 12.5-16 kg recommendation for women of healthy weight. The UK does not have any formal, evidence-based recommendations for healthy weight gain in pregnancy, although a guidance range of 10-12.5 kg is included within Department of Health literature. However, National Institute of Health and Clinical Excellence (NICE) guideline of 2010 recommends that health professionals carefully manage maternal weight. The emphasis of these guidelines is on weight loss prior to, or after pregnancy (NICE 2010). Weight loss is not advised during pregnancy as it may pose a risk to fetal nutrition and development.

The antenatal period puts women into greater contact with health professionals and is therefore an ideal time for health education. Mothers are generally open and more readily motivated to make lifestyle changes that could benefit the health of themselves and their baby (Ritchie *et al.*, 2010; Wilkinson & McIntyre 2012; Wilkinson *et al.* 2014; May *et al.*, 2014). A number of studies have evaluated the impact of antenatal diet, exercise or weight management programmes upon pregnancy outcomes. Thornton and colleagues (2009) found that monitoring the food intake of obese women was associated with lower

gestational weight gain and lower prevalence of gestational hypertension. Shirazian *et al.*, (2010) reported that a lifestyle modification in obese pregnant women reduced weight gain, but had no effect on adverse pregnancy outcomes such as pre-eclampsia. The meta-analysis of Thangaratinam et al., (2012) found that weight management interventions in pregnancy reduced the risk of preeclampsia, but had no impact upon other obstetric outcomes. There are also a number of ongoing studies evaluating intervention strategies, such as the LIMIT trial in Australia (Dodd et al., 2011) and the UK UPBEAT study (Poston et al., 2013). LIMIT has recently reported that a researcher-led diet and physical activity intervention did not achieve lower gestational weight gain, or improved maternal outcomes (Dodd et al., 2014). Alongside randomised controlled trials of interventions, there are many clinical interventions mounted on a local level that aim to reduce the impact of maternal obesity upon health in the community. In this paper we report the findings of a service evaluation of one such programme. The primary aims of the evaluation were to determine whether one-to-one antenatal guidance from midwives and healthy lifestyle advisors resulted in lower gestational weight gain and prevalence of the common complications of pregnancy and labour that are associated with severe obesity.

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Methods

The Bumps and Beyond Intervention

The Bumps and Beyond intervention was designed by the Healthy Lifestyle Midwife lead for Lincolnshire Community Health Services in 2009-10 and Lifestyle midwife lead for Lincolnshire United NHS Trust in 2008-9. Between April 2012 and February 2013, all pregnant women attending first dating

antenatal ultrasound clinics at Lincoln Hospital (UK) with a BMI of \geq 35 kg/m² were invited to take part in the intervention, which was delivered on a one-to-one basis by either a midwife or healthy lifestyle advisors at hospital antenatal clinics or local community 'health shops'. The latter enabled a wider geographical coverage for the intervention across the county of Lincolnshire. Lincolnshire lies in the east of England and has a largely rural economy. In terms of income and employment rates it is one of the most deprived regions of the country (15th out of 149 local authorities). The full intervention comprised eight sessions, beginning when women were around 16 weeks pregnant and continuing every 2-4 weeks until week 36 of pregnancy. Women were weighed at each session and encouraged to attend all of the sessions. The final session (session 8) was delivered postnatally, around 6 weeks after the women had given birth.

