Diet and/or Exercise Treatment for Weight Loss in Overweight and Obese Women after Childbirth

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Gothenburg 2012

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ISBN 978-91-628-8575-5

The e-version of this thesis is available at http://hdl.handle.net/2077/30259

Printed in Gothenburg, Sweden 2012
Kompendiet

“We first make our habits, and then our habits make us.”

John Dryden

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ABSTRACT

AIM: The aim of the research presented in this thesis was to evaluate whether, dietary behavior modification treatment (D), or physical exercise behavior modification treatment (E), or the combination of both (DE), provide short and long-term weight loss compared to control (C) among overweight and obese lactating women, and if so how. METHODS: At 10-14 weeks postpartum, 68 lactating Swedish women with a pre-pregnancy body mass index of 25-35 were randomized to 12 weeks of treatment or control. The study variables were measured at baseline, after the intervention, and again at a 1-year follow-up, 9 months after treatment termination. A total of 29 interviews were also made. RESULTS: Weight changes (kg) after the intervention and 1-year follow-up, respectively, were -8.3 ± 4.2 and -10.2 ± 5.7 in D, -2.4 ± 3.2 and -2.7 ± 5.9 in E, -6.9 ± 3.0 and -7.3 ± 6.3 in DE, and -0.8 ± 3.0 and -0.9 ± 6.6 in C. The main effects of D, but not of E, on weight were significant at both times ($p<0.001$). Weight loss was mainly adipose tissue in all groups. At baseline the women reported a typical Swedish diet. The D treatment led to reduced intake of energy, fat and carbohydrate. The proportion of sugar was reduced, whereas complex carbohydrates and fiber were increased. The women did not reach recommended levels of vitamins A and D, folate, and iron, with no difference between treatments. Based on the interviews a substantive theory of achieving sustainable weight loss in the specific context was developed. The women needed a 'Catalytic Interaction' from the health care provider, to mobilize and support their own resources. 'Transformative Lifestyle Change' was the key to sustainable weight loss. It comprised a journey towards gaining lifestyle control, consisting of seven stages leading to initiation, implementation, identification with, and maintenance of change. CONCLUSIONS: Dietary treatment, with or without exercise treatment, provided significant and clinically relevant weight loss among overweight and obese lactating women, and it was sustained at 9 months after treatment. Further research will be needed to evaluate the effectiveness in the health care setting. Weight loss was achieved with a diet in line with current official recommendations, indicating its usefulness for this purpose. A supplement may be useful to reach recommended intake of certain micronutrients. A successful weight loss depended on a Catalytic Interaction with the health care provider, and on the Transformative Lifestyle Change-process. This theory may be useful in the design and evaluation of weight loss treatments.

Keywords: weight loss, overweight, postpartum, lactation, diet, exercise, behavior modification, DLW, body composition, RCT, Grounded Theory

ISBN: 978-91-628-8575-5 **E-version:** http://hdl.handle.net/2077/30259

SAMMANFATTNING PÅ SVENSKA

För de flesta kvinnor leder graviditeten till en mindre men bestående viktökning. Det handlar oftast om något till några enstaka kilon, men för ungefär var femte kvinna är den bestående viktökningen betydligt större. Eftersom ett högt BMI ökar risken för komplikationer och sjukdom både under och efter graviditet är viktökningstrenden bland kvinnor i reproduktiv ålder ett allvarligt hälsoproblem. Det gäller särskilt de kvinnor som redan före graviditeten är överviktiga.

I en studie på 68 överviktiga eller feta kvinnor utvärderades en metod med kostbehandling, som på 12 veckor fick kvinnor att i genomsnitt gå ner ca 10 % av sin kroppsvikt. Viktminskningen bestod även ett år efter att kostbehandlingen inletts. De kvinnor som kombinerade kostbehandlingen med motion, uppnådde inte någon ytterligare viktminskning och inte heller skiljde sig andelen muskler och fett i kroppen mellan dessa behandlingar. Endast motion gav ingen effekt på vikt eller kroppssammansättning. Det kan bero på att samtliga kvinnor i studien redan var relativt aktiva, och att det alltså inte fanns så stort utrymme för att öka sin totala kaloriförbrukning mer. Men tidigare forskning har också visat att bara motion inte räcker för att gå ner i vikt.

Studien uppdelades i två faser: först en 12 veckor lång behandling, därefter nio månader där kvinnorna fick klara sig på egen hand. Kvinnorna delades upp slumpvis i fyra grupper. En grupp fick individuella kostråd baserade på Nordiska näringsrekommendationer, samt väga sig tre gånger per vecka för att justera kostintaget. Målet var att uppnå 0.5 kg viktminskning per vecka. En annan grupp fick individuella motionsråd samt en pulsklocka för att justera intensiteten på de lättare motionspassen. Målet var att uppnå rekommenderad träningsnivå på 4 45-minuterespass per vecka, med en intensitet på 65 % av maxpulsen. En tredje grupp fick både kost och motionsråd, medan kvinnorna i kontrollgruppen inte fick någon rådgivning.

Resultatet av kostbehandlingen är ovanligt bra. Dels sågs en betydelsefull viktminskning, dels brukar personer som genomgår en diet återfå hälften av viktminskningen under det första året efter behandlingen, men det skedde inte här. Genom att använda avancerade metoder kunde även effekten av behandlingen bekräftas på kaloriintag, kaloriförbrukning och andelen muskler och fett i kroppen. Här sågs att viktminskningen till största delen var fett, att den totala energiförbrukningen inte skiljde mellan grupperna, och att

de kvinnor som lyckats med sin viktminskning hade minskat energiintaget och lagt om sin kost enligt Nordiska näringsrekommendationer. I likhet med andra kvinnor var intaget av vitamin A och D, folsyra och järn lågt.

I intervjuer berättade kvinnorna att skillnaden mellan att lyckas och att inte lyckas uppnå bestående viktminskning berodde på två saker i en upplevd förändringsprocess. Det första var om stödet från behandlaren upplevdes som konkret, användbart och trovärdigt, samt innehöll både press och beröm. Det andra var en personlig förändring där självbild, känslor och uppfattningar kom i fas med den nya livsstilen.

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. F. Bertz, H.K. Brekke, L. Ellegård, K. M. Rasmussen, M. Wennergren, A. Winkvist.
Diet and exercise weight loss trial in lactating overweight and obese women.[a]
American Journal of Clinical Nutrition 2012;96:698-705

II. F. Bertz, A. Winkvist, H.K Brekke.
Sustainable weight loss among overweight and obese lactating women is achieved with an energy reduced diet in line with current recommendations.
(Manuscript)

III. F. Bertz, C. Sparud-Lundin, A. Winkvist.
Transformative Lifestyle Change: key to sustainable weight loss among women in a postpartum diet and exercise intervention; a substantive grounded theory.
(Submitted for publication)

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CONTENT

ABBREVIATIONS

AMP	Active Mothers Postpartum
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
BMR	Basal Metabolic Rate
C	Control
CBF	Breastfeeding with complementary foods
CI	Catalytic Interaction (In statistics: Confidence Interval)
D	Dietary behavior modification treatment
DE	Dietary and physical exercise behavior modification treatment
DXA	Dual-energy x-ray absorptiometry
E	Physical exercise behavior modification treatment
EBF	Exclusive Breastfeeding
EI	Energy Intake
FAO	Food and Agriculture Organization of the United Nations
FFM	Fat Free Mass
FM	Fat Mass
GDM	Gestational Diabetes Mellitus
GWG	Gestational Weight Gain
HBM	Health Belief Model
IAEA	International Dietary Energy Consultancy Group
IOM	Institute of Medicine
LEVA	Livsstil för Effektiv Viktminskning under Amning (Swedish). English translation: "Lifestyle for effective weight loss during lactation."
LTPA	Leisure Time Physical Activity
MEO	Milk Energy Output
MNS	Maternal Nutritional Status
NBF	Non Breastfeeding
NHANES	National Health and Nutrition Examination Survey
NNR	Nordic Nutrition Recommendations
NP/NL	Non Pregnant / Non Lactating
OQDA	Outcome Quantified Dietary Advice
PAL	Physical Activity Level
PBF	Predominant Breastfeeding

PPWR	Postpartum Weight Retention
RI	Recommended Intake
RMR	Resting Metabolic Rate
SCT	Social Cognitive Theory
SD	Standard Deviation
SMBR	Swedish Medical Birth Registry
SPAWN	Stockholm Pregnancy and Women's Nutrition
SWA	Sense Wear Armband
SWAP	Step-wise Weight-determined Accumulative change Plan
TEE	Total Energy Expenditure
TEO	Total Energy Output
TLC	Transformative Lifestyle Change
TPB	Theory of Planned Behavior
TTM	Transtheoretical Model
WHO	World Health Organization

DEFINITIONS IN SHORT

Exercise	Physical activity that is planned, structured and repetitive. It has as a final or intermediate objective the improvement or maintenance of physical fitness.
Fat mass	Adipose tissue mass in the body. Consists mainly of fat.
Fat free mass	Component of total body mass that includes skeletal muscle, non-skeletal muscle and soft lean tissues, and the skeleton.
Gestation	The carrying of an embryo or fetus in the uterus.
Nullipara	A woman who has never given birth.
Parity	The number of children previously born to a woman.
Physical activity	Any bodily movement produced by skeletal muscle that requires energy expenditure.
Prenatal, Antenatal	Preceding birth.
Reproductive cycle	The period from one conception to the next.

1 INTRODUCTION

This thesis concerns the issue of weight loss treatment among lactating overweight and obese women after childbirth. In the face of the obesity epidemic evidence on which to ground clinical and policy decision making is essential; and for this group such evidence has not been available to date. Women of childbearing age are becoming increasingly overweight. This threatens both maternal and child health. The group of lactating women makes up a large proportion of new mothers in Sweden, and by providing those overweight and obese with an efficient weight loss treatment significant health benefits could be achieved in a key part of the population. This group faces a specific and complex context for weight loss. Thus the LEVA-trial (*Swedish:* Livsstil för Effektiv Viktminskning under Amning, *in English:* Lifestyle for effective weight loss during lactation) was initiated to address these issues. A conceptual framework to illustrate the contribution of the three papers based on the LEVA-trial in this thesis (figure 1), including the overarching research question, the research approach and specific main questions and answers, resulting in a summarizing answer is provided below. This will be put in context and outlined in detail in this thesis.

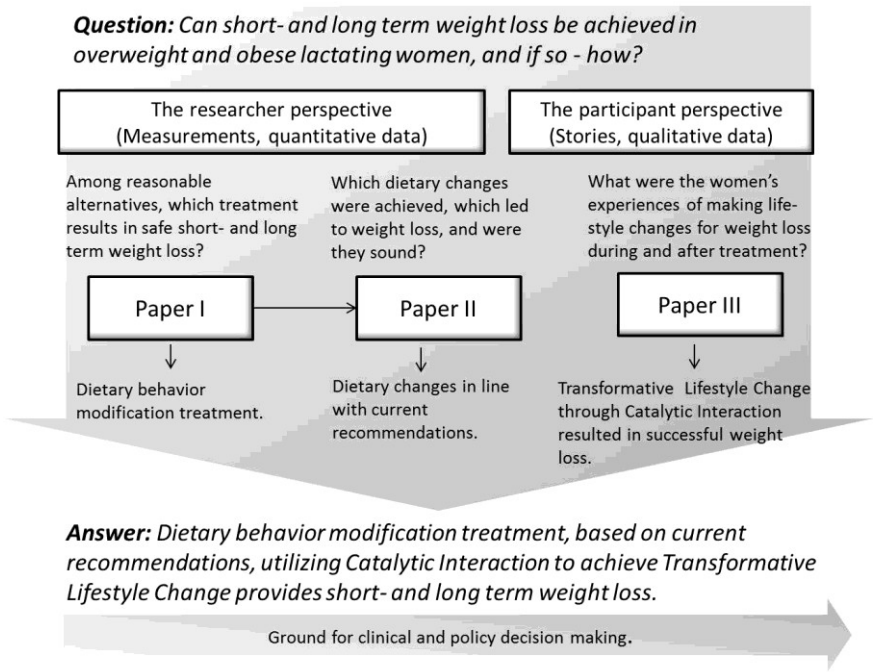

Figure 1. Conceptual framework of thesis.

1.1 Overweight and obesity

Overweight and obesity represent a major global health issue. It is prevalent, and its prevalence is increasing [1]. Overweight is the result of an accumulation of excess body fat, due to energy intake in excess of energy expenditure. This leads to an increase in body weight and size. The body weight measure is used as a proxy for the excess body fat, and together with height the body mass index (BMI) can be calculated. The BMI is calculated as the weight in kilograms divided by height in meters squared *(BMI = weight, kg / height, m^2)*. The BMI is used for classification of the severity of excess weight, which is primarily based on the association between BMI and mortality [1]. The BMI is independent of sex and age. However it should be noted that there are ethnic differences in the relation between body fat and BMI, as well as sex and age differences, which thus affect the association between BMI and mortality [2]. Overweight is defined by the World Health Organisation (WHO) as a BMI of ≥25 kg/m^2. Further, the severity of overweight is classified as overweight (BMI 25.0-29.9), obesity class I (BMI 30.0-34.9), obesity class II (BMI 35.0-39.9) and obesity class III (BMI ≥40.0). For optimal health, the median BMI for an adult population should be in the range of 21 to 23. The goal for individuals should be to maintain a BMI in the range 18.5 to 24.9. There is increased risk of several diseases when BMI is in the range of 25.0 to 29.9, and the risk increases to moderate to severe risk of when BMI is greater than 30.

Overweight and obesity is referred to as a global epidemic by the WHO. Worldwide, at least 2.8 million people die each year as a result of being overweight or obese. Approximately 35% of adults aged 20 and above, worldwide, had a BMI >25 in 2008; 34% of the men and 35% of the women. Among these an estimated half a billion (10^9) adults were obese; 205 million men and 297 million women. The worldwide prevalence of obesity has doubled between 1980 and 2008. In 2008, 10% of men and 14% of women in the world were obese, compared with 5% for men and 8% for women in 1980 [3].

The Swedish population, in a way similar to most Western countries, has been gaining weight steadily for several decades [4, 5]. This weight gain has led to an increase in the prevalence of overweight and obesity. In Sweden the combined prevalence of overweight and obesity from 1980 to 2011, based on self-reported weight and height in 16 to 84 year old men and women, shows an increase among women from 27% in 1980 to 42% in 2011, and among men from 35% in 1980 to 55% in 2011. However, a more rapid increase in the rates of overweight and obesity has occurred among younger women

(presented as the age group 16 – 44 years in national statistics) most representative of those in childbearing age in Sweden; from <10% in 1980 to ~30% in 2011. However, because Swedish women have their first child at an age close to 30 and weight increases with age in this age span, women entering pregnancy are to an even greater extent overweight and obese. Since the year 2000 the increase in rates of overweight and obesity have slowed down, however the prevalence increases still. In total, close to half the adult Swedish population (49%) is currently overweight or obese, of which 36% are overweight and 13% are obese [4, 5].

1.1.1 Body composition in overweight and obesity

As stated overweight is the result of accumulation of excess body fat, and thus by definition it is not the accumulation of (excess) lean tissue. The extent of accumulation of these different body tissues cannot be distinguished by the body weight or the BMI measure. However, based on models derived from body composition measurements BMI can be used as an indicator of body fat in both men and women, although it is dependent on ethnicity, age and sex [2]. At equivalent BMI men and women of Asian ethnicity have a higher percentage of fat than Black and White men and women, and irrespective of ethnicity women have a higher percentage of fat than men. Body fat percentage also increases with age. The larger fat mass among women likely has the biological function to support the increased energy requirements during pregnancy and lactation.

It is currently not possible to directly associate percentage body fat with morbidity and mortality [2]. However, since body fat can be predicted from BMI, the association between a specific BMI range and its corresponding fat percentage range is likely to provide the same information, at least at a group average. Body fat measured with dual-energy x-ray absorptiometry (DXA) in relation to BMI based on American data is presented in table 1, and provides estimates in line with those found by Larsson et al among Swedish individuals at BMI 25 [6]. Still, some individuals have a high BMI because of a large fat free mass and are thus not exposed to the risks of excessive fat mass. At the individual level a direct measure of body composition can thus provide important information on the amount and proportion of body fat, in relation to average levels, as well as the effects of changes in weight, lifestyle or a medical treatment or intervention.

Table 1. Body fat in relation to BMI at different ages among men and women. [2]*

BMI	20-39 years	40-59 years	60-79 years
	% Body fat in Women / Men		
<18.5	21 / 8	23 / 11	24 / 13
≥25	33 / 20	34 / 22	36 / 25
≥30	39 / 25	40 / 28	42 / 30

* Data based on measurements in individuals of White and Black, but not Asian ethnicity.

Excess body fat is the single most important factor behind several metabolic disorders. Epidemiological studies reveal that BMI (as an indicator of body fat) and fat distribution (i.e. where the excess fat is located in the body) independently predict various metabolic diseases. Furthermore, weight gain has also been identified as a strong predictor of most metabolic diseases. Specifically, excess body fat triggers a plethora of metabolic disturbances; insulin resistance, hypertension, hyperglycemia, hypertriglyceridemia, reduced levels of high-density lipoprotein (together referred to as the metabolic syndrome) [7], as well as type 2 diabetes, vascular endothelial dysfunction, gallstone disease, gout, polycystic ovary syndrome, sleep apnea and non-alcoholic fatty liver disease [8]. Although mechanisms linking obesity to the elevated risk of metabolic disorders are not yet fully understood, current evidence suggests that specific hormones, cytokines and free fatty acids secreted by the adipose tissue play central roles. The adipose tissue is a major secretory organ for pro-inflammatory cytokines, and obesity is considered a state of low-level inflammation. This is reflected in elevated levels of plasma C-reactive protein, which has been found to predict the metabolic syndrome, type 2 diabetes, and coronary heart disease [8].

That which is not fat, i.e. the fat free mass (FFM) consists of lean soft tissue mass and bone mass. The FFM represents the main determinant of the magnitude of resting metabolic rate (RMR) (~50-70%). Muscle mass is a part of the FFM that is vital to physical activity. Together with RMR energy expenditure from physical activity makes up most (~90%) of total energy expenditure (TEE). Following from the above summarized, the harmful effects of excess adipose tissue and importance of the FFM; it is crucial that weight loss strategies among the overweight and obese are designed to reduce fat mass while maintaining FFM.

1.1.2 Causes of overweight and it's increase

The accumulation of excess body fat that leads to overweight and obesity is the result of a positive energy balance, i.e. the intake of energy exceeds that of expenditure. Current evidence suggests that on a population level the energy-imbalance that has caused the rapid and substantial increase in overweight and obesity over the past decades has two interesting and quite counter-intuitive features. (1) The population level increase in body weight can be attributed mainly to an increase in dietary energy intake, not a decrease in physical activity [9, 10]. (2) The mean daily positive energy balance that is required to produce a substantial increase in body weight over time is very small [11].

Diet and/or physical activity?

The population level energy-imbalance that has caused the rise in overweight and obesity; the "energy gap" concept, was first suggested and estimated by Hill et al in 2003 [12]. Since then several versions and refinements of how to calculate the energy gap have been made [9, 13]. The energy gap was first defined as the required change in energy expenditure relative to energy intake necessary to restore energy balance. However, the energy gap concept includes two different energy gap meanings. The "energy imbalance gap" is the small average daily imbalance between energy intake and TEE that underlies the observed weight gain, whereas the "the maintenance energy gap" is the average increase of energy intake required to maintain the higher weight [14].

A dynamic approach to modeling the effect of energy imbalance on body weight has recently been developed and published by Hall et al [14]. This can be used to estimate the change in energy intake needed to produce a certain weight change, and model it over time, taking changes in body composition and metabolism into account. Using this simulation model they found that a very small (7 kcal per day) intake in excess of expenditure "the energy imbalance gap" underlies the observed U.S. weight gain since the late 1970's; however the average increased energy intake to sustain the increase in weight "the maintenance energy gap" is ~220 kcal. The energy imbalance gap is so small that it could not likely be detected in terms of amounts of food or hunger/satiety regulation by the individual [15]. However, over a longer period of several decades, as measured cross-sectionally, it produces considerable weight gain and requires a substantially increased energy intake to be maintained. This increased level of energy intake can also be observed in measurements of food consumption. Also, in a population steadily gaining weight the energy intake should be higher than that needed to maintain

weight, due to the metabolic cost of converting energy to body tissues [16, 17].

Loss-adjusted annual per capita food supply data analyses by the USDA's Economic Research Service in the U.S. suggests a ~20% increase in total energy intake (~420 kcal per person per day, from ~2180 to ~2600 kcal per day) from the year 1980 to 2010 [18]. Between 1978 and 2008 the mean body weight increased ~9.5 kg from ~71.5 kg to ~81 kg in the adult U.S. population [14]. The trend in Sweden is lagging compared to the U.S., which is also evident in the rates of overweight and obesity and its co-morbidities. During the period 1980-2008 the total supply of energy from food products in Sweden increased 10% (~310 kcal per person and day, from ~2940 to ~3250 kcal per day) unadjusted for loss and thus higher and not readily comparable numbers to the presented for the U.S [19]. However, Swedish food waste is estimated to 30% of consumed foods at both time points [20]. A crude estimation would thus indicate a ~2050 kcal per day intake in 1980, and a ~2275 kcal per day intake in 2010, equal to a ~225 kcal per day increase. The Swedish increase in energy intake since 1980 is about half of that observed in the U.S., and also the Swedish increase in body weight is approximately half of that observed in the U.S. at ~5 kg between 1980 and 2004. Specifically, among adult Swedish women in 1980 the mean weight was 62.8 kg (BMI 23.3) and in 2004 it was 66.7 kg (BMI 24.5), thus a mean 3.9 kg weight increase has occurred [21]. Among Swedish men the mean weight during the same period has increased from 76.1 kg (BMI 24.3) to 81.9 kg (BMI 25.6); a 5.8 kg increase [21].

Although population level physical activity is very difficult to measure it is evident from the change in body weight that here has not been an increase in energy expenditure to match the past decade's increase in energy intake. However, the more relevant question is if a decrease in energy expenditure has also occurred to contribute to the weight increase. It is only since the 1980's with the introduction of doubly labeled water (DLW) that our ability to accurately quantify energy intake and total energy expenditure (TEE) under non-laboratory conditions has been available [11]. Combined with the measurement of resting metabolic rate (RMR) (or basal metabolic rate (BMR)) the energy expended in activity can be estimated. The accurate quantifications of energy intake and expenditure can be used to validate other methods of investigation, which are used in larger population studies (questionnaires, heart rate monitors, accelerometers). Data from the Northern Sweden MONICA-study show that both men and women are mainly sedentary, and that this has not changed between 1990 and 2000 [22]. In the Västerbotten health exams among 90.000 individuals at the ages 40, 50 and 60 years physical inactivity have not changed between 1990 and 2007.

However, while the proportion of moderately active individuals has decreased, the proportion of those engaging in a high level of physical activity has increased since the year 2000. Also, the proportion reporting that they do not engage in any leisure time physical exercise (LTPA) has decreased from 14% (both men and women) to 7% among women and 11% among men since 1980 [23]. Although it remains to be quantified and evaluated, to the extent that Sweden follows the U.S. development, long term trends in the U.S. resulting from changes in the built environment and increasing sedentary behavior may thus also be ongoing in Sweden. Such U.S. trend indicate that LTPA has remained stable or increased, whereas activities related to work, transportation and household chores have declined, and also sedentary behaviors have increased; putting a majority of the population at high risk of physical inactivity [24]. This is likely to have major negative health implications [25] that however lie outside the scope of this overview concerning body weight changes determined by TEE in relation to energy intake. Due to the nature of the data used for the above described U.S. trends, they lack the accuracy of DLW measurements, and a comprehensive judgment on the total level of energy expenditure cannot be made. However, in a 2010 review [26] Westerterp arguments, based on extensive DLW data from the studies, [9, 10, 27], that: *"Physical inactivity cannot be the major or sole cause for the increasing prevalence of obesity given that review studies do not show a reduction in the levels of physical activity over the years and food intake is difficult to measure in free-living conditions. Physical activity energy expenditure, as measured with doubly labeled water, has not declined since the start of the obesity epidemic in the 1980s. A substantial increase in energy intake has driven the increase in body weight over the past decades."*

Trends in consumption of different foods

The observed increase in energy intake is likely the result of an increase in consumption of foods of low nutrient density and high energy density. This is of particular concern during pregnancy and lactation which require modest increases in energy intake but proportionally greater increases in vitamin and mineral intake. Sugar-sweetened beverages, snacks, fast-food and other semi- or ready-made foods have increased. Since 1960 in Sweden a few quite extreme trends are evident [19, 28]. There has been a radical increase in the consumption of sugar-sweetened beverages (from 22 to 91 liter per person per year), as well as of candy and chocolate (from 6 to 15 kg per person per year), meat and poultry (from 55 to 85 kg per person per year) and fresh vegetables (from 14 to 44 kg per person per year). The consumption of fats (butter, margarine, oil) have decreased radically (from 23 to 13 kg per person per year) [19, 28]. However, due to the large increases in cheese, cream, ice-cream, chocolate and bakery goods the total consumption of fat has only decreased from 39 to 35% of total energy. Interestingly, energy from fat was

33 and 37% of total energy in 1940 and 1950 respectively, even lower before that and appears to have peaked around 1960 to 1980. Also the total consumption of sugar has not changed, but has stayed at ~40 kg per person per year since 1960 [19, 28]. The long-term trends in Sweden indicate that an increasing proportion of the energy intake comes from protein, and a decreasing proportion form fat and carbohydrates. In grams per person per year the total (not waste-adjusted) consumption of all three macronutrients has increased between 1960 and 2010; protein from 74 to 112 g, carbohydrate from 346 to 375 g, and fat from 119 to 130 g [19]. The price of foods compared to other goods has decreased [19]. Likely due to both the nature of the modern foods and the modern food environment; the obesogenic environment, an over-consumption of energy occurs.

