

TARJA I. KINNUNEN

Prevention of Excessive Pregnancy-Related Weight Gain

ACADEMIC DISSERTATION

To be presented, with the permission of the Faculty of Medicine of the University of Tampere, for public discussion in the Auditorium of Tampere School of Public Health, Medisiinarinkatu 3, Tampere, on February 7th, 2009, at 12 o'clock.

ACADEMIC DISSERTATION

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LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following original publications, which are referred to in the text by the Roman numerals I–IV.

- I Kinnunen TI, Luoto R, Gissler M and Hemminki E (2003): Pregnancy weight gain from 1960s to 2000 in Finland. Int J Obes 27:1572–1577.
- II Kinnunen TI, Aittasalo M, Koponen P, Ojala K, Mansikkamäki K, Weiderpass E, Fogelholm M and Luoto R (2008): Feasibility of a controlled trial aiming to prevent excessive pregnancy-related weight gain in primary health care. BMC Pregnancy and Childbirth 8:37.
- III Kinnunen TI, Pasanen M, Aittasalo M, Fogelholm M, Hilakivi-Clarke L, Weiderpass E and Luoto R (2007): Preventing excessive weight gain during pregnancy a controlled trial in primary health care. Eur J Clin Nutr 61:884–891.
- IV Kinnunen TI, Pasanen M, Aittasalo M, Fogelholm M, Weiderpass E and Luoto R (2007): Reducing postpartum weight retention a controlled trial in primary health care. Nutr J 6:21.

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ABBREVIATIONS

ANCOVA analysis of covariance

BMI body mass index

CC child health clinic

CI confidence interval

E% percentage of energy intake

FFQ food frequency questionnaire

GDM gestational diabetes mellitus

IOM Institute of Medicine

LTPA leisure time physical activity

MC maternity clinic

MET multiple of resting metabolic rate

METmin MET minutes

NAF nipple aspirate fluid

PHN public health nurse

SD standard deviation

ABSTRACT

Excessive weight gain during pregnancy predisposes women to higher postpartum weight retention and possibly to long-term overweight and associated health problems. Little has been published on gestational weight gain among Finnish women. Studies from other countries have reported that some of the women gain weight excessively during pregnancy and retain substantial amounts of weight after pregnancy, which may partly be due to unhealthy diet and low level of physical activity. Few studies have aimed at preventing excessive pregnancy-related weight gain by counselling women on diet and physical activity during or after pregnancy. The aim of this dissertation was to study trends in mean gestational weight gain in Finland since the 1960s and to evaluate the feasibility and the effects of implementing a lifestyle intervention designed to prevent excessive pregnancy-related weight gain in a primary health care setting.

Data on three population based samples of pregnant women were used to study trends in gestational weight gain. The women were pregnant in Helsinki 1954–1963 (n=2,262) or in the city of Tampere 1985–1986 (n=1,771) or 2000–2001 (n=371). The intervention study was a controlled trial conducted in three intervention and three control maternity and child health clinics in Tampere and in the town of Hämeenlinna. The participants were pregnant women with no earlier deliveries (n=132) and postpartum primiparas (n=92). The intervention consisted of individual counselling on diet and physical activity at five routine visits to a public health nurse (PHN) and an option for supervised group exercise once a week until 37 weeks' gestation or 10 months postpartum. In the control clinics, the PHNs continued their usual dietary and physical activity counselling practices.

Pregnancy data were obtained from maternity cards. Pre-pregnancy weight was self-reported, but the other weight data were based on measurements. In the intervention study, information on diet and physical activity was collected by questionnaire and the pregnant participants also kept food records. The components of the feasibility evaluation of the study protocol of the intervention study were 1) recruitment and participation, 2) completion of data collection, 3) realization of the intervention and 4) PHNs' experiences.

The comparison of the three samples of pregnant women showed that the mean gestational weight gain, adjusted for age, prepregnancy body mass index (BMI) and parity, increased from 13.2 (95% confidence interval (CI) 13.0–13.4) kg in the 1960s

to 14.3 (95% CI 14.1–14.5) kg in the mid-1980s (p<0.05). The increase was observed in all age, BMI and parity groups. Since the mid-1980s, the mean gestational weight gain has remained at the same level.

Implementation of the study protocol of the intervention study was mostly feasible. 1) The average participation rate of eligible women was high (77%) and the dropout rate low (15%). The recruitment period was prolonged from the three months initially planned to six months. 2) Altogether, 99% of data on weight development, diet and leisure time physical activity (LTPA) and 96% of the blood samples were obtained. 3) In the intervention clinics, 98% of the counselling sessions were carried out as intended and 87% of the participants regurlarly kept the weekly records for diet and LTPA. The mean participation percentage in the group exercise sessions was 45%. 4) The PHNs considered the extra training to be a major advantage for them and the additional workload to be a major disadvantage of the study.

Among the pregnant participants, the intervention group increased the intake of vegetables, fruit and berries by 0.8 (95% CI 0.3-1.4) portions/d (p=0.004) on average and maintained the proportion of high-fibre bread of the total amount of bread (a difference of 11.8 (95% CI 0.6-23.1) %-units between the groups, p=0.04) compared to the control group when adjusted for confounders. No significant effects were observed regarding the intake of high-sugar snacks, total LTPA or proportion of participants exceeding the recommendations for gestational weight gain. However, there were no high birth weight ($\geq 4,000 \,\mathrm{g}$) infants in the intervention group, but eight (15%) of them in the control group (p=0.006). Among the postpartum participants, the intervention group increased the proportion of high-fibre bread of the total amount of bread (a difference of 16.1 (95% CI 4.3–27.9) %-units between the groups, p=0.008) and returned to their pre-pregnancy weight by 10 months postpartum more often than the control group (odds ratio 3.89 (95% CI 1.16-13.04, p=0.028)), when adjusted for confounders. On the other hand, the intervention had no effect on the intake of vegetables, fruit and berries or high-sugar snacks or on the total LTPA.

In conclusion, the mean gestational weight gain has increased after the 1960s, which may increase the risk of pregnant women for postpartum weight retention and subsequent overweight. These data warrant intensified health promotion actions to prevent excessive weight gain during and immediately after pregnancy. The study protocol designed to prevent excessive pregnancy-related weight gain was mostly feasible to implement in a primary health care setting. As some beneficial effects of the intervention were also observed, the results of this study encourage conducting larger trials in comparable settings.

TIIVISTELMÄ

Liiallinen raskauden aikainen painonnousu hankaloittaa palautumista raskautta edeltävään painoon synnytyksen jälkeen ja altistaa myös pitkäaikaiselle ylipainolle ja siihen liittyville terveysongelmille. Suomalaisten naisten raskauden aikaisesta painonnoususta on vähän julkaistua tietoa. Ulkomaisten tutkimusten mukaan paino nousee osalla naisista raskauden aikana liikaa ja ylimääräistä painoa jää huomattavasti raskauden jälkeenkin, mikä voi osittain olla seurausta epäterveellisestä ruokavaliosta ja vähäisestä fyysisestä aktiivisuudesta. Vain muutamassa tutkimuksessa on pyritty ehkäisemään raskauteen liittyvää liiallista painonnousua raskauden aikaisen tai sen jälkeisen ravitsemus- ja liikuntaneuvonnan avulla. Tämän väitöskirjan tavoitteena oli tutkia keskimääräisen raskauden aikaisen painonnousun muutoksia Suomessa 1960-luvun jälkeen ja arvioida sellaisen perusterveydenhuollossa suoritettavan elintapaintervention toteutettavuutta ja vaikutuksia, jolla pyrittiin ehkäisemään raskauteen liittyvää liiallista painonnousua.

Raskauden aikaisen painonnousun muutoksia tutkittaessa käytettiin tietoja kolmesta väestöpohjaisesta raskaana olevien naisten otoksesta. Naiset olivat raskaana Helsingissä vuosien 1954–1963 (n=2262) tai Tampereella vuosien 1985–1986 (n=1771) tai 2000–2001 (n=371) aikana. Interventiotutkimus oli kontrolloitu koe, joka toteutettiin kuudessa äitiys- ja lastenneuvolassa Tampereella ja Hämeenlinnassa. Neuvoloista kolme toimi koe- ja kolme kontrollineuvoloina. Tutkittavat olivat raskaana olevia (n=132) ja synnyttäneitä (n=92) ensisynnyttäjiä. Koeneuvoloissa toteutettiin yksilöllistä ravitsemus- ja liikuntaneuvontaa viidellä tavanomaisella käynnillä terveydenhoitajan vastaanotolla sekä mahdollisuus osallistua ohjattuun ryhmäliikuntaan kerran viikossa 37. raskausviikolle tai 10 kk synnytyksestä saakka. Kontrollineuvoloissa terveydenhoitajat jatkoivat entisiä ravitsemus- ja liikuntaneuvontakäytäntöjään.

Raskauteen liittyvät tiedot kerättiin äitiyskorteista. Raskautta edeltävä paino perustui itse raportoituun tietoon ja muut painotiedot mittauksiin. Interventiotutkimuksessa tiedot ravinnosta ja liikunnasta kerättiin kyselylomakkeilla ja lisäksi raskaana olevat tutkittavat pitivät ruokapäiväkirjaa. Interventiotutkimuksen protokollan toteutettavuutta arvioitiin seuraavien komponenttien osalta: 1) tutkittavien rekrytointi ja osallistuminen, 2) tiedonkeruun toteutuminen, 3) intervention toteutuminen ja 4) terveydenhoitajien kokemukset.

Kolmen raskaana olevien naisten otoksen vertailu osoitti, että keskimääräinen raskauden aikainen painonnousu suurentui 13,2 (95 % luottamusväli 13,0–13,4) kg:sta 14,3 kg:aan (95 % luottamusväli 14,1–14,5) 1960-luvulta 1980-luvun puoliväliin tultaessa (p<0,05), kun tulokset vakioitiin iällä, raskautta edeltävällä painoindeksillä ja pariteetilla. Tämä muutos havaittiin kaikissa ikä-, painoindeksi- ja pariteettiryhmissä. Kuitenkin 1980-luvun puolivälin jälkeen keskimääräinen raskauden aikainen painonnousu on pysynyt samalla tasolla.

Interventiotutkimuksen protokolla oli enimmäkseen hyvin toteutettavissa. 1) Keskimääräinen osallistumisprosentti oli suuri (77 %) ja keskeyttäneiden osuus pieni (15 %). Rekrytointiaikaa jatkettiin alun perin suunnitellusta kolmesta kuukaudesta kuuteen kuukauteen. 2) Yhteensä 99 % painonkehitykseen, ravintoon ja vapaa-ajan fyysiseen aktiivisuuteen liittyvistä tiedoista ja 96 % verinäytteistä saatiin kerättyä. 3) Koeneuvoloissa 98 % neuvontakerroista toteutui tarkoitetulla tavalla ja 87 % tutkittavista kirjasi säännöllisesti viikoittaisen ravinto- ja liikuntasuunnitelmansa toteutumisen. Tutkittavat osallistuivat keskimäärin 45 %:lle ryhmäliikuntakerroista. 4) Terveydenhoitajat pitivät ylimääräistä koulutusta tutkimuksen suurimpana etuna ja lisääntynyttä työmäärää sen suurimpana haittana heille.

Raskaana olevien tutkittavien osalta koeryhmä lisäsi kasvisten, hedelmien ja marjojen käyttöä keskimäärin 0,8 (95 % luottamusväli 0.3-1.4) annoksella/vrk (p=0.004) sekä ylläpiti runsaskuituisen leivän osuutta leivän kokonaismäärästä (ryhmien välinen ero 11,8 (95 % luottamusväli 0,6–23,1) %-yksikköä, p=0.04) kontrolliryhmään verrattuna, kun sekoittavat tekijät huomioitiin analyyseissä. Sen sijaan interventiolla ei ollut vaikutusta makeiden välipalojen käyttöön, vapaa-ajan fyysisen aktiivisuuden kokonaismäärään tai raskauden aikaiset painonnoususuositukset ylittäneiden tutkittavien osuuteen. Kuitenkaan koeryhmän tutkittaville ei syntynyt yhtään suuripainoista (≥4000 g) lasta, vaikka kontrollineuvoloissa heitä syntyi 8 (15 %) (p=0.006). Synnyttäneiden tutkittavien osalta koeryhmä lisäsi runsaskuituisen leivän osuutta leivän kokonaismäärästä (ryhmien välinen ero 16,1 (95 % luottamusväli 4,3–27,9) %-yksikköä, p=0.008) ja useampi heistä palautui raskautta edeltävään painoonsa 10 kk synnytyksen jälkeen kuin kontrolliryhmästä (odds ratio 3,89 (95% luottamusväli 1,16–13,04, p=0.028)), kun sekoittavat tekijät vakioitiin analyyseissä. Toisaalta interventiolla ei ollut vaikutusta kasvisten, hedelmien ja marjojen tai makeiden välipalojen käyttöön eikä vapaa-ajan fyysisen aktiivisuuden kokonaismäärään.

Yhteenvetona voi todeta, että keskimääräinen raskauden aikainen painonnousu on suurentunut 1960-luvun jälkeen, mikä saattaa lisätä raskauden jälkeistä ylipainoriskiä. Tämän tutkimuksen tulosten perusteella terveyden edistämistä on aiheellista tehostaa, jotta voidaan ehkäistä liiallista painonnousua raskauden aikana ja

heti sen jälkeen. Raskauteen liittyvää liiallista painonnousua ehkäisemään pyrkivän interventiotutkimuksen protokolla oli enimmäkseen hyvin toteuttavissa perusterveydenhuollossa. Koska interventiolla havaittiin olevan myös hyödyllisiä vaikutuksia, tämän tutkimuksen tulokset kannustavat tekemään laajempia vastaavia tutkimuksia perusterveydenhuollossa.

1 INTRODUCTION

Overweight and obesity are risk factors for a large number of health problems such as type 2 diabetes mellitus, cardiovascular diseases, certain types of cancer and various psychosocial problems (World Health Organization 2004). The total health and economic consequences of overweight and obesity are significant, as the prevalence of overweight and obesity is high and increasing steadily worldwide. In Finland, 43% of women and 57% of men were overweight or obese (BMI ≥25 kg/m²) according to the latest population based postal survey (Helakorpi et al. 2008). These proportions may still be underestimations due to self-reported data on weight and height. Treatment of obesity is difficult, since many people fail to maintain the achieved weight loss in the long term (World Health Organization 2004, Sarlio-Lähteenkorva et al. 2000, Lahti-Koski et al. 2005). Furthermore, treatment of obesity is expensive and health care systems will not be able to offer treatment for all overweight and obese people. Therefore, preventing the development of overweight and obesity is the primary strategy for solving this public health problem.

Among women, higher parity has been associated with higher BMI (Heliövaara & Aromaa 1981, Brown et al. 1992), although the association is much weaker than the association between aging and weight gain (Brown et al. 1992). In any case, pregnancy and postpartum periods are among the critical stages of life cycle when an individual is at a higher risk of developing overweight (Johnson et al. 2006). Although the average weight retention after a pregnancy is small, ranging from 0.5 to 3 kg in different study populations (Gunderson & Abrams 2001, Gore et al. 2003), the variation is remarkable and 15-25% of women retain at least 5 kg after a pregnancy (Öhlin & Rössner 1990, Olson et al. 2003). The most important risk factor for high postpartum weight retention is excessive weight gain during pregnancy (Gunderson & Abrams 2000, Gore et al. 2003), which is common among pregnant women (Siega-Riz et al. 2004). Additionally, high gestational weight gain is a risk factor for several pregnancy complications (Abrams et al. 2000). Little information has been published on gestational weight gain and postpartum weight retention in Finnish women (Erkkola et al. 1998). In addition, it is not known whether the average gestational weight gain has changed in recent decades, possibly contributing to the increased prevalence of overweight in women.

Due to the adverse consequences of excessive gestational weight gain and postpartum weight retention, strategies to prevent adverse weight development during and after pregnancy should be examined (Gore et al. 2003, Siega-Riz et al. 2004). The evidence on the role of diet and physical activity in gestational weight gain and postpartum weight retention is still limited (Siega-Riz et al. 2004). However, there is convincing evidence that regular physical activity and healthy diet with high intake of dietary fibre and low intake of energy-dense micronutrient-poor foods are related to lower weight gain in general population (World Health Organization 2003).

Information on the dietary intake of pregnant and postpartum women in Finland is limited and partly contradictory (Erkkola et al. 1998, Hoppu et al. 2000, Arkkola et al. 2006). These studies suggest that the diet of pregnant and postpartum women contains less fibre and more fat and sucrose on average than recommended (Hasunen et al. 2004, Nordic Council of Ministers 2004), but this is typical for all women in this age group (Männistö et al. 2003). There are no studies available describing physical activity habits among pregnant and postpartum women in Finland. Studies from other countries have mostly found that physical activity usually decreases during and after pregnancy compared with the time before pregnancy (Mottola & Campbell 2003, Symons Downs & Hausenblas 2004, Whatley Blum et al. 2004, Clarke et al. 2005, Treuth et al. 2005, Pereira et al. 2007, Watson & McDonald 2007). Therefore, many pregnant and postpartum women have the potential to improve their dietary and physical activity habits. On the other hand, pregnancy is often regarded as a good time for behaviour modification (Artal & O'Toole 2003, Hasunen et al. 2004).

Surprisingly few intervention studies have aimed at preventing pregnancy-related weight problems by dietary and physical activity counselling, however, and none of these studies have been carried out in Finland. The interventions conducted among pregnant women have been effective in certain subgroups only, if at all (Gray-Donald et al. 2000, Polley et al. 2002, Olson et al. 2004, Claesson et al. 2008, Wolff et al. 2008). The interventions including postpartum women have had some effect on weight retention but they suffer from small sample sizes and/or high drop-out rates (Leermakers et al. 1998, O'Toole et al. 2003). Therefore, more information is needed on the effect of behavioural interventions to prevent excessive weight gain during pregnancy and to reduce postpartum weight retention.

Before initiating a large intervention study, this dissertation evaluated whether it is feasible to implement such an intervention study in the Finnish maternity and child health care setting. The effects of this pilot study were also examined. Additionally, this dissertation provides information on changes in the average gestational weight gain in Finland since the 1960s.

2 REVIEW OF THE LITERATURE

2.1 Weight development during pregnancy

2.1.1 Definition and characteristics of gestational weight gain

According to the Institute of Medicine (IOM) (1990), there are three approaches to define gestational weight gain: 1) total weight gain (weight just before delivery minus weight just before conception), 2) net weight gain (total weight gain minus the infant's birth weight) or 3) rate per week (weight gained over a specified period divided by the duration of that period in weeks). Unless otherwise stated, gestational weight gain is here defined as the total weight gain during pregnancy. The period for which the total gestational weight gain is computed varies between studies, however (Institute of Medicine 1990). This is mainly due to practical reasons, since it has seldom been possible to obtain information on body weight just before conception or delivery.

The knowledge of the components of total gestational weight gain derives from the calculations of Hytten (1991). He based his theoretical calculations mainly on data from two British studies published in the 1950s (Humpreys 1954, Thompson & Billewicz 1957). In these studies (n=1,000 and n=2,868 respectively), the average total gestational weight gain was 12.5 kg at 40 weeks' gestation in healthy primiparas whose weight gain was not restricted. This average weight gain was composed of products of conception (the foetus 3,400 g, placenta 650 g and amniotic fluid 800 g) and of increases in maternal tissues (the uterus 970 g, breasts 405 g, blood volume 1,450 g, extracellular extravascular fluid 1,480 g if no oedema or only leg oedema and fat tissue 3,345 g) (Hytten 1991). However, the range of gestational weight gain was wide, varying from weight loss to 23 kg or more weight gain. Individual variation in the components of weight gain was also remarkable.

The rate of weight gain is usually slowest during the first trimester of pregnancy, fairly constant during the second and third trimester and slightly slower towards the end of the third trimester (Institute of Medicine 1990, Dawes & Grundzinskas 1991, Hytten 1991, Abrams et al. 1995). Maternal factors (e.g. pre-pregnancy BMI, age and

smoking status) also contribute to the variation observed in the rate of weight gain at different trimesters of pregnancy (Abrams et al. 1995).

2.1.2 Recommendations and associations with maternal and foetal outcomes

The recommendations for optimal gestational weight gain have varied during the past decades (Institute of Medicine 1990). In the USA, a maximum of 8–9 kg weight gain was recommended before the 1960s and a minimum of 11 kg between the 1960s and 1980s for all women during pregnancy. Before the 1960s, the purpose of encouraging restriction of gestational weight gain was to reduce the risk of toxaemia and birth complications associated with larger infants. The weight gain recommendations were liberalized afterwards as caesarean sections became safer and associations between low gestational weight gain and the problems related to low birth weight infants were understood.

The evidence for the association between gestational weight gain and maternal and foetal outcomes was reviewed by the IOM in 1990 (Institute of Medicine 1990). According to this review, there are numerous studies showing that both high and low gestational weight gains are associated with a higher risk of adverse outcomes. Low gestational weight gain increases the risk of a low birth weight infant with elevated risk for neonatal morbidity, developmental problems and mortality. On the other hand, high weight gain increases e.g. the risk of pregnancy complications, prolonged labour, caesarean section and a high birth weight infant (\geq 4,000 g), but also higher maternal postpartum weight retention and subsequent obesity. Between these "low" and "high" weight gains, there seems to be an optimal range for weight gain which is associated with the best maternal and foetal outcomes.

Based on the evidence available, the IOM published new weight gain recommendations for healthy pregnant women with singleton pregnancy in the USA (Institute of Medicine 1990). The European and the Finnish recommendations are similar to the IOM's recommendations (Scientific Committee for Food 1993, Hasunen et al. 2004). These IOM's recommendations were – for the first time – specified by mother's pre-pregnancy BMI group (Table 1), because BMI is a significant modifier of infant's birth weight. Underweight women are more likely to have a low birth weight infant, but the risk is reduced if they gain an appropriate amount of weight during pregnancy. Normal weight women have the lowest risk for delivering a low birth weight or a high birth weight infant. Overweight women have higher risk for developing gestational diabetes mellitus and delivering a high birth weight infant, especially if they gain a lot of weight during pregnancy. On the

other hand, lower weight gain does not affect foetal growth in obese women since the effect of weight gain on birth weight among them is weak. Excessive gestational weight gain is associated with an increase in maternal fat stores rather than being beneficial for foetal growth (Lawrence et al. 1991, Scholl et al. 1995, Lederman et al. 1997, Lederman et al. 1999, Butte et al. 2003). Excessive weight gain may also be related to generalized oedema (Hytten 1991).

TABLE 1. IOM's recommendations for total gestational weight gain by pre-pregnancy BMI¹

Pre-pregnancy BMI (kg/m²)	Recommended total weight gain (kg)
Low (BMI < 19.8)	12.5–18.0
Normal (BMI 19.8-26.0)	11.5–16.0
High (BMI >26.0 to 29.0)	7.0–11.5
Very high (BMI>29.0)	at least 6.8 kg

The cut-off points for these BMI categories correspond to 90, 120 and 135% of the 1959 Metropolitan Life Insurance Company's weight-for-height standards, which have been used in the USA.

The IOM's recommendations are also specified by trimester of pregnancy. During the first trimester, women usually gain weight only 1.0 to 3.5 kg. During the second and the third trimesters, an average weight gain of 0.5 kg per week is recommended for underweight women, 0.4 kg per week for normal weight women and 0.3 kg for overweight women. For young adolescents, IOM recommends weight gain at the upper end of the recommended range because their own growth has not yet ceased. For short adult women (<157 cm), weight gain at the lower end of the range is recommended. Weight gain of 16–20 kg is recommended for women expecting twins.

Later studies have confirmed that gestational weight gain within the IOM's recommendations is associated with the best foetal and maternal outcomes (Parker & Abrams 1992, Cogswell et al. 1995, Lederman et al. 1997, Schieve et al. 1998a, Abrams et al. 2000, Lederman 2001, Thorsdottir et al. 2002, Stotland et al. 2006, Amorim et al. 2007, DeVader et al. 2007, Jain et al. 2007, Rode et al. 2007). Additionally, high gestational weight gain has recently been associated with higher risk of gestational diabetes mellitus in overweight women (Saldana et al. 2006), postmenopausal breast cancer (Kinnunen et al. 2004) and overweight in the offspring (Oken et al. 2007a, Wrotniak et al. 2008). In some studies, the need to revise the recommendations for underweight women (Rode et al. 2007), overweight and obese women (Schieve et al. 1998a, Kiel et al. 2007), all BMI-groups (Cedergren et al. 2007) or specific populations (e.g. Wong et al. 2000, Thorsdottir et al. 2002, Tsukamoto et al. 2007)

has been articulated. The IOM's recommendations have also been criticized for being too high and therefore predisposing the mother to subsequent overweight (Feig & Naylor 1998, Johnson & Yancey 1996).

To achieve the recommended amount of weight gain, extra energy intake is required during pregnancy (Institute of Medicine 1990, Hasunen et al. 2004). The theoretical average extra requirements are negligible during the first trimester, but increase during the second trimester (by 250–350 kcal/d) and third trimester (by 400–500 kcal/d) (Prentice et al. 1996, Butte et al. 2004, Butte & King 2005). The amount of extra energy is controversial, however, especially because of the wide individual variation in factors affecting energy costs of pregnancy, such as gestational weight gain, increase in basal metabolic rate and changes in the amount of physical activity (Abrams 1994, Prentice et al. 1996, Butte et al. 2004, Butte & King 2005). Physical activity level often decreases during pregnancy, which at least partly compensates the increase in energy requirement. Therefore, it is not possible to determine energy requirements for individual women; the best marker of adequate energy intake is appropriate gestational weight gain (Hasunen et al. 2004).

2.1.3 Epidemiology of gestational weight gain

The average total gestational weight gain in singleton pregnancies in adult women has been reported in a number of prospective studies conducted in developed countries during the past decades. Between the 1940s and 1960s, an average total gestational weight gain of 10 kg or less was reported in nationally non-representative studies in the USA (Institute of Medicine 1990). In Britain, the average gestational weight gain was 12.5 kg in the 1950s (Hytten 1991). Later studies have reported higher average weight gains in several countries (Table 2): 13.3–16.1 kg in the 1980s (Institute of Medicine 1990, Abrams & Parker 1990, Öhlin & Rössner 1990, Parker & Abrams 1992, Siega-Riz et al. 1994, Caulfield et al. 1996, Muscati et al. 1996) and 13.6–16.8 kg in the 1990s (Lederman et al. 1997, Erkkola et al. 1998, To & Cheung 1998, Wong et al. 2000, Thorsdottir et al. 2002, Ochsenbein-Kölble et al. 2007). In the 2000s, observations on average gestational weight gain have been more inconsistent, perhaps due to differences in the study populations (Takimoto et al. 2006, Oken et al. 2007a, Tsukamoto et al. 2007, Nohr et al. 2008).

Total gestational weight gain in most of these studies was calculated as the difference between last measured weight during pregnancy and self-reported prepregnancy weight. Lower weight gains were observed in studies in which it was calculated for a shorter period of time from measured weights (Dawes & Grudzinskas

1991, Soltani & Fraser 2000). In some studies, the study population was restricted to women with good pregnancy outcomes (Abrams & Parker 1990, Siega-Riz et al. 1994, Wong et al. 2000, Takimoto et al. 2006) and/or was otherwise selected (Parker & Abrams 1992, Siega-Riz et al. 1994, Muscati et al. 1996, Lederman et al. 1997, Thorsdottir et al. 2002), which also impairs the comparability of these results.

In light of these observations, it seems that average gestational weight gain has increased after the 1960s. However, no studies examining long-term trends in average gestational weight gain have been identified. Schieve et al. (1998) examined trends in gestational weight gain among women attending the Special Supplemental Nutrition Program for Women, Infants and Children in five states in the USA (n=120,531), but only from 1990 to 1996 and information on gestational weight gain was self-reported at the postpartum visit. No significant differences in the average gestational weight gain were reported during this short period.

In addition to comparing the average gestational weight gain in a population, it is interesting and also clinically important to study the proportions of pregnant women gaining weight below, within and above the IOM's BMI-specific recommended range (Institute of Medicine 1990). This is of special importance, since maternal pre-pregnancy BMI has an effect on gestational weight gain. Gestational weight gain is usually highest among underweight or normal weight women and lowest among overweight or obese women, but the variation in weight gain is great, especially among obese women (Abrams & Parker 1990, Institute of Medicine 1990, Dawes & Grudzinskas 1991, Siega-Riz et al. 1994, Bergmann et al. 1997, Erkkola et al. 1998, Tsukamoto et al. 2007, Wong et al. 2000, Olson & Strawderman 2003). Therefore it is difficult to compare the average weight gain in study populations with different mean pre-pregnancy BMI.

Information on the proportion of women exceeding the IOM's BMI-specific recommendations for total gestational weight gain is available only from studies conducted in the USA after the 1980s (Table 2). In these studies, excessive weight gain was observed in 34 to 53% of women. Weight gain was inadequate in 14 to 26% of women and optimal in 28 to 40% of women only. Gestational weight gain was calculated from self-reported pre-pregnancy weight (Caulfield et al. 1996, Carmichael et al. 1997, Lederman et al. 1997, Brawarsky et al. 2005, Stotland et al. 2006, Kleinman et al. 2007, Oken et al. 2007a) or from the weight measured at the first prenatal visit (Olson et al. 2003) to the last measured weight during pregnancy and the populations were relatively comparable to each other. Similar proportions of women with excessive weight gain have been reported in US studies using self-reported gestational weight gain (Schieve et al. 1998b, Keppel & Taffel 1993, Wells et al. 2006).

TABLE 2. Gestational weight gain (GWG) (kg) in adult singleton pregnancies in observational studies in developed countries published since 1990, mean (SD) or proportion (%) of women with excessive GWG¹

Study reference	<u>_</u>	Study population	Information on GWG	GWG (kg), mean (SD) ²	Excessive GWG (%) ¹
Abrams & Parker 1990	4,674	Pregnant women with good pregnancy outcome in California, USA, 1980–1988	Self-reported pre-pregnancy weight, last measured weight	15.0 (5.0)	1
Öhlin & Rössner 1990	2,295	Pregnant women in Stockholm, Sweden, over a one-year period	Self-reported pre-pregnancy weight, last measured weight	14.1 (4.3)	ı
Dawes & Grudzinskas 1991	888	Pregnant women booking <a>20 weeks' and delivering 37–41 weeks' gestation in Oxford, UK, over a one-year period	Measured weight at first prenatal visit, last measured weight	10.7 (4.3)	ı
Parker & Abrams 1992	069'9	Normal weight pregnant women in California, USA, 1980–1988	Self-reported pre-pregnancy weight, last measured weight	15.2 (5.2)	1
Siega-Riz et al. 1994	5,854	Pregnant women without diabetes or hypertension, predominantly low-income, Hispanic immigrants in California, USA, 1983–1986	Self-reported pre-pregnancy weight, last measured weight	14.0 (5.3)	I
Caulfield et al. 1996	2,617 black, 1,253 white	Black and white pregnant women in Maryland, USA, 1987–1989	Self-reported pre-pregnancy weight, last measured weight	black: 13.3 (6.8) white: 15.1 (5.7)	black: 34 white: 43
Muscati et al. 1996	371	Healthy low-income non-smoking pregnant women with good pregnancy outcome in Prince Edward Island, Canada, 1979–1989	Pre-pregnancy weight from family physicians' records, last measured weight	16.1 (6.4)	1
Carmichael et al. 1997	4,218	Pregnant women with good pregnancy outcome in California, USA, 1980–1990	Self-reported pre-pregnancy weight, last measured weight	I	433
Lederman et al. 1997	196	Healthy non-smoking pregnant women in New York City, USA, 1991–1993	Self-reported pre-pregnancy weight, measured weight at 37 weeks' gestation	13.6 (6.1)	393
Erkkola et al. 1998	118	Healthy pregnant women in Oulu, Finland, 1995–1996	Self-reported pre-pregnancy weight, last measured weight	14.0 (4.6)	1
To & Cheung 1998	292	Middle-class, non-smoking women with uncomplicated, full-term pregnancy in Hong Kong, China	"Recorded" weights before pregnancy and delivery	14.1 (3.8)	1

ı	I	I	42	53	43	I	25	I	I	I	I
10.9 (4.7)	13.8 (4.2)	16.8 (4.9)	1	1	1	9.9 (4.3)	1	15.5 (5.9)	15.6 (5.4)	9.6 (3.7)	15.1 (5.9)
Measured weight at 13 and 36 weeks' gestation	Self-reported pre-pregnancy weight, measured weight at the time of labour	Self-reported pre-pregnancy weight, other weights from maternity records	Measured weight at first prenatal visit, last measured weight	Self-reported pre-pregnancy weight, weight measured within one week prior to delivery (n=830) or estimated weight for the time of delivery (n=270)	Self-reported pre-pregnancy weight, last measured weight	Pre-pregnancy weight and weight at delivery, but not reported whether self-reported or measured	Self-reported pre-pregnancy weight, last measured weight	Self-reported pre-pregnancy weight, last measured weight	Self-reported pre-pregnancy weight, last measured weight	Self-reported pre-pregnancy weight, last measured weight	Self-reported gestational weight gain in a telephone interview 6 months postpartum
Pregnant women in Sheffield, UK	Pregnant women with good pregnancy outcome in a developed community in Hong-Kong, China, in 1997	Healthy normal weight pregnant women in Iceland, in 1998	Healthy adult women with a term infant in New York, USA, over a two-year period	Pregnant women with a term infant in California, USA	All women delivering a term infant in California, USA, 1980–2001	Pregnant women with low-risk pregnancy and term vaginal delivery in Japan, 2001–2002	Pregnant women in Massachusetts, USA, 1999–2003	Pregnant women attending an antenatal outpatient clinic in a university hospital in Zurich, Switzerland, 1996–2000	Pregnant women in Massachusetts, USA, 1999–2003	Pregnant women with term infant in Tokyo, Japan, 2002–2003	Pregnant women in Denmark, 1996–2002
77	504	614	540	1,100	20,465	46,659	2,014	4,034	1,044	3,071	60,892
Soltani & Fraser 2000	Wong et al. 2000	Thorsdottir et al. 2002	Olson et al. 2003	Brawarsky et al. 2005	Stotland et al. 2006	Takimoto et al. 2006	Kleinman et al. 2007	Ochsenbein-Kölble et al. 2007	Oken et al. 2007a	Tsukamoto et al. 2007	Nohr et al. 2008

Range of GWG was reported by Öhlin & Rössner 1990 (-2.5–35 kg), Lederman et al. 1997 (-7.2–37.7 kg), To & Cheung 1998 (1.0–25.0) and Tsukamoto et al. 2007 (-9.6–24.0 kg) Based on IOM's recommendations

Calculated from the proportions reported by BMI groups

2.1.4 Risk factors for excessive gestational weight gain

Diet

Most of the past research has focused on diet as a determinant of inadequate gestational weight gain and a low birth weight child (Siega-Riz et al. 2004). Surprisingly few studies have been published investigating the associations between diet during pregnancy and average or, particularly, excessive gestational weight gain. Based on data available by 1990, the IOM concluded that energy intake is a determinant of gestational weight gain, although the observed relationship is tenuous (Institute of Medicine 1990). The IOM emphasizes the difficulty of detecting small changes in energy intake during pregnancy and taking possible changes in physical activity simultaneously into account.