Women with BMI >35 kg/m² were first identified at their dating scan, where height and weight were recorded. Identification of high BMI triggered referral to a consultant-led antenatal care plan and the offer of the intervention at between 16 and 18 weeks gestation, via the consultant clinic. The intervention was delivered by a specialist healthy lifestyle midwife and three healthy lifestyle advisors, all of whom were trained and experienced in delivering behaviour change for weight loss and interventions for families. Women attending the intervention received a pack of information via an intervention booklet, which was used as the focus for the seven antenatal sessions. This comprised an introduction and overview of lifestyle changes and the benefits of avoiding excessive weight gain during pregnancy along with general and pregnancy-

specific nutrition guidance including food safety information, the Eatwell plate model (Public Health England, 2014), population-based dietary advice such as reducing intakes of fat, sugar and salt and increasing consumption of fruit, vegetables and fibre and guidance on food labelling, shopping cooking and eating out. The main focus of the intervention was upon healthy eating due to the practicalities of trying to increase exercise during pregnancy. However, one of the intervention sessions focused on physical activity and included recommendations to increase light activities such as walking or swimming from 15 minutes continuous activity 3 times per week to 30 minutes continuous 5 times per week. Advice was given on eating behaviour, the benefits of breastfeeding for weight loss/maintenance and guidance on the maintenance of healthy lifestyle changes beyond the intervention. Whilst breastfeeding was suggested to aid the return to pre-pregnancy weight, this was in the last session of the intervention where the main focus was on maintaining a healthier lifestyle. All women who took part in the intervention kept a food diary to help identify and modify individual dietary patterns or behaviours. Delivery of the programme did not differ between the clinical and health shop settings.

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For the purposes of this evaluation of the efficacy of the intervention, women are classified as having taken part in the intervention if they attended all 7 antenatal sessions. None of the data reported here considers the postnatal period and so attendance at session 8 is not considered here. Women with a BMI over 35 kg/m^2 who declined the offer of the intervention comprise the non-intervention group in this analysis. In total 194 women were approached to take part in the study and there were 97 in the intervention group and 97 in the non-

intervention group. 13 women were excluded from analysis as they suffered a miscarriage or stillbirth, or were carrying multiple foetuses, leaving only singleton pregnancies with live births in the evaluation. This left 92 and 89 women in the intervention and non-intervention groups respectively. 3 intervention group women failed to attend all antenatal 7 sessions and were excluded from the analysis. The non-intervention group comprised only women who had attended none of the sessions. Whilst women in the intervention group were slightly older (1.7 years) and more likely to report taking a 10 microgram/day supplement of vitamin D at baseline, the two groups of women were otherwise similar in terms BMI at booking, socioeconomic status, ethnicity (this was predominantly a white Caucasian population) and use of folate supplements (Table 1).

Data collection

Information on the most common complications experienced in pregnancy (gestational diabetes, gestational hypertension, preeclampsia, thrombosis, musculo-skeletal disorders, symphysis pubis disorder, premature rupture of membranes, polyhydramnios, small-for-gestational age, large-for gestational age) or labour (post-partum haemorrhage, shoulder dystocia, failure to progress, induction, non-vaginal delivery, manual removal of placenta), along with the mode of infant feeding adopted after delivery were obtained from the medical records of the women by the intervention team (AM and SF). Many of these outcomes are known to be influenced by maternal obesity (Mission *et al.*, 2013). Height and body weights of the women at antenatal booking (average 12 weeks

gestation) and at 36 weeks gestation were similarly obtained from the records of their antenatal care.

Ethical approval

This paper reports the analysis of outcomes of an ongoing clinical intervention using wholly anonymised data provided by the intervention lead (AM) to the evaluation team (JP, SM, MAT and SLE). No ethical approval was required for this service evaluation, which was registered with the clinical audit department of Lincoln County Hospital NHS Trust.

Statistical analysis

Data on weight in pregnancy are expressed as mean ± standard deviations and were analysed by independent samples T-test. Weight gain over pregnancy was analysed using ANOVA with adjustment for weight at booking. Odds ratios for pregnancy and labour complications were determined by binary logistic regression to determine the effect of the intervention with adjustment for potential confounding factors (maternal age, parity, gravidae, socioeconomic status, marital status, and ethnicity). The impact of the intervention on mode of feeding on delivery of infants was determined as a simple unadjusted odds ratio.