Individual and environmental factors associated with excessive weight gain and persistence of overweight

The vulnerability to the obesogenic nature of our society varies in a very complex way among individuals and groups of individuals. On the individual level genetics play a part. There seems to be many genes that define the obese phenotype, i.e. the genetic makeup that increases the risk of a person to become obese in our society. However, monogenic obesity is the cause of a very limited number of known cases (<200 individuals) caused by singe-gene mutations in 11 different genes [29]. The so far strongest genetic factor that has been discovered to be associated with polygenic obesity are a set of single nucleotide polymorphisms in the FTO (fat mass- and obesity associated) locus, leading to increased energy intake and reduced satiety. In 13 cohorts with 38,759 participants an additive association of a common variant in the FTO gene with BMI has been found and replicated. The 16% of adults who were homozygous for the risk allele weighed ~3 kg more and had 1.67-fold increased odds of obesity when compared with those not inheriting a risk allele. This association was observed from age 7 years upward and reflected a specific increase in body fat [30]. Bearing the risk alleles has also been associated with an increased energy intake of approximately 125 to 280 kcal per day, but without impact on energy expenditure [31].

On the individual level also psychological factors are involved. To what part the psychological factors involved in lifestyle behaviors related to excess weight are determined by genetics is not known. It is however clear that individuals, and groups of individuals, have different attitudes and beliefs about their eating and health related behaviors [32]. This leads to a variation in behaviors, of which some lead to overweight. The weight gain often occurs over a prolonged period of time, during which it is most likely unintentional, passive and so small on a daily or weekly basis that when it is noticed it has

already become a problem that is hard to handle [15]. The weight gain appears to be affected by season (likely behaviors related to the season), in that more weight is gained during winter; 'Holiday weight gain', but not lost during the other seasons, and more so among the already overweight and obese [33]. Weight gain may occur more rapidly during a particular time in life, often challenging (e.g. illness, depression, life-structure or social/family-changes) or atypical (e.g. pregnancy or other life event), when personal health is not/cannot be prioritized [34]. It is clear that although explicit physiological changes (i.e. diseases, and their treatment; from drugs to bariatric surgery) may impair regulation of food intake, in many aspects the eating behavior of the majority of humans is very sensitive to the external environment and is determined by both conscious and non-conscious psychological processes [35].

Irrespective of way of accumulating excess weight; when a state of overweight has been reached it requires a substantial effort to be reversed, and it is troublesome that to date the rate of success in long term weight loss is quite poor at ~20% or less [36, 37]. Motivation, sense of control, or belief in the own capacity (i.e. self-efficacy), that are associated with the ability to cope with events or the environmental influence, or the required knowledge, skills and strategies or other resources necessary may not be available to the individual. This may explain failure to prevent weight gain in the first place [38], and is also associated with lack of success in maintaining weight loss [39]. In the longer run the increased weight and body size may also become increasingly normalized and habituated. As the society as a whole also becomes increasingly overweight, the idea of a normal weight and body size, as well as eating norms changes with it [32]. This may lead to a loss of perspective on what is acceptable and healthy and thus delay or offset countermeasures to an increasing body weight [32].

In Sweden, and likely similar in other Western countries, ~50% of the adult population tries to or plans to lose weight [23]. Irrespective of weight loss intentions <2% are inspired by extreme diets (i.e. low-carbohydrate/high-fat, and Paleolithic diets, <1% each), 14% by other diets (vegetarian, vegan, low glycemic index, weight-watchers etc.), and only 11% by current official recommendations. Even more surprising is that as many as 70% are not guided by any particular recommendation on dietary intake at all [23].

The seemingly irrational and diverse behaviors and attitudes associated with weight gain can to a part be explained by observational and experimental findings indicating that humans interact with their environment not only in a conscious way, but also receive and process information in a non-conscious

way [15]. A feature of the obesogenic environment is an increased number and prominence of food stimuli [35, 40]. These stimuli include increased portion sizes, increased variety of food available, higher fat content of the diet, larger number of people eating together, the location where eating occurs (away from home), ease of accessibility to food, and food stimuli presented via print media, television, and Internet. These stimuli have been shown to evoke an increased tendency to eat through a non-conscious psychological process called priming [41]. In addition, using DLW to quantify physical activity is has been found that overeating does not increase physical activity, while undereating decreases habitual or voluntary physical activity. An exercise-induced increase in energy requirement is usually compensated by increased energy intake, while a change to more sedentary behaviors does not induce an equivalent reduction of energy intake [26].

On the population level it is clear that socio-demographic factors are also involved. Regarding both diet and physical activity there is a socio-demographic gradient within the population level data. It seems that among those with high income or high education, and generally more so in women than in men across socio-economic groups, there is less leisure time inactivity and food choices are healthier, i.e. closer to the official recommendations [23]. Overweight and obesity is more common in lower socio-economic groups, and among those with shorter education. In Sweden, among those with higher education (high school and beyond) the proportion of overweight and obese individuals has not increased since the year 2000, in contrast to the situation among those with shorter education. Also in Sweden a complex interplay between gender and ethnicity has been observed. Obesity is twice as common among women born outside the Nordic countries as among women born in Sweden. However, men born outside the Nordic countries have a lower proportion of obesity compared to men born in Sweden [23].

An economic framework provides an explanation for the observed links between socioeconomic variables and obesity when taste, dietary energy density, and diet costs are used as intervening variables. Drewnowski et al have proposed, based on extensive U.S. data, that the association between limited economic resources and obesity may be mediated, in part, by the low cost of energy-dense foods and may be reinforced by the high palatability of sugar and fat [42]. Cheap foods with long shelf-life are to a large extent energy dense, high in sugar and/or fat, whereas more expensive foods have low energy density, are high in water content and thus have a short shelf-life. Nutritional and health knowledge is related to education, which is in turn related to income. Knowledge does not always turn into action, particularly when interests are competing, and it has been found that nutritional concerns

are of less relevance to most people compared to taste and cost of food [43]. Thus those with limited resources are most negatively affected by the modern type, supply, pricing and marketing of foods.

In sum, it appears that the way humans respond to the modern environment, directed by a multitude of complex and intertwined factors, either as individuals alone or in a social context, or as a society as a whole, is not compatible with good health. Given the above described circumstances of the issue, the solution is not as straightforward as the deceptively simple underlying imbalance between energy intake and expenditure might indicate.

1.1.3 Co-morbidities of overweight and obesity

Overweight and obesity increases the risk of several serious medical conditions, mediated mainly by excess adipose tissue as summarized in section 1.1.1. The risks of coronary heart disease, ischemic stroke and type 2 diabetes increase with increasing BMI. Raised BMI also increases the risk of cancer of the breast, colon, prostate, endometrium, kidney and gall bladder. The relative co-morbidity risk attributable to obesity is summarized in table 2, compared to normal weight individuals (from Guh et al. [44]).

Table 2. Relative co-morbidity risk attributable to overweight and obesity.

	Overweight		**Obesity**	
	Women	**Men**	**Women**	**Men**
Co-morbidity				
Type 2 diabetes	3.9	2.4	12.4	6.7
Coronary heart disease	1.8	1.3	3.1	1.7
Hypertension	1.7	1.3	2.4	1.8
Stroke	1.2	1.2	1.5	1.5
Asthma	1.3	1.2	1.8	1.4
Gall bladder disease	1.4	1.1	2.3	1.4
Osteoarthritis	1.8	2.8	2.0	4.2
Chronic back pain	1.6	1.6	2.8	2.8
Cancer*	1.1 - 1.8	1.1 - 1.5	1.1 -3.2	1.1 – 2.3

*Women and men: Colorectal, esophageal, kidney, pancreatic.
Women: Breast (postmenopausal), endometrial, ovarian.
Men: Prostate.

In addition, living with this excess weight is associated with increased depression and anxiety, and decreased quality of life [45-47]. However, a recent Canadian longitudinal study of 10,545 adults for 12 years with seven waves of data collection found that obesity did not predict a past year major depression episode in women, and was a significant negative predictor among

men [48]. Many obese individuals experience social stigmatization, and impaired psychosocial as well as physical functioning [47, 49]. Thus, the causality, as well as the association with obesity severity and different subgroups of disorders is not clear.

*Table 3. The proportion (%) of individuals in Sweden aged 40, 50, and 60 years with hypertension, type 2 diabetes, and the metabolic syndrome (WHO definition) in different BMI-classes, mean for the years 1991 – 2006.**

		Hyper-tension	Type 2 diabetes	Metabolic syndrome
	BMI		(%)	
Normal weight	18.5 – 24.9	30	19	8
Overweight	25.0 – 29.9	46	42	30
Obesity (class I)	30.0 – 34.9	18	27	44
Obesity (class II)	35.0 – 39.9	4	9	13
Obesity (class III)	>40	1	3	4

**Adapted from Folkhälsorapporten 2009 [23].*

Although the risk of hypertension, type 2 diabetes and the metabolic syndrome increases with BMI and thus put those with a BMI above 35 at high risk, the majority of affected individuals, because of the greater number of individuals in these BMI-groups with some or increased risk, have a BMI between 25 and 35 (table 3).

1.2 Childbearing in Sweden

About 100,000 children are born in Sweden every year [50]. In 2010 a total of 115,641 children were born in Sweden, and the mean number of born children per woman of fertile age was 1.98 [51]. The mean age for women having their first child (primiparous) in 2007 was 28.6 years. The age of men having their first child was 31.1 years. The age among women having their first child has increased continuously. In 1977 the mean age was 24.8 years, in 1988 it was 26.0 years, and in 1997 it was 27.5 years [50]. There appears to be no further increase in the age of women having their first child, which has stayed the same for both men and women since 2004. In previous generations the mean number of children per woman has been two. Because of the increasing age among primiparous women this is estimated to become slightly lower [23, 50].

The expected outcome of a pregnancy and delivery is very good in Sweden. The number of pregnancy and delivery related deaths in mothers in Sweden are constant at 2 to 4 women per year (~0.003%) since the year 2000 [23].

The antenatal care reaches close to 100% of all mothers to be. The antenatal care provides health monitoring during pregnancy and includes psychological support. The antenatal care also works with the identification of, and special support directed to, women that suffer from psychosocial difficulties and domestic violence [23].

Approximately 75% of the 100,000 births per year are considered fully normal and require no particular medical intervention. Teenagers and women >35 years of age are at increased risk of preterm delivery or small for gestational age infants [23]. It is very common that women are on sick-leave during the late part of pregnancy. Back-problems is the most common condition, and it affects >50% of all pregnant women. Other health problems such as sleep problems, incontinence, and gastro-intestinal problems are common. Approximately 8 to 10% of the pregnant women suffer from depression [23].

1.3 Breastfeeding in Sweden

Breastfeeding rates are high in Sweden compared to other Western countries [52]. Breastfeeding is socially endorsed and is considered the norm. It is also supported by the health care available to all new mothers, as an extension of the national adaptation of the WHO recommendation that babies should be exclusively breastfed for 6 months and thereafter partially until the child is 2 years old [52, 53]. With the exception of vitamin D, exclusive breastfeeding for the first 6 months is regarded to satisfy the nutritional needs of full-term infants. This is a joint recommendation from the Swedish National Food Administration, together with the Swedish Paediatric Committee on Nutrition in consultation with the National Board of Health and Welfare and the Ministry of Health and Social Affairs [52]. In addition the generous Swedish parental leave provides most mothers with the practical and economic fundamentals to comply well with this recommendation.

Historically, breastfeeding has been the natural way to feed an infant. However, in the modern age changes in the practices of breastfeeding have occurred in Sweden that has produced both declines and increases in breastfeeding rates [52]. In the middle of the 1930's the delivery of babies started to take place in the hospitals instead of the home. This led to a decline in breastfeeding. One important reason for this was the routines in Swedish maternity wards, which did not give the mothers sufficient support for breastfeeding. This led to a lack of knowledge and a low interest in breastfeeding. Also, at this time the manufacturers of baby food and bottles began to market their products, which also contributed to a decline in

breastfeeding. From 1950 to 1970 the proportion of infants exclusively breastfed until the age of two months decreased from 75% to 35%. At the age of 6 months the corresponding decline was from 40% to less than 10% [52].

In the beginning of the 1970's a powerful change of attitudes occurred in society. The social and medical value of breastfeeding was heavily promoted. This resulted in a sharp increase of breastfeeding, which lasted until the mid 1980's. In the beginning of the 1990's, after a short decline in breastfeeding, the rates rose again. However a new decline in rates of breastfeeding has emerged during the last years [52]. The increase in breastfeeding occurred while focus on supporting and endorsing breastfeeding in the public health care was renewed. Also, the Baby Friendly Hospitals Initiative was initiated by UNICEF. The strategies aiming at increasing the breastfeeding rates were successful, at first in the maternity hospitals and thereafter also in the maternal and child primary health care. Currently the WHO/UNICEF joint statement program "Ten steps to successful breastfeeding"[54] is used in Sweden to provide routine support for initiation and continuation of exclusive breastfeeding.

Among children born in 2010 close to 97% were breastfed when they were 1 week old. Among these 83% were exclusively breastfed. At the age of 2 moths a total of 87% were breastfed, of which 67% were exclusively breastfed. At the age of 6 months a total of 63% were breastfed. At the age of 9 months the corresponding figure was 34%, and at 12 months of age it was 16% [52].

1.4 Energy metabolism during lactation

From the FAO/WHO/UNO 1985 report on energy and protein requirements a definition of energy requirements of lactation has been derived by Butte and King [55]:

"The energy requirement of a lactating woman is the level of energy intake from food that will balance her energy expenditure when the woman has a body size and composition and a breast milk production which is consistent with good health for herself and her child; and that will allow her for the maintenance of economically necessary and socially desirable physical activity."

This means that the energy cost of milk synthesis and the energy content of the milk must be added to the woman's normal energy requirements, based on the assumption that they resume their usual level of physical activity. The

amount of milk, the energy content of the milk, and the energetic efficiency of milk synthesis determines the energy cost of lactation.

The amount of milk among women in both richer and poorer societies is almost identical at 749 g per day, trough 5 moths postpartum, for exclusively breastfeeding women. At 6 months and onward, when partial breastfeeding is recommended, the variation is greater, since the intake of the infant is reduced by the complementary feeding [55].

The energy content of milk is determined primarily by the fat concentration. The fat concentration of the milk changes over the day, and also both during feeding and between the breasts. However, the energy content of milk derived from representative 24-hour samples in well-nourished women is estimated to 0.67 kcal/g. Human milk contains >200 recognized constitutes, including different proteins, carbohydrates, lipids, enzymes, hormones, non-protein nitrogen compounds, vitamins, minerals, trace elements and cells [56]. The macronutrient profile of human breast milk is presented in table 4.

Table 4. Macronutrient profile of human milk [56].

	Gram/ liter	Percent of energy
Fat	39.0 ± 4.0	~52
Carbohydrate (lactose)	72.0 ± 2.5	~43
Protein	10.5 ± 2.0	~6

The proteins, carbohydrates and lipids originate from both synthesis in mammary glands and from transfer from plasma to milk, whereas vitamins and minerals only originate from transfer from plasma to milk [56].

The efficiency of milk synthesis has been estimated to ~80%. It can be calculated based on the efficiency of synthesis of lactose (95%), protein (88%), de *novo fat* synthesis (73%) and transfer of pre-formed fat (98%). Depending on the amount of pre-formed fat (i.e. fat from adipose tissue) the efficiency should be 91-94%. However, because of digestive, absorptive and inner-conversion costs and inefficiencies the calorimetric efficiency is likely 10-15% lower than the biochemical efficiency. Correcting for this leads to the 80% efficiency estimate [55].

The (net) total energy requirements during lactation can be estimated from the sum of TEE plus milk energy output (MEO) minus the energy mobilized from tissues:

[*Total energy requirements = TEE + (Milk production (volume) x energy density (i.e. MEO)) – (Energy mobilization from tissue stores)*]

The use of TEE (from DLW) does not depend on assumptions about the energetic efficiency of milk synthesis or activity expenditure, as theses energy costs are included in TEE. Alternatively the total energy requirements can be estimated in the following way [55]:

[*Total energy requirements = (NPNL BMR x PAL)*[b] *+ (Milk production (volume) x energy density x conversion efficiency) – (Energy mobilization from tissue stores)*]

Using the former, more accurate formula, four studies in well-nourished women from Sweden, UK, and USA [57-60] provide an estimate of the total energy requirements and its components. Between 1 and 6 months postpartum mean MEO was 514 kcal per day (range 471 to 533). TEE plus MEO averaged 2806 kcal per day (range 2646 to 3004). Since 172 kcal per day (range 72 to 287) were mobilized from tissue stores, the net total energy requirements were 2720 kcal per day (range 2646 to 2933) [55].

In a small but representative sample of Swedish women it was found that average milk production was 740 ± 150 g breast milk per day. The energy content was determined to 0.64 ± 0.08 kcal per g. This equals a MEO of 470 kcal per day. Given 80% conversion efficiency the increased energy need would be 587 kcal/day. Approximately 160 kcal per day may have been mobilized from adipose tissue, resulting in an actual increased energy need of ~430 kcal/day assuming unchanged physical activity. In addition, this indicated that the increased energy intake of ~550 kcal/day suggested by the WHO during the first 6 months of lactation may be too high [61].

1.5 Overweight and obesity related to childbearing

For women the childbearing years represent an important life-stage, which occurs during the early adulthood. During the early adulthood most of the population level increase of overweight occurs [15], and this period is also considered to have a large impact in forming life-long health behaviors [15]. In the Swedish, as well as U.S. population, young women have experienced

[b] NPNL denotes Non Pregnant Non Lactating, PAL denotes Physical Activity Level (calculated as TEE / BMR)

the largest and most rapid increase in weight during the past decades [62-64] Childbearing may lead to substantial weight gain, resulting in, or exacerbating the development of overweight and obesity. Many women attribute their overweight or obesity to childbearing, stating that weight problems begun as a result of pregnancy. At the Obesity unit at Huddinge hospital in Stockholm 73% of the female patients report that their pregnancies were an important factor for substantial weight gain, and that they have gained >10 kg after each pregnancy [65]. In the SPAWN (Stockholm Pregnancy and Women's Nutrition) long term follow-up study of women who delivered children in 1984-85, it was found that among the 1423 women 13% were overweight before pregnancy and that number rose to 21% at 1 year after pregnancy [66].

There are four major time-periods that need to be examined regarding weight and weight change to understand the effect of childbearing on body weight. This examination should also include potential modifying factors such as lifestyle, breastfeeding and socio-economic, and -demographic factors.

(1) The pre-pregnancy weight.

(2) The pregnancy weight change.

(3) The postpartum weight change.

(4) The long term weight change.

The weight before pregnancy is labeled pre-pregnancy weight, and is defined as the body weight before pregnancy, i.e. at the time of conception. The weight gained during pregnancy, labeled the gestational weight gain (GWG) is defined as the difference between the weight at the time of conception and the weight at the onset of delivery. The postpartum weight is a woman's weight after delivery of the fetus, placenta and amniotic fluid. During the days to weeks following delivery the extracellular and extravascular water that increased during pregnancy is lost and returns to pre-pregnancy values. The weight retained during the postpartum period, the postpartum weight retention (PPWR) is the amount of weight that remains at this later time minus the woman's pre-pregnancy weight. It includes the weight of any increased breast tissue, and remaining fat mass gained during pregnancy. PPWR thus includes GWG, early postpartum weight loss (delivery to 6 weeks postpartum), and may also include later weight changes (both loss and gain) during the postpartum period. It has however been suggested that the definition of the postpartum period should be extended to one year [67], and

it is not always clear what time postpartum is referred to when PPWR is calculated or discussed.

In practice the pre-pregnancy weight measure may either be done around the time of conception by the pregnant woman herself and is then subject to the common problems associated with self-reported weight, or it is measured at the first antenatal care visit at about eight to twelve gestational weeks. Similarly GWG and PPWR may be self-reported or measured at maternal care visits. If measured at a maternal care visit the time of measurement may differ a few weeks for GWG, and more for PPWR between pregnancies and between women. Serial measurements, particularly including longer term weight changes such as 12 to 24 months postpartum and beyond are rare.

Winkvist, Rasmussen and Lissner have developed a conceptual framework to illustrate the determinants of maternal nutritional status (MNS) across the reproductive cycle. The duration of the reproductive cycle is determined by the duration of its component parts; (1) the non-pregnant / non-lactating (NP/NL) interval, (2) pregnancy, (3) lactation, and (4) overlap between lactation and next pregnancy. Change in MNS during pregnancy is determined by the duration of gestation. This change is non-linear due to the changes in maternal body composition that occur during pregnancy, see table 5 below. In addition, both GWG and duration of pregnancy is further determined by cigarette smoking, exercise, pre-pregnant BMI and illness. GWG is also determined by dietary intake. In addition, the above factors are also likely to be influenced by 'proximal and distal determinants' (i.e. genetic, medical, behavioral, psychosocial and sociocultural factors). Changes in MNS during lactation also rely on a complex interplay of factors; both cigarette smoking and high as well as low maternal BMI are associated with shorter duration of breastfeeding. The 'proximal and distal determinants', here mainly the duration of maternity leave, may affect the duration of breastfeeding. The greatest variability in duration occurs in the NP/NL component, and the change in MNS depends largely on how long this period is [68].

Weight changes over the reproductive cycle are studied in either pregnancy cohort studies using self-reported pre-pregnancy weight, or longitudinal cohorts of women of reproductive age that have weight measurements made before and after pregnancies. The former type of studies are hampered both by the extensive use of self-reported weight, and that estimates of PPWR may be exaggerated by secular trends of weight gain [66, 69, 70]. The latter are preferable because these control for secular trends by accounting for the weight changes among women that do not become pregnant, and also rely on measurements made both before and after pregnancy. The results from the

few studies of appropriate design with sufficient numbers of primiparous women across all BMI groups consistently provide evidence that two main factors contribute to a higher postpartum body weight: (1) excessive GWG, and (2) higher pre-pregnancy BMI. Also biological factors are associated with a higher postpartum body weight (low age at menarche, short interval from menarche to first birth) [70-76].

1.5.1 Pre-pregnancy

In 2010 the proportion of pre-pregnant (or more correctly, measured at the first antenatal care visit) overweight and obese women in Sweden was >38%, of which 13% were obese [50]. These are the most recent data from the Swedish Medical Birth Registry (SMBR) including data on 98-99% of all deliveries in Sweden. The trend of increasing weight is clear and ongoing still. The results of a prospective cohort study of 298,648 singleton pregnancies delivered between 1994 through 2004, using the SMBR (information about maternal pre-pregnancy weight and height covered 84% of all registered births) revealed that the prevalence of pre-pregnancy overweight, including obesity, was 33%, and that obesity occurred in 11% of the women [77]. During the 1990's the proportion of women entering pregnancy overweight increased from 20 to 25%, and the proportion with obesity increased from 6 to 10% [23].

1.5.2 Pregnancy

Weight gain during pregnancy is related to health outcomes in mother and child [78]. Thus recommendations for GWG have been formulated. The current recommendations from the Institute of Medicine (IOM) for GWG are now adjusted for BMI, using the WHO classification [78]. They are based on evidence that a greater GWG is appropriate for women of low weight whereas overweight and obese women should restrict their weight gain (Table 1). These recommendations are designed to optimize both maternal and child health outcomes and are intended for use among singleton pregnancies in the U.S. and other developed countries [78].

Table 5. The Institute of Medicine 2009 recommendations for gestational weight gain for women of different BMI-classes. Adapted from (IOM 2009).

	Total weight gain	Rates of weight gain* 2nd and 3rd trimester
Pre-pregnancy BMI	Range in kg	Mean (range) in kg/week
Underweight (<18.5 kg/m2)	12.5-18	0.51 (0.44-0.58)
Normal weight (18.5-24.9 kg/m2)	11.5-16	0.42 (0.35-0.50)
Overweight (25.0-29.9 kg/m2)	7-11.5	0.28 (0.23-0.33)
Obese (≥30.0 kg/m2)	5-9	0.22 (0.17-0.27)

*Calculations assume a 0.5-2 kg weight gain in the first trimester.

In Sweden, similar to the situation in the U.S [79] it has been estimated that approximately 40% of women gain more weight during pregnancy than is recommended (however, Swedish data were based on the 1990 IOM guidelines which differs from the 2009 recommendations in that women with a BMI >29 were advised a GWG of >6 kg, but with no upper limit, thus potentially reducing the number of obese women exceeding the 2009 recommendation) [80]. In the SMBR weight at delivery is missing in 60% of cases, which makes calculations of national GWG impossible. Nor are there any published data describing mean GWG changes over time in Sweden [81]. However, using data from the same cohort as presented above (including 245,526 individuals), Cedergren et al. also showed that GWG in Swedish women was 8.7 kg among the very obese (BMI ≥35), 11.1 kg among the obese (BMI 30-34.9), and ~13.5 kg among the non-obese (BMI <25) [82]. However, low GWG (<8 kg) was found in 30 and 45% of the obese and very obese women respectively. These data are similar to what has been found using U.S. and Danish National Birth Cohort data [78].