Observational studies have subsequently found an association between higher energy intake and higher gestational weight gain, except for one study involving 103 US pregnant women (Stein et al. 1998). In a study including 156 German women, the mean net weight gain was about 1.5 kg greater among women in the medium and highest thirds of mean energy intake during pregnancy than among women in the lowest third (Bergmann et al. 1997). Another study involving 224 US women observed that gestational weight gain by 27 weeks' gestation was positively related to energy intake during the second trimester of pregnancy (Lagiou et al. 2004). One Icelandic study (n=406) found that a higher energy intake in late pregnancy or an increase in the energy intake from early to late pregnancy were associated with higher gestational weight gain, but among overweight women only (Olafsdottir et al. 2006a). Recently, the association of energy density (kcal/g food and caloric beverages consumed) and glycaemic load (dietary glycaemic index multiplied by the amount of carbohydrate intake) to gestational weight gain was explored among 1,231 US women (Deierlein et al. 2008). Higher energy density at 26-29 weeks' gestation was associated with higher total gestational weight gain, whereas glycaemic load was not associated with it.

Two of these studies reported the associations between gestational weight gain and the intake of macronutrients, either as energy-adjusted means (Lagiou et al. 2004) or as percentages of energy intake (E%) (Olafsdottir et al. 2006a). A lower intake or a decrease in the intake of carbohydrates during pregnancy was consistently related to higher gestational weight gain. Weight gain correlated positively with the intake of total fat (Olafsdottir et al. 2006a) and animal fat (Lagiou et al. 2004), but not with the intake of vegetable fat (Lagiou et al. 2004). The findings concerning the association between protein intake and gestational weight gain were also

inconsistent, as a positive correlation was observed in the first study (Lagiou et al. 2004) but no association was reported in the second study (Olafsdottir et al. 2006a). Additionally, a decrease in fibre intake (per 10 MJ) during pregnancy was associated with excessive weight gain in one of the studies (Olafsdottir et al. 2006a). In that study, all associations between diet and gestational weight gain were observed among overweight women only.

An increase in the amount of food during pregnancy has also been associated with greater mean weight gain and/or higher risk for excessive gestational weight gain (Olson & Strawderman 2003, Olafsdottir et al. 2006a). In a sample of 622 US pregnant women, those consuming two or less portions of fruit and vegetables per day exceeded the weight gain recommendations more often than other women (Olson & Strawderman 2003). Drinking more milk and eating more sweets was related to the risk of excessive weight gain in the Icelandic study (Olafsdottir et al. 2006a).

In these studies, the methods of collecting data on dietary intake were very heterogeneous. The most valid methods were the weighed 7-day food records at each pregnancy trimester used by Bergmann et al. (1997) and the validated semi-quantitative food frequency questionnaires (FFQ) used in three of the studies (Lagiou et al. 2004, Olafsdottir et al. 2006a, Deierlein et al. 2008). In the other studies, dietary data were collected by one 24-hour dietary recall twice during pregnancy (Stein et al. 1998) or by a mailed questionnaire including crude multiple-choice questions (Olson & Strawderman 2003). Additionally, definitions of gestational weight gain were very variable and information on physical activity during pregnancy was only reported in two of the studies (Olson & Strawderman 2003, Deierlein et al. 2008), and in one of them at a very crude level (Olson & Strawderman 2003). However, the results suggest that the intake of energy and fat is positively associated whereas the intake of carbohydrates and fibre is negatively associated with gestational weight gain.

Physical activity

Based on two review articles, earlier studies on physical activity during pregnancy have mostly focused on its possible adverse effects for the developing fetus or the mother (Sternfeld 1997, Stevenson 1997). Three other review articles concluded that there is little valid information available on the impact of physical activity on weight development during pregnancy (Rössner 1999, Siega-Riz et al. 2004, Morris & Johnson 2005).

Observational studies have yielded conflicting results. In the study by Olson & Strawderman (2003) (n=622), women who reported having reduced the amount of physical activity during pregnancy had higher average gestational weight gain and higher risk for excessive weight gain. One Norwegian study (n=467) observed that women who exercised vigorously less than 20 min once a week during the third trimester had greater weight gain than physically more active women (Haakstadt et al. 2007). In a Swedish study (n=223), higher pre-pregnancy physical activity level was related to lower rate of weight gain during the third trimester, but not during the second trimester of pregnancy (Löf et al. 2008). Other studies (n=56 to 388) have found no association between physical activity and weight gain during pregnancy (Langhoff-Roos et al. 1987, Sternfeld et al. 1995, Horns et al. 1996, Butte et al. 2004, Watson & McDonald 2007).

The accuracy of data collected on the amount of physical activity has varied from a crude estimate of changes in physical activity during pregnancy (Olson & Strawderman 2003) to measurements of basal metabolic rate and total energy expenditure by using respiration calorimetry and doubly labelled water (Butte et al. 2004). Most of the studies also used different criteria to categorize the women based on their level on physical activity. The type, amount, duration and intensity of total physical activity and pre-pregnancy fitness level should all be taken into account when assessing the association with physical activity and gestational weight gain (Morris & Johnson 2005). As only two of the studies collected data on dietary intake, using 3-day food records (Langhoff-Roos et al. 1987) or 8-day weighed food records (Watson & McDonald 2007), differences in dietary intake may have confounded the relationship between physical activity and gestational weight gain in the other studies. More studies with larger, more representative study populations and valid methods to measure physical activity, energy expenditure and dietary intake are needed to show whether physical inactivity during pregnancy is associated with higher risk of excessive gestational weight gain.

Other factors

Pre-pregnancy BMI seems to be the most important maternal factor affecting the risk of gaining excessive weight during pregnancy. Several studies suggest that overweight and obese women (BMI>26 kg/m²) are more likely to gain weight in excess of the IOM's recommendations (Carmichael et al. 1997, Lederman et al. 1997, Strychar et al. 2000, Olson & Strawderman 2003, Brawarsky et al. 2005, Wells et al. 2006). As the IOM did not specify an upper limit of recommended weight gain

for obese women, the same recommendations were used for overweight and obese women in all except one of these studies (Lederman et al. 1997). In these studies, as many as 45 to 83% of overweight and 41 to 57% of obese women exceeded their recommendations, while the corresponding proportions among underweight and normal weight women were 11 to 38% and 35 to 52%. In one study, the overweight women had a 1.9-fold and obese women 1.5-fold risk for excessive gestational weight gain compared to normal weight women (Caulfield et al. 1996). This is not contradictory with the fact that the average gestational weight gain is usually lower among overweight and obese women than among lighter women (Abrams & Parker 1990, Institute of Medicine 1990, Dawes & Grudzinskas 1991, Siega-Riz et al. 1994, Bergmann et al. 1997, Wong et al. 2000, Olson & Strawderman 2003, Tsukamoto et al. 2007, Deierlein et al. 2008), because the weight gain recommendations are lower for overweight and obese women. Some studies have suggested that higher level of hormones associated with obesity such as leptin (Stein et al. 1998), insulin (Scholl & Chen 2002) and ghrelin (Palik et al. 2007) could be associated with higher gestational weight gain.

There is convincing evidence that parity has some effect on gestational weight gain. Nulliparous women usually gain more weight during pregnancy and exceed the IOM's weight gain recommendations more often than women with one or more previous deliveries (Abrams & Parker 1990, Dawes & Grudzinskas 1991, Caulfield et al. 1996, Harris et al. 1997, Brawarsky et al. 2005, Wells et al. 2006). Information on the effect of maternal age on excessive gestational weight gain is more contradictory. One study reported higher mean weight gain among older (>25 years) than among younger women (<20 years) (Dawes & Grudzinskas 1991), but three other studies found no association (Abrams & Parker 1990, Strychar et al. 2000, Wells et al. 2006). It has been suggested that women under the age of 18 years should be excluded from such studies as their own growth may cause bias in the assessment of gestational weight gain (Gunderson & Abrams 2000). However, they were excluded in one of these studies only (Strychar et al. 2000).

Stopping smoking in early pregnancy has been associated with higher average weight gain (Öhlin & Rössner 1990) and a greater risk for excessive weight gain (Mongoven et al. 1996, Olafsdottir et al. 2006b). However, this association did not remain statistically significant in the study by Olafsdottir et al. (2006b) when adjusted for dietary variables such as eating more food, drinking more milk and eating more sweets, which have been associated with excessive weight gain (Olafsdottir et al. 2006a). As stopping smoking before or during pregnancy is extremely important for foetal and maternal health, women who stop smoking should be provided with guidance to avoid excessive gestational weight gain.

The results concerning the association between education level and gestational weight gain are contradictory. Two studies, using self-reported information on gestational weight gain, observed that weight gain was more often within the recommended range among the most educated women than among the less educated women (DiPietro et al. 2003, Wells et al. 2006). Another study found that the less educated women had a higher risk of inadequate weight gain, but education was not associated with the risk of excessive weight gain (Caulfield et al. 1996). Other studies have found no association between education and gestational weight gain (Strychar et al. 2000, Brawarsky et al. 2005). Conflicting results have been obtained from studies reporting the association between gestational weight gain and ethnicity (Caulfield et al. 1996, DiPietro et al. 2003, Brawarsky et al. 2005, Wells et al. 2006) or various psychosocial factors such as social support, stress, depression, attitudes and self-efficacy (Copper et al. 1995, Conway et al. 1999, Strychar et al. 2000, DiPietro et al. 2003, Olson & Strawderman 2003). All of these studies were conducted in the USA except for two studies conducted in Canada (Strychar et al. 2000) or the UK (Conway et al. 1999).

2.2 Weight development after pregnancy

2.2.1 Definition and consequences of postpartum weight retention and weight loss

After delivery, some weight loss occurs rapidly when the extra fluids deposited during pregnancy are lost (Institute of Medicine 1990). The extra maternal tissues, particularly fat tissue, may be lost more slowly or partly retained. In epidemiological studies, postpartum weight retention is usually defined as the difference between weight at a certain postpartum time point and weight before pregnancy (Gunderson & Abrams 2000, Amorim et al. 2007, Schmitt et al. 2007). There is no consensus in the literature on an ideal time to return to pre-pregnancy weight or a cut-off point for excessive weight retention (Amorim et al. 2007). It has been suggested that the time period for assessing postpartum weight retention should be restricted to 12 or at maximum to 18 months after delivery because life-style related reasons are much more likely than biological reasons to have an effect on body weight after that (Schmitt et al. 2007). In fact, some women gain additional weight during the first year after delivery (Öhlin & Rössner 1990). When postpartum weight retention is assessed within a limited period (e.g. 12 months after delivery), the effect of aging on weight development and therefore the need for a control group of nulliparous

women is minimal (Gunderson & Abrams 2000). Additionally, when assessing the amount of weight retention, focusing on adult pregnancies removes the bias of excess weight increase related to the growth of teenage mothers.

High postpartum weight retention is undesirable, since it predisposes women to long-term weight gain and risk of overweight as shown in a Swedish (Linne et al. 2004) and a US study (Rooney et al. 2005) with 15-year follow-up after delivery. Consequently, higher weight gain during the follow-up period also predicted higher risk of obesity-related diseases such as type 2 diabetes and coronary heart disease (Rooney et al. 2005).

The energy requirements of postpartum women depend on their body size, the duration and intensity of breastfeeding and the level of physical activity (Butte & King 2005). As Butte and King concluded in their review, the average energy costs of exclusive breastfeeding are 2.62 MJ (627 kcal) per day. In well-nourished women, approximately one fourth of this increase in energy requirements is usually mobilized from maternal tissues whereas the rest is covered by diet. On the other hand, a moderate weight loss of 0.5 kg/week by restricting dietary intake and increasing physical activity seems to be safe for breastfeeding women as it does not affect the growth of the infant (Lovelady et al. 2000). The average energy deficit needed to achieve this rate of weight loss was 2.27 MJ (544 kcal) per day in that study. The magnitude of the total energy deficit needed to return to pre-pregnancy weight naturally depends on the amount of weight retained.

2.2.2 Epidemiology of postpartum weight retention

As reviewed by Rössner and Öhlin (1995), the mean postpartum weight retention varied from 0.5 to 2.4 kg in studies published before 1990. However, the follow-up period varied from 6 weeks to 2 years postpartum and in some studies the weight changes were measured between two consecutive pregnancies. Table 3 shows later studies reporting the mean postpartum weight retention during a fixed follow-up period of up to 12 months postpartum in adult singleton pregnancies in observational studies in developed countries. In these studies, the mean weight retention decreased continuously with time, being 0.6 to 2.5 kg at 12 months postpartum, but only three of the studies reported weight retention at more than one time point (Janney et al. 1997, To & Cheung 1998, Soltani & Fraser 2000). In general, the mean weight retention was lower at each time point in the studies using the first measured weight during pregnancy instead of self-reported pre-pregnancy weight as the baseline and

in studies using self-reported pre-pregnancy and postpartum weights (Table 3). Otherwise the study populations were fairly well comparable to each other.

Similar conclusions were drawn in a recent systematic review and meta-analysis of studies published between 1995 and 2005, although the change in BMI compared to pre-pregnancy BMI was used as a measure of postpartum weight retention in this meta-analysis (Schmitt et al. 2007). Concerning the validity of the findings, Schmitt et al. found that the average postpartum weight retention was lowest in studies with at least 80% follow-up rate. They concluded that the true average weight retention could actually be even lower than observed in the meta-analysis because women with lower weight retention were more likely to withdraw from the study than women with higher weight retention.

Although the amount of weight retained after pregnancy is small on average, the range of retention is wide regardless the length of the follow-up period or definition of the baseline weight (Table 3). Above all, it is clinically significant that a subgroup of women retains much larger amounts of weight after pregnancy than women on average (Öhlin & Rössner 1990, Olson et al. 2003).

Few studies have examined the proportion of women who return at least to their pre-pregnancy weight after delivery. In studies using the first measured weight during pregnancy as the baseline, 37% of women returned to that weight within 6 months (Schauberger et al. 1992) and 42% within 12 months postpartum (Olson et al. 2003), whereas 30% of women only returned to their self-reported pre-pregnancy weight by 12 months postpartum (Öhlin & Rössner 1990). None of the studies in Table 3 reported changes in the average waist circumference after delivery.

TABLE 3. Postpartum weight retention (PPWR) (kg) up to 12 months postpartum in adult singleton pregnancies in developed countries in observational studies published since 1990, mean (SD)

Study reference	<u>_</u>	Study population	Information on PPWR	Postpartum follow-up	PPWR (kg), mean (SD)	Range of PPWR (kg)
Jenkin & Tiggemann 1997	92	Primiparous postpartum women in Adelaide, Australia	Self-reported pre-pregnancy and postpartum weight	1 month	4.9 (–)	-5-23
Muscati et al. 1996	371	Healthy, white, non-smoking low-income women with uncomplicated full-term pregnancy in Prince Edward Island, Canada, 1979–1989	Pre-pregnancy weight from family physicians' records, measured postpartum weight	6 weeks	5.3 (5.7)	-8.2–27.7
To & Cheung 1998	292	Middle-class, non-smoking women with uncomplicated, full-term pregnancy in Hong Kong, China	"Recorded" pre-pregnancy and postpartum weights	6 weeks	6.8 (3.3)	-2.0–17.0
Sampselle et al. 1999	1,003	White, Asian and African American women in a Midwestern tertiary care centre in the USA, 1988–1992	Self-reported pre-pregnancy weight, measured postpartum weight	6 weeks	4.8 (–)	ı
Soltani & Fraser 2000	47	Women in Sheffield, UK	Weight measured at the first prenatal visit, measured postpartum weight	6 weeks	2.7 (5.0)	1
Janney et al. 1997	107	Healthy women with uncomplicated full-term pregnancies in Michigan, USA	Self-reported pre-pregnancy weight, measured postpartum weight	2 months	5.8 (0.4)	-5.1–16.8
To & Cheung 1998	292	Middle-class, non-smoking women with uncomplicated, full-term pregnancies in Hong Kong, China	"Recorded" pre-pregnancy and postpartum weights	3 to 4 months	3.6 (2.8)	-2.0–13.0
Janney et al. 1997	105	Healthy women with uncomplicated full-term pregnancies in Michigan, USA	Self-reported pre-pregnancy weight, measured postpartum weight	4 months	4.7 (0.4)	-5.8–15.5
Schauberger et al. 1992	795	White, middle-class postpartum women in Wisconsin, USA, 1989–1990	Weight measured at the first prenatal visit, measured postpartum weight	6 months	1.4 (4.8)	I

Janney et al. 1997	105	Healthy women with uncomplicated full-term pregnancies in Michigan, USA	Self-reported pre-pregnancy weight, measured postpartum weight	6 months	3.9 (0.4)	-7.5–15.1
Soltani & Fraser 2000	47	Women in Sheffield, UK	Weight measured at the first prenatal visit, measured postpartum weight	6 months	1.1 (6.0)	1
Rooney & Schauberger 2002	795	White middle-class women with uncomplicated pregnancies in Wisconsin, USA, 1989–1990	Weight measured at the first prenatal visit, measured postpartum weight	6 months	1.7 (–)	I
Nohr et al. 2008	60,892	Postpartum women in Denmark, 1996–2002	Self-reported pre-pregnancy and postpartum weights in a telephone interview	6 months	1.4 (4.8)	1
Öhlin & Rössner 1990	1,423	Postpartum women in Stockholm area, Sweden, during one year	Self-reported pre-pregnancy weight, measured postpartum weight	12 months	1.5 (3.6)	-12.3–26.5
Janney et al. 1997	96	Healthy women with uncomplicated full-term pregnancies in Michigan, USA	Self-reported pre-pregnancy weight, measured postpartum weight	12 months	2.5 (0.5)	-8.3–13.5
Olson et al. 2003	540	Healthy women with full-term pregnancy in New York, USA, over a two-year period	Weight measured at the first prenatal visit, measured postpartum weight	12 months	1.5 (5.9)	-19.1–27.5
Oken et al. 2007b	905	Postpartum women in Massachusetts, USA, 1999–2003	Self-reported pre-pregnancy and postpartum weights	12 months	0.6 (–)	-17.3–25.5

Diet

Only a few observational studies have investigated the association between diet and postpartum weight retention. Three of these studies observed that women who increased their food intake after pregnancy retained more weight than other women (Öhlin & Rössner 1994, Harris et al. 1999, Olson et al. 2003). The first study followed 1,423 Swedish women from the beginning of pregnancy until 12 months postpartum (Öhlin & Rössner 1994). Weight retention was greater in women who increased their meal sizes and/or snacking frequency during and after pregnancy (a rough estimate of changes in energy intake), who increased their snack frequency to three or more snacks per day after pregnancy, or who decreased their lunch frequency starting during or after pregnancy.

Harris et al. (1999) conducted a follow-up on average of 2.6 years after delivery for women who had participated in a randomized controlled trial of antenatal care during pregnancy in the UK. Of the original study population (n=2,893), 486 women were interested in participating in the follow-up, but only 74 women were considered eligible for the study. Women who felt they had eaten more after delivery were 2.8 kg heavier at follow-up than before pregnancy whereas women who felt they had not eaten more had lost 1.2 kg weight during the same period. A similar relationship was found between weight retention and having had greater access to food postpartum.

The study by Olson et al. (2003) involved 540 women in the USA, who were followed up until 12 months postpartum. Women who had maintained or increased their food intake during the last six months retained significantly more weight on average than women who had decreased their food intake. Additionally, women who had increased their food intake, had a 3.5-fold risk for major weight gain (>4.55 kg) at 12 months postpartum.

Other US studies have obtained different results. The association between energy intake and fat E% and weight retention at 7 to 12 months postpartum was studied among 345 black and white women (Boardley et al. 1995). Compared to white women, black women had higher weight retention, mean energy intake and percentage of fat of energy intake. In the multivariable model, however, energy or fat intakes were not independently associated with postpartum weight change. In another study, a higher intake of trans fat increased the risk of retaining at least 5 kg weight at 12 months postpartum (n=902) (Oken et al. 2007b). Energy-adjusted fibre intake was inversely associated and energy-adjusted total fat intake was directly associated with the risk of retaining at least 5 kg, but not after adjustment for the

other one of these two nutrients. The authors propose that trans fat intake may be a marker for other unhealthy dietary habits or other lifestyle behaviours rather than causally associated with weight retention.

One methodological weakness in these studies was that dietary information was collected by very crude multiple-choice questions (Öhlin & Rössner 1994, Harris et al. 1999, Olson et al. 2003) or by a short 21-item FFQ (Oken et al. 2007b) in all except one study that used a validated FFQ (Boardley et al. 1995). There were also differences in the definition of postpartum weight retention. Three of the studies (Öhlin & Rössner 1994, Boardley et al. 1995, Oken et al. 2007b) used self-reported pre-pregnancy weight as the baseline whereas weight measured at the beginning of pregnancy was used as the baseline in two other studies (Harris et al. 1999, Olson et al. 2003). While the other studies used a measured postpartum weight, it was self-reported by questionnaire in the study by Oken et al. (2007b), which weakens the validity of the outcome. There is definitely room for more research with better methods on the relationship between diet and postpartum weight retention. However, these earlier studies indicate that increasing food intake after delivery results in more weight retention 12 months postpartum or later.

Physical activity

The few observational studies examining the association between total level of physical activity and the risk for weight retention at least 12 months postpartum are the same that have reported the associations between diet and postpartum weight retention. In these studies, a lower level of physical activity either during pregnancy (Boardley et al. 1995), after pregnancy (Harris et al. 1999, Olson et al. 2003, Oken et al. 2007b) or during and after pregnancy (Öhlin & Rössner 1994) was consistently associated with more postpartum weight retention.

Information on physical activity was based on self-reports in all of these studies and there was remarkable heterogeneity in the accuracy of the questions related to physical activity. The average weekly durations of activities at different intensity levels was elicited in two of the studies (Boardley et al. 1995, Oken et al. 2007b). Oken et al. also collected information on hours spent watching television, which was a measure of inactivity. The other studies only used multiple-choice questions to collect data on physical activity at work and in leisure time (Öhlin & Rössner 1994), the frequency and duration of walking and vigorous exercise (Olson et al. 2003) or changes in activity patterns after pregnancy compared to patterns before pregnancy

(Harris et al. 1999). There was also variation in the definition of weight retention in these studies.

In conclusion, the observational studies suggest that a lower level of physical activity during and/or after pregnancy is associated with more weight retention at 12 months postpartum. Nevertheless, there are several methodological factors that make comparison of these studies difficult. As Larson-Meyer (2002) has summarized, most of these observational studies did not define or quantify physical activity properly or take the feeding method of the infant into account and the trials included only breastfeeding women. Therefore, more studies are needed to accurately determine the association between total level physical activity and postpartum weight retention.

Other factors

High gestational weight gain or weight gain above the IOM's recommendations has consistently been regarded as the strongest risk factor for high postpartum weight retention in studies with various follow-up periods (Öhlin & Rössner 1990, Schauberger et al. 1992, Keppel & Taffel 1993, Parker & Abrams 1993, Boardley et al. 1995, Muscati et al. 1996, Thorsdottir & Birgisdottir 1998, Gunderson et al. 2000, Butte et al. 2003, Olson et al. 2003, Walker et al. 2004, Nohr et al. 2008). Timing of gestational weight gain may also be of importance since high weight gain in early pregnancy (<20 weeks' gestation) especially increases the risk for higher postpartum weight retention (Muscati et al. 1996).

Instead, the findings with respect to pre-pregnancy BMI as a risk factor for postpartum weight retention are inconsistent. Three studies found no association between pre-pregnancy weight or BMI and postpartum weight retention (Öhlin & Rössner 1990, Muscati et al. 1996, Olson et al. 2003). In other studies, a higher pre-pregnancy weight predicted more weight retention by 7 to 12 months postpartum (Boardley et al. 1995) and less weight loss after delivery in a median of 2 years follow-up (Gunderson et al. 2001). Additionally, as weight retention is more variable among overweight and obese women, a subgroup of them retains excessively weight associated with pregnancy (Öhlin & Rössner 1990). Two obesity-related hormones that have been associated with gestational weight gain seem also to predict postpartum weight retention. Higher levels of leptin (Stein et al. 1998) and insulin (Scholl & Chen 2002) at the beginning of pregnancy have been related to greater weight retention, even when adjusted for gestational weight gain (Scholl & Chen 2002).

Findings related to maternal age and parity as risk factors for postpartum weight retention are contradictory. Studies have reported higher postpartum weight retention in various age groups (Öhlin & Rössner 1990, Janney et al. 1997, Walker et al. 1997, Gunderson et al. 2000, Olson et al. 2003) or no association at all (Parker & Arbrams 1993). Some studies have failed to show any association between parity and postpartum weight retention (Öhlin & Rössner 1990, Schauberger et al. 1992, Muscati et al. 1996) and other studies have reported mixed results (Parker & Abrams 1993, Boardley et al. 1995, Harris et al. 1997, Walker et al. 1997). The time period between two consecutive pregnancies seems not to be related to postpartum weight retention (Schauberger et al. 1992, Linne & Rössner 2003) or risk of becoming overweight before the second pregnancy (Gunderson et al. 2000).

Breastfeeding is often considered to promote postpartum weight loss, since milk production increases maternal energy expenditure (Butte & King 2005). However, the observed association between breastfeeding and postpartum weight development has been surprisingly weak or absent in most studies. In some studies, women breastfeeding for at least 12 months retained less weight (Janney et al. 1997, Olson et al. 2003) or lost more weight by 12 months after delivery (Dewey et al. 1993) than other women. Additionally, ceasing breastfeeding or switching from exclusive to partial breastfeeding reduced the rate of postpartum weight loss (Janney et al. 1997). In one study, women with higher breastfeeding score lost more weight on average than women with lower score by 6 months but not by 12 months postpartum (Öhlin & Rössner 1990). Many other studies have found no association between breastfeeding and postpartum weight retention or weight loss by 6 to 12 months postpartum (Schauberger et al. 1992, Boardley et al. 1995, Rooney & Schauberger 2002, Wosje & Kalkwarf 2004).

These contradictory findings may be related to e.g. inadequate measures of the duration and intensity of breastfeeding, small sample sizes and inclusion of non-breastfeeding women who restricted their energy intake in order to lose weight (Gunderson & Abrams 2000). On the other hand, there is some evidence that dietary intake is greater among breastfeeding women than non-breastfeeding women, probably due to increases in appetite stimulating prolactin levels (Lederman 2004). Additionally, breastfeeding women may decrease their total level of physical activity. Bearing these aspects in mind, breastfeeding may have a small effect on reducing postpartum weight retention if it is continued for at least 6 months postpartum (Gore et al. 2003, Lederman 2004).

Regarding smoking status, women who stopped smoking in early pregnancy and did not continue smoking after delivery retained more weight on average at 12 months postpartum than smokers and non-smokers in the study by Öhlin and

Rössner (1990). Mixed results were obtained from two other studies comparing smokers to non-smokers (Schauberger et al. 1992, Gunderson et al. 2000). In these studies, women who had stopped smoking were probably classified as non-smokers, which could have affected the results. In any case, while regarding former smokers as a risk group for higher postpartum weight retention, smoking cessation should be promoted among pregnant and postpartum women.

Shorter duration of sleep has been linked to decreased leptin levels, increased ghrelin levels, increased hunger and appetite and obesity in general population (Sarwer et al. 2006). As many postpartum women suffer from sleep deprivation, this might increase their risk for weight retention as suggested by this review article (Sarwer et al. 2006). Gunderson et al. (2008) recently reported that women who slept ≤5 hours/d at 6 months postpartum had 2 to 3-fold risk for retaining at least 5 kg weight at 12 months postpartum compared to women sleeping 7 hours/d, when adjusted for confounders. Addionally, a decrease in sleep duration from 6 to 12 months postpartum doubled the risk of retaining at least 5 kg at 12 months postpartum. More studies are needed to confirm these results and to examine whether duration of sleep is associated with dietary and physical activity habits among postpartum women.

Concerning other potential risk factors of postpartum weight retention, such as socioeconomic status, marital status, psychosocial factors or ethnicity, the findings are contradictory. Lower socioeconomic status (Parker & Abrams 1993), lower education level (Gunderson et al. 2008), lower income (Walker et al. 1997, Gunderson et al. 2008) or not resuming paid work by 6 months (Schauberger et al. 1992) were associated with higher weight retention in some studies, but not in all (Öhlin & Rössner 1994, Gunderson et al. 2000, Olson et al. 2003). In some studies, single women have had higher risk for weight retention (Olson et al. 2003, Gunderson et al. 2008), whereas other studies have found no association between marital status and weight retention (Öhlin & Rössner 1994, Gunderson et al. 2000). Maternal depressive symptoms were related to higher weight retention (Walker 1997, Gunderson et al. 2008), except for the study by Harris et al. (1999). Low social support may also increase the risk of weight retention (Walker et al. 1997, Harris et al. 1999) whereas stress related to the new life situation may not (Walker 1996, Walker 1997, Harris et al. 1999). Results from comparisons of weight retention in different ethnic groups are not consistent but indicate that black women retain more weight postpartum than white women on average (Keppel & Taffel 1993, Parker & Abrams 1993, Boardley et al. 1995, Gunderson et al. 2000, Gunderson et al. 2008). Finally, the results concerning these various risk factors may have been inconsistent partly because of differences e.g. in the study populations, but also because only some of the studies took confounding factors into account in the analyses.

2.3 Lifestyle interventions to prevent excessive pregnancy-related weight gain

2.3.1 During pregnancy

There are five intervention studies that have primarily aimed at examining whether a lifestyle intervention focusing on improving dietary and physical activity habits can prevent excessive gestational weight gain among adult women (Table 4). Additionally, one intervention study has been carried out in the Netherlands, but the results of the study are not yet available (Althuizen et al. 2006).

The first of these studies was conducted among aboriginal Cree women who used the services of prenatal clinics (Gray-Donald et al. 2000). The intervention consisted of several components such as individual dietary counselling, physical activity sessions and other activities related to nutrition. The dietary advice focused on improving the intake of dairy products, fruit and vegetables and decreasing the intake of foods with high-energy density but little nutritional value. The control group was composed of women who were pregnant during the year preceding the intervention. No differences were detected between the intervention and the control groups in gestational weight gain or in diet at 24–30 weeks' gestation, except for a lower caffeine intake in the intervention group. The self-reported usual daily physical activity level was very low in both groups, but a higher proportion of the intervention group than of the control group were sedentary. This study had some methodological limitations, e.g. no baseline data were collected on diet and physical activity and the information on dietary intake was based on a single 24-hour recall in mid pregnancy.

Polley et al. (2002) conducted a randomised controlled trial in which a stepped-care behavioural intervention was compared with usual care at an obstetric clinic serving low-income women. The dietary counselling focused on reducing the intake of high-fat foods and increasing the intake of fruit and vegetables. The importance of increasing walking and having a more active lifestyle was emphasized in physical activity counselling. Individual weight gain graphs were used to monitor the appropriateness of gestational weight gain. Women who exceeded their weight gain goals at some point during pregnancy participated in additional individualized

dietary and physical activity counselling sessions carried out by nutritionists and psychologists. Dietary information was only collected on the consumption of 13 major contributors to fat intake by using a short FFQ at recruitment and at 30 weeks' gestation. Information on physical activity energy expenditure was collected at the same stages of pregnancy by a questionnaire that took stair-climbing, walking and recreational activities during the last week into account. The intervention decreased the proportion of normal weight women gaining weight in excess of the IOM's recommendations (33% in the intervention group vs. 58% in the control group, p<0.05), but it had no statistically significant effect on weight gain among overweight women. However, there were no differences in changes in fat intake or in physical activity energy expenditure between the intervention and the control groups.

