Systematic review of weight management interventions after childbirth

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About the ScHARR Public Health Collaborating Centre

The School of Health and Related Research (ScHARR), in the Faculty of Medicine, Dentistry and Health, University of Sheffield, is a multidisciplinary research-led academic department with established strengths in health technology assessment, health services research, public health, medical statistics, information science, health economics, operational research and mathematical modelling, and qualitative research methods. It has close links with the NHS locally and nationally and an extensive programme of undergraduate and postgraduate teaching, with Masters courses in public health, health services research, health economics and decision modelling.

ScHARR is one of the two Public Health Collaborating Centres for the Centre for Public Health Excellence (CPHE) in the National Institute for Health and Clinical Excellence (NICE) established in May 2008. The Public Health Collaborating Centres work closely with colleagues in the Centre for Public Health Excellence to produce evidence reviews, economic appraisals, systematic reviews and other evidence based products to support the development of guidance by the public health advisory committees of NICE (the Public Health Interventions Advisory Committee (PHIAC) and Programme Development Groups).

Contribution of Authors

Josie Messina was the systematic review lead. Maxine Johnson, Fiona Campbell and Emma Everson-Hock were reviewers on the project. Louise Guillaume developed and undertook literature searches. Alejandra Duenas was lead modeller, and Andrew Rawdin was an additional economic modeller. Elizabeth Goyder and Jim Chilcott were the senior leads.

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Contents

Tables and figures

1. Glossary of terms

Body Fat Percentage: the percentage of total body weight that is comprised of fat (Concepts of Fitness and Wellness).

Body Mass Index: A key index for relating a person's body weight to their height. The body mass index (BMI) is a person's weight in kilograms (kg) divided by their height in meters (m) squared (kg/m^2). (Concepts of Fitness and Wellness)

Fat-free Mass: the mass (weight) of the body (muscle, bone, skin and organs) that is not fat

Gestational diabetes: Carbohydrate intolerance of varying severity which is diagnosed in pregnancy and may or may not resolve after pregnancy.

Metabolic equivalent (METs): a unit of energy expenditure, or metabolic cost, of physical activity. One MET is the rate of energy expenditure while sitting at rest (Fitness Glossary)

Physical activity is any force exerted by skeletal muscle that results in energy expenditure above resting level (Caspersen, Powell, & Christenson 1985). It includes the full range of human movement and can encompass everything from competitive sport and active hobbies to walking, cycling and the general activities involved in daily living (such as housework).

Physical activity: measured in terms of:

- the time it takes (duration)
- how often it occurs (frequency)
- its intensity (the rate of energy expenditure – or rate at which calories are burnt). The intensity of an activity is usually measured either in kcals per kg per minute or in METs (metabolic equivalents – multiples of resting metabolic rate). Depending on the intensity, the activity will be described as: moderate-intensity or vigorous-intensity. Moderate-intensity activities increase the heart and breathing rates but, at the same time, allow someone to have a normal conversation. An example is brisk walking.

Post Partum: the period after birth

List of Abbreviations

BMI: body mass index
GWG: gestational weight gain
Kcal: calorie, or kilocalorie
IOM: Institute of Medicine
LTPA: leisure time physical activity
NRS: non randomised studies
NA: not applicable
NR: not reported
OECD: Organisation for Economic Co-operation and Development
OR: odds ratio
RR: risk ratio
RCTs: randomised control trials

2. Executive summary

Effective weight management following childbirth may reduce the long term risks of heart disease, cancer, obesity and diabetes among childbearing women, as well as reduce the risk of entering future pregnancies overweight or obese (Gore et al. 2003). The National Institute for Health and Clinical Excellence has been asked by the Department of Health to develop public health guidance to promote weight management following childbirth.

2.1 Aims and objectives

The aim of this study was to systematically review the evidence for the effectiveness of weight management interventions targeted at women who have given birth within 2 years. A separate economic modelling paper will be presented at a later date following the findings of this review. The cost-effectiveness of interventions will be provided in that paper.

This systematic review of effectiveness of weight management interventions has addressed the following questions:

- What are the most effective dietary interventions for weight management after childbirth?
- What are the most effective physical activity interventions for weight management after childbirth?
- What are the most effective combined dietary and/or physical activity interventions for weight management after childbirth?
- What are the most effective interventions that may influence weight management after childbirth?
- What interventions are effective in avoiding incremental weight gain over successive pregnancies?
- What interventions are effective for weight management in women who are breast feeding?
- What are the most effective ways of measuring and monitoring weight in women after childbirth? Are there any adverse effects?

- What external factors influence the effectiveness of the intervention (such as content, delivery, setting, who is delivering the intervention, intensity, duration and target setting)?

- What internal factors influence the effectiveness, acceptability and feasibility of the intervention (such as participants age, socio-economic status, ethnicity, medical history, physical activity, breastfeeding status, attempts at weight management, weight or BMI at onset of pregnancy, number of previous pregnancies and/or children?

2.2 Methods

A search strategy was developed in consultation with the NICE team to identify relevant evidence in the area of weight management following childbirth. The search strategy had 6 sections:

- A targeted database search undertaken for the NICE Intervention Guidance on weight management in pregnancy

- Targeted database searches for evidence about weight management interventions after childbirth

- Targeted database searches for evidence linking breastfeeding and maternal weight management

- Keyword searches of relevant websites

- Searches for evidence for the cost effectiveness review and economic model

- Citation searching of papers included in the review as identified through database and website searches.

The search identified 4414 references which were sifted by 2 reviewers who agreed on the inclusion of 7 studies (RCTS n=5; NRS n=2). Studies were from OECD countries (Organisation for Economic Co-operation and Development) and included women who had given birth within the last 2 years.

Dietary interventions and/or physical activity interventions for weight management after childbirth and any intervention after childbirth that may impact on weight management have been included in this review. Interventions focussed on

assessments, monitoring, and support/advice for post partum weight management. Outcomes included in this review can be classed into 5 categories: weight related outcomes, diet and physical activity, breastfeeding, access to and use of services, harms of interventions. Quality assessments were verified by 2 reviewers, completed in consultation with the NICE team, and ratings based on the latest NICE methods manual (2008). Given the heterogeneity of the data and varying aspects of interventions, a narrative analysis was undertaken to compile evidence on the effectiveness of weight management interventions.

2.3 Results

A total of 7 studies have been included in this review. Five randomised control trials, all from the USA, had a total of 278 participants with an average age of 31.3 years. The average BMI of women at enrolment was 27.6 kg/m², and mean weight of 75 kg. All interventions included dietary, physical activity, and monitoring components for weight management, with some trials including extras such as advice, support and mentoring. Four out of the 5 trials were classified as '+' using the NICE methods manual (2008) and one trial was classed as '-' quality rating (O'Toole et al. 2003).

Two non-randomised studies from USA (Hawaii) and Finland were included in this review. A total of 105 participants with an average age of 31 years were examined as part of this study. The mean BMI at enrolment was lower in the NRS included in this review with an average across both studies of 23.8 kg/m². Interventions included a variety of components such as physical activity, advice, support and mentoring, monitoring. One study did not include a dietary component, while the other study had both physical activity and diet as part of their intervention. Both studies were classed as '-' quality rating.

Three out of 5 trials found that women in the intervention groups saw significant changes in weight during the course of the intervention period (Leermakers et al. 1998; McCrory et al. 1999; O'Toole et al. 2003). At follow up, none of the NRS found any significant changes in weight measures (Albright et al. 2009; Kinnunen et al. 2007). The effect of weight management on breast feeding outcomes was measured in 3 trials and found weight management interventions did not have a negative effect on breastfeeding outcomes (Dewey et al. 1994; McCrory et al. 1999 Lovelady et al. 2006), although overweight women had higher milk energy outputs, and leaner women saw a decrease in milk energy output (McCrory et al. 1999).

2.3.1 Evidence statements

For the purpose of this summary, the detailed findings of the reviewed studies have been summarised according to each research question. For some research questions, there are detailed evidence statements, and for others, questions could not be adequately answered given the small evidence base.

What are the most effective dietary interventions for weight management after childbirth?

Evidence statement 1

There is limited evidence from one US based RCT (McCrory et al., 1999 [+]) that dietary intervention alone (aiming for 35% energy deficit) from 12 weeks postpartum may help women across the BMI spectrum start to lose more weight after childbirth compared to usual care. However, the short length of this intervention (11 days) makes it difficult to draw conclusions on the effectiveness of the study. Four day weighed food records suggested that calorie intake was not lower in the intervention compared to the control arm of the trial. The setting of this study (US) makes it somewhat relevant to the UK.

What are the most effective physical activity interventions for weight management after childbirth?

Evidence statement 2

There is weak evidence from one USA (Hawaii) based NRS (Albright et al., 2009 [-]) that a physical activity intervention alone (focusing on counselling and support to improve self efficacy and self monitoring) from 30 weeks post partum may help women be more active after pregnancy. Although women in the intervention group were significantly more active after the 8 to 9 week programme than the control group, observed changes in BMI were not significant. The average BMI of participants in this study was in the healthy range at enrolment. The setting of this study limits its applicability to the UK.

What are the most effective <u>combined dietary and/or physical activity</u> interventions for weight management after childbirth?

What are the most effective interventions that may influence weight management after childbirth?

Evidence statement 3

Four out of 5 US based RCTs addressing diet and physical activity post partum found a significant reduction in total weight among women across the BMI spectrum in the intervention group compared to control (Leermakers et al. 1998 [+]; Lovelady et al., 2006 [+]; McCrory et al., 1999 [+]; O'Toole et al., 2003 [-]). Only one US based RCT found that total weight was not significantly lower in the intervention group compared to control (Dewey et al. 1994 [+]). Results did not appear to vary based on the start dates of intervention or the length of follow up.

Evidence statement 4

Four US based RCTs measured percent body fat (O'Toole et al., 2003 [-]; Lovelady et al. 2006 [+]; McCrory et al., 1999 [+]; Dewey et al. 1994 [+]). Of these, one reported significant decreases in body fat percentage between intervention and control (O'Toole et al., 2003 [-]). Two further trials observed larger reductions in percent body fat for intervention compared to control, but for one of these the P value was not reported (McCrory et al., 1999 [+]) and for another the difference was not significant at the 5% level (Lovelady et al. 2006 [+]). The reduction in the percent body fat in the trial by McCrory (1999 [+]) was accompanied by significant increases in fat free mass for intervention compared to control. Falls in percent fat mass did not differ between intervention and control in only one US based RCT (Dewey et al. 1994 [+]). Results did not appear to vary based on the start dates of intervention or the length of follow up.

Evidence statement 5

Two RCTs assessed post pregnancy weight retention. One US based RCT, among women who were on average overweight pre-pregnancy and postpartum, found that significantly more women returned to their pre-pregnancy weight than the control, and retained significantly less weight gained during pregnancy than the control (3.3kg compared to 6.3kg) (Leermakers et al. 1998 [+]). This finding was not replicated in the one poor quality NRS that also assessed weight retention (and waist

circumference) among Finish women with, on average, a healthy BMI (Kinnunen et al., 2007 [-]).

Evidence statement 6

In line with their results for weight loss, 3 RCTs from the USA found that intervention focusing on diet and exercise resulted in decreased calorie intake (Leermakers et al. 1998 [+]; Lovelady et al., 2006 [+]; O'Toole et al., 2003 [-]) and decreased consumption of unhealthy foods (Lovelady et al., 2006 [+]). Of these studies, one also found significant increase in energy expenditure between exercise groups (O'Toole et al., 2003 [-]) whereas another (Leermakers et al. 1998 [+]) found no significant difference in total energy expenditure between groups. Lovelady et al., 2006 [+]) did not report results for physical activity.

Evidence statement 7

In line with their results for weight loss and fat free mass, McCrory et al. (1999 [+]) reported significant increases in measures of physical activity and energy expenditure between intervention and control groups (McCrory et al., 1999 [+]) although no difference in calorie intake.

Evidence statement 8

The non significant results of Dewey and Kinnunen in relation to measures of weight may be explained by their findings that there was no difference in energy expenditure between groups (Dewey et al. 1994 [+]) or difference in physical activity levels and the quality of dietary intake (Kinnunen et al., 2007 [-]).

What interventions are effective in avoiding incremental weight gain over successive pregnancies?

Evidence statement 9

No evidence was identified which specifically assessed incremental weight gain over successive pregnancies.

What interventions are effective for weight management in women who are breast feeding?

Evidence statement 10

The results of one poor quality trial (O'Toole (2003) [-]) suggests that the effectiveness of a weight management intervention does not significantly differ between women who are breastfeeding and those who are not. While women were known to be breastfeeding to some extent in all other included studies bar 2 (not reported by Albright et al 2009 [-]; breastfeeding women excluded from Leermakers et al. 1998 [+]), they did not specifically investigate this issue.

Evidence statement 11

Energy expenditure through breastfeeding was not found to differ significantly between control and intervention groups in the 2 studies in which this was measured (Dewey et al. 1994 [+]; McCrory et al., 1999 [+]).

Evidence statement 12

The evidence suggests weight management interventions addressing diet and physical activity had little or no adverse effects on breastfeeding outcomes, including milk volume, infant intake and weight, time and frequency feeding (Dewey et al. 1994 [+]; McCrory et al., 1999 [+]). Milk protein was observed to decrease in one short US based trial (McCrory et al., 1999 [+]). Overweight women had higher milk energy outputs, and leaner women saw a decrease in milk energy output (McCrory et al. 1999).

What are the most effective ways of <u>measuring and monitoring</u> weight in women after childbirth? Are there any adverse effects?

Evidence statement 13

The one high quality trial which examined correlations between monitoring and weight loss (Leermakers et al 1998 [+])found that there was a significant correlation between number of self-monitoring records returned and weight loss ($r=0.50$, $P<0.005$). However, homework completion or telephone contact with research staff was not significantly correlated with weight loss. Women enrolled in this trial had an above average BMI bordering on obese classification at start of the intervention.

None of the included studies considered the effectiveness of monitoring alone.

Evidence statement 14

None of the identified studies reported that there were any adverse effects of measuring or monitoring as part of the intervention.

What external factors influence the effectiveness of the intervention (such as content, delivery, setting, who is delivering the intervention, intensity, duration and target setting)?

Evidence statement 15

Due to the variability between included studies, it remains unclear whether the delivery, content, setting, intensity and duration of interventions influenced effectiveness.

Evidence statement 16

The results of one poor quality RCT (O'Toole et al. 2003 [-]) suggests that that women who are supervised by a trained diet and exercise specialist may be more successful in their attempts to lose weight, decrease their calorie intake and increase their physical activity level than women who are self supervised.

Evidence statement 17

It remains unclear whether providing women with support and mentoring influences the effectiveness of a weight management intervention postpartum. Of the included studies, 2 trials (Leermakers et al (1998 [+]) and Lovelady et al. (2006 [+])) and one NRS (Kinnunen et al., 2007 [-]) provided support and mentoring, in addition to components on diet and physical activity.

Evidence statement 18

It remains unclear whether the length of intervention influences effectiveness. Both longer and shorter trials reported some positive results in terms of weight management outcomes. Included studies were 20 weeks in length on average, but varied from 11 days (McCrory et al. 1999 [+]) up to one year (O'Toole et al. 2003 [-]).

What internal factors influence the effectiveness, acceptability and feasibility of the intervention (such as participants age, socio-economic status, ethnicity, medical history, physical activity, breastfeeding status, attempts at weight management, weight or BMI at onset of pregnancy, number of previous pregnancies and/or children ?

Evidence statement 19

There is insufficient evidence to asses the influence of factors such as socioeconomic status and ethnicity on the effectiveness of interventions.

One NRS provided limited data in the analysis of subgroups: A USA Hawaiian based NRS by Albright et al. (2009) [-], found increases in physical activity by ethnic group, infant age, and parity were not significant and declines in perceived barriers to intervention and physical activity were not significant across ethnic groups or parity.

3. Introduction

3.1 Aims and objectives

The aim of this study was to systematically review the evidence for the effectiveness of weight management interventions targeted at women who have given birth within 2 years.

3.2 Research questions

Below are the overarching questions that have been addressed in this review:

- What are the most effective dietary interventions for weight management after childbirth?
- What are the most effective physical activity interventions for weight management after childbirth?
- What are the most effective combined dietary and/or physical activity interventions for weight management after childbirth?
- What are the most effective interventions that may influence weight management after childbirth?
- What interventions are effective in avoiding incremental weight gain over successive pregnancies?
- What interventions are effective for weight management in women who are breast feeding?
- What are the most effective ways of measuring and monitoring weight in women after childbirth? Are there any adverse effects?
- What external factors influence the effectiveness of the intervention (such as content, delivery, setting, who is delivering the intervention, intensity, duration and target setting)?
- What internal factors influence the effectiveness, acceptability and feasibility of the intervention (such as participants age, socio-economic status, ethnicity, medical history, physical activity, breastfeeding status, attempts at weight management, weight or BMI at onset of pregnancy, number of previous pregnancies and/or children?

4. Background

Fifty percent of women of childbearing age are either overweight (body mass index [BMI] 24.9–29.9 kg/m^2) or obese (BMI >29.9 kg/m^2) (The Information Centre 2008). The Confidential Enquiry into Maternal and Child Health (2007) found that over half of mothers who died during pregnancy, childbirth or within 42 days of childbirth were either overweight or obese (Confidential Enquiry into Maternal and Child Health 2007). Available scientific evidence suggests pre-pregnancy weight and BMI are independent predictors of many adverse outcomes in pregnancy and in the post partum period (IOM weight gain during pregnancy 2009). These negative effects of maternal obesity may also continue into the offspring. Reilly et al (2005) found that maternal obesity was a significant risk factor for childhood obesity.

The NICE obesity guideline (2006) identified the postnatal period as a vulnerable life stage for weight gain. The more weight gained during pregnancy, the more likely that it may be retained postpartum. In a study with women from multiple racial and ethnic groups, Gunderson et al (2001) reported that average weight gain at 2 years postpartum was around 4.4 lbs. for underweight and normal-weight women, based on pre-pregnancy BMI, and about 8.8 lbs. for overweight and obese women. There are also inequalities in weight retention. Parker and Abrams (1993) found that compared with white women, black women were more likely to retain 20 lbs at 10 to 18 months postpartum. Olson et al. (2003) also reported that lower income women who gained more than the recommended amount of weight by the American Institute of Medicine (1990) were likely to have retained more than 10 lbs. when compared with women with higher incomes.

The ScHARR review of weight management in pregnancy (considered by PHIAC October 2009), included 2 RCTs (Wolff et al 2008 and Polley et al 2002) and 3 NRS (Claesson et al. 2008; Olson et al. 2003; Gray-Donald et al. 2000) which reported postpartum weight measurements. Of the included trials, one (Wolff et al 2008) reported that intervention groups retained 6.9 kg less weight than control at 4 weeks postpartum (p. 0.003), whereas the other found that women with normal weight retained less weight than controls at 8 weeks postpartum but this was not the case for overweight women (differences non significant) (Polley et al. 2002). Two out of the 3 included NRS found that intervention groups retained signifcantly less weight than controls postpartum (Claesson et al. 2008; Olson et al. 2003), while one NRS found no significant difference between groups postpartum (Gray-Donald et al. 2000).

Some researchers have argued that the postpartum transition period may act as a teachable moment to promote weight loss since women may want to lose excess weight gained during pregnancy, and the weight lost naturally after birth may act as a motivator and positive reinforcement for continued weight loss (Ostbye et al. 2008). According to Peterson et al. (2002) the post partum period provides a window of opportunity for behaviour modification, although the authors argue that effectiveness of interventions is dependant upon how well social contexts and other barriers and constraints are addressed within the intervention.

The key risk factors for excess weight gain after pregnancy which were fairly consistent across studies were high pre-pregnancy weight, high pre-pregnancy BMI, high gestational weight gain and parity (Gunderson et al. 2001). Studies have also indicated a range of factors for (low) postpartum weight retention, which included high levels of exercise, low food intake, still breastfeeding at a year postpartum, low gestational weight gain, and extremes of maternal age (Olson et al 2003). In a study by Polley et al. (2002), weight retention post partum was strongly correlated with weight gain during pregnancy. Similarly, a study of young African American girls found that post partum weight retention was significantly higher in control groups who did not receive any assistance with weight management during or after pregnancy (Betchtel-Blackwell et al. 2002).

According to NICE postnatal guidelines (2006) fatigue, backache, and other mental health issues are some obstacles that women face during the postnatal period while caring for themselves, their new baby, and their families. Women need guidance from professionals on postnatal care to promote well-being after childbirth (NICE postnatal guidance, 2006). This is especially true when the stress of a new lifestyle after the birth of a baby may lead to poor diet, lack of exercise, fatigue, depression, and inability to cope with the pressure of new demands (Peterson et al. 2002; Whelan et al 2002). This may be the case for a first baby, but also when the constant demands of care for a new baby are additional to caring for another child or children (Hewison and Dowswell, 1994). In addition, following the birth of their baby, mothers may resume health behaviours modified during pregnancy such as smoking and drinking alcohol, which may impact on post natal weight. Research by Gunderson et al. (2008) highlights an interesting finding to show that lack of sleep is linked to obesity and other adverse health effects. According to this research, sleeping 5 hours or less at 6 months post partum was associated with retaining 5 or more kilograms from one year after birth (Gunderson et al. 2008).