In sum, the Swedish results are similar to that found in other populations in richer societies; that obese women as a group gain less weight during pregnancy than non-obese, but the variation is wide [83]. Thus, the literature suggests that overweight and obese women exhibit both inadequate and excessive GWG. However, compared to other BMI groups overweight and obese women are 2-6 times more likely to exceed the (BMI-specific) recommended gestational weight gain [84-86]. Thus pregnancies among overweight and obese women are likely to compromise both maternal and child health.

1.5.3 Postpartum

Gestational weight gain has a high positive correlation with weight change from pre-pregnancy to beyond 6 months postpartum, and also impacts long term body weight [66, 87-90]. GWG above the recommended levels has been

associated with a 3-fold higher risk of becoming overweight in under- and normal weight women [91]. Recent data from a Swedish study showed that an intervention program in obese pregnant women consisting of weekly motivational support visits during pregnancy and every 6 months after childbirth reduced weight gain up to 12 months after childbirth for those women in the intervention group who succeeded in restricting their GWG to less than 7 kg. Weight change in the intervention group was -2.2 kg compared to +0.4 kg in the control group from early pregnancy to the follow-up at 12 months after childbirth [92].

Based on self-reported pre-pregnancy weight and not controlled for secular trends and aging, on average women gain 0.5 to 1.5 kg from pre-pregnancy to 6 to 18 months postpartum. [66, 75, 88-90, 93]. However, studies that make a better estimate of the weight change attributable to pregnancy and the postpartum period also take into account secular trends and aging, and in these studies the average weight gain has been found to be greater. By following a cohort of women in which some do and some do not become pregnant, and obtain serial weight measurements from before pre-pregnancy to postpartum, preferably obtained at fixed intervals, such data can be obtained. However, a large sample size is needed to examine parity and pre-pregnancy BMI as effect modifiers. Using population based samples and longitudinal data the Coronary Artery Risk Development in Young Adults study (CARDIA) (n=2070) with 5 measurement points during 10 years of follow-up [71], and the Black Women's Health Study (BWHS) [72] (n=11,196) with 4 years of follow-up provide such information. Together, these studies showed that accounting for secular trends, aging, and lifestyle factors in parous versus nulliparous women, weight gain because of childbearing was greatest after the first child, and the average weight gain when having the first child was much greater among those being overweight pre-pregnancy (3 - 6 kg) compared to those of normal weight (1 kg) [71, 72]. Weight gain did not differ across racial and ethnic groups after controlling for pre-pregnancy BMI [71, 94]. On average women have been found to retain 0.4 to 3.0 kg following a pregnancy [95, 96]. However, about 15 to 20% of women experience a substantial PPWR of 5 kg or more (table 6) [79].

The postpartum period itself has been found to be related to an increase in food intake and a decrease in physical activity [61, 97]. It is thus considered a vulnerable period for weight gain [98], and weight gain during the postpartum period may also have a significant role in what is measured as PPWR and in the development of maternal obesity.

Table 6. Substantial postpartum weight retention (≥5 kg above pre-pregnancy weight at postpartum measurement) in pregnancy cohort studies (n>500). Adapted from Gunderson 2009 [79].

Author, Year, Country, Years Data Collected	Sample size	Time of postpartum measurement	Overweight before pregnancy (%)	Substantial Weight Retention (%)
Schauberger, 1995, USA, 1989-1990 [89]	790	6 weeks	Not reported	>16
Öhlin, 1990, Sweden, 1971-1984 [66]	1423	12 months	7a	14
Keppel, 1993, USA, 1988 [93]	2944	10-18 months	10a	>20
Greene, 1988, USA, 1959-1965 [88]	7116	Variable (between 2 pregnancies)	24b	~20
Gunderson, 2001, USA, 1980-1990 [94]	1300	Variable (between 2 pregnancies)	13a	18
Olson, 2003, USA, not stated [76]	540	12 months	41a	~20
Gunderson, 2008, USA, 1999-2003 [73]	940	12 months	25a	13

a Defined as BMI ≥ 26; b Defined as BMI ≥ 24

The results from a large and recent prospective cohort study in Canadian women confirm findings presented above [99]. It is also of particular interest because of the similarities between the Swedish and Canadian social security and health care system. In this study body weight data during pregnancy and in the early postpartum period was collected for 600 women. It was found that women who gained above the recommended weight during pregnancy were more likely to be overweight or obese before pregnancy, to have a history of smoking, or to be having their first child. Women who gained weight above recommendations and women with low income were more likely to retain higher body weight at 3 months postpartum. Also, 71% of the women exceeded recommended rates of weekly weight gain. Thus, more evidence accumulates to show that pre-pregnancy BMI is a significant predictor of excessive weight gain in pregnancy, and that higher GWG predisposes women to higher PPWR across all BMI categories [99].

A prospective cohort study in Edinburgh revealed that 6% of the women experienced antenatal depression only, 3% both antenatal and postpartum depression, and 4% postpartum depression only [100]. At 1 year, participants retained a mean of 0.6 kg (range -16.4 to 25.5), and 12% retained at least 5 kg. New-onset postpartum depression was associated with more than a doubling of risk of retaining at least 5 kg. However, antenatal depression,

either alone or in combination with postpartum depression, was not associated with substantial PPWR [100].

1.5.4 Long term outcomes of postpartum weight changes

Because of the short duration or cross-sectional nature of many studies investigating prenatal weight, GWG and PPWR, it is not possible to determine whether long term postpartum weight represents retention of GWG or a regain of weight after an initial weight loss. In a study with a 10-year follow-up by Rooney and Shauberger, it was found that among a sample of 540 women the weight gain beyond 5 years (mean 8.5 years) from pre-pregnancy to follow-up was 6.3 kg. No difference in weight gain by pre-pregnancy BMI was found. Women who lost all weight gained during pregnancy by 6 months postpartum were 2.4 kg heavier at follow-up compared to pre-pregnancy. However, women who retained pregnancy weight at 6 months postpartum were 8.3 kg heavier at follow-up. The study further indicates that breastfeeding >12 weeks and engaging in exercise are related to lower long term weight status after pregnancy. The main finding was that excess weight gain and failure to lose weight at 6 months postpartum are important and identifiable predictors of long term obesity [101].

In a 15-year follow-up of the SPAWN study [102], two groups were created and analysed based on the original cohort; those that were normal weight before pregnancy and remained normal weight at follow-up, and those who were normal weight before pregnancy but had become overweight at follow-up (table 7).

Table 7. Weight status 15 years after pregnancy among women who were normal weight before pregnancy, in relation to return to pre-pregnancy weight at 6 and 12 months postpartum.

Weight status 15 years later	Return to pre-pregnancy weight*	
	6 months postpartum	12 months postpartum
Normal weight	57%	60%
Overweight	28%	35%

*Within 1.5 kg of pre-pregnancy weight.

The mean weight gain among the women that remained normal weight was only 0.8 kg at 1 year (weight loss: 12.9 of the 13.7 kg gained during pregnancy). However, the weight gain among the women who became overweight was 3.1 kg at 1 year (weight loss: 12.3 of the 15.4 kg gained during pregnancy). Thereafter the long term weight change from 1 year to

15-year follow-up was ~4 kg in the normal weight group, and ~12 kg in the group that became overweight. This indicative early weight loss is most likely the consequences of lifestyle behaviours; of which some are identified (i.e. longer duration of breastfeeding, and engaging in exercise), and more remain to be identified. In the SPAWN follow-up study the measurements of eating behavior and physical activity were quite imprecise, and this was likely the reason for these factors not showing significant predictive power [102].

In sum, available evidence shows that GWG is greater than recommended in a large proportion of women in richer societies, but that GWG is also highly variable. However, on average women retain 0.4 to 3.0 kg following a pregnancy [95, 96], whereas about 15 to 20% of women retain more than 5 kg [103]. Having a first pregnancy, gaining above recommendations, and being overweight pre-pregnancy are associated with greater PPWR. New onset postpartum depression may also contribute to greater PPWR. In addition, low education and low income are also predictive of greater weight gain, and thus likely also weight retention. It appears that women that do not lose their GWG during the first 6 to 12 months after pregnancy are at higher risk of substantial weight gain. The risk may be exacerbated by subsequent pregnancies, starting at a higher BMI and resulting in greater GWG and PPWR. The risks of developing chronic diseases associated with substantial weight gain may thus be significantly reduced if women return to their pre-pregnancy weight by 6 months to 1 year postpartum.

1.6 Co-morbidities of overweight and obesity specific to childbearing

The past decade's epidemic increase of overweight and obesity among women of childbearing age is of growing concern in relation to maternal and child health [104-106]. Not only do the women face the co-morbidities associated with excess weight that all overweight and obese individuals are subject to, but also co-morbidities specific to the pregnancy and postpartum period.

First, the persistent weight gain due to GWG and/or PPWR, may lead to or exacerbate overweight and all associated conditions for women entering pregnancy overweight [95, 103]. For women with multiple pregnancies the consequences of overweight or obesity may be intensified with each subsequent pregnancy [96], although the first pregnancy appears to have the greatest impact on weight gain. Second, in general weight gain increases future risk of morbidity related to excess weight [44, 101]. Third, more

women enter pregnancy at older age and as a result it is more common that they enter pregnancy with chronic conditions like type 2 diabetes or hypertension. This increases the risk of pregnancy complications and can lead to increased morbidity in the years following pregnancy [78]. Finally, there are several co-morbidities that are specific to reproduction; those related to pregnancy outcomes, and those related to breastfeeding.

1.6.1 Overweight and excessive gestational weight gain

Among women who enter pregnancy overweight or obese, and/or those who gain weight outside the ranges recommended by the IOM are at increased risk of several adverse outcomes. Since many women have more than one child the elimination of PPWR, and preferably also overweight, before a subsequent pregnancy reduces these risks. GWG is related to gestational diabetes (GDM), preeclampsia and gestational hypertension, complications during labor and delivery including cesarean delivery (mainly because larger women tend to have larger babies) and PPWR [78]. The results of a systematic review including 13 cohort studies with in total 1.4 million women showed that the risk of preeclampsia was doubled with every 5-7-kg/m^2 increase of pre-pregnancy BMI [107]. According to Weiss et al the risk of gestational hypertension increased 2.5 fold with obesity class I and 3.2 fold with obesity class II [108].

The risk of GDM increases with increasing overweight. Among those with a BMI of 25 - 29 the risk is doubled, and among those with a BMI > 30 the risk is six-fold [23]. The proportion of obese women with GDM is approximately 3 to 7%. Within 15 years after pregnancy 70% of obese women who had GDM also develop type 2 diabetes. Among all women with prior GDM the corresponding proportion is 35% [109]

The prospective population-based cohort study by Cedergren et al, following 245,526 singleton term pregnancies based on the Swedish SMBR between 1994 through 2002, revealed that the effects of high or low GWG depend on maternal BMI and the outcome variable studied [82]. Obese women with low GWG (<8 kg) had a decreased risk for preeclampsia, Cesarean section, instrumental delivery, and large for gestational age births. An 8 – 16 kg GWG was considered normal and used for reference. A GWG >16 kg was considered as high. There was a 2-fold increased risk for preeclampsia and large for gestational age infants among normal and overweight women with excessive weight gain. High gestational weight gain increased the risk for cesarean delivery in all maternal BMI-classes [82].

1.6.2 Initiation and duration of breastfeeding and excess weight

Overweight and obesity is related to both initiation, including intention, and duration of breastfeeding. However, because both overweight and breastfeeding are related to socioeconomic factors in a similar manner such variables must be considered and also adjusted for when analyzing data on breastfeeding. Obese women have been found to plan to breastfeed for a shorter duration (6.9 months) than other women (9.3 to 9.8 months) [110]. Overweight and obese women are also less likely to commence breastfeeding. The odds ratio of not commencing breastfeeding compared with normal weight women ranged from 1.19 to 2.17 for overweight women and from 1.38 to 3.09 for obese women in ten studies included in a systematic review by Amir and Donath [111].

Furthermore, it has also been found that obese women breastfeed for a shorter duration than normal weight women, also after adjusting for possible confounders [111]. Results from the large Danish National Birth Cohort (37,459 women) are of particular interest to Sweden because of the similarities between the countries regarding both society in general and a supportive social context for breastfeeding. Baker et al reported from this cohort that the risk (compared to normal weight women in the sample) of early termination of any breastfeeding increased progressively with increasing pre-pregnant BMI; from 1.12 for overweight women to 1.39 for class III obese women, and the results were similar for full breastfeeding [112]. However, GWG did not add to or modify the risk of early termination of breastfeeding that was already captured by pre-pregnant BMI. It was also shown that lower education, no physical activity during late pregnancy, caesarean delivery, and smoking during the breastfeeding period increased the risk of early termination of any and full breastfeeding. Interestingly, because of the social environment for breastfeeding in Denmark; including a 24-week maternity leave and support for breastfeeding from health care available to all new mothers, the association between high pre-pregnant BMI and early termination of breastfeeding is not a reflection of poor social support as could be argued based on similar finding among American women. However, the Danish women breastfed for a much longer period than American women, which suggests that the social support plays an important role in overcoming the challenges to breastfeeding associated with overweight [112].

1.7 Breastfeeding and postpartum weight retention

Early studies have provided conflicting results regarding the association between breastfeeding and reduction of PPWR, mainly because women in the studies did not follow current recommendations to exclusively breastfeed for six months and then continue partial breastfeeding. Additionally, the association may be obscured by the above reviewed negative association between pre-pregnancy BMI, postpartum obesity and duration of breastfeeding [113]. Again results from the Danish National Birth Cohort may provide more reliable information. Women who ever breastfed (>98%) were interviewed at 6 and 18 months postpartum about breastfeeding. It was found that higher intensity and longer duration of breastfeeding reduced PPWR among women with BMI <35 kg/m^2. It was also calculated that if women exclusively breastfeed for 6 months, PPWR could be eliminated by that time among women with a GWG of approximately 12 kg [113].

1.8 Treatment of overweight and obesity during the postpartum period

The choice of treatment type to reduce overweight or obesity is limited during the postpartum period for several reasons, particularly if the mother is breastfeeding the infant. With the exception of lifestyle modification, i.e. changing ones diet and/or physical activity to achieve a moderate negative energy balance resulting in weight loss, other currently available weight loss methods are not suitable. Pharmacological treatment will likely result in that the drug is passed onto the infant via the breast milk. Bariatric surgery would compromise both breast feeding *per se*, as well as the ability of the mother to care adequately for the infant. A conventional 450 to 800 kcal per day Very Low Energy (liquid) Diet (VLED) would impose a too great energy restriction that could potentially compromise breast milk production [36]. Thus, the remaining options are interventions aiming at achieving modifications of diet and physical activity or exercise. These should be implemented to produce a suitable energy deficit and dietary quality level and/or correspondingly a suitable level of intensity and duration of exercise using an appropriate type of activity. Also, at least in theory, a meal replacement based diet could be used, as long as sufficient energy and nutrient quality is provided.

1.8.1 Effects of weight loss on breast milk

Initially, ambitions to stimulate women to achieve an increased level of physical activity were hampered by the fear that it could negatively affect breastfeeding and infant well-being. Observational studies have demonstrated that long term and severe under-nutrition is associated with reduced milk-volume and a lower nutrient concentration. However, mild under-nourishment had only a weak correlation with change in milk volume and composition. It has been suggested that short term reduction of food intake leads to increased levels of maternal prolactin concentration, to ensure milk production [114, 115].

Reduction of energy intake

In the 1990's several studies to investigate the effects of both physical activity and dietary restriction during the postpartum period were carried out, likely as it became increasingly evident that the weight gain and weight retention associated with childbearing needed to be addressed. Some of these studies suggested that a calorie-restricted diet had no impact on milk quantity and quality [116, 117]. However, earlier Strode et al. had found that well-nourished mothers who consumed less than 1500 kcal per day experienced a decrease in milk quantity [118].

Exercise

Likewise, the effect of exercise during lactation has been studied with somewhat conflicting results. Two trials by Dewey et al. and Lovelady et al. indicated that exercise had no adverse effect on lactation [119, 120]. On the other hand, a study with another approach demonstrated that the infant's acceptance of post-exercise breast milk was significantly lower than that of pre-exercise breast milk, and suggested that the increase in lactic acid level in breast milk affected the palatability negatively [121].

Environmental toxins in breast milk

The main source of exposure to persistent organic environmental toxins (i.e. chlorinated and brominated substances such as Polychlorinated biphenyls (PCBs), and flame retardants) in the population is food, mainly of animal origin. The substances are lipophilic and are thus accumulated in the adipose tissue. Because of the relatively high fat content of breast milk, and the transfer of fat from adipose tissue to milk, these substances are also found in the breast milk. The hydrophilic toxins that also exist are not found in the milk to the same extent as the lipophilic.

Among women, lactation is an important way of elimination of PCBs, DDT and similar substances [122, 123]. Therefore nulliparous women often have

higher levels of these substances, and the woman's first child is more exposed compared to later children. However, the levels of toxins in breast milk among Swedish women have decreased 3-11% per year from 1996 to 2004 [81].

The age of the woman is the main determining factor of the levels of toxins. Older women have higher levels compared to younger women [81]. Also, the levels are lower in women with a higher BMI, and with a large GWG (relative to body weight). The levels in breast milk are lower in women with a small relative weight loss from delivery to measurement at 3 weeks after delivery. A mean increase of 1-5% of PCBs have been observed per percent of weight loss during the first 4 weeks after delivery [81]. The 2008 evaluation by the National Food Administration concluded that a normal rate of weight loss does not increase the levels of environmental toxins in breast milk among Swedish women [81].

In sum, regarding the effect of diet and/or physical activity during lactation, it appears that a moderate reduction of energy intake and a moderate activity level is safe. To provide a margin of safety in energy intake, and ensure that recommended micronutrient intake is possible, an intake of no less than 1800 kcal per day can be recommended to lactating women [56]. A "normal weight loss" (0.6 - 0.8 kg per week, during the first 6 months [56]) does not increase the levels of environmental toxins in breast milk, among Swedish women [81].

1.8.2 A window of opportunity

The postpartum period may represent a unique window of opportunity to implement lifestyle changes to achieve reduction of excess weight, and also to establish healthy lifestyle habits. Before initiating the LEVA-trial we theorized that 3 factors were likely to contribute positively to creating this window of opportunity; a beneficial psychological state; *motivation*, a beneficial physiological state; *lactation* (for those breastfeeding), and a beneficial environmental factor; *parental leave* (given a sufficient length of parental leave).

Motivation

It is likely that in the postpartum period many women wish to lose weight. Rössner and Ohlin reported that about 40 to 50% of their female patients requested professional support to lose weight after the birth of their babies [124]. The wish to lose weight is also present in a large portion of the population, approximately 50% of adult women wish to lose weight, irrespective of childbearing [23]. However, it is likely that weight gain during

pregnancy, the responsibility for the health and lifestyle of the child i.e. being a role model, and the recognition of potential facilitating factors such as breastfeeding and parental leave, may increase motivation to initiate a weight loss attempt in the postpartum period. Using the above considerations Phelan have theorized pregnancy as a "teachable moment" (based on the definition by McBride; times that (1) increase perceptions of personal risk and outcome expectancies, (2) prompt strong affective or emotional responses, and (3) redefine self-concept or social roles [125]), that would motivate women to change their eating and exercise habits [126]. Among postpartum women enrolled in a diet and exercise weight loss trial it was found that motivation to lose weight increased with parity and non-breastfeeding. This was likely due to a compounding effect of weight gain through pregnancies, the idea of putting off weight loss attempts until one is finished with bearing children, and fear of changes in quality of breast milk or the belief that breastfeeding will be sufficient for weight loss. [127]

Lactation

By utilizing the opportunity of increased energy requirements of lactation it is possible that lifestyle treatment can enhance postpartum weight (i.e. fat mass) loss. If the energy balance is altered so that the energy requirements of the lactating woman are not met, a greater mobilization of energy from adipose tissue stores will occur to compensate for this - at least until the limit of adipose tissue energy stores mobilization per time unit is not exceeded. Although this limit has not been experimentally determined in lactating women, an indication may be derived from the Minnesota semi-starvation experiment by Taylor and Keys [128]. Here it was found that the rate of energy mobilization from adipose tissue, without catabolization of fat free mass, was limited to ~70 kcal per kg body fat per 24-hours [129]. Thus a person with 35 kg fat mass, which would be reasonable for an average height woman with a BMI of 30, could theoretically mobilize ~2600 kcal per 24-hours. This by far exceeds the 500 kcal per day deficit suggested to achieve a 0.5 kg per week weight loss.

Parental leave

The Swedish parental insurance was introduced in 1974. At that time it was the first in the world to provide parents with employment 6 months of paid leave, at a level of 90% of their income. Since then the length of the parental leave has been increased step wise. Today parents (also those unemployed) can use 480 days of paid parental leave per child. The cost is shared by the state and the employer. This parental benefit includes 390 days at 77.6% of income (up to a ceiling level), and thereafter a flat basic level rate. Sixty days

are dedicated to each parent; the remaining days can be divided freely between the parents [130].

Among Swedish women that utilize the parental leave benefits, ~20% have a leave that extends for 9 months or less, ~55% for 10 to 18 months, and ~25% for 19 months or more. The median length of maternity leave is ~13 months. Women are on leave longer with the first and second child than with later children. Among those with little work experience, the pattern is mixed and some return to work quickly whereas others take long parental leave. Women who have high prestige at work also tend to take shorter leaves. Women working in the public sector tend to take longer leaves than women in the private sector [131].

1.9 Lifestyle modification approaches to postpartum weight reduction

The current state of knowledge regarding the potential of lifestyle treatments to produce weight loss in women during the postpartum period rests on a very limited number of studies and subjects included. When these studies are further sub-divided to provide answers to a number of important specific questions, the evidence base becomes even less solid. In respect to weight control three major distinctions must be made, due to the major effect it may have on the outcome:

(1) What/which treatment that was provided and what it was compared to

(2) BMI-status of the women

(3) Breastfeeding-status of the women

According to a Cochrane systematic review from 2007, based on limited data, exercise alone is insufficient for weight loss, dietary restrictions alone or in combination with exercise can enhance postpartum weight loss, and combined treatment is thought to preserve FFM compared to dietary restriction alone and therefore is preferable [132]. The review included six trials (total n=245).

Using the above suggested distinctions the trials included in the review can individually provide answers to the question of which type of treatment(s) that produced weight loss to which sub-group of postpartum women.

The first distinction concerns what type of treatment(s) that was provided and what it was compared to. The possible comparisons that can be made are: (a) diet (D) vs. usual care (UC), (b) exercise (E) vs. UC. (c) diet and exercise (DE) vs. UC, (d) D vs. E, (e) DE vs. E, (f) DE vs. D. The weight change results (weighted mean difference) from the six trials are given for each type of comparison below (table 8).

Table 8. Summary of trial comparisons and outcomes included in 2007 Cochrane systematic review [132].

Comparison	Trials (n)	Participants (n)	Breastfeeding-status	Weight change (kg (95% CI))
(a) D vs. UC	1	45	EBF	-1.7 (-2.08 to -1.32)
(b) E vs. UC	1	33	EBF	0.0 (-8.63 to 8.63)
(c) DE vs. UC	4	169	Mixed	-2.9 (-4.83 to -0.95)
(d) D vs. E	0	-	-	-
(e) DE vs. E	0	-	-	-
(f) DE vs. D	1	43	EBF	0.3 (-0.06 to 0.66)

D denotes dietary intervention, E exercise, DE diet and exercise, and UC usual care. EBF denotes exclusive breastfeeding, CI confidence interval.

Among the six trials only three evaluated the effects of diet and/or exercise on body weight change as a primary outcome among lactating women. The three other studies included one that focused on postpartum depression, and two that covered non-breastfeeding women. The three former trials were all short term, ranging from 11 days to 12 weeks in duration. For each of the comparisons made the breastfeeding- and BMI-status of the women must be considered. The results of the three studies evaluating the effect of an intervention on body weight among breastfeeding women only provide the following information:

The comparisons (a) D vs. UC, (c) DE vs. UC and (f) DE vs. D among exclusively breastfeeding women were all possible in one trial with the 3 groups; diet group, diet and exercise group, and control group. This trial included women with a range of BMI covering normal weight to overweight (n=67). The trial lasted 11 days. The diet group were assigned to a 35% energy deficit, the diet and exercise group to a 35% energy deficit (of which 60% from diet and 40% from additional exercise). A weight loss of ~1.7 kg was achieved with both diet only and diet and exercise in combination, with no difference between the two treatments. Because of the very short duration the results are of limited usefulness.

The comparison (b) E vs. UC was possible in one trial including exclusively breastfeeding normal weight women (*n*=33). The trial lasted 12 weeks. The exercise program consisted of supervised aerobic exercise (at 60 to 70% of maximum heart rate) for 45 minutes per session, 5 days per week. No significant difference in body weight resulted from the exercise.

Finally, among exclusively breastfeeding women, the comparison (c) DE vs. UC was also possible in one trial. This trial evaluated only the effect of diet and exercise treatment combined for 10 weeks compared to control. The trial included women who were overweight (BMI 25-30) at 4 weeks postpartum (*n*=40). The experimental group was assigned to restrict their energy intake by 500 kcal per day and to exercise for 45 minutes per day for 4 days per week. The women in the diet and exercise group lost significantly more weight (4.8 kg weight loss) compared to the control group (0.8 kg weight loss).

In addition, the above trials indicate that none of the interventions adversely affected breast milk volume and plasma prolactin concentrations, or weight and length growth of the infant (one trial only). Number of women who stopped breast feeding, or breastfeeding duration were not assessed in any of the trials. Diet and exercise combined was found to result in preservation of FFM while producing weight loss, whereas diet alone was found to reduce FFM while also resulting in weight loss. Exercise was also found to increase cardiovascular fitness.