The third intervention was carried out among 179 women who were registered for obstetric care at a hospital and primary care clinic system in New York, the USA during the period 2000–2001 (Olson et al. 2004). This study used a historical control group (n=381) consisting of pregnant women participating in an observational study in the same area during the period 1995–1997. The intervention consisted of monitoring of weight gain with the help of weight gain grids and written educational material on healthy diet and physical activity during pregnancy. The intervention reduced the proportion of low-income women who gained weight excessively during pregnancy (33% in the intervention group vs. 52% in the control group, p<0.01), but it had no effect on weight gain in high-income women. The effect of the intervention on dietary and physical activity habits of the women is not known since no data were collected on diet or physical activity in this study.

In contrast to these studies, the two most recent trials have included obese women only and aimed at restricting their weight gain to less than 7 kg during pregnancy (Claesson et al. 2008, Wolff et al. 2008). Both of these interventions were effective in reducing weight gain. In the study by Claesson et al. (2008), the intervention included a weekly weight control and a motivational talk (aiming at changing behaviour) by a midwife at an antenatal care clinic and a physical activity component. The average weight gain was 8.7 kg in the intervention group and 11.3 kg in the control group (p<0.001). Additionally, 36% of the intervention group but only 21% of the control group managed to restrict their weight gain to less than 7 kg (p=0.003). No information was collected on changes in dietary or physical activity habits of the participants. The generalization of the results is limited by the facts that this was not a randomized controlled trial and there were differences in the participation rate and the socio-economic status between the groups.

The study by Wolff et al. (2008) focused on examining the effects of an intensive dietary intervention carried out at 10 visits to a trained dietitian. In this intervention,

the obese women were instructed to adhere to a healthy balanced diet and to reduce their energy intake to a level of individually estimated requirements. Information on dietary intake was obtained by 7-day weighed food records three times during pregnancy. The intervention group managed to reduce their energy intake and fat E% and to increase carbohydrate E% and protein E% compared to the control group. As a result, their total weight gain was lower than in the control group (6.6 kg vs. 13.3 kg, p=0.002).

In addition, some of the intervention studies examining primarily the effects of physical activity e.g. on foetal growth or other pregnancy outcomes have also reported the effects of physical activity on gestational weight gain. A meta-analysis including 18 such intervention studies from the 1970s and 1980s suggests that physical activity does not have an effect on gestational weight gain (Lokey et al. 1991). Later studies have reported mixed results (Clapp & Little 1995, Kardel & Kase 1998, Clapp et al. 2000, Marquez-Sterling et al. 2000, Clapp et al. 2002). The inconsistency of the results is obvious as these later studies have been remarkably heterogeneous and have usually had several methodological problems, such as small (n=15–79, drop-out 0–8%) and selected study populations in all studies, non-randomized study designs in two studies (Clapp & Little 1995, Kardel & Kase 1998) or lack of information on dietary intake in all except for the study by Clapp & Little (1995).

In conclusion, few previous intervention studies have been conducted primarily to prevent excessive gestational weight gain and have been successful only in selective sub-groups or not at all so far. More research is needed that also addresses the methodological problems present in these studies, related e.g. to non-randomized study designs, selected study populations, and methods to measure diet and physical activity.

TABLE 4. Intervention studies primarily aiming to prevent excessive gestational weight gain (GWG) or to reduce postpartum weight retention (PPWR)

Study reference	- <u>-</u>	Sample	Rando- mization	Interventions	Recom- mendation for weight develop- ment	Information on weight development	Drop- out rate (%)	Effects of the intervention (vs. the control group)
Interventions among pregnant women	regnani	' women						
Gray-Donald et al. 2000	219	Aboriginal Cree women in Quebec, Canada. The control group was pregnant in 1995–1996 and the intervention group 1996–1997.	OL C	Intervention: Several components, e.g. individual dietary counselling, physical activity sessions and other activities related to nutrition Control: Not specified	Not specified	Self-reported pre- pregnancy weight, last measured weight during pregnancy	Not specified	GWG: no effect Diet: Caffeine intake decreased only PA ² : no effect
Polley et al. 2002	110	Low-income women in Pennsylvania, USA	yes	Intervention: A stepped-care intervention, dietary and physical activity counselling, individual graphs for GWG Control: Standard nutrition counselling	IOM ³	Self-reported pre- pregnancy weight, last measured weight during pregnancy	∞	GWG: effective among normal weight women only Diet: no effect PA: no effect
Olson et al. 2004	260	Pregnant women in New York, USA. The control group was pregnant 1995–1997 and the intervention group 2000–2001.	OL C	Intervention: Monitoring and feedback on GWG by using weight gain grids, education on GWG, diet and exercise by mail Control: Not specified	MOI	Measured weight at the first and the last visit during pregnancy	0	GWG: effective among low-income women only Diet: not assessed PA: not assessed
Claesson et al. 2008	348	Obese pregnant women in the southeast region of Sweden, 2003–2005	0	Intervention: Weekly weight control and motivational talks by a midwife and aqua aerobic classes once or twice a week Control: Routine antenatal care	< 7 kg	Measured weight at the first and the last visit during pregnancy	Ŋ	GWG: effective Diet: not assessed PA: not assessed
Wolff et al. 2008	20	Non-diabetic, non-smoking obese pregnant women in Denmark	yes	Intervention: Ten 1-h consultations with a trained dietitian Control: Routine antenatal care, no consultations with the dietitian	6–7 kg	Self-reported pre- pregnancy weight, self-reported weight at delivery	24	GWG: effective Diet: energy intake and fat E% decreased, carbohydrate E% and protein E% increased PA: not assessed

	PPWR: effective Diet: no effect PA1: no effect	PPWR: effective Diet: no effect PA: no effect
	15	14
	Self-reported pre- pregnancy weight, measured weight at the end of the six- month study period	Self-reported pre- pregnancy weight, measured weight at 1 year postpartum
	To return to pre- pregnancy weight	Not specified
	Intervention: A behavioural weight To return loss programme including two to pregroup sessions, correspondence materials and telephone contact weight over six months Control: A leaflet on healthy eating and exercise	Intervention: Individualized diet and activity prescriptions made at one session with a dietitian and an exercise physiologist, group education sessions up to 1 year postpartum Control: One 1-hour educational session on diet and PA
	yes	yes
rtum women	Women with at least 6.8 kg PPWR at 3 to 12 months postpartum in Pittsburgh, USA	Overweight non- breastfeeding women with at least 15 kg gestational weight gain and 5 kg PPWR at 6 weeks to 6 months postpartum in Missouri, USA
ng postpa	62	53
Interventions among postpartum women	Leermakers et al. 1998	O'Toole et al. 2003

Number of women completing the study
 PA, physical activity
 Recommendations by Institute of Medicine (1990)

2.3.2 After pregnancy

There are only two intervention studies that have primarily aimed at reducing postpartum weight retention (Table 4). In the study by Leermakers et al. (1998), the participants were women who had recently delivered in a local hospital. The intervention group was instructed to follow a weight loss diet containing 1,000–1,500 kcal/d and 20 E% of fat and to gradually increase the frequency and duration of their walking to two miles per day on at least five days a week. Information on dietary intake over the past six months was collected by a 60-item FFQ and the level of physical activity was assessed by the same questionnaire as in the study by Polley et al. (2002) at baseline and after the 6-month intervention. The intervention group lost more weight (7.8 kg vs. 4.9 kg, p=0.03) and had less weight retention compared to their pre-pregnancy weight than the control group (3.3 kg vs. 6.3 kg, p=0.05). In addition, 33% of the intervention group and 12% of the control group returned to at least their pre-pregnancy weight.

In the other study, the participants were recruited through advertisements in the local media. At baseline, the intervention group received individual diet and activity prescriptions that were planned to create an energy-deficit of at least 500 kcal/d (O'Toole et al. 2003). The group educational sessions were arranged once a week for the first 12 weeks, then biweekly for the following two months and once a month until the end of the intervention (12 months postpartum). Information on diet and physical activity was collected at baseline, at 12 weeks and at 12 months postpartum by using 3-day food records and a physical activity survey inquiring all activities during a typical week in the previous month. The intervention group lost more weight on average than the control group (7.3 kg vs. 1.3 kg, p<0.05) by 12 months postpartum. No data were reported on what proportion of the women returned to their pre-pregnancy weight.

Neither of these two interventions had any effect on between-group differences in energy intake or expenditure. The main reason for this may be the loss of statistical power due to the high drop-out rates, although the authors emphasize limitations in assessing dietary intake and physical activity accurately.

There are also two US randomized controlled trials lasting at least 10 weeks in which the primary aim was to examine the effect of regular aerobic exercise on the volume and composition of breast milk (Dewey et al. 1994) or the effect of weight loss (by exercising and restricting energy intake) on the growth of the infant (Lovelady et al. 2000). In the trial by Dewey et al. (1994) (n=33), the intervention had no effect on postpartum weight retention as the women in the intervention group compensated for the increased exercise with higher energy intake and by decreasing their non-

exercise physical activity. In the second trial (n=40), the intervention group had less weight retention than the control group (Lovelady et al. 2000).

All of these intervention studies were small and/or had a high drop-out rate. However, it seems that interventions including both a diet and an exercise programme are effective in reducing postpartum retention although no effect on diet and physical activity could be observed in those studies. Although an exercise programme alone was not effective in reducing weight, it is preferable to incorporate physical activity to weight loss programmes since it improves cardiorespiratory fitness and preserves lean body mass (Amorim et al. 2007).

2.4 Summary of the literature

The current recommendations for total gestational weight gain are 12.5–18.0 kg for underweight, 11.5–16.0 kg for normal weight and 7.0–11.5 kg for overweight pregnant women. In many studies, weight gain at the recommended level has been associated with best maternal and foetal outcomes. Excessive gestational weight gain increases the risk for several adverse effects including higher maternal weight retention after delivery (Figure 1). High postpartum weight retention predisposes to long-term overweight.

Estimations on the average total gestational weight gain range from 10 to 17 kg in different study populations with varying mean pre-pregnancy BMI. The individual variation in gestational weight gain is large and some US studies suggest that as many as 40–50% of women exceed the BMI-specific recommendations for weight gain during pregnancy. The amount of postpartum weight retention is also extremely variable, although the average weight retention at one year postpartum is only 0.6–2.5 kg. Some studies suggest that 30–40% of women return to their baseline weight by one year postpartum. Because most studies have used self-reported prepregnancy weight as the baseline weight and this may be underreported, the mean values for gestational weight gain and postpartum weight retention may be slightly overestimated. Information on gestational weight gain and postpartum weight retention among Finnish women is sparse. Additionally, studies describing trends in gestational weight gain or postpartum weight retention in long-term follow-up are lacking in Finland and in other countries.

The potential risk factors for excessive gestational weight gain and/or postpartum weight retention are summarized in Figure 1. The evidence is contradictory for many of these factors, especially concerning the risk for postpartum weight retention. The associations between dietary and physical activity habits and gestational weight gain

and postpartum weight retention are still not clear. Earlier studies have suffered from methodological limitations related e.g. to validity of measurement of diet and physical activity and, particularly, collecting data on both behaviours in the same study. However, the data available suggest that increased energy intake and reduced physical activity energy expenditure are associated with excessive weight gain during and after pregnancy as in the non-pregnant population.

The effect of a lifestyle intervention on the prevention of excessive pregnancy-related weight gain has been examined in a few studies. None of these interventions started at the beginning of pregnancy and continued after delivery. Instead, the studies have included only pregnant or only postpartum women. Interventions aiming to prevent excessive weight gain during pregnancy have been successful in certain subgroups only. The interventions aiming to reduce postpartum weight retention have had some effect, but the results may not be valid due to small sample sizes and/or high drop-out rates.

These previous interventions were conducted in various settings mainly in the USA or in Canada. In most of the studies, lifestyle counselling was carried out by researchers or nutritionists. It is not known how an intervention study including lifestyle counselling could be implemented in the maternity and child health care system in Finland. Therefore, before initiating a large intervention study aiming to prevent excessive pregnancy-related weight gain, it is important to evaluate the feasibility of the planned study protocol in that particular setting.

The meaning of feasibility greatly depends on the context in which it is assessed. Therefore, many previous intervention studies have formulated the questions and criteria for assessing feasibility of their study to suit to their needs (e.g. Story et al. 2002, van Sluijs et al. 2004, Yin et al. 2005, Shah et al. 2006). In fact, most of these studies have assessed feasibility by performing a process evaluation. In process evaluation, what is usually evaluated is whether all parts of the programme (e.g. an intervention study) were implemented as intended and whether the programme reached the targeted participants (e.g. Hawe et al. 1990, Rossi et al. 1999). The purpose of process evaluation is to provide feedback to improve the programme and to serve as a basis for the evaluation of the effectiveness of the programme.

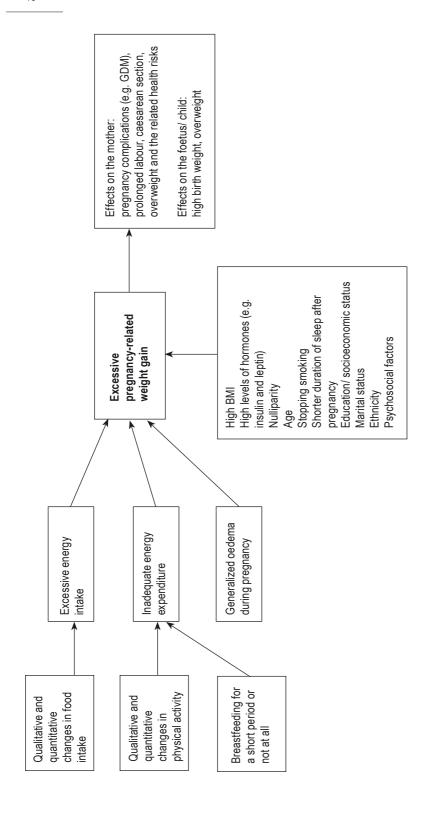


FIGURE 1. Summary of the possible risk factors for and consequences of pregnancy-related weight gain discussed in this literature review

3 AIMS OF THE STUDY

To increase the understanding of the prevention of pregnancy-related overweight among women of childbearing age, this study aimed at assessing trends in the average gestational weight gain in Finland and to evaluate the feasibility and the effects of a lifestyle intervention designed to prevent excessive gestational weight gain and postpartum weight retention.

The specific research questions were:

- 1. Has the average gestational weight gain changed in Finland between the 1960s and 2000, and are such possible changes related to maternal age, prepregnancy BMI or parity (I)?
- 2. Is a study protocol designed to prevent excessive gestational weight gain and postpartum weight retention feasible in a primary health care setting in Finland (II)?
- 3. Has individual counselling on diet and physical activity in maternity clinics (MC) positive effects on diet and physical activity in pregnant women and does it prevent excessive gestational weight gain among them (III)?
- 4. Has individual counselling on diet and physical activity in child health clinics (CC) positive effects on diet and physical activity in postpartum women and does it help them to return to their pre-pregnancy weight (IV)?

4 PARTICIPANTS AND METHODS

4.1 Study setting

The setting for this study was municipal maternity and child health care. In Finland, each municipality has been responsible since 1944 for providing maternity and child health care services in primary health care for its residents (Siivola 1985). Funding for these services is covered by public tax revenue and the services are free of charge for the families. The place of residence determines which MC and CC each family attends.

At present, 11–15 visits to a public health nurse (PHN) and three visits to a physician are recommended during pregnancy for women with no earlier deliveries (Viisainen 1999). For women with earlier deliveries, the recommended number of visits to a PHN is 7–11. The women meet the PHN twice and the physician once after delivery. Concerning the offspring, ten visits to a PHN and three visits to a physician are recommended during the first year of life (Ministry of Social Affairs and Health 2004). Almost all pregnant and postpartum women can be reached through the system as 99.7% pregnant women and 98% of children in Finland attend these clinics for regular check-ups, according to the most recent statistics (unpublished data from the official birth register of National Research and Development Centre for Welfare and Health 2004, NOMESCO 2007).

4.2 Study designs and participants

The research questions of this dissertation were studied using both observational and experimental study designs: Information on three population-based samples of pregnant women was used in Study I and an intervention study including pregnant and postpartum women from six MCs and CCs in Studies II–IV. The women were from three different areas in southern Finland: from Helsinki, the capital of Finland (I), from the city of Tampere and its surrounding area (I–IV) and from the town of Hämeenlinna (II–IV) (Figure 2).



FIGURE 2. Locations of the study areas

4.2.1 The three samples of pregnant women (I)

The first sample included 4,090 women who were pregnant between 1954 and 1963 in Helsinki. This sample was originally collected for a study on hormone exposure during pregnancy, including approximately 2,000 exposed and 2,000 control women (Hemminki et al. 1999a, Hemminki et al. 1999b). The exposed women were a systematic sample of women, who had been prescribed oestrogen or progestin drugs during pregnancy in order to prevent early miscarriage or pre-term delivery. For each exposed woman, a woman next in the MC file, who gave birth during the same year and was not exposed to these drugs during pregnancy, was chosen as a control. Although the hormone-exposed women were a selected group, they were included as their average weight gain was similar to that of the control women (13.5)

vs. 13.2 kg, p=0.11), who were an unbiased sample of women using the services of the MCs. In 1960, 85% of all pregnant women in Helsinki used the services of the MCs (Hemminki et al. 1999a, Hemminki et al. 1999b).

The second sample consisted of 2,048 women who participated in a randomised controlled trial investigating the benefits of routine iron prophylaxis during pregnancy in Tampere region 1985–1986 (Hemminki et al. 1989). The women were randomly assigned to receive either non-routine or routine iron supplementation. All women attending the MCs in the city of Tampere and in five neighbouring municipalities, covering 99.9% of pregnant women in the area, were included.

The third sample was gathered for a study assessing the health care services at the MCs in Tampere and its neighbouring province (Hakulinen-Viitanen et al. 2007). The sample included 421 women, covering 60.3% of all women giving birth in the area between 15 November 2000 and 14 January 2001 (n=698). The main reason for not recruiting all 698 women was the high workload of the hospital personnel. There were no differences with regard to age, proportion of primiparous women and area of residence between the participants and the 698 women or all women giving birth during 2000 or 2001 in this area.

Concerning all three samples, we excluded women whose pregnancies ended in miscarriage, abortion or multiple births and, in the first sample, also women for whom the first and the last weight measurements were not between 4 and 45 weeks' gestation, the time between the measurements was not from 3 to 300 days, or delivery was not between 22 and 45 weeks' gestation (Figure 3). In addition, women with missing values in pre-pregnancy BMI, age, parity or gestational weight gain were excluded from the analyses.

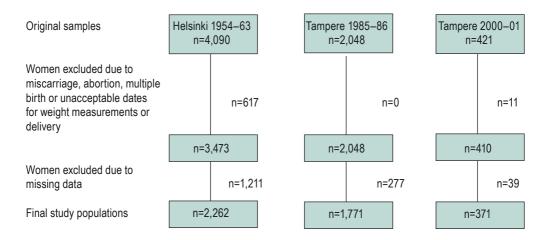


FIGURE 3. Numbers of women in the samples

4.2.2 The intervention study (II–IV)

The intervention study was conducted in six MCs and CCs, three of which volunteered to be intervention clinics while the remaining clinics were treated as control clinics (Figure 4). The allocation was performed at clinic level instead of allocating PHNs or pregnant and postpartum participants to intervention and control groups, which would have increased the likelihood of contamination of PHNs' counselling practices either between the intervention and the control PHNs in each clinic or between the intervention and the control participants of each PHN. The clinics were a convenience sample of the clinics in Tampere and Hämeenlinna as they were selected on the basis of the clinics' administrative personnel's suggestion for suitable clinics. The intention-to-treat approach was not applied in this study as no follow-up data were collected from the participants who dropped out of the study.

The participants consisted of two separate groups: pregnant women with no earlier deliveries and postpartum primiparous women. The exclusion criteria were age under 18 years, type 1 or type 2 diabetes mellitus (but not gestational diabetes mellitus), twin pregnancy, physical disability preventing exercise, otherwise problematic pregnancy (determined by a physician), substance abuse, treatment or clinical history for any psychiatric illness, inadequate language skills in Finnish and intention to change place of residence within three months.

The PHNs recruited pregnant women by phone when making an appointment for the first MC visit and postpartum women when visiting their homes after delivery or on their first visit to the CC. The eligibility of all potential participants was assessed and all eligible women were asked to participate in the study. The aim was to recruit at least 40 pregnant and 40 postpartum participants in the intervention and in the control clinics (160 in total) in August–October 2004. This sample size was estimated to be adequate to test the feasibility of the study protocol for a larger intervention study, but also give some indication of the effectiveness of the intervention. The study was approved by the Ethics Committee of the Pirkanmaa Hospital District.

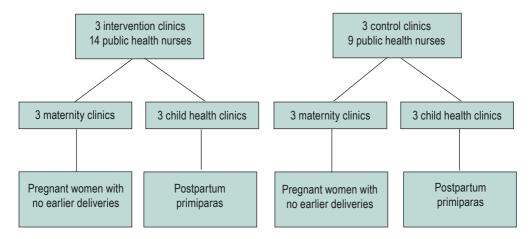


FIGURE 4. Design of the intervention study

4.3 Contents of the intervention (II–IV)

Before the intervention began, the PHNs of the intervention clinics were trained by the research group in the counselling procedures and the study arrangements (12 hours in total). The PHNs were asked to practise the counselling procedures between the training sessions with at least one client who did not participate in the study. The experiences were discussed in small group sessions. The PHNs of the control clinics were trained in the study arrangements (6 hours in total). The training material included a handbook describing the tasks for each research visit. For additional support during the study, one or two researchers visited each clinic monthly and a meeting was separately held for the PHNs of the intervention and the control clinics.

4.3.1 Intervention clinics

The study protocol was mainly implemented on five of the routine visits to a PHN in the MC or in the CC. The components of the intervention were a brief discussion on weight development, individual dietary and physical activity counselling and an option for supervised group exercise sessions. The purpose of the intervention was to promote healthy dietary habits and leisure time physical activity (LTPA) and thereby to help the pregnant participants to keep their gestational weight gain within the recommended range (Institute of Medicine 1990) and the postpartum participants to return to their pre-pregnancy weight during the study.

Discussion on weight development. In the MCs, the pregnant participants were introduced to the recommendation for their total gestational weight gain based on their BMI (Institute of Medicine 1990) at their first visit to the PHN (Figure 5). In the CCs, the PHNs briefly discussed with the postpartum participants about their pre-pregnancy weight at the child's 2-month visit. If the participant's current weight exceeded her pre-pregnancy weight, the PHN encouraged her to lose the extra weight gradually during the intervention.

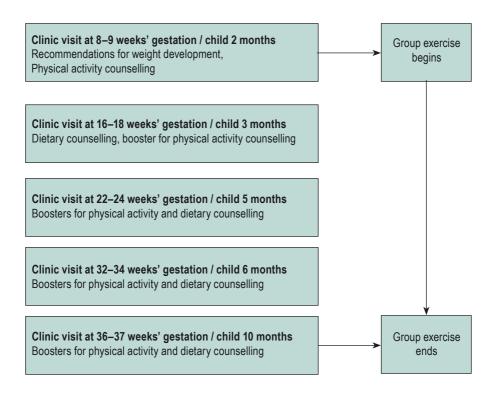


FIGURE 5. Timing of the intervention in the intervention clinics

PREVENTION OF EXCESSIVE PREGNANCY-RELATED WEIGHT GAIN

Dietary counselling. Based on dietary recommendations (Hasunen et al. 2004, Nordic Council of Ministers 2004), a summary of the evidence for prevention of excessive weight gain and obesity (World Health Organization 2003) and information on the diet of Finnish women (Männistö et al. 2003), the dietary counselling focused on four topics that could help in the prevention of excessive gestational weight gain and in reducing postpartum weight retention.

Related to these topics, the following four objectives were set for each participant to achieve or to maintain: 1) to have a regular meal pattern, emphasising the importance of breakfast and ≥ 1 hot meal every day, 2) to eat at least 5 portions (400 g) per day different kinds of vegetables, fruit and berries on at least five days a week, 3) to consume high-fibre bread (≥ 5 g fibre/100 g) at least 50% of the total weekly intake of bread and 4) to restrict the intake of high-sugar snacks to ≤ 1 portion per day (e.g. 50 g sweets, one pastry, one piece of cake, 2 biscuits, 2 dl ice cream or a glass of soft drink).

The dietary counselling consisted of one primary counselling session (allocated time 20–30 min) and three booster sessions (allocated time 10 min) (Figure 5). The model of Laitakari and Asikainen (1998), incorporating two behavioural models, PRECEDE-PROCEED (Green et al. 1980) and Stages of Change (Prochaska & Velicer 1997), was applied in the dietary counselling. Of the five stages of change (precontemplation, contemplation, preparation, action and maintenance) (Prochaska & Velicer 1997), the participants were assumed to be at least in the contemplation stage since they voluntarily participated in the study. Depending on the stage of each participant, they were encouraged either to initiate or to maintain healthy dietary habits.

The PHNs implemented the counselling with the help of a counselling card, which was filled in for each participant at each session. At the primary counselling session, the PHN first assessed the participant's dietary habits concerning these four topics with the help of the baseline FFQ and compared the habits to the recommendations. The PHN and the participant then discussed the participant's need for dietary changes and her opportunities for and barriers to making such changes, described as enabling and reinforcing factors in the PRECEDE-PROCEED model (Green et al. 1980). Two take-home leaflets were introduced and given to the participant. One of them was a general leaflet on healthy diet during pregnancy (published by the Dairy Nutrition Council in Finland) and the other focused on how to increase the intake of vegetables, fruits and berries (published by the Finnish Horticultural Products Society). The PHN asked the participant to keep a weekly record of her adherence to the objectives in her follow-up notebook. At the booster visits, the follow-up notebook was checked and the adherence was discussed.

In addition, each PHN discussed other dietary issues she deemed important for the participant (e.g. the special dietary restrictions during pregnancy and breastfeeding period) and questions raised by the participant.

Physical activity counselling. The physical activity counselling was implemented at one primary counselling session (allocated time 20–30 min) and four booster sessions (allocated time 10–15 min per session in addition to the boosters for dietary counselling) (Figure 5). The counselling procedure was based on the model of Laitakari and Asikainen (1998) and a counselling card was used to guide the PHN in the counselling.

At the primary counselling session, the participant's current LTPA was discussed firstly before moving on to her needs and opportunities to increase LTPA. The general benefits and restrictions of LTPA during or after pregnancy were also introduced using a take-home leaflet developed by the researchers. Lastly, an individual weekly plan for LTPA was made in the participant's follow-up notebook.

The general physical activity recommendations for health (Pate et al. 1995) and fitness (American College of Sports Medicine 1998), which apply to pregnant and postpartum women (Artal & O'Toole 2003, Davies et al. 2003), were taken into consideration when making the plan. In these recommendations, a minimum of 30 min of moderate-intensity physical activity on five weekdays is considered sufficient for health and a minimum of 40 min of high-intensity physical activity three times per week sufficient for fitness.

The PHNs assessed the fulfilment of these recommendations using MET minutes (METmin) calculated by multiplying the frequency, duration (min) and MET value (multiple of resting metabolic rate) of each activity and summing the numbers to calculate the total weekly METmin (Howley 2001). In these calculations, a MET value of 5 was used for moderate-intensity and MET value 7 for high-intensity LTPA. A total of 800 weekly METmin was estimated to represent the minimum LTPA requirements. Contrary to the recommendations, light-intensity LTPA with MET value 3 could also be included in the plan to improve adherence. At the booster sessions, the participant's adherence to the plan was discussed, the plan was revised, if needed, and the METmin were rechecked.

To support the physical activity counselling, supervised group exercise sessions were arranged once a week for 45–60 min at a location close to each intervention clinic and separately for pregnant and postpartum women. These sessions were optional for the participants and could be included in the individual LTPA plans. The sessions consisted of both endurance and muscle training developed specifically for pregnant and postpartum women. Ten exercise instructors were trained for these sessions (10 hours in total) by the research group.

4.3.2 Control clinics

In the control MCs and CCs, the PHNs continued their usual physical activity and dietary counselling practices. Information on all PHNs' usual counselling practices was collected by questionnaire (n=21) before the PHNs were trained for the study. There was considerable variation in the counselling practices between the individual PHNs, but not between the PHNs of the intervention and the control clinics. In the MCs, the mean durations of dietary counselling were approximately 12 min at the first visit and 5 min at subsequent visits. For the physical activity counselling, the corresponding mean durations were 8 min and 5 min. In the CCs, the mean durations of time spent on counselling were shorter than in the MCs, approximately 5 min for dietary counselling and 3–4 min for physical activity counselling at the first and the subsequent visits. These short mean durations of time spent on counselling suggest that the PHNs merely gave general advice on diet and physical activity rather than implementing actual counselling.

The PHNs of the MCs were also asked whether they provided their clients with information on the recommendations for total gestational weight gain. All PHNs provided some information for most or for all of their clients, usually during the first trimester of pregnancy. On average, the PHNs of the control clinics recommended a total weight gain of 13.3 kg for underweight, 10.6 kg for normal weight and 6.7 kg for overweight women during pregnancy.

4.4 Outcomes and data collection

4.4.1 The three samples of pregnant women (I)

The main outcome was the mean gestational weight gain in each sample. All data were obtained from the maternity card of each woman. Information on prepregnancy weight and height was based on self-reports, but weight was measured at the MC visits during pregnancy.

Gestational weight gain was initially defined as the difference between prepregnancy weight and the last measured weight during pregnancy. However, the timing of the weight measurements varied considerably between individual women and between the samples. Therefore, to make the samples more comparable to each other, total gestational weight gain was estimated for each woman from her prepregnancy weight until 40 weeks' gestation, regardless of the timing of the delivery. On average, the women delivered respectively at 40.4, 40.0 and 39.4 weeks' gestation in each sample (p<0.001).

The calculations for the first sample have been described in more detail in Appendix 1. Briefly, as the rate of weight gain is slower during the first trimester than later in pregnancy (Hytten 1991, Institute of Medicine 1990), straight lines for weight gain were calculated for each woman separately for 0–15 and 15–40 weeks' gestation and added up to total gestational weight gain. For the second sample, weight at 40 weeks' gestation was extrapolated for each woman from a straight line calculated based on her first and last weight measurements (at 12 and 36 weeks' gestation on average). For the third sample, the straight lines were calculated using pre-pregnancy weight and the last measured weight (at 39 weeks' gestation on average) as no information on other weight measurements had been collected.

4.4.2 The intervention study (II–IV)

The data collection concerning the pregnant and the postpartum participants is described in Table 5. The PHNs sent the baseline questionnaire to the participants' homes before the participants' first visit to the clinic and the participants returned the completed questionnaire on the visit. The follow-up questionnaires were completed in the waiting room before the visits. When the participants returned the questionnaires, the PHNs checked that they were properly filled in. The blood and the nipple aspirate fluid (NAF) samples were taken by the Medical Laboratory Technologists of the UKK Institute at other visits to any of the three places reserved for that purpose. The reason for collecting these samples was to measure selected hormones and growth factors related to breast cancer risk. To obtain an NAF sample containing no breast milk, the samples were collected at least one month after the participant had ceased breastfeeding.

TABLE 5. Timing of data collection in the intervention study

	Pregnant women (weeks' gestation)	Postpartum women (months postpartum)
Baseline questionnaire		
Background, physical activity and diet	8–9	2
Follow-up questionnaires		
Physical activity	16–18	5
Diet	22–24	5
Background, physical activity and diet	36–37	10
Other data collection		
Adverse events ¹ form	16-18, 22-24,	3, 5, 6 and 10
	32-34 and 36-37	
A copy of the maternity card (weight development, child's birth weight, glucose tolerance and other data on pregnancy)	After delivery	2
Weight and waist circumference measurement form	_	2, 3, 5, 6 and 10
Blood sample	9–11 and 36–37	2-2.5 and 8
A 3-day food record	9–11 and 36–37	_
Nipple aspirate fluid (NAF) sample	-	8–12

Vaginal bleeding, strong contractions (in pregnant participants), dizziness, dyspnea, headache, chest pain, excessive tiredness or fatigue experienced by the participant, calf pain or swelling and musculoskeletal symptoms

The components of the feasibility evaluation of the study protocol were 1) recruitment and participation, 2) completion of data collection, 3) realization of the intervention, and 4) the public health nurses' experiences. Table 6 describes the main indicators and the sources of information for each of the components.

TABLE 6. Evaluation of the feasibility of the study protocol¹

Components and main indicators	Source of information
1) Recruitment and participation Aim for recruitment achieved within three months (40 participants per group, 160 in total)	Standardized recruitment form used by each PHN
Participation rate of eligible women Drop-out rate of participants	Standardized recruitment form used by each PHN Standardized recruitment form used by each PHN
2) Completion of data collection Proportion of data obtained on weight, physical activity and diet	Number of completed and returned baseline and follow-up questionnaires, maternity cards and postpartum weight measurement forms
Proportion of blood samples obtained	Laboratory records
3) Realization of the intervention ² Realization rate of counselling sessions Duration of counselling sessions Proportion of women completing ≥ 75 % of the	Counselling cards Counselling cards Participants' follow-up notebooks
weekly records for physical activity and diet Participation percentage in group exercise sessions ³	Lists of participants recorded by the exercise instructors
4) Public health nurses' experiences Appropriateness of the training for the study (a 5-point Osgood scale: 1 = very poor 5 = excellent) Advantages and disadvantages of the study for the PHNs	•

- ¹ Drop-outs are included only when evaluating component 1)
- ² In the intervention clinics
- Individual participation percentages were calculated from the number of sessions available for each woman

The main dietary outcomes were 1) the proportion of participants having a breakfast and ≥ 1 hot meal every day, 2) change in the mean overall intake of vegetables, fruit and berries (portions/d), 3) change in the mean percentage of high-fibre bread (≥ 5 g fibre/100 g) of the total weekly amount of bread, and 4) change in the mean intake of high-sugar snacks (portions/d). The participants completed a 57-item FFQ three times during the study (Table 5). For each item, the participants reported the average number of portions either per week or per day. The questions concerned diet during the previous month except in the baseline questionnaire of the pregnant participants, which covered a one-month period before the pregnancy. Total energy intake (kJ/d), macronutrient intakes (E%) and fibre intake (g/d) were additional outcomes for pregnant participants only. Therefore, the pregnant participants also

kept food records for three days (one Sunday and two working days) prior to the taking of the blood samples at the beginning and at the end of the pregnancy.

