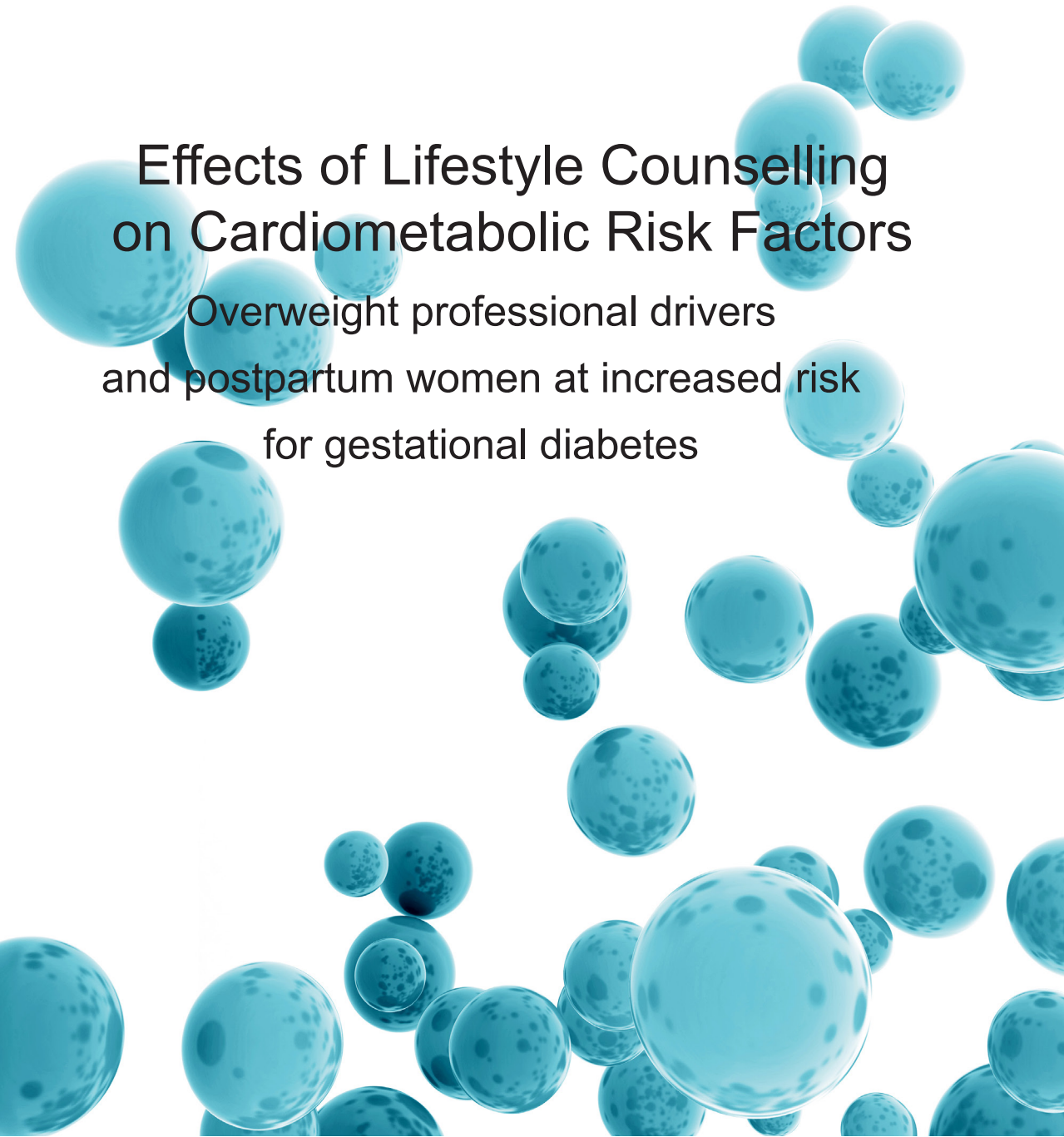


JATTA PUHKALA

# Effects of Lifestyle Counselling on Cardiometabolic Risk Factors

Overweight professional drivers  
and postpartum women at increased risk  
for gestational diabetes





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ACADEMIC DISSERTATION

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JATTA PUHKALA

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University of Tampere, Faculty of Social Sciences  
UKK Institute for Health Promotion Research  
Finland

*Supervised by*

Professor Clas-Håkan Nygård  
University of Tampere  
Finland  
Docent Katriina Kukkonen-Harjula  
University of Tampere  
Finland

*Reviewed by*

Docent Katja Pahkala  
University of Turku  
Finland  
Professor Petra Wark  
Coventry University  
United Kingdom

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# ABSTRACT

Cardiometabolic risk factors include hypertension, dyslipidemias and insulin resistance, which predispose to atherosclerosis and type 2 diabetes (T2DM). Metabolic syndrome (MetS) is a cluster of these risk factors. Gestational diabetes (GDM) is a disorder in glucose metabolism diagnosed during pregnancy, predisposing to an increased risk for developing T2DM and MetS later in life. Lifestyle counselling interventions on diet and physical activity (PA) have yielded promising results in managing cardiometabolic risk factors. Lifestyle changes may reduce the risk both independently and via weight reduction.

In the present dissertation the effects of lifestyle counselling on cardiometabolic risk factors were studied among two target groups: abdominally obese long-distance professional drivers and postpartum women, who in early pregnancy were at increased risk for GDM. The dissertation is based on two randomized lifestyle counselling trials, the Professional Driver Study (Effects of Weight Reduction on Sleep and Alertness in Long-distance Truck and Bus Drivers) and the GDM Prevention Study (Counselling, Lifestyle and Physical Activity in Maternity Care). The objectives were to study 1) effects of a 12-month lifestyle counselling programme on 1) on lifestyle and 2) on cardiometabolic risk factors in overweight professional drivers, and to study 3) the effects of intensified lifestyle counselling in maternity care on MetS at one and seven years postpartum, and 4) to assess early pregnancy risk factors associated with MetS at one and seven years postpartum among women at increased risk for GDM at early pregnancy.

One hundred and thirteen long-distance male drivers participated in the randomized Professional Driver Study. Inclusion criteria were being a 30 to 62-year-old male with waist circumference >100 cm. The lifestyle counselling group (LIFE, N=55) was offered individual dietary and PA counselling over a period of 12 months. The counselling programme consisted of six face-to-face sessions monthly and seven phone contacts with a nutritionist. The second year was a follow-up for the LIFE, while the reference group (REF, N=58) received a three-month counselling during the second year. The assessments took place at

0, 12 and 24 months, and included body composition, blood samples and questionnaires on lifestyle habits.

The GDM Prevention Study was a cluster randomized trial conducted in 14 maternity clinics in Finland for women with risk factors for gestational diabetes (N=442). In the counselling clinics (246 women), the public health nurses delivered intensified PA and dietary counselling at four antenatal consultations. Public health nurses in the usual care clinics (196 women) continued their usual counselling methods. Assessments, including body composition and blood samples, took place twice during pregnancy (at 8-12 and 26-28 weeks), and one and seven years postpartum. Prevalence of MetS was determined one and seven years postpartum, and in addition to the counselling and usual care groups, women with early GDM diagnosis and healthy women who did not meet the inclusion criteria of the study were included in the analyses.

In the Professional Driver Study, 47 (85%) men in the LIFE and 48 (83%) men in the REF participated in the 12-month assessments. Most of the drivers (76%) in the LIFE participated in all 13 counselling sessions offered. The drivers improved their diet and increased PA. On average, their weight was reduced by about four kilograms and waist circumference by five centimetres. In addition, cardiometabolic risk factors diminished.

In the GDM Prevention Study, intensified counselling during pregnancy was not associated with the occurrence of metabolic syndrome one and seven years postpartum. Of the women who participated in the baseline assessments, 24% and 37% participated in the follow-up assessments at one and seven years. Early pregnancy GDM and pre-pregnancy overweight were associated with MetS at one and seven years postpartum.

High compliance and improved lifestyle patterns suggest that lifestyle counselling combining face-to-face and phone contacts is appropriate for overweight long-distance drivers. Drivers should be assured of access to occupational health care with trained nurses to give lifestyle counselling.

Lifestyle counselling in maternity care was not effective in preventing MetS one and seven years postpartum. Pregnancy may be too short a time to achieve such permanent lifestyle changes. Women with GDM and overweight women should be screened and counselled for cardiometabolic risk factors after delivery. Continuity of care should be ensured postpartum, and more co-operation between maternity care, well-child care, health centres and occupational health care is needed.

# TIIVISTELMÄ

Verenkiertoelimistön ja aineenvaihdunnan sairauksien riskitekijät, kuten kohonnut verenpaine, veren rasva-aineenvaihdunnan häiriöt ja insuliini-resistenssi altistavat valtimonkovettumataudille ja tyypin 2 diabetekselle. Metabolinen oireyhtymä (MBO) tarkoittaa näiden riskitekijöiden kasautumista samalle henkilölle. Raskausdiabetes on raskauden aikana todettu glukoosiaineenvaihdunnan häiriö, joka altistaa synnytyksen jälkeen mm. tyypin 2 diabetekselle ja MBO:lle. Ruokavaliomuutoksiin ja liikunnan lisäämiseen keskittyneissä elintapaohjaustutkimuksissa on saatu lupaavia tuloksia verenkiertoelimistön ja aineenvaihdunnan sairauksien riskitekijöiden ehkäisyssä ja hoidossa. Elintapamuutokset voivat korjata riskitekijöitä sekä itsenäisesti että laihutumisen kautta.

Väitöskirjassa selvitettiin elintapaohjauksen vaikutusta verenkiertoelimistön ja aineenvaihdunnan riskitekijöihin kahdessa ryhmässä: vyötärölihavilla kaukoliikenteen ammattikuljettajilla ja naisilla, joilla oli raskauden aikana kohonnut raskausdiabeteksen riski. Tutkimus perustuu kahteen satunnaistettuun elintapaohjaustutkimukseen: Metrimies (Ammattikuljettajien laihdutuksen vaikutus työvireyteen) ja NELLI (Neuvonta, elintavat ja liikunta neuvolassa). Väitöskirjan tavoitteena oli tutkia 1) kuljettajilla vuoden mittaisen elintapaohjauksen vaikutusta elintapoihin ja 2) verenkiertoelimistön ja aineenvaihdunnan sairauksien riskitekijöihin, sekä 3) selvittää äitiysneuvoloissa toteutetun, tehostetun elintapaohjauksen vaikutusta MBO:n ilmenemiseen yhden ja seitsemän vuoden kuluttua synnytyksestä, sekä 4) selvittää alkuraskauden riskitekijöitä, jotka ovat yhteydessä MBO:hon vuoden ja seitsemän vuoden kuluttua naisilla, joilla oli raskauden alussa todettu suurentunut raskausdiabeteksen riski.

Metrimies-hankkeeseen osallistui 113 kaukoliikenteen mieskuljettajaa. Tutkimukseen valittiin 30–62-vuotiaita miehiä, joiden vyötärön ympäryys oli vähintään 100 cm. Elintapaohjausryhmä (N=55) sai yksilöllistä ohjausta ruokavaliosta ja liikunnasta 12 kuukauden ajan. Ohjaus koostui kuudesta kuukausittaisesta tapaamisesta ja seitsemästä puhelinkontaktista ravitsemus-asiantuntijan kanssa. Toinen vuosi oli seurantavuosi elintapaohjausryhmälle,

kun taas vertailuryhmä (N=58) sai kolmen kuukauden ohjauksen. Mittaukset tehtiin tutkimuksen alussa ja 12 ja 24 kk:n kuluttua. Mittauksiin kuuluivat mm. verinäytteet, kehon koostumus ja elintapakyselyitä.

NELLI-hanke on ryvässatunnaistettu kontrolloitu tutkimus, joka toteutettiin 14:ssa Pirkanmaan kunnan äitiysneuvolassa. Tutkimukseen hyväksyttiin naiset, joilla oli raskauden alussa kohonnut raskausdiabeteksen riski (N=442). Koeneuvoloissa (246 naista) terveydenhoitajat toteuttivat tehostettua liikunta- ja ravintoneuvontaa neljällä tapaamiskerralla raskauden aikana. Vertailukuntien neuvoloissa (196 naista) jatkettiin aiempia neuvontakäytäntöjä. Mittaukset tehtiin kahdesti raskauden aikana (raskausviikot 8–12 ja 26–28) sekä vuosi ja seitsemän vuotta synnytyksen jälkeen. MBO:n ilmeneminen selvitettiin vuoden ja seitsemän vuoden kuluttua synnytyksestä. Tähän vaiheeseen kutsuttiin koe- ja vertailuryhmän lisäksi naisia, jotka eivät olleet täyttäneet satunnaistetun tutkimuksen sisäänottokriteerejä (todettiin varhainen raskausdiabetes ja terveet).

Metrimieshankkeessa 47 (85 %) elintapaohjausryhmään kuuluneista ja 48 (83 %) vertailuryhmään kuuluneista kuljettajista osallistui mittauksiin 12 kuukautta tutkimuksen alusta. Suurin osa (76 %) elintapaohjausryhmään kuuluneista kuljettajista osallistui jokaiselle tarjotulle 13 ohjaukskerralle. Keskimäärin elintapaohjausta saaneet kuljettajat laihtuivat neljä kiloa ja heidän vyötärön ympäryksensä pieneni viisi senttiä vertailuryhmään verrattuna. Kuljettajat paransivat ravintotottumuksiaan ja lisäsivät liikuntaa. Verenkierroelimistön ja aineenvaihdunnan sairauksien riski pieneni.

Vuoden ja seitsemän vuoden kuluttua synnytyksestä MBO:n esiintyvyydessä ei ollut eroa koe- ja vertailuryhmän välillä. Seurantamittauksiin osallistui 24 % ja 37 % alkumittauksissa käyneistä naisista. Varhaisraskaudessa todettu raskausdiabetes sekä raskautta edeltänyt ylipaino olivat yhteydessä MBO:hon vuosi ja seitsemän vuotta synnytyksen jälkeen.

Hyvä osallistuminen ja toteutuneet elintapamuutokset viittaavat siihen, että elintapaohjaus, jossa on yhdistetty tapaamisia ja puhelinkontakteja, soveltuu ylipainoisille kaukoliikenteen kuljettajille. Ammattikuljettajille tulisi turvata pääsy työterveyshuoltoon, jossa on valmiuksia tarjota elintapaohjausta.

Raskauden aikainen elintapaohjaus ei vähentänyt MBO:n ilmaantumista vuosi ja seitsemän vuotta synnytyksen jälkeen. Raskaus saattaa olla liian lyhyt aika pysyvien elintapamuutosten aikaansaamiseksi. Raskausdiabetesta sairastaneiden ja lihaviin naisten seuranta ja elintapaohjausta on tärkeää jatkaa synnytyksen jälkeen. Yhteistyötä äitiys- ja lastenneuvoloiden, terveyskeskusten ja työterveyshuollon välillä tulisi lisätä hoidon jatkuvuuden varmistamiseksi.



# LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following original articles. In addition, some unpublished data are presented.

- I Puhkala J, Kukkonen-Harjula K, Aittasalo M, Mansikkamäki K, Partinen M, Hublin C, Kärmeniemi P, Sallinen M, Olkkonen S, Ojala A, Tokola K, Nygård C-H, Fogelholm M. Lifestyle counseling in overweight truck and bus drivers – effects on dietary patterns and physical activity. *Preventive Medicine Reports* 2016;4:435-40. doi: 10.1016/j.pmedr.2016.08.012.
- II Puhkala J, Kukkonen-Harjula K, Mansikkamäki K, Aittasalo M, Hublin C, Kärmeniemi P, Olkkonen S, Partinen M, Sallinen M, Tokola K, Fogelholm M. Lifestyle counseling to reduce body weight and cardiometabolic risk factors among truck and bus drivers - a randomized controlled trial. *Scandinavian Journal of Work, Environment & Health* 2015;41(1):54-64.
- III Puhkala J, Kinnunen TI, Vasankari T, Kukkonen-Harjula K, Raitanen J, Luoto R. Prevalence of metabolic syndrome one year after delivery in Finnish women at increased risk for gestational diabetes mellitus during pregnancy. *Journal of Pregnancy* 2013;2013:139049. doi: 10.1155/2013/139049.
- IV Puhkala J, Raitanen J, Kolu P, Tuominen P, Husu P, Luoto R. Metabolic syndrome in Finnish women seven years after a gestational diabetes prevention trial. *BMJ Open* 2017 doi: 10.1136/bmjopen-2016-014565.

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# ABBREVIATIONS

BMI	body mass index
BP	blood pressure
GDM	gestational diabetes mellitus
GWG	gestational weight gain
HDL-C	high-density lipoprotein cholesterol
IDF	International Diabetes Federation
LIFE	the lifestyle counselling group in the Professional Driver Study
LDL-C	low-density lipoprotein cholesterol
MET	multiples of resting metabolic equivalents
MetS	metabolic syndrome
OGTT	oral glucose tolerance test
PA	physical activity
RCT	randomized controlled trial
REF	the reference group in the Professional Driver Study
T2DM	type 2 diabetes mellitus
TG	triglycerides

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# 1 INTRODUCTION

Cardiometabolic risk factors include hypertension, dyslipidemias and insulin resistance, which predispose to atherosclerosis and type 2 diabetes (T2DM) (Finucane et al. 2011; Lovre and Mauvais-Jarvis 2015). Metabolic syndrome (MetS) is a cluster of cardiometabolic risk factors, including abdominal obesity, hypertension and elevated blood concentrations of triglycerides (TG), decreased HDL cholesterol (HDL-C) and elevated glucose (Eckel et al. 2010). Gestational diabetes (GDM) is a disorder in glucose metabolism diagnosed during pregnancy (Kampmann et al. 2015). Women with a diagnosis of GDM are at increased risk for later development of T2DM and MetS (Akinci et al. 2011; Reece, Leguizamon, Wiznitzer 2009). Risk factors for GDM include pre-pregnancy overweight, excessive gestational weight gain, high maternal age and family history of T2DM (Kampmann et al. 2015).

Over several decades numerous efforts have been made to prevent cardiometabolic diseases (Smith 2016). As a result, the prevalence of smoking has decreased in industrial countries (World Health Organization 2013), and the pharmaceutical care of cardiometabolic risk factors has improved (Cannon 2007). These efforts have resulted in significantly lower rates of mortality related to atherosclerosis, but the growing prevalence of obesity threatens the positive trend (NCD Risk Factor Collaboration (NCD-RisC) 2016).

Lifestyle interventions to promote weight reduction reduce the risk for cardiometabolic diseases in overweight and obese individuals (Jensen et al. 2014). Weight reduction of at least 5% of body weight reduces obesity-related risk factors (Harrington, Gibson, Cottrell 2009; Klein et al. 2004). Adherence to healthier lifestyle may reduce the risk even in the absence of weight loss (Pattyn et al. 2013).

This dissertation is based on two randomized controlled trials which delivered lifestyle counselling: a weight reduction study on long-distance professional drivers, and a GDM prevention trial in primary health care, including a seven-year follow-up. Both study populations were adults at increased risk for cardiometabolic diseases. The aim of this dissertation is to study the effects of dietary and physical activity counselling on lifestyle and

cardiometabolic risk factors among professional drivers and among postpartum women at increased risk for GDM during pregnancy.

## 2 LITERATURE REVIEW

### 2.1 Cardiometabolic risk factors

The main cardiometabolic risk factors include hypertension, dyslipidemias and elevated blood glucose. These risk factors are well known determinants in the pathogenesis of atherosclerotic diseases, such as coronary artery disease and ischaemic stroke and T2DM. In MetS, cardiometabolic risk factors cluster in the same individual, which is especially harmful.

#### 2.1.1 Metabolic syndrome

MetS is a cluster of cardiometabolic risk factors, including abdominal obesity, dysfunctions in glucose metabolism, elevated blood pressure (BP) and elevated plasma TG and decreased HDL-C (Alberti et al. 2009). Insulin resistance and low-grade inflammation have important roles in the pathogenesis and progression of MetS and its components (Despres and Lemieux 2006; Turkoglu et al. 2003). Approximately 93% of patients with MetS are abdominally obese (Lovre and Mauvais-Jarvis 2015). Viscerally located adipose tissue and impaired adipocyte function together activate the low-grade inflammatory state (Bluher 2013; Esser, Paquot, Scheen 2015; Ritchie and Connell 2007).

##### 2.1.1.1 Definition of metabolic syndrome

Several criteria have been developed to diagnose MetS. Commonly used criteria have been developed by the International Diabetes Federation (IDF) (Alberti et al. 2009) and National Cholesterol Education Program – Third Adult Treatment Panel (NCEP/ATPIII) (National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) 2002) (Table 1).

**Table 1.** Diagnostic criteria for metabolic syndrome. At least three components are needed for the diagnosis of metabolic syndrome. [IDF = International Diabetes Federation  
NCEP/ATPIII = National Cholesterol Education Program - Adult Treatment Panel III]

<b>Criteria</b>	<b>Waist circumference</b>	<b>Serum triglycerides</b>	<b>Serum HDL cholesterol</b>	<b>Blood pressure</b>	<b>Plasma fasting glucose</b>
<b>IDF (2009)</b>	Ethnic and nation specific, e.g. for Europeans ≥94 cm in men, ≥80 cm in women	≥1.7 mmol/l, or medication	<1.0 mmol/l in men, <1.3 mmol/l in women, or medication	≥130/85 mmHg, or medication	≥5.6 mmol/l, or medication
<b>NCEP /ATPIII (2002)</b>	≥102 cm in men, ≥88 cm in women	≥1.7 mmol/l, or medication	<1.0 mmol/l in men, <1.3 mmol/l in women, or medication	≥130/85 mmHg, or medication	≥6.1 mmol/l, or medication

### 2.1.1.2 Clinical relevance of metabolic syndrome

The prevalence of MetS varies roughly between 15 and 58% among otherwise healthy adults in industrialized countries, depending on the criteria used, and on the age of the population (Aguilar M, Bhuket T, Torres S, Liu B, Wong RJ 2015; Davila et al. 2010; Hu et al. 2004; Koskinen, Lundqvist, Ristiluoma 2012). In clinical practice it is important to identify patients with MetS because they are at 2-fold risk for developing atherosclerotic disease over the next five to ten years and at five-fold lifetime risk for developing T2DM compared to individuals without the syndrome (Alberti et al. 2009).

### 2.1.1.3 Lifestyle factors related to metabolic syndrome

Obesogenic lifestyle with excess energy intake, unhealthy diet, low physical activity (PA) and sedentary behaviour are typical lifestyle risk factors related to MetS (Greer et al. 2015; Keane et al. 2013). Smoking is also associated with the risk, as it promotes insulin resistance (Chiolero et al. 2008). Western style

dietary pattern, characterized by high intake of red and processed meats, refined grain products and sweets, appears to be independently associated with increased risk of MetS and T2DM (Esmailzadeh et al. 2007; Lutsey, Steffen, Stevens 2008; Schulze et al. 2005; Sonnenberg et al. 2005; van Dam et al. 2002). Meta-analyses of prospective cohorts show that high intake of red and processed meat is associated with increased risk for insulin resistance and T2DM (Aune, Ursin, Veierod 2009; Fretts et al. 2015; Pan et al. 2011).

Low PA is a risk factor for MetS (Golbidi, Mesdaghinia, Laher 2012; Laaksonen et al. 2002a; Roberts, Hevener, Barnard 2013). Sedentary time, such as time spent sitting and lying down (awake) is also inversely associated with several components of MetS (Edwardson et al. 2012; Ekblom et al. 2015; Greer et al. 2015; Laaksonen et al. 2002b). A meta-analysis of cross-sectional and prospective studies with 21,393 participants showed that greater sedentary time increased the odds of MetS by 1.73, and the effect remained unchanged after adjustment for PA (Edwardson et al. 2012). One mechanism leading to MetS is decreased energy expenditure resulting in weight gain (Edwardson et al. 2012).

### 2.1.2 Gestational diabetes

GDM is defined as ‘diabetes diagnosed during pregnancy that is not clearly overt diabetes’ (American Diabetes Association 2014; International Association of Diabetes and Pregnancy Study Groups, Consensus Panel 2009). Major risk factors for GDM include pre-pregnancy overweight or obesity, high maternal age and family history of type 1 or 2 diabetes (American Diabetes Association 2016). Excessive gestational weight gain (GWG) also increases the risk. GDM presents features of insulin resistance typical of T2DM, as well as beta cell dysfunction, which is more common in type 1 diabetes. During pregnancy physiological decreases in insulin secretion and sensitivity take place to ensure foetal glucose and energy intake, but they predispose the pregnant woman to dysfunctions in glucose metabolism. Insulin sensitivity decreases by 50% over the period of gestation (Catalano 2010). In developed countries, pre-pregnancy overweight and obesity leading to insulin metabolism dysfunctions may explain almost half of all GDM cases (Kim et al. 2010). In addition, among fertile-aged women there is a rising incidence of pre-gestational T2DM, of which some are first discovered during pregnancy (American Diabetes Association 2015).

In developed countries, the prevalence of GDM varies between two and 15 per cent of pregnancies, depending on the population and the diagnostic criteria

used (American Diabetes Association 2016; Buckley et al. 2012; Schneider et al. 2012). In Finland, the prevalence was 12% of pregnancies in 2015 (National Institute of Health and Welfare 2016).

Short-term risks for women with GDM include developing pre-eclampsia and increased likelihood of having a large-for-gestational age or macrosomic baby (Schafer-Graf and Vetter 1999). After delivery, long-term risks for the woman include development of MetS and T2DM.

#### 2.1.2.1 Diagnosis of gestational diabetes

The diagnostic criteria by the International Association of Diabetes and Pregnancy Study Groups (2009) include at least one pathological plasma glucose concentration during a two-hour oral glucose tolerance test, using 75 g of glucose. The pathological glucose values are  $\geq 5.1$  mmol/l at baseline,  $\geq 10.0$  mmol/l at 1 hour and  $\geq 8.5$  mmol/l at two hours. In Finland and in many other countries women's glucose tolerance is routinely tested at 24-28 weeks of pregnancy. Among women with very high risk factors, such as pre-pregnancy BMI  $\geq 35$  kg/m<sup>2</sup>, history of GDM, corticosteroid medication or polycystic ovaria syndrome, the test is performed earlier, at between 8 and 12 weeks of gestation (International Association of Diabetes and Pregnancy Study Groups, Consensus Panel 2009).

#### 2.1.2.2 Lifestyle factors related to gestational diabetes

Apart from excess energy intake promoting obesity, there is inconclusive evidence of the role of lifestyle on the development of GDM. However, the lifestyle risk factors conducive to GDM are mostly the same as those related to T2DM and MetS.

The results from a large prospective cohort, the Nurses' Health Study (N=89,311) suggested that higher pre-pregnancy intakes of animal fat, cholesterol, and a Western style diet pattern were associated with elevated GDM risk (Bowers et al. 2012; Zhang et al. 2006a; Zhang et al. 2006b). A low intake of meat and high intake of plant-based food was inversely associated with this risk (Zhang et al. 2006a). Further, an association between pre-pregnancy low-carbohydrate dietary pattern with high protein and animal fat intake, and an increased GDM risk was observed in the same cohort (Bao et al. 2014).

However, such dietary associations with GDM have not been observed in all prospective studies. In a large prospective study among normal weight and overweight women in the USA (N=1,733) in pre-pregnancy, no associations were found between diet quality in early pregnancy and occurrence of disorders in glucose metabolism at 26-28 weeks' gestation (Radesky et al. 2008).

Associations of sedentary behaviour with the risk of GDM have not been studied in prospective studies, but sedentary behaviour is associated with insulin resistance (Hamer, Weiler, Stamatakis 2014; Johnson et al. 2016; Leng et al. 2016). A meta-analysis of epidemiological studies suggests that leisure time PA before pregnancy and in early pregnancy may prevent GDM (Tobias et al. 2011). Nutritional control and PA may decrease the risk of developing GDM via several mechanisms, including increases in skeletal muscle insulin sensitivity, reduced oxidative stress, improved endothelial function and decreased body fat (Ratner et al. 2008; Ryder, Chibalin, Zierath 2001).

## 2.2 Cardiometabolic risk in professional drivers

Prolonged sitting at work is an independent risk factor for atherosclerotic cardiovascular diseases and T2DM (van Uffelen et al. 2010). Indeed, more than half a century ago Morris et al. (1953) found that sedentary workers (busdrivers and telephonists) had significantly higher incidence of coronary heart disease compared to physically active workers (bus conductors and postmen). Further, several factors in the work environment and personal behaviour predispose professional lorry and busdrivers to elevated cardiometabolic risk. Long-distance drivers in particular often have long and irregular hours or shift work, with lengthy bouts of sitting (Lemke et al. 2015; Marqueze, Ulhoa, Moreno 2012; Tse, Flin, Mearns 2006; van der Beek 2012). Unhealthy dietary patterns, low PA during leisure and smoking are also typical of many professional drivers' lifestyles (Apostolopoulos et al. 2013; Tse, Flin, Mearns 2006; van der Beek 2012; Wong et al. 2014). Professional drivers tend to snack, consume less fruit and vegetables and more salt and saturated fat than recommended (Jack, Piacentini, Schroder 1998; McDonough et al. 2014; Nagler et al. 2013). Most professional drivers are males, who generally tend to exercise less and have poorer diet than women (Lipsky, Cannon, Lutfiyya 2014). This accumulates with unfavourable socio-economic factors, such as low level of education.

Shift work and night shifts in many professions have been associated with unhealthy eating habits, physical inactivity as well as with weight gain (Knutsson 2003; Lowden et al. 2010; van Dongen et al. 2011). Shift work may predispose to sleep deprivation, which is associated with obesity and other cardiometabolic risk factors (Cappuccio et al. 2011; Puttonen, Harma, Hublin 2010).

Obesity is one of the main health risk factors among professional drivers (Dahl et al. 2009; Martin et al. 2009; Wiegand, Hanowski, McDonald 2009), and cardiometabolic risk factors related to obesity are common among them (Apostolopoulos et al. 2016; Birdsey et al. 2015; Dahl et al. 2009; Sieber et al. 2014). Worldwide around 28–64% of lorry and busdrivers are obese (Lemke et al. 2015; Martin 2009; Moreno et al. 2004; Whitfield Jacobson, Prawitz, Lukaszuk 2007). For comparison, in Europe the average prevalence of obesity among adults is 17% (van Vliet-Ostapchouk et al. 2014). In the USA obesity and cardiometabolic risk factors, such as dyslipidemias and elevated BP, as well as smoking are more common among lorrydrivers than in general population (Apostolopoulos et al. 2016; Sieber et al. 2014).