Since the 2007 Cochrane review the results of two additional trials have been published. One is the large, long term Active Mothers Postpartum (AMP) trial involving overweight and obese women (*n*=450). The trial consisted of a 9-month combined diet and exercise intervention, with follow-up 1 month after treatment termination. Here the comparison (c) DE vs. UC was made. The participants in the experimental group were offered eight healthy-eating classes, ten physical exercise classes and six telephone-counseling sessions over the 9-month intervention. The mean weight loss was 0.9 ± 1.5 kg in the experimental group and 0.4 ± 4.9 kg in the control group, the difference was not statistically significant [133]. The other was a 16 week intervention trial by Lovelady et al that examined the effects of an intervention aiming to achieve an energy restriction (500 kcal/day) combined with exercise in overweight and obese lactating women [134]. The women had a mean pre-pregnancy BMI of ~26.5, and the intervention started at 4 weeks postpartum. The web-based MyPyramid Menu Planner for Moms was used to support face-to-face dietary counseling. The exercise protocol consisted of strength training 3 times per week, and walking 10,000 steps or 3,000 aerobic steps

per day at least 5 days per week. A significant 5.8 ± 3.5 kg weight loss (7%) was achieved in the intervention group, compared to a 1.6 ± 5.4 kg weight loss (3%) in the minimal care group (p=0.03).

Neither of the trials included in the Cochrane 2007 review lasted longer than 12 weeks and no follow-up after treatment termination was made, thus the sustainability of the achieved weight loss could not be evaluated using the systematic approach. Since 2007 also results from the longer AMP trial have been published, and although the intervention itself lasted for 9 months the final measurements were made one month after treatment termination. Thus, despite its long term intervention design the sustainability of the results was not evaluated.

In sum, the trials that have so far evaluated the effects of diet and exercise alone or in combination as a means to achieve, or enhance, postpartum weight loss among overweight and obese lactating women are few and inconclusive. However, modest diet and exercise changes appear not to affect breast milk or infant growth adversely. Treatments intended to produce dietary change (energy intake restriction) alone, or in combination with exercise, may result in weight loss. Although modest weight loss has been achieved there remain important gaps in the literature on short- and medium term (up to 6 months) postpartum weight reduction among overweight and obese lactating women. Regarding long term even less data are available. Only one long lasting intervention has been reported. That trial was unfortunately ineffective in promoting weight loss, and no measures of long term post-treatment outcomes were made.

The following list indicates major concerns that limit clinical implementation of lifestyle treatments for postpartum weight reduction among breastfeeding overweight and obese women:

(1) The weight loss achieved in previous trials does not reach the widely accepted ~10% weigh loss indicator of clinical relevance.

(2) Other weight-measures of clinical relevance, i.e. return to pre-pregnancy weight, weight loss relative to pre-pregnancy weight (reduction of pre-existing overweight), and shifts in BMI-classes have not been evaluated.

(3) The trials do not differentiate between separate and interactive effects of diet and exercise interventions.

(4) There are no measures of the long term post-treatment effects of the studied treatments, i.e. measures of sustainability are lacking.

(5) The superiority of one treatment model (type of counseling, type of advice, intensity and duration of support, self-monitoring) over other has not been established, mainly due to the small number of trials and the lack of substantial effect on weight resulting from these.

(6) The generalizability and translatability of results have not been evaluated. This is mainly due to the small number of trials and their small effect, the proof-of-concept nature of most trials, and also because of quite homogenous study populations, within and between studies.

(7) The role of the context and maternal factors are not well understood, i.e. the effects of societal/institutional, environmental, community, interpersonal/family factors, or the individual characteristics such as socio-demographic and psycho-social factors.

1.10 Official recommendations for postpartum weight management

The Institute of Medicine has recently recommended that women are offered counselling on diet and physical activity to eliminate postpartum weight retention [78]. Swedish authorities recommend that overweight and obese women seek treatment from a dietitian to reduce postpartum weight retention [135]. Thus, the interpretation of existing data by these expert groups and authorities is that the benefits of elimination of PPWR outweigh potential adverse effects, and that lifestyle treatment is recommended to achieve this. There is also consensus with the respect to that a weight loss rate of 0.5 kg per week is considered safe and should not be exceeded. However, these recommendations are hindered by the lack of research supporting treatment method and clinical relevance.

2 AIM

The overarching aim of the research presented in this thesis was to evaluate whether dietary behavior modification treatment, or physical exercise behavior modification treatment, or the combination of both, provide short and long-term weight loss compared to control among overweight and obese lactating women, and if so how. For the latter issue, specific effects of the treatments on energy metabolism, body composition, dietary intake and psychological and behavioral processes were studied. The three papers included in the thesis are based on the LEVA-trial and each provides a distinct perspective on the overarching research aim.

2.1 Specific aims

Paper I

- To evaluate whether 12-week dietary behavior modification treatment to decrease energy intake (D), physical exercise behavior modification treatment to implement moderate aerobic exercise (E), or combined treatment (DE) reduces body weight among lactating women compared to usual care (C, controls).
    - To evaluate the separate and interactive effects of the D and E treatments measured at (1) end of treatment, and (2) at a 1-year follow-up 9 months after treatment termination on body weight and body composition.
    - To evaluate the effects of the treatments on energy intake and expenditure, physical activity, breastfeeding, and child growth.

Paper II

- To evaluate the short- and long-term changes in dietary intake that occurred during the trial.
    - To evaluate the separate and interactive effects of the D and E treatments
    - To evaluate the outcome in relation to current dietary recommendations.
    - To evaluate the dietary composition among individuals successful in reaching the target weight loss

Paper III

- To provide a substantive theory of how overweight and obese women achieve weight loss during, and after, participating in a postpartum diet and exercise intervention.

3 PARTICIPANTS AND METHODS

3.1 Study participants

Between 2007 and 2010, eligible women were recruited from 15 antenatal clinics in Gothenburg, Sweden. Inclusion criteria were: self-reported pre-pregnant BMI 25–35 kg/m^2, non-smoking, singleton term delivery, intention to breastfeed for 6 months, providing <20% of the infant's energy intake as complementary foods, birth weight of infant >2500 g, and no illness in the mother or infant. The upper BMI limit was set at 35 kg/m^2 to limit the inclusion of women who might be unable to participate in the exercise treatment or who might be at risk of obesity-related conditions requiring additional medical treatment. Women with mild allergies and stable, medicated hypothyroidism were eligible because this would affect neither participation nor outcome measurements.

The study was approved by the Regional Ethics Board in Gothenburg, Sweden. All participants provided written informed consent.

3.2 Study design

Women attended the research clinic for baseline measurements at 8-12 weeks postpartum. At 10-14 weeks postpartum, 68 women were randomized to 4 intervention groups, based on the 2 treatments (D and E) and C in a 2 x 2 factorial design, thus resulting in: (C group) control group, (D group) dietary behavior modification group, (E group) physical exercise behavior modification group, and (DE group) combined dietary and physical exercise behavior modification group. Women were stratified based on pre-pregnancy BMI <28.0 and ≥28.0 kg/m^2, respectively. A blocked randomization (block size of four) was used within each stratum. All possible permutations within a block were identified and selected for each strata from random numbers in a random-number table. In all, 16 blocks of 4 (n=64) were completed and 2 blocks of 4 were partially used until a total of 68 women were randomized. Group allocation was concealed to all until completion of baseline measurements. Time from childbirth to baseline measurements did not differ among the groups (p=0.854). The intervention lasted 12 weeks. At the end of the intervention all baseline measurements were repeated. At 1 year after baseline all measurements except total energy expenditure were repeated (figure 2).

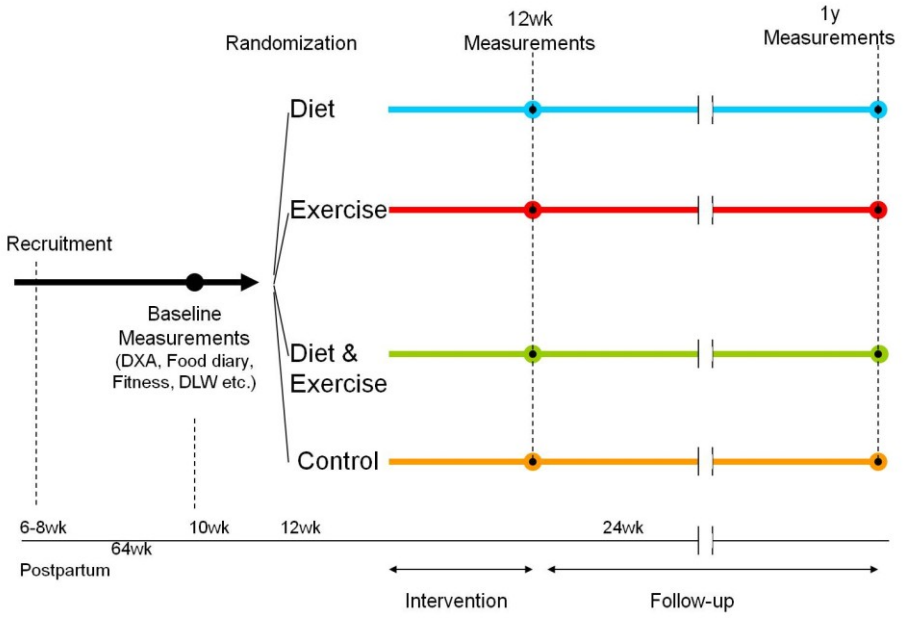

Figure 2. Trial timeline. Wk denotes week, and y year.

3.3 Intervention

Women in the D group received the D treatment and women in the E group received the E treatment for a total of 2.5 hours of individual behavior modification counseling: 1.5 hours at the start of the intervention and 1 hour at a follow-up home visit after 6 weeks of intervention. Women in the DE group received the D and E treatments, a total of 5 hours. Between visits, women were contacted biweekly with cell-phone text messages to report body weight in D group, number of brisk walks in E group, and both in DE group, and were also encouraged to adhere to the program. Women in the C group received usual care (no counseling, home visit or text messages). They were asked not to engage in other lifestyle modification programs.

3.3.1 Dietary behavior modification intervention

The woman met individually with the dietitian at the research clinic, and brought her baby to the counselling session as well. The dietitian explained a 12 week dietary modification plan to achieve a reduction in energy intake of 500 kcal/day; initially relative to reported baseline diet but subsequently relative to actual energy balance as measured by changes in body weight (goal: -0.5 kg/week), and a nutrient composition according to the Nordic Nutrition Recommendations (NNR) [136]. These current recommendations

prescribe a dietary composition of total fat ≤30% of energy (for overweight and obese individuals), saturated fat ≤10% of energy, protein 10-20% of energy, total carbohydrate 50-60% of energy, and ≥12.5 g fiber/1000 kcal. Emphasis was put on reducing fat and sugar, maintaining protein, and increasing fiber. This was communicated in terms of foods, not macronutrients *per se*.

For the LEVA-trial the dietitian designed a structured dietary behaviour modification plan. The implementation of the plan built on four cornerstones; (1) 4 key dietary principles to be implemented in an individualized and stepwise fashion, (2) a specified 12 week weight loss goal, (3) self-monitoring, and (4) a working relationship between the dietitian and the woman; providing support and follow-up.

Specifically, the women were advised to introduce the key dietary principles one at a time, at a pace that facilitated the weekly weight loss goal. Thus the change in body weight as measured by the body scale was used as a proxy for energy balance (i.e. energy intake), and they were advised to adjust energy intake via the introduction of the key principles. This approach was labelled SWAP (Step-wise Weight-determined Accumulative change Plan). The plan consisted of 4 key principles, to be introduced in the following order: (1) limit sweets and snacks to 100 g/week, to be eaten during only one day of the week, (2) substitute regular foods with low fat and low sugar alternatives, i.e. for every food item make sure to find a low fat or low sugar alternative if such exists, preferably marked with the 'Green keyhole' that indicates low sugar, saturated fat and salt, and high fiber, (3) gradually increase vegetables so that vegetables cover half the plate at lunch and dinner, (4) reduce portion sizes by reducing equally from the carbohydrate and the fat content of the meal (figure 3). In effect this meant that all women began by implementing step 1, and thereafter observed the weight-change-effect of this single dietary change, and thereafter added a following step when they did not reach the weekly weight loss goal for two consecutive weeks. Among women where frequent and substantial consumption of sweets, soft-drinks and snacks was an important contributor to overeating, this first step would be effective. Thus, the 'size' of the problem would determine for how long the change would produce weight loss, and also provide more time for implementing this particular change for those needing it more. Among those with lesser consumption of sweets, soft-drinks and snacks, perhaps other high-fat/high-sugar foods or large servings would be the main cause of a high energy intake; therefore they would according to the plan move to those steps faster and stay there for longer. Still, the women were advised to devote no longer than 3 weeks to a single step, before including the next; so that at least the

first 4 steps (i.e. implementing a diet in line with NNR) could be supported during the treatment.

During counselling the original plan included five steps, one additional discrete step to 'increase vegetable consumption, to be implemented before 'vegetables cover half the plate'. However, in practice this step became a part of the 'vegetables cover half the plate'-step. Because it was not specific or quantified in any way, it could not be effectively translated into practice, and can therefore not be considered a part of the SWAP-model. The women were advised to increase intake of fruits and vegetables, but as a part of the counselling where it was specified and quantified as a solution to a barrier to change identified by the woman, e.g. substitute a regular snack with one fruit.

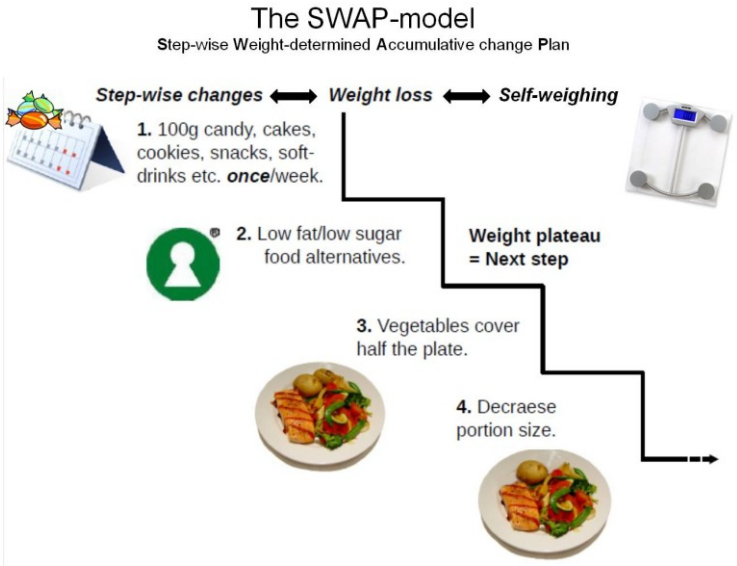

Figure 3. The SWAP-model© as part of the LEVA-intervention illustrated. Adapted and translated to English from the dietary behavior modification counselling booklet.

The plan was presented with a printed booklet covering specific goals, health benefits of weight loss and safety issues regarding nutrient needs and pace of weight loss, instructions on how self-weighing can substitute calorie counting, a presentation of the 4 key dietary principles, general advice regarding planning, grocery shopping, significant others and also space for individualizing the plan to reduce barriers to change regarding the key principles. Further, the booklet included checklists to document weekly

achievements in weight loss and key dietary principles. Finally, the booklet included Outcome-Quantified Dietary Advice (OQDA); a suggestion of concrete changes to the reported baseline diet in accordance with the key dietary principles, and calculations on the weekly and total weight loss that would be achieved if the principles were implemented in accordance with the SWAP-model. The calculations were made for each woman, for principle 1, 2 and 4 separately and accumulated to reach a ≥500 kcal/day deficit. Due to the nature of principle 3 it could not be calculated this way. The calculations for step 4 were made using the following increments of reduction: 1/4, 1/3 and 1/2 of reported fat and carbohydrate content in composite meals. Thus, the following four calculations were made based on the energy value of body tissues [137], assuming that mainly adipose tissue would be reduced because of the modest pace of weight loss.

For each principle separately:

[*Total kcal deficit/day (principle n) = g weight loss (adipose tissue)/week*]

For the principles combined:

[*Total kcal deficit/day (principle 1+2+4) = g weight loss (adipose tissue)/week*]

The women were provided with an electronic body scale (Arko, EKS, Gislaved, Sweden) for self-weighing 3 times/week. The total weight loss goal was set to 6 kg, however it was also divided into a weekly weight loss goal of 0.5 kg. Further, the women were advised to not exceed 1 kg weight loss per week. Physiological rate of fat loss, safety regarding breastfeeding, as well as allocating enough time for each dietary change effort to become a new habit were discussed as reasons for not exceeding the goal rate of weight loss.

A working relationship was sought to be created by the dietitian by establishing agreement on goals and strategies, and by being personal, empathic, non-judgemental and expressing a true belief in the woman's capacity to succeed. This belief was underpinned by the calculation of how certain dietary changes would lead to the target weight loss and the dietitian and the woman jointly agreeing on this as realistic goals. Further, reflective listening and joint solution seeking was used to establish strategies for management of barriers to change and dietary concerns identified by both the dietitian and the woman.

The initial counselling covered all aspects of the plan and was provided at the research clinic. During the second counselling session six weeks later the

plan was followed up with a 24-hour recall and a discussion on achievements of the key dietary principles. Also, information and advice regarding dietary fat quality was provided. Strategies to reduce intake of saturated fat and maintain, or to a lesser extent reduce, intake of unsaturated fats depending on baseline diet and achievement of key dietary principles changes was introduced.

3.3.2 Physical exercise behavior modification intervention

The woman met individually with the physical therapist at her home. The physical therapist explained the physical-exercise modification plan to implement a 45-min brisk walk four days a week, at 60-70% of maximum heart rate. An accurate maximum heart rate had been obtained during the baseline measurement with a bicycle ergometer test performed until exhaustion (EBIKE Comfort, GE Medical System, Milwaukee, WI).The treatment-level of exercise has been recommended and judged as appropriate during the postpartum period [138, 139]. It is of sufficient duration and intensity to produce both an aerobic training effect [140], and also result in a small but meaningful energy deficit.

For the LEVA-trial the physical therapist designed a structured exercise behavior modification plan, to provide the same style of step-wise implementation of exercise, a goal-level of exercise, self-monitoring, support and follow-up, as was used in the dietary behavior modification treatment. The women were provided with an exercise-plan booklet, a heart-rate monitor (Polar FS2C, Polar Electro Oy, Kempele, Finland) and an activity diary for self-monitoring. The plan was presented with a printed booklet covering specific goals, health benefits of exercise and safety issues regarding exercise technique, gear and basic information on proper eating and hydration. It further included instructions on how to conduct self-monitoring using the heart-rate monitor, and general advice regarding planning, significant others and also space for individualizing the plan to reduce barriers to change. Further, the booklet included checklists to document weekly achievements in exercise implementation.

The energy deficit that would be achieved by performing the exercise treatment can be estimated using the following formula by Keytel et al [141], adjusted to provide kcal/min and showing only calculation for women (EE energy expenditure; HR heart rate):

[*EE (Kcal/min) = (-20.4022 + 0.4472 x HR – 0.1263 x weight (kg) + 0.074 x age) / 4.184*]

Thus for a 30 year old woman weighing 85 kg the estimated caloric cost of performing 4 45-min walks would be 1064 kcal per week (266 kcal per session or 152 kcal per day), based on the assumption that walks were performed at 65% of maximum heart rate equal to a heart rate of 120 beats per minute. Given that energy intake was not increased this would result in a 1.8 kg weight loss over the 12 week intervention, based on the energy value of body tissues [137], assuming that mainly adipose tissue would be reduced because of the modest pace of weight loss, and not including the potential weight loss effect of breastfeeding.

However, the women were not presented with a weight loss goal, but with the goal to gradually increase first the number and duration of walks, and thereafter the distance covered during the walks. The duration of walks was gradually increased in the first four weeks. During week 1 3 30-min and 1 45-min walks were performed, during week 2, 2 30-min and 2 45-min walks were performed, and during week 3, 1 30-min and 3 45-min walks were performed. The goal was to perform the walks at a mean of 65 % of maximum heart rate, thus this would produce a modest increase in fitness (as measured by maximal oxygen uptake (VO_2max)). Over the course of the treatment, with gaining an increased level of fitness, a faster pace of walking (or a heavier load, i.e. a heavier baby and/or carriage) would be needed to maintain the target intensity, i.e. target heart rate. With a faster pace the distance covered during the 45-min session should increase gradually, and provide a concrete outcome measure to the woman.

The women were advised to perform the walks with the baby in a carriage. This was intended to simplify the implementation of the exercise by not forcing the woman to find a babysitter several times per week, and also to be able to perform the exercise with the baby either sleeping or awake which ever was perceived as best. Also, stopping to breastfeed the baby would be possible, so that the need to place exercise sessions between frequent nursing sessions would not be a problem. Strategies for managing barriers to change and exercise-related concerns identified by the woman were established jointly.

The initial counseling and the follow-up counseling six weeks later were provided at the woman's home. On both occasions, the physiotherapist joined the woman on her walk to ensure suitable walking paths. During the six-week counseling the exercise plan was followed up with a discussion on the achievements of the exercise goals.

3.4 Post intervention

During the 9-month period following the intervention, the women were instructed to live their lives as they themselves chose. The women were contacted once, after 6 months, and asked about their health status and whether they still intended to attend the 1-year follow-up. Women who became pregnant during the first 8 months of the follow up were excluded from the 1-year follow-up measurements. Women who were <1 month pregnant at follow up were considered eligible because only minimal body weight changes were likely to have occurred [55]. Also women who were unknowingly pregnant may have been included.

3.5 Study outcomes

Paper I
The primary outcomes were change in body weight and body composition from baseline to 12 weeks and 1 year. Measures of treatment included energy intake and expenditure, and daily steps. Involuntary cessation of breastfeeding, reduced breastfeeding duration, and inadequate child growth were indicators of adverse effects.

Paper II
The primary outcomes were changes in macro- and micronutrient intake from baseline to 12 weeks and 1 year. A dietary intake in line with the Nordic Nutrition Recommendations was indicative of compliance and a healthy diet.

Paper III
The primary outcome was the women's stories of the experience of achieving or not achieving short- and/or long term weight loss.

3.6 Measurements and data collection

To produce data of high quality, valid and reproducible, efforts were made to find methods of 'gold standard' or reference method quality, most suitable to the research aim and trial design. Also, all measurements were made according to a precise and detailed set of instructions, and carried out by trained personnel.

3.6.1 Weight and body composition

Measurements were taken after an overnight fast. The women were allowed to drink 0.5 liters of water between the initiation of the fast and the measurement. Weight was determined to the nearest 0.1 kg with women

wearing light underclothing with an electronic scale (MC 180 MA, Tanita, Tokyo, Japan). Height was measured to the nearest 0.5 cm with a wall-mounted stadiometer. Body composition was measured with dual-energy x-ray absorptiometry (DXA) (Lunar Prodigy, GE Lunar Corp, Madison, WI). Muscle mass was calculated from DXA [142]. The children were weighed naked to the nearest 10 g on an electronic scale (model 336, Seca, Hamburg, Germany) and recumbent length was measured to the nearest 1 mm on a measuring board (model 416, Seca, Hamburg, Germany) according to Gibson [143].

3.6.2 Dietary intake

The women were provided with an electronic scale (HR2395, Philips, Drachten, Netherlands) and instructed to weigh and record all foods and beverages consumed for 4 consecutive days that were jointly established to be representative of their habitual diet. Preferably the record should cover 3 weekdays and 1 weekend day. Women were interviewed regarding their infant's intake of type and amount of complementary foods, using a short questionnaire covering most common infant and child foods and drinks and with the possibility to add any other food reported by the mother. Dietary intake was calculated with Dietist XP software (version 3.2, Kost och Näringsdata, Bromma, Sweden), using the 2010 Swedish Food Database, and data from food manufacturers.

3.6.3 Energy expenditure

Resting metabolic rate

Resting metabolic rate (RMR_{IC}) was measured in the fasting state after 20 minutes of rest in the supine position using indirect calorimetry (ventilated hood) (Deltatrac II Metabolic Monitor, Datex, Helsinki, Finland). The equipment was calibrated before each measurement with Quick Cal™ calibration gas (Datex-Ohmeda, Helsinki, Finland) constituting of 95% O_2 and 5% CO_2 according to the manufacturer's instructions. Measurement was performed during 30 minutes out of which the first five minutes were excluded to allow for adaptation to the ventilated hood. Women were resting in a supine position but awake at comfortable room temperature during the measurement. They were instructed to take car or public transportation to the laboratory and not be physically active on the morning before examination to ensure an accurate measurement.

Total energy expenditure

Women received a dose of DLW (0.05 g of deuterium dioxide and 0.10 g of O_2^{18} per kg body weight) after providing a baseline urine sample. They were

instructed to perform the urine sampling at 7 time points during the following 14 days (on day 1, 2, 3, 7, 12, 13 and 14), a total of 15 days. The exact time of collecting each sample was recorded using a calibrated watch (usually participants' cell-phone). Urine samples were stored in participant's freezer until completion. Samples were analysed in triplicates on a Finnigan MAT Delta Plus Isotope-Ratio Mass Spectrometer (ThermoFinnigan, Uppsala, Sweden). Total daily energy expenditure was calculated by the multi-point method by linear regression from the difference between elimination constants of deuterium (^2H) and $O_2{}^{18}$, with the assumptions for fractionating as suggested by International Dietary Energy Consultancy Group (IAEA), 1990) [144]. The energy equivalence of the CO_2 excreted was calculated from the macronutrient intake using estimated food quotient (FQ) from the 4-day dietary record [145]. The relationship between pool size deuterium (N_D) and pool size oxygen-18 (N_O) was used as a quality measurement of the DLW analysis as proposed by IAEA [144].