Results

Women in the non-intervention and intervention groups were of similar weight at the time of antenatal booking (10-13 weeks gestation) and for the whole population the mean BMI was 38.9 ± 3.7 kg/m² (Table 1). Weight and BMI at 36 weeks gestation were not significantly different between the groups, but overall

weight gain was significantly lower in the intervention group (Table 2). Among the women taking part in the intervention sessions, pregnancy weight gain was on average 5.8 kg less than in those who did not take part. For 19 out of the 92 women in the intervention group there was weight loss of up to 4.05 kg (Mean 2.04 ±1.25 kg range 0.2-4.05) across the pregnancy. All women in the non – intervention group gained weight (range 0.20 to 25.95 kg). To assess whether weight gain was similar across the full range of BMI in each group, the population was stratified into quartiles based upon BMI at booking. Whilst weight gain was not significantly different between the quartiles in the non-intervention women, the women of higher BMI (Q3, Q4) at booking in the intervention group gained significantly less weight than those in the lower quartile for BMI (Figure 1).

Weight gain in pregnancy was strongly related to the risk of all maternal pregnancy complications combined and hypertensive conditions, but not gestational diabetes or complications in labour. Figure 2 shows the OR for these complications for the total population of women, divided into quartiles based upon weight gain. Weight gain over 8.25 kg was associated with significantly greater risk of pregnancy complications (Q4 adjusted OR 4.29 [1.46-12.57]), whilst risk of gestational hypertension increased when weight gain exceeded 11.10 kg (adjusted OR 7.31 [1.52-35.10]). No significant relationship between booking BMI or BMI at 36 weeks was noted for any of the conditions.

Table 3 shows unadjusted and adjusted odds ratios for complications experienced during pregnancy among women in the two groups. Overall,

maternal pregnancy complications were reduced by 76.4% among women taking part in the intervention. As many of the recorded complications (musculoskeletal problems, large-for-gestational-age, SPD, PROM and reduced fetal movements) were rare or absent (thrombosis, small-for-gestational age) in this population, no benefits of the intervention with respect to each specific condition could be demonstrated (data not shown). However, gestational hypertension was reduced by 95%. A similar trend was observed for pre-eclampsia (90% reduction). In keeping with the fact that the intervention group remained severely obese throughout pregnancy, there was no beneficial effect of the intervention upon diabetes during pregnancy. Delivery was by elective caesarean for 16% of the women and among the remaining group complications during labour, resulting in emergency section or instrumented delivery were experienced by 48%. As shown in Table 3, the intervention did not alter the risk of labour complications overall, or specifically in terms of labour induction, failure to progress, emergency section or instrumented delivery. Women who had completed the intervention were significantly less likely to suffer postpartum haemorrhage (OR 0.451).

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The intervention had no impact upon the risk of delivery of babies prior to 37 weeks gestation (OR 0.78 [0.18-3.38]). Mean weight at birth did not differ between the two groups (non-intervention 3.61 ±0.60; intervention group 3.69± 0.59 kg). After delivery of the babies up to discharge from hospital, 75% of women in the intervention group were exclusively breastfeeding compared to 49.5% in the non-intervention group (OR for breastfeeding 3.068 [1.623-5.80] for intervention group compared to non-intervention). There was no difference

in terms of length of stay in hospital for either mothers or infants (non-intervention 2.18 ± 1.42 days; intervention 2.19 ± 1.52 days).

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Discussion

The Lincoln antenatal weight management intervention comprised a one-to-one programme involving pregnant women with specialist midwives or healthy lifestyle advisors. The health professionals delivered a programme of health education, dietary advice, recommendations on physical activity and monitored dietary changes made by the participants. The intervention aimed to achieve lower weight gain in a cohort of severely obese women at risk of excessive weight gain, and the adverse sequelae associated with obesity. The current analysis of the outcomes of the programme, indicates that women taking part in the intervention gained significantly less weight than those who did not. Although all women had a BMI of over 35 kg/m² at booking, the majority who took part in the programme gained less weight than the US Institute of Medicine (2009) guidance of 5-9kg for obese pregnant women (89.8% compared to 27.6% of non-intervention women). Associated with this, there was a marked reduction in the risk of pregnancy complications, specifically gestational hypertension and preeclampsia. Women who had taken part in the intervention were more likely to initiate breastfeeding, which was an additional benefit in this obese population, where breastfeeding rates were low.