Among professional lorrydrivers, obesity has been linked to fatigue and increased risk for road traffic accidents (Ronna et al. 2016; Taylor and Dorn 2006; Wiegand, Hanowski, McDonald 2009). Obesity may predispose to breathing disorders during sleep, e.g. sleep apnea (Jordan, McSharry, Malhotra 2014). Some dietary factors, such as irregularity of meals, and intake of fatty foods may also be independently associated with fatigue (Bultmann et al. 2002; Samaha et al. 2007; Tanaka et al. 2008). Low PA and obesity may affect work ability and increase the risk for early retirement (Marqueze, Ulhoa, Moreno 2013; Robroek et al. 2013; Safari et al. 2013).

## 2.3 Cardiometabolic risk in postpartum women at risk for gestational diabetes

GDM, MetS and T2DM share some common lifestyle and genetic risk factors associated with insulin resistance and low-grade inflammation (Bo et al. 2007a; Kaaja and Greer 2005; Volpe et al. 2007). Pregnancy can be seen as a cardiometabolic “stress test”, which may predict future disorders (Gongora and Wenger 2015; Smith 2015a). Women with a history of GDM are at a seven-fold risk of developing T2DM later in life (Bellamy et al. 2009). They are also at



increased risk of MetS (Akinci et al. 2011; Bo et al. 2004). According to studies from the USA and Denmark, approximately 30-40% of women with a history of GDM develop MetS by ten years postpartum (Lauenborg et al. 2005; Verma et al. 2002). In a Finnish cohort of 240 women with GDM, the risk of developing MetS 2–6 years after delivery was 2.4-fold higher than among women without GDM (Vilmi-Kerälä et al. 2015). Bo et al. (2007a) found that at 6.5 years postpartum women with a history of GDM, despite being currently free from metabolic abnormalities, had higher values of endothelial dysfunction markers in circulation than did women without history of GDM, implying an increased cardiometabolic risk.

In addition to history of GDM, pre-pregnancy overweight and excessive GWG may predict increased cardiometabolic risk after delivery (Rayanagoudar et al. 2016; Rich-Edwards et al. 2014; Sullivan, Umans, Ratner 2012). Pregnancy plays an important role in the development of overweight. Mean weight retention associated with pregnancy ranges from 0.4 to 3.8 kg (Brown, Hockey, Dobson 2010; Gore, Brown, West 2003; Wolfe et al. 1997). Excessive GWG is the strongest risk factor for postpartum weight retention (Margerison Zilko, Rehkopf, Abrams 2010; McClure et al. 2013), and weight may increase cumulatively with each pregnancy (Siega-Riz, Evenson, Dole 2004). In addition, adipose tissue retained postpartum appears to accumulate abdominally rather than peripherally (Gunderson et al. 2004; Luoto, Mannisto, Raitanen 2011; Smith 2015b). The Institute of Medicine has set recommendations for appropriate GWG based on pre-pregnancy BMI (Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines 2009). The recommendations for total GWG are 12.0-18.0 kg for women with pre-pregnancy BMI 18.5-19.9 kg/m<sup>2</sup>; 11.5-16.0 kg for women with BMI 20.0-26.0 kg/m<sup>2</sup>, and 7.0-11.5 kg for women with BMI ≥ 26.0 kg/m<sup>2</sup>.

## 2.4 Lifestyle counselling to decrease cardiometabolic risk factors

Lifestyle counselling aiming at weight reduction is effective in the management and prevention of obesity-related disorders (Bassi et al. 2014; Kaur 2014; LeFevre and U.S. Preventive Services Task Force 2014; Lin et al. 2014). A body weight reduction of 5% to 10% reduces cardiometabolic risk factors among overweight and obese adults (Harrington, Gibson, Cottrell 2009; Klein et

al. 2004). Weight reduction can be achieved with several different approaches aiming at energy-deficiency (Sacks et al. 2009; Strasser 2013). The most effective technique for weight reduction and maintenance is the one the person is most easily able to adhere to and follow lifelong (Bassi et al. 2014; Matarese and Pories 2014). For most people, balanced meal frequency, reasonable portion sizes, high intake of vegetables and regular PA are effective in the reduction and management of overweight (Bellisle 2014; Clark 2015; Munsters and Saris 2014). Additionally, lifestyle counselling on healthy dietary habits and PA decrease cardiometabolic risk factors, such as dyslipidemias and hypertension independently of body weight change (Fappa et al. 2008).

#### 2.4.1 Diet

In randomized trials among high risk individuals, individual counselling on healthy dietary patterns, including diet according to national dietary recommendations, Mediterranean diet, Nordic diet and DASH (The Dietary Approaches to Stop Hypertension) diet have been associated with reversed cardiometabolic risk factors, and improvement in MetS components compared to the usual diet group (Lin et al. 2014; Yamaoka and Tango 2012). In several studies adherence to one of these diets has repeatedly been associated with improvements in cardiometabolic risk markers of low-grade inflammation, endothelial function and insulin resistance, as well as glucose tolerance, plasma lipids (HDL-C, LDL-C or TG), waist circumference and BP (Fappa et al. 2008; Keane et al. 2013).

Mediterranean diet has been widely studied in the context of MetS (Kastorini et al. 2011). According to a meta-analysis of 35 randomized controlled trials (RCT) among individuals with MetS or high risk for MetS, lifestyle counselling on Mediterranean dietary patterns rich in vegetables and unsaturated fats, without energy restriction helped to decrease occurrence of MetS (log hazard ratio -0.8, 95% CI -1.4 to -0.2), and to decrease waist circumference (mean difference -0.4 cm, 95% confidence interval (CI): -0.8 to -0.0), systolic BP (-2.4 mmHg, 95% CI: -3.5 to -1.2), diastolic BP (-1.6 mmHg, 95% CI -2.0 to -1.1) and fasting glucose (-0.2 mmol/l, 95% CI :-0.3 to -0.1) (Kastorini et al. 2011), as well as markers of low-grade inflammation compared to the control group (Babio et al. 2014; Esposito et al. 2003; Esposito et al. 2004; Estruch et al. 2006; Estruch 2010; Mitjavila et al. 2013).

A relatively new modification of the Mediterranean diet, a ‘Healthy Nordic Diet’, appears to have health benefits similar to those of Mediterranean diet. Healthy Nordic Diet is a dietary pattern favouring whole-grain cereal products, local berries, fruits and vegetables, fish, low-fat milk products, rapeseed oil and vegetable oil-based margarines, and avoidance of red and processed meat and high-fat milk products. Results of lifestyle counselling RCTs among high risk men and women include decreased waist circumference and markers of low-grade inflammation; and improved insulin sensitivity, plasma lipids and BP (Adamsson et al. 2014; Kolehmainen et al. 2015; Lankinen et al. 2016; Poulsen et al. 2015; Uusitupa et al. 2013).

DASH is a diet with higher consumption of whole grain, fruit and vegetables, low-fat dairy products, lean meat, poultry and fish, and nuts and legumes, and limited intake of total fat, saturated fat, cholesterol and sodium. This diet, which was originally developed to manage hypertension, turned out to be effective in the management of other cardiometabolic risk factors as well (Kwan et al. 2013; Siervo et al. 2015; Soltani et al. 2016). In addition to lower BP, lifestyle counselling on DASH in RCT settings has resulted in better insulin sensitivity, decreased low-grade inflammation, higher HDL-C and lower TG and fasting blood glucose among patients with MetS or at increased risk for MetS (Appel et al. 1997; Azadbakht et al. 2005; Blumenthal et al. 2010a; Blumenthal et al. 2010b; Elmer et al. 2006).

#### 2.4.2 Physical activity

Meta-analyses of RCTs show that both endurance and resistance training are effective in the management of cardiometabolic risk factors among patients with MetS (Lin et al. 2015; Pattyn et al. 2013; Strasser, Siebert, Schobersberger 2010). Pattyn et al. (2013) found in their meta-analysis of eight RCTs that compared to the control group, endurance training decreased waist circumference (mean difference -3.4 cm, 95% CI -4.9 to -1.8), systolic BP (-7.1 mmHg, 95% CI -9.03 to -5.2) and diastolic BP (-5.2 mmHg, 95% CI -6.2 to -4.1), and increased HDL-C (0.06 mmol/l, 95% CI 0.03 to 0.09) among 206 patients with MetS. Lin et al. (2015), in a systematic review and meta-analysis of 160 RCTs with 7,487 participants, found that endurance training improved HDL-C (weightened mean difference 0.06 mmol/l, 95% CI 0.03 to 0.10); TG (-0.66 mmol/l, 95% CI -0.12 to -0.01); insulin metabolism and markers of

systemic inflammation compared to the control group, most of whom were free of MetS.

A meta-analysis of 13 RCTs in 513 participants with abnormal glucose regulation found that resistance training had beneficial effects on body fat mass (mean difference -2.3 kg, 95% CI -4.7 to 0.0), glycosylated haemoglobin (-0.48%, 95% CI -0.76 to -0.21) and systolic BP (-6.2 mmHg, 95% CI -1.0 to -11.4) even in the absence of total body weight loss, but had no statistically significant effects on blood lipids or diastolic BP compared to the control group (Strasser, Siebert, Schobersberger 2010). Balducci et al. (Balducci et al. 2010) and Stensvold et al. (Stensvold et al. 2010) studied the effects of combined dynamic endurance and resistance training among participants with MetS, and reported decreased waist circumference, but no effects on blood lipids, glucose or BP after training.

### 2.4.3 Combination of diet and physical activity

Randomized interventions that combine counselling on diet and PA have been found to be effective in managing or preventing cardiometabolic risk factors among adults with increased cardiometabolic risk factors (Anderssen et al. 2007; Bo et al. 2007b; den Boer et al. 2013; Ilanne-Parikka et al. 2008; Lin et al. 2014; Orchard et al. 2005). Anderssen et al. (2007) conducted an intervention on individualized counselling for 40-year old male Norwegians with cardiometabolic risk factors, and randomly allocated them to four groups: a diet-only (based on nutrition recommendations); exercise-only (supervised endurance-based exercise); both diet and exercise and a control group. They found a significant decrease in the prevalence of MetS among the three counselling groups compared to the control group, with the largest decrease in the group combining diet and exercise.

An Italian RCT on individual dietary and PA counselling by family physician among 375 adults with cardiometabolic risk factors found that body weight, waist circumference and most of the MetS components decreased in the counselling group and increased in the control group after 12 months (Bo et al. 2007b). Additionally, incidence of MetS decreased in the counselling group compared to the control group (OR 0.3, 95% CI 0.2 to 0.4). Den Boer et al. (2013) used individualized, combined diet-and-exercise lifestyle counselling to improve glucose tolerance and prevent T2DM among Dutch adults with impaired glucose tolerance. The counselling led to a lower prevalence of MetS

(53%) compared to the control group (74%) after 4.2 years (den Boer et al. 2013). In the Finnish Diabetes Prevention Study, 522 middle-aged overweight individuals with impaired glucose tolerance were randomized to individualized lifestyle counselling or to standard care group (Ilanne-Parikka et al. 2008). After a mean follow-up of 3.9 years, a significant reduction in the prevalence of MetS (OR 0.6, 95% CI 0.4 to 1.0) and in the prevalence of abdominal obesity (0.5, 95% CI 0.3 to 0.8) was found in the counselling group compared with the standard care group (Ilanne-Parikka et al. 2008). In the U.S. Diabetes Prevention Program among people with impaired glucose tolerance (N=1,711), the incidence of MetS was reduced significantly by 41% in the lifestyle group combining diet and exercise, and by 17% in the metformin group compared with placebo during a three-year intervention with individual lifestyle counselling (Orchard et al. 2005).

#### 2.4.4 Lifestyle interventions for professional drivers

Interventions to improve professional drivers' cardiometabolic health are rare, and only three previous RCTs have been reported (French et al. 2010; Olson et al. 2016; Wong et al. 2013). The trials are presented in Table 2. An American work-site intervention on 1,063 overweight transit workers, mostly metropolitan busdrivers, resulted in some dietary improvements, but no changes in body weight or PA (French et al. 2010). An American cluster randomized SHIFT trial applied a weight-loss competition supported with body weight and behavioural self-monitoring, computer-based training, pedometer and motivational interviewing among 452 overweight lorrydrivers. The trial resulted in a mean difference of  $-1.0 \text{ kg/m}^2$  (95% CI  $-1.4$  to  $-0.6$ ) in BMI, but no differences in blood lipids or BP after the 6-month intervention was found (Olson et al. 2016). In a Chinese RCT on 104 taxi, bus, lorry and private cardrivers with prediabetes, diabetes-related information on diet and PA was delivered by mobile messages, but the incidence of T2DM did not decrease statistically significantly (Wong et al. 2013).

Controlled lifestyle intervention trials (without randomization) for lorrydrivers have led to improvements in health-related habits and body weight. The largest of these, a 4-month smoking cessation and weight management intervention (Sorensen et al. 2010), showed small improvements in 227 lorrydrivers' diet but no changes in body weight compared to a control group with or without overweight. In a pretest-posttest SHIFT pilot study (Olson et al.

2009) decreases in sugary drinks, snacks and fast food intake and self-reported weight (mean -3.5 kg) were found after a 6-month diet and PA intervention among a small sample of overweight lorrydrivers (N=29). The positive self-reported changes in lifestyle were present after 30-month follow-up, and the participants (N=15) reported having lost more weight (Wipfli, Olson, Koren 2013). In a small U.S. WHEEL trial (Thiese et al. 2015), a decrease was found in energy and fat intake and self-reported weight (mean -3.2 kg) after a 12-week health coaching among 12 obese lorrydrivers.

Reaching professional drivers for lifestyle counselling, especially long-distance drivers, is difficult. Three studies have assessed the possibilities of modern technology in reaching them (Gilson et al. 2016; Greenfield et al. 2016; Heaton, Combs, Griffin 2016). Gilson et al. (2016) used a smartphone activity tracking application among 26 Australian professional drivers, and found that drivers monitored their steps consistently, but decreased monitoring of diet between the start and end of the 20-week intervention (Gilson et al. 2016). Greenfield et al. (2016) studied 34 UK lorrydrivers' perceptions of health, lifestyle and work environment, and their expectations from mobile health technologies. They found that drivers were concerned about their health, and were interested in using mobile health technologies such as wearable devices, as a preventive measure to avoid future morbidity. Heaton et al. (2016) studied internet use of 106 long-distance lorrydrivers in the USA, and found that the use was limited. They concluded that mobile messaging could be a more useful way for the health care provider to answer drivers' questions about laboratory and diagnostic results, and schedule appointments.

**Table 2.** Lifestyle intervention trials of professional lorry or busdrivers. [BMI=body mass index; BP=blood pressure; CI=confidence interval; OGTT=oral glucose tolerance test; PA=physical activity; RCT= randomized controlled trial, SMS = short message service]

Author, country	Participants	Design	Intervention	Assessments	Results
French et al. 2005, U.S.A.	1063 overweight metropolitan busdrivers and mechanics in 4 metro transit depots (2 intervention and 2 control depots)	RCT	18-month worksite intervention to prevent obesity and promote lifestyle -availability and lower prices of healthier food and beverage choices in the depots -exercise groups -mentoring and advice on diet, PA and weight maintenance by the researchers	at baseline and at 18 months -BMI -food frequency questionnaire -PA questionnaire -accelerometry	Difference (95% CI) between the groups -BMI -0.1 (-0.8 to 0.6) kg/m <sup>2</sup> -fruit and vegetables servings/week 0.3 (0.0 to 0.5) -snacks and sweets servings/week -0.1 (-0.4 to 0.1) -fast food meals -servings/week 0.3 (-0.7 to 0.0) -energy intake -407 (-778 to -36) kcals/day -no difference in PA
Olson et al. 2016, U.S.A.	Overweight lorrydrivers in 22 terminals (11 intervention and 11 control terminals) N = 229 intervention N = 223 control	Cluster RCT	a 6-month intervention on weight reduction, to improve self-reported dietary and PA habits -weight-loss competition -behavioural self-monitoring -computer-based training -step counter	at baseline and at 6 months -body weight -glucose, blood lipids, BP -dietary intake with short instruments and a food frequency questionnaire	Difference (95% CI) between the groups -BMI -1.0 (-1.4 to -0.6) kg/m <sup>2</sup> -improvements in fruit and vegetable consumption, 0.7 daily servings -increased PA, 0.7 days

Wong et al. 2013, China	-104 (93% males) taxi, bus, lorry and private cardrivers with pre-diabetes N=54 intervention group N=50 control group	Single- blinded RCT (pilot)	-4 motivational interviewing telephone calls by three coaches  SMS intervention to prevent type 2 diabetes -diabetes-related information in reducing the risk of developing diabetes for both groups -a total of 66 messages during 12 months	-PA with a healthy PA scale -sleep quality and quantity with the Pittsburgh Sleep Quality Index  at 6, 12 and 24 months -BMI and waist circumference at 12 and 24 months -BP -fasting glucose, 2-hour OGTT, blood lipids	per week with at least 30 minutes (0.4 to 0.9). -no differences in energy from fat, frequency of sugary snacks, sugary drinks, and fast-food meals -no differences in sleep, BP or blood lipids Relative risk (95% CI) of type 2 diabetes onset in the intervention vs. control group -at 12 months, 0.4 (95% CI: 0.1 to 1.2) -at 24 months, 0.6 (95% CI: 0.2 to 1.6) -no significant differences in BMI, waist circumference, BP, blood lipids or smoking
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## 2.4.5 Lifestyle interventions during pregnancy and postpartum

Because of the similar risk factors for GDM and T2DM, it is likely that strategies that are effective in the prevention of T2D are successful in the prevention of GDM (American Diabetes Association and National Institute of Diabetes, Digestive and Kidney Diseases 2005; Lindstrom et al. 2003; Reimann et al. 2009). These strategies include reducing overweight and obesity, by improving diet and PA behaviour.

During past decades, several RCTs to prevent GDM, excessive GWG and other cardiometabolic risk factors by lifestyle counselling during pregnancy have been conducted (Bain et al. 2015; Facchinetti et al. 2014; Flynn et al. 2016; Han, Middleton, Crowther 2012; Han, Crowther, Middleton 2012; Han et al. 2013; Oostdam et al. 2011). The target populations and study designs of the interventions have been heterogeneous and the results are inconclusive. A systematic review of 13 RCTs on diet and PA counselling in pregnant women found no differences in the risk of GDM between the intervention and usual care groups (RR 0.92, 95 % CI 0.68 to 1.23) (Bain et al. 2015).

The ultimate objective of lifestyle modifications during pregnancy is to decrease the risk of later cardiometabolic diseases, i.e. T2DM (Durnwald 2015; Gilmore, Klempel-Donchenko, Redman 2015; Kim 2010). However, there is meagre evidence of the effects of lifestyle interventions during pregnancy on later cardiometabolic health (Althuisen et al. 2013; Ferrara et al. 2011; Ferrara et al. 2016; Phelan et al. 2014; Ronnberg et al. 2016). Prevention of excessive GWG helps manage postpartum weight retention and may therefore prevent the development of overweight or obesity. A systematic review of 49 RCTs, involving 11,444 women, found that dietary and PA interventions prevent excessive GWG in overweight or obese pregnant women (Muktabhant et al. 2015).

Individual lifestyle counselling RCTs during pregnancy or postpartum with at least 6-week postpartum follow-up in healthy women or women with GDM are listed in Table 3. Five out of the eight studies concern pregnancy-related weight retention. Three studies reported that women in the counselling groups tended have less postpartum weight retention than those in the control groups (Ferrara et al. 2016; Phelan et al. 2014; Ronnberg et al. 2016). However, the effect on weight retention was not found in all interventions or during a longer follow-up period (Althuisen et al. 2013; Ferrara et al. 2011; Phelan et al. 2014;

Ronnberg et al. 2016). Two interventions reported improved dietary habits or increased PA (Ferrara et al. 2011; Ferrara et al. 2016). Additionally, in a Finnish RCT among normoglycaemic women, combining probiotics intake and dietary counselling during pregnancy resulted in improved glucose and insulin metabolism, but not in weight retention over a 12-month postpartum follow-up (Laitinen et al. 2009).

**Table 3.** Lifestyle counselling interventions during pregnancy or postpartum to improve the health of postpartum women or to control postpartum weight retention. [B=effect size; BMI=body mass index; CI=confidence interval; DPP=Diabetes Prevention Program; GWG=gestational weight gain; IOM=Institute of Medicine; N=number; PA=physical activity; RCT=randomized controlled trial, SD = standard deviation]

Author, country	Participants	Design	Intervention	Assessments	Results
Althuisen et al. 2013, The Netherlands	Healthy nulliparous pregnant women N=106 intervention N=113 control (routine care)	RCT	Controlling gestational and postpartum weight gain by individual counselling -face-to-face sessions at 18, 22, 30 and 36 weeks' gestation, and a telephone session at 8 weeks postpartum by maternity care midwives -counselling on weight gain during and after pregnancy -counselling on maintaining or optimizing a healthy lifestyle	At 15 (baseline), 25 and 35 weeks of gestation, and at 8, 26 and 52 weeks postpartum -weight	No effect on postpartum weight gain (B = 0.9; 95% CI -2.4 to 0.5)
Ferrara et al. 2011, U.S.A.	Pregnant women with GDM N=96 intervention N=101 control (routine care)	RCT, pilot	Controlling postpartum weight gain by individual counselling in 3 phases: during pregnancy, postpartum, and maintenance. Delivered by trained dietitians -during pregnancy: 1 face-to-face and 2 telephone sessions	After the GDM diagnosis during pregnancy (baseline), and at 6 weeks, 7 months, and 12 months postpartum. -self-reported pre-pregnancy weight -clinic-measured weight -diet during the previous month (a 120-item food	At 12 months -no between-group difference in the proportion of women who reached the postpartum weight goal (37.5% vs. 21.4%, p=0.07) At 7 months -women in the intervention group

Ferrara et al. 2016, U.S.A.	Pregnant women with GDM in 44 medical facilities N=1087 intervention N=1193 control (usual care)	Cluster RCT	<p>-postpartum: between 6 weeks and 7 months  postpartum: 2 face-to-face and 14 telephone sessions  -maintenance: between 6 weeks and 12 months  postpartum: 3 telephone contacts  -to modify diet and PA similar to the DPP  -IOM guidelines for GWG  -instructions for postpartum weight retention based on pre-pregnancy BMI.  The control group received printed educational materials</p> <p>Controlling postpartum weight retention after a GDM prevention trial  -mailed weight retention recommendations  -13 telephone sessions with a dietitian between 6 weeks and 6 months postpartum  -postpartum weight goals based on pre-pregnancy BMI</p>	<p>frequency questionnaire)  -PA questionnaire)</p> <p>At baseline (early pregnancy)  -clinic-measured or self-reported weight  At 6-week, 6-month and 12-month postpartum  -clinic-measured weight  -food frequency questionnaire  -PA questionnaire</p>	<p>decreased dietary fat (percent of energy) intake more than the women in the usual care (difference - 3.6%, P = 0.002).  No differences in postpartum PA between the groups.</p> <p>By 12 months postpartum -women in the intervention group had higher odds of meeting weight goals than women in the usual care (OR 1.3, 95% CI 1.1 to 1.5)  -the effect was strongest at 6 weeks and 6 months  At 6 months  -women in the intervention had greater increases in self-reported</p>
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Laitinen et al. 2009, Finland	Normoglycaemic pregnant women N=85 diet and probiotics N=86 diet and placebo N=85 control and placebo	RCT	To improve glucose metabolism during pregnancy and postpartum Visits at 14, 24 and 34 weeks of gestation and at 1, 6 and 12 months postpartum -individual dietary counselling given by a dietitian -capsules with probiotic combination or placebo from the first study visit and until the end of exclusive breast-feeding	At 14, 24 and 34 weeks of gestation and at 1, 6 and 12 months postpartum -3 day food diaries -fasting blood samples -self-reported weight -self-reported compliance in consumption of capsules	vigorous-intensity PA (difference 15.4 min/week, 95% CI 4.9 to 25.8) By 12 months postpartum (the diet and probiotics group; diet and placebo, and control and placebo) -fasting blood glucose (baseline-adjusted means) 4.9, 5.0 and 5.0 mmol/l, respectively, p=0.03). -insulin concentration (baseline adjusted means) 7.6, 9.3 and 9.3 mU/l; p=0.03) -reduced risk of elevated glucose concentration in the diet and probiotics group compared with the control and placebo group (OR 0.3, 95 % CI 0.1 to 0.8)
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Phelan et al. 2014, U.S.A.	Healthy women participating a GWG study N=128 intervention N=133 control (standard care)	RCT	<p>Postpartum effects of an excessive GWG prevention study</p> <p>A behavioural lifestyle intervention with an interventionist during pregnancy</p> <ul style="list-style-type: none"> <li>-one individual face-to-face visit</li> <li>-weekly mailed materials promoting an appropriate GWG, healthy eating and exercise</li> <li>-3 brief (10–15 min) supportive phone calls from the dietitian</li> <li>-additional supportive phone calls (2 calls/month) for women who were over or under weight-gain guidelines during any 1-month interval</li> <li>-individual graphs of weight gain with feedback after each contact</li> <li>-PA goal (30 min of walking most days of the week)</li> <li>-energy intake goal (20 kcal/kg) by decreasing high fat foods</li> </ul>	<ul style="list-style-type: none"> <li>-self-reported or a clinic-measured pre-pregnancy or baseline weight</li> <li>At 6 and 12 months postpartum</li> <li>-clinic-measured weight</li> <li>-food-frequency questionnaire</li> <li>-PA questionnaire</li> </ul>	<p>At 6 months postpartum</p> <ul style="list-style-type: none"> <li>-increased proportions of women who returned to their prepregnancy weight or below in the intervention group (30.7%) compared with the control group (18.7%) (P= 0.005).</li> <li>At 12 months postpartum</li> <li>-no significant effect on the odds of achieving pre-pregnancy weight.</li> <li>No intervention-related effects in dietary patterns or energy expended in PA during the postpartum period</li> </ul>
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Polley et al. 2002, U.S.A.	Healthy pregnant women N=61 intervention N=59 control (standard care)	RCT	Controlling GWG and postpartum weight retention. Follow-up through pregnancy to 6 weeks postpartum -education about weight gain, healthy eating, and exercise by staff with training in nutrition or clinical psychology -individual graphs of weight gain. -more intensive intervention to those exceeding weight gain goals	At recruitment, 30 weeks' gestation, and 6 weeks postpartum -self-reported pre-pregnancy weight At every clinic visit and 6 months postpartum -clinic-measured weight -measurements of dietary intake and exercise expenditure	At 6 weeks postpartum -no intervention effect on postpartum weight retention in overweight or obese women -decreased proportion of normal-weight women who exceeded the IOM GWG recommendations (33 vs 58%, P<0.05).
Ronberg et al. 2016, Sweden	Pregnant women with pre-pregnancy BMI >19 kg/m <sup>2</sup> N=87 intervention N=81 control (standard care)	RCT	Controlling GWG and postpartum weight retention -individual education on GWG during each visit during pregnancy, and on admission to the delivery ward -standardized, written and oral information on dietary issues during the first antenatal visit -prescription of exercise at every antenatal visit	pre-pregnancy, and at 16 weeks and at 12 months postpartum -weight	At 16 weeks postpartum -the intervention group had lower mean postpartum weight retention [1.8 kg (SD, 4.5) vs. 3.2 kg (SD 4.8), p = 0.02]. At 12 months postpartum -no significant difference in weight retention between the intervention and the control groups

### 3 AIMS OF THE STUDY

The aim was to study the effects of dietary and physical activity counselling on cardiometabolic risk among abdominally obese male professional drivers and among postpartum women at increased risk for gestational diabetes.

More specific study questions are:

1. Does an intensive 12-month structured lifestyle counselling programme improve dietary patterns and increase habitual physical activity in professional drivers?
2. Does a long-term lifestyle counselling programme reduce body weight and improve cardiometabolic risk factors in professional drivers?
3. Does intensified counselling in primary maternity care for women at increased risk for gestational diabetes lead to decreased cardiometabolic risk at one and seven years postpartum?
4. Which gestational diabetes risk factors in early pregnancy are associated with the metabolic syndrome one and seven years postpartum?



## 4 SUBJECTS AND METHODS

This doctoral dissertation is based on two RCTs aiming to improve lifestyle and health of two working aged populations who have cardiometabolic risk factors. Publications I and II consist of a randomised lifestyle intervention to reduce weight and cardiometabolic risk factors among abdominally obese lorry and busdrivers (the Professional Driver Study) (Figure 1). Publications III and IV consist of a cluster randomised intervention in maternity care clinics, aiming to prevent GDM and excessive GWG among pregnant women at increased risk for GDM (the GDM Prevention Study) (Figure 3).

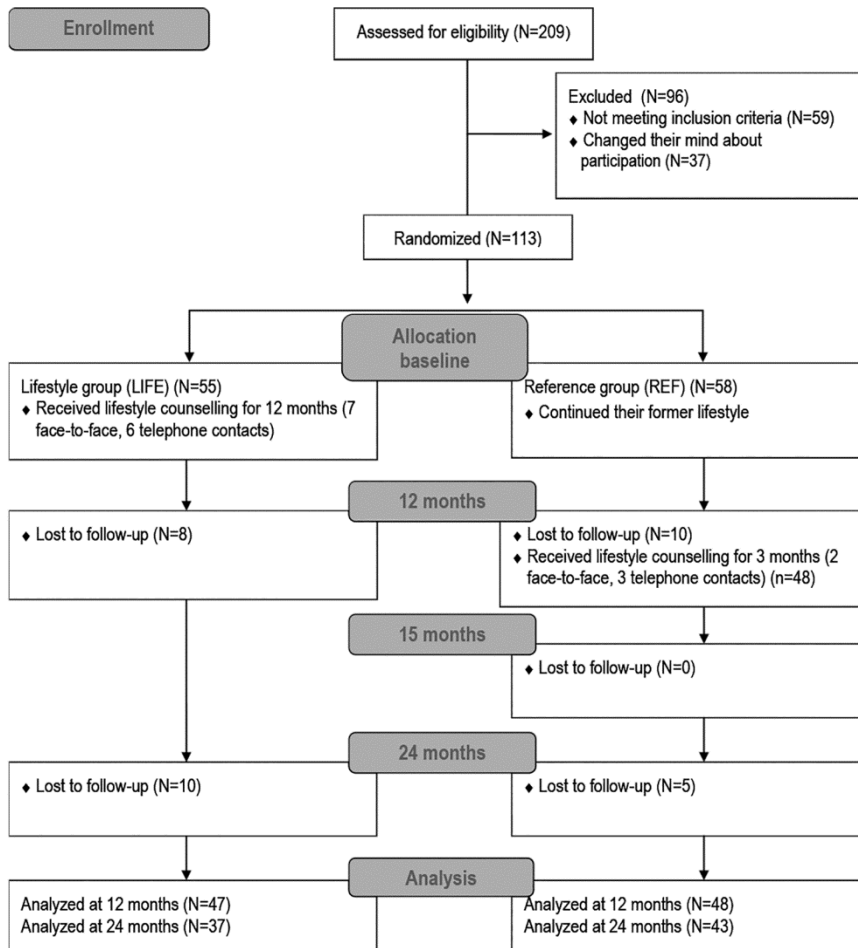
### 4.1 The Professional Driver Study (Publications I & II)

#### 4.1.1 Study design

An RCT on lifestyle counselling to reduce weight and to improve alertness in long-distance professional drivers was conducted in 2009–2012. The primary aim was a 10% body weight reduction. Inclusion criteria were being a 30–62-year-old male lorry or busdriver, with a waist circumference  $\geq 100$  cm and irregular working schedules in long-distance service. The main exclusion criteria were diagnosed sleep apnea, medication for diabetes, and leisure PA more than 2 times weekly for 30 minutes. Voluntary participants were recruited by advertisements in service stations, workplaces, and newspapers, and through labor unions.