The post natal period is also, for many women, an intrapartum or pre-conceptual period for their next baby. A long term study by Bobrow et al (2009), found that BMI increased significantly in women following the birth of each child. Villamor & Cnattingius (2006) reported the impact of inter-pregnancy weight change over an average of 2 years between first and second pregnancy among a large (150,000) cohort of Swedish women. The results suggest that a gain of 1-2 BMI units between pregnancies would increase the risk of gestational hypertension, gestational diabetes, or large for gestational age birth by an average of 20-40% in the next pregnancy and further linear increase would follow weight gain. A gain of 3 or more BMI points was significantly associated with increased risk of stillbirth and that this association was independent of obesity related diseases in pregnancy such as pre-eclampsia, gestational hypertension and diabetes.

The Cochrane Collaboration recently completed a review on the effectiveness of diet and exercise interventions for post partum women and found that diet or diet and exercise during the post partum period assist women with weight management after childbirth (Amorim et al. 2007). According to this review, women who combined both diet and exercise together had significant moderate weight loss when compared to controls (Amorim et al. 2007). Exercise alone was effective in increasing a women's cardiovascular fitness, but a diet and exercise combination are needed for significant weight reductions.

According to recent Institute of Medicine guidelines on weight gain in pregnancy (2009), overweight and obesity rates are rising and more women are entering pregnancy obese, and this has an impact on maternal and child health (refer to weight management in pregnancy review for more information regarding this topic). Weight management prior to, during, and after childbirth has an impact on breastfeeding outcomes (IOM weight gain during pregnancy 2009). According to the IOM guidelines (2009), women who gained more than the recommended weight ranges set out in the recent guidance may experience an adverse outcome of unsuccessful breastfeeding attempts.

NICE has issued guidance for the provision of initiatives that will increase breastfeeding after childbirth stating 'all maternity care providers should implement an externally evaluated, structured programme that encourages breastfeeding' (NICE postnatal care guidance 2006 and Maternal and Child Nutrition 2008). The Department of Health's Pregnancy book (2009) stressed the importance of maintaining a balanced diet, keeping fit and healthy, and also encourages new

mothers to breastfeed their babies. While breastfeeding has many positive benefits, the role of breastfeeding in post partum weight management is unclear; although some studies have found that breastfeeding has had a positive impact on weight status of post partum women. Research by Bobrow et al. (2009) found that women who breastfeed their infants had lower BMIs than women who did not breastfeed. Dewey et al. (1993) also reports that women who breastfeed for a duration of at least 6 months experienced enhanced weight loss compared to women who breastfeed for less than 3 months. In a cross-sectional cohort study of 2516 parous midlife women, increased duration of lactation was associated with lower odds of prevalence of metabolic syndrome (Ram et al. 2006).

The 1991 Dietary Reference Values (COMA 1991) estimates that breastfeeding women require an additional 240 to 570 calories when breastfeeding depending on their stage and exclusivity of feeding. The Scientific Advisory Committee on Nutrition (SACN) are currently considering population average energy requirements, including those for women who are pregnant or breastfeeding (see background briefing paper).

According to the Institute of Medicine, post partum weight loss is variable across women, and some women may lose or even gain weight during lactation (Institute of Medicine (IOM) 1991).The IOM's nutrition during lactation (1991) guide suggests lactating women who maintain a healthy diet may lose 1.3-1.6 kg per month during months 4-6 during lactation and will continue to lose weight after that time period but at a slower rate. Results of a review by Butte et al. (1998) reveal inconsistent evidence on the effects of breastfeeding and weight management during the post partum period.

New mothers may choose to engage in physical activity while breastfeeding. According to a review by Amorim et al. (2007) there were no adverse effects of weight management strategies on milk volume and plasma prolactin concentrations; however, data was limited in this area.

5. Methods

5.1 Methods for identification of evidence

This review aimed to systematically examine evidence for the effectiveness of weight management interventions after childbirth. The research team, in collaboration with NICE, designed a search strategy suitable for this purpose. The search strategy had 6 sections:

- A targeted database search undertaken for the NICE Intervention Guidance on weight management in pregnancy
- Targeted database searches for evidence about weight management interventions after childbirth
- Targeted database searches for evidence linking breastfeeding and maternal weight management
- Keyword searches of relevant websites
- Searches for evidence for the cost effectiveness review and economic model
- Citation searching of papers included in the review as identified through database and website searches.

5.1.1 Search Strategy

A systematic database search was undertaken for the Intervention Guidance on dietary interventions and physical activity interventions for weight management in pregnancy. A sample Medline search strategy is available in Appendix 1. This was a large, systematic search resulting in 5857 references. Although this search was targeted at pre-natal and antenatal weight management, many of the terms used in this search would remain the same in a systematic search undertaken for weight management interventions after childbirth. Therefore, the Reference Manager library of references was re-sifted by the systematic reviewers in order to identify relevant evidence for this review.

In addition, targeted database searches using terms for post pregnancy, post partum and postnatal (as opposed to antenatal/pregnancy) were undertaken. These searches were intentionally specific, in order to limit the number of redundant records to be sifted. A sample Medline search strategy and a list of databases searched are available in Appendix 1.

In addition to the general search, a targeted database search on the relationship between breastfeeding and exercise or diet was undertaken. Again the search strategy was specific, in order to minimise the number of redundant records to be sifted. A sample Medline search strategy and list of databases searched are available in Appendix 1.

Searches for the cost-effectiveness review were undertaken at the same time as the effectiveness searches, using population terms only, with the same date restrictions in NHS EED via Wiley and Econlit via OVID SP. Where additional information requirements were identified, targeted searches were undertaken for model parameters.

A search of key websites for relevant evidence and background evidence using a number of terms was undertaken. Further details are available in the Appendix.

Citation searching was undertaken in Web of Science Cited Reference Search and Google Scholar for included papers identified through the database searches. In addition the systematic reviewers searched reference lists of included papers and reference lists of relevant systematic reviews retrieved through database searches

The search results for all searches (systematic and additional) were imported into Reference Manager and de-duplicated. Following this, the results were sifted by the systematic reviewers and economic modeller (as appropriate).

5.2 Study selection

The sifting process, completed by 3 reviewers, identified 4414 citations. Relevant papers were retrieved and assessed and those fulfilling the criteria were included. During the process, all decisions were checked by a second reviewer with difference resolved by discussion. The following inclusion and exclusion criteria were used in selecting studies.

Inclusion criteria

- Women, (with a BMI greater than 18.5 kg/m^2) up to at least 2 years following the birth of their baby, both those who are breastfeeding and those who are not breastfeeding

- Women (with a BMI greater than 18.5 kg/m^2), up to at least two years following the birth of their baby who are planning a subsequent pregnancy.

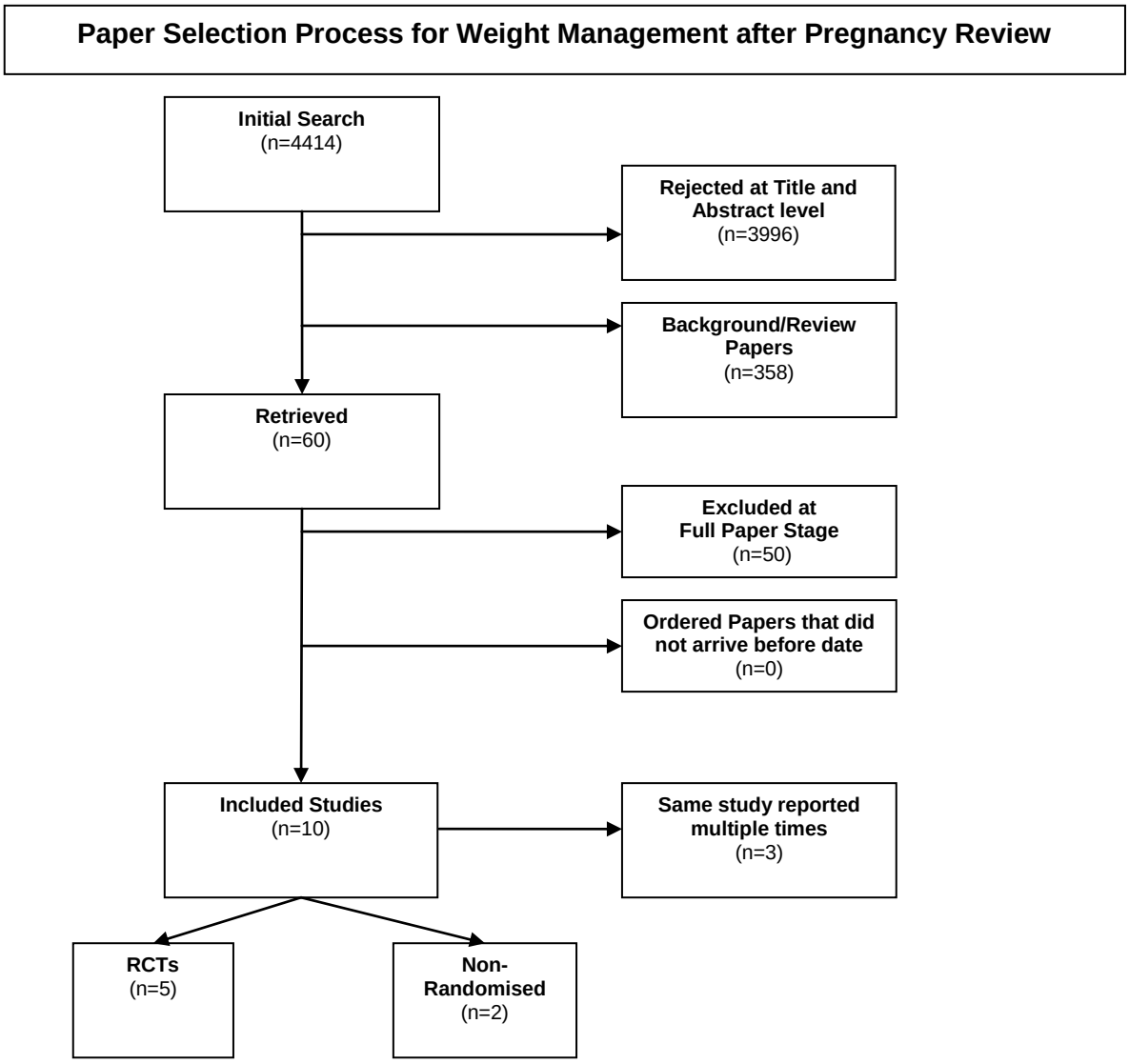
- With a particular focus on women from vulnerable groups such as women who had been diagnosed with gestational diabetes and those with a higher pre-pregnancy BMI (> 25 kg/m²) who are at risk of excess weight retention following pregnancy.

Exclusion criteria

- Women who have been diagnosed with or who are receiving clinical treatment for an existing condition such as type I or type II diabetes or clinically diagnosed with post natal depression.
- Women who are underweight (BMI <18.5 kg/m²) after childbirth.
- Women who have never been pregnant or given birth
- Women more than 2 years after childbirth
- Interventions targeted at pregnant women, not women who have given birth in the last two years
- Clinical interventions (such as surgery or drug treatment for obesity).
- Complementary therapies, treatments or practices (for example, hypnotherapy or acupuncture).
- Non-English papers
- Evidence not originating in economically developed countries (as categorised by membership of the Organisation for Economic Co-operation and Development)

Figure 1 illustrates the final paper selection process for this weight management review following childbirth

Figure 1: Flow chart of paper selection



5.3 Types of studies

- Randomised controlled trials examining weight management interventions for post partum women
- Non-randomised studies examining weight management interventions for post partum women
- Observational studies were screened for interventions during the post partum; however, no studies met the inclusion criteria
- Qualitative studies have been excluded from this review as they where outside of the scope for this project.

5.4 Types of participants

Included papers studied women who have given birth within two years, women who have given birth within two years and planning a subsequent pregnancy with no pre-existing medical complications relating to pregnancy or the post partum period that may affect weight management. No studies identified sub-groups by weight status: normal weight, overweight or obese.

5.5 Types of interventions

Dietary interventions and/ or physical activity interventions for weight management after childbirth and any intervention after childbirth that may impact on weight management have been included in this review. Interventions focussed on assessments, monitoring, and support/advice for post partum weight management.

5.6 Types of outcomes

Weight-related outcomes:

- Changes in body weight using measures such as BMI, self reported weight gain, professional weight measurement
- Post partum weight retention
- Fat-free mass
- Body fat percentage

Dietary, physical activity, and support outcomes:

- Changes in dietary intake
- Changes in levels of physical activity
- Energy expenditure
- Support and mentoring for women attempting to manage their weight post partum

Breastfeeding outcomes:

- Energy expenditure through breastfeeding
- Milk volume

- Uptake and duration of breastfeeding

Access to services and harms of interventions:

- Harms associated with uptake of the intervention
- Access and use of services related to weight management

5.7 Criteria for appraising applicability

Two reviewers screened the titles of all papers identified by the search strategy. Criteria for inclusion and exclusion were applied to determine the relevance of each paper. During this process, the research team would discuss any discrepancies or difficulties with the paper screening process. Once the initial sift was completed, each reviewer checked the other reviewer's exclusions to ensure no relevant studies were missed. Papers were coded into 3 categories in reference manager software. Codes were established for rejected papers, accepted papers, and background material.

Full text copies of all potentially relevant papers were retrieved. A data extraction form was developed in consultation with clinical advisors and piloted. Data on quality, characteristics of participants, intervention and relevant outcomes were independently extracted by one reviewer and checked by the second reviewer.

5.7.1 Quality assessment

One reviewer assessed the quality of the RCTs and nonrandomised studies using a methodology checklist (National Institute for Health and Clinical Excellence, 2008) assessing population bias, method of allocation, outcomes, analyses, and internal and external validity (appendix 2). Another reviewer checked the quality assessments and any discrepancies were discussed and resolved. Four RCTs were deemed reasonable quality (+), with some of the criteria for quality being fulfilled, and criteria that have not been fulfilled are unlikely to affect conclusions (NICE methods manual 2008) (Dewey et al. 1994; Leermakers et al. 1998; Lovelady et al. 2006; McCrory et al. 1999). The O'Toole et al. (2003 RCT), and 2 NRS studies (Albright et al. 2009; Kinnunen et al. 2007) were classed as (-), with few criteria fulfilled, and conclusions are likely to alter (NICE methods manual 2008). See appendix 2.

5.8 Data analysis

RCTs and non-randomised studies (NRS) have been analysed using a narrative approach. Meta-analysis and the use of forest plots was not appropriate for the studies included in this review since there was a high degree of heterogeneity across studies, making it difficult to group studies in a meta-analysis without introducing bias.

6. Results

The findings in this section of the review will be presented by study design. An analysis of RCTs and NRS will be provided. A total of 4414 papers were reviewed at title and abstract level, and 60 papers were retrieved in full text format. Of those 60 papers, 50 were rejected after close scrutiny by the research team, and documented in the list of exclude studies. The main reasons for excluding papers can be found in appendix 3. A total of 7 studies have been included in this review (RCTs n=5; NRS n=2). An additional 3 papers have been identified as duplicates of included studies (Aittasalo et al 2008; Loveday et al 2000, Lovelady et al 2001). See appendix 4 for included studies list. These papers have been examined as part of this review but not counted as separate studies since they report the same data as those studies already included in the analysis. Also, studies reviewed in the Amorim et al. (2007) review have been considered individually as part of this systematic review, with the exception of one study that did not meet our inclusion criteria since women had depression.

Five studies did not report power (Dewey et al. 1994; Leermakers et al. 1996; McCory et al. 1999; Albright et al. 2009; Kinnunen et al. 2007), while the Lovelady et al. (2006) trial suggested decreases in weight, body fat, fat intake, protein intake, carbohydrates, and energy are powered at 100%; however, no further details were given in the paper. The O'Toole paper, on the other hand, suggested that the sample size of 40 was too small for associations.

6.1 RCTs

6.1.1 Summary of setting, recruitment, and participants

Five RCTs were included and the number of participants in randomised control trials ranged from 33 to 90 with a total of 278. All trials were conducted in USA. Two trials (Dewey et al. 1994; McCrory et al. 1999) recruited through letters to new parents and physician's offices. One study recruited through hospitals soon after birth (Leermakers et al 1998). Advertisements were used in two studies as a method of recruitment (Lovelady et al. 2006; O'Toole et al. 2003). It is important to note that advertisements, letters, and direct recruitment into trials from hospital may be a source of selection bias in studies since patients who may already to active or are interested in diet and physical activity may be inclined to join the trial.

Baseline characteristics of participants in randomised controlled trials are summarised in this section. The mean age of the participants ranged from to 31 to

32 years, with a mean of 31.3 years. Three studies reported previous pregnancies with an average of 2 (Dewey et al. 1994; Leermakers et al 1998; O'Toole et al. 2003). One study reported parity with an average of 37% of women in their sample primiparous (McCrory et al. 1999). Lovelady et al. (2006) study did not report parity.

The mean pre-pregnancy BMI ranged from 25.3 to 29.8 kg/m² with an average of 27.6 kg/m² and was measured in 2 studies. (Leermakers et al 1998; O'Toole et al. 2003). The average pre-pregnancy weight ranged from 61.4 to 68.4 kg, with a mean of 65.3 across 3 studies (Dewey et al. 1994; Leermakers et al 1998; McCrory et al. 1999). A recent systematic review published by Connor-Gorber et al. (2007) found that people tend to under-estimate weight and BMI, but over-estimate height. Thus, self report measures of pre-pregnancy weight and height should be interpreted with caution in this review; however, all post partum weight measures during trials were taken by the research team at baseline and follow up to reduce bias. The mean BMI at enrolment was reported in 3 studies and ranged from 25.2 to 29.8 kg/m² with an average of 27.6 kg/m² (Leermakers et al 1998; Lovelady et al. 2006; McCrory et al. 1999). The average weight at study enrolment ranged from 67.2 to 82 kg, with a mean of 75 kg across all studies. Total gestational weight gained was reported in 3 studies with a range from 15.2 to 18.6 kg. The average weight gained during pregnancies was 16.9 kg (Dewey et al. 1994; Leermakers et al 1998; McCrory et al. 1999).

The average weeks postpartum at enrolment was measured in all studies with a mean of 13.7 weeks. In 3 studies, all of the women breastfed their babies (Dewey et al. 1994; Lovelady et al. 2006; McCrory et al. 1999). In the O'Toole et al. study (2003), 57% of women breastfed, while no women were breastfeeding in the Leermakers et al. study (1998). Educational attainment was not reported in 2 studies (Lovelady et al. 2006; O'Toole et al. 2003), and no studies reported socio-economic status.

Two studies reported educational attainment, measured by number of years of formal education, with a mean of 16.5 years (Dewey et al. 1994; McCrory et al. 1999). One study reported that 17.1 percent of participants having a high school degree (Leermakers et al 1998). Three studies reported ethnicity with 87 percent of samples classified as Caucasian (Dewey et al. 1994; Leermakers et al 1998; McCrory et al. 1999). Marital status was only reported in the Leermakers et al. study (1998) with 86.6 percent of the sample being married. Groups were comparable at baseline in 2 studies (Dewey et al. 1994; McCrory et al. 1999). One study's sample was not

comparable at baseline (Leermakers et al 1998), while the other did not report comparability (Lovelady et al. 2006)

6.1.2 Description of Interventions

Interventions varied and were complex as they offered various components for weight management following pregnancy. See Table 1 for details on interventions. Diet and physical activity were major components in all studies reviewed. Women were given general instructions to be independently moderately active, as well as attend exercise classes, so this gives the mother some flexibility and less reliance on childcare. Activities such as walking could be an activity which could involve mother and infant. One trial offered childcare for participants of their study with women in the two arms of the intervention given 46 hours of childcare, and the control allocated less than 28 hours (McCrory et al. 1999). Advice about how to manage weight through diet, exercise, and other means was offered in four trials (Leermakers et al 1998; Lovelady et al. 2006; McCrory et al. 1999; O'Toole et al. 2003). Counselling, support, and mentoring were offered in two studies (Leermakers et al 1998; Lovelady et al. 2006). All studies monitored weight status and program progress of post partum women. Measurements were made at baseline, mid-point, and end-point in 2 studies (Dewey et al. 1994; O'Toole et al. 2003), while the remaining studies included their measurements and monitoring data for baseline and end-points only (Leermakers et al 1998; Lovelady et al. 2006; McCrory et al. 1999). The average weeks postpartum at study enrolment was 13.7 weeks, with a range of 4 to 32.8 weeks. The average length of interventions among the RCTs was 19.9 weeks, with a range from 1.6 to 52 weeks. Evidence tables in appendix 5 provide the details of each intervention with specific information on content, delivery, duration, and assessment.

Table 1: RCT intervention components

	Intervention Component				
Study	Physical Activity	Diet	Advice	Support/ mentoring	Monitoring
Dewey, 1994	✓	✓	x	x	✓
Leermakers, 1998	✓	✓	✓	✓	✓
Lovelady, 2006	✓	✓	✓	✓	✓
McCrory, 1999	✓	✓	✓	x	✓
O'Toole, 2003	✓	✓	✓	x	✓

6.2 NRS

6.2.1 Summary of setting, recruitment, and participants

Two NRS were included and the number of participants in randomised control trials ranged from 20 to 85 with a total of 105. One trial was conducted in the USA Hawaii (Albright et al. 2001) and one in Finland (Kinnunen et al. 2007). Both trials recruited from organizations and health care systems.