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The benefits of limiting gestational weight gain in obese women are well-established and the existence of guidelines such as those issued by the US Institute of Medicine (2009) and the National Institute for Health and Clinical

Excellence (NICE) in the UK (NICE 2010) should provide the basis for routine monitoring of weight gain in the at-risk population. The literature, however, suggests that routine weight screening and advice to control weight gain is often lacking. A study in the UK found that 16% of a group of pregnant women did not have their weight taken at all during antenatal care and that although women wanted advice on weight gain they did not receive this from midwives or doctors (Brown & Avery, 2012). Experience is similar in the USA, where advice on weight gain is not the norm, even where that weight gain is routinely monitored (Phelan *et al.*, 2011; Stengel *et al.*, 2012). Obese and overweight women are often advised to gain more weight than the Institute of Medicine guidance due to a lack of knowledge among health practitioners (Herring *et al.*, 2010). Against a background of inconsistency in the monitoring of gestational weight gain and provision of advice on management of weight gain in obese women, it is important to understand the effectiveness of intervention strategies that may limit the obstetric risks associated with extreme overweight.

Thangaratinam *et al.*, (2012) reported the outcomes of a systematic review and meta-analysis of 44 randomised controlled trials examining weight management strategies in pregnancy. These strategies included interventions with a purely dietary focus, a focus on physical activity, or a mixed approach including diet and exercise. The meta-analysis showed that all interventions combined could limit gestational weight gain and were associated with lower risk of pre-eclampsia. Interventions that included only dietary change also reduced risk of gestational diabetes and hypertension. No interventions were found to impact upon the likelihood of labour induction or caesarean section. However, the majority of

studies included in the meta-analysis included women of all BMI classes and not just obese or severely obese women. Among studies that focused solely on the overweight and obese population the impact of intervention was often less than seen with the current study. Whilst Thornton et al., (2009) found similar outcomes to the present study, Rae et al., (2000) reported that a 30% restriction of maternal energy intake had only subtle effects on glucose homeostasis in pregnancy. Dietary counselling and exercise reduced the prevalence of excessive weight gain in the study of Hui et al, (2012) but did not impact upon gestational diabetes, the prevalence of large-for-gestational age or caesarean delivery rates. The LIMIT trial (Dodd et al., 2011, 2014) found that a researcher-led intervention based upon dietary advice and guidance on physical activity had no effect upon gestational weight gain or pregnancy complications. This trial recruited women of lower initial BMI (>25 kg/m²) than the present study (>35 kg/m²). Guelincx et al., (2010) reported that whilst education around lifestyle change altered eating patterns in pregnancy, it had no effect upon gestational weight gain or obstetric outcomes. The findings of the present study are therefore important as they show clear benefits associated with a 'mixed approach' intervention in severely obese women, consistent with the analysis of Gardner et al., (2011). The reduction in risk of hypertension (95%), preeclampsia (90%) and of complications overall (74%) was greater than reported in the Thangaratinam *et al.*, meta-analysis (pre-eclampsia reduced by 33%, gestational hypertension 70%).

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The women taking part in the intervention gained less weight than those who did not, but remained severely obese. In spite of this, their risk of pregnancy

complications was lower and this highlights that limiting weight gain in pregnancy that is complicated by severe obesity, is a worthwhile target for public health intervention. This can stand as a supplementary strategy to prepregnancy guidance that guide women towards attaining a healthier weight. There were strong relationships between weight gain and pregnancy complications and hypertensive conditions, but the lack of impact of lower weight gain upon diabetes or labour complications emphasises the continuing obesity of the women and the effect this has on metabolic health and the management of delivery.