Statistical power calculations were based on the assumption that 25% of the LIFE participants and 5% of the REF participants had reached the target of losing 10% of body weight after 12 months. Using Fisher's exact test, it was calculated that with 59 LIFE participants and 59 REF participants, there was a 84% probability (power 84%, type II error 16%) to detect a significant difference between the groups at a two-sided 0.05 significance level ( $\alpha=0.05$ , type I error). With the expected drop-out of 15%, we aimed to recruit 140 persons.

After 1.5 years of recruitment, 209 drivers signed up for the trial (Figure 1). Of these, 113 drivers were eligible for the study, and randomised to a lifestyle counselling (LIFE, N=55) and a wait-list reference (REF, N=58) group.



**Figure 1.** Flow diagram of the Professional Driver Study. The lifestyle counselling group (LIFE) participated in 12 months counselling starting from baseline (0 months), and the reference group (REF) participated in three months counselling starting at 12 months. Assessments took place at baseline, and after 12 and 24 months.

Characteristics of participants at baseline are presented in Table 4. Eighty-three (74%) participants were lorrydrivers and thirty (26%) were busdrivers. The mean duration of lorry or bus driving experience was 24.0 years. Twenty-eight (25%) had a body mass index (BMI) of  $<30 \text{ kg/m}^2$ , 53 (47%) of  $30\text{--}34.9 \text{ kg/m}^2$ , and 32 (28%) of  $\geq 35 \text{ kg/m}^2$ . Twenty-four (21%) participants used cigarettes or other tobacco products daily. Twenty-five (22%) participants reported use of medication for hypertension, twelve (11%) for dyslipidemia, and one (1%) for T2DM. The LIFE and REF group did not differ regarding to characteristics at baseline.

Randomization was performed by a statistician separately for lorry and busdrivers using computerized random numbers in blocks ( $N=4$ , with random variation in the block size). The statistician prepared sealed opaque envelopes containing information on the randomization group, and the research secretary delivered the envelopes in consecutive order to eligible participants on arrival to baseline assessments.

**Table 4.** Characteristics of participants (N=113) at baseline in the lifestyle counselling (LIFE) group and the reference (REF) group. Means (SD) or frequencies (%) [BMI=body mass index]

	LIFE (N=55)		REF (N=58)	
Age (years)	47.6	(7.9)	46.5	(8.6)
BMI (kg/m <sup>2</sup> )	32.9	(4.3)	33.1	(4.7)
Smoking or use of other tobacco products				
No	44	(80)	42	(74)
Occasionally	2	(4)	0	(0)
Daily	9	(16)	15	(26)
Profession				
Lorrydriver	41	(75)	42	(72)
Busdriver	14	(26)	16	(28)
Status				
Employee	41	(75)	45	(80)
Self-employed	14	(26)	11	(20)
Lorry or bus driving experience (years)	26.1	(14.7)	22.0	(14.9)
Working hours				
Irregular <sup>a</sup>	37	(74)	37	(65)
Regular day shifts	7	(14)	6	(11)
Regular night shifts	0	(0)	2	(4)
Two-shift work with night shifts	3	(6)	4	(7)
Two-shift work without night shifts	2	(4)	0	(0)
Other kind of shift work	1	(2)	8	(14)

<sup>a</sup>Irregular working hours: working hours outside normal daytime hours on weekdays.

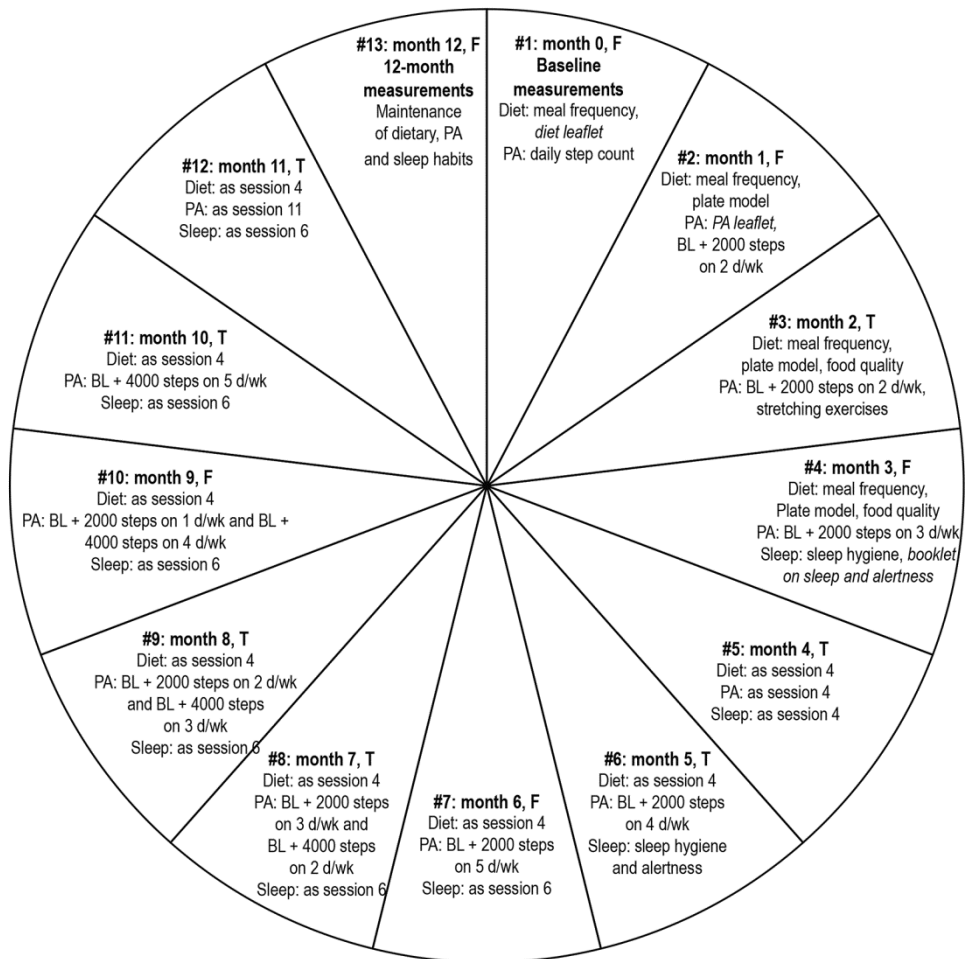
#### 4.1.2 Implementation of counselling

An individual monthly lifestyle counselling programme for 12 months developed by the research team was offered for the LIFE. Three trained counselors (two nutritionists and one physiotherapist) conducted the structured counselling. Counselling included issues on diet, PA and sleep during 13 sessions: a face-to-face session at baseline and 1, 3, 9 and 12 months after baseline, and seven telephone sessions between the face-to-face sessions (Table 6). The face-to-face sessions were allocated to last for 60 minutes, and telephone sessions for 30 minutes. The counselors traveled to meet participants for face-to-face sessions.

After 12 months, the wait-list REF group was offered a three-month counselling programme. It included two face-to-face contacts (at 12 months, and 12 weeks after 12 months) and three telephone contacts (at 3, 6, and 9 weeks after 12 months). It was based on the same elements as those used in the LIFE group. The second year was a follow-up phase (12 months for LIFE, 9 months for REF).

Health Action Process Approach (Lippke, Ziegelmann, Schwarzer 2004; Schwarzer 2008; Schwarzer, Lippke, Ziegelmann 2008) was used as the theory base for developing the procedure and contents of the counselling. The first three counselling sessions targeted at intention building; the fourth through twelfth sessions at putting the intentions into action, and the thirteenth session at maintaining the recommended actions. During each session, the participant and the counselor together established dietary, PA and sleep goal for the following month. The contents of the sessions are described in Figure 2.

The counsellors used a participant-specific notebook to follow the intended procedures and topics of the counselling sessions. The items that were assessed during monthly sessions and recorded in the notebook were date, place, duration and type of the session; weight and waist circumference; setting and reaching the dietary, PA and sleep goals, and perceived facilitators and barriers to lifestyle changes. The participants were provided with printed material on lifestyle habits developed by the research group. The participants had log books to assess lifestyle habits, to plan monthly goals and to monitor daily accomplishment of the goals.



**Figure 2.** Session-specific contents of the 12-month counselling programme. Type (face-to-face, F, or telephone, T) and contents of the monthly counselling sessions related to diet, physical activity (PA) and sleep in the lifestyle counseling group. Material delivered to the participants is in italics. [BL = baseline, d = day(s), wk = week(s)]

## Diet

Dietary goals were based on Finnish nutrition recommendations by the National Nutrition Council. The main goals were to decrease energy intake by balancing meal frequency and by increasing the use of vegetables, fruit and berries. The plate model was used for meals. In the plate model, half of the plate is comprised of vegetables; one fourth of potatoes, rice or pasta, and one fourth of meat, fish or legumes. The other goals were to improve fat quality by favouring

the use of vegetable oils and vegetable oil-based spreads, and low fat milk and meat products, and to reduce the use of low-fibre, rapidly absorbed carbohydrates, such as refined grain products, sweets and sugary drinks.

### **Physical activity**

The major PA goal was to increase habitual walking. The emphasis was on taking walks in leisure and during work breaks. The participants used a pedometer (Omron Walking Style II, HJ-113-E, Omron Healthcare, Kyoto, Japan) for setting daily step goals and monitoring their realization. The ultimate goal of 12-month counselling was to add 4000 steps on five self-selected days of the week. As 4000 steps correspond to approximately 30 minutes of brisk walking, the duration of 150 minutes a week is roughly equivalent to meeting the aerobic part of the U.S. PA guidelines 2008 (U.S. Department of Health and Human Services, 2008). At the first counselling session, the participants were instructed to wear the pedometer on five ordinary working and on two non-working days and to calculate the mean daily step count. The ultimate step goal was approached progressively by setting goals in a sequence of 2000 steps until the 11th session at 10 months (Figure 2). This kind of an approach has been shown achievable in worksite interventions (Aittasalo et al. 2012a; Tudor-Locke et al. 2011; Wyatt et al. 2004).

#### **4.1.3 Assessments**

##### **Anthropometric and laboratory assessments**

The assessments at the research Institute took place at baseline, and after 12 and 24 months. Medical laboratory technologists measured waist circumference, body weight, fat and fat-free mass, and BP during each assessment. Waist circumference was measured from midway between the lowest rib and the iliac crest, and the average of three assessments was used. BP was measured in duplicate, and the mean value was used. Dual-energy X-ray absorptiometry was used to measure fat and fat-free mass. At each counselling meeting, the counselor measured weight and waist circumference.

Medical laboratory technologists took the blood samples for glucose, total cholesterol, HDL-C and TG analysis after a 12-hour fast. Blood sample analyses included determination of glucose, cholesterol, HDL-C and TG. Plasma glucose

concentrations were measured fresh, and plasma samples for lipid analyses were stored frozen at -80° C until analysed. For glucose and total cholesterol, HDL-C and TG concentrations, venous blood was drawn into citric acid/fluoride and EDTA tubes. The concentrations were determined in enzymatic assays using a Roche Cobas Mira Plus analyser. All testing was performed in duplicate. LDL-C was calculated by Friedewald formula if TG concentration was <4.51 mmol/l.

MetS was diagnosed according to the IDF guidelines (Alberti et al. 2009). The criteria were based on five components: waist circumference, BP, fasting glucose, HDL-C and TG. Of these, three pathological values are needed for the diagnosis (See Table 1). Impaired fasting glucose (fasting plasma glucose  $\geq$ 5.6 mmol/l) was determined according to the IDF criteria. MetS was determined at baseline, and at 12 and 24 months.

## **Questionnaires**

Questionnaires were mailed at baseline, and at 12, 15 (only for REF) and 24 months, and included questions on health status, lifestyle and working conditions.

## **Dietary habits**

The participants completed a three-day food diary on two working days and one non-working day at baseline, and at 12 and 24 months. They were sent written instructions to report what they ate and drank, as well as timing, amount of food and drink, and trade names. Based on the food diary and a subsequent interview at baseline, the lifestyle counsellors used a 14-item diet index to assess dietary patterns in the LIFE participants; and after 12 and 24 months in both the LIFE and the REF participants. The 14 items included in the index were meal frequency, plate model, vegetables, fruit and berries, grain products, milk and milk products, meat and meat products, fish, bread spread, cooking fat, salad dressing, fast food, sweets, energy-containing drinks and alcohol. The grading criteria were based on the Nordic nutrition recommendations (Becker et al. 2004). Both the amount and quality of each item were taken into account in grading (three-point scale, 1-3, number 3 denotes the best). For example, the best grade (3) in meal frequency required regular meal frequency with intervals of three to four hours, three main meals (breakfast, lunch and dinner) and one to three snacks daily. The best grade in the use of milk products required three to



five daily portions of fat-free or low-fat milk products (or substitutive plant based products).

### **Physical activity**

Frequency and duration of PA during a usual week were queried as a part of the questionnaires the participants completed at baseline, and at 12 and 24 months. The questions were based on the short version of International Physical Activity Questionnaire (Craig et al. 2003; The IPAQ group 2005), with minor modifications. In addition, there was a question about the duration of sitting during a working and a non-working day.

Participants used pedometers to monitor their daily walking during 12 months (LIFE) or 3 months (REF) counselling programme. The participants were instructed to record daily step counts by using their log books. Mean daily step counts at baseline, and at 12 and 15 months were calculated from the weekly counts in participants' log books.

### **Work ability**

Work ability was assessed by a question about perceived current work ability, which is one question of the work ability index (Ilmarinen, Tuomi, Klockars 1997) at baseline and at 12 and 24 months. Current work ability was graded on a scale of 0-10 (number 10 denotes to the best), as compared with the lifetime best.

## **4.2 The Gestational Diabetes Prevention Study (Publications III & IV)**

### **4.2.1 Study design**

The study was a cluster-randomised trial conducted in Pirkanmaa region in South-Western Finland in 2007-2009. Maternity clinics of primary health centres of 14 municipalities with at least 70 annual deliveries were recruited to the study. The aim of the trial was to prevent the development of GDM by individual intensified counselling on PA, diet, and weight gain integrated into routine maternity care visits.

Pregnant women at 8-12 weeks' gestation were eligible if they had at least one of the following risk factors:

- BMI  $\geq 25$  kg/m<sup>2</sup> based on measured height and self-reported pre-pregnancy weight;
- GDM or any signs of glucose intolerance or newborn's macrosomia ( $\geq 4,500$  g) in any earlier pregnancy;
- type 1 or 2 diabetes in first- or second-degree relatives;
- age  $\geq 40$  y.

Women were excluded if they had any of the following:

- at 8–12 weeks' gestation, at least one of the three baseline glucose concentrations during the glucose tolerance test (OGTT) was abnormal (fasting plasma glucose  $\geq 5.3$  mmol/l,  $>10.0$  mmol/l at 1 h, and  $>8.6$  mmol/l at 2 h);
- pre-pregnancy type 1 or 2 diabetes;
- inability to speak Finnish;
- age  $<18$  years;
- multiple pregnancy;
- physical restrictions preventing PA;
- substance abuse;
- treatment or clinical history for severe psychiatric illness.

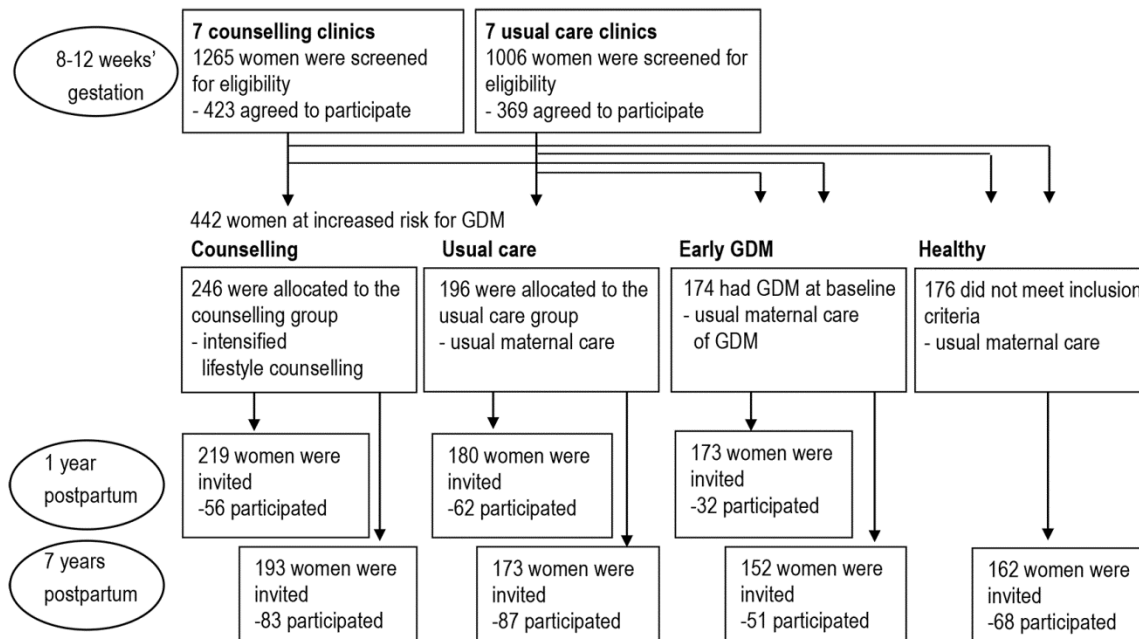
The unit of randomization was municipality. In the randomization process, participating municipalities were first pairwise matched with regard to annual number of births, size and socio-economic level of the population, estimated incidence of GDM, and urbanity level. The municipalities were then randomized by computer.

The power calculations for the pair-matched study were based on the assumption of detecting a 40% reduction in incidence of GDM from 40% in the control clinics to 24% in the trial clinics. The power of the study was 0.80, significance level 0.05 and coefficient of variation of rate between clusters, indicating cluster sampling, 0.1. The dropout rate during the study (estimated 25%) was taken into account in the sample size calculations. Thus, a total number of 560 women should be recruited to the study.

The study included individual counselling on GWG, diet and physical activity by public health nurses during five routine visits to maternity clinics (Luoto et al. 2010). The women in the control clinics received usual maternal care, which also included some lifestyle advice.

A total of 888 women entering the maternity care clinics agreed to participate in the baseline assessments (Figure 3). Of these, 442 (50%) were eligible. According to cluster randomization, 219 were allocated to the counselling and 180 in the usual care group. Further, 374 were excluded from the trial; 174 women were diagnosed with a GDM at 8–12 weeks' gestation (early GDM group) and 176 women did not meet the inclusion criteria (healthy group).

The one-year postpartum follow-up was conducted in 2009-2011, and the seven-year follow-up in 2014-2016. At one (mean 1.3, range 0.9-1.8) and seven (mean 7.2, range 5.6–8.3) years postpartum, 582 and 788 women, respectively, were reached and invited to participate in the assessments, and 150 and 289 women participated. In one-year postpartum follow-up study, women in the counselling, the usual care and early GDM were assessed for MetS. In seven-year follow-up study, all women who participated in baseline assessments, i.e. women in the counselling, usual care, early GDM and healthy groups were assessed.



**Figure 3.** Flow diagram of the GDM prevention study. The counselling, usual care and early GDM groups were invited for follow-up assessments one year postpartum; and the counselling, usual care, early GDM and healthy groups were invited for follow-up assessments seven years postpartum. [OGTT=oral glucose tolerance test; GDM=gestational diabetes]

At one year postpartum, data for analysis of MetS were available for 26% of the 582 women who were invited to participate. Compared to the non-participants in the one year follow-up, participants in the one year follow-up were more likely to belong to the usual care group (55% vs. 45%,  $p=0.026$ ) and were less likely to be daily smokers before pregnancy (10% vs. 18%,  $p=0.005$ ). There were no differences between these two groups in other background characteristic (BMI, age, parity, GDM risk criteria or education) or laboratory measurements.

Data for seven-year follow-up analysis for MetS were available for 37% of the women who were invited to participate ( $n=788$ ). Of the women invited, 17% were not willing to participate, 26% were out of reach, and 20% only completed a follow-up questionnaire. Dropout analyses showed that the women participating the seven-year follow-up study were older at the baseline (30.2 vs. 29.2 years,  $p<0.01$ ); were less often daily or occasional smokers before pregnancy (17% vs. 30%,  $p<0.001$ ), and were higher educated (university degree 28% vs. 19%,  $p<0.009$ ) compared to the non-participants. There were no differences between the groups in other background characteristic (BMI, parity or GDM risk criteria), laboratory measurements or group distribution (counselling or usual care).

Background characteristics of the participants at one and seven years postpartum are presented in Table 5. One year after delivery, the mean age of the women was 33.0 years (range 20-49 years) and the mean number of deliveries was 2.0 (range 1-8). Seven years postpartum, the mean age of was 37.8 years (range 25-52 years) and the mean number of deliveries was 2.5 (range 1-9). The most common inclusion criteria for the GDM Prevention Study were pre-pregnancy overweight or obesity, and diabetes in relatives. Seven years postpartum, women with early GDM fulfilled the inclusion criteria of being overweight ( $p<0.001$ ) and having a history of GDM ( $p=0.002$ ) more often than other groups.

**Table 5.** Background characteristics of the participants in the Gestational Diabetes Prevention Study at one and seven years postpartum. Means (SD) or frequencies (%). [BMI = body mass index]

	One year				Seven years				
	Counselling (N=56)	Usual care (N=62)	Early GDM (N=32)	All (N=150)	Counselling (N=83)	Usual care (N=87)	Early GDM (N=51)	Healthy (N=68)	All (N=289)
Age, years	32.0 (5.0)	33.1 (4.8)	34.3 (4.1)	33.0 (4.8)	37.7 (4.5)	38.0 (4.9)	38.6 (4.3)	37.0 (5.2)	37.8 (4.8)
Parity									
1	20 (44)	19 (34)	8 (28)	47 (36)	8 (10)	12 (14)	6 (13)	6 (9)	32 (12)
2-3	24 (53)	30 (54)	18 (62)	72 (55)	66 (84)	60 (71)	35 (74)	50 (75)	211 (76)
>3	1 (2)	7 (13)	3 (10)	11 (9)	5 (6)	12 (14)	6 (13)	11 (16)	34 (12)
BMI, kg/m <sup>2</sup>	26.3 (5.1)	26.9 (4.6)	28.8 (5.2)	27.1 (5.0)	27.2 (5.5)	28.1 (5.1)	30.1 (5.6)	22.7 (2.5)	26.9 (5.4)
<20.0	3 (7)	2 (4)	1 (3)	6 (5)	4 (5)	1 (1)	1 (2)	7 (10)	13 (5)
20.0–24.9	18 (40)	14 (25)	8 (28)	43 (31)	35 (42)	26 (30)	9 (18)	48 (72)	44 (39)
25.0-29.9	15 (33)	26 (46)	9 (31)	50 (39)	17 (20)	39 (45)	18 (35)	12 (18)	86 (30)
≥ 30	9 (20)	14 (25)	11 (38)	34 (29)	27 (33)	21 (24)	23 (45)	0 (0)	71 (25)
Education									
Basic or secondary education	14 (31)	14 (25)	11 (39)	39 (30)	25 (31)	25 (28)	19 (37)	20 (31)	89 (31)
Polytechnic education	15 (33)	27 (48)	10 (36)	52 (40)	28 (34)	40 (46)	20 (39)	29 (45)	117 (41)
University degree	16 (36)	15 (27)	7 (25)	38 (30)	29 (35)	23 (26)	13 (25)	16 (25)	81 (28)
Smoking									
No	32 (71)	42 (75)	21 (75)	95 (74)	73 (91)	77 (91)	45 (94)	57 (84)	252 (90)
Occasionally	7 (16)	9 (16)	3 (11)	19 (15)	5 (6)	2 (2)	2 (4)	4 (6)	14 (5)
Daily	6 (13)	5 (9)	4 (14)	15 (12)	2 (3)	6 (7)	1 (2)	6 (9)	15 (5)

## 4.2.2 Implementation of counselling

Public health nurses conducted intensified counselling during five routine visits to the maternity clinics: at 8–12 weeks, 16–18 weeks, 22–24 weeks, 32–34 and 36–37 weeks of gestation. Counselling included issues on GWG, PA and diet. It was based on the model of Laitakari and Asikainen (Laitakari and Asikainen 1998) which incorporates central behavioral strategies. At each session for each participant, the nurses filled in a counselling card, which included structure and the topics of the GWG, PA and dietary counselling sessions. The nurses filled in a counselling card for each participant at each session, which included structure and the topics of the GWG, PA and dietary counselling sessions. In the usual care clinics, the public health nurses continued their usual counselling practices.

### **Gestational weight gain**

At the first maternity care visit (8–12 weeks' gestation), the nurses introduced to the participants of the counselling group the recommendations on GWG and an individual BMI-specific chart for follow-up of weight gain. The recommendations for total GWG were 12.0–18.0 kg for women with pre-pregnancy BMI 18.5–19.9 kg/m<sup>2</sup>; 11.5–16.0 kg for women with BMI 20.0–26.0 kg/m<sup>2</sup>, and 7.0–11.5 kg for women with BMI  $\geq$  26.0 kg/m<sup>2</sup> (Institute of Medicine (US) Committee on Nutritional Status During Pregnancy and Lactation 1990). The individual BMI-specific chart to monitor GWG was used during the next four visits. Allocated time for discussion on the weight gain recommendations and weight monitoring was 5 minutes at each of the five visits.

### **Physical activity**

PA counselling took place at the first visit (20-30 min) and at four subsequent visits (10-15 min each). Aims of the PA counselling were to increase leisure time PA of those pregnant women who were not fulfilling the PA recommendations (Artal and O'Toole 2003), and to maintain or adjust leisure time PA of those women who were already fulfilling the recommendations. At the first session at 8-12 weeks' gestation, the participant and the nurse together

assessed current leisure time PA, and the participant's needs and opportunities for leisure time PA. The nurse and the participant agreed on a weekly action plan including leisure time PA modes and their frequency, duration and intensity. The aim was to perform PA for at least 800 MET (multiples of resting metabolic equivalents) minutes per week, which corresponds e.g. to moderate intensity activity approximately for 30 min five times a week (Haskell et al. 2007). The nurses calculated MET minutes from the action plans by multiplying the weekly minutes and the MET value of each leisure time PA mode and by summing up the numbers. In addition, monthly thematic meetings on PA including group exercise were offered for the participants.

## **Diet**

The primary dietary counselling session (20–30 min) took place at 16–18 weeks gestation, and at three subsequent sessions (10–15 min each) at 22–24, 32–34 and 36–37 weeks gestation. The aim of the dietary counselling was to help the participants to achieve a diet containing saturated fat 10% of energy intake, polyunsaturated fat 5–10% of energy intake, total fat 25–30% of energy intake, sucrose <10% of energy intake and fibre 25–35 g/day (National Nutrition Council 2005). The participants were instructed to eat vegetables, fruits and berries, preferably at least five portions (a total of 400 g) a day; to select mostly high-fibre bread (>6 g fibre/100 g) and other whole-meal products; to select mostly fat-free or low-fat milk and milk products and of meat and meat products; to eat fish at least twice a week (excluding the fish species not recommended for pregnant women); to use moderate amounts of soft vegetable spreads on bread, oil-based salad dressing in salad, and oil in cooking and baking; to use foods high in fat seldom and only in small portion sizes; and to use snacks containing lots of sugar and/or fat seldom and only in small portion sizes. At each counselling session, the participants set their individual plans for dietary changes, recorded them in their personal follow-up notebooks and kept record of their adherence to the plan until the next counselling session.



### 4.2.3 Assessments

#### **Anthropometric and laboratory assessments**

The assessments at maternity health care clinics or in the research Institute took place six times during pregnancy, and twice postpartum (one and seven years). The nurses measured body weight and BP at each study visit during pregnancy, and height at the first visit. Pre-pregnancy weight was self-reported. Information on all maternal assessments was obtained from standard maternity cards. At one and seven years postpartum, medical laboratory technologists from the research Institute measured waist circumference, body weight, and BP. Waist circumference was measured from midway between the lowest rib and the iliac crest, and the average of three assessments was used. BP was measured in duplicate, and the mean value was used.

Laboratory technologists from the research Institute or from the Centre for Laboratory Medicine in Pirkanmaa Hospital District took the blood samples, and administered OGTT. Blood samples were taken for glucose, total cholesterol, HDL-C and TG analysis after a 12-hour fast, and a two-hour OGTT was performed at 8-12 and 26-28 weeks' gestation, and one and seven years postpartum. Blood sample analyses included determination of glucose, cholesterol, HDL-C and TG. Plasma glucose concentrations were measured fresh, and plasma samples for lipid analyses were stored frozen at -80° C until analysed. For glucose and total cholesterol, HDL-C and TG concentrations, venous blood was drawn into citric acid/fluoride and EDTA tubes. The concentrations were determined in enzymatic assays using a Roche Cobas Mira Plus analyser. All testing was performed in duplicate. During the OGTT, blood samples were taken 60 and 120 min after the participants had drunk 75 g glucose in 330 ml water (Glucodyn™, Ultimed, Finland).

MetS was diagnosed at one and seven years postpartum according to the IDF guidelines (Alberti et al. 2009). The criteria were based on five components: waist circumference, BP, fasting glucose, HDL-C and TG. Of these, three pathological values are needed for the diagnosis (see table 1).

#### **Questionnaires on background characteristics**

Questionnaires at baseline (8-12 weeks' gestation), and one and seven years postpartum included information on socio-economic status, weight development, health status and lifestyle.

### 4.3 Statistical analyses

In the Professional Driver Study, within group changes in dietary patterns and daily steps were analysed with Wilcoxon ranks test. Spearman's correlation analysis was used to analyse associations between changes in dietary items, step count, and body weight (non-parametric data); and Pearson correlation analysis between changes in dietary index and body weight (parametric data). Linear regression models adjusted by baseline were used to analyse statistical differences in changes between the groups in body composition and cardiometabolic risk factors in assessments after 12 months. Fisher's exact test was used to analyse differences in the proportions of successful weight losers ( $\geq 10\%$  of body weight after 12 months) between the LIFE and REF groups. Generalized estimating equations with binary logistic regression using age, time and quadratic time as covariates were used to estimate between-group differences in proportions of participants with MetS or IFG in time (longitudinal data, three measurement points). Interaction of group and time, and group and quadratic time were added to the model to assess linear and non-linear between-group differences in time. To further evaluate the metabolic risk and its changes, we calculated Z scores for MetS components (waist circumference, BP, glucose, HDL-C and TG). Each component was log-transformed and standardized. The Z score of HDL-C was multiplied by -1 to indicate higher metabolic risk with increasing value. The Z score of BP was calculated as the average of systolic and diastolic pressure Z scores. Z scores from the five components were summed up as the metabolic risk score (Brage et al. 2004). The change in the metabolic risk Z score between the groups was modeled by linear regression using baseline value as a covariate.