The outcome for physical activity was the change in the mean total weekly METmin including light-, moderate- and high-intensity LTPA. LTPA was assessed by a questionnaire at baseline and twice during follow-up (Table 5). The baseline questions concerned a typical week before pregnancy and the follow-up questions a typical week during the past three weeks. The questions were modified from the International Physical Activity Questionnaire (Craig et al. 2003) by using the amount of breathlessness (none, some, marked) to illustrate light-, moderate- and high-intensity LTPA to the participants. For each intensity level, the participants reported the number of sessions per week and the average duration of each session (min). (The calculation of the total weekly METmin is described in Chapter 4.3.1.) Additionally, the physical workload of the pregnant participants was elicited in the baseline questionnaire by a multiple choice question.

The main outcomes for weight development were the proportion of pregnant participants gaining weight in excess of the BMI-specific recommendations (Institute of Medicine 1990) and the proportion of postpartum participants returning at least to their pre-pregnancy weight (weight retention ≤ 0 kg) by 10 months postpartum. Gestational weight development and other pregnancy data were obtained for all participants from the maternity cards (Table 5). Pre-pregnancy weight and height were self-reported, but body weight was measured at every visit during pregnancy. Total gestational weight gain was defined as the difference between the last measured weight and the pre-pregnancy weight. Weight and waist circumference of the postpartum participants were measured at all five CC visits related to the study. All weight measurements were performed in light clothing and without shoes and the scales were calibrated to the reference scale within ± 0.5 kg at the beginning and at the end of the study.

4.5 Statistical methods

In Study I, analysis of variance was used to test the statistical significance of differences in mean age, pre-pregnancy BMI, parity and gestational weight gain between the three samples of pregnant women. The differences in mean gestational weight gain were further examined using analysis of covariance (ANCOVA), adjusted for age, pre-pregnancy BMI and parity when applicable. The women were divided into three groups based on their age (<25 yrs, 25-29.9 yrs and ≥30 yrs), pre-pregnancy BMI (underweight: <20 kg/m², normal weight: 20-24.9 kg/m², overweight: ≥25 kg/

m²) and parity (1, 2, 3 or more deliveries). Gestational weight gain was compared between the samples within these subgroups and between these subgroups within each sample. Additionally, Bonferroni test was used to examine which of the samples or subgroups differed statistically significantly from the others.

Linear regression models were performed in each sample to assess the contribution of age, pre-pregnancy BMI and parity to gestational weight gain. The squared multiple-correlation coefficient (R^2) indicated the proportion of variation in gestational weight gain that was explained by the variables statistically significantly associated with gestational weight gain in the model. To test the differences in child's birth weight between the samples, ANCOVA adjusted for gestational age was used for means, and χ^2 -test was used for proportions of high ($\geq 4,000$ g) and low (< 2,500 g) birth weight children.

In Studies III and IV, differences in the proportions of women having breakfast and at least one hot meal per day were tested between the intervention and the control groups using χ^2 -test. Changes in the other dietary variables from baseline to the first and to the second follow-up were compared between the groups and tested statistically using ANCOVA with selected confounding variables as covariates. The between-group differences in changes in the total weekly METmin from baseline to the first and to the second follow-up were analysed using ANCOVA of repeated measures, adjusted for selected confounders. For the postpartum participants, the weekly METmin were firstly converted into logarithms as they were not normally distributed.

To test group differences in the proportions of pregnant participants who exceeded the recommended weight gain ranges and of postpartum participants who returned to their pre-pregnancy weight, χ^2 -test was used for the unadjusted analyses and logistic regression models for the confounder-adjusted analysis. In Study III, independent samples t-test was used to test the between-group differences in unadjusted mean gestational weight gain and mean child's birth weight. Fisher's exact test was used to test the between-group differences in the proportions of high (\geq 4,000 g) and low (<2,500 g) birth weight children. In Study IV, the between-group differences in average weight retention and waist circumference at 10 months postpartum were compared using ANCOVA with selected confounding variables as covariates. Because 11 women had missing values for the duration of breastfeeding, an indicator variable (0= non-missing, 1= missing) was used in the confounder-adjusted analyses together with the continuous breastfeeding variables to prevent the loss of data. Non-parametric Mann-Whitney U test was used to test the between-group differences in the duration of exclusive and partial breastfeeding.

All statistical tests were two-sided and group differences with p<0.05 were regarded as statistically significant. The analyses were performed using the SPSS statistical packages (versions 11.0, 14.0 and 15.0) for Windows (SPSS Inc., Chicago, IL, USA).

5 RESULTS

5.1 Gestational weight gain from the 1960s to 2000 in Finland (I)

The mean age of pregnant women increased from the 1960s to the mid-1980s and further to 2000 (Table 7). Additionally, the mean pre-pregnancy BMI was significantly higher in 2000 than in the mid-1980s. However, there were no differences in the mean parity between the three samples of pregnant women. Mean gestational weight gain, adjusted for age, pre-pregnancy BMI and parity, increased from 13.2 kg in the 1960s to 14.3 kg in the mid-1980s, but levelled off after that. Table 7 also shows the numbers (%) of women in each age-, BMI- and parity group.

An increase in mean gestational weight gain from the 1960s to the mid-1980s was detected in all age, BMI and parity groups (Figures 6a–c). Concerning the parity groups, the increase was most evident in women giving birth to their first child, as there was minor overlapping in the 95% CIs among women with higher parity despite p-values being smaller than 0.05.

Additionally, the associations of age, pre-pregnancy BMI and parity to gestational weight gain were assessed in each of the three samples. Age was not associated with gestational weight gain in any of these samples (Figure 6a). Overweight women gained less weight than normal weight women in all three samples and less than the underweight women in the first and the second samples (Figure 6b). Parity was associated with gestational weight gain only in the third sample, in which women with at least three children had lower weight gain than women with one child (Figure 6c). These results were adjusted for age, BMI and parity, where applicable. In the linear regression models, age and BMI explained 2.1% of the variation in gestational weight gain in the first sample, BMI explained 1.0% in the second sample, and BMI and parity explained 5.5% in the third sample.

Parallel to the trend in gestational weight gain, the mean child's birth weight and the proportion of high birth weight infants increased from the 1960s to the mid-1980s (Table 7). Additionally, the proportion of low birth weight infants was lower in 2000 than in the 1960s.

TABLE 7. Age, pre-pregnancy BMI, parity, gestational weight gain¹ and child's birth weight by sample, mean (95% CI), number (%) or % (95% CI)

	Helsinki 1954–1963 (n=2,262)	Tampere 1985–1986 (n=1,771)	Tampere 2000–2001 (n=371)
Age (yrs)	26.5 (26.3–26.7)	27.6 (27.3–27.8)2	29.6 (29.1–30.2)2
age groups, n (%)			
< 25.0 yrs	898 (39.7)	482 (27.2)	65 (17.5)
25.0-29.9 yrs	781 (34.5)	708 (40.0)	117 (31.5)
≥30.0 yrs	583 (25.8)	581 (32.8)	189 (50.9)
Pre-pregnancy BMI (kg/m ²)	21.9 (21.8–22.0)	22.3 (22.1–22.4)	23.7 (23.3–24.2) ²
BMI groups, n (%)	,	,	,
< 20.0 kg/m ²	501 (22.1)	403 (22.8)	64 (17.3)
20.0–24.9 kg/m ²	1,500 (66.3)	1,078 (60.9)	195 (52.6)
≥25.0 kg/m ²	261 (11.5)	290 (16.4)	112 (30.2)
Parity	1.80 (1.76-1.84)	1.79 (1.75-1.83)	1.85 (1.75-1.95)
parity groups, n (%)			, ,
1 child	1,114 (49.2)	784 (44.3)	172 (46.4)
2 children	727 (32.1)	687 (38.8)	114 (30.7)
≥3 children	421 (18.6)	300 (16.9)	85 (22.9)
Unadjusted gestational weight gain (kg) ¹	13.3 (13.1–13.5)	14.3 (14.0-14.5) ²	13.9 (13.3-14.3)
Adjusted gestational weight gain (kg) ^{1,3}	13.2 (13.0-13.4)	14.3 (14.1-14.5) ²	14.3 (13.8-14.7)
Child's birth weight (g)	3,442 (3,423-3,463)	3,616 (3,593-3,639)	3,687 (3,637-3,736) ⁴
Low birth weight (<2,500 g) (%)	3.7 (2.9-4.5)	2.4 (1.7–3.1)	1.6 (0.3–2.9) ⁵
High birth weight (>4,000 g) (%)	16.1 (14.6–17.6)	22.0 (20.1–23.9)	21.8 (17.6–26.0) ⁵

¹ estimated for 0–40 weeks' gestation

 $^{^2}$ statistically significant (p<0.05) increase compared to the earlier sample (ANOVA, Bonferroni test)

³ adjusted for age, pre-pregnancy BMI and parity

statistically significant (p<0.05) difference between the samples (ANCOVA, adjusted for gestational age)</p>

statistically significant (p<0.05) difference between the samples (χ^2 -test)

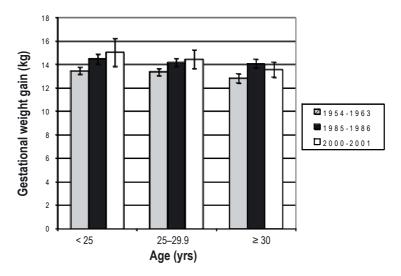


FIGURE 6A. BMI- and parity-adjusted mean gestational weight gain and 95% CI by samples and age groups. For comparisons between the samples (ANCOVA), p<0.001 within each age group. For comparisons between the age groups (ANCOVA), p=0.25, p=0.78 and p=0.65 within the samples respectively.

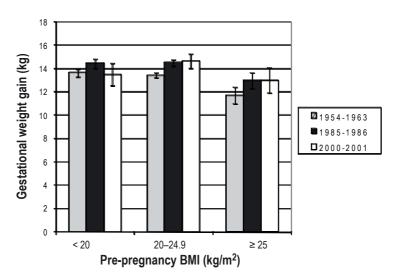


FIGURE 6B. Age- and parity-adjusted mean gestational weight gain and 95% CI by samples and pre-pregnancy BMI groups. For comparisons between the samples (ANCOVA), p=0.006, p<0.001 and p=0.023 within the BMI groups respectively. For comparisons between the BMI groups (ANCOVA), p<0.001, p<0.001 and p=0.026 within the samples respectively. (I)

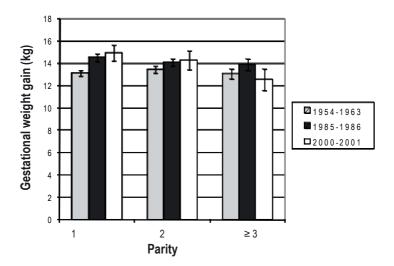


FIGURE 6C. Age- and pre-pregnancy BMI-adjusted mean gestational weight gain and 95% CI by samples and parity groups. For comparisons between the samples (ANCOVA), p<0.001, p=0.012 and p=0.010 within the parity groups respectively. For comparisons between the parity groups (ANCOVA), p=0.07, p=0.21 and p=0.013 within the samples respectively.

5.2 Feasibility of the study protocol of the intervention study (II)

Recruitment and participation. As the recruitment aim was not achieved within three months, the recruitment period was extended to six months. During this period, a total of 323 pregnant women with no earlier deliveries or postpartum primiparas registered for these clinics (Figure 7). Of these, 290 women were eligible for the study and 224 women (of whom 132 were pregnant and 92 postpartum) gave informed consent to participate in the study. A lower proportion of the eligible women in the intervention clinics (73–78%) than in the control clinics (77–85%) participated in the study. The drop-out rate of participants was low (5–11%) in all clinics except for the intervention MCs (29%). The reasons for dropping out are reported in Figure 7. The "other reasons" were such as unwillingness to fill in more questionnaires, food records or the follow-up notebook (in the intervention clinics) or reluctance to give the blood samples or difficulties in finding time for these (mostly in the control clinics). In total, 85% (n=190) of participants who gave informed consent to participate completed the study.

Completion of data collection. The proportions of data obtained on weight, diet and physical activity varied from 96% in the intervention MCs to 100% in the

control MCs and CCs. The proportions of blood samples obtained were 96–98% in the intervention clinics and 95–97% in the control clinics. The timing of obtaining the samples was as intended: at 11.5 (standard deviation (SD) 2.1, range 8–20) and 36.5 (SD 0.7, range 34–38) weeks' gestation or at 2.6 (SD 0.3, range 2–4) and 8.3 (SD 0.3, range 8–10) months postpartum on average.

All PHNs' counselling cards and all but four participants' follow-up notebooks were returned. Concerning the pregnant participants, all 3-day food records were obtained except for one at baseline and two at follow-up. All adverse events forms were returned except two. The NAF samples were obtained from 41 (48%) of the postpartum participants at 12.1 (SD 3.3) months postpartum on average. Reasons for not obtaining the NAF samples were typically unsuccessful attempt to collect sufficient NAF (n=16), breastfeeding during the preceding month (n=11), refusal to give the sample (n=9), change of residence (n=2) and unknown reason (n=6).

Realization of the intervention. In the intervention clinics, nearly all counselling sessions were realized (Table 8). Of the pregnant participants, five participants missed one dietary and/or physical activity booster session and one participant missed two dietary and physical activity booster sessions. Of the postpartum participants, three participants missed one dietary booster session, five participants missed one physical activity booster session and three participants missed the discussion about returning to pre-pregnancy weight. The mean durations of the sessions were as intended and 86% of the participants regularly completed their weekly records for diet and LTPA in the follow-up note book (Table 8). The mean participation percentage in the group exercise sessions was higher among the postpartum than the pregnant women.

PHNs' experiences. In the intervention clinics, the PHNs (n=14) scored the training for study arrangements 3.4 (SD 1.2), dietary counselling 3.6 (SD 1.1) and physical activity counselling 3.9 (SD 1.1) on average. In the control clinics, the PHNs (n=8) scored the training for study arrangements 3.9 (SD 0.7) on average. Training and support during the study were regarded as adequate and the researchers' visits to the clinics as useful by almost all PHNs.

The major advantage of the study reported by the PHNs was the training they were offered on diet, physical activity and counselling skills either before (in the intervention clinics) or after the study (in the control clinics). The major perceived disadvantage, on the other hand, was the extra time needed for the implementation of the study protocol (40–60 min/visit in the intervention clinics and 10–20 min/visit in the control clinics on average).

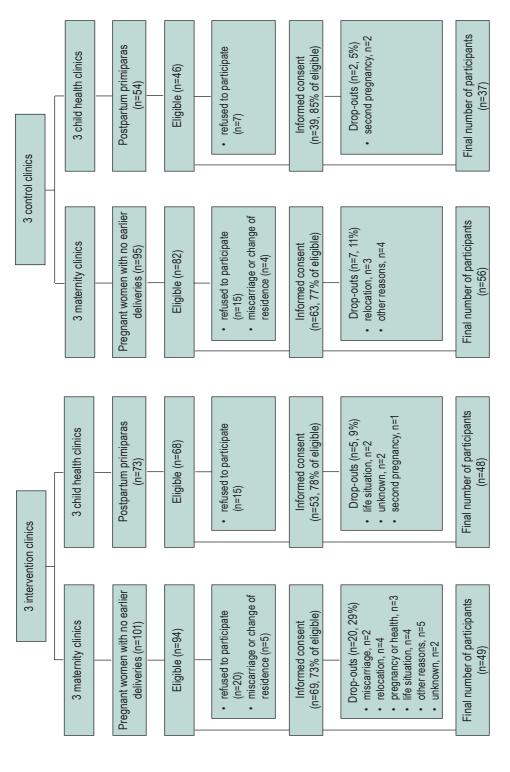


FIGURE 7. Participant flow (II)

TABLE 8. Realization of the intervention in the intervention clinics

	Pregnant participants (n=49)	Postpartum participants (n=56)
Realization rate of counselling sessions (%)	98	98
Duration (min) of counselling sessions, mean (SD)		
Primary sessions	24.0 (4.7)	25.9 (8.3)
Booster sessions	10.4 (3.6)	10.5 (3.3)
Proportion of women completing ≥75% of the weekly records for both diet and physical activity (%)	87	85
Participation percentage in group exercise sessions (mean, SD)	38.6 (28.3)	50.7 (28.5)

5.3 Effects of the intervention (III-IV)

5.3.1 During pregnancy

Background characteristics

The intervention group was younger and had higher BMI before pregnancy than the control group on average (Table 9). The intervention group was also less educated and a higher proportion of them smoked before pregnancy than of the control group.

TABLE 9. Background characteristics of the pregnant participants, means (SD) or numbers (%)

	Intervention group (n=49)	Control group (n=56)
Age at baseline (yrs)	27.6 (4.5)	28.8 (4.1)
Pre-pregnancy BMI (kg/m²) BMI groups, n (%)	23.7 (3.9)	22.3 (2.1)
< 20.0 kg/m ²	4 (8)	10 (18)
20.0-25.9 kg/m ²	36 (75)	44 (79)
\geq 26.0 kg/m ²	8 (17)	2 (4)
Education level, n (%)		
basic or secondary education	27 (57)	20 (36)
polytechnic education	9 (19)	12 (21)
university education	11 (23)	24 (43)
Smoking status 0-6 months before pregnancy, n (%)		
Non-smoker	32 (68)	46 (84)
Daily or occasional smoker	15 (32)	9 (16)

Changes in diet

No differences were observed between the intervention and the control groups in the proportion of women having breakfast and at least one hot meal per day at baseline (88% vs. 86%, p=0.79), at the first follow-up (98% vs. 100%, p=0.28) or at the second follow-up (100% vs. 96%, p=0.22). The intervention group increased their mean overall intake of vegetables, fruit and berries from baseline to the first follow-up by 0.6 portions/d more compared to the control group when adjusted for confounders (Table 10). By the second follow-up, this between-group difference increased further up to 0.8 portions/d. The proportion of high-fibre bread of the total weekly amount of bread decreased more in the control group than in the intervention group (a difference of 12 %-units between the groups) from baseline to the second follow-up, when adjusted for confounders. No between-group differences were detected in changes in the intake of high-sugar snacks.

Regarding nutrient intakes, the confounder-adjusted intake of dietary fibre increased by 3.6 g/d more in the intervention group than in the control group from early pregnancy to 36–37 weeks' gestation (Appendix 2). Differences in changes in the intake of energy or macronutrients were not significant between the groups.

TABLE 10. Unadjusted means (SD) for dietary variables at baseline (before pregnancy) and at follow-up (22–24 and 36–37 weeks' gestation) and adjusted group differences (95% CI) at follow-up

	Intervention group	Control group	Adjusted mean difference to control group ¹	p-value
Vegetables, fruit and berries (portions/d), mean				
(SD)				
Before pregnancy	2.5 (1.3)	2.9 (1.5)		
22–24 weeks' gestation	3.7 (1.6)	3.3 (1.5)	+ 0.6 (0.1-1.2)	0.02
36–37 weeks' gestation	3.8 (1.7)	3.2 (1.5)	+ 0.8 (0.3-1.4)	0.004
High-fibre bread (% of total bread), mean (SD)				
Before pregnancy	69 (27)	58 (25)		
22–24 weeks' gestation	70 (24)	53 (28)	+ 8.2 (-0.9-17.3)	0.08
36–37 weeks' gestation	67 (29)	53 (24)	+ 11.8 (0.6–23.1)	0.04
High-sugar snacks (portions/d), mean (SD)				
Before pregnancy	1.6 (1.5)	1.4 (0.9)		
22–24 weeks' gestation	1.3 (0.7)	1.3 (0.9)	- 0.1 (-0.4-0.2)	0.38
36–37 weeks' gestation	1.6 (1.3)	1.8 (1.1)	- 0.3 (-0.8–0.1)	0.16

ANCOVA, mean group differences adjusted for baseline intake of the dietary variable, prepregnancy age, BMI, education and smoking status. The numbers of women were 44–45 in the intervention and 51–53 in the control group at 22–24 weeks' gestation and 38–39 in the intervention and 52–54 in the control group at 36–37 weeks' gestation.

Changes in physical activity

The unadjusted mean weekly METmin of total LTPA decreased in both groups during pregnancy (Figure 8). However, no significant differences were observed between the groups in changes from baseline to the first or to the second follow-up when adjusted for age, pre-pregnancy BMI and education. Physical workload did not differ between the groups at baseline.

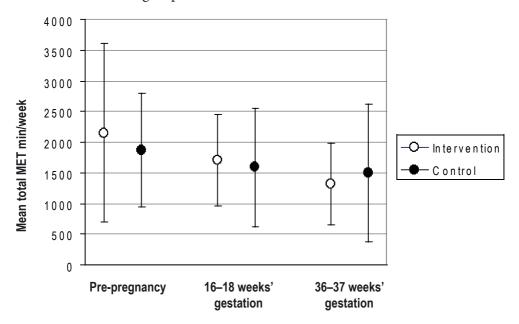


FIGURE 8. Unadjusted mean (SD) weekly METmin of total leisure time physical activity by gestation week in the intervention (n=37) and the control groups (n=51)

Gestational weight gain

Figure 9 shows the unadjusted mean weight gain in the intervention and the control groups by gestation week. The unadjusted mean total gestational weight gain was similar in the intervention and the control groups (Table 11). A greater proportion of the participants in the intervention group exceeded the weight gain recommendations than in the control group, but the difference did not reach statistical significance. Additionally, the confounder-adjusted odds ratio for excessive gestational weight gain did not differ significantly between the groups.

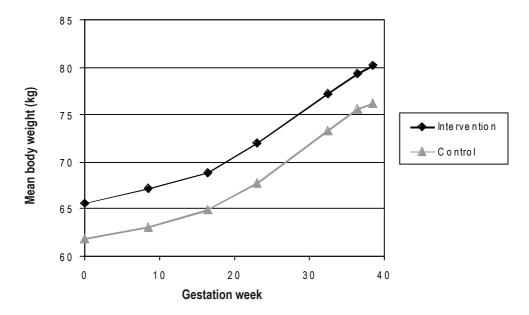


FIGURE 9. Unadjusted mean weight gain by gestation week in the intervention (n=48) and the control groups (n=56) (III)

TABLE 11. Gestational weight gain in the intervention and the control groups, means (SD), numbers (%) or odds ratios (95% CI)

	Intervention group (n=48)	Control group (n=56)	p-value
Total gestational weight gain (kg)	14.6 (5.4)	14.3 (4.1)	0.771
Gestational weight gain, n (%) Below recommendations ³ Within recommendations Exceeding recommendations	16 (33) 10 (21) 22 (46)	15 (27) 24 (43) 17 (30)	0.053 ²
Adjusted odds ratio for exceeding recommendations ³	1.82 (0.65 to 5.14)	1.00 (ref.)	0.264

two-sided independent samples t-test

² two-sided χ^2 -test

³ Institute of Medicine 1990

⁴ Logistic regression model, adjusted for age, pre-pregnancy BMI, education, pre-pregnancy smoking status, oedema and gestation week at the last weight measurement

Child's birth weight and glucose tolerance

There were 8 (15%) high birth weight infants (\geq 4,000 g) in the control group but none in the intervention group (p=0.006). No significant differences were observed in the mean birth weight or in the proportion of low birth weight infants between the groups.

Glucosuria was observed in 4 (8%) participants in the intervention group and in 9 (16%) participants in the control group (p=0.37, Fisher's exact test). Women with fasting plasma glucose concentrations $\geq 4.8 \text{ mmol/l}$, $\geq 10.0 \text{ mmol/l}$ at 1h or ≥ 8.7 mmol/l at 2h were considered to have gestational diabetes mellitus (GDM). The incidence of GDM could not be compared between the groups, however, because the oral glucose tolerance test had only been performed for 14 participants in the intervention group (six of them diagnosed with GDM) and 11 participants in the control group (one of them diagnosed with GDM). The test had been performed on only one of the eight control participants with the high birth weight infant and she did not have GDM. Nevertheless, some factors were identified that may have contributed to the growth of the foetuses of these eight participants. Compared to the other participants in the intervention and in the control groups, these eight women had longer gestation, higher gestational weight gain and they were taller on average. They also consumed more high-sugar snacks, preferred low-fibre bread and decreased their weekly amount of LTPA more during pregnancy than other participants on average. However, they did not have a higher incidence of glucosuria than the other participants.

5.3.2 After pregnancy

Background characteristics

The intervention group was slightly older with slightly higher pre-pregnancy BMI, gestational weight gain and body weight and BMI at 2 months postpartum than the control group on average (Table 12). A greater proportion of the intervention group than of the control group were non-smokers, but the proportions of different education groups and the mean waist circumference at 2 months postpartum appeared to be fairly similar between the groups. There were no significant differences in the duration of exclusive (medians 5.0 vs. 5.0 months, p=0.57) or partial breastfeeding (medians 10.0 vs. 8.5 months, p=0.07) between the groups.

TABLE 12. Background characteristics of postpartum participants, means (SD) or numbers (%)

	Intervention group (n=48)	Control group (n=37)
Age at 2 months postpartum (yrs)	29.5 (3.9)	28.3 (4.4)
Pre-pregnancy BMI (kg/m²)	22.7 (3.7)	22.1 (2.3)
Total gestational weight gain (kg)	16.2 (5.0)	15.3 (5.0)
Body weight at 2 months postpartum (kg)	67.1 (11.1)	64.7 (7.8)
BMI at 2 months postpartum (kg/m²)	24.3 (3.8)	23.6 (2.5)
Waist circumference at 2 months postpartum (cm)	81.8 (9.0)	81.1 (6.7)
Education level, n (%)		
basic or secondary education	23 (48)	17 (46)
polytechnic education	8 (17)	10 (27)
university education	17 (35)	10 (27)
Smoking status ¹ , n (%)		
Non-smoker before and after pregnancy	30 (68)	20 (57)
Smoker before pregnancy and non-smoker after pregnancy	5 (11)	2 (6)
Smoker before and after pregnancy	9 (21)	13 (37)

Smokers include both daily and occasional smokers. Smoking status was assessed for the periods of 0–6 months before pregnancy and 4–10 months postpartum.

Changes in diet

No between-group differences were observed in the proportion of women having breakfast and at least one hot meal per day at baseline (88% in the intervention group vs. 86% in the control group, p=0.85), at the first follow-up (94% vs. 92%, p=0.74) or at the second follow-up (93% vs. 89%, p=0.52). In addition, differences in changes in the intake of vegetables, fruit and berries were not significant between the groups. However, the proportion of high-fibre bread of the total weekly amount of bread increased in the intervention group (a difference of 16 %-units between the groups) compared with the control group at both follow-ups, when adjusted for confounders (Table 13). The mean intake of high-sugar snacks diminished by 0.6 portions/d in the control group compared with the intervention group at the first follow-up, but returned to the baseline level by the second follow-up.

TABLE 13. Unadjusted means (SD) for dietary variables at baseline (2 months postpartum) and at follow-up (5 and 10 months postpartum) and adjusted group differences (95% CI) at follow-up

	Intervention group	Control group	Adjusted mean difference to control group ¹	p-value
Vegetables, fruit and berries (portions/d), mean (SD)				
2 months	2.4 (1.3)	2.7 (2.0)		
5 months	2.6 (1.4)	2.6 (1.8)	+ 0.4 (-0.1-0.9)	0.13
10 months	2.6 (1.4)	2.5 (2.1)	+ 0.2 (-0.3-0.8)	0.42
High-fibre bread (% of total bread), mean (SD)				
2 months	49 (29)	49 (30)		
5 months	60 (29)	45 (33)	+ 16.0 (4.2-27.7)	0.008
10 months	65 (27)	52 (31)	+ 16.1 (4.3–27.9)	0.008
High-sugar snacks (portions/d), mean (SD)				
2 months	1.9 (1.2)	2.0 (1.2)		
5 months	2.2 (1.3)	1.5 (0.9)	+ 0.6 (0.1–1.1)	0.028
10 months	2.1 (1.2)	2.1 (1.4)	0.0 (-0.6-0.6)	0.93

ANCOVA: mean group differences, adjusted for baseline intake of the dietary variable, age, education, smoking status, gestational weight gain and BMI at 2 months postpartum. Intervention group: n=42, control group: n=35.

Changes in physical activity

Figure 10 shows the unadjusted mean weekly METmin of total LTPA in the intervention and the control groups from baseline to 10 months postpartum. The changes from baseline to the first or to the second follow-up did not differ significantly between the groups when adjusted for baseline weekly METmin, age, education, gestational weight gain and BMI at 2 months postpartum.

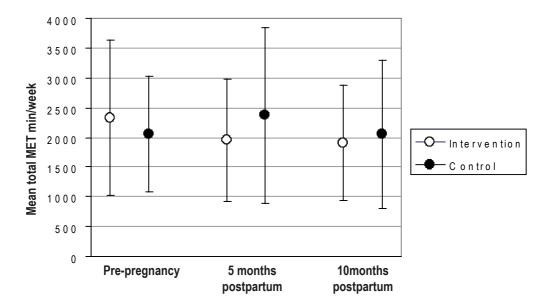


FIGURE 10. Unadjusted mean (SD) weekly METmin of total leisure time physical activity before pregnancy and at 5 and 10 months postpartum in the intervention (n=34) and the control groups (n=41)

Postpartum weight retention

The unadjusted mean body weight changes during pregnancy and during the postpartum intervention period are presented for the intervention and the control groups in Figure 11. Mean weight retention was 4.3 (SD 4.0) kg in the intervention group and 4.2 (SD 3.9) kg in the control group (p=0.91) at 2 months portpartum when the intervention began. Fifty percent of the intervention group and 30% of the control group returned to their pre-pregnancy weight by 10 months postpartum, but the difference between the groups was not significant (Table 14). When adjusted for confounders, the intervention group had almost 4-fold odds ratio for returning to their pre-pregnancy weight by 10 months postpartum compared to the control group (p=0.028). Adjustment for the duration of partial breastfeeding instead of the duration of exclusive breastfeeding did not change the results. However, no differences were found between the groups in the adjusted average weight retention at 10 months postpartum or in the adjusted change in waist circumference from 2 to 10 months postpartum.

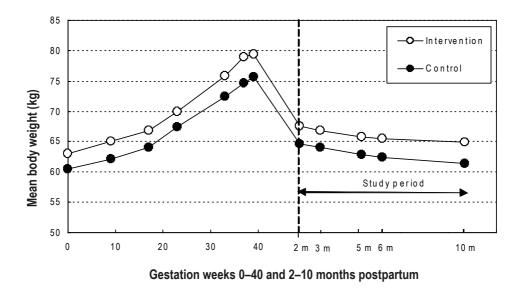


FIGURE 11. Unadjusted mean body weight changes from the beginning of pregnancy to 10 months postpartum in the intervention and the control groups (IV)

TABLE 14. Weight retention compared to pre-pregnancy weight and waist circumference at 10 months postpartum in the intervention and the control groups, numbers (%), odds ratio (95% CI) or unadjusted means (SD)

	Intervention group (n=46) ¹	Control group (n=37) ¹	p-value
Number of women who retained ≤0 kg, n (%)	23 (50)	11 (30)	0.062
Adjusted odds ratio for retaining ≤0 kg	3.89 (1.16-13.04)	1.00 (ref.)	0.028^{3}
Weight retention (kg)	1.8 (4.3)	1.0 (4.4)	0.42^{4}
Waist circumference at 10 months postpartum (cm)	78.1 (10.2)	75.4 (6.2)	0.245

- in the adjusted analysis, n=43 in the intervention group and n=35 in the control group
- ² two-sided χ^2 -test
- logistic regression model, adjusted for age, education, pre-pregnancy BMI, gestational weight gain, weight at 2 months postpartum (baseline), duration of exclusive breastfeeding and smoking status
- ⁴ ANCOVA: weight at 10 months postpartum as the dependent variable, mean difference (0.8, 95% CI -1.1–2.7) adjusted for pre-pregnancy weight
- ANCOVA: waist circumference at 10 months postpartum as the dependent variable, mean difference (1.0, 95% CI 0.7–2.7) adjusted for weight circumference at 2 months postpartum (baseline), age, education, pre-pregnancy BMI, gestational weight gain, duration of exclusive breastfeeding and smoking status

6 DISCUSSION

6.1 Preventing excessive gestational weight gain

This study was the first to examine long-term trends in gestational weight gain adjusting for changes in maternal age, pre-pregnancy BMI and parity. The comparison of the three samples of pregnant women showed that the mean gestational weight gain increased from 13.2 to 14.3 kg between the 1960s and the mid-1980s levelling off after that. The increase was detected in all age, pre-pregnancy BMI and parity groups. Although there are no corresponding trend data available from other studies, these mean weight gains are within the range observed in cross-sectional studies conducted during this time period (Table 2). The increase in mean gestational weight gain is not surprising, since there has been a general upward trend in the average BMI in Finland as well as in many other countries in recent decades due to imbalance in energy intake and expenditure (e.g. World Health Organization 2004). In Finland, the increase in the average BMI has occurred mainly among young adults during the last two decades although the mean waist circumference has also increased in older adults (Lahti-Koski et al. 2007). As age, pre-pregnancy BMI and parity explained only a negligible proportion of gestational weight gain in this study, other factors such as increase in mean energy intake or decrease in mean physical activity energy expenditure among pregnant women have probably contributed to the increase observed in mean gestational weight gain.