Baseline characteristics of participants in non-randomised studies are listed in (appendix 5.2). The mean age of the participants was 31 years. Parity was reported in both studies with one study having 50 percent of sample classified as primiparous (Albright et al. 2001), and one with 100 percent primiparous (Kinnunen et al. 2007). Pre-pregnancy weight was not reported in either trial; however, mean BMI reported in one study at 22.4 kg/m² (Kinnunen et al. 2007). Only BMI, not weight, was reported in both trials, with a mean of 23.8 kg/m². The average weight at study enrolment was only reported in one study as 66.1 kg, and weight retained was 15.8 kg (Kinnunen et al. 2007). The average weeks postpartum at enrolment was measured in all studies with a mean of 19 weeks. Breastfeeding was only reported in one study but exact figures were not available (Kinnunen et al. 2007). In the Albright et al. (2009) study women had 16.8 years of formal education, and 45% worked full or part-time. In the Kinnunen et al. study (2007), 47% of the sample had a basic or secondary education. Ethnicity was only reported in one study, and 50 % of the participants were classified as Caucasian (Albright et al. 2001). Marital status was only reported in Albright et al. (2009) with 95 percent of the sample declared as married. Groups were comparable at baseline in both studies.

6.2.2 Description of Interventions

Interventions varied and were complex as they offered various components for weight management following pregnancy. Physical activity was a component in both studies; however dietary interventions were not part of the Albright et al. (2009) study. As was the case with physical activity advice in the RCTs, the NRS interventions were also flexible in the nature, duration, and physical activity type allowing mothers to choose an activity that suited their lifestyle and childcare needs. Advice about how to mange weight during the post partum period was offered in both studies. Counselling, support, and mentoring was offered in two studies. All studies monitored weight status and program progress of post partum women. Evidence tables in appendix 5 provide the details of each intervention with specific information

on content, delivery, duration, and assessment. The average weeks postpartum at study enrolment within the 2 NRS was 19 weeks. The average length of interventions among the NRS was 24.5 weeks.

Table 2: Non-randomised intervention components

	Intervention Component				
Study	Physical Activity	Diet	Advice	Support/ mentoring	Monitoring
Albright, 2009	✓	x	✓	✓	✓
Kinnunen, 2007	✓	✓	✓	✓	✓

6.3 Weight status outcomes

6.3.1 RCT weight outcomes

Weight measurements were made by members of the research team and reported in all studies. All trials contained components of diet and physical activity interventions. Weights were measured at baseline and endpoints for all studies, and a mid-point in two studies (Dewey et al. 1994; Leermakers et al. 1998). In the McCrory et al (1999) trial, 3 arms of the intervention were offered: diet alone (I1), diet plus exercise (I2), and standard care (C). In the O'Toole et al. trial (2003), the study arms consisted of a structured and self-directed physical activity and dietary intervention.

Table 3: RCT total weight

Study	**N**	**Baseline (wks PP)**	**Duration (wks)**	**End-point (wks)**	**Weight kg (s.d)**		**P-value**
					Baseline	End point	
Dewey, 1994	33	6.5	12	18-20	I: 67.3 (10.2) C:67.0 (7.6)	I: 65.7 (10.7) C: 65.4 (8.3)	Not significant
Leermakers 1998	90	32.8	24	24	NR	**Weight lost** I: 7.8 (4.5) C: 4.9 (5.4)	0.03***
Lovelady, 2006	48	4	10	14	I: 75.9 (9.8) C: 77.2 (8.3)	I: 71.0 (9.2) C: 76.4 (8.9)	Total weight was not significant Weight loss was significant (p<0.001)
McCrory, 1999	67	12	1.6	11 days after baseline	I1: 68.3 (10.2) I2: 69.0 (12.8) C: 68.5 (8.5)	I1: 66.4 (9.8) I2: 67.8 (12.7) C: 68.3 (8.6)	<0.0001 *
O'Toole, 2003	40	13	52 (1 year) (12 wks intense)	52 (1 year)	I: 78.6 (1.5) C: 85.4 (3.5)	I: 71.3 (2.2) C: 84.1 (4.3)	Follow up p<0.05

* Weight loss in the control group was significantly different from that in the diet (I1) and diet + exercise groups (I2)
** not significant.
*** Still significant after intention to treat analysis (p <0.004). After adjusting for age and marital status (p<0.04)

Three studies found statistically significant differences in total weight between the intervention and control groups (Leermakers et al. 1998; McCrory et al. 1998; O'Toole et al. 2003). The O'Toole et al. (2003) trial had the longest follow-up (1 year), with 12 weeks of intense dietary and physical activity components. The McCrory et al. (1999) study was the shortest trial with a 10-12 day baseline period, and an 11 day intervention following baseline. One trial with diet and exercise components saw modest changes in total weight over the intervention period, although these changes were not significant (Lovelady et al. 2006). Statistical significance was found in the Lovelady et al. (2006) trial in terms of weight lost between groups, with the intervention group losing 4.8 kg versus 0.8 in the control ($p<0.001$). BMI was also measured in the Lovelady et al. (2006) trial with BMI at baseline in both groups at 27.8, then 26 in the intervention and 27.6 in control at 14 weeks post partum follow up (p value NR).

One trial provided data on weight retention after pregnancy (Leermakers et al. 1998). In this trial, the percentage of women returning to or lower than their pre-pregnancy weight was 27% in the intervention and 7% in the control using an intention to treat approach ($p<0.04$). A stepwise regression analysis showed that a women's pre-treatment weight was the strongest predictor of how close a women came to returning to her pre-pregnancy weight ($p<0.001$). From subjects who provided follow-up data, women in the intervention lost 79% of their retained pregnancy weight, while women in the control lost significantly less with only 44% of their weight lost (p 0.01) (Leermakers et al. 1998). The mean weight retained at follow-up for women who provided data was 3.3 kg in the intervention, and significantly more than the weight retained by the control group (6.3kg, p 0.05).

6.3.2 Body fat percentage and fat-free mass

Body fat percentage was measured in four studies (Dewey et al. 1994; Lovelady et al. 2006; McCrory et al. 1998; O'Toole et al. 2003). See table 4.

Table 4: RCT Body fat percentage

Study	N	Body Fat Percentage kg (s.d)		P-value
		Baseline	End point	
Dewey, 1994	33	I: 31.5 (5.6) C:31.1 (5.1)	I: 30.0 (6.3) C: 29.4 (6.1)	Not significant
Leermakers 1998	90	NR	NR	-
Lovelady, 2006	48	I: 33.7 (3.4) C: 32.9 (4.1)	I: 30.3 (2.9) C: 32.7 (4.5)	Not significant- total body fat Fat mass loss (p<0.001)
McCrory, 1999	67	I1: 32.5 (6.2) I2: 32.9 (6.5) C: 32.0 (7.0)	I1: 31.6 (6.2) I2: 31.4 (6.7) C: 31.5 (6.9)	NR, biggest change in diet + exercise group
O'Toole, 2003	40	I: 41.3 (1.0) C: 45.8 (1.8)	I: 35.3 (1.9) C: 44.3 (2.3)	0.05

Changes in body fat percentage were non-significant in two trials (Dewey et al. 1994; Lovelady et al. 2006). McCrory et al. (1999) reported significant time-by-group interaction for change in body fat percentage ($p<0.05$). Biggest decreases in body fat percentage were found in the diet and exercise group (-2.3%), followed by the diet group (-1.3%), and finally, the control group (-1.2%). The McCrory et al. (1999) trial was the only study to report fat free mass. Fat-free mass was reduced by 0.7 kg in the diet group, but increased by 0.1 and 0.2 kg in the diet and exercise and control groups, respectively (p 0.003).

6.3.3 NRS weight outcomes

Total weight was only measured in one study (Kinnunen et al. 2007). The Albright et al. (2007) study was not designed for weight loss, thus weight measures were not reported; however, BMI was measured but no actual figures were reported in the paper.

Table 5: NRS total weight

Study	N	Baseline (wks PP)	Duration (wks)	End-point (wks)	Weight kg (s.d)		P-value
					Baseline	End point	
Albright, 2009	20	30	8-9	8-9	NR	NR (narrative BMI)	(BMI change Not significant)
Kinnunen, 2007	85	8	43 wks PP	43 wks PP	I: 67.1 (11.1) C: 64.7 (7.8)	I: 65 (NR) * C: 62 (NR)	Not significant

* Numbers extracted from graph, not a precise figure, estimate only

Total weight measure in the NRS was inconclusive since one study did not report total weight outcomes in their analysis (Albright et al. 2009). The only record of weight-related measures was a narrative discussion of non-significant changes in BMI over the 2 month period. One study reported changes in weight status between groups, although these changes were not large enough to reach statistical significance (Kinnunen et al. 2007). According to the Kinnunen et al. (2007) study, 50% of the intervention group returned to their pre-pregnancy weight by 10 months with a dietary and physical activity intervention, but the difference did not reach statistical significance (Kinnunen et al. 2007). In the same study, weight retained after 10 months post partum was not significant, with the intervention group retaining 0.8 kg more than control (p 0.42). Also, negligible differences in waist circumference between groups (0.7cm) was not significant (p 0.24). Body fat and fat-free mass was not reported in the NRS.

6.4 Energy intake and dietary changes

Dietary intake was measured in all the RCT studies and one of the NRS with different dietary survey methods adopted. Only RCTs measured calorie intake as an outcome, and the NRS did not include this outcome; however, the Kinnunen et al. (2007) study collected data on the quality of food being consumed by participants. One RCT (Lovelady et al. 2006), and one NRS (Kinnunen et al. 2007) examined behavioural dietary changes.

6.4.1 RCT energy intake

Energy intake per day was measured in all 5 randomised control trials. Calorie intake was measured during 3 time periods (baseline, mid-point, and follow-up) in two studies (Dewey et al. 1994; O'Toole et al. 2003). The remaining 3 studies collected caloric intake at baseline and follow-up only (Leermakers et al. 1998; Lovelady et al. 2006; McCrory et al. 1999). Refer to table 3 for time periods.

While some studies used comparable instruments for dietary analysis, there was variation among studies: Two studies used a 3 day weight measure (Dewey et al. 1994, baseline, mid-point, and follow up); Lovelady et al. 2006 (baseline and follow up), and the McCrory et al. (1999) trial used a 4 day weight measure at baseline and follow up. According to Anderson (1995), prospective dietary assessments, such as asking participants to weigh and record all food during a given time period, is seen as one of the more valid methods. The food frequency questionnaire and diet diaries, on the other hand, are subject to recall difficulties and may result in under or over

reporting estimates. One RCT (Leermakers et al. 1996) and one NRS (Kinnunen et al. 2007) adopted a food frequency questionnaire at baseline and follow up as part of their data collection method for energy intake and dietary quality. The O'Toole (2003) trial utilised a 3 day diet diary at baseline, mid-point and follow-up to understand the energy intake of participants in the trial.

Table 6: RCT energy intake per day

Study	N	Dietary survey method	Calories Kcal (s.d)		P-value
			Baseline	End point	
Dewey, 1994	33	3 day weight measure	I: 2551 (438) C:2156 (388)	I: 2497 (436) C: 2168 (328)	NR
Leermakers 1998	90	Food frequency questionnaire	I: 1794 (nr) C: 1957 (nr)	I: 1331 (nr) C: 1340 (nr)	Ps 0.001
Lovelady, 2006	48	3 day weight measure	I: 2213 (574) C: 2378 (436)	I: 1669 (293) C: 2142 (540)	0.05
McCrory, 1999	67	4 day weight measure	I1: 2660 (442) I2: 2571(459) C: 2486 (488)	I1: 1873 (232) I2: 2075 (301) C: NR **	Not significant between baseline and follow-up for I1 and I2
O'Toole, 2003	40	3 day diet diary	I: 2073 (154) C: 2300 (148)	I: 1592 (73) C: 1541 (89)	<0.001 *; p value NR between groups

* Differences across groups from baseline to follow-up
** Data on energy intake was not reported for control at follow up

One trial did not report the significance of caloric intake between groups; however, calorie intake between baseline and follow up was only slightly reduced by 54 calories in the intervention (Dewey et al. 1994). The authors of that paper suggest that women in the intervention may have been less restrained in their caloric intake due to the exercise component of the trial. It is also important to note that the trial monitored caloric intake, but did not set a quota or desired level for caloric intake for the intervention group. Two trials found that the intervention group significantly consumed fewer calories when compared to controls (Leermakers et al. 1998; Lovelady et al. 2006). In these trials, women were instructed to reduce their calorie consumption and were monitored by research staff and/or a dietician on their progress. The O'Toole et al. (2003) trial contained two arms: women who were part of a structured program, and women who were self directed in their approach to weight management. Both women were instructed to reduce calories and were monitored by a diet and exercise physiologist. Both groups reduced their calories significantly from baseline to follow-up ($p < 0.001$), although no p-values were reported between the two groups.

6.4.2 Dietary changes

Two studies examined outcomes relating to behaviour change in regard to diet (Lovelady et al. 2006; Kinnunen et al. 2007). According to Lovelady et al. (2006), the intervention diet and exercise group decreased total calorie intake, and significantly reduced intake of fats, sweet beverages, desserts and snack foods. Due to the caloric restrictions, the intervention group decreased their macronutrient intake, but nutrient intake was not significantly different between groups, with the exception of vitamin D and calcium. All other nutrients were adequately consumed in both groups however intakes of vitamins C and E were low, 76% less than recommended intake (Lovelady et al. 2006). In another study, the intervention group consumed more high-fibre bread (p 0.008 adjusted for confounders) (Kinnunen et al. 2007). There was no significant difference in the consumption of fruits, vegetables, or high sugar snacks between the two groups (Kinnunen et al. 2007).

6.5 Energy expenditure

This section of this report covers energy expenditure outcomes measures such as total energy output, energy expenditure through exercise, and expenditure through breastfeeding. Energy expenditure is a very important component for weight management. RCTs were the only studies to include data on energy expenditure outcomes.

6.5.1 Total energy output

Total energy output was measured in two trials (Dewey et al. 1994; Leermakers et al. 1998). One study reported only baseline data, but failed to provide follow-up data on this particular outcome (McCrory et al. 1999). The Dewey et al. (1994) study reported outcome data at three time points of baseline, midpoint, and follow-up, while the Leermakers et al. (1998) trial provided baseline and follow-up only. Heart-rate monitors were used to calculate total energy output per day (Dewey et al. 1994; McCrory et al. 1999; Leermakers et al. 1998). Leermakers et al. (1998) reported energy output per week, but this was not a total measure, and it was not clear if the calories expended were from exercise or a total measure. In one study, energy expenditure did not change over time in either intervention or control (Leermakers et al. 1998). In the Dewey et al. (1994) trial, energy expenditure increased marginally at 18-20 week follow-up by 115 calories per day in the intervention group (p value not reported).

6.5.2 Energy expenditure through exercise

Three trials measured energy expenditure through exercise with two studies reporting calories expended per day (Dewey et al. 1994; McCrory et al. 1999), and another trial reporting calories expended per week (O'Toole et al. 2003). Two studies had baseline, mid-point, and follow-up period (Dewey et al. 1994; O'Toole et al. 2003). One trial measured net change in energy expended in exercise with baseline and follow-up (McCrory et al. 1999). O'Toole et al. (2003) used the Yale Physical Activity survey to measure dimensions of energy expenditure. Heart rates, pedometers, and self reports were used to calculate energy expended through exercise in the other studies (Dewey et al. 1994; McCrory et al. 1999).

Participants in the Dewey et al. (1994) trial had similar baseline figures for energy expenditure, but the intervention group expended 281 calories per day more than the control at mid-point, but no difference between groups were present at follow-up (not including energy expended through breastfeeding). Women who were most active, as measured by a higher heart rate, within the exercise group of the Dewey et al. (1994) study cut back other activities that were not directly related to exercise after mid-point through the study. The O'Toole et al. (2003) trial had two arms of structured and self directed weight management. The structured group differed significantly in exercise energy expenditure from baseline and at 12 weeks ($p < 0.05$) and at 1 year follow-up ($p<0.001$). At 1 year follow-up, the structured group expended 751 more calories per week than the self-directed group (no p value reported). In the McCrory et al. (1999) study, the control and diet group saw no or little negative difference in energy expenditure through exercise; however, the diet and exercise arm of the intervention had a net change of 370 calories per day expended in exercise at the end of the 11 day brief intervention period ($p<0.0001$).

6.5.3 Energy expenditure through breastfeeding

Energy output through breastfeeding was measured in two RCT studies (Dewey et al. 1994; McCrory et al. 1999). The energy density of breast milk was calculated in one study using the following equation (McCrory et al. 1999): Milk energy density (KJ/g) = 1.46 + (0.397 x milk lipid). The Dewey et al. (1994) calculated breast milk 'gross energy density by multiplying the values for protein, lipid, and lactose by 5.65, 9.25, and 3.95 kcal/gram, respectively, and summing all the products' (p.2). Group changes in milk energy expenditure were slightly significant, but not when adjusted for baseline values (p 0.58) (Dewey et al. 1994). In the second study, there were no

significant differences in energy expenditure through breastfeeding between two intervention groups and controls (McCrory et al. 1999).

6.6 Physical activity

Physical activity was measured as minutes per week, and was self-reported in one RCT trial (McCrory et al. 1999), and in two NRS (Albright et al. 2009; Kinnunen et al. 2007). In two studies (1 RCT and 1 NRS), self-reports were validated by the research team through use of a pedometer (McCrory et al. 1999; Albright et al. 2009). The two NRS report time spent engaging in leisure time physical activity (LTPA). Baseline measures in the Kinnunen et al. (2007) study were based on self-reported LTPA during a typical week before pregnancy. While the RCT did have a slight LTPA focus, women were encouraged to engage in more formal physical activities such as aerobic exercise, stationary physical activity machines, low-impact activities (McCrory et al. 1999).

In the McCrory et al. (RCT) (1999) trial, minutes per week engaging in exercise was significantly higher in the diet plus exercise group (499 minutes) at 11 day follow-up when compared to the diet alone arm (126 minutes), and the control (135 minutes) ($p<0.0001$).

The Albright et al. (NRS) (2009) study focused on physical activity and self-efficacy, but did not have a comparison group. Over 90% of women in this study selected walking as their exercise activity. In this study there was a significant change in the minutes of physical activity per week from baseline (3 minutes) to follow-up (85.5 minutes) ($p<0.001$; Cohen's $D=2.2$; effect size $r=0.7$). By the end of the trial 30% of women met or exceeded national physical activity guidelines for 150 minutes of physical activity, and 55% had increased their physical activity by 60 minutes or more. The Kinnunen et al. (2007) study, a physical activity and diet focused trial, found no statistical differences in activity levels after adjusting for age, education, gestational weight gain and BMI at 2 months postpartum.

6.7 Breastfeeding outcomes

Three trials reported results of weight management on breastfeeding outcomes. (Dewy et al. 1994; Lovelady et al. 2007; McCrory et al. 1999). Two trials reported numerical figures for outcomes (Dewy et al. 1994; McCrory et al. 1999), while the other reported narrative/observational data (Lovelady et al. 2007)

The McCrory (1999) trial reported breast milk volume of women in three arms of their trial (diet, diet and exercise, and control), and found that milk volume did not change significantly between the three groups. Also, time feeding, frequency, and milk lipid concentration, and infant weight gain did not differ between groups. All three groups saw slight decreases in milk protein concentrations (p 0.004). Non protein nitrogen was not affected in any arm of the trial. The Dewey (1994) study also found that energy restrictions did not alter milk volume, energy output, infant intake, infant weight, or milk composition; however, milk protein concentration was significantly greater in the exercise group at follow-up, but no differences existed between groups (p 0.08). Lovelady et al. (2006) did not report any numerical data on breastfeeding outcomes, but noted that there were no complaints about reductions in milk volume or infant troubles relating to breastfeeding due to the intervention.

6.8 Views of weight management

The Albright et al. (2009) study focused on physical activity only with no dietary component in the intervention. In this trial 80% of respondents said they were satisfied with the duration of physical activity counselling, and 80% indicated that they were satisfied with their progress in the intervention. Also, 75% of the sample felt that realistic goal setting and counselling helped them increase their physical activity. Also, by follow-up perceived barriers declined significantly (p 0.03), and was not different across ethnic groups or parity.

6.9 Study compliance

One RCT (Leermakers et al. 1998) and one NRS (Albright et al. 2009) examined study compliance. The Leermakers et al. (1998) trial found that 10 out of a possible 25 self monitoring records, and 7.6 out of 15 homework assignments were completed during the intervention period. Also, on average women received 10.3 phone calls to help them progress through the 6 month intervention. In the Albright et al. (2009) study, 83% of scheduled contacts relating to weight management services were completed.

6.10 Subgroup analysis

Albright et al. (2009) provided limited data in the analysis of subgroups. Increases in physical activity by ethnic group, infant age, and parity were not significant. Also, declines in perceived barriers to intervention and physical activity were not significant across ethnic groups or parity.