In the GDM Prevention Study, binary logistic regression models were used to obtain ORs and their 95% CIs to study associations between MetS and its explanatory variables.

For both studies, descriptive information is reported as means and standard deviations (SD) or medians (interquartile range) for continuous variables and as frequencies and proportions (%) for categorical variables. Differences in continuous variables between the groups were tested by independent samples t-test, binary logistic regression, one-way analysis of variance (ANOVA). A chi-square test was used to investigate whether distributions of categorical variables differed from one another. Coefficients, 95% CI and statistical significance levels (p-values) are reported. All participants who participated in the

assessments were included in the analyses. The analyses were performed with SPSS software (version 22.0).

#### 4.4 Ethical considerations

Both studies were reviewed by Pirkanmaa University Hospital District Ethics Committee (Reference number R09025 for Professional Driver Study; R06230 and R14039 for women in the GDM Prevention Study). All participants completed a written informed consent. The studies were conducted in accordance with the Declaration of Helsinki (2000).

## 5 RESULTS

### 5.1 Effects of lifestyle counselling in overweight professional drivers

#### 5.1.1 Adherence to the counselling programme

One hundred and thirteen professional drivers participated in the baseline assessments; ninety-five men (84% of all randomized) participated in the 12-month assessments, and 80 (71%) in the 24-month assessments. Forty-seven (85%) LIFE participants completed the 12-month counselling programme. Thirty-six (76%) of the 47 LIFE completers participated in all 13 offered counselling sessions, and 46 (98%) participated in at least seven sessions. Forty-seven (98%) of the 48 REF completers participated in all 5 offered counselling sessions between 12 and 15 months.

#### 5.1.2 Diet (Publication I)

Table 6 shows dietary patterns and their changes after the 12-month counselling programme in the LIFE group. Meal frequency and plate model use improved. Intake of vegetables, fruits, and berries; grain products; milk and milk products; meat and meat products; sweets; fast food; and energy-containing drinks also changed to a healthier direction. The mean dietary index score improved by 12% (N=24). Improved dietary index score was associated with decreased body weight at 12 months (Pearson correlation,  $r=0.70$ ,  $p<0.001$ ). Meal frequency; plate model use, and healthier intake of vegetables, fruits, and berries; milk and milk products, and bread spread were also associated with decreased body weight (Spearman correlation,  $r=0.37-0.49$ ).

**Table 6.** Dietary patterns at baseline and changes therein after 12-month counselling in the lifestyle counselling group (LIFE). Means (SD). Each item was scaled as 1-3, the best value being 3. Items were summed as a dietary index score (range 14-42 points). Within-group differences of the changes for dietary items were analysed by Wilcoxon ranks, and for dietary index by paired t-test. Correlations between changes in dietary items and body weight were analysed by Spearman's correlation, and between dietary index and body weight with Pearson's correlation. [SD = standard deviation]

Items of dietary index	N	Baseline	Change after 12 months	P value of the change	Correlation (r) between changes in dietary items and weight
Meal frequency	36	2.2 (0.4)	0.5 (0.5)	<0.001	-0.37*
Plate model use	38	1.9 (0.7)	0.6 (0.9)	0.001	-0.37*
Vegetables, fruits and berries	40	2.0 (0.6)	0.6 (0.8)	<0.001	-0.44**
Grain products	40	2.5 (0.5)	0.4 (0.6)	<0.001	-0.03
Milk and milk products	38	2.1 (0.6)	0.7 (0.7)	<0.001	-0.42**
Meat and meat products	40	2.4 (0.6)	0.3 (0.6)	0.007	-0.40*
Fish	39	2.1 (0.8)	0.3 (0.9)	0.09	-0.15
Bread spread	40	2.5 (0.7)	0.1 (0.7)	0.71	-0.49**
Cooking fat	36	2.6 (0.7)	0.2 (0.7)	0.12	-0.30
Oil-based salad dressing	37	2.0 (0.7)	0.2 (0.8)	0.09	-0.21
Fast food	38	2.5 (0.6)	0.3 (0.7)	0.02	-0.16
Sweets	38	2.2 (0.8)	0.4 (0.9)	0.008	-0.31
Energy-containing drinks	38	2.5 (0.6)	0.4 (0.6)	0.001	-0.13
Alcohol	32	2.4 (0.7)	0.1 (0.6)	0.41	-0.01
Dietary index score	24	32.7 (3.7)	4.0 (5.3)	0.001	-0.70***

Statistical significance of the correlation: \*p<0.05; \*\*p <0.01 \*\*\*p<0.001

### 5.1.3 Physical activity (publication I)

Twenty-two (47%) LIFE participants monitored their daily number of steps at baseline and 12 months. At baseline, the median number of daily steps was 6286 (Q<sub>1</sub>; Q<sub>3</sub> 5332; 7376), and at 12 months, the median was 1811 (Q<sub>1</sub>; Q<sub>3</sub> -832; 3564) steps more ( $p=0.01$ ). The goal of adding 4000 steps daily on five days a week was reached by three of the 22 participants at 12 months. Eleven participants increased 2000 steps daily on five days. No association with changes in steps and body weight was observed at 12 months (Spearman correlation;  $r=-0.21$ ,  $p=0.35$ ).

At baseline, the mean participant-reported duration of habitual walking was 82 (SD 99) minutes a week (N=89). At 12 months, the duration had increased 60 (SD 160) minutes in the LIFE and 9 (SD 81) minutes in the REF, resulting in a between-group difference in change of 62 minutes (95% CI 9 to 115) (Table 7).

At baseline, the mean time spent sitting was 10.0 (SD 3.1) hours on a working day and 5.2 (SD 2.3) hours on a non-working day (N=89). After 12 months, the sitting duration did not change on a working day. During a non-working day, the mean sitting duration decreased 0.6 hours in the LIFE and increased 0.8 hours in the REF (adjusted mean difference 1.3 h, 95% CI -2.3 to -0.4).

### 5.1.4 Work ability

At baseline, the participants' (N=90) mean perceived work ability score when compared to the best possible (scale 0-10, 10 being the best) was 7.8 (SD 1.4). After 12 months, work ability improved by 0.5 (SD 1.7) points in the LIFE and declined by -0.2 (SD 1.4) points in the REF participants, the net increase being 0.6 points (95% CI 0.0 to 1.2).

**Table 7.** Habitual walking and sitting in the lifestyle counselling (LIFE) and the reference (REF) groups at baseline and after 12 months, and baseline-adjusted mean difference between the groups. Linear regression adjusted by baseline value and age. Means (SD). [SD = standard deviation; CI = confidence interval]

	LIFE (N=41-44)		REF (N=41-46)		Mean difference (95% CI)
	Baseline	12 months	Baseline	12 months	
Habitual walking (minutes per week)	101 (110)	161 (145)	64 (85)	73 (134)	62 (9 to 115)
Sitting during a working day (hours per day)	10.0 (2.9)	9.4 (3.1)	10.1 (3.3)	10.3 (3.1)	-0.9 (-1.9 to 0.1)
Sitting during a non-working day (hours per day)	5.3 (2.4)	4.7 (2.1)	5.1 (2.3)	6.0 (2.7)	-1.3 (-2.3 to - 0.4)

## 5.1.5 Weight and cardiometabolic risk factors (Publication II)

### 5.1.5.1 At the end of 12-month counselling programme

The mean body weight change after 12 months was -3.4 kg ( $p=0.001$ , range -26.1 to 9.9 kg) in the LIFE ( $N=47$ ), and 0.7 kg ( $p=0.214$ , range -9.5 to 12.5 kg) in the REF ( $N=48$ ), the baseline-adjusted mean difference being -4.0 kg (95% CI -6.2 to -1.9) (Table 8). Six (13%) LIFE participants reduced weight by at least 10%, and another six (13%) reduced weight by 5-9.9%. The corresponding numbers in the REF were 0 (0%) and three (6%) ( $p=0.01$  and  $p=0.3$ , respectively between the LIFE and REF groups). Seven (15%) LIFE participants and 15 (31%) REF participants gained weight at least 2% ( $p=0.09$  between the groups).

The mean change in waist circumference was -4.7 cm ( $p<0.001$ ) in the LIFE and -0.1 cm ( $p=0.9$ ) in the REF, and the adjusted mean difference -4.7 cm (95% CI -6.6 to -2.7). The mean change in body fat were -2.6 kg ( $p=0.001$ ) in the LIFE and 0.6 kg ( $p=0.240$ ) in the REF (adjusted mean difference -3.1 kg, 95% CI -4.9 to -1.4). The LIFE participants lost 0.9 kg (SD 0.2) of lean body mass

and the REF participants lost 0.2 kg (SD 1.8) (adjusted mean difference -0.6 kg, 95% CI -1.4 to 0.2 kg).

At baseline, 80% (N=44) of the LIFE participants and 62% (N=36) of the REF participants had MetS (Table 8). After 12 months, the prevalence had decreased to 62% (N=29) in the LIFE and to 60% (N=29) in the REF, without a statistically significant difference in the change between the groups (P=0.34, logistic regression analysis). Metabolic risk Z score reduced more in the LIFE compared to the REF group (adjusted mean difference -1.2 points, 95% CI -0.6–-2.0) (Figure 4).

At baseline, 80% (N=44) of LIFE participants and 72% (N=42) of REF participants had impaired fasting glucose. After 12 months, the prevalence had decreased to 64% (N=30) in the LIFE and increased to 77% (N=37) in the REF (P=0.012). Among all LIFE participants, the mean change in glucose concentration after 12 months was -0.15 mmol/l (SD 0.43) and 0.01 mmol/l (SD 0.43) among REF participants, the adjusted mean difference being -0.15 mmol/l (95% CI -0.33 to -0.02). After 12 months, the mean concentration of HDL-C increased by 0.02 mmol/l (SD 0.11) in the LIFE and decreased by 0.03 mmol/l (0.26) in the REF group (adjusted mean difference 0.06 mmol/l, 95% CI 0.02 to 0.18). Also diastolic BP tended to decrease more in the LIFE than REF group, the adjusted mean difference being -2.7 mmHg (95% CI -5.2 to 0.1) after 12 months. There were no statistically significant differences in the changes in total and LDL-C, TG, and systolic BP between the groups.

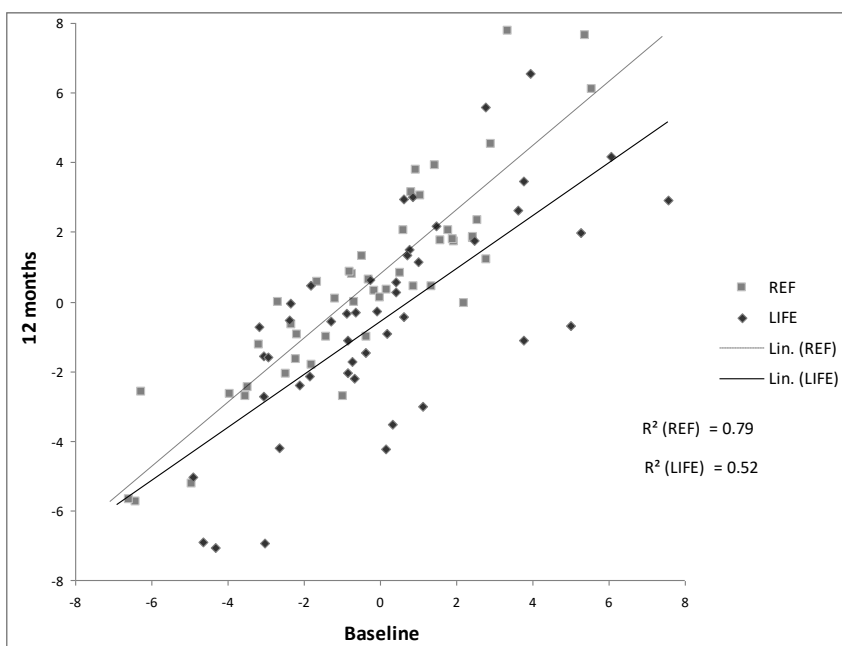


**Table 8.** Components of metabolic syndrome, serum cholesterol, and prevalence of metabolic syndrome in the lifestyle counselling (LIFE) and the reference (REF) group at baseline assessments. Means (SD), medians (percentiles) and frequencies (%).

	LIFE (N=55)		REF (N=58)	
Waist circumference (cm)	113.8	(9.5)	114.9	(10.3)
Systolic pressure (mmHg)	130.5	(13.5)	127.8	(11.3)
Diastolic pressure (mmHg)	84.8	(9.3)	82.5	(8.3)
Fasting plasma glucose (mmol/l)	6.0	(0.6)	6.0	(0.6)
Total cholesterol (mmol/l)	5.47	(0.94)	5.56	(1.01)
HDL cholesterol (mmol/l)	1.27	(0.30)	1.25	(0.26)
LDL cholesterol (mmol/l)	3.39 <sup>a</sup>	(0.87)	3.58	(0.90)
Triglycerides (mmol/l)	1.67	(1.11, 2.08)	1.41	(1.11, 2.11)
Prevalence of MetS	44	(80)	36	(62)
Metabolic risk Z score <sup>b</sup>	0.16	(2.75)	-0.15	(2.84)

<sup>a</sup> N=54

<sup>b</sup> Metabolic syndrome risk Z score from five components (waist circumference, blood pressure, fasting glucose, HDL cholesterol and triglycerides)



**Figure 4.** Linear trend and R square of the metabolic risk Z score in the lifestyle counselling (LIFE, N=47) and the reference (REF, N=48) group between baseline and 12 months. [Lin. = linear regression,  $R^2 = R$  square].

#### 5.1.5.2 At the end of the three-month counselling programme

The wait-list REF group (N=48) received a three-month counselling programme, starting at 12 months. After 3 months, they had lost 4.0 kg (SD 4.2) of their body weight and 4.1 cm (SD 4.1) of waist circumference when compared to the 12-month assessment. Six percent (N=3) of the participants reduced body weight by  $\geq 10\%$  and 13 (28%) reduced body weight by 5–9.9% after the counselling programme. None of the participants gained weight at least 2%.

**Table 9.** Body weight, waist circumference and fat mass at baseline; change, and baseline-adjusted mean difference in change 12 and 24 months after baseline in the lifestyle counselling (LIFE) and the reference (REF) group. Means and standard deviations. [CI = confidence interval]

	LIFE	N	REF	N	Mean difference (95% CI)
<b>Weight (kg)</b>					
Baseline	105.8 (16.3)	55	106.7 (16.4)	58	
12 months	-3.4 (6.6)	47	0.7 (3.9)	48	-4.0 (-6.2 to -1.9)
24 months	-3.1 (9.0)	37	-2.5 (5.9)	43	-0.5 (-3.8 to 2.9)
<b>Waist (cm)</b>					
Baseline	113.8 (9.5)	55	114.9 (10.3)	58	
12 months	-4.7 (5.8)	47	-0.1 (3.6)	48	-4.7 (-6.6 to -2.7)
24 months	-4.5 (7.5)	37	-4.4 (5.5)	43	-0.2 (-3.1 to 2.8)
<b>Fat mass (kg)</b>					
Baseline	37.1 (8.9)	55	38.0 (9.0)	58	
12 months	-2.6 (5.1)	46	0.6 (3.4)	48	-3.1 (-4.9 to -1.4)
24 months	-2.2 (6.9)	36	-2.3 (4.6)	43	0.2 (-2.4 to 2.8)

### 5.1.5.3 At 24-month follow-up

At 24 months, when compared to baseline, the mean changes of body weight, waist circumference and fat mass did not differ between the LIFE and REF group (Table 9). Both the LIFE and the REF group had decreased body weight (-3.1 and -2.5 kg,  $p=0.044$  and  $p=0.008$ , paired sample t-test), waist circumference (-4.5 and -4.4 cm,  $p=0.002$  and  $p=0.003$ ), and fat mass since baseline (-2.2 and -2.3 kg,  $p=0.064$  and  $p=0.002$ ). Approximately one-tenth (11%) LIFE participants and three (7%) REF participant had reduced body weight by  $\geq 10\%$  from baselines. The corresponding numbers with body weight loss of 5–9.9% were nine (24%) in the LIFE and 13 (30%) in the REF group. Eleven (30%) participants in the LIFE and 10 (23%) in the REF gained body weight by  $\geq 2\%$ .

After 24 months, the prevalence of MetS had decreased to 60% (N=22) in the LIFE and 51% (N=22) in the REF. The between-group difference in the prevalence curves during 24 months was not statistically significant (interaction between the group and quadratic time  $P=0.11$ ). Neither was there a difference in the change in metabolic risk Z scores between the groups after 24 months compared to baseline (difference 0.1, 95% CI -0.8–1.0).

## 5.2 Effects of lifestyle counselling on women at risk for gestational diabetes

### 5.2.1 Compliance with the study

Four hundred and forty-two pregnant women in the counselling and usual care groups participated in the baseline assessments at 8-12 weeks' gestation and 399 (90%) completed the trial until delivery. Two hundred and nineteen (89%) women of the counselling group completed the intensified counselling programme, and 214 (98%) of them participated in all 5 offered counselling sessions. Participation in assessments at one and seven years postpartum were 56 (23%) and 83 (34%) in the counselling group; and 62 (32%) and 87 (44%) in the usual care group, respectively.

## 5.2.2 Characteristics of the women at one year postpartum (Publication III)

One-hundred and fifty women participated the assessments at one year postpartum (Table 5). The mean BMI was 27.1 kg/m<sup>2</sup> (range 17.9 to 45.1 kg/m<sup>2</sup>). Women with early GDM had higher mean BMI ( $p < 0.022$ ) compared to women in the counselling or usual care group at one year assessments. Since pre-pregnancy, the mean weight increase was 1.4 kg (range -16.1 to 18.0 kg), with no differences between the three groups.

## 5.2.3 Metabolic syndrome at one year postpartum (Publication III)

The prevalence of MetS one year postpartum was 18% (Table 10). The counselling (11%) and usual care groups (18%) did not differ in MetS prevalence ( $p = 0.42$ ). Among women with early GDM, the prevalence was higher, 31% ( $p = 0.02$ , compared to the combined counselling and the usual care group). Three out of four women exceeded the waist circumference limit of 80 cm and half reached the limit of 88 cm. Women in the early GDM group exceeded the limit of waist circumference 88 cm more often (63%) than women in the combined counselling and the usual care group (45%) ( $p = 0.02$ ). More than one-fourth of all women, and half of the women with early GDM had elevated fasting plasma glucose ( $\geq 5.6$  mmol/l) at one year postpartum ( $p = 0.006$  compared to the counselling and the usual care group). One-fifth of all women had elevated BP. HDL-C was reduced ( $\leq 1.3$  mmol/l) among more than one-fourth of all women.

**Table 10.** Components of metabolic syndrome (MetS) and prevalence of MetS according to International Diabetes Federation criteria in all women and in the counselling, usual care and early GDM groups at one year postpartum. Means (SD or frequencies (%)) of participants. [GDM = gestational diabetes, SD = standard deviation]

	Counselling (N=49-56)	Usual care (N=56-62)	Early GDM (N=30-32)	All (N=135-150)
Waist circumference (cm)	86.7 (11.5)	88.8 (10.2)	92.7 (12.7)	88.8 (11.4)
Waist ≥80 cm	36 (69)	43 (77)	23 (77)	102 (74)
Waist ≥88 cm	20 (39)	30 (54)	19 (63)	69 (50)
Fasting glucose (mmol/l)	5.3 (0.4)	5.3 (0.4)	5.7 (0.5)	5.4 (0.4)
Fasting glucose ≥5.6 mmol/l	11 (20)	16 (26)	16 (50)	43 (29)
Systolic pressure (mmHg)	114 (9)	116 (12)	118 (12)	116 (11)
Diastolic pressure (mmHg)	72 (7)	76 (10)	75 (10)	74 (9)
Blood pressure ≥130 or ≥85 mmHg	4 (8)	12 (21)	7 (23)	23 (17)
HDL cholesterol (mmol/l)	1.43 (0.30)	1.57 (0.37)	1.49 (0.30)	1.50 (0.34)
HDL cholesterol ≤1.3 mmol/l	17 (32)	14 (23)	9 (28)	40 (27)
Triglycerides (mmol/l)	0.93 (0.37)	0.94 (0.44)	1.06 (0.49)	0.97 (0.43)
Triglycerides ≥1.7 mmol/l	3 (6)	4 (7)	5 (16)	12 (8)
Metabolic syndrome	6 (11)	11 (18)	10 (31)	27 (18)

### 5.2.3.1 Risk factors for metabolic syndrome one year postpartum

In the univariable logistic regression models, the OR for developing MetS one year postpartum did not differ between the counselling and usual care group (Table 11). The odds for MetS were increased among women with early GDM compared to the counselling group (OR 3.73, 95% CI 2.7 to 13.2,  $p=0.023$ ). Increased pre-pregnancy BMI (OR 1.18, 95% CI 1.07 to 1.30,  $p=0.001$ ) was also associated with increased MetS occurrence. The GDM risk factors at early pregnancy were not associated with the MetS occurrence one year postpartum.

In multivariable logistic regression analysis model 1, adjusted with pre-pregnancy BMI, the odds for MetS in the group with early GDM tended to be higher compared to the counselling group (OR 3.30, 95% CI 1.00 to 10.9,  $p=0.051$ ) (Table 11). Increased pre-pregnancy BMI was also associated with increased odds for MetS (OR 1.17, 95% CI 1.06 to 1.29,  $p=0.002$ ). In a multivariable regression model 2, adjusted for BMI and GDM or any sign of glucose intolerance in any previous pregnancy, early GDM as compared to the healthy group tended to be associated with increased MetS occurrence (OR 3.20, 95% CI 0.96 to 10.6,  $p=0.058$ ). Increased pre-pregnancy BMI was associated with increased MetS occurrence (OR 1.17, 95% CI 1.05 to 1.29,  $p=0.003$ ). GDM or any sign of glucose intolerance in any previous pregnancy was not associated with the MetS occurrence one year postpartum.

**Table 11.** Occurrence of metabolic syndrome by its explanatory variables (group, age and five GDM risk factors) one year postpartum. Odds ratios (ORs) and 95% confidence intervals (CI) and p value, N=150. Univariable and multivariable logistic regression models. [GDM = Gestational diabetes, BMI = Body mass index]

	Univariable logistic regression models		Multivariable logistic regression model 1		Multivariable logistic regression model 2	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Group (reference = counselling group)						
Usual care	1.57 (0.53 to 4.65)	0.42	1.49 (0.48 to 4.61)	0.49	1.48 (0.48 to 4.58)	0.50
Early GDM	3.73 (1.20 to 11.6)	0.023	3.30 (1.00 to 10.9)	0.051	3.20 (0.96 to 10.6)	0.058
Age (early pregnancy, continuous)	1.06 (0.97 to 1.15)	0.22				
BMI (pre-pregnancy, continuous)	1.18 (1.07 to 1.30)	0.001	1.17 (1.06 to 1.29)	0.002	1.17 (1.05 to 1.29)	0.003
GDM risk factors during early pregnancy						
BMI $\geq$ 25 kg/m <sup>2</sup> (pre-pregnancy)	2.66 (0.94 to 7.56)	0.066				
A macrosomic baby ( $\geq$ 4500 g) in any previous pregnancy	1.53 (0.29 to 8.04)	0.62				
GDM or any sign of glucose intolerance in any previous pregnancy	2.30 (0.83 to 6.35)	0.11			1.97 (0.65 to 5.96)	0.23
Type 1 or 2 diabetes in first- or second-degree relatives	1.32 (0.56 to 3.11)	0.53				
Age $\geq$ 40 years	0.89 (0.10 to 7.94)	0.92				

Univariable logistic regression models: separate models for each explanatory variable without adjustments

Multivariable logistic regression: model 1: adjusted for one explanatory variable (BMI); model 2: adjusted for BMI and GDM or any sign of glucose intolerance in any previous pregnancy



#### 5.2.4 Characteristics of the women at seven years postpartum (Publication IV)

Two-hundred and eighty-nine women participated in the assessments at seven years postpartum (Table 5). Among women in the counselling, usual care and early GDM group, the prevalence of overweight and obesity seven years postpartum (53%, 69%, 80%) had stayed around the same level, or slightly increased, compared to early pregnancy (48%, 68%, 78%). Four women (2 in the early GDM and 2 in the healthy group) had medication for T2DM. Sixteen (5%) women had medication for dyslipidemias and eight (3%) for hypertension, with no difference between the four groups. Twelve (9%) women of the counselling group and 7 (5%) women of the usual care group and none of the healthy group had been diagnosed for GDM at 26-28 weeks' pregnancy.

Women with early GDM had higher mean weight ( $p<0.001$ ) and BMI ( $p<0.001$ ) compared to women in the other three groups. Significant association between group and overweight ( $p<0.001$ ) and obesity ( $p<0.001$ ) were found so that women with early GDM were more often overweight and obese than women in the other three groups. Women in the healthy group, on the other hand, had lower mean weight ( $p<0.001$ ) and lower BMI ( $p<0.001$ ). They were less often overweight or obese compared to women in the other three groups, both of the associations being significant ( $p<0.001$ ). There were no other between-group differences in the background characteristics. Compared to baseline (at 8-12 weeks' pregnancy), the women had gained weight on average 3.1 kg (SD 7.0, range -33.2 to 25.1 kg). The groups did not differ statistically significantly from each other. The healthy group tended to have had gained less weight than the other three groups (1.8 vs. 3.5,  $p=0.13$ ).

#### 5.2.5 Metabolic syndrome at seven years postpartum (Publication IV)

The prevalence of MetS did not differ between the counselling (14%) and the usual care group (15%) (Table 12). The prevalence was the highest in the early GDM group (50%) and the lowest among the healthy group (7%). Two (11%) of the 19 women with the GDM diagnosis at 26-28 weeks' gestation had MetS at seven years follow-up postpartum.

Seventy-two percent of the women exceeded the waist circumference of 80 cm (the limit of increased waist circumference) and almost half exceeded 88 cm

(the limit of abdominal obesity). HDL-C was reduced among half of the women. All women with the MetS exceeded the waist circumference of 80 cm. Women in the early GDM group had larger mean waist circumference ( $p<0.001$ ), higher fasting glucose ( $p<0.001$ ), higher systolic BP ( $p=0.047$ ) and higher TG ( $p<0.0001$ ). They more often exceeded the limits for increased waist circumference and abdominal obesity ( $p<0.001$  and  $p=0.002$ ), impaired fasting glucose ( $p<0.001$ ), and increased TG ( $p<0.001$ ) when compared to the three other groups. Women in the healthy group had smaller mean waist circumference ( $p<0.001$ ), lower systolic ( $p=0.01$ ) and diastolic ( $p=0.03$ ) BP and higher HDL-C ( $p=0.02$ ), and they less often exceeded the limits for increased waist circumference ( $p<0.001$ ) and decreased HDL-C ( $p=0.03$ ) compared to the other three groups. There were no differences in the components of MetS between the counselling and usual care group.

Fifty-five women (27%) did not meet the criteria for any MetS component: 14 (23%) women in the counselling group, 14 (22%) in the usual care group, 7 (18%) in the early GDM group, and 20 (46%) in the healthy group. Most women ( $n=115$ , 56%) met one or two MetS components.

**Table 12.** Components of metabolic syndrome (MetS) and the prevalence of MetS according to International Diabetes Federation criteria seven years postpartum in the counselling, usual care, early GDM and healthy groups. Means (SD) or frequencies (%) of participants. [GDM = gestational diabetes, SD = standard deviations]

	Counselling (N=64-74)	Usual care (N=69-78)	Early GDM (N=40-45)	Healthy (N=44-50)	All (N=217-235)
Waist circumference (cm)	89.9 (13.0)	90.9 (12.8)	97.9 (14.6)	79.5 (6.5)	89.5 (13.5)
Waist ≥80 cm	52 (70)	59 (79)	42 (93)	24 (47)	177 (72)
Waist ≥88 cm	41 (55)	42 (56)	32 (71)	6 (12)	121 (49)
Fasting glucose (mmol/l)	5.2 (0.5)	5.2 (0.4)	5.6 (0.5)	5.2 (0.4)	5.3 (0.5)
Fasting glucose ≥5.6 mmol/l or medication	10 (15)	7 (11)	21 (49)	4 (9)	42 (19)
Systolic pressure (mmHg)	119 (13)	118 (12)	122 (11)	114 (14)	118 (12)
Diastolic pressure (mmHg)	77 (10)	78 (10)	79 (7)	75 (10)	77 (10)
Blood pressure ≥130 or ≥85 mmHg or medication	10 (14)	13 (17)	8 (18)	6 (13)	37 (16)
HDL cholesterol (mmol/l)	1.30 (0.27)	1.28 (0.38)	1.28 (0.36)	1.41 (0.30)	1.32 (0.34)
HDL cholesterol ≤1.3 mmol/l or medication	33 (52)	41 (53)	25 (58)	18 (36)	117 (50)
Triglycerides (mmol/l)	0.91 (0.34)	1.05 (0.67)	1.36 (0.88)	0.95 (0.38)	1.05 (0.61)
Triglycerides ≥1.7 mmol/l	1 (2)	9 (12)	12 (28)	5 (10)	27 (12)
Metabolic syndrome	9 (14)	10 (15)	20 (50)	3 (7)	42 (19)

#### 5.2.5.1 Risk factors for metabolic syndrome seven years postpartum

In the univariable logistic regression models, the OR for developing MetS among women with early GDM was 21.0 (95% CI 4.47 to 98.7) compared to the healthy group (Table 13), and 6.0 (95% CI 2.7 to 13.2) compared to the counselling and the usual care group (data not shown). The occurrence of MetS did not differ between the counselling and usual care group. Pre-pregnancy BMI (OR 1.20, 95% CI 1.11 to 1.29,  $p < 0.001$ ), pre-pregnancy overweight or obesity (OR 8.06, 95% CI 3.21 to 20.2,  $p < 0.001$ ), and GDM or any sign of glucose intolerance in any previous pregnancy (OR 3.21, 95% CI 1.34 to 7.69,  $p < 0.01$ ) were associated with increased occurrence of MetS. The other GDM risk factors (macrosomic baby in any previous pregnancy, diabetes in relatives, or age) were not associated with the MetS occurrence seven years postpartum. The OR for developing MetS seven years postpartum among women in the counselling and the usual care group (i.e. with increased GDM risk during pregnancy) did not differ statistically significantly from that of the healthy group.