These observations and the earlier reports on the large proportions (34–53%) of women gaining weight excessively during pregnancy (Table 2) revealed the importance of developing interventions to prevent excessive gestational weight gain, and above all, the adverse maternal and foetal effects of excessive weight gain (Institute of Medicine 1990). In the present intervention study, the aim was to keep the gestational weight gain of healthy pregnant women within the IOM's recommended range. The intervention had positive effects on the intake of vegetables, fruit and berries and high-fibre bread and therefore on the intake of fibre, but no significant effects on the intake of high-sugar snacks or on energy intake. Therefore, it may be easier to add some healthy food items (e.g. vegetables) to one's diet rather than to decrease the consumption of one's favourite less healthy food items (e.g. high-

sugar snacks). Although there were no between-group differences in changes in the weekly METmin of total LTPA, the intervention group managed to maintain their level of moderate- and high-intensity LTPA until late pregnancy better than the control group (Aittasalo et al. 2008), which is important in terms of the general health benefits of moderate- and high-intensity LTPA (Artal & O'Toole 2003, Davies et al. 2003). These changes in diet and LTPA were not large enough to reduce the proportion of women exceeding the recommendations for gestational weight gain.

The previous five interventions have reported mixed results (Table 4). In one of the studies only (Wolff et al. 2008), the intervention had remarkable effects on dietary intake among obese women, being also able to reduce their gestational weight gain. Two of the studies reported effects on weight gain in the subgroup of low-income women (Olson et al. 2004) or in obese women (Claesson et al. 2008), but the effects on diet and physical activity are not known since no data were collected on them. Interestingly, the intervention carried out by Polley et al. (2002) reduced gestational weight gain among normal weight low-income women, although no changes in diet and physical activity were observed. No significant effects of the intervention were observed in the study by Gray-Donald et al. (2000).

The intensive dietary intervention implemented by trained dietitians during ten 1-hour consultations (Wolff et al. 2008) seemed to have greater effects on the dietary intake of the participants than the other interventions. In our study, however, we managed to show some changes in participants' diet after four relatively short counselling sessions implemented by PHNs at routine visits to MCs.

It is not clear why none of these interventions reporting data on participants' physical activity had any effect on it. Physical activity was not considered desirable during pregnancy in the aboriginal Cree community, which may have made the participants inactive at baseline unwilling to initiate physical activity during pregnancy (Gray-Donald et al. 2000). On the other hand, in the study by Polley et al. (2002), the participants seemed to be active already at baseline. In a US cohort study (n=1,535) (Evenson et al. 2008), the main barriers to physical activity during pregnancy were lack of time (in 25% of women) and tiredness (23%), followed by medical conditions, pain or discomfort (17%) and concern about harming the foetus (11%). The lack of effects of the interventions on the participants' physical activity or dietary habits may also be a consequence of the limitations of the tools used to measure them. In these multicomponent interventions, it is not possible to separate the effect of each component on weight gain. For instance, in the study by Polley et al. (2002), the frequent follow-up and feed-back on weight gain as such could have helped the participants to keep their weight gain to the recommended level. There are also inadequate data available to conclude whether dietary counselling or physical activity counselling is more effective in preventing excessive gestational weight gain.

Excessive gestational weight gain and high pre-pregnancy BMI increase the risk for high birth weight infants and related adverse outcomes (Institute of Medicine 1990, Lederman 2001). Therefore, an important finding in this study was that there were no infants with ≥4,000 g birth weight in the intervention group, but 8 (15%) of them in the control group, even if the intervention group had higher pre-pregnancy BMI and similar weight gain during pregnancy. On the other hand, glucose intolerance during pregnancy is associated with higher infant's birth weight, but healthy diet and physical activity have beneficial effects on glucose tolerance during pregnancy (King 2006, Oken et al. 2006). Therefore, the lifestyle changes observed in the intervention group might have improved the participants' glucose tolerance and thus prevented excessive foetal growth. Unfortunately, there was inadequate data available to compare the participant's glucose tolerance between the groups.

6.2 Reducing postpartum weight retention

In this study, the participants in the intervention group were more likely to return to their pre-pregnancy weight by 10 months after delivery than the participants in the control group after adjusting for confounding factors. No differences were observed between the groups in average weight retention or waist circumference at 10 months postpartum. The reason for this discrepancy is that among those participants who did not return to their pre-pregnancy weight, the average weight retention was higher in the intervention group than in the control group. The intervention group increased the proportion of high-fibre bread of the total weekly amount of bread, which was observed at both follow-ups. On the other hand, no beneficial effects of the intervention were observed on the other dietary outcomes or weekly METmin of total LTPA.

Since the effects of the intervention on the participants' dietary and physical activity habits were minor, it is not clear why the participants in the intervention clinics returned to their pre-pregnancy weight more often than controls, despite similar weight retention at baseline. The intervention group may have decreased their total energy intake during the study, which could not be assessed by the semi-quantitative FFQ. It may also reflect the general difficulties in reporting one's diet and physical activity accurately, because similar results have been reported in previous interventions aimed at reducing weight retention after delivery (Table 4). In both studies (Leermakers et al. 1998, O'Toole et al. 2003), the intervention had

an effect on weight retention although no differences were observed in changes in energy intake or expenditure between the intervention and the control groups. However, small daily changes in diet are usually difficult to detect, although they may have some impact on body weight in the long term.

It is difficult to compare the magnitude of weight loss or weight retention in this study and in these two previous studies in more detail since the study populations were so different. For this study, the participants were recruited regardless of the amount of weight retention at baseline whereas the other studies recruited women with at least 5 kg weight retention. However, the internal validity and therefore also the external validity of the results of the studies by Leermakers et al. (1998) and O'Toole et al. (2003) is poor due to the high drop-out rates (31% and 41% respectively). As none of these intervention studies or the observational studies (Table 3) reported changes in waist circumference after delivery, comparisons with this study are not feasible.

6.3 Methodological considerations

6.3.1 Representativeness of the participants

In general, there may be a selection bias in a study population if the participants differ from non-participants or if the drop-outs differ from the participants completing the study (dos Santos Silva 1999). This may affect the results of a study, particularly if the differences and the proportions of non-participants and drop-outs vary between the groups that are compared to each other.

The three samples in this study were relatively representative samples of pregnant women in Helsinki or in Tampere. There may have been some selection bias in the first sample, however, as half of the women had been prescribed oestrogen or progestin drugs during pregnancy and their weight gain was on average 300 g greater than weight gain among the other women (p=0.11). If the hormone-exposed women had been excluded from the analysis the difference between the first and second samples in mean gestational weight gain could have been slightly larger. The purposes for which the second and third samples were originally collected for should not have had any effect on gestational weight gain. Similar exclusion criteria were used for all samples when comparing gestational weight gain between the samples. As the number of excluded women was much higher in the first sample than in the other samples (Figure 3) and no information was available on the excluded women, the possibility of selection bias cannot be entirely ruled out.

In the intervention study, the average participation rate was 77%, being slightly higher in the control clinics than in the intervention clinics. No data are available on the characteristics of the non-participants or on the reasons for not participating in the study, but the reasons may be related to the participants' background characteristics or to their reluctance to improve or monitor their dietary and physical activity habits. Additionally, there may have been between-clinic differences in the PHNs' motivation to recruit participants. In any case, the high participation rate suggests that the participants represented the eligible population relatively well.

An important issue in any intervention study is to assess whether the intervention and the control groups were similar with respect to confounding factors at baseline. Particularly in small studies, all between-group differences in baseline characteristics may be sources of confounding regardless of the statistical significance of the differences (Senn 1994). In this study, the participants in the intervention clinics had more risk factors for excessive gestational weight gain and postpartum weight retention at baseline (e.g. higher pre-pregnancy BMI). These factors were included as confounders in the analyses, but the differences may have affected the effectiveness of the intervention. Randomizing a small number of clinics (n=6) in this study would not have guaranteed similarity of the groups at baseline, however, especially due to the remarkable regional variation in the participants background characteristics. Importantly, the participating pregnant and postpartum women could not choose their clinic, which may have decreased the bias associated with the non-randomized design.

The drop-out rate in the intervention study was very low in general except for the intervention MCs (29%). Many of the drop-out reasons (Figure 7) could be expected. For instance, some participants were lost due to change of residence or due to reasons related to pregnancy, e.g. two miscarriages, one twin pregnancy, one because of risk of premature delivery and two because of a second pregnancy during the postpartum follow-up period. Six participants were not willing to continue the study due to a stressful life situation. On the other hand, some participants considered the data collection too burdensome or were reluctant to give the blood samples or did not find time for it. These three reasons were related to this study as such and they should be paid more attention when further studies are planned. Nevertheless, the drop-outs may have been less motivated to change their dietary or physical activity habits than the participants completing the study.

One of the three intervention MCs was less successful both in recruiting participants and retaining them in the study. In this clinic, the participation rate was lower (68% vs. 77% and 85%) and the drop-out rate was higher (38% vs. 15%).

and 27%) than in the two other intervention MCs. There were no major differences in these rates between the individual PHNs in this clinic.

To assess the possible selection bias associated with the drop-outs in the intervention study, data on variables available at baseline (e.g. age, education level, smoking status, the baseline variables for diet and LTPA) was compared between the drop-outs and the participants completing the study (independent samples t-test, χ^2 -test). Among the pregnant participants, there were no significant differences in these variables between the drop-outs (n=27) and the participants who completed the study (n=105). However, there was a tendency for a lower energy intake among the drop-outs (p=0.07). Therefore, differences in the drop-out rate between the intervention and the control clinics may not have had a major effect on the results. The postpartum drop-outs (n=7) had higher BMI before pregnancy (p=0.013) and at 2 months postpartum (p<0.001) on average than the participants completing the study (n=85), but no significant differences were observed in other variables between the groups. As the drop-out rates were no more than 9% in the intervention group and 5% in the control group, the effects of the few differences on the results were probably minor.

6.3.2 The intervention study

A major strength of the intervention study was that the counselling was carried out by PHNs during routine visits to MCs and CCs, where practically all pregnant and postpartum women can be reached in Finland. Therefore, no extra study personnel were needed for the counselling. This enhances the possibilities of utilizing the counselling model later at wider scale in clinical practice. As a result of this approach, all primary counselling sessions were realized and only a few booster sessions did not materialize. The contents and the durations of the counselling sessions were as intended according to the records in the PHNs counselling cards. Additionally, adherence to the dietary and physical activity plans was regularly recorded in the follow-up notebook by most participants. A possible limitation of this approach was that the presence of infants may have interfered with the counselling in the CCs.

The timing of the counselling sessions was selected according to the recommended timing of routine visits to a PHN (Viisainen 1999, Ministry of Social Affairs and Health 2004). The visits when the participants met both a PHN and a physician could not be included in the protocol due to hectic time schedules at those visits. Partly due to this, the time span between some of the booster sessions may have

been too long to motivate the participants to adhere to the dietary and LTPA plans. Nevertheless, increasing the number of counselling sessions may not be feasible.

The physical activity counselling began at the first visit and the dietary counselling at the second visit. The time span between these visits was approximately two months in the MCs and one month in the CCs. The effects of the intervention on weight development could have been greater, particularly among the pregnant participants, if the dietary counselling had been initiated at the first visit as recommended (Viisainen 1999, Hasunen et al. 2004). This is supported by the findings that the improvements in diet in the intervention group were already observed at the first follow-up and they persisted until the second follow-up both among pregnant and postpartum participants. Therefore, earlier initiation of dietary counselling could have increased the clinical significance of these changes in terms of weight management. Secondly, the intervention did not have an effect on the total amount of LTPA among the pregnant or the postpartum participants.

With regard to the contents of the counselling, some points need to be addressed. Firstly, the main focus of the intervention was on promoting healthy dietary and physical activity habits rather than on monitoring the appropriateness of gestational weight gain beyond the routine weight measurements. The recommendations for total gestational weight gain were introduced to the participants at the first MC visit only. It might have been easier for the participants to keep their weight gain within the recommendations if individual weight gain charts such as in some earlier studies (Polley et al. 2002, Olson et al. 2004) had been used in this study.

The dietary counselling focused on four topics that were expected to help in preventing excessive pregnancy-related weight gain (Männistö et al. 2003, World Health Organization 2003, Hasunen et al. 2004, Nordic Council of Ministers 2004). Total fat intake, which is also an important topic with respect to weight management, was not discussed for the following reasons. The number of topics had to be restricted as the time allocated for counselling was limited. The average fat intake among the Finnish women was within the recommended range whereas the intake of fibre and sucrose was not (Männistö et al. 2003). Additionally, if a participant had achieved the other four dietary objectives, her fat intake could have decreased as a result of these changes. One of the four topics focused on a proper meal rhythm. The objective of having a breakfast and a hot meal every day seemed not to have been sensitive enough to detect changes in meal rythm, since most of the participants fulfilled this objective already at baseline. The average number of snacks per day would have provided important additional information.

The objective for LTPA was based on the physical activity recommendations, in which at least 30 min of moderate-intensity physical activity on five days per week

is regarded as sufficient for health and at least 40 min of high-intensity physical activity on three days per week as sufficient for fitness (Pate et al. 1995, American College of Sports Medicine 1998, Artal & O'Toole 2003, Davies et al. 2003). In Finland, a minimum of 30 min/d of moderate-intensity physical activity is currently recommended for the general population as well as for for pregnant and postpartum women (Valtion ravitsemusneuvottelukunta 2005). However, it seems that at least 45–60 min of moderate intensity activity per day is needed to prevent unhealthy weight gain in general population (Saris et al. 2003, Wareham et al. 2005). This corresponds to approximately 1,575–2,100 weekly METmin of moderate intensity physical activity. Therefore, higher level of LTPA than the minimum recommended in this study might have been needed to have an effect on weight development during or after pregnancy. Nevertheless, participants who exceeded the minimum recommendations before pregnancy were engouraged to maintain their activity level for as long as possible during pregnancy or to resume that level gradually after delivery.

The counselling was based on the model developed by Laitakari & Asikainen (1998). Although other behavioural theories might also have been applicable, this model was found to be feasible for physical activity counselling in this maternity and child health care setting (Aittasalo et al. 2008). In this model, the objectives for behavioural changes are set individually. However, the dietary objectives were set close to the recommended level for all participants in order to simplify the counselling. Although some changes in diet were observed, individually set objectives might have motivated the participants more to change their dietary habits.

The group exercise sessions were specifically planned for pregnant and postpartum women, but the average participation rates were quite low, especially among the pregnant participants. Information on the reasons for the low participation rate is not available. As discussed earlier (Aittasalo et al. 2008), the reasons might include less need for peer support than among portpartum participants, working schedules preventing participation, no need for special maternity exercise in early pregnancy or preference to continue one's previous physical activity practices.

In the control MCs and CCs, the PHNs were asked to continue their usual counselling practices during this study. To control for this, they were inquired by questionnaire three months after the initiation of the study whether they had managed to maintain their counselling practices. Some of the control PHNs reported that they now bear in mind the new dietary recommendations (Hasunen et al. 2004) when counselling their clients on diet. No changes were reported in physical activity counselling practices. Nevertheless, the possibility that they might have changed their counselling practices to some extent during the study cannot be excluded. Another

important issue is that the control PHNs usually recommended their pregnant clients 2–3 kg smaller gestational weight gain on average compared to the IOM's recommendations used in the intervention clinics. As the amount of gestational weight gain recommended by health professionals has been related to actual weight gain during pregnancy (Cogswell et al. 1999), the lower recommendations in the control clinics may have restricted weight gain among the control women.

A sample size of this study was not based on power calculations as the main purpose of this study was to pilot the study protocol for a larger study. In any case, the small sample size reduced the chances of detecting statistically significant effects of the intervention. On the other hand, this emphasizes the importance of those statistically significant effects that were observed in this small study. Another statistical limitation in this study was that multilevel analyses could not be used due to the small number of the clinics. Multilevel analyses are recommended, although not commonly used, in cluster randomized trials as they take the intra-cluster correlation into account (Varnell et al. 2004).

6.3.3 Validity of the outcome data

In this study, information on gestational weight gain was obtained from the maternity cards for all participants. All weight data recorded during pregnancy was based on measurements at the MC visits. Additionally, weight and waist circumference of the postpartum participants were measured at each study visit to the CCs. In the intervention study, the scales of the clinics were calibrated to the reference scale.

The baseline for determining gestational weight gain and postpartum weight retention was the pre-pregnancy weight, which was based on self-reported information for all participants as in most other studies (Gunderson & Abrams 2000). In general, self-reported body weight may be underreported, especially among overweight women (Jalkanen et al. 1987, Engstrom et al. 2003). In a Swedish study (Öhlin & Rössner 1990), the self-reported pre-pregnancy weight was on average 0.8 kg lower than the measured pre-pregnancy weight among those 39 women for whom data were available. Underreported pre-pregnancy weight results in overestimation of total gestational weight gain and postpartum weight retention and may cause bias in the findings, especially if the proportions of overweight women are different between the groups that are compared to each other. However, as pregnant women usually report their pre-pregnancy weight at the first MC visit when weight is also measured, this context may reduce their desire to deliberately underreport their

weight. Pre-pregnancy weight may also be estimated inaccurately if a woman has not weighed herself for a long time.

It is not known whether underreporting of pre-pregnancy weight has increased since 1960s, but the proportion of overweight women was higher in the third sample (30%) than in the earlier samples (12–16%). Although this should not affect the comparison between the first two samples, the possibility that actual weight gain was slightly lower in the third sample cannot be fully excluded. In the intervention study, there were more overweight women in the intervention than in the control groups. The effect of possible BMI-dependent underreporting was considered to be small, since among the pregnant participants, weight gain from pre-pregnancy to first MC visit was similar in all BMI groups, and among the postpartum participants the results on weight retention did not change when overweight participants were excluded from the analyses.

In addition to self-reported pre-pregnancy weight, another possible source of measurement bias in this study is related to the estimation of total gestational weight gain performed for the three samples of pregnant women. The total gestational weight gain had to be estimated for the first sample especially, because there were numerous missing values for pre-pregnancy weight and weight measured close to delivery and the timing of the other weight measurements varied considerably. To improve the comparability of the samples, weight gain was estimated until 40 weeks' gestation for the other samples, although the calculations could not be performed in exactly the same way. A similar type of estimation of gestational weight gain has been successfully used in other studies (e.g. Olson & Strawderman 2003).

Regarding the assessment of diet and LTPA, there may be measurement bias if the instruments are not valid or if the accuracy of self-reports varies between the intervention and the control groups. Whether the questionnaires used in this study were valid among pregnant and postpartum women was not ascertained. Information on energy intake could not be obtained by this semi-quantitative FFQ, but it was used because FFQs are more applicable than food records in the envisaged larger study for which this study protocol was piloted and because the PHNs utilized the FFQ in counselling. By using an FFQ, it was also possible to elicit usual dietary habits over a longer time period, which is important due to the large day-to-day variation in dietary habits. To obtain a reliable estimate of the average intake of energy and macronutrients of an individual, food records for 3-10 days are considered sufficient (Willet 1998). Food records provide more detailed information on dietary intake, but they are much more laborious for the participants to fill in and for the researchers to process. Therefore, additional food record data were collected from pregnant participants only.

In the LTPA questionnaire, the amount of breathlessness was used to describe different intensity levels to the participants. However, the amount of everyday light-intensity LTPA may have been especially difficult to report accurately, which may have caused some bias in the assessment of total weekly METmin. Another point needs to be addressed with respect to the validity of this outcome. Based on Howley (2001), MET value 3 was concluded to represent light-intensity, MET value 5 moderate-intensity and MET value 7 high-intensity LTPA in women aged 20-39 years on average. These values are not exact at individual level, however, since the MET values of each intensity level activity vary across the fitness continuum, being higher for people with high fitness level and lower for people with low fitness level. In any case, the weekly METmin was the best possible outcome for comparing the total level of LTPA between the intervention and the control groups as it is related to LTPA energy expenditure (Howley 2001). Conversion of the METmin to energy expenditure would not have been accurate, however, mainly because these MET values were derived from measurements made in non-pregnant adults (Howley 2001) and because the energy cost of a given activity changes as pregnancy progresses e.g. due to increase in body weight (Prentice et al. 1996).

In conclusion, these possible sources of measurement bias in assessment of diet and LTPA are actually similar in the intervention and the control groups. Therefore, this kind of non-differential bias does not affect the group comparisons, but it is more likely to underestimate the differences observed between the groups (dos Santos Silva 1999).

6.4 Implications for further studies

In response to the weight gain problems common among women in childbearing age, an intervention study protocol was developed for prevention of excessive pregnancy-related weight gain in a primary health care setting. With a few exceptions, the study protocol was found to be feasible with regard to recruitment and participation, completion of data collection, realization of the intervention and the PHNs experiences. Although some promising effects of the intervention were observed, the effectiveness of this kind of intervention needs to be shown in larger trials. Due to the pilot nature of this intervention study, it was conducted for separate groups of pregnant and postpartum women. Future studies should ideally begin in early pregnancy in order to prevent excessive gestational weight gain and continue after delivery to help the women to return to their pre-pregnancy weight. No such studies have so far been published.

Alternatively, future studies could examine whether it is possible to prevent GDM by counselling pregnant women on diet and physical activity. Prevention of GDM is of importance to public health, since the incidence of GDM has increased (e.g. Ferrara 2007) and GDM is associated with adverse effects such as mother's or child's risk of subsequently developing type 2 diabetes (Kim et al. 2002, Dabelea 2007). In this study, there were no high birth weight infants in the intervention group although no effects on gestational weight gain were observed. Therefore, positive changes in dietary and physical activity habits may have a greater effect on glucose tolerance than on gestational weight gain. According to a review article, improvements in the quality of dietary fat, fibre intake, physical activity level and gestational weight gain may prevent GDM (Luoto et al. 2007). If future interventions to prevent excessive gestational weight gain or GDM proved successful, a long-term follow-up of the participants would show whether the interventions were also able to reduce the risk for overweight and type 2 diabetes both in the mother and in the offspring.

In this intervention study, the participants were healthy women with relatively healthy dietary and LTPA habits. For this reason, it may have been difficult for them to further improve their habits. To increase the effectiveness of the counselling, a risk group approach should be considered. Another reason for focusing on a risk group is to limit the PHNs' workload. That way the PHNs could target the counselling more efficiently instead of reducing time allocated for all clients, which could impair the effectiveness of the counselling.

Several potential risk groups can be identified for studies aiming to prevent excessive pregnancy-related weight gain (see chapters 2.1.4 and 2.2.3). Women who are pregnant for the first time, probably regardless of their age, exceed the weight gain recommendations more often than women with earlier deliveries. On the other hand, women who gained weight excessively in any previous pregnancy or retained substantial weight after any pregnancy can be regarded as a risk group. Additionally, women who are overweight or obese before pregnancy are at increased risk for gaining excessive weight during pregnancy and a subgroup of them retains much weight postpartum. When aiming to prevent GDM, the risk group includes e.g. overweight women, women aged at least 40 years, women with GDM or high birth weight infant (\geq 4,500 g) in a previous pregnancy and women with a family history of diabetes (e.g. Hasunen et al. 2004). Women with unhealthy dietary habits or inadequate physical activity levels can also be considered a risk group for both GDM and excessive weight gain during and after pregnancy. After all, these risk groups include a large proportion of pregnant and postpartum women.

Some methodological implications can also be noted. Future studies conducted in this setting should be cluster-randomized trials with a larger number of clusters and participants than in this study. Data on the behavioural outcomes should preferably be collected using questionnaires validated in pregnant and postpartum women. Later studies should also aim to collect some follow-up data (e.g. a copy of the maternity card) on participants who drop out of the study since it would make intention-to-treat analysis possible. To be able to assess the representativeness of the study participants, the non-participants could be systematically asked if they were willing to give the reason for not participating in the study and to provide the data collected at baseline. Future studies could also investigate the cost effectiveness of the intervention, which was not included in the feasibility evaluation in this study.

Safety aspects need to be carefully considered in studies including pregnant and postpartum women. It is therefore of utmost importance that this intervention had no adverse effects on the mother or on the offspring (III, Aittasalo et al. 2008). This suggests that similar interventions can be conducted safely in this vulnerable group.

Several other practical lessons were learned from this study, which can help in planning future intervention studies. Firstly, the recruitment of participants may be slower than initially expected and therefore it should be allocated sufficient time. When the number of participants recruited is frequently monitored by the researchers, the estimated time needed for recruitment can be updated during the process and communicated to the PHNs. In order to achieve a high participation rate, how the PHNs introduce the study to their clients and motivate them to participate is crucial.

Secondly, although the data collection was very successfully performed by the PHNs, other ways of collecting data should be considered. The amount of data collection and other paper flow should be restricted as much as possible to reduce the burden on the PHNs and the participants. Blood samples were obtained from most participants, although the participants had to make two additional visits to give the samples. Instead, the collection of NAF samples from the postpartum participants was less successful, which concurs with the experience of an earlier study (Baltzell et al. 2006). In this study, the baseline blood samples from some pregnant participants were obtained several weeks later than intended because they did not make appointment for drawing the samples and were later phoned by the study personnel. To avoid delays in collecting any samples in future studies, the appointment for taking the samples should be made by the study personnel rather than by the participants themselves.

Thirdly, as the average participation percentage in the group exercise was relatively low, particularly among the pregnant participants, other ways to support physical activity counselling could be considered. For instance, the group exercise sessions could take place less often during pregnancy, but the exercise instructor could encourage the participants to adhere their individual plans by phoning them between sessions. Future studies could examine the feasibility of arranging supportive activities also for dietary counselling.

Lastly, the quality and adequacy of training arranged for the PHNs will need to be paid attention in future studies. The increased knowledge about diet and physical activity and the improved counselling skills were the most important personal benefits for the PHNs in this study, for which they received no financial compensation for their extra work. Therefore, satisfaction with the training provided for PHNs in future studies could increase their motivation to implement the study protocol for a long period of time as is inevitably needed. Additional supportive and informative meetings will probably be needed during the study.

In summary, this pilot study provided scientific and practical information that can be utilized in planning further intervention studies, especially those to be conducted in a primary health care setting. In the light of the experiences of this pilot study, we initiated a larger intervention study in the maternity clinic setting in September 2007 (http://www.controlled-trials.com/ISRCTN33885819). Briefly, the primary aim of this ongoing study is to examine whether the intervention is able to prevent the development of GDM among pregnant women with risk factors for GDM. The study is a cluster-randomized controlled trial in which 14 municipalities from Pirkanmaa area were randomized to the intervention and the control conditions. Approximately 400 participants will be recruited by the end of the recruitment period (31 December 2008). The intervention is mostly similar to the intervention in the pilot study. However, the rate of gestational weight gain is now being monitored more intensively using individual BMI-specific weight gain charts (Althuizen et al. 2006). The dietary counselling now also focuses on improving the quality of fat in the diet and the objectives are now set individually for each participant according to her preferences. Additionally, the group exercise sessions are now arranged monthly. The intervention will continue until the end of pregnancy, but the participants will be followed up after delivery.

7 CONCLUSIONS

The conclusions related to the specific study questions are as follows:

- 1. Mean gestational weight gain has increased in Finland since the 1960s independently of parallel increases in maternal age and pre-pregnancy BMI. The increase in mean gestational weight gain was observed in all age, BMI and parity groups. This suggests that pregnant women may nowadays be more prone to postpartum weight retention and possibly also to subsequent overweight than pregnant women in the 1960s.
- 2. The study protocol of the intervention study aiming to prevent excessive pregnancy-related weight gain was mostly feasible to implement in the primary health care setting. The high participation rate, low drop-out rate, successful data collection and realization of the intervention and the positive experiences of the PHNs speak for conducting larger intervention studies in comparable settings. The experiences of this pilot study can be utilised in planning future studies.
- 3. Among the pregnant participants, the intervention had positive effects on the intake of vegetables, fruit and berries and high-fibre bread, but not on the intake of high-sugar snacks or the total weekly amount of LTPA. The intervention was not able to reduce the proportion of participants gaining excessive weight during pregnancy.
- 4. Among the postpartum participants, the intervention had positive effects on the intake of high-fibre bread, but not on the other dietary outcomes, the total weekly amount of LTPA or average weight retention. Nevertheless, the intervention increased the proportion of participants returning to their prepregnancy weight by 10 months postpartum.

This study showed that it was possible to integrate an intervention study aiming to prevent excessive pregnancy-related weight gain in the daily routines of Finnish maternity and child health care, which is important in terms of utilisation of the results in clinical practice. Some promising effects of dietary and physical activity counselling were also observed in this study. Due to the limitations of this pilot study, the results on the effectiveness of the intervention need to be interpreted with caution until confirmed in larger randomized controlled trials.

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APPENDICES

Appendix 1. Estimation of total gestational weight gain for the sample of pregnant in Helsinki 1954–1963

Total gestational weight gain was estimated by calculating straight lines for weight gain for each woman for 0–15 and 15–40 weeks' gestation separately and by adding the lines up to total gestational weight gain.

The formula used to calculate the lines was:

$$y = a + bx$$
, where $b = \frac{w_2 - w_1}{g_2 - g_1}$ and $a = \overline{y} - b\overline{x} = \frac{w_2 + w_1}{2} - b\frac{g_2 + g_1}{2}$

For Line A (0-15 weeks' gestation), w_1 = mothers pre-pregnancy weight, w_2 = weight measured before 15 weeks' gestation (or if that was not available, 45.1%, abstracted from Line B at 15 weeks' gestation), g_1 = gestation week for w_1 (0) and g_2 = gestation week for w_2 (mean 11.3 weeks).

For Line B (15–40 weeks' gestation), w_1 = weight measured between 15–24 weeks' gestation (or if that was not available, 51.4%, abstracted from Line A at 15 weeks' gestation), w_2 = weight measured after 30 weeks' gestation, g_1 = gestation week for w_1 (mean 18.2 weeks) and g_2 = gestation week for w_2 (mean 39.1 weeks).

The calculations were originally described by Kinnunen et al. (2004).

Appendix 2. Intake of energy, macronutrients and fibre at 9–11 and at 36–37 weeks' gestation in the intervention (n=49) and the control (n=54) groups in the MCs, unadjusted means (SD)

	9–11 weeks' gestation	36–37 weeks' gestation	Adjusted mean difference to control group ¹	p-value ¹
Energy intake (kJ/d)				
Intervention	7,813 (1,298)	8,478 (1,762)	+53	0.87
Control	7,691 (1,658)	8,408 (1,578)		
Protein (E%)				
Intervention	16.4 (3.0)	16.3 (2.8)	+0.8	0.12
Control	16.3 (2.6)	15.7 (2.2)		
Carbohydrate (E%)				
Intervention	51.2 (6.2)	51.0 (4.9)	-1.1	0.28
Control	51.9 (6.2)	51.5 (5.4)		
Fat (E%)				
Intervention	31.1 (5.7)	31.3 (5.2)	+0.3	0.75
Control	30.4 (6.5)	31.5 (5.3)		
Fibre (g/d)				
Intervention	20.8 (6.6)	23.5 (7.6)	+3.6	0.007
Control	20.9 (6.2)	20.7 (6.4)		

ANCOVA, mean group differences adjusted for baseline intake of the dietary variable, prepregnancy age, BMI, education and smoking status. Intervention: n=45, Control: n=53

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PAPER

Pregnancy weight gain from 1960s to 2000 in Finland

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OBJECTIVE: To study secular trends in average pregnancy weight gain between the 1960s and 2000 in Finland, and whether the changes were related to body mass index (BMI), age or parity.

DESIGN: Three cross-sectional population surveys in Finland from three different periods.

SUBJECTS: Women who were pregnant in Helsinki in the period 1954–1963 (N = 2262), or in Tampere in the period 1985–1986 (N = 1771) or in 2000–2001 (N = 371).

MEASUREMENTS: Pregnancy weight gain was determined from self-reported prepregnancy weight and measured weights during pregnancy.

RESULTS: The mean age and prepregnancy BMI of all pregnant women increased between the 1960s and 2000 (from 26.5 to 29.6 y, from 21.9 to 23.7 kg/m²). The mean pregnancy weight gain, adjusted for mother's age, BMI and parity, increased from the 1960s to the mid-1980s from 13.2 to 14.3 kg. The increase was observed in all BMI categories. Compared to the 1960 cohort, the proportion of women with a pregnancy weight gain of less than 10 kg decreased and the proportion of women with a weight gain of 15 kg or more increased in the 1980 cohort. After the mid-1980s, the average pregnancy weight gain remained the same. In all cohorts, overweight women gained least weight during pregnancy, but age and parity were not associated with BMI and parity-/age-adjusted pregnancy weight gain. Higher pregnancy weight gain was associated with higher mean child's birthweight and higher proportion of high birthweight babies in all cohorts.