One RCT conducted a subgroup analysis on breastfeeding women and found no differences in weight loss between mothers who breastfed and those who did not at 12 weeks midpoint or 1 year follow up. At Baseline, 57% of the sample were breastfeeding, and this number increased to 70% at follow up (O'Toole et al. 2003).

6.11 Loss to follow up

6.11.1 RCT Loss to follow up

Loss to follow up varied from 3 to 43% in the RCTs included in this review with an average loss to follow up of 21.8% across studies. Longer trials had the highest drop out rate, while shorter trials had the fewest loss of participants. For instance, the O'Toole (2003) trial which was offered as a 52 weeks intervention, with a 12 week intensity period had the highest drop out rate of 43%, and the McCrory trial (1999) offered over 11 days had a drop out rate of 3%. See table 7 for the exact figures and reasons for drop outs, as well as any differences related to those who dropped out and those who remained in the study.

Table 7: RCT Loss to follow-up

Study	Drop outs n (%)	Total N	Reasons	Differences between drop outs and sample
Dewey, 1994	5 (15)	33	▪ 2 withdrew (reason NR) ▪ 1 unreliable data ▪ 1 previously undetected thyroid condition ▪ 1 very low milk production at base line that required intervention, ineligible to continue in the study. ▪ All but the last woman had been assigned to the control group.	▪ The five women who withdrew were similar to those who remained in terms of their weight, height, age, education, and parity and the sex of their infants, ▪ Infants had significantly lower birth weights than the infants of the women who remained in the study (mean [±SD] birth weight, 3.31 ±0.20 vs. 3.77 ±0.46 kg; P<0.05).
Leermakers, 1998	28 (31)	90	▪ 5 had another pregnancy (remaining women's reasons NR) ▪ 11 women dropped out of the intervention group ▪ 17 dropped out of the control group	▪ Attrition did not vary by treatment group (x^2=2.7, P=0.1) ▪ There were no differences between drop-outs and completers in marital status, ethnicity, age, months since delivery or number of full-term deliveries (Ps>0.1). ▪ Dropouts were significantly heavier at pre-treatment (85.4+-14.1 kg) than completers (78.6+-12.6 kg) (P<0.05) and retained significantly more weight (above their pre-pregnancy weight) at pre-treatment (14.8+-7.3 kg) than completers (11.1+-4.0 kg) (P<0.005).
Lovelady et al, 2006	8 (17)	48	▪ 8 did not complete the study ▪ 5 returned to work full time and were not able to breastfeed exclusively ▪ 3 women withdrew because of personal issues ▪ Food records were incomplete for 5 participants (two in diet and exercise group and three in control group); therefore, they were excluded from analysis. ▪ 6 in the diet and exercise group ▪ 2 in the control group	▪ The baseline characteristics of the women who discontinued the study were similar to those who completed the study, except that the women who withdrew were significantly heavier before pregnancy and had a lower level of cardiovascular fitness.
McCrory et al, 1999	2 (3)	68	▪ 1 withdrew after assignment to the diet + exercise group, but before the intervention began because she had difficulty completing the baseline measurements. ▪ 1 in the diet + exercise group did not continue with the intervention after day 8 because of a previously unreported exercise-induced asthma condition (data for this subject were included in the analysis up to the time that she stopped participating in the intervention)	▪ There were no significant group differences in the characteristics
O'Toole et al, 2003	17 (43)	40	▪ 8 dropouts from structured program ▪ 9 dropouts self directed	▪ No differences in drop outs and those who remained in study

6.11.2 NRS Loss to follow up

Of the two NRS included in this review, one study did not have any drop outs (Albright et al. 2009), whereas the other study (Kinnunen et al. 2007) had a loss to follow up rate of 8%. The Albright intervention was significantly shorter in duration (8-9 weeks) and size (n=20), while the Kinnunen trial lasted 40 weeks and had 85

participants. See table 8 for the exact figures and reasons for drop outs as well as any differences related to those who dropped out and those who remained in the study.

Table 8: NRS Loss to follow-up

Study	Drop outs n (%)	Total N	Reasons	Differences between drop outs and sample
Albright et al, 2009	0 (0)	20	NA	▪ All women returned the post-test survey
Kinnunen et al, 2007	7 (8)	85	▪ All 48 women in the intervention group participated in the primary physical activity and dietary counselling sessions. ▪ Five women missed one physical activity booster session, ▪ 3 women missed one dietary booster session ▪ 3 women missed the discussion about returning to pre-pregnancy weight. ▪ On average, the women participated in 4.9 of the five physical activity counselling sessions and in 3.9 of the four dietary counselling sessions. ▪ The average participation rate in the group exercise sessions was 50.7 % (sd 28.5) of the sessions available for each woman.	▪ Participants who dropped out of the study were younger, less educated and had higher pre-pregnancy and postpartum BMI, but lower gestational weight gain and weight retention at 2 months postpartum on average than participants who completed the study ▪ No major differences were observed in smoking status or in the main dietary and physical activity outcomes between the groups. ▪ There is no follow-up information available on the drop-outs.

7. Discussion and conclusions

7.1. Summary of evidence

The total number of participants in RCTs was 278 and 105 in the NRS. All trials were conducted in the USA, while one NRS was conducted in Hawaii and another in Finland. The average age of participants was 31 across all studies. Findings on based on age were limited by the lack of evidence on younger women enrolled in the interventions. The average BMI at enrolment was 27.6 in RCTS, and 23.8 in NRS. Weight at enrolment was higher in RCTs (75 kg) than NRS (66.1 kg). Pregnancy weight retained at study entry was similar for RCTs (16.9 kg) and NRS (15.8 kg). Women were enrolled into RCTs at an average of 13.7 weeks post partum, while the average weeks post partum for NRS was 19 weeks. Mother breastfed their infants in four out of 5 RCTS, and 1 out of 2 NRS. In both RCTS and NRS, the majority of the sample was Caucasian.

Diet and physical activity were major components in all RCTs reviewed. Counselling, support, and mentoring were offered in 2 studies out of 5. Advice about how to manage weight through diet, exercise was offered in four trials. All studies monitored weight status and program progress of post partum women. NRS included all the intervention components of physical activity, advice, support, mentoring, and monitoring, although one NRS did not include a diet component in their intervention. The average length of RCT interventions was 19.9 weeks, while NRS had an average intervention length of 25.5 weeks.

Evidence for effectiveness for weight management interventions on weight loss is mixed across all study designs; however, three RCTs indicated a positive effect on weight management during the post partum period. Three out of five trials found that women in the intervention groups saw significant changes in weight during the course of the intervention period (Leermakers et al. 1998; McCrory et al. 1999; O'Toole et al. 2003). None of the NRS found any significant changes in weight measures at follow up (Albright et al. 2009; Kinnunen et al. 2007).

Energy intake in 2 trials showed that the control group saw a greater decrease in energy intake over the trial period (Leermakers et al. 1998; O'Toole et al. 2003). The Leermakers et al. (1998) trial intervention group reduced energy intake by 463 calories and the control decreased by 617 calories. O'Toole (2003) intervention's structured programme decrease by 481 calories and the self-directed control saw a reduction of 759 calories per day. In both instances, the control group had higher

baseline energy intake values, while the intervention group began the trial with lower daily energy intake. This may suggest that women in the intervention groups in both trials were more restrained in their eating habits or ate more healthily prior to the intervention. Another possibility for the greater energy decrease in the control groups would be that women in the intervention required more energy to engage in higher levels of physical activity compared to the controls.

In three trials, weight management interventions did not have a negative effect on breastfeeding outcomes (Dewey et al. 1994; McCrory et al. 1999 Lovelady et al. 2006), although overweight women had higher milk energy outputs, and leaner women saw a decrease in milk energy output (McCrory et al. 1999). These findings are similar to a review by Hammer et al. (1998) that found that women can safely engage in diet and exercise programmes without compromising the quality of breast milk, or infant health.

Comparing across studies was difficult since follow up time and length of intervention varied considerably. One intervention was offered over 11 days (McCrory et al. 1999), while another was presented over a 1 year timeframe (O'Toole et al. 2003). Longer trials also had the highest drop out rates suggesting that women may find it difficult to participate in weight management programmes. Given that a primary outcome for this review is weight loss, longer interventions are favourable for demonstrating effectiveness of weight management strategies during the post partum period. Also results from the shorter McCrory trial should be interpreted with caution as obesity-related behaviour changes may not be possible during that timeframe or results of this study may be biased due to the short length of trial. It should also be noted that changing behaviour (diet and exercise) is best done over time so that results can be sustained (Aittasalo et al. 2008; NICE Obesity Guidance 2006).

Clinical trials are the strongest study design for answering questions of effectiveness of weight management interventions in post partum period since they introduce the least amount of bias (Larson-Meyer 2002); however, this type of evidence is not widely available as seen in the small number studies included in this review.

This systematic review has examined all studies found in the Cochrane review with the exception of one study that focused on women with depression as part of our exclusion criteria (Amorim et al. 2007). In an attempt to cover more evidence, this review looked across all designs to find studies that introduced an intervention. Two non-randomised studies were found in addition to the Amorim review (2007). This

review examined several other outcomes in addition to those found in the Cochrane review (Amorim et al. 2007):

- Review of non-randomised studies (2 new studies included)
- Detailed information about the context, setting, delivery, duration and assess of interventions (see appendix 5)
- Dietary behaviour change as a result of interventions (2 studies)
- Views of weight management intervention trials (1 study)
- Cost-effectiveness of interventions (included in modelling report)

7.2 Research questions for which little or no evidence was identified

There was a lack of evidence in areas that linked socio-economic status and ethnicity to the effectiveness of interventions. Studies that reported ethnicity focused on Caucasian women (over 50% Caucasian) (Albright et al. 2009; Dewey et al. 1994; Leermakers et al. 1998; McCrory et al. 1999). Studies did not exclusively look at the effects of socio-economic status on weight management, thus the evidence in this area is inconclusive and insufficient to answer the research question. There was also a lack of evidence in relation to access and use of health and weight management services, as no studies reported on this outcome.

External factors relating to intervention delivery, setting, context, and intensity were well covered in all studies. It was difficult to determine if intervention delivery, setting, context, and intensity had a direct impact on effectiveness since trials did not report this type of data. In terms of delivery and setting, all studies were delivered by research teams and or experts in the field of diet and exercise, and set within the context of laboratory or health clinics. No data on effectiveness in regards to elements of delivery or setting were covered in studies. Slightly more evidence was provided regarding the impact of context and intensity of interventions on effectiveness of studies on weight management: In the McCrory et al. (1999) trial, the more intense arm of the trial (diet plus exercise group) saw more of an effect on weight management when compared to the control and diet alone arms. Also, in terms of content, the structured group (individualised diet and exercise programme) was significantly more successful in their weight management attempts when compared to those who followed a more self-directed approach to weight management. (O'Toole et al. 2003).

Results from the website searches did not provide evidence for effectiveness of interventions for weight management after childbirth. We found mostly observational reports in the subject areas related to diet, physical activity, and maternal and post partum health, but no data on interventions that monitored changes in participations.

7.3 Adverse or unexpected outcomes

There were no major adverse events, harms, or unexpected outcomes as a direct result of interventions. Outcomes related to breastfeeding, infant outcomes, and nutrient intake all indicated that there were no or minimal harms associated with interventions. Adverse outcomes and harms of interventions should be interpreted with caution in view of the fact that the number of participants in studies was not sufficiently powered to detect rare adverse events in the post partum populations.

7.4 Applicability in the UK context

All RCTs and one NRS (Hawaii) included in this review were conducted in the USA, and one NRS was conducted in Finland. Since the majority of studies were conducted in the USA findings may not be fully applicable to a UK population. All countries are part of developed economies, but health care systems, policies and social contexts may be much more varied between countries.

Care is required when applying USA evidence to the UK. For instance, the antenatal care women receive in the USA may be slightly different than the UK, as well as the amount of attention given to weight and weight gain/retention before, during and after pregnancy may vary between countries. Cultural norms and expectations of weight loss after pregnancy may also vary across countries, as well as the policies that are in place to prevent, aid, or inhibit weight gain or retention during the post partum period.

Although differences exist, similarities are present that may make the findings of the included studies more applicable to the UK. The included studies focused on primarily Caucasian women, and these findings may have some relevance to UK women of the same ethnicity. In addition, interventions offered in other countries may be reasonably adopted and relevant for a UK population. Expectations, delivery and measurements of studies would also be appropriate for a UK population, making the results of these studies somewhat applicable to the UK. The types of foods consumed, nutritional guidelines of trials, exercise activities, and methods of monitoring all appear to be somewhat relevant to the UK. The McCrory et al. (1999)

trial, however, may be more difficult and expensive to implement on a larger scale since food was provided for the two arms of the intervention (diet alone; diet plus exercise).

7.5 Implications of the review findings

Many papers examined for this review call for more evidence in this area of weight management during the post partum period (Amorim et al. 2007; Fraser and Grimesl. 2003; Gore et al. 2003; Gunderson et al. 2000; Keller et al. 2008; Kuhlmann et al. 2002). Quality randomised control trials are needed in order to fill evidence gaps that exist in terms of effectiveness of interventions. The literature reviewed has a substantial geographical bias, with most studies conducted in the USA which limits UK applicability.

7.6 Evidence statements

What are the most effective dietary interventions for weight management after childbirth?

Evidence statement 1

There is limited evidence from one US based RCT (McCrory et al., 1999 [+]) that dietary intervention alone (aiming for 35% energy deficit) from 12 weeks postpartum may help women across the BMI spectrum start to lose more weight after childbirth compared to usual care. However, the short length of this intervention (11 days) makes it difficult to draw conclusions on the effectiveness of the study. Four day weighed food records suggested that calorie intake was not lower in the intervention compared to the control arm of the trial. The setting of this study (US) makes it somewhat relevant to the UK.

What are the most effective physical activity interventions for weight management after childbirth?

Evidence statement 2

There is weak evidence from one USA (Hawaii) based NRS (Albright et al., 2009 [-]) that a physical activity intervention alone (focusing on counselling and support to improve self efficacy and self monitoring) from 30 weeks post partum may help women be more active after pregnancy. Although women in the intervention group were significantly more active after the 8 to 9 week programme than the control

group, observed changes in BMI were not significant. The average BMI of participants in this study was in the healthy range at enrolment. The setting of this study limits it's applicability to the UK.

What are the most effective <u>combined dietary and/or physical activity</u> interventions for weight management after childbirth?

What are the most effective interventions that may influence weight management after childbirth?

Evidence statement 3

Four out of five US based RCTs addressing diet and physical activity post partum found a significant reduction in total weight among women across the BMI spectrum in the intervention group compared to control (Leermakers et al. 1998 [+]; Lovelady et al., 2006 [+]; McCrory et al., 1999 [+]; O'Toole et al., 2003 [-]). Only one US based RCT found that total weight was not significantly lower in the intervention group compared to control (Dewey et al. 1994 [+]). Results did not appear to vary based on the start dates of intervention or the length of follow up.

Evidence statement 4

Four US based RCTs measured percent body fat (O'Toole et al., 2003 [-]; Lovelady et al. 2006 [+]; McCrory et al., 1999 [+]; Dewey et al. 1994 [+]). Of these, one reported significant decreases in body fat percentage between intervention and control (O'Toole et al., 2003 [-]). Two further trials observed larger reductions in percent body fat for intervention compared to control, but for one of these the P value was not reported (McCrory et al., 1999 [+]) and for another the difference was not significant at the 5% level (Lovelady et al. 2006 [+]). The reduction in the percent body fat in the trial by McCrory (1999 [+]) was accompanied by significant increases in fat free mass for intervention compared to control. Falls in percent fat mass did not differ between intervention and control in only one US based RCT (Dewey et al. 1994 [+]). Results did not appear to vary based on the start dates of intervention or the length of follow up.

Evidence statement 5

Two RCTs assessed post pregnancy weight retention. One US based RCT, among women who were on average overweight pre-pregnancy and postpartum, found that significantly more women returned to their pre-pregnancy weight than the control, and retained significantly less weight gained during pregnancy than the control (3.3kg compared to 6.3kg) (Leermakers et al. 1998 [+]). This finding was not replicated in the one poor quality NRS that also assessed weight retention (and waist circumference) among Finish women with, on average, a healthy BMI (Kinnunen et al., 2007 [-]).

Evidence statement 6

In line with their results for weight loss, three RCTs from the USA found that intervention focusing on diet and exercise resulted in decreased calorie intake (Leermakers et al. 1998 [+]; Lovelady et al., 2006 [+]; O'Toole et al., 2003 [-]) and decreased consumption of unhealthy foods (Lovelady et al., 2006 [+]). Of these studies, one also found significant increase in energy expenditure between exercise groups (O'Toole et al., 2003 [-]) whereas another (Leermakers et al. 1998 [+]) found no significant difference in total energy expenditure between groups. Lovelady et al., 2006 [+]) did not report results for physical activity.

Evidence statement 7

In line with their results for weight loss and fat free mass, McCrory et al. (1999 [+]) reported significant increases in measures of physical activity and energy expenditure between intervention and control groups (McCrory et al., 1999 [+]) although no difference in calorie intake.

Evidence statement 8

The non significant results of Dewey and Kinnunen in relation to measures of weight may be explained by their findings that there was no difference in energy expenditure between groups (Dewey et al. 1994 [+]) or difference in physical activity levels and the quality of dietary intake (Kinnunen et al., 2007 [-]).

What interventions are effective in avoiding incremental weight gain over successive pregnancies?

Evidence statement 9

No evidence was identified which specifically assessed incremental weight gain over successive pregnancies.

What interventions are effective for weight management in women who are breast feeding?

Evidence statement 10

The results of one poor quality trial (O'Toole (2003) [-]) suggests that the effectiveness of a weight management intervention does not significantly differ between women who are breastfeeding and those who are not. While women were known to be breastfeeding to some extent in all other included studies bar two (not reported by Albright et al 2009 [-]; breastfeeding women excluded from Leermakers et al. 1998 [+]), they did not specifically investigate this issue.

Evidence statement 11

Energy expenditure through breastfeeding was not found to differ significantly between control and intervention groups in the two studies in which this was measured (Dewey et al. 1994 [+]; McCrory et al., 1999 [+]).

Evidence statement 12

The evidence suggests weight management interventions addressing diet and physical activity had little or no adverse effects on breastfeeding outcomes, including milk volume, infant intake and weight, time and frequency feeding (Dewey et al. 1994 [+]; McCrory et al., 1999 [+]). Milk protein was observed to decrease in one short US based trial (McCrory et al., 1999 [+]). Overweight women had higher milk energy outputs, and leaner women saw a decrease in milk energy output (McCrory et al. 1999).

What are the most effective ways of measuring and monitoring weight in women after childbirth? Are there any adverse effects?

Evidence statement 13

The one high quality trial which examined correlations between monitoring and weight loss (Leermakers et al 1998 [+])found that there was a significant correlation between number of self-monitoring records returned and weight loss (r=0.50, P<0.005). However, homework completion or telephone contact with research staff was not significantly correlated with weight loss. Women enrolled in this trial had an above average BMI bordering on obese classification at start of the intervention. None of the included studies considered the effectiveness of monitoring alone.

Evidence statement 14

None of the identified studies reported that there were any adverse effects of measuring or monitoring as part of the intervention.

What external factors influence the effectiveness of the intervention (such as content, delivery, setting, who is delivering the intervention, intensity, duration and target setting)?

Evidence statement 15

Due to the variability between included studies, it remains unclear whether the delivery, content, setting, intensity and duration of interventions influenced effectiveness.

Evidence statement 16

The results of one poor quality RCT (O'Toole et al. 2003 [-]) suggests that that women who are supervised by a trained diet and exercise specialist may be more successful in their attempts to lose weight, decrease their calorie intake and increase their physical activity level than women who are self supervised.

Evidence statement 17

It remains unclear whether providing women with support and mentoring influences the effectiveness of a weight management intervention postpartum. Of the included studies, two trials (Leermakers et al (1998 [+]) and Lovelady et al. (2006 [+])) and

one NRS (Kinnunen et al., 2007 [-]) provided support and mentoring, in addition to components on diet and physical activity.

Evidence statement 18

It remains unclear whether the length of intervention influences effectiveness. Both longer and shorter trials reported some positive results in terms of weight management outcomes. Included studies were 20 weeks in length on average, but varied from 11 days (McCrory et al. 1999 [+]) up to one year (O'Toole et al. 2003 [-]).

What internal factors influence the effectiveness, acceptability and feasibility of the intervention (such as participants age, socio-economic status, ethnicity, medical history, physical activity, breastfeeding status, attempts at weight management, weight or BMI at onset of pregnancy, number of previous pregnancies and/or children ?

Evidence statement 19

There is insufficient evidence to asses the influence of factors such as socioeconomic status and ethnicity on the effectiveness of interventions.
One NRS provided limited data in the analysis of subgroups: A USA Hawaiian based NRS by Albright et al. (2009) [-], found increases in physical activity by ethnic group, infant age, and parity were not significant and declines in perceived barriers to intervention and physical activity were not significant across ethnic groups or parity.

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Ostbye, T., Krause, K. M., Brouwer, R. J. N., Lovelady, C. A., Morey, M. C., Bastian, L. A., Peterson, B. L., Swamy, G. K., Chowdhary, J., & McBride, C. M. 2008, "Active Mothers Postpartum (AMP): rationale, design, and baseline characteristics", *Journal of Women's Health*, vol. 17, no. 10, pp. 1567-1575.