Weight loss during pregnancy is not advised, but in approximately 21% of the women in the intervention group there was either no weight gain between booking and 36 weeks, or some degree of loss. There was no evidence of any negative impact of this loss either on maternal outcomes, or fetal outcomes. This is consistent with the meta-analysis of Thangaratinam $et\ al.$, (2012) who reported that interventions in pregnancy were safe with no evidence of small-for-gestational age or fetal death. In the current study, birthweights were not significantly different between women who gained weight in pregnancy and those who did not (gained weight 3.69 ± 0.56 kg, lost weight 3.38 ± 0.67 kg, P>0.05). Within the intervention group, there were no differences in risk of pregnancy complications (OR 0.94 [0.30-2.97] or labour complications (OR 0.81 [0.29-2.32], between women who lost weight and those who gained weight during pregnancy.

This brief paper does not report the findings of a randomised controlled trial and as such the limitations of the work must be acknowledged. All women with a BMI in excess of 35 kg/m² were invited to take part in the intervention but half (the non-intervention group chose not to do so. This means that the intervention group may have been more motivated to control their weight, representing a selection bias. It is unlikely however, that these women could have achieved the observed restriction of weight gain without the healthy lifestyle advice and monitoring. As such, the observed effects of the intervention must therefore be regarded as an effect of the intervention protocol combined with the selection bias. Given the one-to-one nature of the intervention, the personalised nature of the advice provided by the intervention team may have introduced some variability into the experience of the women on the programme. However, this study does provide an appropriate evaluation of putting weight management interventions into practice, using an individualised and patient-centred approach. Whilst a follow-up using a robust randomised design is now desirable, there were no systematic differences in the characteristics of the women in the two groups that could explain or confound the observed reduction in weight gain or benefits or benefits in terms of obstetric outcome. This evaluation was not designed to consider the way in which the intervention impacted upon the behaviour of the participants and no data was available on eating patterns, energy or nutrient intake or physical activity. Understanding the process underlying the success of the intervention is essential if the scheme is to have a wider application, with training for health professionals to deliver it in other locations.

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This study adds to the literature that supports the implementation of weight maintenance interventions during pregnancy as well as in the pre-pregnancy and post-partum periods. As described above, in the UK most of the guidance relating to weight management and reproduction is focused on pre-pregnancy and the need to attain a healthy weight in order to aid conception and to minimise complications during pregnancy (NICE 2010). It is recognised that weight gain during a pregnancy is a factor which determines the pre-pregnancy weight and weight gain trajectory for subsequent pregnancies, and so managing weight between conceptions is desirable. Walsh and colleagues (2007) showed that increasing BMI by 3 kg/m² in one pregnancy, even in women of healthy weight, doubled the risk of preeclampsia in a subsequent pregnancy, with that risk disappearing if the excess pregnancy weight could be lost. The success of the intervention in reducing gestational weight gain emphasises the fact that severely obese women are open to the idea of changing their diet and behaviour in order to achieve benefits for their health and the health of their babies, whilst pregnant (Wilkinson et al. 2014). Wider use of interventions to target pregnancy should be a priority for the future. To inform and optimise the development of such interventions further work is required to determine which elements of the intervention programme were most effective in achieving the outcomes, through qualitative evaluation of the experience of the women. Gardner et al., (2011) reported that whilst interventions focused on dietary change and physical activity can be effective in reducing gestational weight gain, too little emphasis has been given to evaluation of the psychological determinants of behaviour change. This makes it difficult to identify the processes by which weight change can be achieved. It would also be of interest to determine what happens to

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women in the post-partum period having completed an antenatal weight management programme. The intervention described in this paper followed women to 6 weeks post-partum, but as data was not available for the non-intervention group it is not possible to assess whether differences seen in pregnancy persisted.