CONCLUSIONS: The mean pregnancy weight gain has increased since the 1960s, which may be of importance with regard to the development of later obesity. Factors other than changes in prepregnancy BMI, age and parity must explain the increased pregnancy weight gain over time.

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Keywords: pregnancy weight gain; body mass index; parity; trends; Finland

Introduction

High pregnancy weight gain is associated with higher postpartum weight retention and higher risk of obesity, ^{1,2} as well as higher child's birthweight, whereas low weight gain increases the risk of delivering a low birthweight baby. ^{3–5} Population-based data on trends in pregnancy weight gain over time are only available for the United States. The data from several nationally nonrepresentative studies indicate that the mean pregnancy weight gain increased from 10 kg during the period 1940–1960 to 15 kg in the 1980s. ⁶ The upward trend may have been related to more liberal recommendations regarding weight gain in the 1970s. ^{1,5–7}

Several maternal characteristics contribute to the magnitude of pregnancy weight gain. It has consistently been shown that obese women gain less weight during pregnancy

on average than other women.^{3,4,8–11} Some studies suggest that primiparous women gain more weight than multiparous women.^{1,3,4} The results from the few studies examining the effect of age on pregnancy weight gain are contradictory.^{3,4}

In this study, we examine how pregnancy weight gain has changed in Finland during the last four decades, and whether the possible changes can be explained by prepregnancy body mass index (BMI), age or parity. In addition, we examine the relation between maternal weight gain and child's birthweight in the different time periods.

Material and methods

Cohorts

We used the data of three population-based cohorts of pregnant women. The first cohort consisted of women who were pregnant between 1954 and 1963 in Helsinki, the capital of Finland ($n\!=\!4090$). The cohort was a sample gathered for a study on hormone exposure during pregnancy, including about 2000 exposed women and 2000

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controls. The cohort was collected from the standard maternity cards of municipal maternity centres, which were used by 85% of the pregnant women. The hormone-exposed women were a systematic sample of women who had been prescribed oestrogen or progestin drugs during pregnancy. For each exposed woman, a woman next in the maternity centre file, who gave birth during the same year and had not been prescribed hormones during pregnancy, was chosen as a control. The exposed women were a selected group, but they were included because their weight gain did not differ statistically significantly from that of controls, an unbiased sample of maternity centre users (13.5 vs 13.2 kg, P=0.111). The cohort has been described in detail earlier.

The second cohort included 2048 women, who participated in a randomised controlled trial examining the benefits of routine iron prophylaxis during pregnancy in Tampere area in 1985–1986. Tampere is one of the major towns in southern Finland. All women attending the municipal maternity centres in Tampere (15 centres) and in the five neighbouring communities (12 centres), covering 99.9% of pregnant women in the area, were included. Data on mother's pregnancy and health, anthropometric measurements and background characteristics were collected from forms based on data abstraction from maternity cards.

The third cohort was collected for a study on health-care services at maternity centres in Tampere and its neighbouring province. Of all 698 women giving birth in the area between November 15, 2000 and January 14, 2001, 421 (60.3%) women were included in the study. The large number of nonrespondents was mainly due to the fact that the women were not asked to participate, nor did they receive the study questionnaire due to the high workload of the hospital personnel. The data were abstracted from maternity cards and patient records. When age, proportion of primiparous women, area, sections and deliveries of the study population were compared to those of all 698 women, or of all women giving birth in 2000 or 2001 in this area, no statistically significant differences were found.

In all cohorts, the measurements and the data recording were based on the same nation-wide system, in which midwives record all pregnancy data on a standard maternity card. Mother's weight is measured several times during pregnancy, but prepregnancy weight is self-reported.

For this study, we excluded mothers whose pregnancies ended in miscarriage, abortion or multiple births, and, in the first cohort, mothers whose weight measurements were outside the following time ranges: first and last visit at the maternity centre between the fourth and 45th gestation weeks, the time between the body weight measurements 3–300 days and delivery between 22nd and 45th gestation weeks (n=260), leaving 3473, 2048 and 410, respectively. After women with missing values in prepregnancy BMI, age, parity or pregnancy weight gain were excluded from the analyses, the final numbers of women included in the three cohorts were 2262, 1771 and 371, respectively.

Calculation of pregnancy weight gain

Pregnancy weight gain was initially determined as the difference between prepregnancy weight and the weight at the last measurement during pregnancy. Since in the first cohort, the timing of the weight measurements varied considerably, the total pregnancy weight gain was extrapolated until the 40th week of gestation by using the measured weight values (TI Kinnunen, R Luoto, M Gissler, E Hemminki and L Hilakivi-Clarke—unpublished data). In the second cohort, the last weight measurement was the mean in the 36th week of gestation. The mother's weight in the 40th week was estimated from a straight line from the first measurement (around the 12th gestation week) to the last measurement. In the third cohort, the last weight measurement was the mean at the 39.3th week of gestation, but varied from the 34th to the 43rd week of gestation. To make the third cohort better comparable to the other cohorts, we estimated the mother's weight at the 40th week from a straight line from prepregnancy weight to the last measurement.

Statistical analyses

The mothers' age, parity, height, prepregnancy weight and BMI and pregnancy weight gain were compared between the cohorts. The significance of the differences in means was tested by analysis of variance and further by the Bonferroni test, and the proportions were tested by χ^2 test. Pregnancy weight gain was compared between the cohorts in each category of prepregnancy BMI (underweight: BMI less than 20 kg/m², normal weight: 20–24.9 kg/m², overweight: 25 kg/ m² or more) and parity (1, 2, 3 or more). The statistical significance of the differences between the cohorts was tested by analysis of covariance in which adjustments were made for BMI, age and parity. The differences were further tested by the Bonferroni test. In addition, linear regression models were used in each cohort to assess the contribution of BMI, age and parity to pregnancy weight gain. The estimated pregnancy weight gain was modelled as the dependent variable. The independent variables included prepregnancy BMI, age and parity. The differences in the child's mean birthweights (adjusted for gestational age) were tested between the cohorts and between the groups of pregnancy weight gain (<10.0, 10.0-14.9, 15.0-19.9, \geq 20 kg) in each cohort by using analysis of covariance. χ^2 test was used to test the differences in the proportions of low (<2500 g) and high birthweight babies (>4000 g) between the cohorts and between the groups of pregnancy weight

Results

From the first to the last cohort, the mean age of all pregnant women increased, the proportion of young mothers (<25 y) declined and the proportion of older mothers ($\ge35 \text{ y}$)



Table 1 Background characteristics by cohort, mean or proportion (95% confidence interval, CI)

	Helsinki, 1954–1963 (n = 2262)	Tampere, 1985–1986 (n = 1771)	Tampere, 2000–2001 (n = 371)
Mother's mean (CI) age (y)	26.5 (26.3–26.7)	27.6 (27.3–27.8) ↑	29.6 (29.1-30.2) ↑
<25 y (%; CI)	40 (38–42)	27 (25–29) ↓	18 (14-22) ↓
25–29.9 y (%; CI)	35 (33–37)	40 (38–42) ↑	32 (27-37) ↓
30–34.9 y (%; CI)	18 (16–19)	24 (22–26) ↑	30 (26-35)
≥35 y (%; CI)	8 (7–9)	9 (8–10)	20 (16-24) ↑
Mean (CI) parity at index birth	1.80 (1.76–1.84)	1.79 (1.75–1.83)	1.85 (1.75–1.95)
Mother's height, mean (cm; CI)	162.1 (161.8–162.3)	165.1 (164.8–165.3) ↑	166.1 (165.5–166.7)
Mother's mean prepregnancy weight (kg; CI)	57.6 (57.3–57.9)	60.7 (60.3–61.2) ↑	65.5 (64.2–66.9) ↑
Age-adjusted (kg)	57.8 (57.4–58.2)	60.6 (60.2–61.1) ↑	65.3 (64.3–66.2) ↑
Mean (CI) prepregnancy BMI ^a (kg/m ²)	21.9 (21.8–22.0)	22.3 (22.1–22.4)	23.7 (23.3–24.2) ↑
Age-adjusted (kg/m ²)	22.0 (21.9–22.1)	22.2 (22.1–22.4)	23.5 (23.2–23.8) ↑
< 20 kg/m ² (%; CI)	22 (20–24)	23 (21–25)	18 (14–21)
20–24.9 kg/m ² (%; CI)	66 (64–68)	61 (59–63) ↓	53 (48–58) ↓
$\geq 25 \text{ kg/m}^2 \text{ (%; CI)}$	12 (10–13)	16 (15–18) ↑	30 (25–34) ↑

 \uparrow or \downarrow : a statistically significant increase or decrease compared to the earlier cohort (ANOVA, Bonferroni-test, χ^2 -test). Otherwise, the differences were statistically insignificant (P>0.05). ^aBMI, body mass index.

Table 2 Pregnancy weight gain by cohort and parity, mean (95% confidence interval, CI)

	Helsinki, 1954–1963 (n = 2262)	Tampere, 1985–1986 (n = 1771)	Tampere, 2000–2001 (n = 371)
Mean (CI) estimated pregnancy weight gain (kg) ^a	13.3 (13.1–13.5)	14.3 (14.0–14.5) ↑	13.9 (13.3–14.3)
Mean (CI) adjusted pregnancy weight gain (kg) ^b	13.2 (13.0–13.4)	14.3 (14.1–14.5) ↑	14.3 (13.8–14.7)
By parity (kg) ^b			
First child (n = 1114, 784, 172)	13.1 (12.9–13.4)	14.5 (14.2–14.9) ↑	15.0 (14.3–15.7)
Second child (n = 727, 687, 114)	13.5 (13.1–13.8)	14.1 (13.8–14.4)	14.3 (13.5–15.2)
\geq Third child ($n=421$, 300, 85)	13.1 (12.6–13.5)	13.9 (13.4–14.4)	12.6 (11.6–13.6)

 \uparrow : a statistically significant increase or decrease compared to the earlier cohort (ANOVA, Bonferroni-test, χ^2 -test). Otherwise, the differences were statistically insignificant (P>0.05). ^aEstimated weight gain for the 0–40th gestation week. ^bAdjusted for mother's age, parity and prepregnancy BMI.

increased (Table 1). No statistically significant changes were found in the mean parity of pregnant women. An upward trend was observed in the mother's height, prepregnancy weight and prepregnancy BMI. The proportion of pregnant women with BMI $\geq 25 \, \text{kg/m}^2$ increased. The proportion of obese women (BMI $\geq 30 \, \text{kg/m}^2$) increased from 1.4% (95% confidence interval, CI 0.9–1.9%) in the first cohort, to 3.6% (CI 2.7–4.5%) in the second cohort and to 9.7% (CI 6.7–12.7%) in the third cohort. However, the proportion of women with BMI $<\!20 \, \text{kg/m}^2$ remained at the same level.

The mean pregnancy weight gain increased from 13.3 kg in the 1960 cohort to 14.3 kg in the 1980 cohort, but did not further increase in the 2000 cohort (Table 2). Adjustment for BMI, age and parity did not change the results. The normal distribution of pregnancy weight gain is described by the cohort in Figure 1. Compared to the 1960 cohort, the proportion of women with a pregnancy weight gain of less than 10 kg decreased from 18 to 13% and the proportion of women with a weight gain of more than 17 kg increased from 22 to 28% in the 1980 cohort (P<0.001). Pregnancy weight gain was not associated with age in any of the cohorts when the results were adjusted for BMI and parity. Parity was not associated with pregnancy weight gain in the two earliest cohorts. In the third cohort, pregnancy weight gain was lower in women who had three or more children than in women with one or two children (P = 0.002). When adjusted

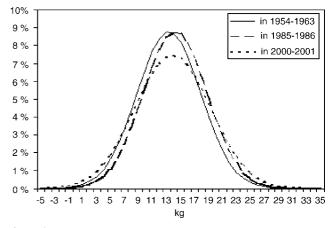


Figure 1 Normal distribution of pregnancy weight gain by cohort.

for age and BMI, the results were essentially the same. The increase in pregnancy weight gain between the first and second cohorts was statistically significant only in women delivering their first child (Table 2).

Pregnancy weight gain was lower in overweight women compared to underweight and normal weight women in all the three cohorts (P<0.001, P<0.001, P=0.023, respectively). Adjustment for age and parity did not essentially change the results (Figure 2). Compared to the first cohort,

pregnancy weight gain in the second cohort increased among both underweight (P = 0.006), normal weight (P < 0.001) and overweight women (P = 0.008). After adjustments for age and parity, the results were essentially the same (Figure 2).

Linear regression models were performed in each cohort to determine which of the variables statistically significantly contributed to pregnancy weight gain, and whether these variables were the same in each cohort. Variables that were not associated with pregnancy weight gain were excluded from the model. The squared multiple-correlation coefficient (R^2) indicates the proportion of variation in weight gain explained by all the variables in the model. In the first cohort, prepregnancy BMI and mother's age accounted for

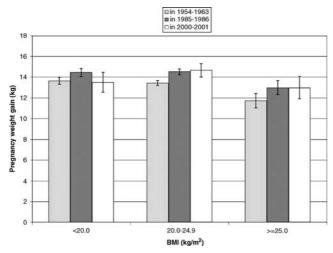


Figure 2 Adjusted estimated pregnancy (estimated weight gain for 0–40th gestation week) weight gain (kg; age- and parity-adjusted mean and 95% confidence interval. Comparison between cohorts in each BMI category (ANCOVA): P=0.006, P<0.001, P=0.023, respectively) by cohort and prepregnancy BMI.

2.1% of the variance in pregnancy weight gain. In the second cohort, prepregnancy BMI explained 1.0% of pregnancy weight gain. In the third cohort, parity and prepregnancy BMI explained 5.5% of the variance in pregnancy weight gain.

The mean child's birthweight, adjusted for gestational age, increased between the first and second cohorts (P < 0.001), and remained at the same level in the third cohort (Table 3). Higher pregnancy weight gain was associated with higher adjusted child's birthweight in all cohorts (Table 3). The proportions of low birthweight babies (<2500 g) in the cohorts were 3.7% (95% CI 2.9–4.5), 2.4% (1.7–3.1) and 1.6% (0.3-2.9), respectively (P=0.011). There were no statistically significant differences in the proportions of low birthweight babies between the groups of pregnancy weight gain in any of the cohorts. The proportion of high birthweight babies (>4000 g) increased from the first to the second cohort (P < 0.001) (Table 3). Higher pregnancy weight gain was associated with higher proportion of high birthweight babies in all cohorts, although not statistically significantly in the third cohort. In all, 25-36% of mothers with pregnancy weight gain $\geq 20 \,\mathrm{kg}$ delivered a high birthweight baby.

Discussion

All cohorts were relatively representative samples of pregnant women in the areas. The first cohort was collected in Helsinki and the others in Tampere, both of which are urban areas and quite near to each other. Even though the cohorts were originally collected for other purposes, we assume that pregnancy weight gain in these cohorts represented the weight gain of other pregnant women in these areas. However, we cannot exclude the possibility that the samples were selected. As the first cohort was somewhat biased to hormone-exposed women with (statistically nonsignificant) higher weight gain, the differences between the first and

Table 3 Pregnancy outcome by cohort, mean or proportion (95% confidence interval, CI)

	Helsinki, 1954–1963 (n = 2249)	Tampere, 1985–1986 (n = 1770)	Tampere, 2000–2001 (n = 371)
Mean (CI) adjusted birth weight (g) ^a	3442 (3423–3463)	3616 (3593–3639)	3687 (3637–3736)
By pregnancy weight gain (g)			
<10 kg (CI)	3275 (3227–3323)	3470 (3406-3533)	3596 (3485–3707)
10.0–14.9 kg (CI)	3420 (3392–3449)	3598 (3565-3632)	3669 (3594–3744)
15.0–19.9 kg (CI)	3531 (3494–3568)	3635 (3598–3673)	3733 (3642–3824)
\geq 20.0 kg (CI)	3632 (3561-3703)	3784 (3713–3855)	3805 (3655-3954)
P-value ^b	< 0.001	< 0.001	0.015
High birth weight ($>4000\mathrm{g}$) (%; CI)	16.1 (14.6–17.6)	22.0 (20.1–23.9)	21.8 (17.6–26.0)
By pregnancy weight gain (%)			
<10 kg (CI)	9.2 (6.4–12.0)	13.4 (9.0–17.8)	13.0 (5.5–20.5)
10.0–14.9 kg (CI)	14.0 (11.9–16.1)	20.6 (17.7–23.5)	22.4 (15.7–29.1)
15.0–19.9 kg (CI)	21.3 (18.1–24.5)	22.5 (19.1–25.9)	23.8 (15.5–32.1)
≥ 20.0 kg (CI)	24.6 (18.6–30.6)	35.8 (29.2–42.4)	30.4 (17.1–43.7)
P-value ^c	< 0.001	< 0.001	0.123

^aAdjusted for gestational age. ^bANCOVA. ^cχ²-test.



second cohorts may have been somewhat higher. The third cohort was much smaller than the other cohorts, and the confidence intervals for pregnancy weight gain were larger, making the results largely statistically nonsignificant.

Self-reported body weight is often an underestimation of the real weight, especially among overweight people. ^{15,16} One strength of our data is that all crucial variables are based on records made by midwives. However, as our data on prepregnancy weight are based on women's self-reports to midwives, under-reporting of prepregnancy weight may cause an overestimation of pregnancy weight gain, especially among overweight women. ^{1,17,18} However, the context of reporting of prepregnancy weight, including the actual measurement in the first visit, may have decreased false reporting, assuming that women knew their weight. We did not find any studies describing trends in under-reporting of body weight during the past decades. However, under-reporting of energy intake has increased, ¹⁹ which may also indicate that body weight is increasingly underestimated.

There were a lot of missing values of prepregnancy weight in the first cohort, and we had to exclude a large number of women (35%). Another possible source of bias, especially in the first cohort, was the estimation of total pregnancy weight gain, which aimed to increase the comparability of the cohorts. As a result of estimation, pregnancy weight gain may have been under- or overestimated. It is not known whether overweight women visited maternity centres less often or whether BMI varied by socioeconomic status in the 1950–60s. In the 1950s, women in the highest socioeconomic group may have used mainly private services, but, in the 1960s, practically all women attended the municipal maternity centres. ^{12,13}

Our study is the first to report pregnancy weight gain over time by prepregnancy weight. The mean pregnancy weight gain increased in all BMI categories over time. High pregnancy weight gain is associated with higher postpartum weight retention.^{1,2,5} In 1990, the Institute of Medicine in the United States (IOM) recommended 12.5-18.0 kg weight gain for underweight, 11.5-16.9 kg for normal weight and 7.0–11.5 kg for overweight pregnant women.⁶ In this study, pregnancy weight gain was within the recommended range in underweight and normal weight women in all three cohorts. In all cohorts, overweight women gained more weight than recommended. If we had considered women with BMI $\geq 26 \text{ kg/m}^2$ (instead of BMI $\geq 25 \text{ kg/m}^2$) to be overweight, as in the IOM's guidelines, pregnancy weight gain would have been in the recommended range in the first cohort, but not in the two later cohorts. Although only overweight mothers exceeded the weight gain recommendations, the public health impact is great because obesity is increasing.

The findings concerning the development of women's BMI and age at pregnancy in Finland concur with previous studies and statistics, which gives further support to the reliability of our data. In Finland, the mean BMI of nonpregnant women younger than 35 y began to increase

significantly only after the early 1980s.^{20,21} The mean age of having the first child has increased by several years and the number of children decreased after the 1960s.^{22,23} The mean birthweight has remained quite stable since the 1980s.²⁴

The average pregnancy weight gain increased in Finland and in the USA during the same period of time. However, the increase was much smaller in this study (from 13.3 to 14.3 kg, unadjusted) than in the USA (from 10 to 15 kg). The difference may be due to the sampling, as the studies in the USA did not have representative samples of their population. Another possible explanation is that, possibly, pregnancy weight gain was not restricted as effectively in Finland as in the USA. From other countries, no time trends are available and knowledge of average pregnancy weight gain is limited to cross-sectional studies, in which weight gain has varied from 10.7 kg in the United Kingdom to 14.1 kg in Sweden. In the mid-1990s, the mean pregnancy weight gain in another Finnish study with smaller sample size $(n=118)^{11}$ was in the same range (14.6 kg) as our 2000 cohort

In this study, overweight women gained the least weight in all the three cohorts. These findings are similar to the results from earlier studies. ^{8–10} In some studies, underweight women gained less weight than normal weight and overweight women, but obese women gained the least. ^{3,4,11} On the other hand, variation in pregnancy weight gain has been the largest among overweight and obese women. ^{3,26} This was also observed in all cohorts in this study. Instead, there were no differences between the whole cohorts in terms of variation of pregnancy weight gain.

In this study, higher maternal weight gain during pregnancy was related to higher mean child's birthweight as well as to higher proportion of high birthweight babies, which concurs with the earlier literature.^{3–5} High pregnancy weight gain is associated with large infants, which increases the risk of prolonged labour and birth, birth trauma, caesarean birth and perinatal morbidity illnesses. 5,6 On the other hand, low pregnancy weight gain is associated with increased risk for preterm birth and reduced fetal growth, which are associated with neonatal morbidity, developmental problems and other illnesses.^{5,6} In our study, the number of low birthweight babies was low (1.6–3.7%) in all cohorts. The linear regression models explained only a minor proportion of the variation in pregnancy weight gain. These results are consistent with previous studies in which BMI, age and parity in addition to some other variables have explained only 3–10% of pregnancy weight gain. 4,27 The results of this study suggest that factors other than changes in the age or BMI of pregnant women or in parity are responsible for the increase observed in the mean pregnancy weight gain. These factors may be the same as those that have contributed to the weight gain observed in the general population, for example, reduced total physical activity.^{28,29} The effect of diet and physical activity on pregnancy weight gain should be studied further.



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Open Access Research article

Feasibility of a controlled trial aiming to prevent excessive pregnancy-related weight gain in primary health care

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Abstract

Background: Excessive gestational weight gain and postpartum weight retention may predispose women to long-term overweight and other health problems. Intervention studies aiming at preventing excessive pregnancy-related weight gain are needed. The feasibility of implementing such a study protocol in primary health care setting was evaluated in this pilot study.

Methods: A non-randomized controlled trial was conducted in three intervention and three control maternity and child health clinics in primary health care in Finland. Altogether, 132 pregnant and 92 postpartum women and 23 public health nurses (PHN) participated in the study. The intervention consisted of individual counselling on physical activity and diet at five routine visits to a PHN and of an option for supervised group exercise until 37 weeks' gestation or ten months postpartum. The control clinics continued their usual care. The components of the feasibility evaluation were I) recruitment and participation, 2) completion of data collection, 3) realization of the intervention and 4) the public health nurses' experiences.

Results: 1) The recruitment rate was slower than expected and the recruitment period had to be prolonged from the initially planned three months to six months. The average participation rate of eligible women at study enrolment was 77% and the drop-out rate 15%. 2) In total, 99% of the data on weight, physical activity and diet and 96% of the blood samples were obtained. 3) In the intervention clinics, 98% of the counselling sessions were realized, their contents and average durations were as intended, 87% of participants regularly completed the weekly records for physical activity and diet, and the average participation percentage in the group exercise sessions was 45%. 4) The PHNs regarded the extra training as a major advantage and the high additional workload as a disadvantage of the study.

Conclusion: The study protocol was mostly feasible to implement, which encourages conducting large trials in comparable settings.

Trial registration: Current Controlled Trials ISRCTN21512277

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Background

Obesity has become an epidemic throughout the world and increases the risk of several diseases such as type 2 diabetes, cardiovascular disease and certain cancers [1]. For women, long-term weight problems sometimes begin during pregnancy or the postpartum period [2]. A large proportion of women gain weight in excess of the recommendations [3] during pregnancy [4-6]. Excessive weight gain increases the risk of pregnancy complications, infant macrosomia, caesarean section [7] and possibly also subsequent breast cancer [8]. In addition, excessive gestational weight gain is the primary risk factor for high postpartum weight retention [4,6]. Although the average postpartum weight retention is quite small (0.5 to 3 kg) [5], up to 20 percent of women retained at least 5 kg after pregnancy in some studies [4].

The effect of dietary and physical activity habits on gestational weight gain and postpartum weight retention is still unclear [6]. Therefore, behavioural interventions are needed to study whether counselling women on diet, physical activity and healthy weight development during and after pregnancy can prevent pregnancy-related weight problems and subsequent obesity [5,6]. One exceptionally good setting for this is the Finnish maternity and child health care system, which is funded through public taxation and utilized by almost all pregnant women (99.7%) and children (98%) in Finland [9,10]. Before initiating such a large behavioural intervention, a pilot study was conducted. The aim of the present pilot study was to evaluate the feasibility of implementing such intervention in maternity clinics (MC) and child health clinics (CC) in primary health care in Finland. The feasibility was evaluated because previous interventions with similar aims [11-15] have been carried out in different settings in countries not having a primary health care system comparable to that in Finland. The specific objectives for feasibility evaluation were to assess selected indicators for recruitment and participation, completion of data collection, realization of the intervention and public health nurses' experiences on implementing the study protocol. The feasibility of the physical activity counselling has been described elsewhere in detail [16]. We hypothesized that the study protocol would be feasible to implement in the routine maternity and child health care.

Methods

Study design

The study was conducted in six MCs and CCs in the city of Tampere and the town of Hämeenlinna. The selection of the clinics was based on the clinics' administrative personnel's suggestion for suitable clinics. In the larger trial, a larger number of other clinics will be randomized to intervention and control clinics. The most important reason for randomizing the clinics instead of individuals - i.e.

public health nurses (PHN) or pregnant and postpartum women - is the likelihood of contamination of the PHNs' counselling practices. In this pilot study, three MCs and CCs volunteered to be intervention clinics and the remaining clinics were treated as control clinics. Feasibility of the study protocol was evaluated separately in the MCs and the CCs, because the larger trial was meant to begin in early pregnancy and continue after delivery.

Study protocol

In Finland, women with no earlier deliveries are recommended to make 11-15 visits to a PHN and three visits to a physician during pregnancy [17]. In the CCs, ten visits to a PHN and three visits to a physician are recommended during the child's first year of life [18]. The study protocol was mainly implemented on five of the routine visits to a PHN in the MC or the CC. The visits at which the women met both a PHN and a physician could not be utilized due to tight schedules.

Fourteen PHNs from the intervention clinics and nine PHNs from the control clinics participated in the study. The PHNs recruited pregnant and postpartum women with no previous deliveries for the study. The exclusion criteria were age under 18 years, type 1 or 2 diabetes mellitus, twin pregnancy, physical disability preventing exercise, substance abuse, treatment or clinical history of any psychiatric illness, otherwise problematic pregnancy (defined by a doctor), inadequate language skills in Finnish and intention to change residence within three months. The PHNs recruited the pregnant women by phone when making an appointment for the first MC visit. The postpartum women were recruited when the PHN visited the participant's home after delivery or on the participant's first visit to the CC. As this was a pilot study, the sample size was not based on power calculations. Instead, the aim was to recruit at least 40 pregnant and 40 postpartum women from the intervention and the control clinics (160 participants in total). All participants provided written informed consent to participation. The study was approved by the Ethics Committee of the Pirkanmaa Hospital District.

Data collection was similar in the intervention and the control clinics (Table 1). The PHNs sent the baseline guestionnaire to the participants' homes and the participants returned the completed questionnaire on their first visit. The follow-up questionnaires and the first feedback questionnaire were completed in the waiting room before the consultation. The researchers sent the last feedback questionnaire to the participants' homes and the participants returned them in sealed envelopes on their last visits. The PHNs took a copy of the standard maternity cards of the pregnant and the postpartum participants after delivery. As an additional measurement not generally included in

Table 1: Data collection in the intervention and the control clinics

	Pregnant women (weeks' gestation)	Postpartum women (months postpartum)
Questionnaires for the participants		
Background, physical activity, diet, psychosocial wellbeing	8–9	2
Physical activity, feedback for physical activity counselling	16–18	5
Diet, feedback for dietary counselling	22–24	5
Background, physical activity, diet, psychosocial wellbeing	36–37	10
Feedback for the physical activity and dietary counselling and the study as a whole Other data collection	36–37	10
Adverse events form	16-18, 22-24, 32-34 and 36-37	3, 5, 6 and 10
A copy of the maternity card (weight development and other data on pregnancy)	after delivery	2
Weight and waist circumference measurement form	-	2, 3, 5, 6 and 10
Blood sample	9-11 and 36-37	2-2.5 and 8
A 3-day food record prior to the blood sample	9-11 and 36-37	-
Nipple aspirate fluid (NAF) sample	-	8–12

care, they also measured the weight and waist circumference of the postpartum women at each of the five visits. The PHNs used a structured form to record the incidence of selected adverse events reported by the participants at four of the visits. These adverse events included vaginal bleeding, strong contractions (in pregnant participants), dizziness, dyspnea, headache, chest pain, excessive tiredness or fatigue experienced by the participant, calf pain or swelling and musculoskeletal symptoms. Blood and nipple aspirate fluid (NAF) samples were collected in order to measure the selected hormones and growth factors related to breast cancer risk. To obtain a milk-free NAF sample, the NAF samples were collected at least one month after the participant had stopped breastfeeding. The blood and NAF samples were taken by the Medical Laboratory Technologists of the UKK Institute. No attempt was made to collect data from the drop-outs.

In the control clinics, the PHNs continued their usual physical activity and dietary counselling practices. In the intervention clinics, the intervention included individual counselling on physical activity and diet and an option to attend supervised group exercise sessions once a week at a location close to the clinic (Figure 1). The content of the intervention is described in more detail elsewhere [19,20]. Briefly, the purpose was to promote leisure time physical activity and healthy dietary habits and thereby to hold the gestational weight gain of the pregnant participants within the recommended range [3] and to support the postpartum participants' return to their pre-pregnancy weight during the study. The PHNs proceeded in the counselling with the help of counselling cards, and 20-30 min was allocated for each primary counselling session and 10–15 min for each booster session. The participants used a follow-up note book to keep record of their compliance with the physical activity and the dietary plans agreed at the counselling sessions.

Before the study began, the PHNs of the intervention clinics were trained in the counselling procedures and the study arrangements (12 h in total) and the PHNs of the control clinics for the study arrangements (6 h in total) by the research group. All PHNs received a handbook in which the tasks related to each visit were explained. One or two researchers visited each clinic monthly during the study. One supportive meeting was held for the PHNs of the intervention and the control clinics separately. The exercise instructors (n = 10) were trained for the group exercise sessions by the research group (10 h in total).

Baseline comparability of the clinics

The location of the clinics should not have any effect on the services the clinics provide, because all clinics are supposed to follow the national guidelines for maternity and child health care [17,18]. In these guidelines, the number, timing and main content of the visits are defined. On the

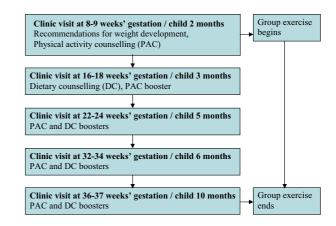


Figure I Intervention in the intervention clinics.

other hand, PHNs' work is quite autonomous and they implement counselling in their personal way.

Information on the background characteristics and the usual counselling practices of the PHNs was collected by a questionnaire (n = 21) before the PHNs were trained for the study. The responses varied between the six MCs and CCs, but the numbers of PHNs in each clinic were too small to test the statistical significance of the betweenclinic differences. Concerning all clinics, 15 (71%) PHNs were aged 40 years or more. The PHNs had either the official degree of PHN (n = 15), midwife (n = 1) or both (n = 1) 5). Of those PHNs who had worked in a MC, the median time of working in a MC was 3.5 (range 1 to 30) years. Likewise, of those PHNs who had worked in a CC, the median time of working in a CC was 13.0 (range 1 to 26) years. The counselling practices varied remarkably between the PHNs, but not between the PHNs of the intervention and the control clinics [19,20].

In Finland, the clinic attended by each pregnant and postpartum woman is determined by her place of residence. The socioeconomic background of the residents varies between these areas, which may also have affected the characteristics of the participants. There was some variation in the participants' mean age, mean pre-pregnancy BMI, education level, smoking status and the baseline dietary and physical activity habits between the six clinics (results not shown), but the statistical significance of the differences could not be tested due to the small number of participants in each clinic. Information on these variables has been reported earlier in the intervention and the control clinics [19,20].

Feasibility evaluation

The feasibility assessment of the study protocol comprises the following four components. The main indicators and data collection for each component are described below.

1) Recruitment and participation

Information on the achievement of the recruitment aim (40 participants per group, 160 in total) within three months, the participation rate of the eligible women and the drop-out rate of participants were obtained from the standardized recruitment forms used by each PHN.

2) Completion of data collection

The proportion of data obtained on weight development, diet and physical activity was assessed from the number of completed and returned baseline and follow-up questionnaires, maternity cards and postpartum weight measurement forms. Information on the proportion of blood samples obtained was collected from the laboratory records.

3) Realization of the intervention

Concerning the intervention clinics, the realization rate, content and duration of counselling sessions was assessed from the PHNs' counselling cards. Each counselling session was regarded to have been implemented as intended if all essential parts of the counselling card were filled in for the session. The proportion of women completing ≥ 75% of the weekly records for physical activity and diet was obtained from the participants' follow-up notebooks. The mean participation percentage in the group exercise sessions was determined by calculating first the participation percentage of each woman separately from the number of sessions available for her and then averaging the individual participation percentages. Information on participation was obtained from the participant lists kept by the exercise instructors.