Step count

Step count was used as a measure of physical activity. Step count provides a reasonable measure of physical activity although not all activity generates steps. There were two major advantages of using step count in this trial. First, it is a simple, convenient and inexpensive measurement that does not burden the participants much. Second, it provides an outcome variable that can be compared to both a large number of studies and a general recommendation on steps per day for both general health and weight control.

Daily steps were measured with the multi-sensor arm-worn accelerometer SenseWear Armband (SWA) Immediately after receiving the DLW dose, a SWA Pro_2 (version 6.03, BodyMedia, Inc., PA) was placed on the upper right arm of the women. They were instructed to wear the armband during the consecutive 7 24-hour periods (8 days) and only to take it off when swimming/taking a bath or showering. Information about body weight, height, smoking status (all were non-smokers), and right/left-handedness were entered into the InnerView Professional software 5.1 (version 5.1, BodyMedia, Inc., PA). Daily step count was analyzed for five consecutive days, during which the women had worn the SWA for >90% of the 5 24-hour periods, using InnerView Professional software.

3.6.4 Statistical analysis

The sample size in the trial was calculated based on predicted difference in the primary outcome body weight change, between dietary treatment group and control group (-6.0 ± 2.0 kg vs. -1.5 ± 2.0 kg). Assuming a dropout rate of 20%, 17 women per group would be needed to detect a significant

difference between these two groups with 80% power. By using a 2 x 2 factorial design, power was increased further [146].

The 2 x 2 factorial design included 2 levels (absence (-) or presence (+)) of each of two factors (D treatment and E treatment), leading to four intervention combinations in total; i.e. C group:-/-, D group +/-, E group: -/+, and DE group: +/+. This allows for analysis of both main effects of the D and E interventions and their interaction, which were analyzed using 2-way ANCOVA.

The differences among groups at baseline were analyzed with the 1-way ANOVA, Chi-square and Kruskal-Wallis non-parametric tests. Statistical significance was indicated by P values < 0.05. All statistical analyses were performed using the SPSS software (version 19.0, IBM, Somers, NY).

Paper I

Analyses of the intervention outcomes included all women who completed both baseline and post-intervention body weight measurements (n=62). Analyses of the 1-y follow-up included all women who completed both baseline and 1-y body weight measurements (n=57). Change in outcome variables was calculated as the value obtained at 12 weeks and 1 year minus the baseline value.

Paper II

Analyses of the intervention outcomes included all women who completed dietary recordings, at baseline and 12 weeks (n=61). Analysis of the 1-year follow-up included all women who completed both baseline and 1-year dietary recordings (n=54). Change in outcome variables was calculated as the value obtained at 12 weeks and 1 year minus the baseline value.

3.7 Qualitative Grounded Theory analysis

When the goal is to generate a theoretical framework or model regarding a particular situation or process Grounded Theory is a useful qualitative approach. It is also appropriate to use to explore an area that is not well studied [147]. Thus the choice of Grounded Theory is well justified, as both the above goals were sought in this study.

Grounded Theory is a general research methodology developed by the sociologists Barney Glaser and Anselm Strauss [147], and thereafter further by Strauss together with Juliet Corbin [148], and also a more recent constructivist approach to Grounded Theory by Kathy Charmaz [149] has

been developed. We were guided by Grounded Theory methodology based on Glaser, Strauss and Corbin.

Grounded Theory is based on a systematic generation of theory from data, using both inductive (theories created from data) and deductive (a hypothesis created from existing theory that can be tested empirically) reasoning. In Grounded Theory the aim is to create new theories built on observations of a reality one observes without preconceptions about the nature of the observed, while in a parallel process also testing the theories one generates on reality. This results in constant comparisons between data and reality. Based on this the method was initially labeled 'the constant comparative method'.

In Grounded Theory the goal is to discover the participant's main problem or issue, and how they try to solve it. Continuously the questions "What is going on?" and "What is the main problem and how are the participants trying to solve it?" are asked [147, 148]. These questions about the problem are answered by the core category, supported by its underpinning categories and codes, which are generated in the analysis process. The generated theory provides a framework for understanding the processes and the solution to the problem. The underpinning categories and codes are the result of the abstraction of concepts from data, and thereafter linking related concepts to each other. The level of abstraction is then increased by sorting this information under increasingly complex and contents-rich codes. The codes are labeled so that the code-label reflects the whole underpinning contents and thus possesses a descriptive and explanatory power. The process of abstraction is repeated as the codes are sorted into categories. Finally, the core category represents the highest level of abstraction. It is related to all categories in the generated theory, and explains the variation that can occur within these categories [148].

The process of analysis to generate a grounded theory is performed in parallel with the collection of data. The analysis of data provides direction for further data collection. Initially the data collection is open, but subsequently becomes more theoretical and oriented to saturate the codes and categories that are generated [148]. The process is driven by the emerging theory, in contrast to an a-priori specification [147]. The data collection is considered complete when new data no longer adds to generation of new codes or increases the understanding of previously generated codes and categories, or the relation between codes and codes, codes and categories, or categories and categories. This is called saturation. The process of collecting new data to saturate the material is called theoretical sampling. To aid the process of analysis memos are continuously written and read. These include thoughts

and reflections on data, leads to follow in data collection and sampling, emerging codes, categories and conceptual frameworks [148].

Two levels of theories are generated with Grounded Theory; formal theory and substantive theory. These theories are models of individual's perspectives on a certain phenomenon and the way they address a problem within a distinct context. A formal theory relates to a wide-ranging conceptual area. It is generated in the study of a phenomenon observed in various types of situations. A substantive theory relates to a focused research question, generated within a study of a phenomenon situated in a specific situational context. A substantive theory is generally valuable to health professionals, because of the situation-specific nature and often rich and detailed data [148].

According to Glaser and Straus the trustworthiness of the generated theory can be judged on basis of its fit, relevance, workability and modifiability [147]. The generated theory must fit the empirical problem under study, and much of the variation must be explained by the core category. A relevant study/theory deals with the real concern of the participants; it should capture attention and not only be of academic interest. The workability of the generated theory refers to its ability to explain how the main problem is solved. The modifiability concerns that the theory can be modified when new relevant data occur.

3.7.1 Data Collection

A sub-sample of women from all intervention groups in the LEVA-trial were interviewed using an interview guide with open-ended questions. The interviews were digitally recorded and transcribed verbatim. A pilot interview was performed and thereafter the interview guide was constructed. The interview guide was revised continuously in line with issues emerging in data analysis in accordance with Grounded Theory. The main focus was: "What are your experiences from making diet and/or exercise changes in the context of the intervention?" Follow-up questions were posed and recurrent interviews were carried out in which women were asked about their experiences of maintaining life-style changes. Additionally, e-mail correspondence and memos from the intervention were used as data sources.

Starting in October 2008, women finishing either the 12-week intervention or the 1-year follow-up were invited to be interviewed. All invited women accepted within two weeks (n=21). In total 29 interviews were made with; 11 women at post intervention only, 10 at 1-year follow-up only, and 8 on both occasions. Initially 8 women were sampled consecutively from the ongoing

intervention study for interviews representing Diet, Exercise and Diet plus Exercise groups and both time points. Thereafter theoretical sampling was initiated. A total of 15 interviews were made following successful weight loss or maintenance, whereas 14 were made following unsuccessful weight loss or maintenance, to achieve saturation regarding both outcomes. Women achieving and sustaining a weight loss of 6 kg or more were considered successful in accordance with the intervention trial goals, based on weight loss recommendations for postpartum women [78, 136]. Because of the theoretical sampling procedure not all women were interviewed at both time points, but were selected to add to or saturate the emerging theory. Interviews with women from Control group were included as negative cases [148]. The interviews were conducted in privacy in the women's homes. For women who were interviewed twice, the follow-up interview 9 months later was conducted by phone. The first interviews were approximately 45 minutes in length, and the follow-up interviews lasted between 20 and 35 minutes.

3.7.2 Data Analysis

The analysis started with open coding by F. Bertz, using the NVivo 8.0 software, in which the interviews were read and coded line by line or paragraph by paragraph. The process of coding continued until categories emerged, and properties and dimensions were identified. These were thoroughly discussed by the whole team (F. Bertz, C. Sparud-Lundin, A. Winkvist). During axial coding, linking categories, general patterns and similarities and differences were continuously sought by constant comparisons within and between codes and categories. In the analysis process, statements from interviewed women were also considered in relation to success of weight loss/management. Selective coding was used to saturate the categories. Memos were written throughout the process to aid the concurrent data collection and analysis. High replication of data within emerging categories and verification of actions, incidents and strategies by several participants indicated saturation. An example of the coding process, from verbatim transcription of interview through increasing abstraction into codes and categories is illustrated in table 9.

To improve trustworthiness, all interviews were conducted by a research group member who was not associated with the intervention (C. Sparud-Lundin). The different backgrounds of the research group members brought different perspectives into the process. Also, triangulation took place during the data analysis, with researchers representing both the insider perspective (nutrition science) and the outsider perspective (caring science). In addition, every 5th interview was coded individually by two researchers, and thereafter

any differences were negotiated. Using NVivo allowed all authors to access data and coding schemes, ensuring transparency throughout the process.

Table 9. Illustration of coding scheme. From verbatim transcription of interview to codes and categories.

Core category	**Transformative Lifestyle Change**			
Overarching category		***Catalytic Interaction***		
Category	**Discontentedly lacking lifestyle control**	**Spark**	**Direction**	**Pressure & Praise**
Substantive codes and concepts	Stress	Personally relevant	Following a plan	Being monitored
	Social norms	Applicable	A specified attractive goal	Feeling accountable
	Lack of structure or discipline	Emotionally convincing	Sub-goals	Encouragement
	Lack of sufficient motivation	Trustworthy information	Gradual introduction	Praise
		Professional credibility	Clearly specified changes	
		Advanced medical technology		

4 MAIN RESULTS

4.1 Paper I Weight and body composition

4.1.1 Study population

A total of 68 women were randomized to treatment or control; 62 (91%) completed the intervention period and 57 (84%) remained to complete the 1-year follow-up (Figure 4). Between the intervention and the 1-year follow-up no women dropped out, but 5 were excluded from measurements because of a new pregnancy. There were no significant differences in baseline characteristics (age, parity, education, marital status, breastfeeding practice, infant complementary feeding, infant gender, infant weight and length) and anthropometric variables (weight, BMI, fat mass, lean mass and muscle mass) among the groups. Women who dropped out or were excluded for reasons other than pregnancy had a higher mean BMI and higher parity at baseline than did women who remained in the trial.

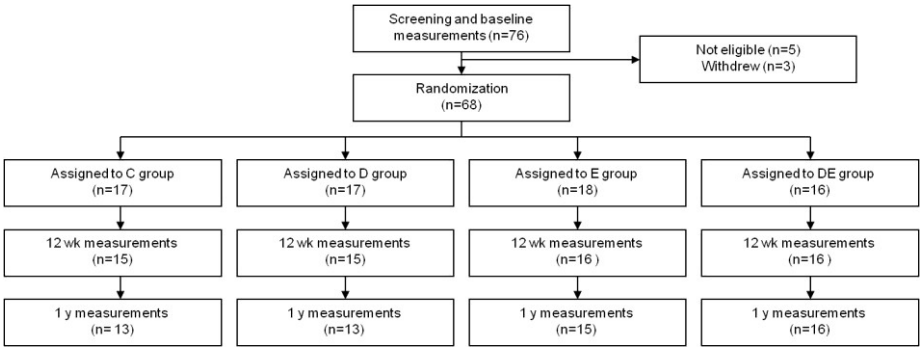

Figure 4. Screening, randomization, and follow-up of study participants in the Swedish dietary and/or exercise behavior modification intervention trial among lactating overweight and obese women. C denotes control, D dietary behavior modification, E exercise behavior modification, and DE combined dietary plus exercise behavior modification.

At baseline the women later excluded because of pregnancy did not differ from those who remained in the trial. During the intervention period 2 women were excluded; 1 from E group because of pregnancy, and 1 from D group because of being prescribed a metabolism affecting drug. One woman in C group and 1 in E group dropped out because they wanted weight loss, and 1 woman in C group and 1 in D group dropped out because of time constraints. Women who dropped out or were excluded for other reasons than pregnancy had a higher mean BMI and higher parity at baseline than those who remained in the trial ($p=0.006$ and $p=0.005$ respectively).

4.1.2 Treatment implementation indicators

The D, but not the E, treatment resulted in a significant reduction of reported energy intake at 12 weeks ($p<0.001$). At 1 year, a reduction of reported energy intake as a main effect of the E, but not the D, treatment was instead found ($p=0.023$). TEE at 12 weeks was reduced as a main effect of D treatment, which may be explained by the reduction of body mass. Interestingly, neither the D nor the E treatment led to significant changes in daily step count or RMR at 12 weeks or 1 year.

4.1.3 Treatment outcomes

Only the D, but not the E, treatment caused significant loss of weight and fat mass (both $p<0.001$) at 12 weeks and at 1 year ($p<0.001$ and $p=0.002$, respectively). Weight changes (kg) after the intervention and 1-year follow-up, respectively, were -8.3 ± 4.2 and -10.2 ± 5.7 in D, -2.4 ± 3.2 and -2.7 ± 5.9 in E, -6.9 ± 3.0 and -7.3 ± 6.3 in DE, and -0.8 ± 3.0 and -0.9 ± 6.6 in C.

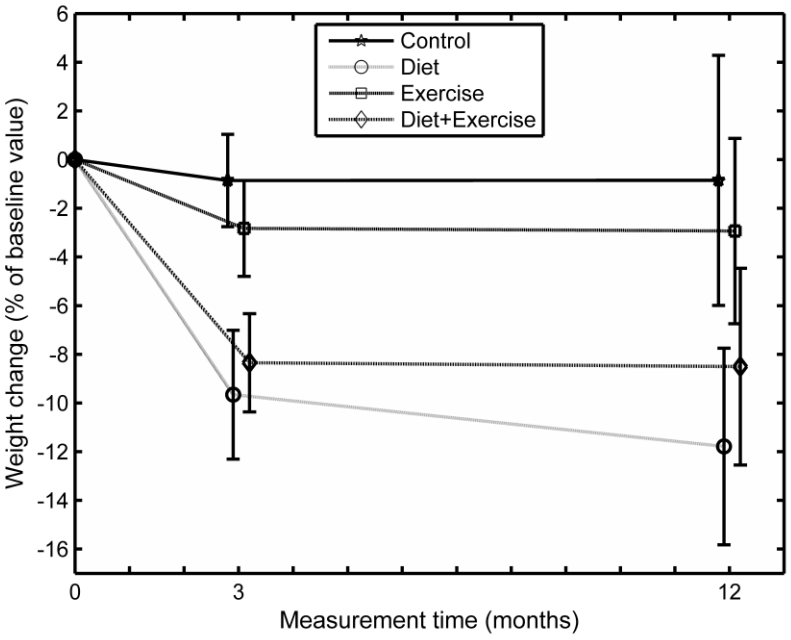

Figure 5. Effect of 12 week intervention on percent weight change during 1 year. Lines represent mean percent change with 95% CI indicated. After the 12 week intervention (n=62), and at 1 y (n=57), weight loss was a significant main effect of dietary treatment (p<0.001 for both time pints). Significant differences between treatment outcomes were determined by 2-way ANCOVA. Measurements were made at 12 weeks and 1 year in all groups, markers are slightly parted along the timeline to allow illustration of CI.

After the 12 week intervention relative weight loss (9.7 ± 4.8% in D group and 8.4 ± 3.8% in DE group) and relative fat mass loss (18.4 ± 9.4% in D group and 17.8 ± 9.7% in DE group) were achieved as a significant main effect of D treatment (both $p<0.001$). At 1 year, relative weight loss (11.8 ± 6.7% in D group and 8.5 ± 7.6% in DE group) and relative fat mass loss (23.9 ± 14.8% in D group and 17.5 ± 19.5% in DE group) were sustained as a significant main effect of D treatment ($p<0.001$ and $p=0.002$ respectively). There were no main effects of D and E treatments on muscle mass, lean soft tissue mass (non-adipose and bone mass as measured by DXA) or bone mineral content at 12 weeks. At 1 year the D, but not the E, treatment had resulted in small but significant reductions of lean soft tissue mass and muscle mass (figure 5 and 6). There were no statistically significant interactions between D and E treatments on any of these measures of treatment outcome, neither at 12 weeks nor at 1 year.

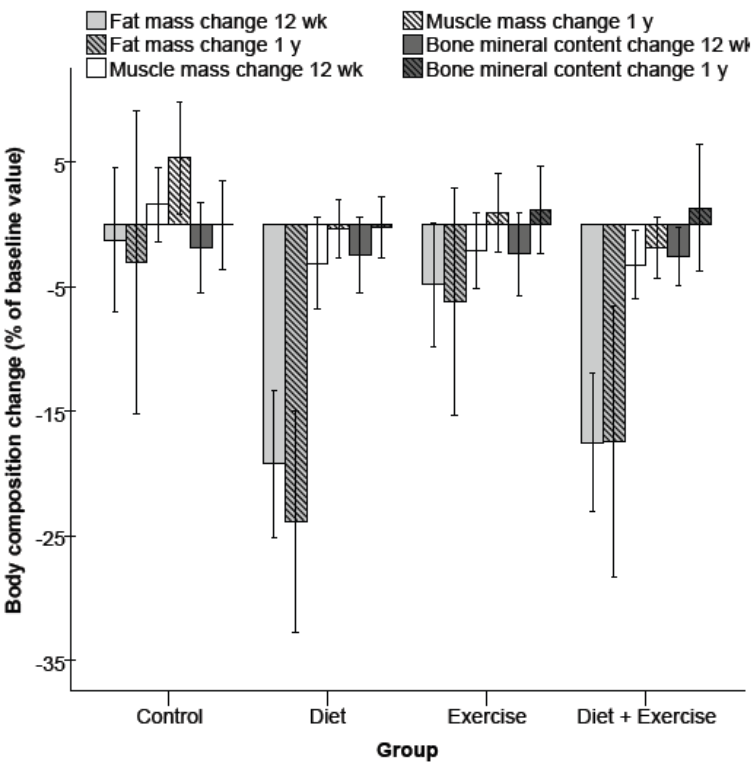

Figure 6. Percent body composition change among the four treatment groups. Bars represent mean percent change with 95% CI indicated. After the 12 week intervention (n=62), and at 1 year (n=57), fat mass reduction was a significant main effect of dietary treatment ($p<0.001$ and $p=0.002$ respectively). At 1 year reduction of muscle mass was a significant main effect of dietary treatment ($p=0.010$ and $p=0.005$ respectively). Significant differences between treatment outcomes were determined by 2-way ANCOVA.

4.1.4 Infant growth and breastfeeding outcomes

There were no significant differences in infant weight and length gain between infants with mothers taking part in the D or E treatments compared to the C group. All infants' weights and lengths were within ± 2 SD of the WHO infant growth standards at all times, and no infant deviated (i.e. clinically relevant as determined by the maternal and child health care practitioner) from their expected growth curve.

At 12 weeks, 11% of the women practiced exclusive breastfeeding, 82% breastfeeding with complementary foods, and 6% were non-breastfeeding. At the 1-year follow-up none of the women practiced exclusive breastfeeding,

7% provided breastfeeding with complementary foods and 93% were non-breastfeeding. No statistically significant associations between treatment group and breastfeeding patterns were found at 12 weeks. At the 1-year follow-up, all women from the D and DE groups were non-breastfeeding, while 2 women from C and E groups were still breastfeeding with complementary foods, leading to a significant main effect of D treatment on introducing non-breastfeeding ($p=0.030$). No women reported involuntary decrease of milk or cessation of breastfeeding.

4.2 Paper II Diet

4.2.1 Study population

A total of 61 (90%) women completed the intervention and the dietary recording at baseline and at 12 weeks, and 54 (79%) completed the 1-year follow-up including dietary records (Figure 7). There were no significant differences in baseline characteristics, including dietary intake, between women in the C, D, E and DE groups.

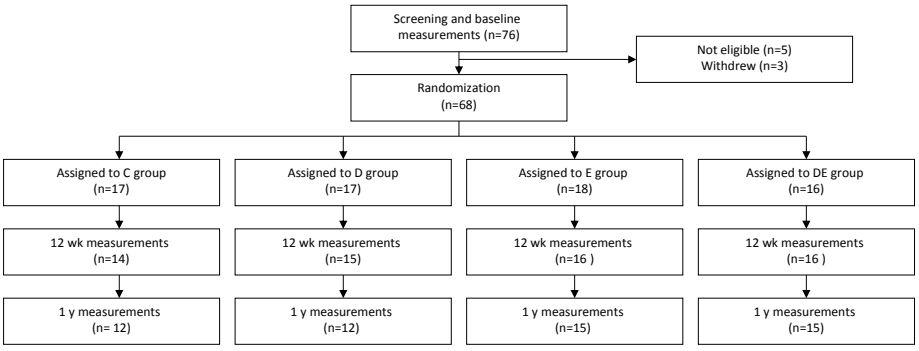

Figure 7. Screening, randomization, and follow-up of study participants in the Swedish trial among postpartum women. C denotes control, D dietary behavior modification, E exercise behavior modification, and DE combined dietary plus exercise behavior modification. Measurements indicate obtained dietary records and body weight measurement.

4.2.2 Dietary intake at baseline

Mean baseline intake relative to total energy intake (E%) was for total carbohydrate 47 ± 5 E%, total fat 37 ± 5 E%, protein 15 ± 2 E%, and 10 ± 2 g fiber/1000 kcal. Intake of saturated fat was 14 ± 3 E%, and intake of sucrose (added and naturally occurring) was 10 ± 3 E%. Intake of vitamins A (950 ±3 77 µg) and D (6.9 ± 2.9 µg), folate (347 ± 131 µg), and iron (14 ± 4 mg) were below recommended intake (RI) [136], and intake of sodium (3.6 ± 0.9 g) was above.

4.2.3 Dietary changes after treatment

The D, but not the E, treatment resulted in significant energy intake reduction ($p<0.001$). Significant main effects of the D treatment were reductions in total fat (g/d) ($p<0.001$) and carbohydrate ($p=0.002$) intake, which were the main contributors to the energy intake reduction. The D treatment resulted in a significant reduction of E% total fat ($p<0.001$), which was also a borderline

significant main effect of the E treatment (p=0.048). The treatments did not result in reduced intake of E% total carbohydrate, but the D treatment resulted in reduced intake of E% sucrose (p=0.005) whereas E% complex carbohydrates were increased (p=0.025). The absolute amounts of protein and fiber were not changed, but as a result of reduced energy intake following the D treatment the amount of fiber relative to energy intake (g/1000 kcal) was increased (p=0.015), as was E% protein (p<0.001). Intake of vitamin C was increased as a main effect of D treatment, whereas vitamin E was reduced. Intake of vitamin B_6 and niacin were reduced as a main effect of E treatment, whereas selenium was increased (all p<0.05).

At 12 weeks the women taking part of the D treatment (*n*=31); the D and DE groups (D+DE), compared those not taking part of the dietary treatment (*n*=30); the C and E groups (C+E), reported a diet close to the NNR [136]. Significant differences were found for total fat, saturated fat, and fiber between D+DE and C+E groups (table 10). Intake of sucrose was 7 ± 3 E% in D+DE versus 9 ± 4 E% in C+E group (p=0.013). The D+DE group had a significantly higher intake of vitamin C, and lower intake of vitamin E. Also, women in both D+DE and C+E had intakes of vitamins A and D, iron and folate lower than recommended, and intake of sodium higher than recommended; however not significantly different between the groups.

4.2.4 Dietary changes at 1-year follow-up

The E, but not the D, treatment resulted in significant energy intake reduction (p=0.034). Significant main effects of the E and D treatment included reductions in total fat (g/d) (p=0.001 and p=0.024 respectively). The E and D treatments also resulted in significant reductions of E% total fat (p=0.003 and p=0.045 respectively). Intake of vitamin E was reduced as a main effect of E treatment, and intake of thiamin was reduced as a main effect of D treatment (both p<0.05).

At 1 year dietary intake among D+DE (*n*=27) was maintained close to the NNR, although some attenuation had occurred. The D+DE group had a significantly lower intake of energy, fat and saturated fat, compared to the C+E group. Intake of sucrose was 7 ± 3 E% in D+DE versus 8 ± 3 E% in C+E group (p=0.111). Women in both D+DE and C+E had intakes of vitamin D, iron and folate lower than recommended, and intake of sodium higher than recommended, with no significant differences between the groups.

Table 10. Dietary intake among women in dietary treatment groups or control and exercise groups, at 12 weeks and 1year.