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Prentice, A. 1994, "Should lactating women exercise?", *Nutrition Reviews*, vol. 52, no. 10, pp. 358-360.

Ram, K.T, Bobby, P., Hailpern, S.M. Lo, J.C. Schocken, M. Skurnick, J. Santoro, N. 2008. Duration of lactation is associated with lower prevalence of metabolic syndrome in mid life – Swan, the study of women's health across the nation. Am J Obstet Gynecol., Mar; 1vol.98(3):268.e1-6.

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Wolff, S., Legarth, J., Vangsgaard, K., Toubro, S., & Astrup, A. 2008, "A randomized trial of the effects of dietary counseling on gestational weight gain and glucose metabolism in obese pregnant women", *International Journal of Obesity*, vol. 32, no. 3, pp. 495-501.

9. Appendices

Appendix 1: Search Strategies

Search One - A search already undertaken for the NICE Intervention Guidance on weight management in pregnancy

List of terms

1. (pre-pregnancy or prepregnancy).ti,ab.
2. *Pregnant Women/
3. *Pregnancy/
4. pregnan*.ti,ab.
5. maternal.ti,ab.
6. gestational.ti,ab.
7. (pre-natal or prenatal).ti,ab.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. *Weight Gain/
10. *Obesity/
11. *Overweight/
12. *Body Mass Index/
13. obes*.ti,ab.
14. weight gain*.ti,ab.
15. weight change*.ti,ab.
16. weight loss*.ti,ab.
17. body mass index.ti,ab.
18. bmi.ti,ab.
19. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20. 8 and 19
21. *diet/
22. *energy intake/
23. diet*.ti,ab.
24. calori*.ti,ab.
25. energy.ti,ab.
26. nutrition*.ti,ab.
27. (food adj2 intake).ti,ab.
28. 21 or 22 or 23 or 24 or 25 or 26 or 27
29. Exercise/
30. exercis*.ti,ab.
31. (physical adj2 activit*).ti,ab.
32. 29 or 31 or 30
33. *counseling/
34. *health education/
35. (health adj2 promotion*).ti,ab.
36. counsel?ing.ti,ab.
37. advi*.ti,ab.
38. support*.ti,ab.
39. information.ti,ab.
40. media.ti,ab.
41. 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40
42. monitor*.ti,ab.
43. assess*.ti,ab.
44. weighing.ti,ab.
45. (adipos* adj2 measur*).ti,ab.
46. (body adj2 composition).ti,ab.

47. mid arm circumference.ti,ab.
48. waist hip ratio*.ti,ab.
49. 42 or 43 or 44 or 45 or 46 or 47 or 48
50. 20 and 28
51. limit 50 to (humans and yr="1990 - 2008")
52. 20 and 32
53. limit 52 to (humans and yr="1990 - 2008")
54. 20 and 41
55. limit 54 to (humans and yr="1990 - 2008")
56. 20 and 49
57. limit 56 to (humans and yr="1990 - 2008")

List of databases

ASSIA via CSA
British Nursing Index via OVID SP
Cinahl via OVID SP
Cochrane – Central via Wiley
Cochrane – DARE via Wiley
Cochrane – HTA via Wiley
Cochrane - NHS EED via Wiley
Cochrane Database of Systematic Reviews via Wiley
Econlit via OVID SP
Embase via OVID SP
Maternity and Infant Care via OVID SP
Medline via OVID SP
PyscINFO via OVID SP
Science Citation Index via Web of Science
Social Science Citation Index via Web of Science

Search Two - Targeted database searches for evidence about weight management interventions after childbirth

List of terms

1. *Postpartum period/
2. (post natal or postnatal).ti,ab.
3. (post pregnancy or postpregnancy).ti,ab.
4. ((Post or after or following) adj birth).ti,ab.
5. (postpartum or post partum).ti,ab.
6. (interpregnanc* or inter pregnanc* or (between adj pregnanc*)).ti,ab
7. 1 or 2 or 3 or 4 or 5 or 6
8. *Weight Gain/
9. *Obesity/
10. *Overweight/
11. *Body Mass Index/
12. obes*.ti,ab.
13. weight gain*.ti,ab
14. weight change*.ti,ab.
15. weight loss*.ti,ab.
16. body mass index.ti,ab.
17. bmi.ti,ab.
18. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

19. 18 and 7
20. limit 19 to (english language and humans and yr="1990 - 2009")

List of databases

ASSIA via CSA
British Nursing Index via OVID SP
CINAHL via EBSCO
Cochrane Central Register of Controlled Trials via Cochrane Library (Wiley)
Cochrane Database of Systematic Reviews via Cochrane Library (Wiley)
Database of Abstracts of Reviews of Effects via Cochrane Library (Wiley)
Econlit via OVID SP
EMBASE via OVID SP
Health Technology Assessment Database via Cochrane Library (Wiley)
Maternity and Infant Care via OVID SP
MEDLINE via OVID SP
NHS EED via Cochrane Library (Wiley)
PsycINFO via OVID SP
Science Citation Index via Web of Knowledge
Social Science Citation Index via Web of Knowledge

Search Three - Targeted database searches on evidence linking breastfeeding and diet and/or physical activity

List of terms

1. exercise.ti.
2. *Exercise/
3. (physical adj activit*).ti.
4. *Motor Activity/
5. 1 or 2 or 3 or 4
6. *Diet/
7. *Energy Intake/
8. (diet* or calori* or energy or nutrition).ti.
9. 8 or 6 or 7
10. 9 or 5
11. *lactation/
12. (breastfeed* or lactation or lactating).ti.
13. 11 or 12
14. 13 and 10
15. limit 14 to (english language and humans and yr="1990 - 2009")

List of databases

British Nursing Index via OVID SP
CINAHL via EBSCO
EMBASE via OVID SP
Maternity and Infant Care via OVID SP
MEDLINE via OVID SP

Search Four – Website searches

List of terms

Weight
Obesity
Pregnancy
Childbirth
Postpartum
Postnatal
Breastfeeding
Maternal

List of websites

American College of Obstetricians and Gynaecologists
British Dietetic Association
Chartered Society of Physiotherapy
Department of Health
Food Standards Agency
Health Development Agency
Institute of Medicine
Joseph Rowntree Foundation
NHS Scotland
NICE
NHS Evidence – Women's Health
Public Health Observatories
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Scientific Advisory Committee on Nutrition
SIGN
Welsh Assembly Government

Search Five - Searches for evidence for the cost effectiveness review and economic model

List of terms

1 (post natal or postnatal).ti.
2 (post pregnancy or postpregnancy).ti.
3 ((Post or after or following) adj birth).ti.
4 (postpartum or post partum).ti.
5 obes*.ti.
6 weight gain*.ti.
7 weight change.ti.
8 weight loss.ti.
9 body mass index.ti.
10 bmi.ti.
11 10 or 6 or 1 or 9 or 4 or 3 or 7 or 2 or 5 or 8
12 (child* or adolescen*).ti.
13 11 not 12

List of databases

Econlit via OVID SP
NHS EED via Cochrane Library via Wiley

Appendix 2: Quality Assessments

2.1 RCT Quality Assessment

	Dewey	Leermakers	Lovelady	McCrory	O'Toole
1.Population					
1.1	-	-	-	-	-
1.2	-	-	+	-	+
1.3	+	+	NR	+	-
2. Method of allocation					
2.1	+	+	++	++	++
2.2	+	++	+	+	+
2.3	NR/NA	NR	-	NR	++
2.4	NR	NR	NA	NA	NR/NA
2.5	NR	-	+	+	NR
2.6	-	+	+	+	+
2.7	+	+	+	+	+
2.8	-	-	+	+	-
2.9	+	+	+	+	-
2.10	-	-	-	-	-
3. Outcomes					
3.1	+	-	+	+	+
3.2	NR	NR	NR	NR	NR
3.3	+	-	+	+	+
3.4	++	+	+	++	++
3.5	+	++	++	++	++
3.6	-	-	-	-	+
4. Analyses					
4.1	+	+	+	+	+
4.2	-	+	NR	NR	-
4.3	NR	NR	+	NR	-
4.4	NR	NR	NR	NR	NR
4.5	+	+	-	++	-
4.6	+	-	-	+	-
5. Summary					
5.1	+	+	+	+	-
5.2	-	-	-	-	-
Final rating	**+**	**+**	**+**	**+**	**-**

2.2 Non-Randomised Study Quality Assessment

	Albright	Kinnunen
1.Population		
1.1	-	-
1.2	-	NR
1.3	-	-
2. Method of allocation		
2.1	NA	-
2.2	++	+
2.3	NA	-
2.4	NA	NA
2.5	NA	++
2.6	NA	+
2.7	NA	+
2.8	NA	+
2.9	+	+
2.10	-	++
3. Outcomes		
3.1	+	+
3.2	NR	NR
3.3	-	+
3.4	+	+
3.5	NA	+
3.6	-	+
4. Analyses		
4.1	NA	+
4.2	NR	-
4.3	NR	NR
4.4	++	+
4.5	+	-
4.6	-	-
5. Summary		
5.1	-	-
5.2	-	-
Final rating	**-**	**-**

Appendix 3: Excluded studies list

List of Excluded Studies (n=50)

Systematic Reviews and Literature Reviews

*Amorim, A. R., Linne, Y. M., Lourenco, P. M., Amorim, A. R., Linne, Y. M., and Lourenco, P. M. C. Diet or exercise, or both, for weight reduction in women after childbirth.[see comment]. [Review] [68 refs]. *Cochrane Database of Systematic Reviews* 2007;CD005627

* Individual studies from the Amorim review included as part of this systematic review

Crowell, D. T. Weight Change in the Postpartum Period - A Review of the Literature. *Journal of Nurse-Midwifery* 1995; **40** 418-423.

Fraser, A. B., Grimes, D. A., Fraser, Anna B., and Grimes, David A. Effect of lactation on maternal body weight: a systematic review. [Review] [57 refs]. *Obstetrical & Gynecological Survey* 2003; **58** 265-269.

Gore, S. A., Brown, D. M., and West, D. S. The role of postpartum weight retention in obesity among women: A review of the evidence. *Annals of Behavioral Medicine* 2003; **26** 149-159.

Gunderson, E. P., Abrams, B., Gunderson, E. P., and Abrams, B. Epidemiology of gestational weight gain and body weight changes after pregnancy. [Review] [68 refs]. *Epidemiologic Reviews* 2000; **22** 261-274.

Hammer, R. L. H. An independent study continuing education program: exercise and dietary programming to promote maternal health fitness and weight management during lactation. *Journal of Perinatal Education* 2002; **vol 7, no 2, 1998, pp 12-26.**

Harris, H. E. and Ellison, G. T. H. Do the changes in energy balance that occur during pregnancy predispose parous women to obesity? *Nutrition Research Reviews* 1997; **10** 57-81.

Keller, C., Records, K., Ainsworth, B., Permana, P., Coonrod, D. V., Keller, Colleen, Records, Kathie, Ainsworth, Barbara, Permana, Paska, and Coonrod, Dean V. Interventions for weight management in postpartum women. [Review] [42 refs]. *JOGNN - Journal of Obstetric, Gynaecologic, & Neonatal Nursing* 2008; **37** 71-79.

Kuhlmann, A. K., Dietz, P. M., Galavotti, C., England, L. J., Kuhlmann, Anne K. S., Dietz, Patricia M., Galavotti, Christine, and England, Lucinda J. Weight-management interventions for pregnant or postpartum women. [Review] [23 refs]. *American Journal of Preventive Medicine* 2008; **34** 523-528.

Larson-Meyer, D. E. and Larson-Meyer, Dawnine Enette Effect of postpartum exercise on mothers and their offspring: a review of the literature. [Review] [73 refs]. *Obesity Research* 2002; **10** 841-853.

Lederman, S. A. The effect of pregnancy weight gain on later obesity. *Obstetrics and Gynaecology* 1993; **82** 1993-

Morin, K., Gennaro, S., and Fehder, W. Nutrition and exercise in overweight and obese postpartum women. *Applied Nursing Research* 1999; **12** 13-21.

Ozanne, S. E. and Ozanne, S. E. The long term effects of early postnatal diet on adult health. [Review] [44 refs]. *Advances in Experimental Medicine & Biology* 2009; **639** 135-144.

Prentice, A Should lactating women exercise? *Nutrition Reviews* 1994; **52** 358-360.

Schmitt, N. M., Nicholson, W. K., and Schmitt, J. The association of pregnancy and the development of obesity - results of a systematic review and meta-analysis on the natural history of postpartum weight retention. *International Journal of Obesity* 2007; **31** 1642-1651.

Study Design (non-intervention, qualitative)

Baker, C. W., Carter, A. S., Cohen, L. R., Brownell, K. D., Baker, C. W., Carter, A. S., Cohen, L. R., and Brownell, K. D. Eating attitudes and behaviors in pregnancy and postpartum: global stability versus specific transitions. *Annals of Behavioral Medicine* 1999; **21** 143-148.

Boyington, J., Johnson, A., Carter-Edwards, L., Boyington, Josephine, Johnson, Allan, and Carter-Edwards, Lori Dissatisfaction with body size among low-income, postpartum black women. *JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing* 2007; **36** 144-151.

Carter, A. S., Baker, C. W., and Brownell, K. D. Body mass index, eating attitudes, and symptoms of depression and anxiety in pregnancy and the postpartum period. *Psychosomatic Medicine* 2000; **62** 264-270.

Chang, M. W., Nitzke, S., Guilford, E., Adair, C. H., Hazard, D. L., Chang, Mei Wei, Nitzke, Susan, Guilford, Eileen, Adair, Constance H., and Hazard, Diana L. Motivators and barriers to healthful eating and physical activity among low-income overweight and obese mothers. *Journal of the American Dietetic Association* 2008; **108** 1023-1028.

Devine, C. M., Bove, C. F., and Olson, C. M. Continuity and change in women's weight orientations and lifestyle practices through pregnancy and the postpartum period: the influence of life course trajectories and transitional events. *Social Science & Medicine* 2000; **50** 567-582.

Ebbeling CB, Pearson MN, Sorensen, G., Levine RA, Hebert, J. R., Salkeld JA, and Peterson, K. E. Conceptualization of a theory-based healthful eating and physical activity intervention for postpartum women who are low income. *Health Promotion Practice* 2007; **8** 50-59.

Fowles, E. R. and Fowles, Eileen R. Comparing pregnant women's nutritional knowledge to their actual dietary intake. *MCN, American Journal of Maternal Child Nursing* 2002; **27** 171-177.

George, G. C., Milani, T. J., Hanss-Nuss, H., Freeland-Graves, J. H., George, Goldy C., Milani, Tracey J., Hanss-Nuss, Henry, and Freeland-Graves, Jeanne H. Compliance with dietary guidelines and relationship to psychosocial factors in low-

income women in late postpartum. *Journal of the American Dietetic Association* 2005; **105** 916-926.

Gray-Donald, K., Robinson, E., Collier, A., David, K., Renaud, L., Rodrigues, S., Gray-Donald, K., Robinson, E., Collier, A., David, K., Renaud, L., and Rodrigues, S. Intervening to reduce weight gain in pregnancy and gestational diabetes mellitus in Cree communities: an evaluation.[see comment]. *CMAJ Canadian Medical Association Journal* 14-11-2000; **163** 1247-1251.

Harris, H. E., Ellison, G. T., Clement, S., Harris, H. E., Ellison, G. T., and Clement, S. Do the psychosocial and behavioral changes that accompany motherhood influence the impact of pregnancy on long-term weight gain? *Journal of Psychosomatic Obstetrics & Gynecology* 1999; **20** 65-79.

Keller, C., Allan, J., and Tinkle, M. B. Stages of change, processes of change, and social support for exercise and weight gain in postpartum women. *Jognn-Journal of Obstetric Gynecologic and Neonatal Nursing* 2006; **35** 232-240.

Nowak, M., Harrison, S. L., and BÇ¬ttner, P. G. General nutrition-related knowledge and beliefs of post-partum women. *Nutrition & Dietetics* 2004; **61** 82-87.

Nuss, H., Clarke, K., Klohe-Lehman, D., Freeland-Graves, J., Nuss, Henry, Clarke, Kristine, Klohe-Lehman, Deborah, and Freeland-Graves, Jeanne Influence of nutrition attitudes and motivators for eating on postpartum weight status in low-income new mothers. *Journal of the American Dietetic Association* 2006; **106** 1774-1782.

Shrewsbury, V. A., Robb, K. A., Power, C., Wardle, J., Shrewsbury, Vanessa A., Robb, Kathryn A., Power, Chris, and Wardle, Jane Socioeconomic differences in weight retention, weight-related attitudes and practices in postpartum women. *Maternal & Child Health Journal* 2009; **13** 231-240.

Stein, A., Fairburn, C. G., Stein, A., and Fairburn, C. G. Eating habits and attitudes in the postpartum period. *Psychosomatic Medicine* 1996; **58** 321-325.

Symons, Downs D., Hausenblas, H. A., Symons Downs, Danielle, and Hausenblas, Heather A. Women's exercise beliefs and behaviors during their pregnancy and postpartum. *Journal of Midwifery & Women's Health* 2004; **49** 138-144.

Outcomes not reported/ not relevant

Fahrenwald, N. L. and Sharma, M. Development and expert evaluation of "Moms on the Move," a physical activity intervention for WIC mothers. Women, Infants, and Children. *Public Health Nursing.* 1919;423-439.

Kinnunen, T. I., Aittasalo, M., Koponen, P., Ojala, K., Mansikkamaki, K., Weiderpass, E., Fogelholm, M., Lu

oto, R., Kinnunen, Tarja I., Aittasalo, Minna, Koponen, Paivikki, Ojala, Katriina, Mansikkamaki, Kirsi, Weiderpass, Elisabete, Fogelholm, Mikael, and Luoto, Riitta Feasibility of a controlled trial aiming to prevent excessive pregnancy-related weight gain in primary health care. *BMC Pregnancy & Childbirth* 2008; **8** 37-

Lambert, L., Raidl, M., Safaii, S., Conner, C., Geary, E. J., and Ault, S. Perceived benefits and barriers related to postpartum weight loss of overweight/obese postpartum WIC participants. *Topics in Clinical Nutrition* 2005; **20** 16-27.

Ostbye, T., Krause, K. M., Brouwer, R. J., Lovelady, C. A., Morey, M. C., Bastian, L. A., Peterson, B. L., Swamy, G. K., Chowdhary, J., McBride, C. M., Ostbye, Truls, Krause, Katrina M., Brouwer, Rebecca J. N., Lovelady, Cheryl A., Morey, Miriam C., Bastian, Lori A., Peterson, Bercedis L., Swamy, Geeta K., Chowdhary, Jaspreet, and McBride, Colleen M. Active Mothers Postpartum (AMP): rationale, design, and baseline characteristics. *Journal of Women's Health* 2008; **17** 1567-1575.

Ostbye, T., McBride, C., mark-Wahnefried, W., Bastian, L., Morey, M., Krause, K. M., Brouwer, R., Turner, B., Ostbye, Truls, McBride, Colleen, mark-Wahnefried, Wendy, Bastian, Lori, Morey, Miriam, Krause, Katrina M., Brouwer, Rebecca, and Turner, Barbara Interest in healthy diet and physical activity interventions peripartum among female partners of active duty military. *Military Medicine* 2003; **168** 320-325.

Peterson, K. E., Sorensen, G., Pearson, M., Hebert, J. R., Gottlieb, B. R., McCormick, M. C.. Design of an intervention addressing multiple levels of influence on dietary and activity patterns of low-income, postpartum women. *Health Education Research* 2002; **17** 531-540.

Women with Depression (exclusion criteria)

Armstrong, K. A. and Edwards, Helen The effects of exercise and social support on mothers reporting depressive symptoms: A pilot randomizwed controlled trial. *International Journal of Mental Health Nursing* 2003; **12** 130-138.

Armstrong, Kylie and Edwards, Helen The effectiveness of a pram-walking exercise programme in reducing depressive symptomatology for postnatal women. *Int J Nurs Pract* 2004; **10** 177-194.

Krummel, D. A., Semmens, E., Boury, J., Gordon, P. M., and Larkin, K. T. Stages of change for weight management in postpartum women. *Journal of the American Dietetic Association* 2004; **104** 1102-1108.

Intervention studies targeted at pregnancy weight management

Bechtel-Blackwell DA, Bechtel-Blackwell DA. Computer-assisted self-interview and nutrition education in pregnant teens. *Clinical Nursing Research* 2002;**11** : 4.450-462.

Olson CM, Strawderman MS, Reed RG, Olson CM, Strawderman MS, Reed RG. Efficacy of an intervention to prevent excessive gestational weight gain. *AM J OBSTET GYNECOL* 2004;**191**: 2.530-536.

Polley BA, Wing RR, Sims CJ, Polley BA, Wing RR, Sims CJ. Randomized controlled trial to prevent excessive weight gain in pregnant women. *Int J Obes Relat Metab Disord* 2002;**26**: 11.1494-1502.

Abstracts or Dissertation Papers

Bell, R., Weir, Z., Stothard, K., Pearce, M., and Adamson, A. Maternal obesity: when should we intervene? A systematic review of lifestyle interventions in women before, during and after pregnancy. *International Journal of Obesity* 2007; **31** S40-S40.