4) The PHNs' experiences

Information on the PHNs' opinions of the appropriateness of the training for the study was collected using a questionnaire three months after the initiation of the study. The PHNs assessed the training on the Osgood scale (1 = very poor ... 5 = excellent). Additionally, the advantages and the disadvantages of the study for the PHNs were inquired from them by a semi-structured interview within two weeks each PHN's last participant had finished the study.

Results

Recruitment and participation

As only 113 participants were enrolled within the three months allocated, the recruitment period was prolonged to six months (Table 2). Finally, of all potential 327 women with no earlier deliveries, 277 women were eligible and 224 women participated in the study (Figure 2). The participation rate was lower in the intervention than in the control clinics (Table 2). The drop-out rate was low (\leq 11%) in all clinics except for the intervention MCs (29%). Figure 2 presents the reasons for dropping out. Of the reasons related to this study, some drop-outs in the intervention clinics were unwilling to fill in more questionnaires, food records or the follow-up notebook. Other reasons, reported mostly in the control clinics, were reluctance to give the blood samples or difficulties to find the time for this.

Completion of data collection

The proportions of data obtained on weight, physical activity and diet were 96–100% and the proportions of blood samples obtained were 95–98% (Table 2). The blood samples were obtained as intended at 11.5 (sd 2.1) and 36.5 (sd 0.7) weeks' gestation or at 2.6 (sd 0.3) and 8.3 (sd 0.3) months postpartum on average. The food records were obtained from all pregnant participants except for one at baseline and two at follow-up. Of the

Table 2: Feasibility of the study protocol

Components and main indicators	Maternity	clinics	Child healtl	h clinics	
·	Intervention	Control	Intervention	Control	Total
I) Recruitment and participation					
Aim for recruitment achieved within three months (40 of participants per group, 160 in total)	yes	no	no	no	no
Participation rate of eligible women (%)	73	77	78	85	77
Drop-out rate of participants (%)	29	11	9	5	15
2) Completion of data collection					
Proportion of data obtained on weight, physical activity and diet (%)	96	100	99	100	99
Proportion of blood samples obtained (%)	98	95	96	97	96
3) Realization of the intervention					
Realization rate of counselling sessions (%) ²	98		98		98
Duration (min) of counselling sessions, mean (sd)					All mean durations were within allocated time ²
Primary sessions	24.0 (4.7)		25.9 (8.3)		
Booster sessions	10.4 (3.6)		10.5 (3.3)		
Proportion of women completing \geq 75% of the weekly records for both physical activity and diet (%) ³	87		85		86
Participation percentage in group exercise sessions (mean, sd)	38.6 (28.3)		50.7 (28.5)		45.1 (28.7)

¹ The drop-outs are included only when evaluating the component I). The results concerning the component 4) are described in the text only.

postpartum participants, the NAF samples were obtained from 41 (48%) participants, on average at 12.1 (sd 3.3) months postpartum. NAF samples were not obtained from participants who had not stopped breastfeeding at least one month ago (n = 11), participants who were not willing to give the sample (n = 9), changed residence (n = 2) or for unknown reasons (n = 6). In addition, the Medical Laboratory Technologists did not succeed in collecting sufficient NAF from 16 women. All but two adverse events forms were returned.

Realization of the intervention

In the intervention clinics, 98% of the counselling sessions were realized as intended and the mean durations of the sessions were as intended (Table 2). All primary counselling sessions were realized. The proportion of participants completing the follow-up notebook records regularly ($\geq 75\%$ of weekly records) was high (86%). The mean participation percentage in the group exercise sessions was higher among the postpartum than the pregnant women (51% vs. 39%).

Public health nurses' experiences

Using the 5-point scale, the PHNs of the intervention clinics scored the training for study arrangements 3.4 (sd 1.2), physical activity counselling 3.9 (sd 1.1) and dietary counselling 3.6 (sd 1.1) on average. The PHNs of the control clinics scored the training for study arrangements 3.9

(sd 0.7) on average. Nearly all PHNs regarded the training and the support during the study as sufficient and the researchers' visits to the clinics as useful.

The PHNs of the intervention clinics considered the increased knowledge on physical activity and diet and the improved counselling skills to be the major advantages of the study for them. The PHNs of the control clinics appreciated the training they were promised after the study. The major disadvantage reported by the PHNs was that implementation of the study protocol took too much time. The extra time needed for the visits was 40–60 min/visit in the intervention clinics and 10–20 min/visit in the control clinics on average.

Discussion

We evaluated whether a study protocol aiming at preventing excessive gestational weight gain and postpartum weight retention could be feasibly implemented in the Finnish maternity and child health care system. Integrating a study protocol into the routine functions of primary health care is a demanding task, but we managed to implement the protocol mostly as intended.

The overall participation rate was high (77%) and the drop-out rate low (15%). Data on weight development, diet and physical activity was collected very successfully. The proportion of blood samples obtained was extremely

² None of the counselling cards was missing.

³ Numbers of missing follow-up note books were 3 in the maternity clinics and 1 in the child health clinics.

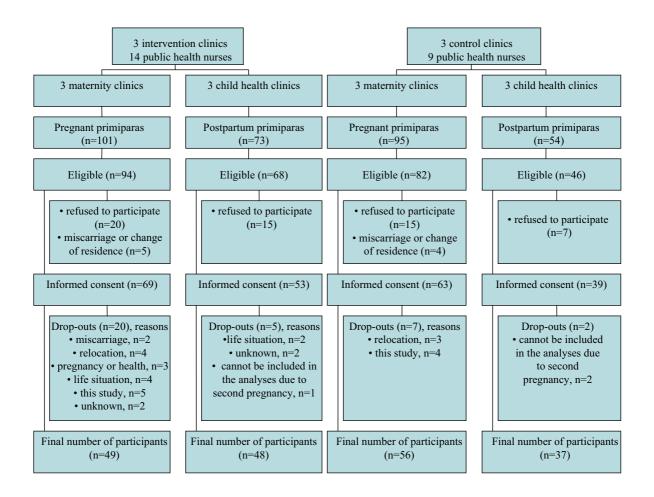


Figure 2 Participant flow.

high, indicating that collection of this kind of material is possible in studies conducted in real health care settings. In the intervention clinics, almost all counselling sessions were realized as intended and most participants recorded their adherence to the physical activity and dietary plans regularly to their follow-up notebook. This success reflects the PHNs' and the participants' strong commitment to the study, possibly because they were able to see the importance of the study and to see some personal benefits compensating the burden.

Although the main experiences were positive, some problems were encountered. The recruitment time needed to be prolonged because the recruitment of the participants was slower than expected. The experience helps in estimating the realistic time needed for recruitment in further studies. The participation rate was slightly lower in the intervention clinics than in the control clinics, which may be related to the participants' background characteristics, to their reluctance to improve or monitor their dietary and physical activity habits or to the PHNs' motivation to recruit participants. In further studies, the way in which study is introduced to the participants and how they are motivated to participate in it will be especially important.

The drop-out rate was higher in the intervention MCs than in the other clinics, but the reasons for drop-out seemed quite plausible in all clinics. Pregnancy is often associated with changing residence and, consequently, clinics. For some women who changed residence, we managed to collect the follow-up questionnaires and the maternity cards by mail, thus preventing them dropping out of the study. Some women withdrew for reasons related their pregnancy (such as twin pregnancy or risk for premature delivery) or a stressful life situation. Additionally, as postpartum weight retention was the main outcome for

postpartum participants in the effectiveness analyses, we had to exclude women who were pregnant again 10 months after their first delivery. On the other hand, the drop-outs related to the missing blood samples actually occurred due to misunderstanding because the participants would have been allowed to continue the study despite not giving the blood samples. Some participants in the intervention clinics withdrew because they found the data collection too burdensome. Therefore, the amount of data collection should be paid more attention in further studies. For this pilot study, we collected feasibility information, which may not be necessary in further studies.

Although the other data collection was successful, NAF samples were obtained from only 41% of the postpartum participants. The sample could not be obtained from women who were still breastfeeding when the collection of the samples was finished. Further studies should allocate a longer time period for collection of NAF samples. As NAF samples are not routinely collected in health care, some women may have been suspicious or afraid of giving them. To minimize the number of women refusing to give the sample, the methods of collecting NAF sample should be described in detail to the participants beforehand. However, the most frequent reason for a missing NAF sample was that no NAF could be obtained from the breast despite attempts. Other studies have also reported difficulties in obtaining NAF [21]. Therefore, collection of NAF samples can also be expected to be laborious in future studies.

The average participation percentage in the group exercise sessions was relatively low, especially among the pregnant participants. No information is available on the reasons why the women did not participate more often. The reasons have been discussed earlier [16] and they may be related to the fact that these pregnant women with no previous deliveries were physically relatively active before pregnancy. Therefore, part of them may have preferred to continue their previous physical activity habits instead of participating in these group exercise sessions. In further studies, one option could be to arrange group exercise sessions less often for pregnant participants. Additionally, the exercise instructor could keep in touch with the participants between the sessions to encourage them to adhere to their individual physically activity plans.

The quality and adequacy of training of the PHNs will be of crucial importance in future studies, since the PHNs regarded the increased knowledge about physical activity and diet as well as improved counselling skills as the major advantage of participating in the study. However, as the PHNs found that the implementation of the study protocol was time-consuming, the time spent on study

arrangements and all paper flow should be kept to a minimum in further studies. A risk group approach should also be considered to limit the PHNs' workload and to better target counselling at those in need. Allocating shorter times for counselling may impair the effectiveness of the intervention.

A major strength of the study was that the counselling was implemented during routine visits to primary health care instead of using extra study personnel. Using this approach, we also aimed at developing counselling practices, which could be incorporated into real health care situations. Safety issues are especially important when implementing interventions among pregnant and postpartum women. Therefore, another major strength of the study was that no statistically significant differences were observed in the incidence of selected adverse events between the intervention and the control groups [16]. Nor were any between-group differences observed among pregnant participants in pregnancy or foetal outcomes [19].

One limitation of the pilot study was that we were not able to randomize the clinics, which may have caused some baseline differences between the participants of the intervention and the control clinics [19,20]. However, the participants could not choose their clinic, which may have decreased this bias. In any case, randomization of the clinics is a priority, which should be highlighted when recruiting the clinics for further studies.

Conclusion

Implementation of the study protocol proved to be feasible in this setting, which encourages the undertaking of a large study in Finland and possibly also in other countries with maternity and child health care services funded by public taxation [22]. Such behavioural intervention studies are needed to develop maternal health care services in order to prevent pregnancy-related weight problems and the associated health problems relevant to public health.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TIK participated in the development of the study design and the intervention protocols (especially dietary counselling) and in the acquisition and analysis of the data. MA participated in the development of the study design and the intervention protocols (especially physical activity counselling) and in the acquisition of data. PK and EW were involved in the development of the study design. KO participated in the development of the intervention protocols (group exercise sessions) and in the acquisition of the data. KM participated in the development of the inter-

vention protocols (laboratory issues) and in the acquisition of the data. MF was involved in the development of the study design and the intervention protocols. RL was the principal researcher and responsible for the study concept and design and she participated in the development of the intervention protocols. All authors participated in the interpretation of the data and preparation of the manuscript. Additionally, all authors have read and approved the final manuscript.

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ORIGINAL ARTICLE

Preventing excessive weight gain during pregnancy – a controlled trial in primary health care

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Objective: To investigate whether individual counselling on diet and physical activity during pregnancy can have positive effects on diet and leisure time physical activity (LTPA) and prevent excessive gestational weight gain.

Design: A controlled trial.

Setting: Six maternity clinics in primary health care in Finland. The clinics were selected into three intervention and three control clinics.

Subjects: Of the 132 pregnant primiparas, recruited by 15 public health nurses (PHN), 105 completed the study.

Interventions: The intervention included individual counselling on diet and LTPA during five routine visits to a PHN until 37 weeks' gestation; the controls received the standard maternity care.

Results: The counselling did not affect the proportion of primiparas exceeding the weight gain recommendations or total LTPA when adjusted for confounders. The adjusted proportion of high-fibre bread of the total weekly amount of bread decreased more in the control group than in the intervention group (difference 11.8%-units, 95% confidence interval (CI) 0.6–23.1, P=0.04). The adjusted intake of vegetables, fruit and berries increased by 0.8 portions/day (95% CI 0.3–1.4, P=0.004) and dietary fibre by 3.6 g/day (95% CI 1.0–6.1, P=0.007) more in the intervention group than in the control group. There were no high birth weight babies ($\geq 4000 \, \text{g}$) in the intervention group, but eight (15%) of them in the control group (P=0.006). **Conclusions**: The counselling helped pregnant women to maintain the proportion of high-fibre bread and to increase

vegetable, fruit and fibre intakes, but was unable to prevent excessive gestational weight gain. European Journal of Clinical Nutrition (2007) 61, 884–891; doi:10.1038/sj.ejcn.1602602; published online 17 January 2007

Keywords: pregnancy; weight gain; intervention; diet; physical activity

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Introduction

The prevalence of obesity is rising among women of childbearing age. Further, a great proportion of women gain weight in excess of the recommendations (Institute of Medicine, 1990) during pregnancy (Gunderson and Abrams, 2000, Gore et al., 2003, Siega-Riz et al., 2004). In Finland, the mean gestational weight gain has increased by 1 kg since the 1960s (Kinnunen et al., 2003). Recommended gestational weight gain is associated to optimal foetal and maternal outcomes, whereas excessive weight gain increases the risk of pregnancy complications, infant macrosomia and caesarean delivery (Abrams et al., 2000). Moreover, excessive gestational weight gain per se may increase subsequent risk of breast cancer (Kinnunen et al., 2004). Excessive gestational

weight gain is also one of the main factors explaining high postpartum weight retention (Gunderson and Abrams, 2000, Siega-Riz *et al.*, 2004).

The role of diet and physical activity as determinants of gestational weight gain is still unclear (Siega-Riz et al., 2004). However, there is a need for behavioural interventions to advise pregnant women on the recommended ranges of gestational weight gain and promote healthy diet and regular physical activity to prevent subsequent obesity and the associated health problems (Siega-Riz et al., 2004). To our knowledge, there are three previous interventions aimed at preventing excessive gestational weight gain (Gray-Donald et al., 2000, Polley et al., 2002, Olson et al., 2004). In these studies, excessive gestational weight gain was prevented only among the subgroups of normal-weight or low-income pregnant women or not at all.

The aim of our study was to investigate whether individual counselling on diet and physical activity and information on gestational weight gain recommendations (Institute of Medicine, 1990) during pregnancy can have positive effects on diet and total leisure time physical activity (LTPA) and reduce the proportion of primiparas exceeding the recommended level of gestational weight gain.

Methods

Setting and general study design

Each municipality in Finland is responsible for arranging maternity health-care services for its residents. Funding for maternity health care is covered by public tax revenue. Almost all (99.7%) pregnant women attend these public maternity clinics (MC) (National Research and Development Centre for Welfare and Health, 2004). The present study was conducted in six MCs in the city of Tampere and the town of Hämeenlinna, situated in southern Finland. The selection of the clinics was based on the MC clinics' administrative personnel's suggestion for suitable clinics. Three MCs volunteered to be intervention clinics and the remaining MCs were treated as control clinics.

In the Finnish maternity health-care system, primiparas are recommended to make 11–15 visits to a public health nurse (PHN) and three visits to a physician during pregnancy (Viisainen, 1999). This study was implemented during five of these routine visits to PHNs at 8–9, 16–18, 22–24, 32–34 and 36–37 weeks' gestation. Altogether nine PHNs in the intervention clinics and six PHNs in the control clinics participated in the study.

Participants

The participants were pregnant women with no earlier deliveries. The exclusion criteria were age under 18 years, type I or type II diabetes mellitus (but not gestational diabetes mellitus), twin pregnancy, physical disability that prevents exercising, otherwise problematic pregnancy, sub-

stance abuse, treatment or clinical history for any psychiatric illness, inability to speak Finnish and intention to change residence within 3 months. The PHNs recruited the participants when they enrolled at the MC first time at the beginning of their pregnancy, usually by phone. Altogether, 69 women in the intervention clinics and 63 women in the control clinics gave informed consent for participation (Figure 1). Recruitment took place between August 2004 and January 2005. The study was approved by the Ethics Committee of the Pirkanmaa Hospital District.

Control clinics

The participants of the control clinics received the standard maternity care. Information on the PHNs' standard counselling practices was collected by questionnaire before the PHNs were trained for the study. According to the responses (n=13), the mean duration of dietary counselling was $12.4 \, \text{min}$ (range $5-30 \, \text{min}$) at the first visit and $5.2 \, \text{min}$ (range $3-10 \, \text{min}$), min at the subsequent visits. The mean

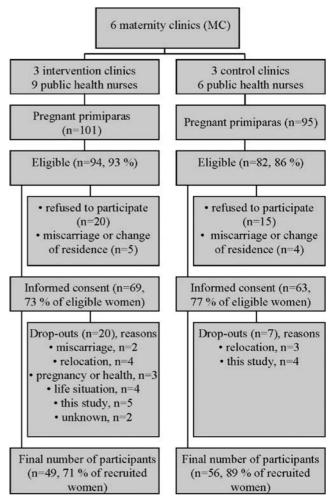


Figure 1 Participant flow.



duration of the physical activity counselling was 7.5 min (range 3–13 min), min at the first visit and 4.5 min (range 2–8 min), min at the subsequent visits. The short mean durations of time spent on counselling refer merely to brief advice rather than actual counselling. All PHNs gave some information on gestational weight gain recommendations to most or all of their clients, usually during the first trimester of pregnancy. In the control clinics, the average recommended weight gain was 13.3 kg for underweight body mass index (BMI $<\!20\,\text{kg/m}^2$), 10.6 kg for normal weight (BMI $20\!-\!26\,\text{kg/m}^2$) and 6.7 kg for overweight (BMI $>\!26\,\text{kg/m}^2$) women.

Intervention clinics

Recommendation for gestational weight gain. The participants were given information on the recommendations of Institute of Medicine (IOM) (1990) for total gestational weight gain during their first visit to the PHN at 8–9 weeks' gestation. These recommendations are specific for different pre-pregnancy BMI categories: $12.5-18.0\,\mathrm{kg}$ for BMI $<20\,\mathrm{kg/m^2}$, $11.5-16.0\,\mathrm{kg}$ for BMI $20-26\,\mathrm{kg/m^2}$ and $7.0-11.5\,\mathrm{kg}$ for BMI $>26\,\mathrm{kg/m^2}$.

Physical activity counselling. The physical activity counselling consisted of one primary counselling session (allocated time 20–30 min) at the 8–9 weeks' gestation visit and four booster sessions (allocated time 10–15 min) until the 37th gestation week. The counselling procedure was based on the behaviourally grounded model of Laitakari and Asikainen (1998). The primary counselling session began with a discussion about the participant's current LTPA and continued with a discussion about the participant's needs and opportunities to increase LTPA. The general benefits and restrictions of LTPA were also raised with the help of a take home leaflet. Finally, an individual weekly LTPA plan was written into the participant's follow-up notebook.

Concluded from the physical activity recommendations for health (Pate et al., 1995) and fitness (American College of Sports Medicine, 1998), which also apply during pregnancy (Artal and O'Toole, 2003, Davies et al., 2003), a minimum of 30 min of moderate-intensity physical activity on 5 weekdays was considered sufficient for health and a minimum of 40 min of high-intensity physical activity three times per week for fitness. By using multiples of resting metabolic equivalents (METs) with MET value 5 for moderate-intensity and MET value 7 for high-intensity LTPA, 800 MET minutes (METmin) was estimated to represent both of the minimum requirements. After making the weekly plan, the fulfilment of 800 METmin in the LTPA plan was checked by the PHNs by multiplying the frequency, duration (minutes) and MET value of weekly LTPA. As opposed to physical activity recommendations, light-intensity LTPA (MET value 3) was also taken into account in the calculations to improve compliance to the plan. At the booster sessions, the participant's adherence to the plan was assessed, the plan was revised, if needed, and the METmin were checked.

As a part of the LTPA plan, the participant had an option to attend supervised group exercise sessions, which included both endurance and muscular training. The group sessions were held once a week for 45–60 min at a location close to each intervention clinic.

Dietary counselling. Dietary counselling focused on four topics considered to be important in the prevention of excessive gestational weight gain in this population (Männistö *et al.*, 2003, Hasunen *et al.*, 2004, Nordic Council of Ministers, 2004). The following dietary objectives were set for each participant to achieve or to maintain: (1) to have a regular meal pattern, emphasising the importance of breakfast and $\geqslant 1$ hot meal every day, (2) to eat at least five portions (400 g) per day in total of different kinds of vegetables, fruit and berries, (3) to consume mostly highfibre bread ($\geqslant 5$ g fibre/100 g) and (4) to restrict the intake of high-sugar snacks to $\leqslant 1$ portion per day (e.g. 50 g sweets, one pastry, once piece of cake, two biscuits, 2 dl ice cream or a glass of soft drink).

The dietary counselling consisted of one primary counselling session (allocated time 20-30 min) at 16-18 weeks' gestation visit and three booster sessions (allocated time 10 min) until the 37th gestation week. The model of Laitakari and Asikainen (1998) was also applied to the dietary counselling. At the beginning of the primary counselling session, the PHN assessed the participant's current dietary habits concerning these four topics using the baseline food frequency questionnaire. After comparing the personal habits to the recommendations, the PHN and the participant discussed the participant's need for dietary changes, as well as her opportunities for and barriers to making the changes. The participant also received two take home leaflets on healthy diet. The participant was asked to keep record weekly of her compliance to the four objectives in her follow-up notebook. At each booster visit, the followup notebook was checked and the records were discussed.

Main outcomes

The outcome for gestational weight gain was the proportion of women gaining weight over the BMI-specific recommendations. The dietary outcomes included meal pattern (breakfast and $\geqslant 1$ hot meal/day), overall intake of vegetables, fruit and berries (portions/day), use of high-fibre bread (% of bread with $\geqslant 5$ g fibre/100 g of total weekly amount of bread), intake of high-sugar snacks (portions/day) and total energy intake (kJ/day). Total METmin/week were used as an outcome for LTPA.

Data collection

Body weight and other pregnancy data were obtained from the maternity card. Pre-pregnancy weight and height were self-reported. Body weight was measured in light clothing and without shoes at every MC visit. The scales were calibrated to the reference scale within $\pm 0.5\,\mathrm{kg}$ at the beginning and at the end of the study.

The baseline questionnaire including questions on background (e.g. education, smoking), dietary intake (a 57-item food frequency questionnaire) and LTPA was completed before the first visit (at 8–9 weeks' gestation). The first LTPA and dietary follow-up questionnaires were completed before the first booster sessions, which were at 16-18 weeks' gestation for LTPA counselling and at 22-24 weeks' gestation for dietary counselling. The second follow-up questionnaires were completed at the end of the study, that is, at the 37th gestation week. The baseline dietary information was based on diet during 1 month before pregnancy and the follow-up information on diet during the previous month. LTPA at baseline illustrated a typical week before pregnancy and at follow-up a typical week during the past 3 weeks. The questions on LTPA were modified from the International Physical Activity Questionnaire, IPAQ (Craig et al., 2003), and the amount of breathlessness was used to describe light-, moderate- and high-intensity LTPA to the respondents. The participants also kept food records for 3 days (one Sunday and two working days) after the first visit and in the 37th gestation week.

Statistical methods

Baseline information on age, weight, height, BMI, education level and smoking status were reported in the intervention and the control groups. These variables were later included when necessary as confounding factors in the multivariable analyses. In all statistical analyses, P<0.05 was used as the level of statistical significance.

Differences in body weight changes by gestation week were compared between the intervention and the control groups using analysis of covariance (ANCOVA) of repeated measures. The dependent variables in the model were the weight measurements at the four last visits related to the study and at the last visit during pregnancy. Average total pregnancy weight gain was compared between the groups and the differences were tested statistically using the twosided independent samples t-test. The group differences in the proportions of women who gained weight below, within and over the recommended ranges were tested by using twosided χ^2 -test. The proportion of women exceeding the weight gain recommendations was further analysed with logistic regression model. The groups of women with weight gain below or within the recommendation were combined in this analysis. The changes in the dietary outcomes and total METmin/week from baseline to 36-37 weeks' gestation were compared between the groups and tested statistically by using ANCOVA for dietary outcomes and ANCOVA of repeated measures for total METmin/week.

The proportions of glucosuria, proteinuria, hypertension, oedema, preeclampsia, low (<2500 g) and high birth weight

(\geq 4000 g) infants were compared between the intervention and the control groups and tested statistically using Fisher's exact test. The two-sided independent samples *t*-test was used to test the differences in gestation weeks at delivery, duration of delivery and infant's birth weight between the groups.

Results

The flow of participants and reasons for drop-outs are summarized in Figure 1. Forty-three women (88%) in the intervention group participated in all physical activity and dietary counselling sessions, but all 49 women participated in the primary physical activity and dietary counselling sessions. Five women missed one physical activity and/or dietary booster session and one woman missed two physical activity and dietary booster sessions. Women in the intervention group were younger, less educated, more often smokers and they had higher pre-pregnancy weight and BMI on average than the women in the control group (Table 1).

Gestational weight gain

Figure 2 shows the unadjusted mean body weight changes in the intervention and the control groups by gestation week. The intervention had no significant effect on weight change at any of the six measurement points, when adjusted for age, pre-pregnancy BMI, weight at the first visit, education, pre-pregnancy smoking status, oedema and gestation week at the last weight measurement (ANCOVA of repeated measures, $P\!=\!0.88$). Moreover, the mean gestational weight gain did not differ between the groups (Table 2). A greater proportion

Table 1 Background characteristics of the participants, means (s.d.) or numbers (%)

	1.1	Control
	Intervention group (n = 49)	Control group $(n = 56)$
	$(\Pi = 49)$	$(\Pi = 30)$
Age at baseline (years)	27.6 (4.5)	28.8 (4.1)
Pre-pregnancy weight (kg)	65.7 (11.0)	61.0 (7.0)
Height (cm)	166.4 (5.5)	166.6 (5.5)
Pre-pregnancy BMI (kg/m²)	23.7 (3.9)	22.3 (2.1)
By BMI groups, n (%) (kg/m²)		
<20.0	4 (8)	10 (18)
20.0–25.9	36 (75)	44 (79)
≥26.0	8 (17)	2 (4)
Education level, n (%)		
Basic or secondary education	27 (57)	20 (36)
Polytechnic education	9 (19)	12 (21)
University education	11 (23)	24 (43)
Smoking status 0–6 months before	pregnancy, n (%)	
Non-smoker	32 (68)	46 (84)
Daily or occasional smoker	15 (32)	9 (16)

Abbreviations: BMI, body mass index; s.d., standard deviation.



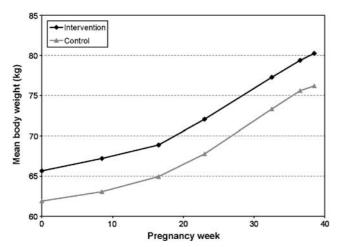


Figure 2 Body weight changes by gestation week in the intervention (n=48) and the control groups (n=56), unadjusted means.

of the women in the intervention group exceeded the BMI-specific gestational weight gain recommendations than in the control group (46 vs 30%), but the difference was not statistically significant (Table 2). When adjusted for confounders, the odds ratio (OR) for excessive gestational weight gain did not differ statistically significantly between the groups (OR 1.82, 95% confidence interval 0.65–5.14).

Changes in diet and physical activity

The intake of vegetables, fruit and berries, adjusted for confounders, increased by 0.8 portions/day more in the intervention group from baseline to 36–37 weeks' gestation compared with the controls (Table 3). The proportion of high-fibre bread of the total weekly amount of bread decreased more in the control group than in the intervention group (a difference of 12%-units between the groups), when adjusted for confounders. Both of these between-group differences were also observed at the short-term follow-up at 22–24 weeks' gestation (results not shown). In addition, the

Table 2 Gestational weight gain in the intervention and the control groups, means (s.d.), numbers (%) or OR (95% CI)

	Intervention group (n = 48)	Control group (n = 56)	P-value
Total gestational weight gain (kg)	14.6 (5.4)	14.3 (4.1)	0.77 ^a
(range, kg)	(3.6–25.1)	(5.7–25.0)	
Gestational weight gain, n (%)	,	` ,	0.053 ^b
Below recommendations ^c	16 (33)	15 (27)	
Within recommendations	10 (21)	24 (43)	
Exceeding recommendations	22 (46)	17 (30)	
OR for exceeding recommendations ^c	1.94 (0.87–4.34)	1.00 (ref.)	0.11 ^d
Adjusted OR for exceeding recommendations ^c	1.82 (0.65–5.14)	1.00 (ref.)	0.26 ^e

Abbreviations: CI, confidence interval; OR, odds ratio; s.d., standard deviation.

Table 3 Diet at baseline and at 36–37 weeks' gestation and adjusted group differences (95% CI) at the 36–37 weeks' gestation

	n	Baseline mean (s.d.)	36–37 weeks' gestation mean (s.d.)	Adjusted mean difference to controls ^a	P-value ^a
Vegetables, fruit and berries (portions/day)				
Intervention	40	2.5 (1.3)	3.8 (1.7)	+0.8 (0.3-1.4)	0.004
Control	53	2.9 (1.5)	3.2 (1.5)	, ,	
High-fibre bread (% of total b	read)				
Intervention	39	69 (27)	67 (29)	+11.8 (0.6-23.1)	0.04
Control	54	58 (25)	53 (24)	, ,	
High-sugar snacks (portions/a	lay)				
Intervention	40	1.6 (1.5)	1.6 (1.3)	-0.3 (-0.8-0.1)	0.16
Control	55	1.4 (0.9)	1.8 (1.1)	,	

Abbreviations: CI, confidence interval; OR, odds ratio; s.d., standard deviation.

^aTwo-sided independent samples t-test.

^bTwo-sided χ²-test.

^cInstitute of Medicine, 1990.

^dLogistic regression model.

^eLogistic regression model, adjusted for age, pre-pregnancy BMI, education, pre-pregnancy smoking status, oedema and gestation week at the last weight measurement.

^aANCOVA, mean group differences adjusted for baseline intake of the outcome variable, pre-pregnancy age, BMI, education and smoking status. Intervention: n=38-39, control: n=52-54.

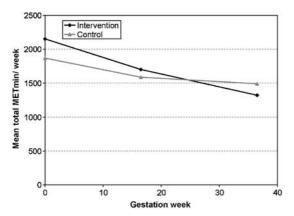


Figure 3 LPTA (total METmin/week) at baseline, at 16-18 and 36–37 weeks' gestation in the intervention (n=37) and the control groups (n=51), unadjusted means.

adjusted intake of dietary fibre increased by 3.6 g/day more from early pregnancy to 36-37 weeks' gestation in the intervention group compared to the controls. Differences in the changes in the use of high-sugar snacks or in the intake of energy or macronutrients were not statistically significant between the groups. Moreover, there were no differences between the groups in the proportion of women having breakfast and at least one hot meal per day. This criterion was fulfilled by 88% of the intervention and 86% of the control women at baseline and by 100% of the intervention and 96% of the control women at 36–37 weeks' gestation.

Figure 3 shows the changes in the unadjusted mean of weekly METmin by gestation week in the intervention and the control groups. As expected, the level of total LTPA was reduced from baseline to the 36th-37th gestation week in both groups. However, no statistically significant differences were observed between the groups from baseline to the 22nd-24th gestation week or the 36th-37th gestation week, when adjusted for age, pre-pregnancy BMI and education. There were no differences in the physical workload between the groups at baseline.

Pregnancy and fetal outcomes

There were eight infants (15%) with high birth weight $(\ge 4000 \,\mathrm{g})$ in the control group but none in the intervention group (P = 0.006). However, there were no statistically significant differences between the groups in the incidence of low birth weight ($<2500\,\mathrm{g}$) infants (0 in the intervention group vs 1 in the control group) or in the other pregnancy or fetal outcomes.

Discussion

This study is one of the few interventions aiming at preventing excessive gestational weight gain. The intervention was carried out in a primary health-care setting where the PHNs implemented the dietary and physical activity counselling at five routine MC visits. The intervention maintained the proportion of high-fibre bread of total weekly amount of bread and increased the intake of vegetables, fruit and berries and dietary fibre, but did not have an effect on total weekly LTPA or gestational weight gain.

These results partly concur with the results from the other three interventions with a similar aim but a somewhat different study design and/or population than in our study. In the first study, conducted among aboriginal Cree-women, the intervention included, for example, individual dietary counselling and physical activity sessions (Gray-Donald et al., 2000). The intervention had no effect on gestational weight gain, physical activity or diet (except for caffeine intake). The second study (Polley et al., 2002) was a randomized controlled trial comparing a stepped-care behavioural intervention with usual care. The intervention significantly decreased the proportion of women exceeding the IOM recommendations for gestational weight gain among the normal weight women, but not among the overweight women. However, the intervention had no effect on changes in fat intake (the only dietary outcome) or in exercise level. In the third study (Olson et al., 2004), the intervention included guidance on and monitoring of gestational weight gain by health-care providers and education on weight gain, diet and exercise during pregnancy by mail. A historical control group was used in this study. The intervention was effective in low-income women (both normal weight and overweight women) but not in highincome women. However, data on the effect of the intervention on dietary intakes or physical activity were not reported. In summary, two of these studies were able to prevent excessive gestational weight gain, but only in selective subgroups.