In the multivariable regression model 1, adjusted for pre-pregnancy BMI, the OR for developing MetS seven years postpartum among women with early pregnancy GDM compared to the healthy group was 9.18 (95% CI 1.82 to 46.20,  $p = 0.007$ ) (Table 13). Also increased pre-pregnancy BMI was associated with increased odds for MetS (OR 1.20, 95% CI 1.11 to 1.29,  $p < 0.001$ ). In the multivariable regression model 2, adjusted for BMI and GDM or any sign of glucose intolerance in any previous pregnancy, early GDM as compared to the healthy group (OR 97.75, 95% CI 1.50 to 40.0,  $p = 0.014$ ), and increased pre-pregnancy BMI (OR 1.19, 95% CI 1.09 to 1.31,  $p < 0.001$ ) were associated with increased MetS occurrence. GDM or any sign of glucose intolerance in any previous pregnancy was not associated with the MetS occurrence seven years postpartum.

**Table 13.** Occurrence of metabolic syndrome (according to International Diabetes Federation criteria) by its explanatory variables (group, age and five GDM risk factors) seven years postpartum. Odds ratios (ORs) and 95% confidence intervals (CI), and p values, N=217. Univariable and multivariable logistic regression models. [GDM = Gestational diabetes, BMI = Body mass index]

	Univariable logistic regression models		Multivariable logistic regression model 1		Multivariable logistic regression model 2	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Group (reference = healthy control)						
Counselling	3.44 (0.71 to 16.8)	0.13	1.64 (0.31 to 8.79)	0.56	1.29 (0.23 to 7.18)	0.77
Usual care	3.15 (0.65 to 15.3)	0.16	1.39 (0.26 to 7.41)	0.70	1.17 (0.21 to 6.41)	0.85
Early GDM	21.0 (4.47 to 98.7)	<0.001	9.18 (1.82 to 46.20)	0.007	7.75 (1.50 to 40.0)	0.014
Age (early pregnancy, continuous)	1.07 (1.00 to 1.15)	0.052				
BMI (pre-pregnancy, continuous)	1.20 (1.11 to 1.29)	<0.001	1.17 (1.08 to 1.28)	<0.001	1.19 (1.09 to 1.31)	<0.001
GDM risk factors during early pregnancy						
BMI $\geq$ 25 kg/m <sup>2</sup> (pre-pregnancy)	8.06 (3.21 to 20.2)	<0.001				
A macrosomic baby ( $\geq$ 4500 g) in any previous pregnancy	0.74 (0.09 to 6.34)	0.78				
GDM or any sign of glucose intolerance in any previous pregnancy	3.21 (1.34 to 7.69)	<0.01			2.07 (0.74 to 5.78)	0.17
Type 1 or 2 diabetes in first- or second-degree relatives	1.04 (0.52 to 2.09)	0.91				
Age $\geq$ 40 years	0.74 (0.09 to 6.34)	0.78				

Univariable logistic regression models: separate models for each explanatory variables without adjustments

Multivariable logistic regression model 1: adjusted for one explanatory variable (BMI), multivariable regression model 2: adjusted for BMI and GDM or any sign of glucose intolerance in any previous pregnancy

# 6 DISCUSSION

The present dissertation was intended to study the effects of lifestyle counselling on diet and PA, and cardiometabolic risk factors among abdominally obese professional drivers, and on MetS one and seven years postpartum among women who were at increased GDM risk during pregnancy, and to assess early pregnancy risk factors associated with postpartum MetS.

## 6.1 The Professional Driver Study

After the 12-month lifestyle counselling programme, positive changes in dietary patterns and PA were found among overweight professional drivers. Changes in dietary patterns were associated with weight reduction. Body weight and cardiometabolic risk factors decreased.

### 6.1.1 Feasibility of the counselling programme

Our study suggests that weight reduction with improvement in cardiometabolic risk factors among overweight long-distance drivers is possible through lifestyle counselling in spite of their challenging working conditions. Low drop-out rates, high participation in the counselling sessions offered and participants' good adherence to the counselling programme suggest that the procedure involving both face-to-face and telephone contacts was appropriate for long-distance drivers.

Recruitment of long-distance drivers all over Finland was challenging and took altogether 15 months. The challenging recruitment process may be due to drivers' long and irregular working hours, and to the fact that counselling sessions and assessments were implemented during participants' leisure time.

Eight of the 55 randomized LIFE participants discontinued participation before the 12-month assessments: one after baseline assessment, four after 1 to 6 months of counselling, and three after 9 to 11 months of counselling. Compared to other lifestyle counselling studies, the number of drop-outs (15%)

was low (Franz et al. 2007; Galani and Schneider 2007; Lin et al. 2014). Reported reasons for discontinuation were lack of motivation, timetable clashes and changes in life circumstances. Good attendance may indicate the participants' interest on health issues and their appreciation of the offered counselling by health professionals.

The frequency of the counselling sessions in our trial was high and reaching the participants required a lot of time and effort in terms of travelling. Thus a less intensive lifestyle counselling protocol needs to be planned to be adapted to public or occupational health care. Modern technologies may make it easier to reach professional drivers and to conduct the counselling. After starting our intervention in 2009, several modern technologies for lifestyle change have been introduced, including smartphone apps (Lyzwinski 2014; Stephens and Allen 2013). Smartphone app users adhered better to monitoring diet and PA than did paper users. Gilson et al. (2016) conducted a 20-week PA and dietary intervention for Australian lorrydrivers (N=36) using a smartphone app, and reported frequent monitoring of steps and variable monitoring of dietary choices, but there numerous technical problems. Heaton et al. (Heaton, Combs, Griffin 2016) studied internet use in 106 long-distance lorrydrivers, and concluded that the internet use was limited, and that mobile messaging could be a more useful way to reach lorrydrivers to improve their health.

## 6.1.2 Diet and physical activity

### **Diet**

Several dietary patterns improved after the 12-month counselling programme among the professional drivers. Improvements in dietary patterns were associated with body weight reduction after 12 months. The findings are in line with other adult weight reduction studies, in which associations of healthier dietary choices with weight reduction have been observed (Bellisle 2014; Fogelholm et al. 2012).

Previous interventions on drivers' eating patterns are few and inconclusive. French et al. (2010) in their randomized study on motor freight workers reported decreased energy intake and improvements in fruit and vegetable consumption, but no changes in consumption of sugary drinks, snacks and sweets. Olson et al. (2016) in their RCT on overweight lorrydrivers found improvements in fruit and

vegetable consumption, but no changes in energy from fat, frequency of sugary snacks, sugary drinks, and fast-food meals. Sorensen et al. (2010) in their non-randomized intervention on lorrydrivers reported decreases in consumption of sugary drinks, but no change in consumption of sugary snacks, fruits, and vegetables. In small samples non-randomized interventions on overweight lorrydrivers (N=12-29), some improvements in diet, such as decreased intake of saturated fat, sugary snacks and drinks, have been reported (Thiese et al. 2015; Wipfli, Olson, Koren 2013). Our results complement the results of earlier research, and show that improvements in several dietary patterns can be achieved among professional drivers.

### **Physical activity**

The LIFE participants reported increased habitual walking after the 12-month counselling programme. About half of the participants (47%) in the LIFE monitored their daily number of steps at baseline and 12 months. The median number of steps increased on group level, but only two LIFE participants achieved the step goal of adding 4,000 steps daily on five days a week. The moderately increased PA did not correlate with weight reduction.

French et al. (2010) reported no changes in PA among motor freight workers, but Olson et al. (2016) reported a small increase in PA among lorrydrivers. In general, to reduce weight men seem to prefer to choose increasing PA to changing dietary habits (Kiefer, Rathmanner, Kunze 2005; Robertson et al. 2014). In this respect male professional drivers may differ from other male populations; drivers find it difficult to increase PA, most likely due to environmental barriers (Turner and Reed 2011). Perceived barriers to increasing PA were common in our study. The participants' most often reported barriers to achieving PA goals were working schedules, ailments and old injuries, and bad weather conditions or darkness (Puhkala et al. 2016). Earlier studies on long-distance drivers likewise suggest that factors related to working schedules and timetable pressures are major environmental barriers (Hedberg, Wikstrom-Frisen, Janlert 1998; McDonough et al. 2014; Turner and Reed 2011).

Our results suggest that dietary improvements had a larger role in the achieved weight loss than the observed increases in PA, which may not be as effective as dietary modification in affecting energy balance and decreasing overweight (Schwingshackl, Dias, Hoffmann 2014). However, PA may be



effective in reducing cardiometabolic risk factors, even in the absence or with minor body weight reduction (Hellenius et al. 1993; Pattyn et al. 2013).

### 6.1.3 Work ability

Our study showed an increase in perceived work ability among the LIFE group after 12-months of counselling. The number of high-quality health promotion RCTs with a perspective on work ability is limited (Rongen et al. 2013). Lifestyle interventions focusing on diet, PA and weight reduction have shown little or conflicting effects on perceived work ability, being most effective among employees under 40 years (Cloostermans et al. 2014; Kettunen, Vuorimaa, Vasankari 2014; Rongen et al. 2013; Viester et al. 2014). A Dutch weight-reduction RCT managed to improve PA and dietary patterns among construction workers having the same socio-economic status as professional drivers, but it showed no effects on work ability (Viester et al. 2014). Our positive results regarding work ability in experienced long-distance drivers may be due to the greater perceived alertness the participants reported after improving their eating habits and PA, and paying more attention to getting enough sleep.

### 6.1.4 Cardiometabolic risk factors

After the 12-month lifestyle counselling programme, mean body weight, waist circumference and fat mass decreased among overweight lorry and busdrivers. Thirteen percent of subjects in the LIFE and no subjects in the REF group reduced 10% of their initial body weight. The between-group change in the prevalence of MetS did not differ, but the metabolic risk Z score decreased more in the LIFE than that in the REF group after 12 months. At the start of the second year of the trial, the REF participants took part in a three-month counselling programme, and managed to catch up with the weight loss that the LIFE participants had achieved in 12 months. Thus there were no differences in body composition and metabolic risk factors between the groups after 24 months, but both groups had decreased body weight and waist circumference compared to baseline.

The aim was to lose 10% of initial body weight among  $\geq 25\%$  of the LIFE participants after 12 months. Weight loss of at least 5–10% is associated with reduction in obesity-related cardiovascular risk factors (Klein et al. 2004; National Institutes of Health 1998; Vidal 2002), and it is a common goal in obesity treatment guidelines (National Institutes of Health 1998). The proportion of LIFE participants achieving the 10% weight loss goal was around half our assumption (13%). In the REF group, our assumption was that 5% of the participants would achieve the goal at 12 months, but none succeeded. The proportion of participants losing  $\geq 10\%$  of their body weight has seldom been reported or achieved in lifestyle counselling interventions (Franz et al. 2007). Meta-analyses of the treatment of overweight and obese individuals found that the mean body weight loss in lifestyle interventions varied between 2.3 and 3.5 kilograms at follow-up for 1–2 years (Galani and Schneider 2007; Paul-Ebhohimhen and Avenell 2009). Thus the mean difference of -4.0 kg after 12 months in our study was above average (Galani and Schneider 2007; Paul-Ebhohimhen and Avenell 2009). Earlier health education RCTs among professional drivers are rare and have achieved a mean weight loss ranging from 0.5 to 3.3 kg (French et al. 2010; Olson et al. 2016; Wong et al. 2013). Our study was one of the few RCTs on professional drivers.

The mean body weight regain in the LIFE group during follow-up between 12 and 24 months was 0.5 kg (SD 4.8), meaning that on average they maintained 86% of their weight loss. According to systematic reviews, about 50% of weight loss is maintained after one-year follow-up (Barte et al. 2010; Curioni and Lourenco 2005). Our results on low weight regain at 24 months may reflect high adherence to lifestyle changes after the counselling programme.

In our study the changes in body weight and lifestyle after 12 months did not lead to a reduction in the prevalence of MetS among the LIFE participants, but the metabolic risk Z score decreased more than in the REF. Fasting glucose and HDL-C also improved, and waist circumference decreased in the LIFE group more than in the REF group. Several studies suggest that even a modest body weight reduction (3.5–4.2 kg in 1–2 years) through changes in diet and PA may suffice to achieve a reduction in cardiometabolic risk factors like insulin resistance, dyslipidemia and hypertension (Hellenius et al. 1993; Torjesen et al. 1997; Tuomilehto et al. 2001). Our study results were in line with these studies. Importantly, weight reduction can be achieved with lifestyle counselling,

despite challenging working conditions complicating adaptation to healthier lifestyle routines.

Interestingly, the shorter three-month counselling programme in the REF group led to an almost equal body weight reduction compared to the more intensive 12-month programme of the LIFE group. This finding suggests that lifestyle changes leading to weight reduction among professional drivers may also be achievable with a less intensive and shorter counselling programme more appropriate to occupational healthcare.

## 6.2 The Gestational Diabetes Prevention Study

As reported earlier concerning the same cohort by Kinnunen et al. (2012), the lifestyle counselling for pregnant women was moderately effective in preventing excessive GWG. The intervention also improved the women's diet in line with the nutrition recommendations during pregnancy (Kinnunen et al. 2014). Additionally, the counselling group had a slightly smaller decrease in habitual PA during pregnancy compared to the usual care group (Aittasalo et al. 2012b). However, the healthy lifestyle changes achieved in the counselling group during pregnancy seemed not to be associated with improved cardiometabolic health as defined by prevalence of MetS at one or seven years postpartum. After one and seven years, the prevalence of MetS was similar in the counselling and the usual care group.

### 6.2.1 Postpartum effects of lifestyle counselling

Intensified lifestyle counselling during pregnancy did not result in lower prevalence of MetS one or seven years after delivery. However, as reported earlier, counselling had positive effects on women's weight gain and lifestyle during pregnancy (Aittasalo et al. 2012b; Kinnunen et al. 2012; Kinnunen et al. 2014; Luoto et al. 2011). After one year, there was a tendency for a smaller prevalence of MetS in the counselling group (11%) compared to the usual care group (18%), but the difference was not statistically significant, possibly due to a lack of study power postpartum. After seven years the prevalence was very similar: 14% in the counselling and 15% in the usual care group. However, seven years especially is a long time, and several factors, including new pregnancies and changes in their employment status may have affected the

women's lifestyle. Mothers with small children are short of time and they may have grown tired of following the lifestyle recommendations discussed in the lifestyle counselling during pregnancy. Further, participation in the GDM Prevention Study during pregnancy may have raised health awareness and improved lifestyle habits in both the counselling and the usual care group. Routine care in Finnish primary care maternity clinics also includes counselling on GWG as well as dietary and PA issues.

GDM prevention programmes are conducted during pregnancy for women at risk of developing GDM. The key factors to prevent GDM are improving diet, keeping physically active and avoiding excessive weight gain during pregnancy (American Diabetes Association 2016). Lifestyle counselling interventions to prevent GDM and excessive GWG have yielded inconsistent results (Flynn et al. 2016; Oteng-Ntim et al. 2012; Russo et al. 2015). Good adherence to healthier lifestyle habits is key to improving lifestyle counselling outcomes (Ferrara et al. 2011). However, pregnancy may be too short a time to achieve metabolic effects in lifestyle change (Catalano and deMouzon 2015). As lifestyle changes and their metabolic effects often take several months, lifestyle counselling for women at increased risk for GDM should be started as early as possible during pregnancy, preferably already during pregnancy planning, the more efficiently to prevent GDM and excessive weight gain during pregnancy (Koivusalo et al. 2016; Oteng-Ntim et al. 2012; Thomaz de Lima et al. 2013). Screening of women at risk for GDM in public health care, however, is difficult before pregnancy, and pre-pregnancy lifestyle counselling interventions are rare (Dodd et al. 2014; Maitland et al. 2014).

Some follow-up studies on the effects postpartum of lifestyle counselling during pregnancy on pregnancy-related weight retention and lifestyle habits have been conducted. The studies have covered up to one year postpartum, and with inconclusive results (Althuisen et al. 2013; Ferrara et al. 2011; Ferrara et al. 2016; Phelan et al. 2014; Ronnberg et al. 2016). Around half of the studies claimed that lifestyle counselling during pregnancy was effective in preventing pregnancy-related weight retention. Effects of maternal counselling on later postpartum cardiometabolic risk factors have not been reported prior to our study.

It has been suggested that women with a history of GDM, who are at high cardiometabolic risk, should be screened and monitored for postpartum cardiometabolic risk factors, and should be offered postpartum lifestyle counselling to reduce their future risk (Hoedjes et al. 2010). Systematic reviews

of interventions that include postpartum lifestyle counselling for women at high cardiometabolic risk have reported promising effects on weight reduction and prevention of future morbidity, such as MetS and T2DM (Guo et al. 2016; Hoedjes et al. 2010; van der Pligt et al. 2013). The possibilities for reaching pregnant women in countries like Finland are good due to comprehensive public maternity care, but many countries often lack long-term follow-up as health care providers may change (Pierce et al. 2011).

## 6.2.2 Prevalence of metabolic syndrome one and seven years postpartum

At one year postpartum, MetS was diagnosed in 18% of the women in who increased risk for GDM or GDM was diagnosed in early pregnancy. The prevalence differed between the groups, being 11% in the counselling, 18% in the usual care, and 31% in the early GDM group. Increased pre-pregnancy BMI and early GDM diagnosis were associated with higher odds for developing MetS one year postpartum.

At seven years postpartum, the prevalence of MetS had increased slightly to 14% in the counselling group, and decreased slightly to 15% in the usual care group. Further, the MetS prevalence had increased to 50% among women with a diagnosis of early GDM. Among the healthy women without GDM risk factors, the MetS prevalence was only 7%. Increased pre-pregnancy BMI and diagnosis of early GDM were the strongest risk predictors for developing MetS seven years postpartum. Pre-pregnancy and present overweight or obesity were common among women with GDM risk factors (counselling and usual care groups), and especially among those with early GDM.

In a Finnish population study among non-pregnant women aged 30 and 33 years, the prevalence of MetS was 7% and 14% according to the IDF definition (Raiko et al. 2010). In our study at one year postpartum the prevalence was around the same magnitude in the counselling group (11%); slightly increased in the usual care (18%), and substantially increased in the early GDM group (31%). Among Finnish women aged 36 and 39, in turn, the prevalence of MetS was 18% and 23% (Raiko et al. 2010). At seven years postpartum, the MetS prevalence in our study was somewhat lower among the counselling (13%) and usual care (14%) groups, substantially higher in the early GDM group (50%) and substantially lower among healthy group (7%).

In 2012, the prevalence of obesity among women aged 25–34 and 35–45 years according to a Finnish population study was 10% and 16% respectively

(Borodulin et al. 2013). In our participants with GDM risk factors one year after delivery, the prevalence of obesity was 2.5 times higher (27%); and seven years postpartum, less than twice higher (28%). Around half of the participants were abdominally obese (waist circumference  $\geq 88$  cm) at both one (50%) and seven years (56%) postpartum. The prevalence of abdominal obesity at both one and seven years postpartum was higher than it was in a Finnish prospective study among women aged 25-60 years (30%) (Männistö, Laatikainen, Vartiainen 2012). Abdominal obesity is the most important independent factor in the development of MetS (Han and Lean 2016; Ritchie and Connell 2007), and our finding indicates future risk in our participants. Overweight was also the most common inclusion criterion in the GDM Prevention Study, which apparently had an influence on the high prevalence of overweight and obesity postpartum.

Regarding the prevalence of MetS, at seven years women with early diagnosis of GDM and women in the healthy group represented the extremes (50% vs. 7%). Earlier studies have found that a history of GDM is strongly associated with a higher risk of future MetS and other cardiometabolic diseases (Akinci et al. 2010; Sullivan, Umans, Ratner 2012). Further, in our study women with early GDM had increased odds for MetS at one and seven years postpartum compared to the other groups, and the association persisted in a multivariable regression model with increased pre-pregnancy BMI as a covariate. Women with early GDM are also at an especially high risk for future cardiometabolic diseases. A large meta-analysis suggested that women with early pregnancy GDM are at a 2-fold risk for future T2DM compared to women with later GDM (Rayanagoudar et al. 2016).

Already in early pregnancy women with early GDM had more often been overweight or obese, and seven years postpartum they were still more often overweight or obese, and had components of MetS more frequently than the other groups. Between the one- and seven-year assessments, the prevalence of MetS among the early GDM groups had increased by 19 percentage points from 31% to 50%, while it remained at the same level among women in the counselling and usual care groups. Clustering of lifestyle-related risk factors in the same individual is common (Althuisen et al. 2011; Ohlin and Rossner 1996; Wolfe et al. 1997). Pregnancy-related weight retention tends to be greatest among those women who have been overweight or obese before pregnancy (Margerison Zilko, Rehkopf, Abrams 2010; Siega-Riz et al. 2009). To prevent clustering of cardiometabolic risk factors, screening, monitoring and counselling of high risk women needs to continue after delivery.

At seven years postpartum the healthy group was healthier than the other three groups with GDM risk factors, as assessed by components and the prevalence of MetS. Also compared to the Finnish female population of the same age, they represented an unexceptionally healthy group in terms of prevalence of obesity (0% vs. 16%), abdominal obesity (12% vs. 30%), as well as MetS (7% vs. 17-23%) (Borodulin et al. 2013; Männistö, Laatikainen, Vartiainen 2012). The results underline that maintaining normal weight and preventing excessive pregnancy-related weight retention is important in not only preventing GDM, but also in preventing future cardiometabolic risk factors.

## 6.3 Strengths and limitations of the studies

### 6.3.1 The Professional Driver Study

The study has several strengths. It is one of the few RCTs aiming to improve professional drivers' lifestyle by individual counselling. At two years, the follow-up was fairly long. To ensure uniformity among the three counsellors, the counselling programme was structured and theory-based. Professional drivers were known to be hard to reach and retain in the study, therefore the counselling was planned to be intensive and individually tailored. The counsellors travelled to the drivers, which made participation in each monthly counselling meeting as easy as possible, as long-distance drivers have no stable working place. However, travelling took a lot of time and effort. We tried to plan the best conditions to ensure weight reduction and the counselling programme was free of cost for the drivers. In real life, a less intensive and costly setting needs to be modified for use in occupational or public health care.

We succeeded in changing dietary patterns and increasing PA in these male drivers, resulting in weight loss and diminished cardiometabolic risk factors. Participants' preferences, abilities and experiences were discussed and taken into account when setting and revising the monthly dietary and PA goals.

The most important limitation of the study is the number of participants, which made the trial underpowered. We lacked 23 participants from the target of 118 at 12-month assessments, meaning a gap of 19%. We attribute the lack of participating volunteers to drivers' challenging working hours and lack of interest in health issues. Participation during their leisure time may moreover have reduced participation. In the statistical analyses, we included all

participants who participated in the assessments at 12 or 24 months, but instead of a formal intention-to-treat analysis, we compared the characteristics of the drop-outs with those who completed the study. The results may be biased because who discontinued may differ from those who participated in all assessments. Most probably the most health-conscious drivers participated in the assessments at 12 and 24 months, as well as in the counselling sessions provided, as shown in other studies (Lassen et al. 2007; Sabinsky et al. 2007). In any case the participant drop-out (16% after 12 months and 29% after 24 months) was low compared to other male-only weight loss trials (Young et al. 2012). Good participation reflected appreciation of free and easily accessible counselling sessions, and the attention and advice given by health professionals.

Another limitation is that dietary patterns and daily steps were not monitored in the REF during the 12-month intervention, when they served as controls. Furthermore, assessment of dietary patterns in the LIFE was based by the counsellors on participants' food diaries and subsequent interviews. Even though there were certain criteria for assessing each dietary pattern, the assessments were made subjectively. There may have been variation between the counsellors, and also counsellors' expectations and attitudes may have influenced the results. Misreporting eating is common (Ferrari et al. 2002). Inaccurate reporting is also probable in self-reported walking and sitting. Daily step counts were monitored by fewer than half of the LIFE participants, who probably were those who were most interested in PA. Findings in lifestyle patterns need to be replicated in a larger sample in a randomized design.

### 6.3.2 The Gestational Diabetes Prevention Study

Our GDM prevention trial was one of the largest RCTs for preventing the development of GDM and improving pregnancy outcomes by lifestyle counselling during pregnancy among women at increased GDM risk. Our study included a very long follow-up, from early pregnancy until up to seven years postpartum. Our follow-up studies with assessments at one and seven years are the first follow-up studies after delivery on the effects of counselling on MetS after delivery among women at risk for GDM in early pregnancy. In general, there is a limited number of studies of the prevalence of MetS among reproductive aged female populations, even though obesity is rapidly increasing worldwide, especially among young adults (NCD Risk Factor Collaboration (NCD-RisC) 2016; O'Neill and O'Driscoll 2015). In our study we analysed



MetS prevalence among different risk groups – women with an increased GDM risk in early pregnancy (in the counselling and usual care groups; one and seven years postpartum), women diagnosed with early GDM (one and seven years postpartum), and healthy pregnant women (seven years postpartum). Associations between GDM risk factors assessed in early pregnancy and MetS one and seven years postpartum have not previously been reported.

One limitation of the study was the low participation in follow-up assessments at one and seven years postpartum (26% and 37% respectively). The total number of participants was modest (N=150 and N=289). For the one- and seven-year follow-up, we aimed to reach and invite all women who participated in the baseline assessments of the trial. We were able to reach more women at seven-year (N=788) than at one-year (N=582) follow-up, due to making more effort in searching for the women's contact details. Our statistical power calculations were based on a reduction in incidence of GDM, but admittedly the study was underpowered to detect differences between randomized groups especially at one-year follow up. There are many possible reasons for the loss. Women with small children may have found it difficult to find time to participate, especially as the visit included the two-hour OGTT. The women who participated in the one and seven-year follow-up studies were less often smokers and were more highly educated than the women who only participated in the original study. Therefore the women participating in follow-up assessments may have been more health-conscious than the non-participants, which may have caused the prevalence of MetS in our cohort to be underestimated. Further, some may have been concerned about ill health due to being at increased GDM risk, or being diagnosed with GDM. The study was implemented among Caucasian women, and thus the results can be only generalized to Caucasian women.

At one-year follow-up the subjects were not asked about new pregnancies or medications for hypertension or dyslipidemia, which influence the components of MetS. At seven years postpartum, around two to five percent of the women included were taking medication for hypertension, dyslipidemias or T2DM. Two women at seven years postpartum were pregnant. The medications were taken into account in the MetS diagnosis.

## 6.4 Future implications

Our study suggested that lifestyle counselling combining monthly face-to-face and telephone contacts is feasible in decreasing body weight and improving cardiometabolic risk factors, as well as work ability among overweight long-distance professional drivers. Access to occupational health care or public health care with trained nurses to give lifestyle counselling should be ensured for professional drivers. The investment could be beneficial for employers, as professional drivers' health and work ability potentially improve. Mobile technology could offer new ways to reach long-distance drivers especially who have no fixed workplaces (Gilson et al. 2016; Heaton, Combs, Griffin 2016). Based on the results and experiences of the Professional Driver Study, our study team constructed a set of lifestyle counselling materials for workers with irregular working hours for use in occupational health care.

In our study a decrease in body weight among professional drivers was achieved both during the 12-month (intervention for the LIFE group) and three-month lifestyle counselling (for the wait-list REF), which suggests that a shorter intervention could also be effective in improving dietary and PA patterns in professional drivers. Shorter and less intensive counselling, combining face-to-face and telephone contacts would be more appropriate in occupational health care. However, the long-term effects of shorter counselling on weight maintenance are not known, therefore future randomized trials are needed.

The GDM Prevention Study was moderately effective in preventing excessive GWG and improving lifestyle in women at increased risk of GDM during pregnancy. However, our study showed no remaining effects of the counselling on the occurrence of MetS after one and seven years postpartum. Lifestyle changes and their health effects require time and therefore the monitoring and counselling of high-risk women need to continue postpartum (Hoedjes et al. 2010). Continuity of care should be ensured postpartum, therefore different providers, i.e. maternity care, well-baby clinics, health centres and occupational health care need to increase cooperation. Intensified care in well-baby clinics soon after delivery, and, further, e.g. in occupational health care could have potential to inculcate the lifestyle changes achieved during pregnancy. Early prevention of cardiometabolic risk factors is important, but it often lacks organization and follow-up. A recent study suggested that early prevention of cardiovascular diseases in early middle age may improve health, lower morbidity and reduce healthcare costs up to 40 years later in life

(Allen et al. 2017). Importantly, lifestyle counselling of the mother may also benefit the lifestyle and health of the children and the father.

Larger population studies on the prevalence of MetS and evaluation of preventive strategies are needed among reproductive aged women, especially among those who are overweight or who have a history of GDM.

## 7 CONCLUSIONS

According to the main findings of the study the following conclusions may be drawn:

### **The Professional Driver Study**

After the 12-month lifestyle counselling programme, positive changes in dietary patterns and PA were found among abdominally obese lorry and busdrivers. Changes in dietary patterns were associated with weight reduction. Weight and cardiometabolic risk decreased. The monthly counselling programme combining face-to-face and telephone contacts seemed appropriate for long-distance male drivers. Access to occupational health care with trained nurses to give lifestyle counselling should be ensured for professional drivers.

### **The Gestational Diabetes Prevention Study**

Intensified counselling during pregnancy led to improvements in women's lifestyle, but was not associated with the prevalence of MetS at one and seven years postpartum. At one and seven years postpartum the odds for MetS were highest among women with a diagnosis of GDM in early pregnancy and among women with increased pre-pregnancy BMI. Pregnancy may be too short a time to achieve permanent changes in lifestyle. To prevent accumulation of cardiometabolic risk factors, women with GDM diagnosis, and also overweight and obese women, should be monitored and counselled for cardiometabolic risk factors after delivery. To ensure the continuity of the health care after delivery, actions to increase co-operation between different providers, i.e. maternity care, well-child clinics, health centres and occupational health care are needed.