Brouwer, R., Ostbye, T., and Revels, J. Factors Associated With Participation in a Postpartum Weight-Loss Intervention. *Obesity* 2008; **16** S164-S165.

Cahill, J. M., Sanghani, B. V., Lu, H. X., Bose, T., Kitchen, J. F., Klohe-Lehman, D. M., and Freeland-Graves, J. H. Nutritional adequacy in overweight/obese low-income, postpartum women. *Faseb Journal* 2007; **21** A671-A672.

Davis, Catherine Lucy Insulin metabolic syndrome in postpartum women who had gestational diabetes or healthy pregnancies. *Dissertation Abstracts International: Section B: The Sciences and Engineering* ; **58**

Durham, H., Lovelady, C., Ayella, H., Harvin, M., Ostbye, T., Brouwer, R., Chowdhary, J., and Krause, K. Dietary intake of overweight or obese women enrolled in an intervention program to lose postpartum weight. *Faseb Journal* 2006; **20** A1030-A1030.

Ferrari, Renee Marie Influence of provider advice and maternal attitudes on weight change and physical activity during pregnancy and postpartum. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 2008; **69**

Mccarthy, Margaret Elizabeth A longitudinal study of body image and adjustment during pregnancy and the puerperium. *Dissertation Abstracts International: Section B: The Sciences and Engineering* 1999; **60**

Appendix 4: Included studies

RCTs (n=5)

1. Dewey KG, Lovelady CA, Nommsen-Rivers LA, et al. A randomized study of the effects of aerobic exercise by lactating women on breast-milk volume and composition. *N ENGL J MED* 1994;**330**: 7.449-453.

2. Leermakers EA, Anglin K, Wing RR, Leermakers EA, Anglin K, Wing RR. Reducing postpartum weight retention through a correspondence intervention. *Int J Obes Relat Metab Disord* 1998;**22**: 11.1103-1109.

3. Lovelady CA, Williams JP, Garner KE, et al. Effect of energy restriction and exercise on vitamin B-6 status of women during lactation. *MED SCI SPORTS EXERC* 2001;**33**: 4.512-518.

   Lovelady CA, Garner KE, Moreno KL, et al. The effect of weight loss in overweight, lactating women on the growth of their infants**.[see comment].** *N ENGL J MED* 2000;**342**: 7.449-453.

   Lovelady CA, Stephenson KG, Kuppler KM, et al. The effects of dieting on food and nutrient intake of lactating women. *J AM DIET ASSOC* 2006;**106**: 6.908-912.

4. McCrory MA, Nommsen-Rivers LA, Mole PA, et al. Randomized trial of the short-term effects of dieting compared with dieting plus aerobic exercise on lactation performance. *AM J CLIN NUTR* 1999;**69**: 5.959-967.

5. O'Toole ML, Sawicki MA, Artal R, O'Toole ML, Sawicki MA, Artal R. Structured diet and physical activity prevent postpartum weight retention. *J Womens Health* 2003;**12**: 10.991-998.

NRS (n=2)

1. Albright CL, Maddock JE, Nigg CR, Albright CL, Maddock JE, Nigg CR. Increasing physical activity in postpartum multiethnic women in Hawaii: results from a pilot study. *BMC Women's Health* 2009;**9**:4

2. Kinnunen TI, Pasanen M, Aittasalo M, et al. Reducing postpartum weight retention--a pilot trial in primary health care. *Nutr J* 2007;**6**:21

   Aittasalo M, Pasanen M, Fogelholm M, Kinnunen TI, Ojala K, Luoto R. Physical activity counseling in maternity and child health care - a controlled trial. *BMC Women's Health* 2008;**8**: 14.

Appendix 5: Evidence tables

5.1 RCTs

<table>
<tr><th>Study Details</th><th>Participant characteristics</th><th>Intervention Characteristics</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Dewey et al, 1994 [+]

Study design: RCT

Location: USA

Recruitment: participants were recruited through letters to new parents

Objective: investigated whether regular aerobic exercise had any effects on the volume or composition of breast milk.

Length of Follow Up: 18-20 weeks post partum (PP)

Randomisation: mentioned but not described

Allocation Concealment: NR

Blinding: NA

Intention-to-treat: No

Loss to follow up:
▪ 5 participants did not</td>
<td>Number of participants: 33 sedentary women whose infants were being exclusively breast-fed

Mean Age: 30.5

Previous Pregnancies: 1.8

Pregnancy outcomes infant weight: 3766.5 g

Pre-pregnancy Weight: 61.4

BMI at enrolment: NR

Number wks post-partum: 6.5

Pre-treatment weight kg: 67.2

Pre-treatment BMI: NR

Weight gained during pregnancy kg: 16.2

Breastfeeding status: all breastfeeding

Medical history: NR

History of weight management:
NR

Education years: 16.6</td>
<td>Intervention: n=18

Delivered by: research team
Setting: Laboratory
Content:
▪ Exercise sessions were individually tailored and included rapid walking, jogging, or bicycling.
▪ Sessions began with 10 minutes of stretching and low-intensity exercise, followed by aerobic exercise prescribed to achieve 60-70% heart rate reserve. The program began with 20-minute sessions, with 5-minute increments every three days until the woman could complete 45 minutes of continuous exercise at the target heart rate.
Intensity: aerobic exercise (at a level of 60 to 70 percent of the heart-rate reserve)
Duration/timing:
▪ 45 minutes per day, 5 days per week, for 12 weeks beginning 6 to 8 weeks post partum. The exercise-frequency goal was five times per week, but the women occasionally missed some sessions because of illness, injury, or other reasons. The</td>
<td><u>WEIGHT STATUS OUTCOME MEASURES</u>

Weight (kg)
<table>
<tr><th></th><th colspan="3">Baseline 6-8 wk PP</th><th colspan="3">Midpoint 12-14wkpp</th><th colspan="3">Endpoint 18-20 wk</th></tr>
<tr><th></th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th></tr>
<tr><td>I:</td><td>67.3</td><td>10.2</td><td>18</td><td>66.7</td><td>10.6</td><td>18</td><td>65.7</td><td>10.7</td><td>18</td></tr>
<tr><td>C:</td><td>67.0</td><td>7.6</td><td>15</td><td>66.0</td><td>8.1</td><td>15</td><td>65.4</td><td>8.3</td><td>15</td></tr>
</table>
P value nr

Height (cm)
<table>
<tr><th></th><th>Baseline</th><th></th><th></th></tr>
<tr><th></th><th>m</th><th>sd</th><th>n</th></tr>
<tr><td>I:</td><td>163.2</td><td>6.9</td><td>18</td></tr>
<tr><td>C:</td><td>167.6</td><td>6.5</td><td>15</td></tr>
</table>

Body fat %
<table>
<tr><th></th><th colspan="3">Baseline 6-8 wk PP</th><th colspan="3">Midpoint 12-14wkpp</th><th colspan="3">Endpoint 18-20 wk</th></tr>
<tr><th></th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th></tr>
<tr><td>I:</td><td>31.5</td><td>5.6</td><td>18</td><td>30.8</td><td>5.9</td><td>17</td><td>30.0</td><td>6.3</td><td>17</td></tr>
<tr><td>C:</td><td>31.1</td><td>5.1</td><td>15</td><td>30.4</td><td>5.7</td><td>11</td><td>29.4</td><td>6.1</td><td>11</td></tr>
</table>
P value nr

▪ Weight declined significantly in both groups during the study; there was no significant difference in the amount of weight lost or in the change in the percentage of body fat between the exercise and control groups. The exercise program significantly improved aerobic capacity, however; maximal oxygen consumption increased by 25 percent among the exercising women (from 27.0 ±4.8 to 33.8 ±4.4 ml of oxygen per kilogram per minute), as compared with only 5 percent among the control women (from 27.6 ±3.9 to 28.9 ±4.4 ml of oxygen per kilogram per minute; P<0.001).

Incremental weight gain (kg) NR
Rates of overweight and obesity at subsequent pregnancies NR
Long-term overweight and obesity rates NR</td>
<td></td>
</tr>
</table>

complete the study: 1 was excluded because of unreliable data, 1 had a previously undetected thyroid condition, 2 withdrew, and 1 had very low milk production at base line that required intervention, making her ineligible to continue in the study. All but the last woman had been assigned to the control group.

- The five women who withdrew were similar to those who remained in terms of their weight, height, age, education, and parity and the sex of their infants, but their infants had significantly lower birth weights than the infants of the women who remained in the study (mean [±SD] birth weight, 3.31 ±0.20 vs. 3.77 ±0.46 kg; P<0.05).

Ethnicity:
White 85%
Non-white 15%

Marital status: NR

Socio-economic status: NR

Baseline comparability: no significant differences between groups

Inclusion Criteria:
- they had no chronic illness
- used no regular medication,
- did not smoke
- not exercised more than twice per week during the previous 3 months
- planned to breast-feed their infants exclusively for at least 20 weeks
- delivered healthy infants at term (37 to 43 weeks' gestation).

Exclusion Criteria: NR

average frequency of exercise was 4.5 times per week. If a woman missed three or more days of exercise in any week (as was the case for three women), an extra week was added to the program.

Assessment:
- An assistant monitored the heart rate of each woman during each session.
- Measurements were made at base line (6 to 8 weeks post partum), at the midpoint of the study (12 to 14 weeks), and at the end of the study (18 to 20 weeks).
- Maximal oxygen uptake and the plasma prolactin response to nursing were assessed at 6 to 8 and 18 to 20 weeks.
- The women's energy expenditure, resting metabolic rate, body composition, dietary intake, and breast-milk volume and composition were measured at all three points.
- Dietary intake was recorded by each woman with a tape recorder during the three-day periods of heart-rate monitoring. The portions of food consumed were weighed to the nearest 2 g. Nutrient intake was calculated with the Food Processor II computer program (ESHA Research, Salem, Oreg.), food-composition tables, and data from food manufacturers. Breast milk was also measured and tested

WEIGHT MANAGEMENT OUTCOMES

Total energy output kcal/day

	Baseline 6-8 wk PP			Midpoint 12-14wkpp			Endpoint 18-20 wk		
	m	sd	n	m	sd	n	m	sd	n
I:	2509	423	18	2842	540	18	2708	405	18
C:	2419	294	15	2592	423	15	2593	392	15

P value nr

Calorie intake kcal/day

	Baseline 6-8 wk PP			Midpoint 12-14wkpp			Endpoint 18-20 wk		
	m	sd	n	m	sd	n	m	sd	n
I:	2551	438	18	2456	512	18	2497	436	18
C:	2156	388	15	2052	466	15	2168	328	15

P value nr

Energy expenditure in exercise only kcal/day

	Baseline 6-8 wk PP			Midpoint 12-14wkpp			Endpoint 18-20 wk		
	m	sd	n	m	sd	n	m	sd	n
I:	--NR	--	18	388	108	18	421	110	18
C:	NA								

P value nr

Energy expenditure in milk output only kcal/day

	Baseline 6-8 wk PP			Midpoint 12-14wkpp			Endpoint 18-20 wk		
	m	sd	n	m	sd	n	m	sd	n
I:	479	79	18	493	81	18	505	85	18
C:	515	105	15	524	90	15	541	101	15

P value nr

- The resting metabolic rate did not change significantly over time in either group. The mean energy expenditure (not including energy expended in producing milk) was similar between the groups at base line, differed by 281 kcal per day (1.2 MJ per day) (P = 0.09) at the midpoint of the study because of the exercise program, but did not differ significantly at the end of the study even though the exercising women continued to expend about 400 kcal per day (1.7 MJ per day) in exercise.

Infant milk intake g/day

	Baseline 6-8 wk PP			Midpoint 12-14wkpp			Endpoint 18-20 wk		
	m	sd	n	m	sd	n	m	sd	n
I:	775	129	18	822	146	18	841	147	18

		Components: **Diet:** yes **Physical activity**: yes, described above **Dietary**: **Advice**: no **Support/mentoring**: no **Monitoring**: women were weighed on a beam-balance scale to the nearest 10 g. Height was measured with a steel tape measure and headboard to the nearest 0.5 cm. Body composition was determined by hydrostatic weighing. The infants' weights were measured to the nearest gram on an electronic balance. **Control**: n=15 control group did not engage in aerobic exercise more than once per week during the same period.	C: 838 176 15 822 156 15 884 155 15 P value nr ▪ We observed no main effect of energy deficit on milk volume or energy output. NR **Support and mentoring** **Monitoring of weight status** **Involvement/attendance in weight management groups/clubs** **Views of weight management** **Potential harms of intervention** **<u>MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH</u>** **Initiation and duration of breast feeding** ▪ The intake of breast milk by the infants was slightly lower in the exercise group than in the control group at all three study points when expressed in terms of grams per day (because the infants of the exercising mothers were smaller initially and thus consumed less milk), but not when expressed in terms of grams per kilogram of body weight per day. ▪ The breast-milk composition (lipid, protein, and lactose concentrations, and energy density) did not differ between the two groups except for the concentration of protein, which was significantly higher in the exercise group than in the control group at the final measurement. However, the change in the protein concentration did not differ between the groups (P = 0.80); both declined significantly over time (P<0.001 by repeated-measures analysis of variance). ▪ volume of breast milk- the output of energy in milk was somewhat lower in the exercise group than in the control group at all measurements when expressed in terms of kilocalories per day, but not when adjusted for the body weight of the infants (kilocalories per kilogram per day). There were no significant differences between the two groups in the changes in breast-milk intake by the infants, energy output in milk, or the infants' body weight during the study ▪ Total maternal energy output (energy expenditure plus energy output in milk) was similar in the two groups at base line; by the midpoint of the study it had increased to 2842 kcal per day (11.9 MJ per day) in the exercise group, as compared with 2592 kcal per day (10.9 MJ per day) in the control group. Energy intake was significantly higher in the exercise group than in the control group; this was evident even before the intervention (possibly because the women assigned to the exercise group were less restrained in their eating in anticipation of beginning an exercise program).	

			NR **Measures of maternal wellbeing (depression, self-esteem, etc)** **Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management)** **Health of child /mother following a subsequent pregnancy** **Health-related quality of life** **Access/use of appropriate health and support services**	

Study Details	Participant characteristics	Intervention Characteristics	Results	Comments
Leermakers et al., 1998 **[+]** **Study design**: RCT **Location**: USA **Objective**: to determine whether a behavioural weight loss intervention was effective in returning women to their pre-pregnancy weight **Recruitment**: recently given birth at a local women's hospital **Length of Follow Up**: 6 months **Randomisation**: NR **Allocation Concealment**: NR	**Number of participants**: 90 **Mean Age**: 31 **Previous Pregnancies**: mean of 1.8 full pregnancies including current **Pregnancy outcomes: NR** **Pre-pregnancy weight kg:** 68.4 **Pre-pregnancy BMI**: 25.3 **BMI at enrolment**: 29.8 **Pregnancy weight gain kg:** 18.6 **Pre-treatment weight kg**: 80.7 **Pre-treatment BMI**: 29.8 **Weight retained at study entry**	**Intervention**: n= 47) **Delivered by**: research team **Setting**: laboratory **Content:** ▪ correspondence behavioural weight loss program that focused on low-fat/low-calorie eating habits and increasing physical activity. ▪ Components: 1) two group sessions 2) correspondence materials 3) telephone contact. ▪ Start of program: participants were invited to attend two group sessions, held at the beginning of the intervention and at Month 2. ▪ First session, women received group instruction in self-monitoring and getting	**<u>WEIGHT STATUS OUTCOME MEASURES</u>** **<u>Total Weight Loss after 6 months (kg)</u>** m sd n I: 7.8 4.5 36 C: 4.9 5.4 26 p value 0.03 **Height: NR** **<u>Percentage of pre-treatment weight lost</u>** m sd n I: 10 5.8 36 C: 5.8 5.7 26 p value 0.005 After adjusting for baseline differences in age and marital status, differences remained significant (P<0.05 and P<0.009, respectively) **<u>Percentage of post-partum excess weight lost</u>** m sd n I: 79 51 36 C: 44 53 26 p value 0.01 **Percentage of women returning to, or lowering of pre-pregnancy weight**	

Blinding: No

Intention-to-treat: yes

Loss to follow up:
- Twenty-eight women (31%) did not provide follow-up weight data, 5 because of another pregnancy.
- Attrition did not vary by treatment group (x^2=2.7, P=0.1)
- 11 women dropped out of the intervention group (23%)

17 dropped out of the control group (40%).
- There were no differences between drop-outs and completers in marital status, ethnicity, age, months since delivery or number of full-term deliveries (Ps>0.1).
- dropouts were significantly heavier at pre-treatment (85.4+-14.1 kg) than completers (78.6+-12.6 kg) (P<0.05) and retained significantly more weight (above their pre-pregnancy weight) at pre-treatment (14.8+-7.3 kg) than completers (11.1+-4.0 kg) (P<0.005).

kg: 12.3

Number wks post-partum: 32.8

Exceeding IOM guidelines %: 70.2

Breastfeeding status: study excluded breast feeding women

Medical history: NR

History of weight management: **NR**

Education %:
High school: 17.1
Some college 18.2
College degree: 43.2
Graduate degree: 21.6

Ethnicity: 97% Caucasian

Marital status %:
Married: 86.6
Single: 11.1
Separated/divorced: 2.2

Socio-economic status: % employed: 62

Baseline comparability: Intervention participants were significantly older than control participants (32.4 vs 30.3 y P<0.05), and a greater percentage of correspondence women were married, compared to control women (93.5% vs 79.1%, respectively, P<0.05). There were no other significant differences between the correspondence and control groups in the demographic or weight variables.

started on the weight loss program.
- They were instructed to follow a diet consisting of 1000-1500 kcal/day, with fat restricted to 20% of caloric intake

- Participants were also instructed to begin an aerobic exercise program, consisting primarily of walking, and to gradually increase the frequency and duration of their walking until they reached two miles per day on at least five days per week.

- Women monitored calorie, fat intake and exercise on a daily basis for six months and return their records by mail.
- At the second group session, there was a discussion of eating and exercise progress and problem-solving.
- The correspondence component consisted of 16 written lessons about nutrition, exercise and behaviour change strategies, which were mailed to participants. Sent weekly for the first 12 weeks, then biweekly for the next four weeks, and monthly for the last 8 weeks
- Behavioural lessons, which focused on strategies to modify diet and exercise behaviours - tailored to the special needs of new mothers. Each lesson included a 1-2 page homework assignment, which

	m	sd	n
I:	33	nr	36
C:	11.5	nr	26

p value 0.05

- ITT: imputed missing post-treatment weight data by assuming that women who did not complete the post-treatment assessment had no weight change from their pre-treatment weight. The 5 women who became pregnant during this study were excluded from this analysis.
- The average weight losses in both groups were lessened, but all of the between group differences were maintained. The correspondence group lost 6.3 (SD=5.0) kg, while the control group lost only 3.1 (SD=4.9) kg (P<0.004). This difference remained significant after adjusting for age and marital status (P<0.01).
- Of the correspondence group, 27% returned to their pre-pregnancy weight, while only 7% of the control group did (P<0.04).

Incremental weight gain
- the amount of weight retained at pre-treatment (kg above pre-pregnancy weight) was the strongest predictor of how close a woman came to returning to her pre-pregnancy weight (P<0.001). The more weight a participant retained at pre-treatment, the farther she was from her pre-pregnancy weight at post-treatment.