Dietary intake/d	RI		C + E groups		D + DE groups	
			n=30	*n*=27	*n*=31	*n*=27
	12wk	1y	12wk	1y	12wk	1y
Fat (E%)[1]	≤30/35	≤30/35	36 ± 5	36 ± 5	30 ± 5[2]	31 ± 7[4]
Saturated fat (E%)	≤10	≤10	15 ± 3	15 ± 3	11 ± 3[2]	12 ± 3[3]
Carbohydrate (E%)	50-60	50-60	46 ± 5	44 ± 5	48 ± 5	45 ± 6
Protein (E%)	10-20	10-20	15 ± 3	16 ± 3	19 ± 3	17 ± 3
Fiber (g/1000 kcal)	≥12.5	≥12.5	10 ± 4[4]	10 ± 3	13 ± 4	12 ± 3

Values are means ± SD. Wk denotes week, y denotes year. C denotes control, D denotes diet treatment, E denotes exercise treatment, and DE denotes combined diet and exercise treatment.
RI = Recommended daily intake for women [136].
[1]According to NNR the recommended total fat intake is 25-35 E%. However, <30 E% is desirable for obese individuals, and 30-35 E% is acceptable for lean individuals [136].
[2] $p<0.001$
[3] $p<0.010$
[4] $p<0.05$

4.2.5 Dietary intake after treatment and at 1-year follow-up among women successful in weight loss after dietary treatment

Among women who reached the target weight loss (≥6 kg) after the D treatment at 12 weeks (*n*=22 of 31), the diet was in accordance with NNR regarding total fat, saturated fat, protein, sucrose (7 ± 3 E%), and fiber (table 11). Energy from total carbohydrate intake was slightly lower than recommended. At 1 year the women who had received the D treatment and lost ≥6 kg at 1 year compared to baseline weight reported a diet in accordance with NNR regarding protein and sucrose (6 ± 2 E%) (*n*=17 of 27, among these 17 women 16 had also reached the weight loss goal at 12 weeks. Women who reached the target weight loss goal did not have a higher TEE or number of steps per day, or a greater change in these measures of energy expenditure, compared to those that did not reach the weight loss goal. Thus, as for the D treatment group as a whole, the weight loss among these women was caused by dietary changes. Women who reached the target weight loss after the D treatment did not reach the RI according to the NNR for vitamin A, D, folate, iron, and also sodium intake was higher than recommended.

Table 11. Dietary intake among women reaching ≥6 kg weight loss with D treatment, at 12 weeks and 1 year.

Dietary intake/d	≥6 kg weight loss & D treatment	
	n=22	*n*=17
	12 wk	1y
Fat (E%)[1]	29 ± 5	32 ± 7
Saturated fat (E%)	10 ± 3	12 ± 3
Carbohydrate (E%)	49 ± 5	45 ± 6
Protein (E%)	19 ± 3	18 ± 3
Fiber (g/1000 kcal)	14 ± 4	12 ± 3

Values are means ± SD. Wk denotes week, y denotes year. D denotes diet treatment.
[1]According to NNR the recommended total fat intake is 25-35 E%. However, <30 E% is desirable for obese individuals, and 30-35 E% is acceptable for lean individuals [136].

4.3 Paper III A substantive theory of sustainable weight loss

4.3.1 Study population

In total 29 interviews were made with; 11 women at post intervention only, 10 at 1-year follow-up only, and 8 on both occasions (*n*=21). A good variation in baseline BMI was reached (range 26 to 36), as well as treatment weight change (range -12 kg to 4 kg), and 1-year follow-up weight change (range -25 kg to 1 kg). A total of 15 interviews were made following successful weight loss or maintenance, whereas 14 were made following unsuccessful weight loss or maintenance, to achieve saturation regarding both outcomes (table 12). Women achieving and sustaining a weight loss of 6 kg or more were considered successful in accordance with the intervention trial goals.

Table 12. Sampling order, group allocation, interview time points and weight among study women (qualitative sub study).

Sampling order	Intervention group allocation	Baseline weight (kg)	Baseline BMI (kg/m^2)	Post intervention weight change (kg)	Post intervention interview	1-year follow-up weight change (kg)	1-year follow-up interview
1	Exercise	87	29	-3		-12	×*
2	Diet+Exercise	92	34	-4	×	-5	
3	Diet+Exercise	70	26	-3	×	-4	
4	Diet	100	32	-12	*	-9	×*
5	Diet	84	34	-2	×	-4	×
6	Exercise	99	36	-1	×	-3	×
7	Exercise	89	27	-7	*	-7	×*
8	Diet	86	27	-6	×*	-1	
9	Diet+Exercise	83	30	-12	×*	-16	×*
10	Diet	77	28	-6	*	-10	×*
11	Diet+Exercise	87	27	-7	*	-6	×*
12	Diet+Exercise	82	33	-2	×	-5	×
13	Diet	80	32	-5	×	-13	×*
14	Exercise	92	34	-5	×	0	×
15	Diet+Exercise	90	28	-6	×*	-6	×*
16	Diet+Exercise	90	30	-11	×*	-25	×*
17	Diet+Exercise	88	31	-7	×*	1	
18	Exercise	99	33	-3		-9	×*
19	Control	88	30	0		-2	×
20	Exercise	85	29	4		-1	×
21	Control	90	33	2		-4	×

× Interview performed
*Successful according to short and/or long term intervention weight loss goal

4.3.2 Overall Model of generated theory

A substantive theory illustrating the process of achieving and maintaining weight loss during and after a diet and/or exercise intervention in the postpartum period, is presented in figure 8. The model represents a theory of Transformative Lifestyle Change (TLC) that captures the categories and interactions that emerged, representing the women's experiences. A trajectory (circular arrow) holds seven action-stages (boxes) defined by the central action of each stage, beginning and ending with two opposite lifestyle states defined by the central experience of each (block-arrows), and interaction (thin arrows) with the intervention (circle) through Catalytic Interaction (CI). The core category (in italics) occurs as a result of the progression along the action stage trajectory. The dashed arrow depicts possible reverse movement between action-stages.

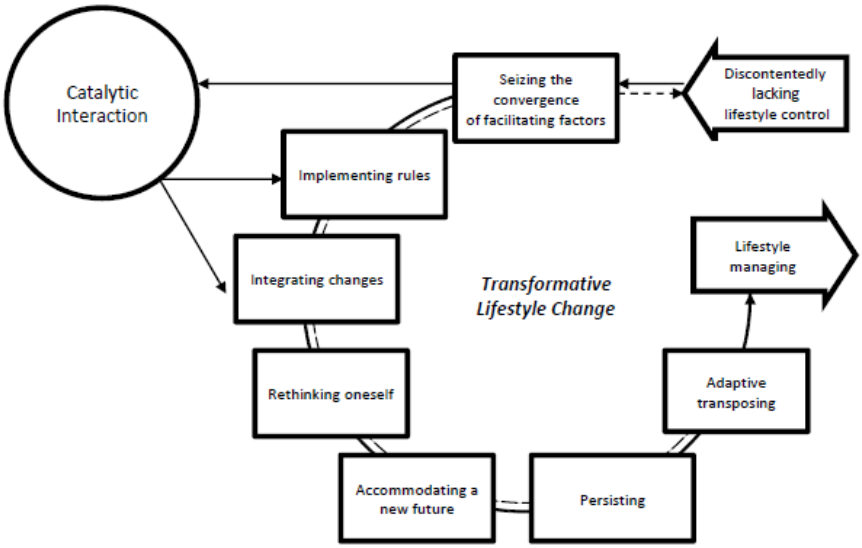

Figure 8. Conceptual model of the Transformative Lifestyle Change process of achieving and maintaining weight loss, aided by a diet and/or exercise intervention in the postpartum period.

4.3.3 Core category

Transformative Lifestyle Change (TLC) answers to the main issue of the participants; how to achieve sustainable weight loss, and how they tried to solve this issue. The TLC-construct describes the multileveled and intertwined changes that led to weight management; changing women from

discontentedly lacking lifestyle control to become lifestyle managing. The construct is composed of 'transformative' and 'lifestyle change', to conceptualize how lifestyle changes produced significant and deeply rooted changes in the self and life among these women. The transformative change was initially catalyzed by the intervention through an external impetus; the Catalytic Interaction which led to the implementation of the initial behavioral changes, and thereafter by a self-reinforcing interplay between step wise behavioral changes and the effects of these changes. The effects of the behavioral changes (mainly dietary) were the rewarding and sought after bodily changes of decreased weight and improved fitness. The experience of a successful outcome following behavioral changes increased mental energy and motivation, improved self-image, and led to alignment of inner cognitive and emotional drivers. This created a positive feedback loop that supported further change and persistence, and over time established the cognitive and emotional changes (a change in the perceived self) needed to maintain the new weight and lifestyle. The process begun and ended in a 'normal life' state (i.e. working/studying, not in active lifestyle treatment), after the trajectory had progressed forth and then back again over a state-of-mind cycle in which focus was put on the actions of change, outweighing many concerns of normal life for a limited time. The environment became subject to concrete changes, mainly to hinder the negative influence of an obesogenic environment by rearranging the day-to-day practical and social environment, and the broader life context was approached with new strategies, insights and an attitude that made it more manageable.

4.3.4 Summary of findings

Two new constructs emerged in this study; Transformative Lifestyle Change (TLC) and Catalytic Interaction (CI), which we believe are valuable to the understanding and execution of successful weight loss treatment. To overcome initial barriers to weight loss the women needed treatment to provide a 'Catalytic Interaction'. It depended on the health care provider delivering individualized, concrete, specific and useful information, and an emotional bond through joint commitment, trust and accountability. Reaching the weight loss goal during treatment was important for subsequent weight maintenance. Weight loss was underpinned by gradual introduction of new behaviors; reducing sweets, consuming low fat/low sugar foods, increasing fruits and vegetables, regular meals, regular exercise, self-weighing, planning of meals and exercise, and walking or bicycling for transport. TLC developed through, and reinforced continuous, implementation of new behaviors. This led to fundamental and reciprocal changes in the women's emotions, cognitions, body, behavior and environment. The seven stages of the TLC led

towards habituating the new behaviors and gaining lifestyle control. Women accomplishing the stages of the TLC-process were successful in weight loss, in contrast to those who did not. This stresses and defines the importance of the health care provider – patient relationship, particular health behaviors, achieving initial weight loss, allowing time for habituation, and persistence through the process. Table 13 provides a comprehensive list (not included in paper III manuscript) of factors found to be related to self-sustained weight loss after the initial treatment period had provided CI. Our findings indicate that TLC, through CI, is a key feature of successful weight loss and weight loss maintenance among overweight and obese women who seek weight loss support during the postpartum period. Thus, the model created provides a practical tool to design and implement treatment.

Table 13. Factors among women related to self-sustained weight loss after catalytic interaction.

Sustainable weight loss	**No weight loss / Weight regain**
Perspectives	
Increased perceived resourcefulness and control	No perceived change of self
Evolving belief in oneself in reaching desired goals	No perceived change of self
Flexible and evolving integration of "lifestyle rules" and new behaviors, acceptance of variability in progress and set-backs	Dichotomous mindset, or paralyzing ambiguity
New views on diet/exercise	No shift in diet/exercise perspective
Satisfaction with weight loss achievement and/or further goal-setting	Overweight acceptance/resignation
Perceived competitiveness	Perceived laziness
Context	
Workplace/end of parental leave allows for adaptive transposing of lifestyle	Workplace/end of parental leave de-integrates new lifestyle (stress, structure, culture)
Supportive/involved partner/relevant others	Unsupportive/counteracting partner/relevant others
Predictable continuity of life	Life events/major changes that require extensive time/attention
Behaviors	
Self-monitors	Irregular/omitted self-monitoring
Keeps self-verified version of intervention diet	Tries fad diet
Regular exercise of any kind	Irregular/omitted exercise
Rearranges the everyday environment	No changes of the everyday environment
Plans	Irregular/omitted planning

5 DISCUSSION

5.1 Main findings

The 12 week dietary treatment used in the LEVA-trial provided significant and clinically relevant weight loss among overweight and obese lactating women, and it was sustained at 9 months after treatment. The dropout rate was very low, which indicates that this treatment format was acceptable to the women. Physical exercise treatment alone did not increase total energy expenditure or weight loss. The combined treatment did not yield significant weight or body composition changes beyond those of dietary treatment alone, and reduction of fat free mass was very low. At baseline the women consumed a typical Swedish diet. Dietary treatment led to reduced intake of fat and carbohydrate, while maintaining intake of protein and fibre. The proportion of sucrose was reduced, while the proportion of complex carbohydrates was increased. Weight loss through dietary treatment was achieved with a diet in line with current official recommendations, i.e. the Nordic Nutrition Recommendations. Micronutrient intake was below recommendations, but only marginally compromised by dietary treatment. A successful weight-loss outcome depended on two phenomen in the postpartum weight loss trial context; conceptualized as Catalytic Interaction and Transformative Lifestyle Change, outlined in the substantive theory of Transformative Lifestyle Change. The Catalytic Interaction occurred in partnership with the health care professional and provided an energizing collaboration built on individualized, practical, and useful information coupled with encouragement and accountability. Transformative Lifestyle Change conceptualizes the process that led to the development of reciprocal changes in cognitions, emotions, body, behavior, and environment, which jointly reduced the barriers to a new lifestyle.

5.2 Study population

The results of this trial are relevant to many women; however they may not be generalizable to lactating women in general. The women were recruited from all areas of Gothenburg to obtain a variation in socio-demographic factors. The sample included women living in areas of the city with a high mean income as well as women living in areas with a low mean income level.

Even so, the study sample was mainly white (97%)[c] and well educated (73% had more than 3 years of education beyond high school). Most women had one or two children, and a few had three. All women could speak and write in Swedish, indicating a high level of integration also among those of foreign origin.

All but one woman were on full-time maternity leave during the 12 week intervention. However, at the 1-year follow-up, at 15 months postpartum, maternity leave was terminated among 83%. Thus, the sample is representative in relation to the general practice in Sweden.

Similar research in more diverse populations is needed. Women of diverse cultures/social contexts, ethnicity, socio-economic and education levels need also to be included in future research, as these factors are known to influence lifestyle in general and also reproductive-cycle specific outcomes, as outlined in the introduction.

5.3 Recruitment

Women were recruited from a total of 15 maternal health care clinics in Gothenburg. During the first year of recruitment only 5 clinics were involved; however due to a low rate of recruitment more clinics were subsequently contacted and involved. Posters with information about the study were placed on a central billboard at the clinic. Also, the midwives were informed about the study and agreed to participate in recruitment by informing potential women about the trial. In 2009 approximately 7700 pregnancies were registered with the public prenatal care in Gothenburg, and an additional 1400 with the private care. Among the 7700 registered with the public care, through which recruitment was made, anthropometric data were available; 25% of the women were overweight, and additionally 12% were obese at the first antenatal care visit, i.e. pre-pregnancy (personal communication). Thus Gothenburg is nationally representative regarding overweight and obesity rates. Recruitment lasted from mid 2007 to mid 2010; approximately 3 years. An estimated total of at least 2000 women per year were thus theoretically in the correct BMI-range to participate in the trial. Considering that 75% of all pregnancies in Sweden are uncomplicated, and that although back-pain and depression are rather common in this group the prevalence of most diseases is low in this age group, indicating that there would still be a large number of women that could potentially participate.

[c] Because of the number or participants calculations of proportions (%) should be interpreted with caution.

About 70% of Swedish women breastfeed their babies at 6 months, and it is likely that this proportion, or a greater proportion, intended to do so. The intention to breastfeed for 6 months was a requirement to participate in the trial, and thus reduced the number of potential women. The fact that the women were in the correct BMI range to participate meant that they were more likely to have a complicated pregnancy, have other medical problems, and intend to breastfeed less, which would decimate the potential sample. Also, half of the female population in Sweden plans to, or actively tries, to lose weight. This proportion is however most likely much higher among those overweight and obese. It is thus difficult to estimate how many women that were both eligible and also interested in participating in the trial. Many of the factors are interrelated, and other factors related to the women's perception of the trial are unknown. During the trial the recruitment was judged to be slow, i.e. including a low proportion of what was considered theoretically potentially eligible women. However likely, this cannot be said with certainty. In addition to a potentially low number of eligible and interested women there are other possible reasons for a slow recruitment. First, the time that the midwives could direct to informing women about the study was limited. Second, high weight may be a sensitive topic, and it was perceived as problematic to suggest a weight loss intervention to some overweight or obese women, in fear of stigmatization or harming the relationship with the woman. Based on interviews with women declining to participate in the AMP-weight loss intervention, it was concluded that postpartum women face difficult and complex challenges to prioritizing their health and weight management. Specifically; time availability, prioritizing other competing life responsibilities above their own health, support from family members, friends, and/or co-workers, and lack of flexibility in the intervention structure [150]. Such concerns may also have been relevant to the women deciding not to participate in our trial. The interviews that were made in our Grounded Theory study (Paper III) revealed, in line with previous findings in diverse populations [151], that among these women initial motivation to address the weight issue included health, appearance and well-being, and specifically for these postpartum women; responsibility for the child. Since motivation is a key factor, these findings can guide how women can be recruited to research or how they can be motivated to treatment.

5.4 Attrition

The drop-out rates were low. This strengthens the conclusions that can be drawn from the study. It also indicates that the treatment format was acceptable to the women. Among the included 68 women, randomized to

treatment or control, 62 (91%) completed the intervention period and 57 (84%) remained to complete the 1-year follow-up. Between the intervention and the 1-year follow-up no women dropped out, but 5 were excluded from measurements because of a new pregnancy. Interestingly there were no drop-outs from the DE group. We had expected a high rate of drop-out from this group due to the heavy burden of making both dietary and physical activity changes concurrently. However, there were low and equally distributed rates of drop-outs in the other three groups, and it appears that treatment (D or E) did not influence attrition. At baseline the women later excluded because of pregnancy did not differ from those who remained in the trial. Women who dropped out or were excluded for other reasons than pregnancy had a higher mean BMI and higher parity at baseline than those who remained in the trial. The women took part of a weight loss intervention trial, thus the ambition to lose weight was present among all. It appears rational to discontinue if weight loss is not achieved; as was the mean outcome of the E and C groups. This may be even more urgent at a higher BMI. Although it is based on few observations, this indicates that women with higher BMI, higher parity, and feelings of time constraint may have needs that could be better met, whether the aim is research or treatment.

5.5 Implementation of the interventions

To implement the D and E treatments, we used 2 individual counseling sessions per treatment. The remaining contact was handled by letter, e-mail and cell phone text messages. The low dropout rate indicates that this treatment format was acceptable to the women. Although group counseling has been proven effective in other groups [152], the AMP trial indicated that this may not be appropriate among postpartum women due to their time constraints and need for flexibility [133, 150].

The D treatment counseling was carried out by a dietitian (F. Bertz ~70% of the women, and one other (female) dietitian ~30% of the women). The E treatment counseling was carried out by a physiotherapist (three (female) physiotherapists responsible for each ~33% of the women). Text-message contact to support implementation of treatment was handled by the dietitian. That more than one dietitian/physiotherapist carried out the treatments indicates that the outcome was not dependent on the person providing the treatment. Since we found personal contact and accountability to be important parts of a successful treatment (Paper III), it would perhaps have been better if the physiotherapist handled the text message contact with the women in the E treatment. However, compliance with the treatment plan was

high (according to text messages and activity diary), thus it appears that personal contact and accountability could also be provided by the dietitian.

Self-weighing, used in our D and DE groups, and physical activity diary, used in our E and DE groups, are known to improve weight management [153]. Among our participants, both self-monitoring and also at-clinic measurements were important features to reinforce motivation and adherence to our interventions. Also, most of our women were on maternity leave during the intervention, a circumstance that most likely aided in the implementation of the treatments.

The AMP trial provided a multi component intervention based on Social Cognitive Theory (SCT), Transtheoretical Model (TTM) (i.e. "Stages of change"), and motivational models [133] and thus share basic concepts with the design of the LEVA-trial. However, the 12-month AMP-trial did not lead to weight loss. Differences between the AMP design and our trial were highlighted in our Grounded Theory analysis (Paper III), and these differences could represent important mediators of a successful weight loss treatment implementation: (a) Individual counseling; providing each woman with a personalized and concrete intervention plan, including the outcome-quantified effect of the suggested changes; (b) Meticulous and/or objective measurements (i.e. the ambitious four-day weighed dietary recording, TEE measured with DLW, physical activity measured with a multi–sensor accelerometer armband, and body composition measurement measured with DXA); (c) Flexibility in appointments and communication through the individualized approach and cell phone text messaging. Also, the geographic setting of the AMP trial, as well as diverse ethnicity and socioeconomic characteristics in the study populations differed from our trial.

The intervention included novel treatment techniques and thus differs from that reported in previous trials. No specific diet plan was prescribed, and no foods provided. Instead a structured treatment plan was used to provide a set of principles according to the SWAP-model, which each woman was to apply to her habitual diet and lifestyle. The nature of the plan provided a (somewhat restricted) 'need based' behavioural change structure in that the 'size' of a dietary problem would determine for how long the change would produce weight loss and thus provide more time for implementing the more relevant changes. During counselling the individualized outcome-quantifying dietary advice, labelled OQDA, enabled us to convey the impact on body weight that would be achieved if the dietary treatment principles were followed; to strengthen motivation and self-efficacy. OQDA may require an initially greater work load than conventional dietary counselling, but this is likely outweighed by the positive impact and the simple straightforwardness of (the

integration with) the SWAP-model. It should be stressed that frequent self-weighing was an integrated part of the plan, and thus the dietary advice (SWAP and OQDA) may not be effective when given outside the treatment-model used here. However, the technique of step-wise adjustment food intake to a planned weight loss trajectory, and thus using body weight as a measure of energy intake, rather than other measures (i.e. calories, servings), combined with awareness of the potential weight loss effect of particular dietary changes, and intermittent personalized cell-phone text message follow-up of the treatment progression is new. The model provided a dynamic approach to adjustment of energy intake in response to energy balance as measured by weight change. As shown with dynamic modelling of weight loss by Hill et al [14], a 500 kcal energy reduction compared to baseline energy expenditure would not produce a linear and constant long term 0.5 kg weight reduction. However, the frequent weighing and adjustment of energy intake in response to body weight provided a model that allowed the women to continuously adjust their energy intake relative to a changing energy expenditure (whether due to weight loss or change in physical activity) to continue the 0.5 kg weight loss trajectory during the 12 week treatment. The potential of these techniques remains to be tested further.

An alternative, or advance in the delivery of the treatment, is to rely more extensively on the Internet. A recent 16 week intervention trial by Lovelady et al examined the effects of energy restriction (500 kcal/day) and exercise on weight in overweight and obese lactating women [134]. Here the web-based MyPyramid Menu Planner for Moms was used to support face-to-face dietary counseling. A significant 5.8 kg (7%) weight loss was achieved in the intervention group, compared to a 1.6 kg weight loss in the minimal care group. Also changes in intake of energy, saturated fat, and percent of energy from added sugars were significantly different between the intervention group and minimal care control group, based on data from 24-hour dietary recalls. Although the web-based approach was not evaluated against a non web-based intervention, the study suggests that this web-based system may be a functional dietary counseling support tool. Results from other populations also indicate that Internet-based interventions may provide value [154]. Because of the high level of Internet access in Sweden it may be of particular interest here, whereas low access may present a problem in other populations.

Weight loss and weight maintenance may be understood as implementing healthy eating habits, underpinned by a shift in behaviors and identity, leading to increased control, resourcefulness, flexibility and self-efficacy [155-158]. By using positive deviance to determine successful weight-control

practices, themes in the areas of (a) nutrition, (b) physical activity, (c) restraint, (d) self-monitoring, and (e) motivation have been found [159]. This understanding of weight loss, the themes in weight loss practices and the ways in which they were applied were corroborated by our findings. In line with this, successful women in our trial strove to adhere to dietary and exercise behaviors in line with current recommendations, [136] which is similar to habits of other successful weight loss maintainers found in the National Weight Control Registry [160, 161]. In addition, women successful in weight loss and maintenance realized that their environment was to a large extent obesogenic, and 'manipulating' them to eat more than they felt they actually should. Thus continuous, conscious pro-active measures or enduring life-restructuring had to be made to counter this (Paper III).

5.6 To what extent was a healthy weight reached and sustained?

After taking part of the D treatment 65% of the women reached the weight loss goal of -6 kg at 12 weeks, and 63% at 1 year. Among those that were successful at 12 weeks 80% had maintained or increased the weight loss at the 1-year follow-up. In the C group no one of the women reached a 6 kg weight loss at 12 week, but 15% had done so at 1 year. In the E group 19% reached a 6 kg weight loss at 12 weeks, and 40% had done so at 1 year.

However, the 6 kg weight loss goal was based on the recommended weight loss rate for lactating women at 0.5 kg per week. Thus it was not based on cut-offs for reaching or maintaining a weight loss associated with long term health outcomes.

5.6.1 A 10% weight loss

A ~10% intentional weight loss is a generally accepted cut-off definition of a weight loss that is expected to have substantial health benefits, particularly improvements in risk factors for type 2 diabetes and cardiovascular disease [36]. The proportion of women reaching a ≥10% weight loss at 12 weeks and 1 year respectively were: in C group 0 and 8%, in D group 40 and 54%, in E group 0 and 13%, and in DE group 31 and 31%. Compared to the average 20% of individuals that are expected to achieve a successful sustainable weigh loss (≥10%) according to Wing et al [37], the proportion of women reaching a ≥10% weight loss at 12 weeks and 1 year following the D treatment was substantially higher at approximately 40%. A 10% weight loss in this group is in the upper range of what can be considered a normal and safe weight loss in lactating women [56].

5.6.2 Changes in BMI-class

According to the WHO recommendations for BMI, the goal for individuals should be to maintain a BMI in the range 18.5 to 24.9 [1]. Furthermore, there is increased risk of several diseases when BMI is in the range of 25.0 to 29.9, and the risk increases to moderate to severe risk of when BMI is greater than 30 [44]. Thus, a change in BMI class among the women serves as an important indicator of whether a healthy or healthier weight was reached and sustained.

No women had a BMI <25 at baseline. However, after the intervention this had changed. Particularly in the D group a quite large proportion of women became normal weight during the treatment, and at 1 year this was true for both D and DE groups (table 14).

Table 14. Women reaching normal weight, among treatment groups at 12 weeks and 1 year.