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## ORIGINAL PUBLICATIONS



## Lifestyle counseling in overweight truck and bus drivers - Effects on dietary patterns and physical activity

Jatta Puhkala M.Sc.<sup>a,\*</sup>, Katriina Kukkonen-Harjula M.D. Ph.D.<sup>a</sup>, Minna Aittasalo Ph.D.<sup>a</sup>,  
Kirsi Mansikkamäki Ph.D.<sup>a,b</sup>, Markku Partinen M.D. Ph.D.<sup>c</sup>, Christer Hublin M.D. Ph.D.<sup>d</sup>,  
Paula Kärmeniemi M.Sc.<sup>e</sup>, Mikael Sallinen Ph.D.<sup>d,f</sup>, Seppo Olkkonen M.D. Ph.D.<sup>d</sup>, Kari Tokola M.Sc.<sup>a,g</sup>,  
Anna Ojala M.Sc.<sup>a</sup>, Clas-Håkan Nygård Ph.D.<sup>g</sup>, Mikael Fogelholm D.Sc.<sup>h</sup>

<sup>a</sup> UKK Institute for Health Promotion Research, Tampere, Finland

<sup>b</sup> Tampere University of Applied Sciences, Tampere, Finland

<sup>c</sup> Vitalmed Sleep Clinic and Research Centre, Helsinki, Finland

<sup>d</sup> Finnish Institute of Occupational Health, Helsinki, Finland

<sup>e</sup> Rehabilitation, South Karelia, Social and Health Care District, Lappeenranta, Finland

<sup>f</sup> Agora Center, University of Jyväskylä, Jyväskylä, Finland

<sup>g</sup> School of Health Sciences, University of Tampere, Tampere, Finland

<sup>h</sup> Department of Food and Environmental Sciences, University of Helsinki, Helsinki, Finland

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### ABSTRACT

We studied dietary patterns, physical activity (PA), and monthly goal setting in a weight reduction intervention in long-distance professional drivers. The study was conducted in Finland in 2009–2012. Male drivers with waist circumference > 100 cm were randomized to a lifestyle counseling (LIFE, N = 55) and a reference (REF, N = 58) group. During 12 months, LIFE participated in 6 face-to-face and 7 telephone counseling sessions on diet and PA. Dietary patterns were assessed using an index combining food diary and counselor interview, and PA with the number of daily steps using a pedometer. Monthly lifestyle goals, perceived facilitators and barriers, and adverse effects of PA in the LIFE participants were monitored using counselors' log books. Forty-seven (85%) LIFE participants completed the 12-month program. After 12 months, the mean dietary index score improved by 12% ( $p = 0.002$ ,  $N = 24$ ), and the number of daily steps increased by 1811 steps (median;  $p = 0.01$ ,  $N = 22$ ). The most frequent dietary goals dealt with meal frequency, plate model, and intake of vegetables, fruits, and berries. The most common PA mode was walking. Typical facilitators to reach monthly lifestyle goals were support from family and friends and ailment prevention; typical barriers were working schedules and ailments. Adverse effects, most commonly musculoskeletal pain, occurred among 83% of the LIFE participants. Positive changes in lifestyle habits were observed during counseling. Monthly lifestyle counseling combining face-to-face and phone contacts seemed appropriate to long-distance drivers. Barriers for reaching lifestyle changes, and adverse effects of PA were common and need to be addressed when planning counseling.

**Trial registration:** Clinical Trials NCT00893646

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### 1. Introduction

Obesity and cardiometabolic risk factors are common health concerns in professional truck and bus drivers (Sieber et al., 2014; Dahl et al., 2009; Apostolopoulos et al., 2013). Factors related to work environment and personal behavior affect drivers' lifestyle, which often

consists of long sitting periods at work, unhealthy dietary patterns, and low leisure-time physical activity (PA) (Birdsey et al., 2015; Tse et al., 2006; van der Beek, 2012; Varela-Mato et al., 2016; Wong et al., 2014). Professional drivers tend to snack; they also consume fewer fruits and vegetables and more salt and saturated fat than recommended (Jack et al., 1998; McDonough et al., 2014; Nagler et al., 2013). Irregular driving hours and working at night often characterize drivers' schedules (Tse et al., 2006; van der Beek, 2012; Marqueze et al., 2012), which may result in sleep disturbances and obesity (Marqueze et al., 2013; Hemio et al., 2015).

Despite problems in professional drivers' health and lifestyle, few intervention studies have been conducted to improve their health (Gilson

Abbreviations: BMI, body mass index; LIFE, lifestyle counseling group; PA, physical activity; REF, reference group (control).

\* Corresponding author at: UKK Institute for Health Promotion Research, P.O. Box 30, FI-33501 Tampere, Finland.

E-mail address: [jatta.puhkala@uta.fi](mailto:jatta.puhkala@uta.fi) (J. Puhkala).

et al., 2016; Ng et al., 2015; Tse et al., 2006); the results have been inconclusive. A randomized controlled trial (RCT) among 1061 overweight transit workers, mostly metropolitan bus drivers, resulted in some dietary improvements, but no changes in PA or weight (French et al., 2010). A 4-month smoking cessation and weight management intervention in 227 truck drivers and dock workers, of whom 89% were overweight, showed small improvements in diet but no changes in weight (Sorensen et al., 2010). In general, men are less likely than women to adhere to lifestyle interventions (Pagoto et al., 2012); but when they start, men succeed equally with women (Young et al., 2012).

We conducted a RCT to reduce weight in overweight long-distance truck and bus drivers, using structured, individual counseling on diet and PA. Results on body weight and cardiometabolic risk have been published (Puhkala et al., 2015). In this report, we studied the effects of the structured counseling program on dietary patterns and habitual PA, assessed monthly lifestyle goals, and identified facilitators and barriers to achieving those goals.

## 2. Methods

### 2.1. Study design and participants

Our RCT was conducted in Finland in 2009–2012. A more detailed description of the study design has been reported (Puhkala et al., 2015). The main inclusion criteria were being a male truck or bus driver in long-distance service, waist circumference  $\geq 100$  cm, and being physically inactive (less than twice weekly, moderate-intensity leisure PA for 30 min). Drivers were mainly recruited by fliers in service stations, workplaces, and through labor unions.

After recruitment for 18 months, 113 eligible drivers were randomized to lifestyle counseling (LIFE,  $N = 55$ ) and reference (REF,  $N = 58$ ) groups (Fig. 1). LIFE participated monthly in counseling for 12 months aiming at a 10% body-weight-reduction. Waiting-list REF participants were instructed to follow their former lifestyle during the 12-month

period. Assessments for all participants took place at baseline and 12 months, including questionnaires, biochemical blood samples, and body weight measurement.

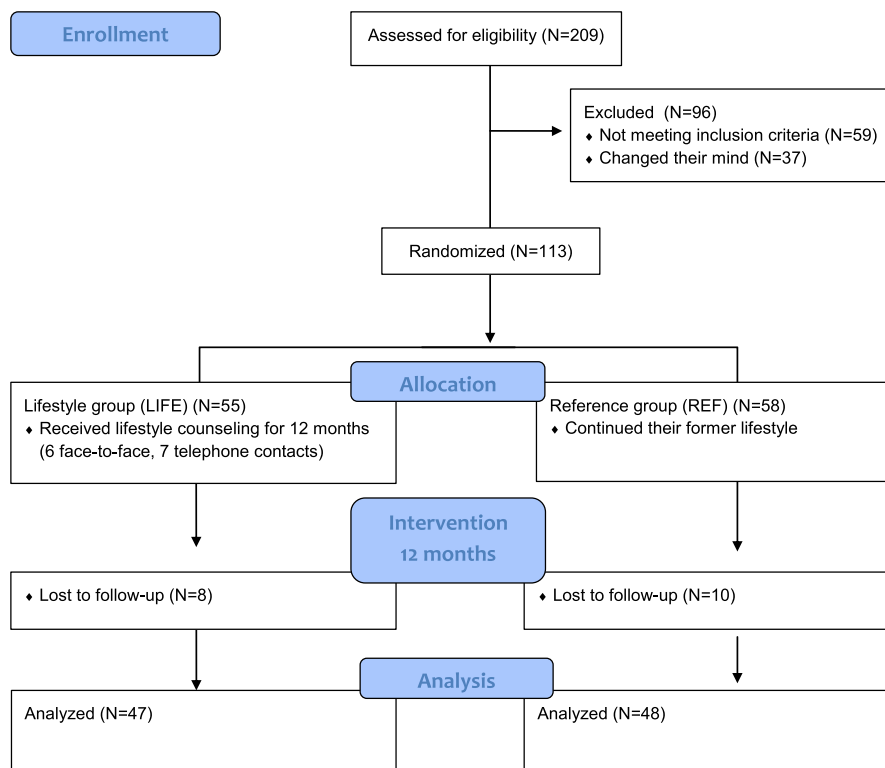
The study was reviewed by Pirkanmaa University Hospital District Ethics (Ref. number R09025). The participants completed a written informed consent. The research was conducted in accordance with the Declaration of Helsinki (2000).

### 2.2. Counseling program in LIFE

Three trained counselors conducted the program. Topics included diet and PA. The program consisted of 13 individual sessions: 6 face-to-face sessions (baseline and months 1, 3, 6, 9 and 12) with 7 telephone sessions in between. Face-to-face sessions were planned to last for 60 min, telephone sessions for 30 min. All sessions took place during participants' leisure or work breaks. The counselors traveled to meet participants for face-to-face sessions.

We used the Health Action Process Approach (Lippke et al., 2004; Schwarzer et al., 2008; Schwarzer, 2008) as the theory base for developing the program and content of the counseling. The first three sessions focused on intention building, the fourth through twelfth sessions on putting the intentions into action via planning, and the thirteenth session on maintaining the recommended actions. During each counseling session, the participant and the counselor together established dietary and PA goals for the following month. The content of the sessions is described in Table 1.

The counselors used a participant-specific notebook to follow the intended procedures and topics of the counseling sessions. The following items were assessed monthly and recorded in the notebook: weight and waist circumference; setting and reaching the dietary and PA goals; perceived facilitators and barriers to lifestyle changes; and adverse effects of PA. The participants were provided with printed material on lifestyle habits. The participants had log books to assess lifestyle habits, to plan monthly goals, and to monitor daily accomplishment of the goals.



**Fig. 1.** Flow diagram of the study. The lifestyle counseling group (LIFE) participated in 12-month lifestyle counseling program starting from baseline. Assessments took place at baseline and at 12 months. Data from weight reduction study in Finnish professional drivers in 2009–2012. The figure is adapted from Puhkala et al. (2015).

**Table 1**

Contents of the monthly counseling sessions in the lifestyle counseling group (LIFE). Material delivered to the participants is in *italics*.

Session: number, timing and type	Contents
1st, month 0 Face-to-face	Baseline assessments Diet: check-list for dietary patterns; meal frequency (establishing goals for next 4 weeks); <i>diet leaflet</i> PA: instructions to measure daily step count with a pedometer
2nd, month 1 Face-to-face	Diet: meal frequency (compliance, revision of goals); plate model (establishing goals) PA: BL + 2000 steps on 2 d/wk; <i>PA leaflet</i>
3rd, month 2 Phone	Diet: meal frequency and plate model (compliance, revision of goals); food quality (establishing goals) PA: adverse effects, compliance; BL + 2000 steps on 2 d/wk, stretching exercises
4th, month 3 Face-to-face	Diet: meal frequency, plate model and food quality (compliance and revision of goals) PA: adverse effects, compliance; BL + 2000 steps on 3 d/wk
5th, month 4 Phone	Diet: as 4th session PA: as 4th session
6th, month 5 Phone	Diet: as 4th session PA: adverse effects, compliance; BL + 2000 steps on 4 d/wk
7th, month 6 Face-to-face	Diet: as 4th session PA: adverse effects, compliance; BL + 2000 steps on 5 d/wk
8th, month 7 Phone	Diet: as 4th session PA: adverse effects, compliance; BL + 2000 steps on 3 d/wk and BL + 4000 steps on 2 d/wk
9th, month 8 Phone	Diet: as 4th session PA: adverse effects, compliance; BL + 2000 steps on 2 d/wk and BL + 4000 steps on 3 d/wk
10th, month 9 Face-to-face	Diet: as 4th session PA: adverse effects, compliance; BL + 2000 steps on 1 d/wk and BL + 4000 steps on 4 d/wk
11th, month 10 Phone	Diet: as 4th session PA: adverse effects, compliance; BL + 4000 steps on 5 d/wk
12th, month 11 Phone	Diet: as 4th session PA: as 11th session
13th, month 12 Face-to-face	12-month assessments Diet: compliance, check-list for dietary patterns PA: adverse effects, compliance Maintenance of dietary patterns and PA

PA = physical activity, BL = baseline, d = day(s), wk = week(s).

Data from weight reduction study in Finnish professional drivers in 2009–2012. Adapted and modified from Puhkala et al. (2015).

## 2.3. Lifestyle

### 2.3.1. Dietary patterns

The LIFE participants completed a 3-day food diary on two working days and one non-working day at baseline and 12 months. They were instructed to report what they ate and drank, as well as timing, amount, and brand names. Based on the food diary and a subsequent interview, the counselors graded 14 dietary items to form a healthy diet index during baseline and 12-month counseling sessions. The items were meal frequency; plate model use; vegetables, fruit, and berries; grain products; milk and milk products; meat and meat products; fish; bread spread; cooking fat; salad dressing; fast food; sweets; energy-containing drinks; and alcohol. The grading criteria (scale 1–3, number 3 being the best) were based on the Finnish Nutrition Recommendations (National Nutrition Council, 2005). Both the amount and quality of each item were taken into account in grading. The dietary index score was the sum of the grades for the 14 items (score range 14–42).

### 2.3.2. Physical activity

The LIFE participants used log books to record daily steps during the 12-month program. The information on mean daily step count at baseline and 12 months were used in the analyses. Weekly minutes of walking and daily hours of sitting were asked of LIFE and REF participants at baseline and 12 months, using a questionnaire based on the short

version of International Physical Activity Questionnaire (Craig et al., 2003; The IPAQ group, 2005).

## 2.4. Dietary and PA goals

Dietary goals were based on Finnish nutrition recommendations by the National Nutrition Council (2005). The main goals were to decrease energy intake by balancing meal frequency and increasing the intake of vegetables, fruits, and berries. The plate model was used for meals: half of the plate consists of vegetables; one fourth of potatoes, rice, or pasta; and one fourth of meat, fish, or legumes. The other goals were to use vegetable oils and spreads, consume low fat milk and meat products, and reduce the use of low-fiber, rapidly-absorbed carbohydrates (e.g. refined grain-products, sweets, and sugary drinks).

Increasing habitual walking was the major PA goal. The emphasis was on taking walks in leisure time and during work breaks. A pedometer (Omron Walking Style II, HJ-113-E, Omron Healthcare, Kyoto, Japan) was used for setting daily step goals and monitoring their achievement. The ultimate goal at 12 months was to add 4000 steps on five self-selected days of the week. As 4000 steps corresponds to approximately 30 min of brisk walking, the additional steps equate to a total of 150 min a week, meeting the aerobic exercise recommendation of the 2008 United States PA guidelines (U.S. Department of Health and Human Services, 2008). At the first counseling session, the participants were instructed to wear the pedometer on five ordinary working and two non-working days and to calculate the mean number of daily steps. The ultimate step goal was approached progressively with smaller goals of adding increments of 2000 steps to an increasing number of days each week (Table 1). Such an approach has been shown to be achievable in worksite interventions (Wyatt et al., 2004; Aittasalo et al., 2012; Tudor-Locke et al., 2011).

## 2.5. Factors related to accomplishment of lifestyle goals

Monthly dietary and PA goals, as well as perceived facilitators and barriers to achieve the goals were assessed as total number of times (mentions) the goal was established, and number of times (mentions) the facilitator or barrier was reported by the LIFE participants during 12 months. The first facilitator and barrier mentioned in each session were included in the analyses.

Adverse effects due to PA, or those which prevented participants from performing PA were listed in the counselors' notebooks. They were discussed with the participant during each session. The adverse effects included muscle pain; back pain; hip, knee, or ankle pain; chest pain; cardiac arrhythmia; dyspnea; fatigue; sprains or distortions; and falls or other accidents leading to symptoms. Adverse effects were reported both by the total number of mentions and by the number of days adverse effects kept participants from reaching PA goals.

## 2.6. Statistical analyses

Descriptive data are presented as frequencies and percentages, means or medians and standard deviations (SD), or percentiles (Q<sub>1</sub>, Q<sub>3</sub>, i.e. interquartile range). Changes in dietary patterns and daily steps in LIFE were analyzed with the Wilcoxon ranks test, and change in dietary index with paired *t*-test. Differences in changes between LIFE and REF in weekly duration of habitual walking and daily sitting were analyzed with linear logistic regression adjusted by baseline values and age. Spearman correlation analysis was used to analyze associations between changes in dietary items, step count, and body weight (non-parametric data); and Pearson correlation analysis between changes in dietary index and body weight (parametric data). All results were considered to be statistically significant if *p* < 0.05 or if 95% confidence intervals (CI) did not cross point zero. The analyses were performed with SPSS software (version 22.0).



### 3. Results and discussion

At baseline, the mean age of the participants ( $N = 113$ ) was 47 years, and the mean BMI  $33 \text{ kg/m}^2$ . Eighty-three (73%) participants were truck drivers and the rest were bus drivers. Seventy-four (65%) participants had irregular working hours, 17 (18%) shift work, and 12 (13%) regular day shifts. There were no differences between LIFE and REF in background characteristics.

After 12 months, the mean body weight change was  $-3.4$  in the LIFE ( $N = 47$ ). When compared to the REF ( $N = 48$ ), the net change was  $-4.0 \text{ kg}$  (95% CI  $-6.2$  to  $-1.9$ ) (Puhkala et al., 2015).

#### 3.1. Adherence to the counseling program

Forty-seven (85%) participants in LIFE completed the 12-month program. Compared to other lifestyle counseling studies on males, the proportion of dropouts (15%) was low (Robertson et al., 2014). Reasons for discontinuation were lack of motivation, schedule conflicts, and changes in life circumstances. Thirty-six (76%) of the 47 LIFE completers participated in all 13 offered counseling sessions, and 46 (98%) participated in at least seven sessions.

Good attendance suggested that the program involving both face-to-face and telephone contacts is appropriate to this target group. Participation in counseling meetings was made as easy as possible for the participants, as the counselors traveled to them. It also indicated the participants' interest in health issues and their appreciation of the free counseling offered by health professionals. It is obvious that the most health-conscious drivers were enrolled in the study (Lassen et al., 2007; Sabinsky et al., 2007).

#### 3.2. Lifestyle

##### 3.2.1. Dietary patterns

Table 2 shows dietary patterns and their changes during the 12-month counseling program in the LIFE group. Meal frequency and plate model use improved. Intake of vegetables, fruits, and berries; grain products; milk and milk products; meat and meat products; sweets; fast food; and energy-containing drinks changed to a healthier direction. The mean dietary index score improved significantly by 12% ( $N = 24$ ). Improved dietary index score was associated with decreased body weight at 12 months (Pearson correlation,  $r = 0.70$ ,  $p < 0.001$ ). Meal frequency; plate model use; and healthier intake of vegetables,

fruits, and berries; milk and milk products; and bread spread were associated with decreased body weight (Spearman correlation,  $r = 0.37$ – $0.49$ ). These results are similar to other adult weight reduction studies in which associations of healthier choices with weight reduction have been observed (Bellisle, 2014; Fogelholm et al., 2012).

Previous interventions on drivers' eating patterns are few and inconclusive. French et al. (2010) reported decreased energy intake and improvements in fruit and vegetable consumption, but no changes in consumption of sugary drinks, snacks, and sweets in motor freight workers. Sorensen et al. (2010) found decreases in consumption of sugary drinks, but no change in consumption of sugary snacks, fruits, and vegetables in truck drivers. In small interventions on overweight truck drivers ( $N = 12$ – $29$ ), some improvements in diet, such as decreased intake of saturated fat, and sugary snacks and drinks, have been observed (Thiese et al., 2015; Wipfli et al., 2013).

##### 3.2.2. Physical activity

Daily number of steps was monitored at baseline and 12 months by 22 participants (47%) in LIFE. At baseline, the median number of daily steps was 6286 ( $Q_1$ ;  $Q_3$  5332; 7376). At 12 months, the participants took 1811 (median,  $Q_1$ ;  $Q_3$  – 832; 3564) daily steps more than at baseline ( $p = 0.01$ ). The goal of adding 4000 steps daily on five days a week was reached by three of the 22 participants. Eleven participants managed to increase 2000 steps daily on five days. No association with changes in steps and body weight was observed at 12 months (Spearman correlation;  $r = -0.21$ ,  $p = 0.35$ ).

At baseline, the mean duration of self-reported habitual walking was 82 (SD 99) minutes a week ( $N = 89$ ). At 12 months, the duration had increased 60 (SD 160) minutes in LIFE and 9 (SD 81) minutes in REF, resulting in a between-group difference in change of 62 min (95% CI 9 to 115) in favor of LIFE (Table 3). In a subgroup of LIFE that completed the pedometer-based monitoring ( $N = 22$ ), mean self-reported walking increased a little more (70, SD 139 min).

At baseline, the mean duration of sitting was 10.0 (SD 3.1) hours on a working day and 5.2 (SD 2.3) hours on a non-working day ( $N = 89$ ). After 12 months, the duration of sitting did not change on a working day. During a non-working day, the mean duration of sitting decreased 0.6 h in LIFE and increased 0.8 h in REF, leading to a net decrease of 1.3 h (95% CI  $-2.3$  to  $-0.4$ ) in favor of LIFE. Reduction of sitting was not one of the major goals of counseling but was often discussed during the counseling sessions. Sedentary time on non-working days may have decreased as participants increased habitual walking.

Even though the number of steps and minutes of habitual walking increased and hours of sitting during a non-working day decreased at the group level, most of the LIFE participants did not achieve the step goal. Therefore, our LIFE participants' dietary improvements may have contributed more to the achieved weight loss than their moderate increases in PA. PA may not be as effective as dietary modification to affect energy balance and decrease overweight (Schwingshackl et al., 2014).

Perceived barriers to increase PA, such as working schedules, ailments, adverse effects of PA, and lack of company, were common, and may have hampered adoption of walking and other PA. In French et al.'s RCT (2010), no changes in PA were observed among motor freight workers. In general, men tend to choose increasing PA for losing weight over changing dietary habits (Kiefer et al., 2005; Robertson et al., 2014). However, male professional drivers seem to differ from other male populations: drivers find it difficult to increase PA, most likely due to environmental barriers (Turner and Reed, 2011).

#### 3.3. Goal setting

The two most frequently mentioned dietary goals dealt with meal frequency (195 mentions) and plate model use (134). Meal frequency goals included balancing frequency of main meals and avoiding snacking. Other frequently mentioned goals dealt with the intake of vegetables, fruits, and berries (65); milk and milk products (24);

**Table 2**

Dietary patterns at baseline and their changes after 12-month counseling in the lifestyle counseling group (LIFE). Means (SD). Each item was scaled as 1–3, the best value being 3. Items were summed to a dietary index score (range 14–42 points). Within-group differences of the changes ( $p$  value) for dietary items were analyzed by Wilcoxon ranks, and for the dietary index score by paired  $t$ -test.

Items of dietary index	N	Baseline	Change after 12 months	$p$ Value of the change
Meal frequency	36	2.2 (0.4)	0.5 (0.5)	<0.001
Plate model use	38	1.9 (0.7)	0.6 (0.9)	0.001
Vegetables, fruits and berries	40	2.0 (0.6)	0.6 (0.8)	<0.001
Grain products	40	2.5 (0.5)	0.4 (0.6)	<0.001
Milk and milk products	38	2.1 (0.6)	0.7 (0.7)	<0.001
Meat and meat products	40	2.4 (0.6)	0.3 (0.6)	0.007
Fish	39	2.1 (0.8)	0.3 (0.9)	0.09
Bread spread	40	2.5 (0.7)	0.1 (0.7)	0.71
Cooking fat	36	2.6 (0.7)	0.2 (0.7)	0.12
Oil-based salad dressing	37	2.0 (0.7)	0.2 (0.8)	0.09
Fast food	38	2.5 (0.6)	0.3 (0.7)	0.02
Sweets	38	2.2 (0.8)	0.4 (0.9)	0.008
Energy-containing drinks	38	2.5 (0.6)	0.4 (0.6)	0.001
Alcohol	32	2.4 (0.7)	0.1 (0.6)	0.41
Dietary index score	24	32.7 (3.7)	4.0 (5.3)	0.001

SD = standard deviation.

Data from weight reduction study in Finnish professional drivers in 2009–2012.

**Table 3**

Habitual walking and sitting in the lifestyle counseling (LIFE) and the reference (REF) group at baseline and after 12 months, and net difference between the groups. Linear regression adjusted by baseline value and age. Means (SD).

	LIFE (N = 41–44)		REF (N = 41–46)		Net difference (95% CI)
	Baseline	12 months	Baseline	12 months	
Habitual walking (minutes per week)	101 (110)	161 (145)	64 (85)	73 (134)	62 (9 to 115)
Sitting during a working day (hours per day)	10.0 (2.9)	9.4 (3.1)	10.1 (3.3)	10.3 (3.1)	−0.9 (−1.9 to 0.1)
Sitting during a non-working day (hours per day)	5.3 (2.4)	4.7 (2.1)	5.1 (2.3)	6.0 (2.7)	−1.3 (−2.3 to 0.4)

SD = standard deviation; 95% CI = 95% confidence interval.

Data from weight reduction study in Finnish professional drivers in 2009–2012.

candies and pastries (10); and alcohol (10). These goals were in line with the ultimate dietary counseling goals. Repeated mention of these goals also reflected participants' challenges in improving certain habits.

The most popular PA mode was walking (208 mentions). Biking was the second most popular (33), followed by gym exercises, swimming, jogging, cross-country skiing, and ball games. Many participants preferred leisure-time housekeeping and repair jobs instead of structured exercises.

### 3.3.1. Facilitators and barriers

The most mentioned factors that facilitated reaching dietary goals were good quality roadside resting places (8 mentions), support from family and friends (7), and their own preferences (7). The most common barriers were working schedules (15), their own attitudes and habits (13), and family habits (6). The most common facilitators for reaching PA goals were ailment prevention (10 mentions), good opportunities to perform PA (5), improved perceived alertness and well-being (4), spending time with family and friends (3), and social support from family and friends (3). The most common barriers were working schedules (29), ailments and old injuries (21), bad weather conditions or darkness (6), lack of company (3), and fatigue (3).

Facilitators and barriers for reaching dietary and PA goals were very similar to previous findings on professional drivers. Perceived facilitators to healthy lifestyle have been support from family and friends, PA support from management, and health reasons (Hedberg et al., 1998; Wong et al., 2014). Most studies on long-distance drivers suggest that factors related to working schedules and timetable pressures are major environmental barriers (Hedberg et al., 1998; McDonough et al., 2014; Nagler et al., 2013; Turner and Reed, 2011). In many countries, hours-of-service rules are set for professional heavy vehicle drivers; but because of tight competition, unrealistic schedules often cause rule violations (McCartt et al., 2008). Other barriers are poor availability of healthy food; poor or lack of exercise environment; and attitudes and preferences of family, friends, and colleagues (Jack et al., 1998; McDonough et al., 2014; Nagler et al., 2013; Turner and Reed, 2011; Wong et al., 2014). These barriers need to be addressed when providing lifestyle counseling to professional drivers. Roadside resting places should enable healthier food choices and possibilities for PA.

### 3.3.2. Adverse effects of PA

Thirty-nine (83%) LIFE participants reported one or more adverse effects of PA during the 12-month program. Overall, they reported 50 adverse effects, of which 42 (84%) during the first six months. Most adverse effects were minor. The two most common ones were hip, knee, or ankle pain (17 mentions), and muscle pain (17), mostly due to shin splints. Falls and other such accidents (either during leisure time or at work) leading to injuries such as sprains and distortions, were reported 12 times. Thirty participants reported that adverse effects interfered with the achievement of step goals on 37 days (median).

Frequent adverse effects imply that musculoskeletal problems are common in overweight men not used to regular exercise, and who begin to increase PA. PA-related adverse effects during lifestyle interventions among professional drivers have not been reported earlier;

only injuries related to physically demanding work tasks have been reported (Krueger et al., 2007).

### 3.4. Strengths and limitations of the study

The study has several strengths. It was the first RCT aimed at decreasing overweight in professional drivers through individual lifestyle counseling. We succeeded at changing dietary patterns and increasing PA in male drivers, resulting in weight loss and improved cardiometabolic risk factors (Puhkala et al., 2015). Participants' preferences, abilities, and experiences were discussed and taken into account when establishing and revising the monthly goals.

Some limitations must also be stated. Dietary patterns and daily steps were not monitored in REF during the 12-month intervention. Data on dietary patterns in LIFE were obtained from counselors' subjective assessments based on participants' food diary and subsequent interview. Misreporting eating is common (Ferrari et al., 2002). In addition, some of the lifestyle habits – for example, PA opportunities – were related to work schedules, which we could not control. Daily step counts were monitored by fewer than half of the LIFE group, probably only those participants who were interested in PA. These findings in dietary and PA patterns need to be replicated in a larger sample in a randomized design.

## 4. Conclusions

Positive changes in dietary patterns and PA were found in overweight professional drivers during 12-month counseling program, and dietary changes were associated with weight reduction. The monthly counseling program using both face-to-face and telephone contacts seemed appropriate to long-distance drivers. The drivers mentioned support from family and friends, and prevention of ailments as the most frequent facilitators for reaching dietary and PA goals. Frequently mentioned barriers, such as working schedules and ailments, as well as adverse effects of PA hampered adoption of the goals. Such barriers need to be addressed when planning counseling.

### Competing interests

The authors declare no conflict of interest.

### Transparency document

The [Transparency document](#) associated with this article can be found in an online version.

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## Lifestyle counseling to reduce body weight and cardiometabolic risk factors among truck and bus drivers – a randomized controlled trial

Jatta Puhkala, MSc,<sup>1</sup> Katriina Kukkonen-Harjula, DMedSc,<sup>1</sup> Kirsi Mansikkamäki, MSc,<sup>1,2</sup> Minna Aittasalo, DSc,<sup>1</sup> Christer Hublin, DMedSc,<sup>3</sup> Paula Kärmeniemi, MSc,<sup>3</sup> Seppo Oikkonen, DMedSc,<sup>3</sup> Markku Partinen, DMedSc,<sup>4</sup> Mikael Sallinen, PhD,<sup>3,5</sup> Kari Tokola, MSc,<sup>1,6</sup> Mikael Fogelholm, DSc<sup>7</sup>

Puhkala J, Kukkonen-Harjula K, Mansikkamäki K, Aittasalo M, Hublin C, Kärmeniemi P, Oikkonen S, Partinen M, Sallinen M, Tokola K, Fogelholm M. Lifestyle counseling to reduce body weight and cardiometabolic risk factors among truck and bus drivers – a randomized controlled trial. *Scand J Work Environ Health*. 2015;41(1):54–64. doi:10.5271/sjweh.3463

**Objectives** We conducted a randomized trial among overweight long-distance drivers to study the effects of structured lifestyle counseling on body weight and cardiometabolic risk factors.

**Methods** Men with waist circumference >100 cm were randomized into a lifestyle counseling (LIFE, N=55) and a reference (REF, N=58) group. The LIFE group participated in monthly counseling on nutrition, physical activity, and sleep for 12 months aiming at 10% weight loss. After 12 months, the REF group participated in 3-month counseling. Assessments took place at 0, 12, and 24 months. Between-group differences in changes were analyzed by generalized linear modeling. Metabolic risk (Z score) was calculated from components of metabolic syndrome.