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The intervention has been shown to be highly effective in limiting the weight gain of severely obese women during pregnancy, and was in fact most effective in women whose BMI at booking was over 40 kg/m². Unfortunately the nonintervention group in this study represents a large population of women, who when given the advice that excessive weight gain may be detrimental to their health during pregnancy and in terms of pregnancy outcome, chose not to engage with the service. The reasons for non-engagement were not explored in the current study but other work suggests that women decline to use antenatal weight management services due to lack of motivation, not wanting to focus on weight during pregnancy and a lack of time due to work commitments (Olander and Atkinson, 2013; Patel et al., 2013). These factors need to be considered in designing intervention programmes based upon the model described in this paper. Indeed, Heslehurst and colleagues (2014) suggest that the views of women on antenatal weight management services should be incorporated into the design of such services. Shaping the expectations of women at an early stage may influence uptake of services. Where positive outcomes for mother and child are given high emphasis over stressing the negative impact of not addressing weight management, engagement may be stronger (Gardner et al., 2012). In the

439	UPBEAT study, women who perceived the greatest benefits associated with		
440	healthy eating patterns, were those most likely to reduce unhealthy eating.		
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442	The efficacy of the intervention in limiting weight gain was complemented by a		
443	dramatic reduction in hypertensive disorders of pregnancy. If barriers to		
444	participation can be overcome in the morbidly obese population, targeted,		
445	personalised weight management intervention may therefore be a useful adjunct		
446	to routine antenatal care. Greater use of this approach to obesity management in		
447	pregnancy would be expected to have significant benefits for the health of		
448	women and their babies.		
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450	Acknowledgements and declaration of author interests		
451	The Bumps and Beyond intervention was a clinical service funded by Public		
452	Health Lincolnshire County Council. The authors, AM, SF, JP, SM, MAT and SLE		
453	have no conflicts of interest to declare.		
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635 Figure 1. Weight gain from booking to 36 weeks gestation, in groups 636 stratified by booking BMI. 637 Data are shown as mean ± standard deviation. * indicates significant difference 638 in weight gain comparing intervention group to non-intervention within same 639 quartile of booking BMI (P<0.05). § indicates significantly different to quartile 1 640 within intervention group (P<0.05). Q1 BMI 35-36.1 kg/m²; Q2 36.11-38.04 641 kg/m^2 ; Q3 38.05-40.25 kg/m^2 ; Q4 >40.25 kg/m^2 . 642 643 Figure 2. Weight gain in relation to complications in pregnancy and labour. 644 The total population was stratified by quartiles of pregnancy weight gain. Q1 645 <3.66 kg; Q2 3.66-8.25 kg; Q3 8.25-11.1 kg; Q4 >11.1 kg. Data are shown as 646 unadjusted odds ratios. * indicates statistically significant (lowest quartile is 647 reference).

Figure 1

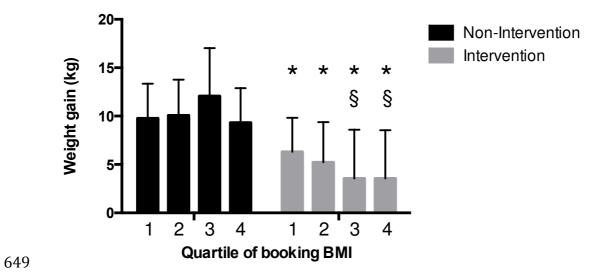
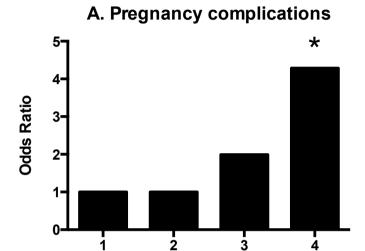
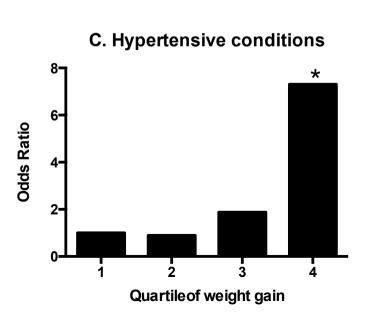