Group	C	D	E	DE
Normal weight (BMI <25)*				
Baseline	0% (0)	0% (0)	0% (0)	0% (0)
12 weeks	0% (0)	33% (5)	6% (1)	13% (2)
1 year	7% (1)	38% (5)	7% (1)	38% (6)

* % and (*n*) of individuals at time of measurement

Because there was a parallel change in BMI-classes from ≥30 to <30 and ≥25 to <25 the proportion of women in the 25.0 to 29.9 range remained fairly constant. However, the number of women who reduced their BMI from ≥30 to <30, i.e. from the obese to the non-obese state, at 12 weeks and 1 year compared to baseline differed considerably between the groups (table 15).

Table 15. Obese women among treatment groups at baseline, 12 weeks and 1 year.

Group	C	D	E	DE
Obese (BMI > 30)*				
Baseline (*n*)	8	8	7	8
12 weeks	5 (63%)	2 (25%)	6 (86%)	3 (38%)
1 year	6 (75%)	2 (25%)	6 (86%)	6 (75%)

* *n* obese, and (% of *n* obese at baseline) at time of measurement

5.6.3 Reaching pre-pregnancy weight

Another definition of weight loss that has health implications is the distinction between reaching pre-pregnancy weight or not. This could also represent an important psychological weight loss cut-off. Weight changes from pre-pregnancy to the 1-year follow-up were -5% and -7% in the D and DE groups, -1% in C group, and an increase of 2% in the E group. Among women receiving D treatment, 90% returned to their pre-pregnancy weight by 6 months postpartum, compared to 41% from E and C groups combined.

In a previous study by Lovelady et al, women who received a combined diet and exercise intervention for 10 weeks lost 4.8 kg vs. 0.8 kg in controls, and 48% compared to 21%, respectively, were within 1 kg of their pre-pregnancy weight after the intervention, but no longer-term data were gathered [140, 162]. In a Finish diet and exercise intervention trial during 2 to 10 months postpartum among normal weight primiparous women, 50% of the intervention group compared to 30% of the control group returned to prepregnancy weight [163].

It appears by the results from the SPAWN-study follow-up [102] and the long term follow-up study by Rooney and Shauberger [101] that women that do not lose their GWG during the first 6 to 12 months after pregnancy are at higher risk of substantial weight gain. Perhaps this first period is a reflection of the time to come, and the weight change trajectory that has been initiated is likely to be continued. It could "simply" reflect that lifestyle choices differ between women of different weight trajectories, and that given sufficient time this will have a substantial effect on weight. However, it could also reflect the psychological phenomenon that failure to reach a weight loss goal (which as indicated in our Grounded Theory study may likely be to return to pre-pregnancy weight), leads to a full discontinuation of weight loss or weight control efforts [164]. If this is true, it leads to two important observations regarding postpartum weight loss treatment; (1) treatment should be designed to implement healthy lifestyle behaviours that can be maintained in the long term, and (2) treatment should be designed to allow for the woman to reach her pre-pregnancy weight by 6 to 12 months postpartum.

5.6.4 Can the achieved weight loss be considered sustainable?

The weight loss achieved in the D and DE groups was sustained at 9 months after treatment, contrary to the common pattern of substantial weight regain following a weight-loss treatment; that after a successful short term weight loss at least half the weight is regained one year after treatment termination [165]. Wing et al [37] have suggested a definition of successful sustainable

weight loss as follows: *"Successful long-term weight loss maintenance [is defined] as intentionally losing at least 10% of initial body weight and keeping it off for at least a year."* The mean weight loss resulting from the D treatment does not fully comply with this definition, since the follow-up measurements were made 9 months after treatment termination. However, it is unlikely that the 3 months following the follow-up should impose a radical change that would alter the weight trajectories of the women. Important events that could have an impact on the weight trajectory had already occurred; most women had stopped breastfeeding and had also ended their full time maternity leave. Elfhag and Rössner have proposed a more inclusive definition of what constitutes weight maintenance; *"an initial weight loss that has been subsequently maintained for at least 6 months"*. This definition could be used to define the weight loss in D and DE groups as sustainable [39].

However, also very long term sustainability of weight loss should be considered, i.e. 5, 10, 20 years and beyond. Several indicators found among the women in the LEVA-trial may predict a good chance of long term sustainability; return to pre-pregnancy weight, preservation of fat free mass and no decline in RMR, adoption of diet-, physical activity-, and self-monitoring- behaviors and a psychological profile observed among longer term weight loss maintainers [37, 38, 166-168]. On the other hand, these women became overweight because of vulnerability to an (increasingly) obesogenic environment. The women's experiences of what caused their overweight (Paper III) reveals factors that are likely to re-occur in their lives. In general the long term outcomes of weight loss treatments are quite poor, and the *Expert Panel on the Identification, Evaluation, and Treatment of Overweight in Adults* suggests that a weight maintenance program should be continued indefinitely to counter this [36]. There are yet no data on which to draw conclusions regarding the longer term sustainability of weight loss achieved with the D treatment used in the LEVA-trial. It is however likely that some women will encounter life events that alter their weight trajectory, some will fall back into old habits and slowly regain weight, and some will maintain their new weight and lifestyle. Future studies will be needed to evaluate the determinants of different outcomes, and in what way long term sustainable weight loss can be supported.

5.6.5 Body composition

It is important to consider the effects of weight loss on body composition because of the different implications of FM and FFM in health and disease. As summarized in the introduction it is preferable that weight loss treatments result in reduction of adipose tissue while preserving FFM. The effects on

body composition of diet, exercise, or diet plus exercise treatments for weight loss, both in general and specifically among postpartum women have provided similar results. Approximately 30% of weight loss is FFM after dietary restrictions only, and that the combination of diet plus exercise may be preferable over diet only because of better preservation of FFM with a reduction of ~0-20% [132, 169]. However it may be that the observed preservation of FFM from exercise is due to retention of water and glycogen, and thus not functional proteins *per se* [169].

Interestingly, in our trial two central findings differed from our assumptions based on previous research. First, the reduction of FFM was lower than expected in D group, at ~15%. Second, the addition of exercise to the dietary treatment did not lead to better preservation of FFM during weight loss. The results of limited reduction of FFM may be explained by the moderate rate of weight loss that did not exceed the theoretical limit of transfer of energy from adipose tissue [129], the initially high level of physical activity, and the moderate to high intake of protein [170]. The lack of effect on FFM of the exercise treatment likely reflects that it did not lead to increased TEE. The finding that the control group had increased their FFM at the 1 year follow-up may indicate that this is a natural trajectory of regaining FFM (likely muscle mass) upon resuming normal activity patterns after pregnancy.

Using the above definitions of reaching and sustaining a healthy weight it can be summarized that; the D treatment resulted in almost all women returning to pre-pregnancy weight or below, about 40% lost 10% of their body weight and kept it off, about 40% of women reached normal weight, and finally 75% of the obese women reduced their BMI to below 30. Neither the exercise treatment, nor the control group, displayed such positive results. The weight loss can be considered to be sustainable, and have a fair chance of remaining so over a long period of time. The weight loss consisted to a high degree of fat while preserving FFM well which may indicate better long term sustainability of weight loss, but with no difference between treatments.

5.7 To what extent was a healthy diet reached and sustained?

The definition of a healthy diet used here is a diet in accordance with the Nordic Nutrient Recommendations at an appropriate level of energy intake [136]. There is considerable evidence supporting this dietary composition as appropriate for achieving good health, a conclusion that is internationally endorsed by expert committees and authorities including The Swedish National Food Administration, the United States Department of Agriculture

(USDA), the United States Department of Health and Human Services (HHS), and WHO/FAO [136, 171, 172].

Virtually no experimental evidence exists on the short and long term maternal and child health implications of alternative dietary compositions. In the modern Western diet and obesity context the low-carbohydrate/high-fat diet appears as the most relevant alternative, from the standpoint of what now seeks to challenge the official recommendations in the eye of the public, through popular science and testimonials [173]. However, the magnitude of this movement should not be exaggerated as <1% in Sweden state that they are inspired by these ideas when choosing their diet [23]. Also, there is sufficient evidence to conclude that potential weight-loss outcomes of low-carbohydrate or other popular diets are due to how well these succeed in promoting a reduction of energy intake and not macronutrient composition *per se* [174, 175]. A short term trial including seven women (mean BMI 23) compared a reduced-calorie (approximately -500 kacl), high-carbohydrate diet (25 E% fat, 60 E% carbohydrate), to an isonitrogenous, isocaloric high-fat diet (55 E% fat, 30 E% carbohydrate) on two occasions for eight days in a controlled in-clinic setting. Milk volume, lactose, and protein concentrations were unaffected. Milk fat (4.8 vs. 4.3 g/dl) and milk energy output (645 vs. 649 kcal per day) were higher during the high-fat diet. This resulted in a greater negative energy balance. The lactating mothers adapted to the low-carbohydrate intake by decreasing carbohydrate oxidation [176]. However, the potential benefit of the greater negative energy balance in the mother may be offset by the appetite regulation of the infant through a decreased milk volume intake because of the greater energy density. If this would not occur, it remains questionable whether an increased energy intake would be beneficial to the infant in the modern Western lifestyle context.

At baseline the women in the LEVA-trial consumed a Western diet; a typical Swedish diet. The 12 week dietary intervention provided an energy intake reduction through reductions in fat and carbohydrate that led to substantial weight loss. It is noteworthy that the proportion of sucrose was reduced, while the proportion of complex carbohydrates was increased, as was protein and fiber. At 12 weeks the dietary composition among women taking part of the D treatment was in all very close to the NNR, and significantly different from those not taking part of the D treatment. This indicates that this dietary composition is well suited to promote weight loss. These differences were well maintained at 1 year, although the dietary composition regressed slightly towards the baseline diet composition. Also the exercise treatment resulted in a small but significant energy intake reduction at 12 weeks. At the 1-year follow-up energy intake reduction was found to be a main effect of the E treatment; however it was not accompanied by a corresponding weight loss

(or change in estimated energy expenditure), and is thus likely an effect of underreporting.

The weight loss achieved through the D treatment was maintained during the 9 month follow-up by a reported mean energy intake of ~1850 kcal per day, slightly below that of ~1900 kcal per day achieved during the intervention. However, due to the transition from exclusive breastfeeding to cessation of breastfeeding, the caloric deficit produced by these reported intakes were smaller during follow-up compared to treatment. This was also reflected in the different rates of weight loss achieved during the two periods.

The subgroup analysis of women reaching a ≥6 kg weight loss (the intervention weight loss goal) further demonstrated that energy intake reduction through reductions of the proportions of dietary fat and sucrose, while increasing the proportions of complex carbohydrates, protein and fiber resulted in successful weight loss at 12 weeks. Among all women, sweets, snacks, ice cream, soft drinks, crisps, nuts and dessert-cheeses made up 20 to 30% of the baseline energy intake, contributing to the discrepancy from recommended intakes of fat and sugar. When the women limited the intake of these foods in accordance with the SWAP dietary treatment principles, energy intake was reduced through limiting both fat and sugar intake. Similar dietary changes were included in the portfolio of changes shown to be associated with weight loss and weight loss maintenance in the National Weight Control Registry [161].

Among the women that reached the weight loss goal at 12 weeks after taking part of D treatment, 77% had maintained or increased that weight loss at the 1-year follow-up. The mean weight change in this group was -14% (range -27.7 to -7.4%). The women who reached and maintained the weight loss goal achieved a dietary composition according to the NNR at 12 weeks, and stayed very close to this composition also at 1 year. This indicated that the recommended diet was appropriate for weight loss and sustainable among those who achieved to implement it during treatment.

Previous research has indicated that combined diet and exercise treatment can reduce weight among overweight and obese lactating women [132]. However, even with modest weight loss intake of vitamin D and calcium was found to be reduced [177]. Also, other studies have indicated that lactating women may not reach recommended levels of micronutrient intake [116, 177, 178]. The D treatment used in our trial appears not to put women at increased risk of intakes below recommended intake (RI) levels, except for vitamin E (at 12 weeks) and thiamine (at 1 year) which were reduced as a main effect of the D treatment, and for which intake was slightly below RI. However, mean

intake among all women was below RI at baseline for vitamins A and D, folate, and iron, at 12 weeks for vitamins A and D, folate, iron and selenium, and at 1 year for vitamin D, folate, and iron. Considering the repeated intakes below RI and the particularly important roles of vitamin D, folate and iron for women of reproductive age this is of concern. In accordance with conclusions drawn in previous studies, as well as suggested in the NNR [136], vitamin and mineral supplementation may be generally recommended to this group of women for them to meet the current recommendations.

The dietary composition achieved to produce sustainable weight loss in our trial represents an interesting mixture of both reversing and adopting or maintaining modern trends in food consumption. The overarching trend that was reversed was the increase in energy intake. Although a food group analysis has not been made, the experiences as told by the women and also indicative macro and micronutrients point towards that certain changes in food choices were made. The trend of increased intake of candy, chocolate, and soft-drinks was most likely reversed. It is likely that also the trend of increased intake of cheese and cream was attenuated. However, the recent trends of eating more vegetables and less fat (butter, margarine and oils), were adopted or maintained.

5.8 Why did the exercise intervention not increase energy expenditure or improve body composition?

In contrast to our assumptions based on previous research, there were no interactive effects of the D and E treatments on anthropometric outcomes. Weight loss was not improved, and lean soft tissue and muscle mass were not better preserved with the combination of dietary modification and moderate exercise treatment compared to dietary treatment only. At the 1-year follow-up small but significant reductions of lean soft tissue mass and muscle mass, relative to the increase among controls, were detected as a main effect of the D treatment. However, these reductions were surprisingly low across treatments at both times compared to previous research [132, 169].

In our trial, TEE and number of daily steps did not increase among women assigned to the E treatment, neither during treatment nor during follow up. Physical activity estimated as [*TEE – RMR*] i.e. energy expenditure above that expended as RMR, indicated that there was little difference in active energy expenditure between groups at baseline and at 12 weeks. The mean change in the groups was in C 162 ± 423, in D 131 ± 215, in E 115 ± 277, and in DE -97 ± 352 kcal per day. Thus active energy expenditure did not

increase as a result of the E treatment, and the effect of adding exercise to normal activity cannot be evaluated. The mean change in active energy expenditure observed among women receiving the E treatment is thus smaller than the anticipated increase (~150 kcal per day) from the exercise sessions. If self-reported compliance-data is accurate, this indicates that exercise was performed as planned to a high degree, while other activities decreased.

At baseline all groups already met recommended levels of physical activity [136, 138, 139, 179] at >8000 steps per day (~75 min per day) and this level was maintained at both time points of follow up. The TEE/kg body weight, which was measured during treatment only, was higher than among normal-weight lactating Swedish women [57], confirming that these women were indeed quite active. Increasing TEE further, as a means to increase the energy deficit to produce weight loss, may be unrealistic because of postpartum women's limited time [150]. Similarly, failure to increase TEE or to sustain increased energy expenditure levels was found among lactating women participating in a trial of supervised aerobic training for 12 weeks by Dewey et al [120]. In that trial the mean energy expenditure was similar between the groups at baseline, as it was in ours. It differed significantly by 281 kcal per day at the midpoint of the study because of the exercise program. However, similar to our trial it did not differ significantly at the end of the study. Also similar to what was found in our trial; compliance with the exercise protocol was good. It was measured that the exercising women continued to expend about 400 kcal per day in exercise, but still TEE was not increased. Based on data on energy expenditure in the active range it was found the women in the exercise group cut back on other activities during the second half of the study. However, starting at a very low level of daily steps (3249/day) it was found among Iranian postpartum women that a physical activity intervention using pedometers during 12 weeks for daily self-monitoring, and a goal to gradually increase steps to 10.000/day (sub-divided into an accumulative increase of 500 steps/week), produced increased physical activity and an increase to 9960 steps/day [180].

This is similar to results on the effectiveness of diet plus exercise interventions compared to diet only for weight loss in other populations. A meta analysis of 18 randomized controlled trials showed an overall difference between diet plus exercise and diet of only 0.25 kg (95% CI -0.36 to -0.14) [181]. It may be difficult to overcome the diet-induced reduction in physical activity with exercise training. At a negative energy balance the additional exercise was likely compensated by a reduction of other (non-exercise) activity, resulting in similar decreases of TEE from both types of intervention [10]. Thus a likely explanation for our result is that the planned exercise sessions were performed, but replaced other physical activity.

5.9 Were breastfeeding and child growth adversely affected?

The WHO definitions of breastfeeding practices [53] were used to classify the practices of the women. This makes data standardized and internationally comparable. Direct measures of frequency of nursing, amount of breast milk produced or consumed by the infant were not obtained. There are ways of gathering such data, by observations or nursing diaries, or by different methods of weighing the milk or the child before and after feeding. However, because of the additional burden this would place on the women, in relation to the value the information would have to the research aim, such measurements were not made.

The breastfeeding pattern, according the WHO classification, was not affected by the treatments as measured when the babies were 6 months old. However, we noted introduction of non-breastfeeding at the 1 year follow-up, when the children were 15 months old, as a significant main effect of D treatment. This occurred because 4 women who had not received the D treatment were still providing breastfeeding with complementary foods. Importantly, none of the women reported involuntary cessation of breastfeeding. Thus, this finding more likely reflects that more women in the C and E groups, for reasons unknown to us, chose to continue partial breastfeeding rather than it being an adverse effect of the D treatment.

Higher intensity and longer duration of breastfeeding have been found to reduce postpartum weight retention among women with a BMI <35, and may facilitate return to pre-pregnancy weight [113]. The minimal weight loss observed in C group (breastfeeding only) during intervention and follow-up does not contradict the idea that breastfeeding reduces postpartum weight retention among overweight and obese women. Rather it reflects that most of that weight loss had occurred already before the intervention period commenced at 3 moths postpartum. The small, <1 kg, weight loss experienced by the women in the C group during the period from 3 months postpartum to 15 months postpartum would represent a, for most women, quite small part of the total postpartum weight loss since these women on average had returned to their pre-pregnancy weight at the 1-year follow up.

Infant growth was measured when these babies were transitioning from exclusive to partial breastfeeding with the addition of solid foods. Thus, their growth was not completely determined by maternal milk production, so we can only say that we observed no adverse effects. This is in line with previous studies showing that short-term maternal weight reduction did not negatively affect infant growth or the quantity or quality of breast milk [120, 140, 182].

To ensure validity and to obtain measurments comparable to both the WHO growth standards for children, and other measurments in the literature and clinical practice, the two standard measurments of infant growth, weight and length, were made and they were carried out in accordance with general practice and using standard equipment and technique [143]. There were no significant main or interaction effects in child weight and length gain among children with mothers taking part of the D or E treatments. All children's weights and lengths were within ± 2 SD of the WHO child growth standards at all times, and the children's individual growth curves were also monitored. When (even a) suspicion of deviance from the growth curve occurred (<5 times in total) the woman was instructed to consult the maternal and child health care. The potential influence of the trial treatments was investigated (i.e. weight loss, exercise intensity). However, at no time during the trial the small deviances from the growth curves that were observed were considered to be outside the normal variation or caused by the treatments.

In sum, no evidence of adverse effects on breastfeeding or child growth was found. Based on the available data a reasonable interpretation is that the treatments did not impose any harmful effect on breastfeeding or child growth.

5.10 Validity of primary outcome measurements

5.10.1 Body weight

Body weight measurements were taken at the research clinic using a standardized procedure to ensure validity and reproducibility. The same calibrated electronic scale was used throughout the trial. The measurements were taken in the morning after an overnight fast; the women were instructed not to eat anything after 22:00 on the night before the measurement, resulting in a 10 to 12 hour fast. Before the measurement they were asked again if they had eaten anything, if they had eaten the measurement was postponed to the following day. They arrived to the clinic by car or public transport, thus any physical activity that could cause short-term weight changes was avoided.

Since the women were breastfeeding, at least at the two first measurements, the timing of the measurement in relation to infant feeding could affect the weight. It was decided that the natural rhythm of feeding should not be tampered with, and thus this potential variation was accepted. Following the same reasoning the 0.5 liters of water the women were allowed to drink, to avoid discomfort or adversely affect milk production, could also affect the

weight measurement. However, the main aim was to evaluate differences among groups. Thus randomization and adherence to the measurement protocol ensured that these factors did not bias the outcome in terms of comparisons among groups.

5.10.2 Body composition

The DXA is considered a 'gold standard' reference method for measuring body composition, and changes in body composition over time. However, the precision for measuring fat and fat-free mass can be as low as 0.5 kg using DXA or other reference techniques (i.e. hydrodensitometry, air-displacement plethysmography), and approximately 0.7 kg for changes between two time points [137].

During the study the DXA software version was upgraded after the 10 first baseline measurements, from Version 12.2 to Version 12.3. The old software algorithm slightly overestimated FM and underestimated FFM compared to the newer version, used in the following measurements of these and all other participants. Thus, the potential influence of this software change is a slight underestimation of the FM reduction and a slight overestimation of the FFM reduction observed in the study.

The DXA measurement with its measurement error of 0.7 kg for changes in FM and FFM (approximately 4300 kcal) are of little or no value for calculating energy balance over short periods of time, but they may be over long periods of time The measurement error over 1 year corresponds to an average daily energy balance which is <1% of a normal dietary energy intake. Body composition measurements of this precision can be useful in calculating changes in energy balance when the changes in body weight and composition are large >5-10 kg [137], and were thus judged to be useful also for this purpose in our trial.

5.11 Validity of treatment implementation indicators

5.11.1 Total Energy Expenditure

The DLW technique is considered the 'gold standard' method for measurement of TEE because it provides an objective and accurate measure of TEE under free living conditions over one to several weeks. We measured DLW over 15 days corresponding to more than 2 periods of t½ (water turnover) with a total imprecision of 3.9% ($\sqrt{kd^2 + ko^2}$), which is similar or

better than the precision found in most DLW studies [183-185]. The method has been shown to provide accurate measures of TEE in weight stability and also weight loss of 2 to 4 kg during the measurement period [186, 187].

Lovelady et al compared a heart-rate monitor to DLW in exclusively lactating women (weight 57-75 kg) and argued that the DLW method may not be appropriate to use in lactating women due to high water turnover and low physical activity level [59]. However, they measured DLW for only 8 days, corresponding to less than 2 periods of t½ of water and with a lower technical precision compared to our trial. In our trial the mean ratio between elimination constants k_O (^{18}O disappearance rate/day) and k_D (^{2}H disappearance rate/day) was 1.25 which is somewhat higher than in the study by Lovelady et al (where it was 1.20) [59], and hence less prone to interaction from deviations of the true N_D/N_O ratio (pool size ^{2}H / pool size ^{18}O). Consequently it is less prone to errors in the calculation of carbon dioxide production (and therefore energy expenditure), at maximum 12%, according to Roberts et al [188]. Also the women in our study were considered quite physically active, which differs from the study by Lovelady et al. Based on this we judged that the DLW method provided an accurate measure of TEE in our trial.

5.11.2 Dietary intake

Recording diet may have effects on what and how much that is eaten, and underreporting is common, particularly among those overweight and obese [57, 189, 190]. Thus the validity of the reported dietary intake may be questioned. Therefore calculations to estimate the validity of the reported dietary intake were made.

By using an estimation principle based on calculating energy intake from TEE and change in body composition energy stores, the average energy intake difference from the reported energy intake can be estimated [11]. This has previously been used by Forsum et al among lactating women [57]. The level of underreporting can be calculated from the measurements available in our study. Using these calculations two observations regarding the reported dietary intake could be made: (1) the accuracy of the reported energy intake, i.e. how well it reflected the mean energy intake, and (2) whether achieving weight loss affected the accuracy of the reported energy intake. This determines the strength of the conclusions that can be drawn from the observed changes in dietary intake, and its role as a true indicator of treatment implementation. Since the DLW measurements were only

performed at baseline and at 12 weeks the calculations could only be made for the treatment period.

Energy intake from dietary records for mother (4-day weighed) and infant (interview), body composition by DXA, TEE, and breastfeeding data to calculate milk energy output (MEO) data collected at baseline and after the intervention was used. Total energy output (TEO = TEE + MEO) was estimated with representative values for milk production during exclusive breastfeeding [191] and corrected for energy of the infant's complementary foods. Baseline TEO is equal to true EI, during weight stability, which was assumed at baseline. Post intervention TEO corrected for the energy contribution of body composition-changes [137] was used as an objective measure of EI and energy balance over time. The formula used to estimate EI;

[*Estimated true EI (kcal per day) = (TEE_{DLW} per day + MEO per day) + Δ Energy content of body tissue stores ((FM_{DXA}: 9403 kcal/kg + FFM_{DXA}: 883 kcal/kg) / n days between measurements)*]

Underreporting of EI was calculated as the relative (%) difference between (a) baseline TEO and reported EI, and (b) post intervention body composition-corrected TEO and reported EI. Linear regression was used to analyze the effect of weight loss on change in underreporting.

The 60 women (1 was excluded from analysis because of extreme and highly unlikely EI values) who completed baseline and follow up measurements underreported baseline EI relative to estimated true EI with C 33 ± 36, D 29 ± 21, E 21 ± 17, DE 26 ± 20% respectively, with no difference found based on which treatment group they were thereafter randomized to (p=0.650). Estimates of true post intervention EI, revealed that underreporting at follow up was, for C 29 ± 20, D 19 ± 21, E 21 ± 17, and DE 11 ± 19% respectively, with no significant difference between groups (p=0.105). However, weight loss, which mainly occurred in the D and DE groups, was associated with decreased underreporting of EI (p=0.001).

The trial was designed and powered to detect a treatment effect regarding body weight. Thus, it cannot provide evidence for the absence of differences in dietary intake that did not reach statistical significance. However, these calculations reveal that the ability to detect differences between the groups was decreased. Furthermore, the total level of underreporting can be judged as modest, and in line with previous studies [57, 189]. Bland and Altman plots were used to further investigate the reported EI compared to the

estimated true EI. This confirmed that among all women, at both baseline and 12 weeks, the food diary underestimated EI by on average ~600 kcal.