Rates of overweight and obesity at subsequent pregnancies NR
Long-term overweight and obesity rates NR

WEIGHT MANAGEMENT OUTCOMES

Energy expenditure per week

	Baseline			6 months		
	m	sd	n	m	sd	n
I:	924	nr	36	1000	nr	16
C:	1184	nr	26	1229	nr	30

Ps value nr

Daily caloric intake

	Baseline			6 months		
	m	sd	n	m	sd	n
I:	1794	nr	36	1331	nr	16
C:	1957	nr	26	1340	nr	30

Ps value 0.001

Percentage daily caloric intake from fat

	Baseline	6 months

	Inclusion Criteria: ▪ at least 18 years old ▪ delivered within the last 3-12 months ▪ currently exceed their pre-pregnancy weight by at least 6.8 kg. ▪ women with a current BMI 22+ **Exclusion Criteria**: ▪ currently lactating were excluded from the study because of ▪ concerns that dieting and weight loss might affect lactation.	was to be completed and returned with the self-monitoring diaries. ▪ Phone calls by program staff on a regular basis during the six month intervention period (approx. 5-15 min) were made weekly or biweekly, depending on desires and needs. The discussions focused on eating and exercise progress, goal-setting and problem-solving. Weekly self-reports weights collected during phone calls **Assessment:** ▪ Pre-pregnancy weight and amount of weight gained during pregnancy were self-reported on a weight history questionnaire completed at pre-treatment. ▪ The following measures were completed at pre-treatment and six months ▪ Weight: balance beam scale ▪ Height was measured with a stadiometer and used to calculate BMI (kg=m^2). ▪ Physical activity was assessed using the Paffenbarger Physical Activity Questionnaire, a measure which estimates weekly energy expenditure from self-reports of stairs climbed, blocks walked and other recreational activities performed in the past week. ▪ Eating behaviour was assessed using the 60-item Block Food frequency Questionnaire. ▪ Program Adherence.	<table><tr><th></th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th></tr><tr><td>I:</td><td>34.6</td><td>nr</td><td>36</td><td>29.4</td><td>nr</td><td>16</td></tr><tr><td>C:</td><td>37.6</td><td>nr</td><td>26</td><td>31.2</td><td>nr</td><td>30</td></tr></table>Ps value 0.001 ▪ Weight loss was unrelated to these changes in diet or exercise (Ps>0.1). **Number of returned self monitoring records (out of a possible 25)** <table><tr><th></th><th>m</th><th>sd</th><th>n</th></tr><tr><td>I:</td><td>10.1</td><td>7.8</td><td>36</td></tr><tr><td>C:</td><td>Na</td><td>-</td><td>-</td></tr></table>p value nr **Number of returned homework assignment (out of a possible 15)** <table><tr><th></th><th>m</th><th>sd</th><th>n</th></tr><tr><td>I:</td><td>7.6</td><td>5.0</td><td>36</td></tr><tr><td>C:</td><td>Na</td><td>-</td><td>-</td></tr></table>p value nr **Number of phone calls** <table><tr><th></th><th>m</th><th>sd</th><th>n</th></tr><tr><td>I:</td><td>10.3</td><td>3.1</td><td>36</td></tr><tr><td>C:</td><td>Na</td><td>-</td><td>-</td></tr></table>p value nr ▪ There was a significant correlation between number of self-monitoring records returned and weight loss (r=0.50, P<0.005). There were no significant associations between homework completion or telephone contact and weight loss (Ps>0.1). **Involvement/attendance in weight management groups** ▪ The only other variable significantly related to return to pre-pregnancy weight was treatment group membership (p 0.03). Correspondence participants came closer to returning to their pre-pregnancy weight than control participants. ▪ The model including amount of weight retained at pre-treatment and treatment group accounted for 34% of the variance in return to prepregnancy weight **Views of weight management NR** **Potential harms of intervention NR** **MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH** **Measures of maternal wellbeing (depression, self-esteem, etc) NR** **Initiation and duration of breast feeding NR**	

		1) number of self-monitoring records returned; 2) number of homework assignments returned; and 3) number of phone contacts completed. **Control**: ▪ n=43 ▪ Informational brochure about healthy eating and exercise (C. Everett Koop's On Your Way to Fitness). Did not receive any treatment, but participated in assessments at pre-treatment and six months later.	**Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management) NR** **Health of child /mother following a subsequent pregnancy NR** **Health-related quality of life NR** **Access/use of appropriate health and support services NR**	

Study Details	Participant characteristics	Intervention Characteristics	Results	Comments
Lovelady et al, 2006 **[+]** *(also reported in Lovelady et al 2000)* **Study design**: **RCT** **Location**: USA **Objective**: to identify and evaluate dietary changes in women who were participating in a study on the effects of weight loss in overweight lactating women on the growth of their infants **Recruitment**: Participants were recruited through advertisements (flyers) of	**Number of participants**: 48 (35 at follow-up) **Mean Age**: 32 **Previous Pregnancies**: NR **Pregnancy outcomes NR** **Pre-pregnancy BMI**: NR **BMI at enrolment**: 27.8 **Number wks post-partum**: 4 **Pre-treatment weight kg**: 76.5 **Weight retained at study entry kg**: NR **Breastfeeding status**: all breastfeeding	**Intervention**: N=27 (N=19 at follow-up) **Delivered by**: ▪ Registered dietician, who is a research nutritionist with extensive experience in cardiovascular fitness and body composition and dietary assessment techniques, trained the graduate research assistants who worked with the participants. **Setting**: **NR** **Content**: ▪ All participants were given a multivitamin supplement that contained at least 50% of the RDA for lactating women ▪ Women in the diet and exercise group were prescribed an eating plan	**WEIGHT STATUS OUTCOME MEASURES** **Weight (kg)** |	Baseline 4wk PP			Follow up 14 wk PP		
---	---	---	---	---	---	---
	m	sd	n	m	sd	n
Diet + exer	75.9	9.8	19	71.0	9.2	19
Control	77.2	8.3	16	76.4	8.9	16 | Not significant **Height (cm)** |	Follow up 14 wk PP		
---	---	---	---
	m	sd	n
Diet + exer	165.0	6.1	19
Control	166.0	5.2	16	 **Weight lost (kg)** 		Follow up 14 wk PP		
---	---	---	---
	m	sd	n
Diet + exer	4.8	1.6	19
Control	0.8	1.8	16 | P<0.001	

the study in obstetricians' offices and childbirth classes. **Length of Follow Up**: 14 weeks post partum **Randomisation**: Participants were randomly assigned, stratifying by infant sex, by using a random-number table. Assignment to groups was done after baseline measurements were made. Measurements were made at 4 weeks (baseline) and at 14 weeks (end) postpartum. **Allocation Concealment**: **Blinding**: NA **Intention-to-treat**: No **Loss to follow up**: ▪ 8 did not complete the study (six in the diet and exercise group and two in the control group) ▪ 5 returned to work full time and were not able to breastfeed exclusively ▪ 3 women withdrew because of personal issues. ▪ The baseline characteristics of the women who discontinued the study were similar to those who completed the	**Medical history**: NR **History of weight management**: sedentary women **Education**: NR **Ethnicity**: **NR** **Marital status**: NR **Socio-economic status**: NR **Baseline comparability**: NR **Inclusion Criteria**: ▪ Healthy (free from chronic disease) ▪ Sedentary ▪ non-smoking, ▪ overweight (body mass index(25 -30) ▪ exclusively breastfeeding **Exclusion Criteria**: **NR**	that had 500 kcal fewer than their daily energy requirements. ▪ The diet prescription was 25% of energy from fat, 20% from protein, and 55% from carbohydrate, with no diet less than 1,800 kcal (7,531 kJ) total per day. ▪ Women were instructed by trained graduate research assistants to meet their dietary recommendations using the Food Guide Pyramid. Food models were used to demonstrate portion sizes. ▪ Cognitive and behaviour strategies such as slowing the rate of eating, recognizing hunger and satiety, and problem solving were discussed at individual weekly sessions. ▪ Six low-fat, low-calorie frozen dinners were given to the women each week to assist with compliance. ▪ The exercise program instructed women to have moderate intensity exercise. Consisted of brisk walking, jogging, or aerobic dancing. **Intensity**: ▪ Exercise was at 65% to 80% of maximum heart rate four times per week for 10 weeks. The initial exercise session was 15 minutes. The following sessions were increased by 2 minutes per day until women were exercising within their target heart-rate range for 45 minutes.	**Body fat %** 		Baseline 4wk PP			Follow up 14 wk PP		
---	---	---	---	---	---	---
	m	sd	n	m	sd	n
Diet + exer	33.7	3.4	19	30.3	2.9	19
Control	32.9	4.1	16	32.7	4.5	16 | Not significant **BMI** |	Baseline 4wk PP			Follow up 14 wk PP		
---	---	---	---	---	---	---
	m	sd	n	m	sd	n
Diet + exer	27.8	2.5	19	26.0	2.3	19
Control	27.8	2.3	16	27.6	2.6	16 | P value nr NR **Incremental weight gain (kg)** **Rates of overweight and obesity at subsequent pregnancies.** **Long-term overweight and obesity rates** **<u>WEIGHT MANAGEMENT OUTCOMES</u>** **Physical activity NR** **Calorie intake** kcal/day |	Baseline 4wk PP			Follow up 14 wk PP		
---	---	---	---	---	---	---
	m	sd	n	m	sd	n
Diet + exer	2213	574	19	1669	293	19
Control	2378	436	16	2142	540	16	 P value nr NR **Support and mentoring** **Monitoring of weight status** **Involvement/attendance in weight management groups/clubs** **Views of weight management** **Potential harms of intervention** ▪ All women who completed the study exclusively breastfed their infants during the study period. None of the participants complained of reduced milk volume, "fussy" infants, or fatigue as a result of the dietary and exercise intervention. **<u>MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH</u>**	

study, except that the women who withdrew were significantly heavier before pregnancy and had a lower level of cardiovascular fitness. ▪ Food records were incomplete for 5 participants (two in diet and exercise group and three in control group); therefore, they were excluded from this analysis.		**Duration/timing**: ▪ individual weekly sessions for diet counselling. ▪ Exercise sessions were 4 times per week **Assessment**: ▪ All measurements were performed by either the registered dietician or the research assistants. ▪ A research assistant, trained in cardiopulmonary resuscitation, monitored exercise activity compliance at each session ▪ Dietary intake was recorded at 4 and 14 weeks postpartum (baseline and end measurements). ▪ All foods and beverages consumed for 3 consecutive days were weighed on a portable digital scale ▪ Participants recorded their dietary intake by speaking into a tape recorder. Diets were analyzed by trained graduate research assistants ▪ Graduate research assistant weighted women at home and in office on balance beam or digital scale ▪ Research assistants asked if there were any problems infant feeding, milk production, or fatigue **Components**: **Physical activity**: yes **Dietary**: yes **Advice**: yes **Support/mentoring**: yes **Monitoring**: yes	**NR** **Measures of maternal wellbeing (depression, self-esteem, etc)** **Initiation and duration of breast feeding** **Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management)** **Health of child /mother following a subsequent pregnancy** **Health-related quality of life** **Access/use of appropriate health and support services**	

		Control: n=21 (n=16 at follow-up) ▪ The control group was instructed not to change their dietary intake or physical activity during the study. ▪ All participants were given a multivitamin supplement that contained at least 50% of the RDA for lactating women.		

Study Details	Participant characteristics	Intervention Characteristics	Results	Comments
McCrory et al, 1999 **[+]** **Study design: RCT** **Location**: USA **Objective**: evaluated whether weight loss by dieting, with or without aerobic exercise, adversely affects lactation performance **Recruitment**: Exclusively breast-feeding women between 8 and 16 wk postpartum were recruited through local physicians' offices, childbirth classes, and letters to new parents. **Length of Follow Up:** 11 day intervention with	**Number of participants**: 67 **Mean Age**: 31.5 **Previous Pregnancies**: Primiparious: 37% Multiparious: 63% **Pregnancy outcomes** Infant birth weight g: 3546 **Pre-pregnancy weight kg**: 66.2 **Pre-pregnancy BMI**: NR **BMI at enrolment**: 25.2 **Number wks post-partum**:12 **Pre-treatment weight kg**: 68.6 **Pre-treatment BMI**: 25.2 **Pregnancy weight gain kg:**	**Intervention**: Diet n= 22 Diet plus exercise n=22 **Delivered by:** research team **Setting**: exercise sessions were self supervised **Content**: ▪ During a 10–12-d baseline period, dietary intake, resting metabolic rate (RMR), energy expenditure, maximal oxygen consumption, body composition, milk volume and composition, and plasma prolactin concentrations were measured. ▪ Subjects were then randomly assigned to 1 of 3 groups for 11 d: *1*) a diet group (35% energy deficit), *2*) a diet plus exercise group (diet + exercise: 35% net energy deficit, 60% by dietary	**WEIGHT STATUS OUTCOME MEASURES** **Weight (kg)** |	Baseline			Follow up		
---	---	---	---	---	---	---
	m	sd	n	m	sd	n
Diet	68.3	10.2	22	66.4	9.8	22
Diet + exer	69.0	12.8	22	67.8	12.7	21
Control	68.5	8.5	23	68.3	8.6	23 | P value nr **Height (cm)** |	Baseline		
---	---	---	---
	m	sd	n
Diet	165.0	10.01	22
Diet + exer	164.6	7.7	22
Control	166.5	7.1	23 | Height ▪ Weight loss did not differ significantly between the diet and diet + exercise groups (1.9 and 1.6 kg, respectively) and was minimal in the control group (0.2 kg); weight loss in the control group was significantly different from that in the diet and diet + exercise groups ($P < 0.0001$).	The total energy requirement (TER) at baseline was determined individually by averaging energy expenditure (including breast-milk output and exercise) and intake. For the diet group, the amount of energy to be provided during the intervention was calculated as 0.65 x TER and no additional exercise was prescribed. For the diet + exercise group, additional energy expenditure prescribed in exercise during the

follow up.

Randomisation: randomly assigned to 3 groups: diet, diet plus exercise, or control, computer-based randomisation using the Moses-Oakford algorithm wit variable block size

Allocation Concealment: NR

Blinding: NA

Intention-to-treat: No

Loss to follow up:
- 68 subjects enrolled
- 1 withdrew after assignment to the diet + exercise group, but before the intervention began because she had difficulty completing the baseline measurements.
- There were no significant group differences in the characteristics
- of the remaining 67 subjects One subject in the diet + exercise group did not continue with the intervention after day 8 because of a previously unreported exercise-induced asthma condition; data for this subject were included in the analysis up to the time that she stopped participating in the intervention.

15.9

Breastfeeding status: all women breastfed

Medical history: NR

History of weight management: **NR**

Education years: 16.3

Ethnicity:
White: 79%
Non-white: 21%

Marital status: NR

Socio-economic status: NR

Baseline comparability: yes

Inclusion Criteria:
- no chronic illnesses
- not taking medication regularly;
- Non-smokers
- had delivered a single, healthy, term infant
- willing to exercise 3 d/wk for ≥ 1 mo before the intervention (to prepare physically in case they were assigned to the group with intensive exercise).

Exclusion Criteria: **NR**

restriction and 40% by additional exercise), and *3*) a control group.
- For the diet and diet + exercise groups, diets were individually tailored and food was provided in preweighed amounts. Meals and snacks were prepared from fresh, pre-packaged, and frozen commercial foods. Subjects were encouraged to drink plenty of water and other non-energy-containing beverages and a daily multivitamin and mineral supplements
- Due to the study's measurement and exercise requirements, part-time child care of £28 h for the control and diet groups and 46 h for the diet + exercise group was offered.

Intensity:
- Exercise sessions were self-supervised; the subjects exercised at their own convenience in one or more sessions per day. They were allowed to perform any aerobic exercise activity or combination, including walking, jogging, low-impact aerobics, step aerobics, bicycling, swimming, and use of exercise machines such as stair steppers and stationary cycles

Duration/timing:
- 11 day intervention.
- For the control and diet groups, exercise frequency and intensity were held constant between the

- The decrease in fat mass also did not differ significantly between the diet and diet + exercise groups; however, fat-free mass decreased by 0.7 kg in the diet group, but increased by 0.1 and 0.2 kg in the diet + exercise and control groups, respectively ($P = 0.003$). The change in percentage body fat also differed among groups, with the diet + exercise group having the biggest decrease and the control group having the smallest decrease.
- short-term weight loss (1.1 ± 0.4 kg/wk) resulting from a combination of dieting and aerobic exercise appears safe for breast-feeding mothers and is preferable to weight loss achieved primarily by dieting because the latter reduces maternal lean body mass. Note that this conclusion may not apply under other circumstances, such as during periods of weight loss >11 d or among women with lower initial body fatness than the women in the present study had.

Body fat percentage

	Baseline			Follow up		
	m	sd	n	m	sd	n
Diet	32.5	6.2	22	31.6	6.2	22
Diet + exer	32.9	6.5	22	31.4	6.7	21
Control	32.0	7.0	23	31.5	6.9	23

P value nr

Fat-free mass (kg)

	Baseline			Follow up		
	m	sd	n	m	sd	n
Diet	45.7	4.9	22	45.1	4.8	22
Diet + exer	45.7	6.0	22	46.0	5.9	21
Control	46.2	4.2	23	46.4	4.1	23

P value nr

NR

Incremental weight gain (kg)

Rates of overweight and obesity at subsequent pregnancies.

Long-term overweight and obesity rates

WEIGHT MANAGEMENT OUTCOMES

Physical activity minutes per week

	Baseline			Follow up		
	m	sd	n	m	sd	n
Diet	134	80	22	126	86	22
Diet + exer	130	44	22	499	87	21
Control	122	57	23	135	126	23

P value nr

intervention was calculated as 0.40 x 0.35 x TER. Energy provided during the intervention for the diet + exercise group was calculated as 0.65 x (TER + additional energy expenditure prescribed in exercise) so that a net 35% energy deficit would be achieved

		baseline and intervention periods ▪ exercise for the diet + exercise group was prescribed in terms of a target heart rate range (50–70% of maximal heart rate) and total time, divided into 9 of the 11 d **Assessment**: ▪ Energy expended in exercise was determined by monitoring the heart rate ▪ During the baseline period, subjects kept detailed activity records for 4 d by talking into a tape recorder every 15–30 min, and energy expenditure during sleep and daily activity ▪ For 4 d during baseline, subjects weighed and recorded all food items consumed ▪ Heights and weights were measured ▪ Twenty-four–hour milk volume, feeding frequency, and total time spent breast-feeding were assessed in the home on 4 consecutive days during baseline and on days 5, 6, 9, and 10 of the intervention; milk volume was measured by standard test-weighing procedures (with an electronic scale) **Components**: **Physical activity**: yes **Dietary**: diet was only monitored (and food was provided in pre-weighed amounts for both diet and diet + exercise groups). No advice given	**Calorie intake kcal/day** Baseline: Diet m 2660, sd 442, n 22; Diet + exer m 2571, sd 459, n 22; Control m 2486, sd 488, n 23 Follow up: Diet m 1873, sd 232, n 22; Diet + exer m 2075, sd 301, n 21; Control m NA, sd NA, n 23 P value nr **Energy expenditure kcal** Baseline: Diet m 2502, sd 370, n 22; Diet + exer m 2474, sd 423, n 22; Control m 2462, sd 344, n 23 Follow up: Diet m NR, n 22; Diet + exer m NR, n 21; Control m NR, n 23 P value nr **Energy output for breastfeeding kcal** Baseline: Diet m 547, sd 98, n 22; Diet + exer m 595, sd 108, n 22; Control m 523, sd 86, n 23 Follow up: Diet m 557, sd 74, n 22; Diet + exer m 571, sd 96, n 21; Control m 540, sd 91, n 23 P value nr NR **Support and mentoring** **Monitoring of weight status** **Involvement/attendance in weight management groups/clubs** **Views of weight management** **Potential harms of intervention** **MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH** **Milk volume g/per day** Baseline: Diet m 830, sd 168, n 22; Diet + exer m 878, sd 165, n 22; Control m 801, sd 115, n 23 Follow up: Diet m 829, sd 122, n 22; Diet + exer m 863, sd 156, n 21; Control m 818, sd 140, n 23 P value nr **NR**	

		Advice: some advice given for exercise **Support/mentoring**: no **Monitoring**: yes, women were assessed throughout intervention **Control**: n=23 The control group was asked to maintain their weight during the intervention by maintaining their usual diet and activity patterns.	**Measures of maternal wellbeing (depression, self-esteem, etc)** **Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management)** **Health of child /mother following a subsequent pregnancy** **Health-related quality of life** **Access/use of appropriate health and support services**	

Study Details	Participant characteristics	Intervention Characteristics	Results	Comments
O'Toole et al, 2003 [-] **Study design**: RCT **Location**: USA **Objective**: examines the impact of an individualized, structured diet and physical activity intervention on weight loss in overweight women during the first year postpartum **Recruitment**: advertisements in local newspapers and TV **Length of Follow Up**: 1 year post partum	**Number of participants**: 40 at baseline, 23 at Follow up **Mean Age**: 31.5 **Previous Pregnancies**: 2.3 **Pregnancy outcomes**: NR **Pre-pregnancy BMI**: NR **BMI at enrolment**: 29.8 **Number wks post-partum**: 13 **Pre-treatment weight kg**: 82.0 **Weight retained at study entry kg**: NR **Body fat %:** 43.2	**Interventions** **Structured program n=13** **Delivered by**: diet and exercise physiologist **Setting**: women's exercise laboratory **Content**: ▪ individualised diet and exercise program derived from baseline measurements. Participants also kept a diary of diet and physical activity. ▪ Specific 12-week dietary plan that was tailored to each women's needs (provided from a 3-day food diary at baseline) ▪ Healthy cooking demonstrations were offered	**<u>WEIGHT STATUS OUTCOME MEASURES</u>** **Weight (kg)** Baseline: m 78.6, sd 1.5, n 13 / 12 wks: m 73.0, sd 2.2, n 13 / 1 year Post Part: m 71.3, sd 2.2, n 13 Self Direct: m 85.4, sd 3.5, n 10 / 12 wks: m 84.8, sd 4.2, n 10 / 1 year Post Part: m 84.1, sd 4.3, n 10 Structured group differed significantly from baseline ($p<0.001$) and from the self-directed group ($p<0.05$) at 12 weeks and 1 year postpartum. **Height (cm)** Baseline: m / sd / n Structured: 164 / 5.4 / 21 Self Direct: 167 / 6.6 / 19 **Body fat Percentage** Baseline: m 41.3, sd 1.0, n 13 / 12 wks: m 36.4, sd 1.8, n 13 / 1 year Post Part: m 35.3, sd 1.9, n 13 Self Direct: m 45.8, sd 1.8, n 10 / 12 wks: m 44.1, sd 2.3, n 10 / 1 year Post Part: m 44.3, sd 2.3, n 10	▪ Of those, structured program (n = 13) had a significant weight loss (7.3 kg, $p < 0.01$), a significant decrease in percent body fat (6%, $p < 0.01$), and no change in fat-free mass. ▪ Self directed group (n = 10) had no significant

Randomisation: randomised to two different groups (blinded drawing of labels containing group assignment)

Allocation Concealment: Yes (blinded drawing of labels containing group assignment)

Blinding: NA

Intention-to-treat: No (reported baseline means differ between tables suggesting that only those cases followed up were analysed at all time points)

Loss to follow up:
- 23/40 participants stayed in study until 1 year post partum
- Structured program n=13
- Self-directed n=10
- 8 dropouts from structured
- 9 self directed dropouts
- No differences in drop outs and those who remained in study

Breastfeeding status: 57% breastfed at baseline

Medical history: NR

History of weight management: not active, not engaging in dietary management

Education NR

Ethnicity: **NR**

Marital status: NR

Socio-economic status: NR

Baseline comparability: yes, no significant difference between groups at baseline p >0.05

Inclusion Criteria: (characteristics of women who enrolled)
- Overweight BMI 25-29.9 prior to pregnancy, had gained more than 15kg during pregnancy, and were more than 5kg heavier than pre-pregnancy weight at time of enrolment.