**Results** The mean body weight change after 12 months was -3.4 kg in LIFE (N=47) and 0.7 kg in REF (N=48) [net difference -4.0 kg, 95% confidence interval (95% CI) -1.9– -6.2]. Six men in LIFE reduced body weight by ≥10%. Changes in waist circumference were -4.7 cm in LIFE and -0.1 cm in REF (net -4.7 cm, 95% CI -6.6– -2.7). Metabolic risk decreased more in the LIFE than REF group (net -1.2 points, 95% CI -0.6– -2.0). After 24 months follow-up, there were no between-group differences in changes in body weight (net -0.5 kg, 95% CI -3.8–2.9) or metabolic risk score (net 0.1 points; 95% CI -0.8–1.0) compared to baseline.

**Conclusions** Weight reduction and decreases in cardiometabolic risk factors were clinically meaningful after 12 months of counseling.

**Key terms** exercise; metabolic syndrome; MeS; nutrition; obesity; professional driver; walking; weight loss.

The work of long-distance truck and bus drivers typically consists of long and irregular hours or shift work, and lengthy sitting periods (1, 2). Busy schedules and lack of healthy food choices and opportunity for exercise while on the road may predispose drivers to an unhealthy lifestyle (1, 3, 4). Irregular eating and snacking is common (3). Shift work and night shifts in general have been found to be associated with unhealthy eating habits as well as with weight gain (5–7). Prolonged sitting at work is an independent risk factor for athero-

sclerosis and diabetes (8). There are also socioeconomic aspects behind drivers' lifestyles. Truck drivers are often sedentary in their leisure time, and they consume less fruit and vegetables and more sausages and milk fat than recommended (9–11). Most professional drivers are males, who tend to be sedentary more often and have poorer diet than women (12).

Long and irregular work hours predispose drivers to sleep deprivation, which is associated with obesity and other cardiometabolic risk factors (13, 14), as well as

<sup>1</sup> UKK Institute for Health Promotion Research, Tampere, Finland.

<sup>2</sup> Tampere University of Applied Sciences, Tampere, Finland.

<sup>3</sup> Finnish Institute of Occupational Health, Helsinki and Lappeenranta, Finland.

<sup>4</sup> Helsinki Sleep Clinic, Vitalmed Research Centre, Helsinki, Finland.

<sup>5</sup> Agora Center, University of Jyväskylä, Jyväskylä, Finland.

<sup>6</sup> School of Health Sciences, University of Tampere, Tampere, Finland.

<sup>7</sup> Department of Food and Environmental Sciences, University of Helsinki, Helsinki, Finland.

Correspondence to: Jatta Puhkala, UKK Institute for Health Promotion Research, Box 30, FI-33501 Tampere, Finland. [E-mail: jatta.puhkala@uta.fi]

increased risk of road accidents (15, 16). Based on studies about actual sleeping time, truck drivers often suffer from sleep deprivation up to several hours per 24 hours compared to recommendations of 7–8 hours of sleeping time (17–19). Among professional drivers, obesity is associated with increased risk of being fatigued and involved in road traffic accident (15, 20). Among the underlying pathological processes, the central ones are breathing disorders during sleep that are induced by obesity (21).

Obesity is one of the most important health risk factors among professional drivers (15, 22, 23). Worldwide around 57%–87% of truck and bus drivers are overweight or obese (23–26), and obesity comorbidities such as hypertension, dyslipidemia, and type 2 diabetes are common to this profession (23). Overweight and obese truck drivers have substantially greater direct medical costs when compared to drivers of normal weight (23). In a Danish study, hospitalization for obesity or diabetes was more common among truck drivers than among other working populations (22). Additionally, in Europe, obese persons have a 50% higher risk for disability pension when compared to persons who are not overweight (27).

Although unhealthy lifestyle and cardiometabolic risk factors are frequent among professional drivers (22, 28–30), few health education interventions have been targeted at this group. To our knowledge, the only previous randomized trial to prevent obesity was conducted among 1061 overweight transit workers, mostly metropolitan bus drivers, lasting 18 months (25). Participants in the experimental group were encouraged to make healthy food choices and increase physical activity by being offered sports activities and healthy and affordable options in snack vending machines. Dietary habits improved but the modest body weight reduction did not differ from the control group. A Chinese randomized intervention delivered diabetes-related information by mobile messages, which led to a decreased risk of developing diabetes among 104 professional drivers with pre-diabetes symptoms (31).

According to previous studies, the most important factor preventing professional drivers from adopting a lifestyle change is irregular working schedule (3, 25, 32), which disrupt healthy eating habits, as well as sleep, exercise and social life (1). In a US study, almost half of 542 motor freight workers, most of whom were truck drivers, reported that they would not have time to eat right because of their work, although 86% thought it would be especially important to eat right (11). In addition, there are few intervention studies focusing on male workers with the same socioeconomic status as drivers, such as construction and manufacturing industrial workers, with or without shift work. These intervention studies have resulted in clinically meaningful decreases in body weight and cardiovascular risk factors (33, 34). However, males are often less likely than females to participate in lifestyle counseling to improve lifestyle

habits, especially to decrease overweight (35–37).

Our primary aim was to study the effects of individual lifestyle counseling (nutrition, physical activity, and sleep) for 12 months on weight reduction and prevalence of cardiometabolic risk factors (especially metabolic syndrome: MeS) among abdominally obese male truck and bus drivers. A secondary aim was to study weight maintenance during a subsequent 12-month follow up (at 24 months).

## Methods

### Recruitment and randomization of participants

Inclusion criteria included: (i) 30–62-year-old male truck or bus driver, (ii) waist circumference  $\geq 100$  cm, (iii) irregular working schedules in long-distance service, (iv) absence of sleep apnea diagnosis or medication for diabetes, and (v) little physical activity during leisure ( $\leq 2$  times weekly for 30 minutes per session). Voluntary participants were recruited by advertisement in service stations, workplaces, and newspapers and through labor unions. After 1.5 years of recruitment, 209 drivers signed up for the trial (figure 1).

Of these, 113 drivers were eligible for the study and randomized into a lifestyle counseling (LIFE) and a wait-list reference (REF) group. Randomization was performed by a statistician not involved in the study. It was done separately for truck and bus drivers using computerized random numbers in blocks ( $N=4$ , with random variation in the block size). The statistician prepared sealed opaque envelopes containing information on the randomization group, and the research secretary delivered the envelopes in consecutive order to eligible participants after a written informed consent was obtained from the participants. Pirkanmaa University Hospital District Ethics Committee approved the study. The research was conducted in accordance with the Declaration of Helsinki (2000). The ultimate aim of the trial, to improve alertness at work and improve sleep through weight loss, will be reported separately.

### Lifestyle counseling

The participants in the LIFE group participated in structured monthly lifestyle counseling for 12 months focusing on diet but including also counseling on physical activity and sleep. The contents of the session-specific counseling are described in table 1. Counseling consisted of six individual face-to-face contacts (allocated time 60 minutes) and seven telephone contacts (30 minutes) with trained counselors (two nutritionists and one physiotherapist). The counselors traveled to the participants for the

**Table 1.** The contents of session-specific counseling in the lifestyle counseling group. [F=face-to-face; T=telephone; PA=physical activity]

Session number (months from baseline) type of contact	Contents
1 <sup>st</sup> (0) F	General: overview of counseling, working methods Diet: checklist for eating habits, based on food diary, meal frequency (establishing goals for next 4 weeks) PA: instructions to measure average daily step count with a pedometer
2 <sup>nd</sup> (1) F	Diet: meal frequency (compliance, revision of goals); plate model (establishing goals) PA: current PA and step count results; PA recommendations; establishing the first goal
3 <sup>rd</sup> (2) T	Diet: meal frequency and plate model (compliance, revision of goals); food groups and their quality (establishing goals) PA: adverse effects, compliance, revision of goals and modes, stretching exercises
4 <sup>th</sup> (3) F	Diet: meal frequency, plate model and food quality (compliance, revision and establishing goals) PA: adverse effects, compliance, revision of goals and modes Sleep: Sleep hygiene (establishing goals)
5 <sup>th</sup> (4) T	Diet: as session 4 PA: as session 4 Sleep: Sleep hygiene (compliance, revision of goals)
6 <sup>th</sup> (5) T	Diet: as session 4 PA: as session 4 Sleep: Sleep hygiene (compliance, revision of goals), alertness (establishing goals)
7 <sup>th</sup> (6) F	Diet: as session 4 PA: as session 4 Sleep: as session 6
8–12 <sup>th</sup> (7–11) 4T, 1F	Diet: as session 4 PA: as session 4 Sleep: as session 6
13 <sup>th</sup> (12) F	Diet: check list for eating habits, compliance with goals during the year, maintenance, how to continue? (goals) PA: adverse effects, maintenance Sleep: compliance with goals during the year; how to continue?

face-to-face meetings. After 12 months, the REF group participated in a shorter 3-month counseling protocol including two face-to-face contacts (at 12 and 15 months after baseline) and three telephone contacts (3, 6, and 9 weeks after 12 months). Counseling was based on the same elements as those used in the LIFE group but in a shortened version. The second year was a follow-up phase (12 months for LIFE, 9 months for REF).

LIFE group counseling aimed at 10% body weight reduction after 12 months. The ultimate dietary targets were to improve meal frequency, increase the consumption of fruit and vegetables (with the help of a “plate model”: half of the portion is filled with vegetables, one fourth with potatoes, rice or pasta, and one fourth with meat or fish), improve fat quality, and reduce low-fiber, rapidly absorbed carbohydrates (38) (table 1). The ultimate goal of physical activity counseling was to add 4000 steps – approximating 30 minutes of

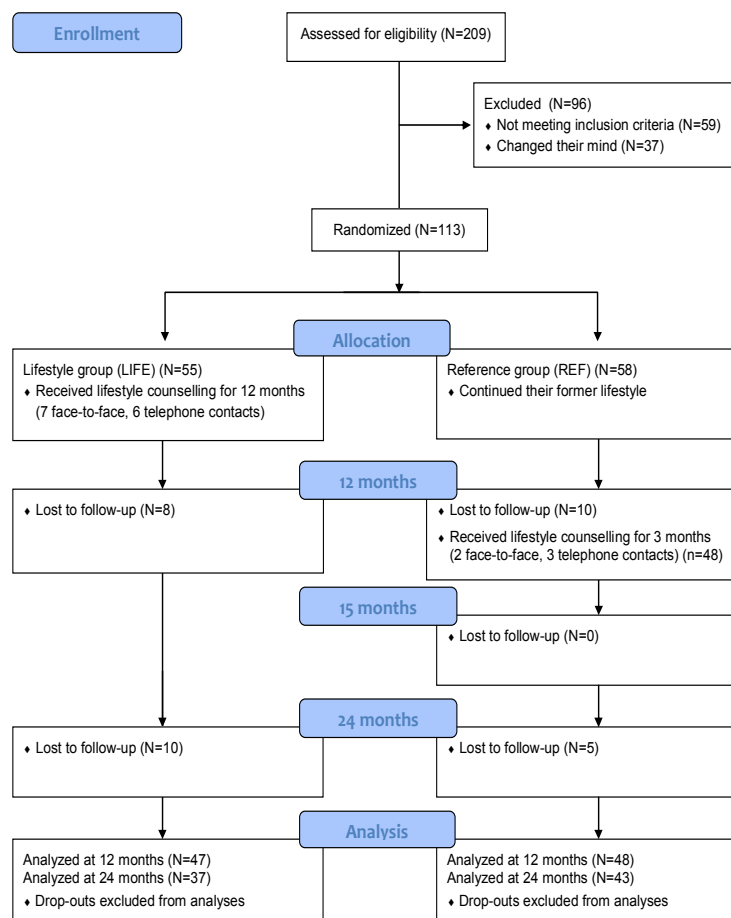
moderate-intensity walking (39) – to the daily baseline on five self-selected days of the week. The goal was approached progressively with the help of a pedometer (Omron Walking Style II, HJ-113-E-03-10/05, Omron Healthcare, Kyoto, Japan) by setting smaller goals in a sequence of 2000 steps, which has previously been shown to be achievable (40, 41). The sleep target was  $\geq 6$  hours of sleep per 24 hours.

The Health Action Process Approach (42–44) was used as a context to formulate the procedure and contents of the counseling sessions (table 1). The counselors used a manual developed by the research group to follow the intended procedure and content of each counseling session but were also free to emphasize topics most relevant to the participant. At each session, individual goals for diet, physical activity and sleep were set based on participant’s preferences, abilities, and experiences. The participants had a log book of their own to monitor the daily accomplishment of their dietary, physical activity and sleep goals. Feasibility and results of counseling on living habits will be reported separately.

#### Outcome measurements

Assessments took place at baseline, and at 12- and 24-month follow-up. Body weight was measured by a precision scale (F150S-D2, Sartorius, Goettingen, Germany). Waist circumference was measured three times: (midway between the lowest rib and the iliac crest) and the mean value was used. Dual-energy X-ray absorptiometry (DXA, Lunar Prodigy Advance, GE Lunar, Madison, WI, USA) was used to measure fat and fat-free mass. Blood pressure was measured in duplicate in the morning and afternoon, and the mean value was used. The participants answered a questionnaire on health status and working conditions. At each counseling meeting, weight (Omron HBF-500-E, Omron Healthcare, Kioto, Japan) and waist circumference were measured.

Blood samples were taken for glucose, cholesterol, high-density lipoprotein (HDL) cholesterol and triglyceride analyses after a 12-hour fast. Venous blood was drawn into citric acid/fluoride and ethylenediaminetetraacetic acid (EDTA) tubes. Plasma glucose concentrations were measured fresh, and plasma samples for lipid analyses were stored frozen at  $-80^{\circ}\text{C}$  until analyzed. Glucose, total cholesterol, HDL cholesterol and triglyceride concentrations were determined in enzymatic assays in duplicate (Roche Cobas Mira Plus analyzer; Roche Diagnostic Systems, Basel, Switzerland). Low-density lipoprotein (LDL) cholesterol was calculated by Friedewald formula if triglyceride concentration was  $<4.51$  mmol/l. MeS was diagnosed according to the International Diabetes Federation (IDF) guidelines (45), based on five components: waist circumference, blood pressure, fasting glucose, HDL cholesterol and triglyc-



**Figure 1.** Flow diagram of the study. The lifestyle counseling (LIFE) group participated in 12 months of counseling starting from baseline and the reference (REF) group participated in three months of counseling starting at 12 months. Assessments took place at baseline, 12, and 24 months from baseline.

erides. Of these, three pathological values are needed for the diagnosis. Impaired fasting glucose (IFG: fasting plasma glucose  $\geq 5.6$  mmol/l) was diagnosed according to the IDF guidelines.

#### Power calculation

Statistical power calculations were based on the assumption that 25% of LIFE participants and 5% of REF participants had reached the target of losing 10% of their initial body weight after 12 months. Using Fisher's exact test, it was calculated that with 59 LIFE participants and REF 59 participants, there was a 84% probability (power 84%, type II error 16%) to detect a significant difference between the groups at a two-sided 0.05 significance level ( $\text{Alfa}=0.05$ , type I error). The drop-out rate was expected to be 15%, and therefore we aimed to recruit 140 persons.

#### Statistical analysis

Linear regression models adjusted by baseline were used to analyze statistical differences in changes between the groups in body composition and cardiometabolic risk

factors in assessments after 12 and 24 months. Fisher's exact test was used to analyze differences in the proportions of successful weight losers ( $\geq 10\%$  of body weight after 12 months) between the LIFE and REF groups. Generalized estimating equations with binary logistic regression using age, time and quadratic time as covariates were used to estimate between-group differences in proportions of participants with MeS or IFG in time (longitudinal data, three measurement points). Interaction of group and time, and group and quadratic time were added to the model to assess linear and non-linear between-group differences in time.

To further evaluate the metabolic risk and its changes, we calculated Z scores for MeS components (waist circumference, blood pressure, glucose, HDL cholesterol and triglycerides). Each component was log-transformed and standardized. The Z score of HDL cholesterol was multiplied by -1 to indicate higher metabolic risk with increasing value. The Z score of blood pressure was calculated as the average of systolic and diastolic blood pressure Z scores. Z scores from the five components were summed up as the metabolic risk score (46). The change in the metabolic risk Z score between

the groups was modeled by linear regression using baseline value as a covariate. All results were considered to be statistically significant if  $P < 0.05$  or if 95% confidence intervals (95% CI) did not cross zero. All analyses were performed with SPSS software, version 21.0 (IBM Corp, Armonk, NY, USA).

## Results

Eighty-three (74%) participants were truck drivers and thirty (26%) were bus drivers. The mean duration of truck or bus driving experience was 24.0 [standard deviation (SD) 14.9] years. Twenty-four (21%) participants used cigarettes or other tobacco products daily. Age, body composition, and components of MeS at baseline are presented in table 2. One fourth (25%,  $N=28$ ) had a body mass index (BMI) of  $<30$  kg/m<sup>2</sup>, about half (47%,  $N=53$ ) of 30–34.9 kg/m<sup>2</sup>, and about one fourth (28%,  $N=32$ ) of  $\geq 35$  kg/m<sup>2</sup>. Twenty-five (22%) participants reported use of medication for hypertension, twelve (11%) for dyslipidemia, and one (1%) for type-2 diabetes. One participant had coronary heart disease. More than two out of three (71%,  $N=80$ ) had MeS at baseline.

Of the 113 randomized participants, 95 (84%) participated in 12-month and 80 (71%) in 24-month measurements (figure 1). One LIFE participant died before the 24-month measurements (the cerebrovascular cause of death was not related to the intervention). The mean participation of LIFE ( $N=47$ ) in allocated monthly counseling sessions was 10.8 sessions (out of 11 allocated sessions) between months 1–11, resulting in participation rate of 98%. The corresponding results in the REF group ( $N=48$ ) between months 12–15 were 3.97 sessions (out of 4 allocated sessions) and a 99% participation rate.

The mean body weight change (versus baseline) after 12 months was -3.4 ( $P=0.001$ , range -26.1–9.9) kg in LIFE ( $N=47$ ) and 0.7 ( $P=0.214$ , range -9.5–12.5) kg in REF ( $N=48$ ), the net difference being -4.0 kg (95% CI -6.2– -1.9) (table 3). The differences of changes in waist circumference and body fat were statistically significant in favor of the LIFE group after 12 months. The change in lean body mass did not differ between the LIFE and REF group (net difference -0.6 kg, 95% CI -1.4– -0.2). Six (13%) LIFE participants ( $N=47$ ) reduced body weight by  $\geq 10\%$ , and another six (13%) lost 5–9.9% of initial body weight. In the REF group ( $N=48$ ), the corresponding numbers were zero and three (6%) ( $P=0.01$  and  $P=0.3$  between the groups). Seven (15%) and fifteen (31%) LIFE and REF participants gained body weight by  $\geq 2\%$ , respectively ( $P=0.09$  between the groups).

At baseline, 44 (80%) of 55 LIFE participants and 36 (62%) of 58 REF participants had MeS. After 12 months, the prevalence had decreased to 62% (29 of

47 LIFE) and to 60% (29 of 48 REF). The difference in the change of proportions between the groups was not statistically significant ( $P=0.34$ , logistic regression analysis). Metabolic risk Z score reduced more in the LIFE compared REF group (net difference -1.2 points, 95% CI -0.6– -2.0, linear regression) (figure 2).

At baseline, 44 (80%) of 55 LIFE participants and 42 (72%) of 58 REF participants had IFG. After 12 months, the prevalence had decreased to 64% (30 of 47 LIFE) and increased to 77% (37 of 48 REF) ( $P=0.012$  between the groups). Among all LIFE participants, the mean change in glucose concentration after 12 months was -0.15 mmol/l (SD 0.43) and 0.01 mmol/l (SD 0.43) among REF participants, the net difference being -0.15 mmol/l (95% CI -0.33– -0.02). After 12 months, the mean concentration of LIFE group HDL cholesterol increased by 0.02 mmol/l (SD 0.11) and decreased by 0.03 mmol/l (0.26) in the REF group (net difference 0.06 mmol/l, 95% CI 0.02–0.18). Also diastolic blood pressure tended to improve more in the LIFE than REF, group the net difference being -2.7 mmHg (95% CI -5.2–0.1) after 12 months. There were no statistically significant differences in the changes in total and LDL cholesterol, triglycerides, and systolic blood pressure between the groups after 12 months.

The waitlist REF group received 3 months of counseling, starting at 12 months from baseline. After 3 months, they lost 4.0 kg (SD 4.2) of body weight and 4.1 cm (SD 4.1) of waist circumference when compared to the 12-month assessment. Of 48 participants, 3 (6%) reduced body weight by  $\geq 10\%$  and 13 (28%) reduced body weight by 5–9.9% after the counseling.

After 24 months, there were no statistically significant differences in the changes of body weight, waist circumference and fat mass between the LIFE and REF group when compared to baseline (table 2). About one-tenth had reduced body weight by  $\geq 10\%$  from baseline, ie, four (11%) LIFE participants and three (7%) REF participants. The corresponding numbers with body weight loss of 5–9.9% were nine (24%) in the LIFE and 13 (30%) in the REF group. There were 11 (30%) participants in LIFE and 10 (23%) in REF who gained body weight by  $\geq 2\%$ .

After 24 months, the prevalence of MeS had decreased to 60% (22 of 37 LIFE) and 51% (22 of 43 REF). The between-group difference in the prevalence curves during 24 months (assessment at 0, 12, and 24 months from baseline) was not statistically significant (interaction between the group and quadratic time  $P=0.11$ ). Neither was there a difference in change in metabolic risk Z scores between the groups after 24 months compared to baseline (net difference 0.1, 95% CI -0.8–1.0).

According to drop-out analysis, there were no differences in baseline characteristics (body composition,



**Table 2.** Characteristics of participants (N=113) at baseline in the lifestyle counseling (LIFE, N=55) group and reference (REF, N=58) group. [SD=standard deviation; MD=median; Q=quartile; BMI=body mass index; HDL=high-density lipoprotein; LDL=low-density lipoprotein]

	LIFE (N=55)					REF (N=58)				
	Mean	SD	MD	Q1	Q3	Mean	SD	MD	Q1	Q3
Age (years)	47.6	7.9				46.5	8.6			
Waist circumference (cm)	113.8	9.5				114.9	10.3			
Body weight (kg)	105.8	16.3				106.7	16.4			
BMI <sup>a</sup> (kg/m <sup>2</sup> )	32.9	4.3				33.1	4.7			
Fat mass (kg)	37.1	8.9				38.0	9.0			
Systolic pressure (mmHg)	130.5	13.5				127.8	11.3			
Diastolic pressure (mmHg)	84.8	9.3				82.5	8.3			
Glucose (mmol/l)	6.0	0.6				6.0	0.6			
Total cholesterol (mmol/l)	5.47	0.94				5.56	1.01			
HDL cholesterol (mmol/l)	1.27	0.30				1.25	0.26			
LDL cholesterol (mmol/l) <sup>a</sup>	3.39	0.87				3.58	0.90			
Triglycerides (mmol/l)			1.67	1.11	2.08			1.41	1.11	2.11
Metabolic risk Z score <sup>b</sup>	0.16	2.74				-0.15	2.84			

<sup>a</sup> N=54 (LIFE) and N=57 (REF).

<sup>b</sup> The sum of five components (waist circumference, blood pressure, glucose, HDL cholesterol and triglycerides) of metabolic syndrome.

**Table 3.** Body weight, waist circumference and fat mass at baseline (N=113) and their changes in assessments after 12 and 24 months versus baseline and net differences of the changes between the lifestyle (LIFE) and reference (REF) group. [SD=standard deviation; N=number of participants; 95% CI=95% confidence interval]

	Baseline		Change versus baseline							Net difference <sup>a</sup>	95% CI
	All (N=113)		LIFE			REF					
	Mean	SD	Mean	SD	N	Mean	SD	N			
Weight (kg)	106.3	16.3									
12 months			-3.4	6.6	47	0.7	3.9	48	-4.0	-6.2– -1.9	
24 months			-3.1	9.0	37	-2.5	5.9	43	-0.5	-3.8–2.9	
Waist (cm)	114.4	9.9									
12 months			-4.7	5.8	47	-0.1	3.6	48	-4.7	-6.6– -2.7	
24 months			-4.5	7.5	37	-4.4	5.5	43	-0.2	-3.1–2.8	
Fat mass (kg)	37.5	8.9									
12 months			-2.6	5.1	46	0.6	3.4	48	-3.1	-4.9– -1.4	
24 months			-2.2	6.9	36	-2.3	4.6	43	0.2	-2.4–2.8	

<sup>a</sup> Baseline value as a covariate.

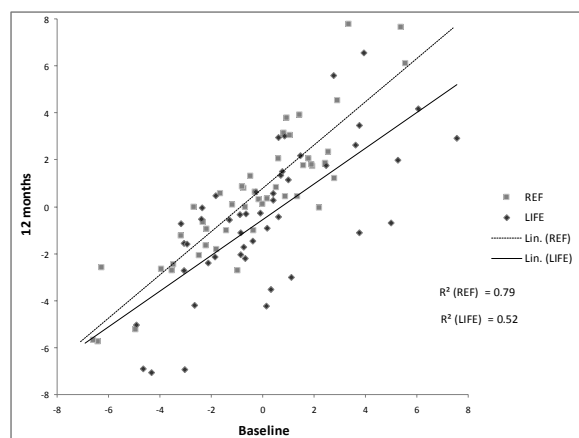
components of MeS or smoking) between completers and non-completers after 12 months (N=95 versus N=18) or 24 months (N=80 versus N=33). Neither were there differences after 12 months between completers and non-completers after 24 months (N=80 versus N=33).

## Discussion

After 12 months of counseling, the mean body weight loss was 3.4 kg in the LIFE group and the net difference of body weight change was 4.0 kg favoring LIFE participants. The results are meaningful from a clinical and public health perspective. Thirteen percent in the LIFE and none in the REF group managed to reduce 10% of initial body weight. There was no difference between the groups in the change in the prevalence of MeS, but the metabolic risk Z score decreased more in the LIFE than

REF group after 12 months. Waist circumference and HDL cholesterol improved more and the prevalence of IFG decreased more in the LIFE than REF group after 12 months. At the end of the study, after three months of counseling (months 12–15), REF participants had caught up with the weight loss that LIFE had achieved during 12 months. Thus there were no differences in body composition and metabolic risk factors between the groups after 24 months.

Recruitment of overweight long-distance drivers all over Finland was challenging and took 15 months. This was probably mostly due to their long and irregular working hours and because counseling sessions and measurements were implemented during participants' leisure time. Thus we suppose that the most motivated and health conscious men participated. This is also reflected by the fact that only 21% of the participants were smokers, while the prevalence of regular smoking is around 27% among Finnish men at the same educa-



**Figure 2.** Linear trend and  $R^2$  of metabolic risk Z score of the lifestyle counseling (LIFE, N=47) and the reference (REF, N=48) group between baseline and 12 months. [Lin =linear regression]

tional level (47). Internationally, smoking is more common among professional drivers than in other working populations (1, 9, 48).

We aimed at a 10% loss of initial body weight in  $\geq 25\%$  of the LIFE participants after 12 months. Weight loss of at least 5–10% has been found to be related to reduction in cardiovascular risk factors associated with obesity (49–51). In our study, the proportion of the LIFE participants to actually reach the 10% weight loss goal was around half of our assumption (13%). In the REF group, we had assumed 5% of the participants would reach the goal, but none succeeded. In lifestyle counseling interventions the proportion of participants reducing  $\geq 10\%$  of body weight is rarely reported, though this is a common goal in obesity treatment guidelines (51). However, when compared to previous lifestyle counseling interventions aiming at weight reduction, our result after 12 months (net effect -4.0 kg) is in the same magnitude and clinically relevant (52, 53).

According to meta-analyses on treatment of overweight and obese persons, the mean body weight loss in lifestyle interventions varied between 2.3–3.5 kilograms at follow-up for 1–2 years (52, 53). Previous health education interventions have achieved slight to moderate changes in drivers' health behavior and body weight (25, 32, 54, 55), and only one of them has been a randomized intervention (25). Previous weight reduction studies concentrating only on males or shift workers are heterogenic and few. A randomized 6-month Dutch lifestyle counseling intervention resulted in a -2.2 kg (95% CI -3.1– -1.3) net difference at one year among 372 overweight male construction workers (33). Another randomized intervention by phone and email in a Dutch overweight working population (N=1386, of whom 67%

were males) lead to a net weight loss of 1.5 kg (95% CI -2.2– -0.8) (by phone) and 0.6 kg (95% CI -1.3– -0.01) (by email) compared to control group after six months of lifestyle counseling (56). In an Australian randomized study, a three-month workplace-based weight loss program among 110 overweight male shift workers, led to a net difference of -4.4 kg (95% CI -2.6– -6.1) (34). Overall, in addition to more intensive and expensive individual counseling, work-site interventions (with different methods like group classes, leaflets, poster displays, work-shops, improved cafeteria food choices, and community events) have demonstrated promising results in obesity prevention and reducing cardiovascular disease risk (57, 58). However, workplace-bound approaches are not applicable to long-distance drivers.

The body weight regain in the LIFE group from 12 to 24 months was moderate (mean 0.5 kg, SD 4.8 kg). According to systematic reviews, about 50% of weight loss is maintained after one-year follow-up (59, 60). In a Finnish weight maintenance study among abdominally obese men, 37% of achieved body weight loss was maintained for two years after weight reduction by very-low-energy diet followed by exercise training (61).

The body weight decrease of 3.4 kg among LIFE participants after 12 months in the present study did not lead to a clear reduction in the prevalence of MeS. However, in the metabolic risk Z score the mean decrease of 1.2 points (95% CI -0.6– -2.0) was significant. Also fasting glucose and HDL cholesterol improved. According to several studies (62–64) it seems that even a modest body weight reduction (3.5–4.2 kg in 1–2 years) with the aid of diet and exercise is enough for reduction in cardiometabolic risk factors like insulin resistance, impaired glucose tolerance, dyslipidemia, and hypertension. The results of the present study are in line with these studies.

The present study shows that weight reduction with some improvement in cardiometabolic risk factors among long-distance truck and bus drivers is possible through lifestyle counseling, despite challenging working conditions. In addition to the weight loss achieved, an interesting finding was that the shorter three months of counseling in the REF group led to an almost equal body weight loss compared to the more intensive 12 months of counseling in the LIFE group. This may imply that in the short run, lifestyle changes are also achievable with less intensive counseling, which might be more applicable in occupational healthcare. Future studies are, however, needed to support this finding, since the effects of shorter counseling on long-term weight maintenance are not known.

Especially working hours, long absences from home, and dependence on road site food and rest services are substantial barriers to a healthy lifestyle of long-distance drivers. To improve the environment, resting and eating locations should serve healthier food, more showering

facilities and possibilities to engage in exercise and rest. Professional drivers have shown interest in eating in a healthier way if there were options for these at the resting places (2, 11, 24). In many countries, including those in EU, Northern America, and some parts of Asia, hours-of-service rules are officially set to control the working and resting times of heavy vehicle professional drivers. In spite of that, economic aspects and international competition may lead to unrealistic delivery schedules and rule violations (65). In our study, we had no possibility to affect drivers' working schedules or access to occupational healthcare.