Dietary data reported at 1 year could not be validated against DLW. However, by judging physical activity from daily steps, and energy balance from DXA, it is reasonable to conclude that groups D and DE underreported energy intake somewhat more than at 12 weeks. On the other hand, C group appears to have underreported energy intake to the same extent as at 12 weeks, and E group appears to have underreported intake extensively. It is therefore likely that the finding that the E treatment resulted in significant main effects on EI and nutrient intake at 1 year, indicating decreased intakes, was a result of underreporting.

In addition to the accuracy of reported energy intake also the intake of macro- and micronutrients should be considered. It is of interest that particular foods and nutrients are more prone to underreporting than others. Historically this has been seen particularly for fat, or high fat foods, and more so in obese individuals [192, 193]. However, as a result of the lively Swedish debate regarding whether carbohydrates or fat is the cause of overweight and ill-health during the last decade [173], the respondents potential miss-reporting in line with what she thinks is "good food", and also what the researcher is thought to want to see (i.e. 'social desirability bias' [194]) may have been skewed in a yet unknown manner and extent. The reported (baseline) diet was however in line with a typical Swedish diet, both in terms of macronutrient and micronutrient intakes [195]. The reported proportion of calories from of sweets, snacks, soft-drinks, bakery goods, ice-cream etc. was also similar to higher, compared with a typical Swedish diet [195].

In sum, the dietary data reported here at baseline and at 12 weeks can be regarded as reasonably accurate compared to what can be expected from self-reported dietary intake. However, estimates of true intake were provided which is rare and aids in interpretation. This reveals that self-reported EI was lower than estimated true EI, and the differences detected between groups as a result of the treatments have not been exaggerated but rather the opposite. These additional findings of estimated true EI and the effect of weight loss on dietary reporting may have implications for analysing and understanding dietary data collected during other interventions and treatments among overweight and obese individuals. Dietary data at 1 year was likely accurate to a similar extent, except for group E in which the women appear to have underreported extensively.

5.12 Statistical approach

The sample size in the trial was calculated based on predicted difference in the primary outcome body weight change, between dietary treatment group and control group, with 80% power. The required number of women were recruited and randomized, and drop-out was low. There were no differences in baseline characteristics that indicated that randomization was not effective or that may have affected the women's response to the treatments. Thus the trial was adequate to test the main hypothesis.

All secondary outcomes were tested based on a relevant hypothesis. Because of multiple comparisons the risk of significant findings due to a large number of tests arises. All findings were judged on the condition that significant findings support causality or association if a plausible biological mechanism could support the finding. The significance level was not adjusted (e.g. Bonferroni corrected) since most of the tests were related to the main hypothesis, and the outcomes were correlated because they were in part measurements of the same thing (i.e. change in weight, BMI, fat mass, energy intake). Thus multiple tests would not be expected to provide statistical significance by chance, but from a common underlying mechanism. Among differences in secondary outcomes potential lack of power causes the risk of type 2 errors to occur, thus absence of evidence should not be considered evidence of absence.

Regarding breastfeeding and child growth a significant effect of the treatment could indicate an adverse effect, thus no difference between treatments and control represented a good outcome. However, we could not statistically prove no-difference. Therefore by judging other criteria such as breastfeeding practice, reported involuntary cessation of breastfeeding, child growth in absolute numbers, and child growth in relation to the WHO growth standards were used.

The 2 x 2 factorial design included 2 levels (absence (-) or presence (+)) of each of two factors (D treatment and E treatment), leading to four intervention combinations in total; i.e. C group:-/-, D group +/-, E group: -/+, and DE group: +/+. This allowed for analysis of both main effects of the D and E interventions and their interaction, which were analyzed using 2-way ANCOVA to adjust for baseline values. The ANCOVA analysis evaluates whether population means of the dependent (outcome) variable, adjusted for differences on a covariate, differ across levels of the independent variables (the treatments). The results of such an analysis does not provide the actual group mean outcomes, but estimated marginal means of the dependent variable (i.e. predicted, not observed means) for both levels of the two

factors, and the p-value of the main and interaction effects. For clarity and proper understanding of the results the observed mean outcomes of the groups, not the estimated marginal means, have been presented consistently.

Data were not primarily analyzed according to the strictest interpretation of the intention to treat principle, “if randomized – analyze”. Instead, based on the nature of data we used an approach recommended by Altman [196]; only women for whom measurements were made were included in the analysis. The criteria for making a fair analysis and interpretation of data using this approach are that the number of women lost to follow-up is low and the proportion does not differ between treatments. Our data fulfilled these criteria. It should be noted for clarity, that irrespective of how compliant the woman was with the treatment protocol she was included in the analysis.

A strict intention to treat analysis imputing last value carried forward (here equal to baseline value carried forward) was also performed for the primary outcomes to ensure that the treatment effect was not overestimated in our original interpretation. This analysis confirmed the findings on which our interpretation was based. The main effect of the D treatment was highly significant ($p<0.0001$) with no significant main effect of the E treatment and no interaction between treatments.

5.13 Trustworthiness and quality of qualitative findings

In Grounded Theory the aim is to create new theories built on observations of a reality one observes without preconceptions about the nature of the observed, while in a parallel process also testing the theories one generates on reality. This results in constant comparisons between data and reality. When the data and the analysis process are approached with systematic honesty and rigor the influence of preconceptions is minimized. Thus, the role and potential influence of the researcher/research team is recognized and must be addressed properly.

High trustworthiness was achieved through the research group composition allowing for different professional and personal perspectives, an ‘outsider performing the interviews, full participation among respondents, repeated interviews, interviews being done during active participation in the intervention study and in parallel with analysis, avoidance of literature review before analysis, and use of multiple data sources [148].

The interview was performed by a researcher not involved in the trial, and who had not had prior contact with the study participant. The recruitment of an 'outsider' to perform the interviews aimed to minimize the risk of participants feeling obliged to say 'what the intervention team would like to hear'. This could result from feeling uncomfortable telling someone from the intervention team face the face about a negative experience of the intervention, or about lack of compliance with the intervention.

In qualitative research the preconceptions and interpretations of the researcher is a particular concern, as these are known and expected to influence the outcome [197]. Glaser and Strauss argued that the researcher should be "free from theory" [147]. A rigorous literature review before starting the study should be avoided for this reason. Accordingly the literature review concerning health behavior theories and psychological theories was not initiated until after the theory had been developed. Also, in each step of the coding process the researcher must reflect on whether the understanding and conceptualization belongs to pre-understanding or comes from empirical data.

According to Glaser and Straus the trustworthiness of the generated theory can be judged on basis of its fit and relevance, workability and modifiability [147]. We judge the generated theory to fit the empirical problem under study well, and much of the variation to be explained by the core category. Based on the interviews and other interactions with the women, we are convinced that the generated theory deals with the real concern of the women, and that it is not only of academic interest. The workability of the generated theory can only be judged on how well it explains and allows for interpretation of the phenomenon, and not yet how well it predicts it. The generated theory explains much of the phenomenon in that it provides answers to 'who, why, how, where, when' regarding most codes and categories, and finally fulfills the overarching goal of explaining how the main problem is solved. When new data appear, the modifiability of the theory will be evaluated. The theory can be considered valid since the identified concepts and categories repeatedly emerged and were saturated in data. The theory can also be considered reliable since similar relationships between phenomena recurrently were found to emerge in the data. There may however be additional factors that operate in ways not recognizable to the women, or that actually exist in the data but have not been recognized by the researcher.

According to Malterud [197] *"Rather than thinking of qualitative and quantitative strategies as incompatible, they should be seen as complementary."* This primarily refers to how the different approaches

provide complementary data and enhances understanding of medical issues. However, it also indicates that discrepancy between qualitative and quantitative findings warrant further investigation, and vice versa that coherency in results may be an indicator of quality (i.e. triangulation between methods). Apart from the fact that the qualitative findings provided answers to how and why a number of quantitatively measurable outcomes occurred, some interesting discrepancies and coherencies were found. The most striking discrepancy regarded exercise. Many women reported that they experienced exercise to be a useful approach to reduce and control weight. This was however not confirmed in the quantitative findings. On the other hand coherency was found in the experience of dietary changes, both quality/quantity and usefulness, and the quantitative outcome measurements of body weight and treatment implementation indicators.

5.13.1 Integration of findings with other behavior theories; exploring the causes and facilitators of change

Although it is not a ground on which the quality of a Grounded Theory should be judged, according to the originators of the method, a discussion of the findings in relation to other theories in the area provides insights on what is new, what is consistent with previous theories, and what contradicts previous theories. If the generated theory substantially contradicts some or most previous findings an explanation to this is needed, particularly if the previous theories are functional and have predictive or explanatory power. On the other hand, if the generated theory is consistent with some or most previous findings, this may indicate trustworthiness. However, it could also indicate that the findings are biased by preconceptions based on previous research. If the Grounded Theory method has been executed correctly the risk of the latter error should be minimized.

The influential health behavior theories; the Health Belief Model (HBM), [198], the Theory of Planned Behavior (TPB) [199], SCT [198], and TTM [200], share several major concepts with our newly identified theory of TLC. These include motivation to make health issues relevant, the perception of a health problem or threat, and the perception that action can be taken to solve this problem. Also, prominent in these theories are versions of the concepts self-efficacy and outcome-expectancy, which also emerged in our model as central to engaging in and maintaining lifestyle changes.

Some form of interaction including initiation, and often support and follow-up, is part of all intervention plans. However, to generate and sustain a high level of motivation and compliance it appears beneficial if the health care

provider utilizes an intervention plan that corresponds to the three Catalytic Interaction (CI) - concepts (1) spark, (2) direction, and (3) pressure & praise, as these emerged in our study as most relevant to successful change. CI integrates well with the 'working alliance construct', which includes three components: (1) the agreement between therapist and client about the goals of intervention, (2) the agreement about the therapy tasks needed to accomplish those goals, and (3) the emotional bond developed between therapist and client that allow the client to make therapeutic progress [201]. As described in the introduction Phelan has theorized pregnancy as a "teachable moment" that would motivate women to change their eating and exercise habits [126], (based on the definition by McBride; times that (1) increase perceptions of personal risk and outcome expectancies, (2) prompt strong affective or emotional responses, and (3) redefine self-concept or social roles [125]). In addition to pregnancy, based on the women's experience of the LEVA-trial to provide TLC through CI, the trial itself may have provided such a teachable moment. This may contribute to the understanding of why and how motivation, compliance and retention were high during the trial.

In a correlational study the Integrated Theory of Health Behavior Change was evaluated among 250 postpartum women regarding weight self-management [202]. A survey questionnaire measured concepts, including knowledge and beliefs (self-efficacy, outcome expectancy and goal congruence), self-regulation skills and abilities, and social facilitation (social support and social influence) and weight retention. The model explained 26% of the variance in self-regulation at four months, but did not explain weight retention. This could indicate that although the above found concepts are important, and were also found to be so in our study, the phenomenon that contributed to the CI of the treatments in our trial plays an important part in facilitating weight loss. In the above discussed study the following reflection that indicates and captures this well this was made: *"Why is it that weight self management knowledge was not one of the concepts included in the factors influencing behaviour? Perhaps the type of knowledge people need to change health behaviours differs from factual information commonly used to educate people about a condition. Perhaps standardized information needs to become patient-centred, that is congruent with a person's values and goals, pragmatic to their lifestyle and action oriented so that it is easily translated into their lifestyle."*

Like TTM, our model is dynamic and predicts that adoption of health behaviors consists of several stages. We also suggest that the stages leading to lifestyle change include pre-action contemplations, followed by actions of increasingly internalized behavior changes towards self-directed and

sustainable weight maintenance. However, our model is more segmented, comprising seven distinct 'action-stages'. Furthermore, it includes a shift in identity process. We also identified the 'Adaptive transposing'-stage that emerged as highly relevant to postpartum women, but may be equally important in other populations. This highlights the importance of assessing the behavior/environment-interaction, particularly in transition periods. The transformation from 'Discontentedly lacking lifestyle control' to 'Lifestyle managing' represents a shift from externality to internality in agreement with the locus of control theory [203].

TTM has been investigated cross-sectionally among postpartum women participating in a weight management program. The pro-to-con ratio was highest in the action stage for losing weight, avoiding high-fat foods, and exercising three times per week. A lower ratio was found during the maintenance stage [204]. In accordance with our model this attenuation of the pro-to-con ratio of healthy lifestyle behaviors is likely detrimental to long term weight loss, and must be compensated for by a shift in attitudes, underpinned by suitable strategies for changes to endure.

The triadic reciprocal determinism proposed in SCT offers a dynamic approach in the relationships between behavior, person and environment, which also emerged in our study. Three of the four factors that according to SCT increase self-efficacy [198] were in our study perceived to be promoted by the CI and intervention program design; (1) performance accomplishments (successful mastery of new behaviors), (2) verbal persuasion (by authority) and (3) physiological state (successful elimination of negative effect, i.e. by becoming less overweight or unfit). Also, biofeedback (evaluation of achievement of goals by physiological or biological markers) strengthened the belief that barriers can be overcome and new behavior established, in agreement with Rosenstock et al [198]. The fourth strong promoter of self-efficacy: observing other people in a group context (vicarious experiences) was not experienced by our study participants due to the study design.

The determinants of diet composition are complex, multileveled and interconnected, as outlined in the background of the thesis. Among postpartum women there are some findings that provide further insights regarding these determinants. Diet quality among overweight and obese, low-income women in early postpartum has been found to be related to greater fruit and vegetable availability, resistance to convenience eating (i.e. being less vulnerable to environmental eating cues), and vegetable taste preference [205]. Women with high fruit and vegetable availability consume more vegetables, as compared to those with low availability. High convenience eating resistance was associated with lower discretionary energy intakes.

High taste preference for vegetables was related to greater intakes of these foods. Resistance to convenience eating was the strongest predictor of diet quality followed by vegetable taste preference, and fruit and vegetable availability. A nutritional knowledge survey among low-income minority women in the postpartum period showed that nutritional knowledge, implying knowledge of the benefits for fruit and vegetable consumption and the low nutritional value of convenience foods and other discretionary calories, was related to PPWR. Women that retained <5% of GWG had greater nutritional knowledge than those who retained >5% [206].

In our trial the women that experienced TLC, and thus achieved and maintained weight loss, decreased the environmental eating cues or found strategies to handle them. They also increased their nutritional knowledge and (perhaps as an effect of this) their resistance to convenience eating, and also found their taste preferences for fruits and vegetables to have increased. Findings by Epiphaniou and Ogden among >1000 individuals either successful or not in weight loss maintenance also confirms a similar dietary behavior pattern, and supports the TLC-model. They found that successful weight loss maintenance was facilitated by a reduced choice over their previous unhealthy diet, more choice over their exercise behaviors and more benefits from the new healthy behaviors, and a belief that behavioral solutions will be effective [207]. However no differences in demographic factors were found. Using qualitative interviews Ogden and Hills also found that initial change was translated to sustained change if (a) the function of the unhealthy behavior was disrupted, (b) the individual perceived their choice over carrying out the unhealthy behavior had been reduced, and (c) they adhered to a behavioral model of their problem. Also, these conditions functioned by enabling a process of reinvention leading to a perceived shift in identity to a new healthier self [168]. Also this latter observation was a major aspect of the TLC-model.

Psychological experiments, in agreement with our findings, have shown that self-control is a taxing endeavor, dependent on a limited source of energy. Exerting self-control expends self-control strength, which reduces the amount of strength available for following self-control efforts. Resisting temptations, regulating negative feelings and coping with stress require self-control. After a few self-control efforts, following attempts are more likely to fail. Continuous self-control efforts also decline over time. However, behaviors that do not require self-control do not expend nor require self-control strength [208]. This supports how TLC, through producing new automatic behaviors and a self-image aligned with new lifestyle, leads to behaviors more likely to endure because the perception of these behaviors are changed from self-

control strength taxing towards evoking no or few inner conflicts. Furthermore, self-control strength is like a muscle; not only can it be exhausted but it can also be exercised. Repeated practice and rest over time can improve self-control strength. This may explain the gradual accumulation of small changes perceived as surprisingly effortless by many women in our study. By gradual introduction of both magnitude and complexity of self-control demanding actions, an exercise effect may have been attained.

Finally, cognitive dissonance theory provides a useful way to understand how inner conflicts were attenuated. We found inner conflicts to be an important barrier to change, causing the seemingly irrational behavior of despite "knowing better" and almost against one's own will engaging in unhealthy behaviors, that the women experienced. Cognitive dissonance theory states that inconsistency among cognitions lead to a psychological tension with drive-like properties to reduce this tension, e.g. by changing attitude towards a behavior, or vice versa [209]. During the intervention, repetition of new behaviors may have caused a change in attitude towards these behaviors through resolving the cognitive dissonance that was generated. While women were initially driven by both initial motivation and pressure, these behaviors were likely to lead to changes in attitude, which later underpinned the change process through reduction of resistance to change from new attitudes aligned with the new behavior.

5.14 Concluding reflections

The study population consisted of Swedish overweight and obese women, mainly well-educated and married. In relation to the general health and lifestyle trends observed in society these women would thus be expected to have a reasonable level of leisure time physical activity, and to have a healthier diet than other groups in society. However, they would also be expected to consume too much energy derived from all macronutrients, and specifically a high intake of candy, chocolate, ice-cram, cheese, snacks and soft-drinks. They would most likely wish to reduce their weight. These expectations were confirmed in our trial.

The treatments aimed to, and to a fair extent resulted in, providing tools to manage the obesogenic environment at the individual level. These results are promising and of importance to the current public health situation. However, it also highlights that for the person seeking change; support, conscious effort, persistency, and time were necessary to reverse what appears to be caused mainly by an unhealthy environment rather than active choice. Therefore also strategies at the broadest societal level, to change the built environment that appears to cause so many individuals ill health, are most likely needed to combat the obesity epidemic. However, also positive factors exist and should be utilized. Specific to the population studied here, the Swedish supportive environment for breastfeeding is beneficial, and also the generous parental leave was found to be a facilitating factor in weight loss efforts.

By providing mothers with the conviction and the strategies necessary to achieve and maintain a healthy lifestyle and weight, change can be achieved in a key part of the population. A majority of women have one child or more, and the lifestyle of the mother will most likely influence that of the child. If the results of our trial come to guide clinical decisions and policy, and the treatments used here prove functional also in the health care, this could benefit both mothers of today and generations to come.

6 CONCLUSION

The 12 week dietary treatment used in the LEVA-trial provided significant and clinically relevant weight loss among lactating postpartum women, and it was sustained at 9 months after treatment. The dropout rate was low, which indicates that this treatment format was acceptable to the women. Further research will be needed to evaluate the effectiveness in the health care setting.

Physical exercise treatment alone did not increase total energy expenditure or weight loss. The combination of dietary and exercise treatment did not yield significant weight or body composition changes beyond those of dietary treatment alone. Dietary treatment should thus be prioritized to achieve weight loss. Among lactating women like our participants, who already meet recommended levels of physical activity, physical exercise treatment should not be prioritized for weight loss. However, among less active women this strategy should be explored further.

At baseline the women consumed a typical Swedish diet. Dietary treatment led to reduced intake of fat and carbohydrate, while maintaining intake of protein and fibre. The proportion of sucrose was reduced, while the proportion of complex carbohydrates was increased. Weight loss through dietary treatment was achieved with a diet in line with current official recommendations, i.e. the Nordic Nutrition Recommendations. This dietary composition, implemented using the dietary treatment evaluated here, is thus useful for sustainable weight loss.

Micronutrient intake was below recommendations, but only marginally compromised by dietary treatment. The low intakes particularly concerns vitamin D, iron and folate. To reach recommended intakes a supplement may be recommended.

A successful weight-loss outcome depended on two phenomen in the postpartum weight loss trial context; conceptualized as Catalytic Interaction and Transformative Lifestyle Change. The Catalytic Interaction occurred in partnership with the health care professional and provided an energizing collaboration built on individualized, practical, and useful information coupled with encouragement and accountability. Transformative Lifestyle Change is the conceptualization of the process that led to the development of reciprocal changes in cognitions, emotions, body, behavior, and environment,

which jointly reduced the barriers to a new lifestyle. This theory may be useful in the design and evaluation of weight loss treatments.

7 FUTURE PERSPECTIVES

The 12 week dietary treatment used in the LEVA-trial provides a basis on which to design a primary health care treatment program. Although women were recruited from diverse socio-economic areas, the final study population included predominantly white and well educated women. Future research should evaluate the treatment in the Swedish primary health care, and also evaluate the treatment in other populations. Recruitment of a more diverse population of lactating overweight and obese postpartum women of varied ethnic and socio economic groups should be a priority.

The exercise intervention did not produce an increase in total energy expenditure. To evaluate the interactive effect of increased physical activity and dietary modification an exercise intervention that increases total energy expenditure should be studied. Both effect and feasibility should be assessed. A potential improvement to the exercise intervention could be to provide the women with a measurable target for increased total energy expenditure (as opposed to only an exercise goal), decrease sedentary behaviors, and a device for self-monitoring of total activity.

Use of the dietary treatment in other groups in need of weight loss treatment should be evaluated. Since the postpartum period and pregnancy share specific features and concerns, the model may be of particular use here. The intervention may be used to achieve gestational weight gain within the recommended ranges. The LEVA-dietary treatment including the Step-wise Weight-determined Accumulative change Plan (SWAP) and Outcome Quantified Dietary Advice (OQDA) may be used, however with underlying calculations adjusted to the energy requirements during pregnancy. The concepts of the treatment model are however not specific to weight control and lifestyle during pregnancy and postpartum, and could also be evaluated as a general approach to weigh loss treatment.

Longer term weight outcome, the influence of prolonged minimal, moderate and extensive weight loss and maintenance support based on the treatment model developed for this trial, and the life events that determine the long term weight trajectory among women after childbirth should be evaluated.

The developed treatment program could be integrated with contemporary information technology. This could provide interactive weight change graphics, self-monitoring of weight, diet and physical activity data to be easily shared with clinical practitioner/researcher and/or supportive peer-

community. Novel ways to provide wireless "in person" feedback, encouragement, and accountability could be utilized.

The model generated in the Grounded Theory analysis could be utilized to design, implement and evaluate weight loss treatment and research. The substantive nature of the findings provides health care professionals and researchers with an understanding of the cognitive, emotional and contextual grounds for the implementation and adaptation, or rejection or discontinuation of lifestyle changes. If this model proves useful, the process along the suggested trajectory can be assessed and supported to improve chances of improved outcome.

ACKNOWLEDGEMENT

I would like to acknowledge all of those who have in different ways contributed to my understanding of clinical nutrition, to my PhD-training and to this thesis; thank you! Some particular contributions merit further elaboration.

Hilde Brekke: My main supervisor. Thank you for always mentoring with a smile. For the balancing act of keeping me on the right track, while also letting me explore science my own way. Always ready to discuss or re-read, always with a fresh and well grounded perspective. I have learned so much.

Anna Winkvist: My co-supervisor. Your mentorship and accomplishments are immensely inspiring and always gave me energy in times of doubt. Thank you also for superb guidance, from statistics and qualitative methods to career development.

Anna and Hilde, simply put; with you I experienced Catalytic Interaction, and also a Transformative Change under your guidance. Thank you also for your limitless support and compassion in challenging times.

Carina Sparud-Lundin: Thank you for your contribution to the qualitative work, and for mentoring me in the ways of Grounded Theory.

Kathleen Rasmussen: For great inspiration; high standards, dazzling intellect and a sharp eye. Working with you has been an eye-opener. Thank you for your contribution to the first LEVA-article, including lightning-fast editing, and for advice, encouragement and support.

Lars Ellegård: Thank you for helping me understand measurements of metabolism and body composition, and for your contribution to the first LEVA-article. A trusted living encyclopedia on close to everything, always with a good answer to my wonderings.

Mette Axelsen: For first inspiring me to do research, for believing in me, and for arranging my first position at clinical nutrition. I am forever grateful.

Anna-Carin Hagstig: Thank you for doing a great job as the LEVA-dietitain during my parental leave.

Cecilia Elam-Edwen, Sofia Augustsson, Louise Sernryd: Thank you for your devoted and thorough work as LEVA-physical therapists.

Elisabeth Gramatkovski: Thank you for stepping in when I was away, or when there was just too much work. Thank you for thorough data collection (and babysitting) no matter time of day or place.

Vibeke Malmros: Without your guidance I would be lost, literarily. Thank you, and **Annica Alklind**, for performing and arranging high quality research measurements.

Monica Hunsberger: Thank you for thorough language editing and thoughtful comments on our qualitative work.

The PBL-group: It has been great to be part of this group of maternal and child health researchers. Thank you for reflective listening, good suggestions, and the sense of community.

Petra Brembeck: Best laughter, chatter, and science talk room-companion a doctoral candidate could ever wish for.

Sofia Klingberg: Thank you for always being updated and sharing the how-to's of doctoral work technicalities.

Ola Wallengren: Thank you for statistics help, and for sharing your never ending enthusiasm and knowledge of body (re)composition.

All present and former colleagues at the department of clinical nutrition. Thank you for making our department a really nice place, and for support and understanding.

Mormor: Without you I would not be where I am now. Thank you for financial support so that I could study to become a dietitian. Thank you for always believing in me.

Mamma & pappa: Thank you for showing me the value of hard and diligent work, truthfulness and ambition. The family interest in food lives on.

Vanja: My love. My most loyal supporter. Thank you for believing in me and encouraging me through thick and thin.

Jack & Judith: My precious, wonderful, fantastic children.

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