Figure 2



Quartile of weight gain





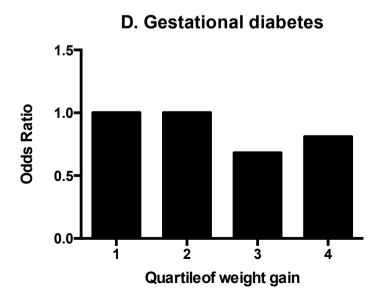


Table 1. Characteristics of the women

690

	Non-intervention Group (n=89)	Intervention Group (n=89)	P
Age (years)	27.3 ± 5.5	29.0 ± 5.8	0.0
Height (m)	1.65 ± 0.08	1.65 ± 0.06	0.8
Weight at booking (kg)	105.1 ± 11.5	107.8 ± 13.4	0.1
BMI at booking (kg/m²)	38.4 ± 3.2	39.4 ± 4.1	0.0
Primagravidae n (%)	36 (40.4)	32 (34.8)	0.3
Home owner n (%)	14 (15.7)	22 (24.7)	0.1
White ethnicity n (%)	86 (96.6)	86 (96.6)	1.0
Folate supplements n (%)	60 (67.4)	78 (84.7)	0.6
Vit. D supplements n (%)	51 (57.3)	79 (88.8)	0.0
Single mother n (%)	9 (12.0)	16 (17.4)	0.6
Married n (%)	28 (31.5)	27 (30.3)	8.0

688 <u>n (%)</u> 689 Frequency data were analysed by chi square test.

Table 2. Weight and body mass index at 36 weeks gestation

692				
693		Non-intervention	Intervention	P
694				
695	Weight (kg)	115.6 ± 12.5	112.4 ± 13.4	0.113
696	BMI (kg/m ²)	42.1 ± 3.4	41.1 ± 4.2	0.072
697	Weight gain (kg)	10.3 ± 4.4	4.5 ± 4.6	<0.001§

Data are shown as mean ± standard deviation. For n see Table 1. § indicates P

after adjustment for booking weight. Unadjusted P=0.012.

Table 3. Impact of the intervention upon complications during pregnancy and labour

703			-
704	Complications	Unadjusted OR (95% CI) ¹	Adjusted OR (95% CI) ^{1§}
705	Antenatal		
706	All complications	0.265 (0.142-0.497)	0.236 (0.121-0.461)
707	Gestational diabetes	1.139 (0.419-3.100)	1.082 (0.372-3.148)
708	Gestational hypertension	0.103 (0.034-0.307)	0.049 (0.011-0.220)
709	Pre-eclampsia	0.115 (0.014-0.940)	0.103 (0.011-0.901)
710	Musculo-skeletal disorders	1.0 (0.138-7.260)	1.183 (0.158-8.878)
711			
712	Labour		
713	All complications	1.112 (0.614-2.089)	1.115 (0.639-2.590)
714	Labour induction	1.219 (0.657-2.261)	1.018 (0.529-1.957)
715	Emergency CS	1.077 (0.519-2.209)	1.078 (0.529-2.219)
716	Instrumented delivery	1.265 (0.328-4.874)	1.598 (0.400-6.378)
717	Failure to progress	1.536 (0.418-5.641)	1.682 (0.877-25.125)
718	Post-partum haemorrhage	0.352 (0.279-1.094)	0.451 (0.211-0.963)
719			

⁷²⁰ ¹For all outcomes the non-intervention group is the reference group (OR=1.0). § adjusted for gravidae, parity, maternal age, ethnicity,

home ownership and marital status. NI- non-intervention; INT- intervention group.