With regard to the fetal outcomes, there were no high birth weight infants (≥4000 g) in the intervention group, whereas eight (15%) infants in the control group had a high birth weight. A high birth weight increases the risk of prolonged labour, birth trauma, birth asphyxia, caesarean birth and perinatal mortality, although most prominently in infants with birth weight ≥4500 g (Institute of Medicine, 1990, Lederman, 2001). There were some characteristics of the eight control women, which might explain the high birth weights of their infants. On average, these women were taller, they had higher gestational weight gain and a longer gestation than the other women in the intervention and the control groups. In addition, they consumed more high-sugar snacks, favoured low-fibre bread and decreased the total level of LTPA during pregnancy more than the other women. However, there were no differences in the incidence of glucosuria between the mothers of high birth weight infants and the other women. Based on the maternity cards, oral glucose tolerance test had been performed only for 14 women in the intervention group and 11 women in the



control group on average at 26 (range 16–36) weeks' gestation. Of them, six women in the intervention group and one woman in the control group had gestational diabetes mellitus (diagnosed if serum glucose concentrations were \geqslant 4.8 mmol/l at fasting, \geqslant 10.0 mmol/l at 1 h or \geqslant 8.7 mmol/l at 2 h). However, the oral glucose tolerance test was performed only to one of the eight women with a high birth weight infant and she did not have gestational diabetes mellitus at 28 weeks' gestation.

The limitations of this study were partly due to the fact that this was primarily a pilot study testing the protocol for a larger study. The lack of randomization was probably the most important limitation. The baseline differences between the groups might have been smaller if we could have randomized the clinics. The intervention group had a higher mean pre-pregnancy BMI than the control group, which may have increased their risk for excessive gestational weight gain (Siega-Riz et al., 1994, Caulfield et al., 1996, Carmichael et al., 1997, Lederman et al., 1997, Cogswell et al., 1999, Olson and Strawderman, 2003). Stopping smoking during pregnancy is another risk factor for high gestational weight gain (Öhlin and Rössner, 1990). There were more smokers in the intervention group than in the control group at baseline and all smokers in both groups either stopped smoking (n=21)or cut it down from daily to occasional smoking (n=3)during pregnancy. The intervention group was also less educated than the control group. Although it is not clear whether education is associated with excessive gestational weight gain, education is known to be associated with diet and BMI but not with physical activity in Finnish women (Helakorpi et al., 2005). Pre-pregnancy BMI, smoking status and education were taken into account in the analyses, but the baseline differences in these variables between the groups may have contributed to the efficacy of the intervention.

The control PHNs usually recommended their clients a 2–3 kg smaller weight gain on average than that recommended by the IOM; the PHNs in the intervention clinics followed the IOM recommendations. This may have led to a lower gestational weight gain among the control women, as the amount of gestational weight gain recommended by health professionals is linked to actual weight gain during pregnancy (Cogswell *et al.*, 1999). Another possible explanation for the minor effects of this intervention is that the control group had some dietary and physical activity counselling as a part of the standard maternity care. Finally, awareness of being in a trial may have influenced both the control PHN's counselling practices as well as the control women's health behaviour.

The small sample size was also a major limitation of this study, reducing possibilities to detect statistically significant effects of the intervention. The clinic-level variation could not either be taken into account by using multilevel analysis due to the small number of clinics. There were also more drop-outs in the intervention group (29%) than in the control group (11%). Although the drop-out reasons were

only partly related to the study, the drop-outs might have been less motivated to change their health behaviour. Body weight was measured at each visit, but pre-pregnancy weight was self-reported. Overweight women are known to underreport their body weight more often than normal weight or underweight women (Rowland, 1990). However, as the amount of weight gain from pre-pregnancy to the first visit was similar in all the BMI categories, it is unlikely that underreporting was common among the overweight women. Information on diet and LTPA was obtained by questionnaires, which have not been validated among pregnant women.

Several lessons were learned from this pilot study. The PHNs implemented the counselling sessions as a part of the routine visits in primary health care. The participation rate in the counselling sessions was excellent as only a few booster sessions were missed. The pregnant women in this study were healthy primiparas who had relatively healthy dietary and LTPA habits. Therefore, their possibilities to further improve some of these habits were limited. Selecting a risk group (e.g. overweight and obese women) might have increased the effectiveness of the intervention. In the following larger study, it might be useful to concentrate on increasing the intake of vegetables, fruit and berries and the proportion of high-fibre bread (and other high-fibre cereal products). Additionally, inclusion of counselling related to dietary fat should be considered instead of trying to reduce the intake of high-sugar snacks, which was not successive in this study. The above mentioned topics are emphasized in the general dietary recommendations (Nordic Council of Ministers, 2004), although the evidence of their effect on gestational weight gain is limited. It could also be beneficial to monitor gestational weight gain more intensively, for example, by using individual BMI-specific weight gain charts such as in other studies (Polley et al., 2002, Olson et al., 2004, Althuizen et al., 2006).

In conclusion, this intervention had an effect on some dietary habits, but not on total LTPA or gestational weight gain. Larger randomized controlled trials are needed to show whether and how excessive gestational weight gain can be prevented by dietary and physical activity counselling.

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Reducing postpartum weight retention – a pilot trial in primary health care

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Abstract

Background: Postpartum weight retention may contribute to the development of obesity. We studied whether individual counselling on diet and physical activity from 2 to 10 months postpartum has positive effects on diet and leisure time physical activity and increases the proportion of primiparas returning to their pre-pregnancy weight.

Methods: A controlled trial including ninety-two postpartum primiparas was conducted in three intervention and three control child health clinics in primary health care in Finland. The intervention included individual counselling on diet and physical activity during five routine visits to a public health nurse; the controls received the usual care.

Results: In total, 50% of the intervention group and 30% of the control group returned to their pre-pregnancy weight (weight retention \leq 0 kg) by 10 months postpartum (p = 0.06). The confounder-adjusted odds ratio for returning to pre-pregnancy weight was 3.89 (95% CI 1.16–13.04, p = 0.028) for the intervention group compared with the controls. The mean proportion of high-fibre bread (of total weekly amount of bread) increased by 16.1% (95% CI 4.3–27.9) by 10 months postpartum in the intervention group compared with the controls when adjusted for confounders (p = 0.008). No significant differences were observed in changes in leisure time physical activity between the groups.

Conclusion: The intervention increased the proportion of primiparas returning to pre-pregnancy weight and the proportion of high-fibre bread in their diet. Larger randomized controlled trials are needed to show whether counselling can improve dietary and leisure time physical activity habits in postpartum women and also to confirm the results concerning the effect on reducing postpartum weight retention.

Trial registration: Current Controlled Trials ISRCTN21512277

Background

Obesity is a growing problem which also increases the burden of several diseases such as type 2 diabetes, cardio-vascular disease and certain cancers [1]. In Finland, 41% of women aged 15-64 years were overweight or obese (body mass index, BMI ≥ 25 kg/m²) in 2006, but the data is based on self-reported information [2]. For some women, pregnancy is a triggering factor for long-term overweight and obesity [3]. Postpartum weight retention is usually highly variable and a subgroup of women retains large amounts of weight after pregnancy. In some studies, up to 20 percent of women have retained at least 5 kg by 6–18 months postpartum [4]. The average postpartum weight retention varies from 0.5 kg to 3 kg in different study populations [5].

Excessive gestational weight gain is the primary risk factor for retaining weight in the postpartum period [4-6]. Other factors associated with an increased risk of high postpartum weight retention include high pre-pregnancy BMI, primiparity, short duration of breastfeeding, stopping smoking, high energy intake and low physical activity, although these associations have not been found in all studies [4,7]. Only few studies have assessed the influence of diet and physical activity on postpartum weight change. Higher or increased energy intake and lower physical activity were associated with higher postpartum weight retention in some studies [8-10], but not in all [11].

Relatively few weight loss interventions have been conducted among postpartum women. Only two of these studies aimed primarily to reduce postpartum weight retention [12,13], while the other studies aimed to investigate the effect of weight loss on lactation or child growth [14-16]. In most of these studies, the intervention consisted of a prescribed diet and an exercise programme. In four studies, the women in the intervention group lost more weight than the women in the control group [12,13,15,16], but all these studies were small and/or had a high dropout-rate. More information is needed on the effect of behavioural interventions to prevent weight retention in this group of women [5].

The aim of the study was to investigate whether individual counselling on diet and physical activity after pregnancy has positive effects on diet and leisure time physical activity (LTPA) and increases the proportion of primiparas who return to their pre-pregnancy weight by 10 months postpartum. This study is a part of a pilot study testing the feasibility of the study protocol for a larger study also including pregnant women [17].

Methods

Setting and general study design

The postpartum women were recruited through the child health care system, which is available to all families with children in every municipality in Finland and is funded by public tax revenue. Almost all (98%) children attend these public child health clinics (CC) for regular check-ups, as concluded from the proportion of children who are immunized according to immunization schedules under the age of two [18]. The study was conducted in six CCs in the city of Tampere and the town of Hämeenlinna in southern Finland. The clinics were selected on the basis of the clinics' administrative personnel's suggestion for suitable clinics. Three CCs volunteered to be intervention clinics and the remaining CCs were treated as control clinics. The study protocol was implemented during five routine visits to a public health nurse (PHN) at the CC. These visits coincided with the child's age of 2, 3, 5, 6 and 10 months.

All PHNs from the intervention clinics and the control clinics participated in the study (n = 8 and n = 6 respectively). Before the intervention began, the PHNs of the intervention clinics were trained in applying the counselling procedures, data collection and other study arrangements by the research group (12 h in total). The PHNs were also asked to practise the counselling between the training sessions with at least one client not participating in the study. The experiences were shared in small group sessions. The PHNs of the control clinics were trained for data collection and other study arrangements (6 h in total). All PHNs received a handbook in which the tasks for each research visit were explained and summarized. The researchers visited the clinics monthly during the intervention.

Participants

All participants were primiparas. The exclusion criteria were age under 18 years, type 1 or type 2 diabetes mellitus, twin pregnancy, physical disability that prevents exercising, otherwise problematic pregnancy, substance abuse, treatment or clinical history of any psychiatric illness, inadequate language skills in Finnish and intention to change residence within three months. Between August 2004 and January 2005, the PHNs approached all postpartum primiparas in these six CCs and assessed their eligibility for the study either on their visit to the participant's home after delivery or on the first visit to the CC. All eligible women were asked to participate in the study. In total, 53 women in the intervention clinics and 39 women in the control clinics gave informed consent to participation (Figure 1). The study was approved by the Ethics Committee of the Pirkanmaa Hospital District.

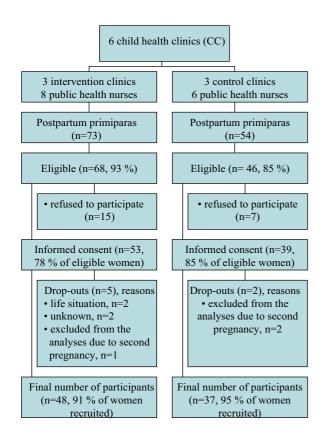


Figure I
Participant flow.

Counselling practices before the study

Information on all PHNs' usual counselling practices was collected by a questionnaire before the PHNs were trained for the study. The responses showed that the counselling practices varied widely between PHNs, but not between the PHNs of the intervention and the control clinics. However, the mean durations of time spent on counselling were short (approximately 4 min for both physical activity and dietary counselling), suggesting that the PHNs merely gave general advice on diet and physical activity rather than implementing actual counselling. During this study, the PHNs of the control clinics continued their usual physical activity and dietary counselling practices.

Intervention clinics

Discussion on weight development

The PHNs had brief discussions with the participants about pre-pregnancy body weight at the child's 2-month visit to the CC. If the pre-pregnancy weight was lower than the current weight, the PHN encouraged the participant to try to return to that weight with the help of dietary and

physical activity objectives (see below) during the study period. Extensive weight loss programmes, however, were not recommended.

Physical activity counselling

The physical activity counselling consisted of one primary counselling session (allocated time 20-30 min) at the 2month visit and four booster sessions (allocated time 10-15 min) at the 3, 5, 6 and 10 month visits. The counselling was implemented using the model of Laitakari and Asikainen [19], which is based on two behavioural models, PRE-CEDE-PROCEED [20] and Stages of Change [21]. The PHN proceeded in the counselling by following a counselling card, which was filled in for each participant at each session. The primary counselling session began with a discussion about the participant's current LTPA and continued with a discussion about the participant's needs and opportunities to increase LTPA. The general benefits and restrictions of LTPA were also raised with the help of a take home leaflet. Finally, an individual weekly LTPA plan was written into the participant's follow-up notebook.

According to the physical activity recommendations for health [22] and fitness [23], which also apply to postpartum women [24,25], a minimum of 30 min of moderateintensity physical activity on five weekdays was considered sufficient for health and a minimum of 40 min of high-intensity physical activity three times per week for fitness. By using multiples of resting metabolic equivalents (METs) with MET value 5 for moderate-intensity and MET value 7 for high-intensity LTPA [26], 800 MET minutes (METmin) was estimated to represent the minimum LTPA requirements. After making the weekly plan, the fulfilment of at least 800 METmin in the LTPA plan was checked by the PHN by multiplying the frequency, duration (minutes) and MET value of weekly LTPA. As opposed to physical activity recommendations, lightintensity LTPA (MET value 3) could also be included in the plan to improve compliance with the plan. At the booster sessions the participant's adherence to the plan was assessed, the plan was revised, if needed, and the METmin were checked.

As a part of the LTPA plan, the participant had an option to attend supervised group exercise sessions held once a week for 45–60 min at a location close to each intervention clinic. The group exercise included both endurance and muscular training and it was developed specifically for postpartum women.

Dietary counselling

Based on dietary recommendations [27,28], a summary of the evidence for prevention of excessive weight gain and obesity [29] and information on the diet of Finnish women [30], the dietary counselling focused on four topics that could help the participants to return to their prepregnancy weight. The following dietary objectives were set for each participant to achieve or to maintain: 1) to have a regular meal pattern, emphasising the importance of breakfast and ≥ 1 hot meal every day, 2) to eat at least 5 portions/d (400 g/d) in total of different kinds of vegetables, fruit and berries, 3) to consume mostly high-fibre bread (≥ 5 g fibre/100 g) and 4) to restrict the intake of high-sugar snacks to ≤ 1 portion/d (e.g. 50 g sweets, one pastry, once piece of cake, 2 biscuits, 2 dl ice cream or a glass of soft drink).

The dietary counselling consisted of one primary counselling session (allocated time 20-30 min) at the 3-month visit and three booster sessions (allocated time 10 min, in addition to the physical activity boosters) at the 5, 6 and 10 month visits. The model of Laitakari and Asikainen [19] was also applied to the dietary counselling. A counselling card was also used in the dietary counselling. At the beginning of the primary counselling session, the PHN assessed the participant's current dietary habits concerning these four topics using the baseline food frequency questionnaire. After comparing the personal habits to the recommendations, the PHN and the participant discussed the participant's need for dietary changes, as well as her opportunities for and barriers to making the changes. The participant also received two take home leaflets on healthy diet. The participant was asked to keep a weekly record of her compliance with the four objectives in her follow-up notebook. At each booster visit, the follow-up notebook was checked and the compliance was discussed.

Main outcomes

The main outcome for postpartum weight retention was the proportion of women returning to their pre-pregnancy weight (weight retention ≤ 0 kg) by 10 months postpartum. The dietary outcomes were changes in meal pattern (breakfast and ≥ 1 hot meal/d), overall intake of vegetables, fruit and berries (portions/d), use of high-fibre bread (% of bread with ≥ 5 g fibre/100 g of total weekly amount of bread) and intake of high-sugar snacks (portions/d). The physical activity outcome was the change in the weekly METmin of LTPA.

Data collection

Body weight was measured in light clothing and without shoes at every CC visit related to the study. The scales were calibrated to the reference scale within \pm 0.5 kg at the beginning and at the end of the study. Additionally, waist circumference was measured at these visits. Data on gestational weight development was obtained from the maternity card. Pre-pregnancy weight and height were self-reported.

The baseline questionnaire including questions on background (e.g. education, smoking), dietary intake and LTPA was completed before the child's 2-month visit. The first LTPA and the dietary follow-up questionnaires were completed at the 5-month visit and the second follow-up questionnaires at the 10-month visit. These questionnaires were returned to the PHN, who checked that they were properly filled in. Information on dietary intake was obtained using a 57-item food frequency questionnaire that was a simplified version of the food frequency questionnaire used in the Health 2000 study in Finland [31]. The baseline and the follow-up dietary information were based on diet during the previous month. The questions on LTPA were modified from the International Physical Activity Questionnaire, IPAQ [32], by using the amount of breathlessness (none, some, marked) to describe light, moderate and high-intensity LTPA to the respondents. LTPA at baseline illustrated a typical week before pregnancy and at follow-up a typical week during the past three weeks. These dietary and LTPA questions have not been validated among postpartum women, however.

Statistical methods

To test the baseline differences in background characteristics (Table 1), t-test was used for continuous variables and χ^2 -test for categorised variables. Differences in the duration of exclusive and partial breastfeeding were tested using non-parametric Mann-Whitney U test, since these variables were not normally distributed. As there were missing values in the duration of breastfeeding for 11 women, an indicator variable (0 = non-missing, 1 = missing) together with the continuous breastfeeding variables was used in the multivariable analyses to prevent the loss of data. These background variables were used, when necessary, as covariates in the multivariable analyses regardless the statistical significance of the baseline differences.

The unadjusted differences between the groups in the proportions of women who returned to their pre-pregnancy weight were tested by χ^2 -test. The confounder-adjusted analysis of the proportions of women returning to prepregnancy weight, and retaining a maximum of 2 or 5 kg were done by using a logistic regression model. Analysis of covariance (ANCOVA) with confounding variables as covariates was used to test the between-group differences in average weight retention and waist circumference at 10 months postpartum, also changes in the dietary outcomes from 2 to 5 and to 10 months postpartum. As the weekly METmin were not normally distributed, they were converted into logarithms. The between-group differences of the log-transformed METmin variable at 5 and 10 months postpartum were analysed using ANCOVA of repeated measures. All statistical tests were two-sided and p < 0.05was used as the level of statistical significance.

Table I: Background characteristics of the participants, means (SD) or numbers (%)

	Intervention group (n = 48)	Control group (n = 37)	p-value
Age at 2 months postpartum (y)	29.5 (3.9)	28.3 (4.4)	0.21
Education level, n (%)	, ,	, ,	0.46
basic or secondary education	23 (48)	17 (46)	
polytechnic education	8 (17)	10 (27)	
University education	17 (35)	10 (27)	
Smoking status ¹ , n (%)	. ,	. ,	0.22
Non-smoker before and after pregnancy	30 (68)	20 (57)	
Smoker before pregnancy and non-smoker after pregnancy	5 (11)	2 (6)	
Smoker before and after pregnancy	9 (21)	13 (37)	
Pre-pregnancy BMI (kg/m²)	22.7 (3.7)	22.1 (2.3)	0.36
Total gestational weight gain (kg)	16.2 (5.0)	15.3 (5.0)	0.41
Gestational weight gain, n (%)	·		0.78
Below recommendations ³⁷	9 (19)	9 (24)	
Within recommendations	13 (28)	11 (30)	
Exceeding recommendations	25 (53)	17 (46)	
Body weight at 2 months postpartum (kg)	67.1 (11.1)	64.7 (7.8)	0.26
Weight retention at 2 months postpartum compared to pre- pregnancy weight (kg)	4.3 (4.0)	4.2 (3.9)	0.91
BMI at 2 months postpartum (kg/m²)	24.3 (3.8)	23.6 (2.5)	0.30
by BMI groups, n (%)			0.25
18.5–24.9 kg/m ²	30 (63)	27 (73)	
25.0–29.9 kg/m ²	15 (31)	I0 (27)	
≥ 30.0 kg/m ²	3 (6)	0 (0)	
Waist circumference at 2 months postpartum (cm)	81.8 (9.0)	81.1 (6.7)	0.66

¹ Smokers include both daily and occasional smokers. Smoking status was assessed for the periods of 0–6 months before pregnancy and 4–10 months postpartum

Results

Figure 1 shows the flow of participants. The participants who dropped out of the study (n = 7) were younger, less educated and had higher pre-pregnancy and postpartum BMI, but lower gestational weight gain and weight retention at 2 months postpartum on average than participants who completed the study (n = 85). No major differences were observed in smoking status or in the main dietary and physical activity outcomes between the groups. There is no follow-up information available on the drop-outs.

In the intervention group, 43 (90%) women participated in all physical activity counselling sessions and 45 (94%) women in all dietary counselling sessions. All 48 women participated in the primary physical activity and dietary counselling sessions. Five women missed one physical activity booster session, three women missed one dietary booster session and three women missed the discussion about returning to pre-pregnancy weight. On average, the women participated in 4.9 of the five physical activity counselling sessions and in 3.9 of the four dietary coun-

selling sessions. The average participation rate in the group exercise sessions was 50.7 % (sd 28.5) of the sessions available for each woman.

The differences in the background characteristics were not statistically significant between the groups (Table 1). There were also no statistically significant differences in the duration of exclusive (medians 5.0 vs. 5.0 months, p = 0.57) or partial breastfeeding (medians 10.0 vs. 8.5 months, p = 0.07) between the intervention and the control groups.

Weight retention

Figure 2 shows the unadjusted mean body weight changes during pregnancy and during the intervention (2 to 10 months postpartum) in the intervention and the control groups. Fifty percent of the intervention group and 30% of the control group returned to their pre-pregnancy weight by 10 months postpartum, but the difference did not reach statistical significance (Table 2). The confounderadjusted odds ratio (OR) for returning to pre-pregnancy

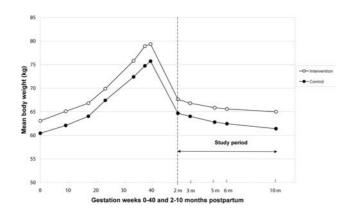


Figure 2 Mean body weight changes from the beginning of pregnancy to 10 months postpartum. Values represent unadjusted means in the intervention and the control groups. Intervention group: n = 46, except for pre-pregnancy weight (n = 45), 17^{th} gestation week (n = 42) and 37^{th} gestation week (n = 44). Control group: n = 37, except for 9^{th} and 33^{rd} gestation week (n = 36).

weight was 3.89 (95% CI 1.16–13.04) for the intervention group compared to the control group. The results were essentially the same when adjusted for the duration of partial breastfeeding instead of the duration of exclusive breastfeeding. The ORs for retaining maximum 2 kg or 5 kg at 10 months postpartum did not differ statistically significantly between the groups. Among those women who did not return to their pre-pregnancy weight, the unad-

justed average weight retention at 10 months postpartum was 5.2 kg in the intervention group (n = 23) and 3.2 kg in the control group (n = 26). However, of these women, the intervention group had higher weight retention than the control group (6.7 vs. 5.7 kg) already at 2 months postpartum when the intervention began. Among all women, there were no differences between the groups in the adjusted average weight retention at 10 months postpartum or in the adjusted change in waist circumference from 2 to 10 months postpartum (Table 2).

Changes in diet and physical activity

The proportion of high-fibre bread of total weekly amount of bread increased in the intervention group compared to the control group when adjusted for confounders (Table 3). The mean increase in favour of the intervention group was 16% both at the first follow-up (5 months postpartum) and the second follow-up (10 months postpartum). The intake of high-sugar snacks decreased on average by 0.6 portions/d at the first follow-up in the control group compared with the intervention group, but returned to the baseline level by the second follow-up. There were no statistically significant differences in changes in the intake of vegetables, fruit and berries between the groups. Moreover, no between-group differences were observed in the proportion of women having breakfast and at least one hot meal per day. The respective proportions of women in the intervention and the control groups fulfilling this criterion were 88% and 86% at baseline, 94% and 92% at the first follow-up and 93% and 89% at the second follow-up.

Table 2: Comparison of weight retention¹ and waist circumference at 10 months postpartum between the groups. The values represent numbers (%) and odds ratio (OR) (95% confidence intervals, CI) or means (SD) and mean differences (95% CI)

	Intervention group $(n = 46)$	Control group (n = 37)	Intervention vs. control	p-value
Proportion of women who retained ≤0 kg, n (%)	23 (50)	11 (30)		0.062
			Adjusted OR = 3.89 (1.16–13.04)	0.0283
Weight retention, mean (SD) (kg)	1.8 (4.3)	1.0 (4.4)	Adjusted mean difference = 0.8 (-1.1-2.7)	0.424
Waist circumference at 10 months postpartum, mean (SD) (cm)	78.1 (10.2)	75.4 (6.2)	Adjusted mean difference = 1.0 (0.7–2.7)	0.24 ⁵

¹ compared with pre-pregnancy weight

² two-sided χ²-test

³ logistic regression model, odds ratio for retaining ≤0 kg adjusted for age, education, pre-pregnancy BMI, gestational weight gain, weight at 2 months postpartum (baseline), duration of exclusive breastfeeding and smoking status. Intervention group: n = 43, Control group: n = 35.

⁴ unadjusted means for weight retention, ANCOVA: weight at 10 months postpartum as the dependent variable, mean difference adjusted for prepregnancy weight

⁵ unadjusted means for waist circumference, ANCOVA: waist circumference at 10 months postpartum as the dependent variable, mean difference adjusted for weight circumference at 2 months postpartum (baseline), age, education, pre-pregnancy BMI, gestational weight gain, duration of exclusive breastfeeding and smoking status. Intervention group: n = 43, Control group: n = 35.

Table 3: Diet at baseline (2 months) and at follow-up (5 and 10 months). The values represent means (SD) and adjusted group differences (95% confidence intervals, CI) at follow-up.

	n	2 months postpartu m, mean (SD)	5 months postpartu m, mean (SD)	Adjusted mean difference to controls ¹	PI	10 months postpartu m, mean (SD)	Adjusted mean difference to controls ¹	PΙ
Vegetables, fruit and berries (portions/d)								
Intervention	44	2.4 (1.3)	2.6 (1.4)	+ 0.4	0.13	2.6 (1.4)	+ 0.2	0.42
Control	37	2.7 (2.0)	2.6 (1.8)	(-0.1-0.9)		2.5 (2.1)	(-0.3-0.8)	
High-fibre bread (% of total bread)								
Intervention	44	49 (29)	60 (29)	+ 16.0	0.008	65 (27)	+ 16.1	0.008
Control	37	49 (30)	45 (33)	(4.2-27.7)		52 (31)	(4.3-27.9)	
High-sugar snacks (portions/d)		. ,	` ,	,		` ,	,	
Intervention	44	1.9 (1.2)	2.2 (1.3)	+ 0.6	0.028	2.1 (1.2)	0.0	0.93
Control	37	2.0 (1.2)	1.5 (0.9)	(0.1–1.1)		2.1 (1.4)	(-0.6–0.6)	

ANCOVA: mean group differences, adjusted for baseline intake of the outcome variable, age, education, smoking status, gestational weight gain and BMI at 2 months postpartum. Intervention group: n = 42, Control group: n = 35

The unadjusted mean weekly METmin during leisure time were 2 328 (SD 1 308) in the intervention group and 2 061 (SD 975) in the control group before pregnancy (the baseline). At 10 months postpartum the values were 1 906 (SD 970) and 2 051 (SD 1 249) respectively. There were no statistically significant differences between the groups in changes in the weekly METmin from baseline to 5 or 10 months postpartum when adjusted for baseline weekly METmin, age, education, gestational weight gain and BMI at 2 months postpartum.

Discussion

This study aimed at reducing postpartum weight retention in primiparas by counselling them on diet and physical activity during five of the child's routine visits to a CC. We observed that a higher proportion of the women in the intervention group than in the control group returned to their pre-pregnancy weight by 10 months postpartum, when adjusted for confounders. However, among those women who did not return to their pre-pregnancy weight, the intervention group retained more weight than the control group on average. Therefore, the average weight retention was not lower in the intervention group than in the control group.

The changes in dietary habits were modest, since only the mean proportion of high-fibre bread of total weekly amount of bread increased by 15–16 %-unit in the intervention group compared to controls from baseline to 5 and 10 months postpartum. This change corresponds e.g. to replacing one slice of low-fibre bread by one slice of high-fibre bread for every sixth slice consumed. No between-group differences were found in the intake of vegetables, fruit and berries or high-sugar snacks in favour of the intervention group. As the proportion of women having breakfast and a hot meal every day was already high at baseline, there was little potential to promote

these habits by counselling. The counselling did not have an effect on the total amount of LTPA, possibly at least partly due to the fairly high level of LTPA at baseline (before pregnancy) or difficulties in arranging more time for LTPA in the new life situation.

The results of this study mostly concur with the two earlier interventions aimed at reducing postpartum weight retention [12,13]. In both of these studies, the intervention group lost more weight and/or returned to their pre-pregnancy weight more often than the control group, but no between-group differences were observed in changes in energy intake or expenditure. The methods of these studies differed from our methods to some extent. In the study by Leermakers et al. [12], women (n = 90) with at least 6.8 kg weight retention were randomised at 3-12 months postpartum either to a no-treatment control group or to a six-month behavioural weight loss intervention delivered via correspondence. In the study by O'Toole et al. [13], the participants (n = 40) were overweight women, who gained at least 15 kg during pregnancy and had at least 5 kg of postpartum weight retention at the time of recruitment (6 weeks to 6 months postpartum). They were randomized to a structured or a self-directed intervention continuing up to 1 year postpartum. These studies also had smaller sample sizes and much higher drop-out rates (31% and 41% respectively) than in our study. The dropout rate was very low (8%) in our study, which improves the internal validity of the results. The external validity was improved by a high participation rate (81%) in a highly representative sample.

However, this study primarily piloted the study protocol for a larger study, which contributes to some limitations of this study. Firstly, the CCs were not randomized, which may have increased the baseline differences between the groups. The intervention group had slightly higher mean gestational weight gain and BMI, which are risk factors for high postpartum weight retention [4-6]. Although these variables were included in the analyses as confounders, these baseline differences, although not statistically significant, may have affected the efficacy of the intervention. The small sample size was another major limitation in this study and therefore the opportunities to observe statistically significant effects of the intervention were limited. As the number of CCs was also small, the multilevel analysis could not be used in order to take the clinic-level variation into account. Any future study should be a cluster-randomized controlled trial with a larger number of clusters and participants.

It is not clear why a higher proportion in the intervention group than in the control group returned to their pre-pregnancy weight as the effects of the intervention on dietary and LTPA habits were so minor. This discrepancy could be related to difficulties in assessing one's diet and LTPA accurately or to the limitations of our questionnaires not validated among postpartum women. The LTPA questionnaire may not have been sensitive enough in measuring changes, particularly in everyday light-intensity LTPA, which contributes significantly to the total energy expenditure. In addition, the intervention group may have decreased their total energy intake as a result of the dietary counselling, but it could not be measured by the semiquantitative food frequency questionnaire. On the other hand, neither Leermakers et al. [12] nor O'Toole et al. [13] observed between-group differences in changes in energy intake or expenditure in their studies, although the intervention had an effect on weight retention. Concerning the validity of the weight retention outcome, body weight was measured at each visit but pre-pregnancy weight was selfreported. As overweight women usually underreport their body weight more often than thinner women [33] and there were more overweight women in the intervention group than in the control group before pregnancy, it is possible that the intervention group could have had lower average weight retention than was reported. Removing the overweight women from the analyses did not change the results essentially, however.

To our knowledge, this was the first study conducted in a primary healthy care setting aiming to reduce postpartum weight retention by dietary and physical activity counselling. The PHNs implemented the five counselling sessions on the child's routine visits to the CC and therefore the participation rate at the counselling sessions was very high. The counselling focused on promoting healthy dietary and physical activity habits. Individual recommendations for energy intake and expenditure, and thereby for energy deficit (as kJ or kcal), were not applied, because it would have been too complicated, especially as the time allocated for the counselling was short. It is possible that

the women would have needed even more counselling or support to improve their dietary or physical activity habits. The time span between the last two booster sessions (4 months) may have been too long to motivate the women to adhere to the dietary and LTPA plans without support from their PHN. On the other hand, increasing the number of counselling sessions may not be feasible, since the time resources of the PHNs are limited and the main focus on the visits is on the infant's health and growth. It is possible that the presence of infants interfered with the counselling.

The need for postpartum counselling and support for healthy diet and weight management has been emphasised in several papers [34-36]. In particular, women with high pre-pregnancy BMI or high postpartum weight retention could benefit from it. Another option is that the intervention would begin in early pregnancy in order to prevent excessive gestational weight gain (the primary risk factor for high postpartum weight retention) and continue during the postpartum period.

Conclusion

Integrating individual dietary and physical activity counselling for mothers into the routine visits to CCs increased the proportion of postpartum primiparas returning to their pre-pregnancy weight, although it did not have an effect on the average weight retention. Larger randomized controlled trials are needed to show whether counselling can improve dietary and physical activity habits in postpartum women and also to confirm the results concerning the effect of counselling on reducing postpartum weight retention.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

TIK: study design, intervention protocols (especially dietary counselling), acquisition of data, analysis and interpretation of data, and preparation of manuscript.

MP: study design, intervention protocols, statistical methodology, analysis and interpretation of data, and preparation of manuscript.

MA: study design, intervention protocols (especially physical activity counselling), acquisition of data, interpretation of data, and preparation of manuscript.

MF: study design, intervention protocols, interpretation of data and preparation of manuscript.

EW: study design, interpretation of data, and preparation of manuscript.

RL: principal researcher, obtained funding, study concept and design, intervention protocols, interpretation of data, and preparation of manuscript.

All authors read and approved the final manuscript.

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