Exclusion Criteria:
- In a regular exercise program
- In formal weight loss program
- Medical condition that would make it difficult to participate in diet and exercise program

for nutritional education and motivation
- Group educational sessions dealing with nutrition and physical activity were provided. Goal to create an energy deficit of 500 calories per day through diet (350kcal/day) and exercise (at least 150kcal/day)
- Individualised exercise program based on physical activity level at baseline

Intensity:
- moderate intensity exercise as measured by a heart rate monitor. Intensity was gradually built upon to reach the target level of over 1050 kcal/wk by week 3 of intervention

Duration/timing:
- group educational sessions were held once a week for 12 weeks, biweekly for the following two months, and then monthly for remaining time.

Assessment:
- Assessments at baseline, 12wks, 1 year post partum
- heart rate monitors used in the first 12 weeks to assess intensity of exercise
- 3 day food diary and women were instructed on how to record consumption accurately by dietician

Components:
Physical activity: yes
Dietary: yes
Advice: yes
Support/mentoring: yes
Monitoring: yes

Structured group differed significantly from baseline at 12 weeks and 1 year postpartum (p<0.001) and from the self-directed group at all time points (p<0.05).

NR
Incremental weight gain (kg)
Rates of overweight and obesity at subsequent pregnancies.
Long-term overweight and obesity rates

WEIGHT MANAGEMENT OUTCOMES

Calorie intake kcal/day

	Baseline			12 wks			1 year Post Part		
	m	sd	n	m	sd	n	m	sd	n
Structured:	2073	154	13	1758	95	13	1592	73	13
Self Direct	2300	148	10	1918	156	10	1541	89	10

Both groups were significantly different from baseline at 12 weeks and 1 year postpartum (p<0.001) and the self-directed group were differed significantly from baseline at 12 weeks (p<0.05).

Exercise calorie expenditure kcal/week

	Baseline			12 wks			1 year Post Part		
	m	sd	n	m	sd	n	m	sd	n
Structured:	431	120	13	1501	172	13	1987	612	13
Self Direct	768	256	10	1273	295	10	1236	206	10

Structured group differed significantly from baseline at 12 weeks (p<0.05) and 14 year postpartum (p<0.001).

NR
Support and mentoring
Monitoring of weight status
Involvement/attendance in weight management groups/clubs
Views of weight management
Potential harms of intervention

MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH

Measures of maternal wellbeing (depression, self-esteem, etc)

Breast feeding % (entire sample)

	Baseline			12 wks			1 year Post Part		
	%	n	N	%	n	N	%	n	N
Sample	57	23	40	69	20	29	70	16	23

P value NR

change in weight, percent body fat, or fat-free mass.

		Self-directed program n=10 **Delivered by**: diet and exercise physiologist **Setting**: women's exercise laboratory **Content**: ▪ Met with dietician and exercise physiologist for a single 1-hour educational session where they were instructed on healthy diet and exercise ▪ Goal to create an energy deficit of 500 calories per day. ▪ Given copies of American dietetic association brochure 'Nutrition & Health for Women' and Food Guide Pyramid ▪ Encouraged to create a350 kcal deficit in diet ▪ Given copies of an exercise and fitness brochure 'Exercise & Fitness: A Guide for Women' ▪ Encouraged to participate in aerobic physical activity **Intensity**: at own pace **Duration/timing:** ▪ single hour education session **Assessment**: ▪ Assessments at baseline, 12wks, 1 year post partum ▪ No heart rate monitors provided for this group **Components**: **Physical activity**: yes **Dietary**: yes **Advice**: yes **Support/mentoring**: no **Monitoring**: yes	▪ There was no significant within group or between group differences in weight loss by breast feeding status at 12 weeks or one year post partum **NR** **Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management)** **Health of child /mother following a subsequent pregnancy** **Health-related quality of life** **Access/use of appropriate health and support services**	

5.2 NRS

Study Details	Participant characteristics	Intervention Characteristics	Results	Comments
Albright et al., 2009 **[-]** **Study design**: pre-test/post-test design **Location**: USA (Hawaii) **Objective**: to test the efficacy of a brief tailored intervention to increase physical activity (PA) in women 3–12 months after childbirth **Recruitment**: a non-profit organization that educates new mothers about infant care and parenting **Length of Follow Up**: 9 weeks after baseline **Randomisation**: NA **Allocation Concealment**: NA **Blinding**: NA **Intention-to-treat**: NR **Loss to follow up**: All women returned the post-test survey	**Number of participants**: 20 **Mean Age**: 32.9 **Previous Pregnancies**: Number of children: 1.7 Primiparous 50% **Pregnancy outcomes** infant age at time of study: 6.9 months **Pre-pregnancy BMI**: NR **BMI at enrolment**: **23.6** **Number wks post-partum**: 29.9 **Pre-treatment weight kg**: NR **Weight retained at study entry kg**: NR **Breastfeeding status**: NR **Medical history**: NR **History of weight management**: Sedentary women **Education**: years of formal education 16.8 **Ethnicity**: White 50%	**Intervention**: n=20 **Delivered by**: health educators **Setting**: research centre **Content**: ▪ primary goal was to alter key mediators of physical activity including personal, social, and environmental factors ▪ the intervention was designed to enhance self-efficacy through promoting a series of successful experiences in meeting realistic physical activity goals ▪ telephone counseling, pedometers, referral to community PA resources, social support, email advice on PA/pedometer goals, and newsletters ▪ advice was given during telephone counselling calls and were incorporated into print materials (tip sheets and newsletters) ▪ At the baseline visit, participants had an individualized counselling session with the health educator. During this visit the health educator discussed the woman's personal benefits and barriers to physical activity, helped her problem solve her most	**<u>WEIGHT STATUS OUTCOME MEASURES</u>** ▪ There was no significant change in BMI over the two-month period (note: the physical activity intervention was not designed to promote weight loss). **NR** **Weight (kg)** **Height (cm)** **Incremental weight gain (kg)** **Rates of overweight and obesity at subsequent pregnancies.** **Long-term overweight and obesity rates** **<u>WEIGHT MANAGEMENT OUTCOMES</u>** **Physical activity** ▪ Over 90% of the mothers choose to walk during the intervention, ▪ At endpoint 30% of the women met or exceeded national recommendations for 150 minutes per week of moderate or greater intensity physical activity. Over half (55%) had increases of 60 minutes or more of MVLPA per week ▪ The pre-post increases in minutes of MVLPA among ethnic groups, between women with an infant less than 6 months of age versus those with an infant older than six months, and between primiparous and multiparous women were all not significant. **Minutes of LTPA per week** Baseline: m 3.0, sd 13.4, n 20 — Follow up 2 mon: m 85.5, sd 76.4, n 20 I:: p < .001 Cohen's d = 2.2; effect size r= 0.7 NR **Dietary or Calorie intake** **Support and mentoring** **Monitoring of weight status** **Involvement/attendance in weight management groups/clubs** **Potential harms of intervention**	

	Asian-American 35% Native Hawaiian/other 15% **Marital status**: 95% married **Socio-economic status**: Working fulltime/part-time 45% **Baseline comparability**: There were no baseline differences in demographic characteristics between whites and all other ethnic groups combined **Inclusion Criteria**: ▪ sedentary (i.e., not doing more than 30 minutes a week of moderate or vigorous physical activity) ▪ 18–45 years of age ▪ postpartum 3 months to 12 months ▪ free of chronic diseases ▪ not pregnant ▪ free of medical conditions that would limit moderate intensity exercise **Exclusion Criteria**: **NR**	significant barrier(s), negotiated her first physical activity goal, and set the time for her telephone calls. ▪ The telephone counseling was designed to provide regular, credible, individualized counseling. ▪ The telephone contacts set short-term physical activity goals in order to increase self-efficacy, evaluated success in meeting physical activity goals, problem solved social/environmental barriers to adherence, discussed future barriers and plans to effectively cope with them, and provided reinforcement and social support for physical activity **Intensity**: ▪ moderate to vigorous intensity leisure activity **Duration/timing**: ▪ The baseline and endpoint visits typically took between 30 and 40 minutes to complete and took place at the Centre's office ▪ The schedule for telephone calls was once a week over the 2 month period **Assessment**: ▪ Teaching new mothers to apply self-monitoring, self-evaluation, and self-reinforcement through goal-setting, positive self-talk, and problem- solving was expected to develop skills that would enhance their ability to integrate physical activity into their daily lives. ▪ To encourage self-	**Views of weight management** ▪ The mean score across all 12 barriers was 2.57 (1.4) at baseline and the mean score at endpoint was 2.31 (1.2). This represented a significant ($p < .03$) pre-post reduction in perceived barriers. This pre-post change was not significantly different across ethnic groups or between primiparous and multiparous women. ▪ At post-test participants provided anonymous feedback about the intervention. Over 75% found setting realistic weekly goals via the pedometer and receiving PA counselling from the health educators helped increase their PA. ▪ Over 80% were very satisfied with the amount of time they spent with the counsellors, and 80% were satisfied with their PA progress during the intervention **MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH** **NR** **Measures of maternal wellbeing (depression, self-esteem, etc)** **Initiation and duration of breast feeding** **Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management)** **Health of child /mother following a subsequent pregnancy** **Health-related quality of life** **Access/use of appropriate health and support services** ▪ 5.8 ± 1.6 contacts out of the 7 scheduled contacts (83%) were completed	

		monitoring, women were given a pedometer ▪ Participants were instructed to write down their weekly minutes of activity and the number of daily steps on a calendar and report them back to health educator at phone call ▪ Questionnaire where given to women and they also had physiological assessments at baseline and 8–9 weeks later. **Components**: **Physical activity**: yes **Dietary**: do **Advice**: yes **Support/mentoring**: yes **Monitoring**: yes **Control**: No control		

<table>
<tr><th>Study Details</th><th>Participant characteristics</th><th>Intervention Characteristics</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Kinnunen et al., 2007 [-]

Study design: non-randomised

Location: Finland

Objective: studied whether individual counselling on diet and physical activity from 2 to 10 months postpartum has positive effects on diet and leisure time physical activity and increases the proportion of primiparas returning to their pre-pregnancy weight

Recruitment: recruited through the child health care system, which is available to all families with children in every municipality in Finland and is funded by public tax revenue

Length of Follow Up: 10 months postpartum

Randomisation: Not randomised

Allocation Concealment: No

Blinding: NA</td>
<td>Number of participants: 85

Mean Age: 29.0

Previous Pregnancies: Primiparas 100%

Pregnancy outcomes NR

Pre-pregnancy BMI: 22.4

BMI at enrolment: 24.0

BMI by category %:
18.5-24.9: 67
25-29.9: 29
30+: 4

Number wks post-partum: 8

Total gestation weight gain kg: 15.8

Total gestation weight gain%:
Below recommendation 21.2
Within recommendation 28
Above recommendation 49

Weight at study entry kg: 66.1

Weight retained at study entry kg: 4.3

Breastfeeding status: no statistically significant differences in the duration of exclusive (medians 5.0 vs. 5.0 months, p = 0.57) or partial breastfeeding (medians 10.0 vs. 8.5 months, p</td>
<td>Intervention: N=48

Delivered by: public health nurse (PHN)
Setting:
▪ Conducted in six child health clinics.
▪ The clinics were selected on the basis of the clinics' administrative personnel's suggestion for suitable clinics.
▪ Three clinics volunteered to be intervention clinics and the remaining clinics were treated as controls
Content:
▪ PA counselling was based on the PRECEDE-PROCEED model and Stages of Change.
▪ PHNs had brief discussions with the participants about pre-pregnancy body weight at the child's 2-month visit to the CC (public health child health clinics). If the pre-pregnancy weight was lower than the current weight, the PHN encouraged the participant to try to return to that weight
▪ The physical activity primary counselling session began with a discussion about the participant's current leisure time physical activity (LTPA) and continued with a discussion about the participant's needs and opportunities to increase LTPA.</td>
<td><u>WEIGHT STATUS OUTCOME MEASURES</u>

Weight (kg)
<table>
<tr><th></th><th>Baseline</th><th>2m Postpartum</th><th></th><th>Follow up 10 m postpartum*</th><th></th><th></th></tr>
<tr><th></th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th></tr>
<tr><td>I:</td><td>67.1</td><td>11.1</td><td>48</td><td>65</td><td>nr</td><td>46</td></tr>
<tr><td>C:</td><td>64.7</td><td>7.8</td><td>37</td><td>62</td><td>nr</td><td>37</td></tr>
</table>
* numbers pulled from graph

Proportion of women who retained I<0 kg %
<table>
<tr><th></th><th>Follow up 10 m postpartum</th><th></th><th></th></tr>
<tr><th></th><th>n</th><th>N</th><th>%</th></tr>
<tr><td>I:</td><td>23</td><td>46</td><td>50</td></tr>
<tr><td>C:</td><td>11</td><td>37</td><td>30</td></tr>
</table>
P 0.06
▪ Fifty percent of the intervention group and 30% of the control group returned to their pre-pregnancy weight by 10 months postpartum, but the difference did not reach statistical significance
Weight retention kg
<table>
<tr><th></th><th>Follow up 10 m postpartum</th><th></th><th></th></tr>
<tr><th></th><th>m</th><th>sd</th><th>n</th></tr>
<tr><td>I:</td><td>1.8</td><td>4.3</td><td>46</td></tr>
<tr><td>C:</td><td>1.0</td><td>4.4</td><td>37</td></tr>
</table>
P 0.42

Waist circumference cm
<table>
<tr><th></th><th>Baseline</th><th>2m Postpartum</th><th></th><th>Follow up 10 m postpartum*</th><th></th><th></th></tr>
<tr><th></th><th>m</th><th>sd</th><th>n</th><th>m</th><th>sd</th><th>n</th></tr>
<tr><td>I:</td><td>81.8</td><td>9.0</td><td>48</td><td>78.1</td><td>10.2</td><td>46</td></tr>
<tr><td>C:</td><td>81.1</td><td>6.7</td><td>37</td><td>75.4</td><td>6.2</td><td>37</td></tr>
</table>
P 0.24

NR
Height (cm)
Incremental weight gain (kg)
Rates of overweight and obesity at subsequent pregnancies.
Long-term overweight and obesity rates

<u>WEIGHT MANAGEMENT OUTCOMES</u></td>
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Intention-to-treat: No **Loss to follow up**: ▪ Participants who dropped out of the study (n = 7) were younger, less educated and had higher pre-pregnancy and postpartum BMI, but lower gestational weight gain and weight retention at 2 months postpartum on average than participants who completed the study (n = 85). No major differences were observed in smoking status or in the main dietary and physical activity outcomes between the groups. There is no follow-up information available on the drop-outs. ▪ All 48 women participated in the primary physical activity and dietary counselling sessions. ▪ Five women missed one physical activity booster session, ▪ 3 women missed one dietary booster session ▪ 3 women missed the discussion about returning to pre-pregnancy weight. ▪ On average, the women participated in 4.9 of the five physical activity counselling sessions and in 3.9 of the four dietary counselling	= 0.07) between the intervention and the control groups. **Medical history**: nr **History of weight management**: NR **Education %**: Basic or secondary 47 Polytechnic 21 University 32.0 **Ethnicity**: NR **Marital status**: NR **Socio-economic status**: NR **Baseline comparability**: no significant differences between groups **Inclusion Criteria**: NR **Exclusion Criteria**: ▪ under 18 years ▪ type 1 or type 2 diabetes mellitus ▪ twin pregnancy ▪ physical disability that prevents exercising ▪ problematic pregnancy, ▪ substance abuse ▪ treatment or clinical history of any psychiatric illness ▪ inadequate language skills in Finnish ▪ intention to change residence within three months.	▪ The general benefits and restrictions of LTPA were also raised with the help of a take home leaflet. ▪ An individual weekly LTPA plan was written into the participant's follow-up notebook. ▪ the participant had an option to attend supervised group exercise sessions held once a week for 45–60 min at a location close to each intervention clinic. The group exercise included both endurance and muscular training and it was developed specifically for postpartum women. ▪ The following dietary objectives were set for each participant to achieve or to maintain: 1) to have a regular meal pattern, emphasising the importance of breakfast and ≥1 hot meal every day, 2) to eat at least 5 portions/d (400 g/d) in total of different kinds of vegetables, fruit and berries, 3) to consume mostly high-fibre bread (≥5 g fibre/100 g) and 4) to restrict the intake of high-sugar snacks to ≤1 portion/d **Intensity**: ▪ a minimum of 30 min of moderate intensity physical activity on five weekdays was considered sufficient for health and a minimum of 40 min of high-intensity physical activity three times per week for fitness. **Duration/timing**: ▪ The physical activity	**Physical activity- METmin during leisure time** Baseline before pregnancy / Follow up 10 m postpartum* I: 2328 1308 48 1906 970 46 C: 2061 975 37 2051 1249 37 ▪ There were no statistically significant differences between the groups in changes in the weekly METmin from baseline to 5 or 10 months postpartum when adjusted for baseline weekly METmin, age, education, gestational weight gain and BMI at 2 months postpartum. **Dietary or Calorie intake** ▪ The mean increase intake of high fibre bread in favour of the intervention group was 16% both at the first follow-up (5 months postpartum) and the second follow-up (10 months postpartum).The intake of high-sugar snacks decreased on average by 0.6 portions/d at the first follow-up in the control group compared with the intervention group, but returned to the baseline level by the second follow-up. There were no statistically significant differences in changes in the intake of vegetables, fruit and berries between the groups. Moreover, no between-group differences were observed in the proportion of women having breakfast and at least one hot meal per day. The respective proportions of women in the intervention and the control groups fulfilling this criterion were 88% and 86% at baseline, 94% and 92% at the first follow-up and 93% and 89% at the second follow-up. **NR** **Support and mentoring** **Monitoring of weight status** **Involvement/attendance in weight management groups/clubs** **Views of weight management** **Potential harms of intervention** **MATERNAL AND INFANT OUTCOMES AFTER CHILDBIRTH** **NR** **Measures of maternal wellbeing (depression, self-esteem, etc)** **Initiation and duration of breast feeding** **Health related outcome during subsequent pregnancies (gestational diabetes, pre- eclampsia in relation to weight management)** **Health of child /mother following a subsequent pregnancy** **Health-related quality of life** **Access/use of appropriate health and support services**	

sessions. ▪ The average participation rate in the group exercise sessions was 50.7 % (sd 28.5) of the sessions available for each woman.		counselling consisted of one primary counselling session (allocated time 20–30 min) at the 2- month visit and four booster sessions (allocated time 10– 15 min) at the 3, 5, 6 and 10 month visits. ▪ The dietary counselling consisted of one primary counselling session (allocated time 20–30 min) at the 3-month visit and three booster sessions (allocated time 10 min, in addition to the physical activity boosters) at the 5, 6 and 10 month visits. ▪ At the beginning of the primary counselling session, the PHN assessed the participant's current dietary habits concerning these four topics using the baseline food frequency questionnaire. ▪ After comparing the personal habits to the recommendations, the PHN and the participant discussed the participant's need for dietary changes, as well as her opportunities for and barriers to making the changes. ▪ also received two take home leaflets on healthy diet. ▪ The participant was asked to keep a weekly record of her compliance with the four objectives in her follow-up notebook. ▪ At each booster visit, the follow-up notebook was checked and the compliance was discussed **Assessment**: ▪ Body weight (in light clothing		

		without shoes) and waist circumference measured at every visit. ▪ Data on gestational weight development was obtained from the maternity card. ▪ Pre-pregnancy weight and height were self-reported. ▪ At the booster sessions the participant's adherence to the plan was assessed, the plan was revised, if needed, ▪ The first LTPA and the dietary follow-up questionnaires were completed at the 5-month visit and the second follow-up questionnaires at the 10-month visit ▪ The baseline questionnaire, completed before the child's 2-month visit, included questions on background (e.g. education, smoking), dietary intake and LTPA. ▪ Information on dietary intake was obtained using a 57-item food frequency questionnaire (a simplified version of the food frequency questionnaire used in the Finnish Health 2000 study). ▪ Questions on LTPA were modified from the International Physical Activity Questionnaire (IPAQ). ▪ Dietary and LTPA questions have not been validated among postpartum women. **Components**: **Physical activity**: yes **Dietary**: yes **Advice**: yes **Support/mentoring**: yes		

		Monitoring: yes **Control**: n=37 ▪ usual care		