### Strengths and limits of the study

There are several strengths in the present study. First, our study is the first randomized controlled trial on lifestyle counseling in long-distance drivers. The counseling was planned to be intensive and individually tailored as the group was known to be hard to reach and maintain involvement. As long-distance drivers have no stable working place, participation in each counseling meeting was made as easy as possible for the participants as the counselors traveled to them. The counseling was structured and theory-based, which ensured homogeneity among the three counselors. The duration of the study with follow-up was rather long, namely, two years.

The most important limitation of the study is the number of participants, which makes the study underpowered. We lacked 23 participants from the target of 118 at 12-month measurements, meaning a gap of 19%. As the recruitment was countrywide, the less-than-optimal number of participating volunteers most probably reflects challenging working hours or lack of interest in health issues. However, the participant drop-out (16% after 12 months and 29% after 24 months) was rather low compared to other weight loss studies (37). This probably reflects appreciation of free and easy-to-reach counseling sessions and the attention and advice given by health professionals.

### Concluding remarks

Intensive lifestyle counseling on nutrition, physical activity, and sleep was effective in reducing body weight and cardiometabolic risk factors in overweight professional drivers.

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The authors declare no conflict of interest.

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## Clinical Study

# Prevalence of Metabolic Syndrome One Year after Delivery in Finnish Women at Increased Risk for Gestational Diabetes Mellitus during Pregnancy

Jatta Puhkala,<sup>1</sup> Tarja I. Kinnunen,<sup>2</sup> Tommi Vasankari,<sup>1,3</sup> Katriina Kukkonen-Harjula,<sup>1</sup> Jani Raitanen,<sup>1,2</sup> and Riitta Luoto<sup>1,3</sup>

<sup>1</sup> UKK Institute for Health Promotion Research, P.O. Box 30, FI-33501 Tampere, Finland

<sup>2</sup> School of Health Sciences, University of Tampere, FI-33014 University of Tampere, Finland

<sup>3</sup> National Institute for Health and Welfare, P.O. Box 30, FI-00271 Helsinki, Finland

Correspondence should be addressed to Jatta Puhkala; [jatta.puhkala@uta.fi](mailto:jatta.puhkala@uta.fi)

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**Background.** Women with a history of gestational diabetes mellitus (GDM) are at increased risk for metabolic syndrome (MeS) after delivery. We studied the prevalence of MeS at one year postpartum among Finnish women who in early pregnancy were at increased risk of developing GDM. **Methods.** This follow-up study is a part of a GDM prevention trial. At one year postpartum, 150 women (mean age 33.1 years, BMI 27.2 kg/m<sup>2</sup>) were evaluated for MeS. **Results.** The prevalence of MeS was 18% according to the International Diabetes Federation (IDF) criteria and 16% according to National Cholesterol Education Program (NCEP) criteria. Of MeS components, 74% of participants had an increased waist circumference ( $\geq 80$  cm). Twenty-seven percent had elevated fasting plasma glucose ( $\geq 5.6$  mmol/L), and 29% had reduced HDL cholesterol ( $\leq 1.3$  mmol/L). The odds ratio for the occurrence of MeS at one year postpartum was 3.0 (95% CI 1.0–9.2) in those who were overweight before pregnancy compared to normal weight women. **Conclusions.** Nearly one-fifth of the women with an increased risk of GDM in early pregnancy fulfilled the criteria of MeS at one year postpartum. The most important factor associated with MeS was prepregnancy overweight. Weight management before and during pregnancy is important for preventing MeS after delivery.

## 1. Introduction

Metabolic syndrome (MeS) is defined as a cluster of atherosclerotic risk factors, including abdominal obesity, elevated serum triglycerides, decreased HDL cholesterol, elevated blood pressure, and elevated serum plasma glucose [1–3]. Insulin resistance is a central feature in the pathogenesis of MeS [4] in addition to an unhealthy diet and physical inactivity promoting overweight and genetic factors [1, 5–7]. As obesity increases worldwide, this leads to an increased incidence and an earlier onset of MeS [3, 8, 9].

Gestational diabetes mellitus (GDM), a disorder in glucose and insulin metabolism, is one of the most common

complications in pregnancy [10]. Depending on the population and the diagnostic criteria used, the prevalence is roughly 1%–14% of pregnancies [10, 11]; and the occurrence is increasing worldwide [12, 13]. The most important risk factors for GDM are prepregnancy overweight, high maternal age and a family history of type 2 diabetes [14]. Women with a history of GDM are at increased risk of developing type 2 diabetes and also MeS after delivery [15–17]. Among Canadian women with a history of GDM, the prevalence of MeS was 20% at as early as three months postpartum [18]. According to studies from the USA and Denmark, approximately 30%–40% of women with a history of GDM develop MeS by ten years postpartum [19, 20].

The aim of this study was to determine the prevalence of MeS and its components at one year postpartum among Finnish women who in early pregnancy were at increased risk of developing GDM. A secondary aim was to characterize risk factors associated with the development of MeS.

## 2. Subjects and Methods

The study is a part of a cluster-randomized controlled trial, NELLI (counseling and lifestyle during pregnancy, ISRCTN33885819) [21]. A detailed description of the design and methods has been published previously [22]. The primary aim of the trial was to prevent GDM among pregnant women who were assessed in early pregnancy to have an increased risk of GDM. The study was conducted in primary health care maternity clinics in Western Finland in 2007–2009. The intervention included structured individual counselling on weight gain, diet, and physical activity by public health nurses during five routine visits to maternity clinics. The women in the control clinics received the usual maternal care, including some lifestyle advice.

Pregnant women were recruited by nurses at their first visit (8–12 weeks' gestation) in maternity clinics. Women were eligible if they had at least one of the following GDM risk factors: age  $\geq 40$  years, prepregnancy body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup>, GDM or any sign of glucose intolerance, a macrosomic baby ( $\geq 4500$  g) in any previous pregnancy, or diabetes in first- or second-degree relatives. The main exclusion criteria were age  $< 18$  years, a GDM diagnosis at 8–12 weeks' gestation, twin pregnancy, physical restrictions that precluded exercise, or a clinical history of chronic disease. A diagnosis of GDM was based on a two-hour 75-gram oral glucose tolerance test (OGTT) whose results met at least one of the following criteria: a fasting plasma glucose of  $\geq 5.3$  mmol/L,  $>10.0$  mmol/L at one hour, or  $>8.6$  mmol/L at two hours [14].

Six hundred forty pregnant women participated in baseline assessment at 8–12 weeks' gestation (Figure 1). Of them, 442 (69%) were eligible for the randomized clinical trial (RCT; intensified counselling or usual care), while 198 (31%) were excluded, most of them ( $n = 174$ , 88%) due to a GDM diagnosis at 8–12 weeks' gestation. At postpartum followup, MeS component data were available for 150 women. The intensified counselling, the usual care, and the early GDM (originally excluded from the RCT) groups were merged for present analysis.

Information on maternal measurements was obtained from the standard maternity cards. Height was measured at the first maternity care visit, and weight was measured at each maternity care visit and one year postpartum. Waist circumference was measured (the average of three measurements) at one year postpartum. Blood pressure was measured in duplicate at each maternity care visit and one year postpartum. Because 15% of the weight data from the first visit were missing, self-reported prepregnancy weight was used as the baseline weight.

Blood specimens were taken for glucose, cholesterol, HDL cholesterol, and triglyceride analysis after a 12-hour fast,

and a two-hour OGTT was performed at 8–12 and 26–28 weeks' gestation and one year postpartum. All blood analysis was performed at the UKK Institute. For glucose and lipid analysis, venous blood was drawn into citric acid/fluoride and EDTA tubes. During the OGTT, blood samples were taken between 60 and 120 min after the participants had drunk 75 g glucose in 330 mL water (Glucodyn, Ultimed, Finland). Plasma glucose concentrations were measured fresh within 24 hours after the OGTT, but plasma samples for lipid analysis were stored frozen at  $-80^{\circ}\text{C}$  until analysed. Glucose, total cholesterol, HDL cholesterol, and triglyceride concentrations were determined in enzymatic assays using a Roche Cobas Mira Plus analyser. All testing was performed in duplicate. MeS was diagnosed according to the International Diabetes Federation (IDF) [6] and the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP-III) [23] criteria. At one year postpartum, oral glucose tolerance was evaluated according to the American Diabetes Association (ADA) [24] and the World Health Organization (WHO) [25] criteria. The primary outcome of this study was the prevalence of MeS and its components at one year postpartum.

The background characteristics and descriptive information on components of metabolic syndrome are reported here as means and standard deviations (SDs) or frequencies and proportions. A multivariate logistic regression model was used to obtain odds ratios (ORs) and their 95% confidence intervals (95% CIs) to study associations between metabolic syndrome and its explanatory variables. Explanatory variables included were age (continuous), group (intensified counselling, usual care, and early GDM); and five GDM risk factors (as used in entrance criteria to the study, that is, BMI  $\geq 25$  kg/m<sup>2</sup>, age  $\geq 40$  years, GDM or any sign of glucose intolerance in any previous pregnancy, a macrosomic baby [ $\geq 4500$  g] in any previous pregnancy, and diabetes in first- or second-degree relatives). The results were considered to be statistically significant if  $P < 0.05$ . All analysis was performed with SPSS software (version 20.0).

## 3. Results

**3.1. Background Characteristics.** Before pregnancy, self-reported weight was 74.2 kg (range 50.0–120.0 kg), which was 0.9 kg less than the weight measured at the first maternal clinical visit at 8–12 weeks' gestation (75.1 kg,  $n = 127$ ). The mean prepregnancy BMI was 26.7 kg/m<sup>2</sup> (range 18.1–39.5 kg/m<sup>2</sup>). At followup measurement; one year after delivery, the mean weight increase was 1.4 kg (range from  $-16.1$  to 18.0 kg) compared with prepregnancy weight. Table 1 shows that one year after delivery, the mean age of the women was 33.1 years (range 20–49 years) and the mean number of deliveries was 2.0 (range 1–8). The most common inclusion criteria for the study were prepregnancy overweight (66%) and diabetes in relatives (53%). Twenty-one percent ( $n = 30$ ) smoked frequently or occasionally before pregnancy.

**3.2. Metabolic Syndrome and Its Components at One-Year Postpartum.** The prevalence of MeS and its components



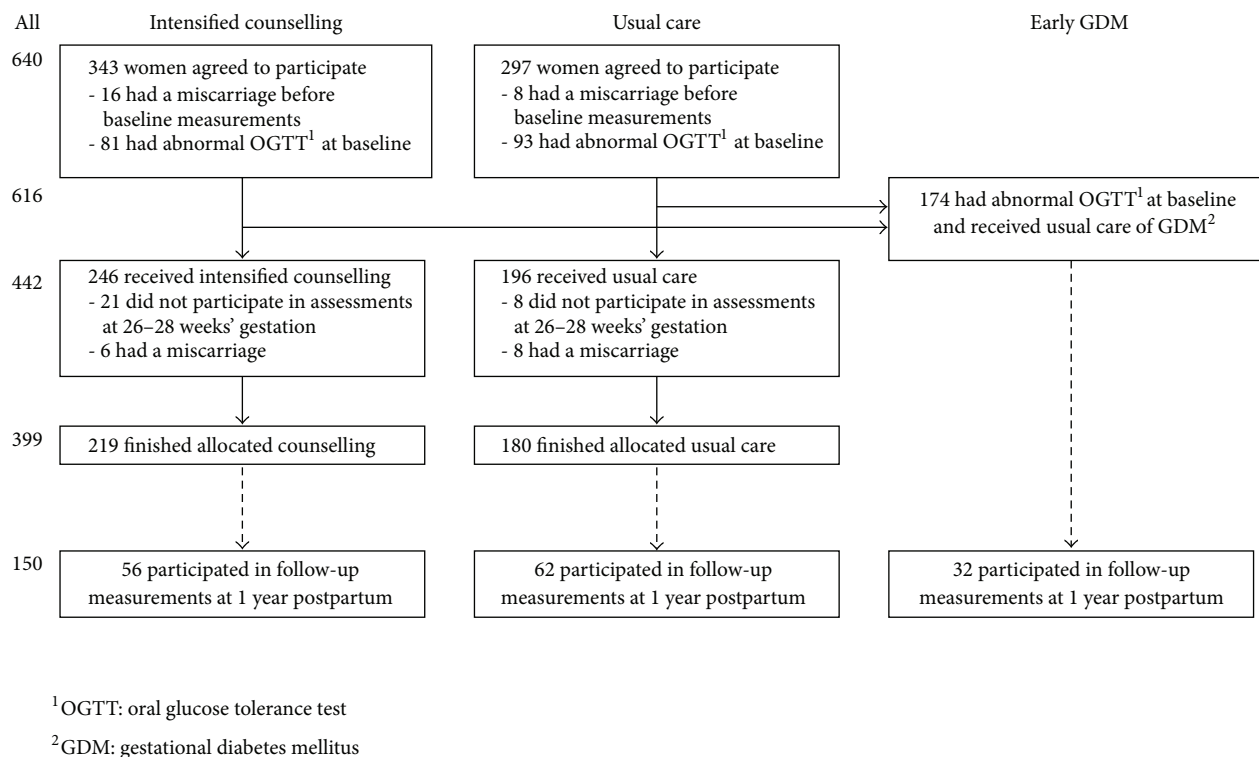


FIGURE 1: Flow diagram of the study, ending in followup assessments at one year postpartum. The two intervention groups (intensified counselling and usual care) and those with GDM diagnosed at early pregnancy (8–12 weeks' gestation) were invited for followup measurements at one year postpartum.

one year after delivery in all women and in the intensified counselling, usual care, and abnormal OGTT groups is presented in Table 2. Three out of four women exceeded the waist circumference limit of 80 cm, and about half reached the limit of 88 cm. Compared to the intensified counselling group, there tended to be more abdominally obese (waist circumference  $\geq 88$  cm) women in the early GDM and usual care group. More than one-fourth of all and half of the women with early GDM had elevated fasting plasma glucose ( $\geq 5.6$  mmol/L) at one year postpartum. One-fifth of all and one-fourth of women with early GDM also had elevated blood pressure. HDL cholesterol was reduced ( $\leq 1.3$  mmol/L) among more than one-fourth of all women.

On the other hand, almost one-third (31%) according to NCEP criteria and one-sixth (16%) according to IDF criteria did not meet the criteria for any MeS components. Most women (52% according to IDF and 63% according to NCEP) had one or two MeS components, while 8% (according to both IDF and NCEP) had four or five components. According to IDF criteria, the prevalence of MeS among the participants was 18% ( $n = 27$ ) and according to NCEP criteria 16% ( $n = 24$ ). In OGTT, at followup, 8 women (5%) had impaired glucose tolerance according to both WHO and ADA criteria. Seven had MeS according to both IDF and NCEP criteria.

In multivariate logistic regression analysis, the risk of MeS in the group with early GDM tended to be higher

compared to the intensified counselling group (OR 3.4, 95% CI 1.0–11.3,  $P = 0.051$ ) (Table 3). When analysed by trial inclusion criteria (GDM risk factors at baseline), prepregnancy overweight (BMI  $> 25$  kg/m<sup>2</sup>) was a strong predictor for developing MeS (OR 3.0, 95% CI 1.0–9.2,  $P = 0.053$ ).

**3.3. Dropout Analyses.** Measurements of MeS components at one year postpartum were available for 24% of the women who participated in the baseline measurements and for 32% of those who participated in the followup. Compared with the participants for whom the data for MeS diagnosis at followup were not available ( $n = 466$ ), participants with data for MeS ( $n = 150$ ) were more likely to belong to the usual care group (55% versus 45%,  $P = 0.032$ ) and were less likely to be frequent smokers before pregnancy (10% versus 22%,  $P = 0.013$ ). There were also some more women with GDM diagnosed at 26–28 weeks' gestation (abnormal OGTT) among women with MeS data available at one year postpartum than among those without MeS data (18% versus 10%,  $P = 0.064$ ), but there were no differences in the occurrence of GDM at 8–12 weeks' gestation (20% versus 24% had early GDM,  $P = 0.393$ ). Neither were there differences between these two groups in any other background characteristic (weight or BMI, age, parity, or education) or laboratory analysis other than OGTT at 26–28 weeks' gestation.

TABLE 1: Background characteristics of women at one year postpartum. Means and standard deviations or frequencies (and proportions) of participants ( $n = 150$ ).

Age (years)	33.1 ± 4.9
<30	37 (25)
30–34	60 (40)
≥35	53 (35)
Weight (kg)	75.6 ± 15.3
BMI <sup>a</sup> (kg/m <sup>2</sup> )	27.2 ± 5.0
BMI ≥ 25 kg/m <sup>2</sup>	88 (64)
BMI ≥ 30 kg/m <sup>2</sup>	37 (27)
Education	
Basic or secondary education	48 (32)
Polytechnic education	60 (40)
University degree	41 (28)
Parity	2.0 ± 1.2
1	56 (37)
2–3	82 (55)
≥4	12 (8)
GDM <sup>b</sup> risk criteria (at 8–12 weeks' pregnancy, $n = 148$ )	
BMI <sup>a</sup> ≥ 25 kg/m <sup>2</sup>	97 (66)
Macrosomic child in any previous pregnancy	8 (5)
GDM <sup>b</sup> in any previous pregnancy	25 (17)
Diabetes in first- or second-degree relatives	78 (53)
Age ≥ 40 years	6 (4)

<sup>a</sup>BMI: body mass index.

<sup>b</sup>GDM: gestational diabetes mellitus.

## 4. Discussion

At one year postpartum, MeS was diagnosed in nearly one-fifth of the women who had an increased risk of gestational diabetes at the beginning of their pregnancy. Especially; prepregnancy overweight was associated with a higher risk of developing MeS. In a prospective Finnish population study among nonpregnant women aged 30–33, the prevalence of MeS was 7%–14% according to the IDF definition and 4%–11% according to the NCEP definition [26]. The prevalence of MeS was more common in our study due to our risk-group approach. According to other studies, the prevalence of MeS among parous women aged 30–40 is no more than 10% depending on country, criteria, and time after delivery [18, 19, 27].

Our study is one of the first followup studies on the prevalence of MeS after delivery among young women with risk factors for GDM. According to earlier studies, a history of GDM is strongly associated with a higher prevalence of MeS [16, 20, 27]. The present study suggests that the risk is high, also among women with risk factors for GDM in early pregnancy, but does not necessarily lead to GDM. GDM and MeS share some risk factors, such as overweight and a genetic tendency towards impaired glucose metabolism. Still, the development of MeS after glucose disorders during pregnancy has not been given as much attention as the increased risk of type 2 diabetes after GDM. In any case, the cardiometabolic risk factors in women at increased risk of GDM should also be followed after delivery.

In 2007, the prevalence of obesity among women aged 25–34 years in Finland was 11.1% [28]; in our subjects, one year after delivery, it was 2.5 times higher at 27%. Half of the subjects were abdominally obese (waist circumference ≥88 cm). Abdominal obesity is one of the most important independent factors in development of metabolic syndrome [29]. Although overweight among young adults is on the rise worldwide [30], there are few studies of the prevalence of MeS among young adults.

The NELLI study [21] is one of the largest randomized controlled trials about preventing the development of gestational diabetes. The NELLI trial showed that the lifestyle counselling was effective in controlling the proportion of large-for-gestational-age newborns and improving the women's diet and had a minor effect on gestational weight gain and decrease in physical activity [21, 31–33]. Since participation in followup measurements at one year postpartum was low (24% of the original cohort) and the total number of participants was modest, the results must be interpreted carefully. Because of low number of participants, some findings were only borderline statistically significant.

There are many possible reasons for the loss. Among followup participants, there were more women from the usual care group and fewer frequent smokers before pregnancy. Participants in followup also were more likely to have been diagnosed with GDM in midpregnancy (26–28 weeks) as compared with the women who did not participate in MeS testing at followup. Women with small children may have found it difficult to find time to come in for testing, especially as it included the two-hour OGTT. Some subjects who showed up for followup testing may have been more health conscious, which is advocated by the fact that there was a smaller proportion of smokers among them. Some may have been concerned about ill health due to their GDM diagnosis during pregnancy. Nevertheless, some women with a GDM diagnosis were already being monitored by the healthcare system, and they may have refused to participate in our testing for that reason. Another reason for refusal was a new pregnancy, but the number of these women was unclear. This study was limited to Finnish women, and the results can only be extrapolated to Caucasian populations.

One limitation of this study is that, at the followup, the subjects were not queried about hormonal contraception or medications for hypertension or dyslipidemia, which influence the components of MeS. However, when medications were queried in the baseline, none of the women reported taking any cardiovascular medication.

We used self-reported weight before pregnancy, which is not as reliable a measurement as using a scale. When self-reported weight was compared to the available weight measurement at the first maternity clinical visit, the mean difference was less than 1 kg, which could easily be explained by a minimal early pregnancy weight gain.

## 5. Conclusion

Our study suggests that MeS at one year postpartum seems to occur more often among women who in early pregnancy

TABLE 2: Components of metabolic syndrome (MeS) and prevalence of MeS by two criteria in all women and in the intensified counselling, usual care, and abnormal OGTT groups at one year postpartum. Means and standard deviations or frequencies (and proportions) of participants.

	All ( <i>n</i> = 135–150)	Intensified counselling ( <i>n</i> = 49–56)	Usual care ( <i>n</i> = 56–62)	Early GDM <sup>a</sup> ( <i>n</i> = 30–32)
Waist circumference (cm)	88.8 ± 11.4	86.7 ± 11.5	88.8 ± 10.2	92.7 ± 12.7
Waist ≥ 80 cm	102 (74)	36 (69)	43 (77)	23 (77)
Waist ≥ 88 cm	69 (50)	20 (39)	30 (54)	19 (63)
Fasting glucose (mmol/L)	5.4 ± 0.4	5.3 ± 0.4	5.3 ± 0.4	5.7 ± 0.5
Fasting glucose ≥ 5.6 mmol/L	43 (29)	11 (20)	16 (26)	16 (50)
Systolic pressure (mmHg)	116 ± 11	114 ± 9	116 ± 12	118 ± 12
Diastolic pressure (mmHg)	74 ± 9	72 ± 7	76 ± 10	75 ± 10
Blood pressure ≥ 130 or ≥85 mmHg	23 (17)	4 (8)	12 (21)	7 (23)
HDL cholesterol (mmol/L)	1.50 ± 0.34	1.43 ± 0.30	1.57 ± 0.37	1.49 ± 0.30
HDL cholesterol ≤ 1.3 mmol/L	40 (27)	17 (32)	14 (23)	9 (28)
Triglycerides (mmol/L)	0.97 ± 0.43	0.93 ± 0.37	0.94 ± 0.44	1.06 ± 0.49
Triglycerides ≥ 1.7 mmol/L	12 (8)	3 (6)	4 (7)	5 (16)
Metabolic syndrome (IDF) <sup>b</sup>	27 (18)	6 (11)	11 (18)	10 (31)
Metabolic syndrome (NCEP) <sup>c</sup>	24 (16)	4 (7)	10 (16)	10 (31)

<sup>a</sup>GDM: gestational diabetes mellitus.

<sup>b</sup>International Diabetes Federation.

<sup>c</sup>National Cholesterol Education Adult Treatment Panel III.

TABLE 3: Occurrence of metabolic syndrome by its explanatory variables (group, age, and five GDM risk factors). Odds ratios (ORs), 95% confidence intervals (CIs), and *P* values, *n* = 150. Multivariate logistic regression model.

	OR (95% CI)	<i>P</i> value
Group (reference = the intensified counselling)		
Usual care	1.5 (0.5 to 4.6)	0.48
Early GDM <sup>a</sup>	3.36 (1.00 to 11.4)	0.051
Age (continuous)	1.0 (0.9 to 1.2)	0.44
BMI <sup>b</sup> ≥ 25 kg/m <sup>2</sup> (prepregnancy)	3.0 (1.0 to 9.2)	0.053
A macrosomic baby (≥4500 g) in any previous pregnancy	0.9 (0.1 to 6.5)	0.91
GDM <sup>a</sup> or any sign of glucose intolerance in any previous pregnancy	2.6 (0.9 to 7.6)	0.077
Type 1 or 2 diabetes in first- or second-degree relatives	1.6 (0.6 to 4.00)	0.32
Age ≥ 40 years	0.9 (0.1 to 11.8)	0.92

<sup>a</sup>GDM: gestational diabetes.

<sup>b</sup>BMI: body mass index.

had an increased risk of GDM. The most important factor associated with MeS seemed was prepregnancy overweight. This study suggests that especially women with an increased risk of GDM should be followed up on for cardiometabolic risk factors after delivery. Weight management or reduction before pregnancy and prevention of excessive weight gain during pregnancy are important for the prevention of GDM and of MeS. Overweight and obesity among pregnant women may increase, as the average maternal age is rising along with the obesity epidemic, and this represents an even greater challenge in following up on and managing risk factors for chronic diseases. There is a need for larger population studies on the prevalence of MeS among young women, especially among those who are at an elevated risk of GDM.

## Conflict of Interests

The authors have no conflict of interests.

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# BMJ Open Metabolic syndrome in Finnish women 7 years after a gestational diabetes prevention trial

Jatta Puhkala,<sup>1</sup> Jani Raitanen,<sup>1,2</sup> Päivi Kolu,<sup>1</sup> Pipsa Tuominen,<sup>1</sup> Pauliina Husu,<sup>1</sup> Riitta Luoto<sup>1,2</sup>

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<sup>1</sup>UKK Institute for Health Promotion Research, Tampere, Finland

<sup>2</sup>School of Health Sciences, University of Tampere, Tampere, Finland

**Correspondence to**  
Jatta Puhkala;  
[jatta.puhkala@uta.fi](mailto:jatta.puhkala@uta.fi)

## ABSTRACT

**Background:** Risk for developing metabolic syndrome (MeS) after delivery is high among women with gestational diabetes mellitus (GDM), but little is known about development of MeS among women with risk factors for GDM during pregnancy. In the present study, we studied the prevalence of MeS 7 years postpartum among women with GDM risk factors during pregnancy, women with early GDM diagnosis and women without GDM risk factors. We also analysed the early pregnancy risk factors associated with MeS.

**Methods:** A Finnish cluster randomised controlled GDM prevention trial was conducted in 2007–2009. The prevalence of MeS according to International Diabetes Federation criteria was determined in the follow-up study 7 years after original trial. Eligible participants (n=289) in 4 study groups (intervention (n=83) and usual care (n=87) with GDM risk factors; early GDM (n=51), and healthy control without GDM risk factors (n=68)) were evaluated for MeS. Binary logistic regression models were used to analyse risk factors associated with MeS.

**Results:** 7 years postpartum, the MeS prevalence was 14% (95% CI 8% to 25%) in the intervention group; 15% (CI 8% to 25%) in the usual care group; 50% (CI 35% to 65%) in the early GDM group and 7% (CI 2% to 18%) in the healthy control group. OR for MeS in women with GDM risk factors did not differ from the healthy control group. Body mass index (BMI)-adjusted OR for MeS was 9.18 (CI 1.82 to 46.20) in the early GDM group compared with the healthy control group. Increased prepregnancy BMI was associated with MeS (OR, 1.17, CI 1.08 to 1.28, adjusted for group).

**Conclusions:** Increased prepregnancy BMI and early GDM diagnosis were the strongest risk factors for developing MeS 7 years postpartum. Overweight and obese women and especially those with early GDM should be monitored and counselled for cardiometabolic risk factors after delivery.

## INTRODUCTION

Metabolic syndrome (MeS) is a clustering of atherosclerotic risk factors, including abdominal obesity, elevated plasma triglycerides,

## Strengths and limitations of this study

- Our study was a long-term follow-up of a large gestational diabetes mellitus (GDM) prevention trial.
- The study was one of the first follow-up studies on the prevalence of metabolic syndrome (MeS) after delivery among women with risk factors for GDM.
- The results include data of the MeS prevalence among different risk groups.
- Thirty-seven per cent of the invited women entered the measurements for MeS, and the four subgroups were relatively small.
- The results may have been moderately affected by a healthy selection bias.

decreased high density lipoprotein (HDL) cholesterol, elevated blood pressure and elevated fasting glucose.<sup>1 2</sup> Insulin resistance and low-grade inflammation are central drivers in the pathogenesis of MeS.<sup>3 4</sup> In addition to genetic features, obesogenic lifestyle defined by unhealthy diet and physical inactivity increase the risk for MeS.<sup>5–9</sup> The prevalence of MeS is increasing worldwide, along with the obesity epidemic and population ageing.<sup>10 11</sup> Estimates of MeS prevalence vary between 15% and 34% in adult populations,<sup>12–15</sup> and around 8–19% in reproductive-aged women in industrial countries.<sup>16–18</sup> It is relevant to identify patients with MeS, as they are at twice the risk for developing cardiovascular disease over the next 5–10 years, and at fivefold lifetime risk of developing type 2 diabetes compared with individuals without the syndrome.<sup>1</sup>

Gestational diabetes mellitus (GDM) is a disorder in glucose and insulin metabolism first diagnosed during pregnancy.<sup>19</sup> The most important risk factors for GDM are pre-pregnancy overweight, high maternal age and a family history of type 2 diabetes.<sup>20</sup> Women with a history of GDM are at

increased risk for developing cardiometabolic disorders, such as type 2 diabetes and MeS after delivery.<sup>21 22</sup> MeS and GDM share mutual risk factors, suggesting that women with risk factors for GDM may be at increased risk for future MeS, even in the absence of GDM.<sup>23 24</sup> Overweight and excessive gestational weight gain have been linked to development of GDM and later cardiometabolic disorders.<sup>23 25–27</sup> Long-term follow-up studies on development of MeS among women at increased GDM risk are lacking.

Our cluster randomised controlled trial (RCT) in Finnish pregnant women at increased GDM risk showed that lifestyle counselling was effective in controlling the proportion of large-for-gestational-age new-borns and improving the women's diet, and preventing excessive gestational weight gain and decrease in physical activity.<sup>28–31</sup> One year after delivery, the prevalence of MeS among women with GDM risk factors was 16–18% depending on the criteria; with no differences between the intervention and usual care group.<sup>24</sup>

Our aim is to study MeS and its components 7 years postpartum among Finnish women who in early pregnancy were at increased risk of developing GDM (intervention or usual care), among women with early pregnancy GDM diagnosis and among women without GDM risk factors during pregnancy (healthy control). We also studied risk factors associated with the development of MeS 7 years postpartum.

## METHODS

### Participants and study design

The study is a 7-year follow-up of a cluster RCT on GDM prevention (ISRCTN33885819). Detailed descriptions of the design and methods of the original study have been published previously.<sup>32</sup> The study was conducted in 14 primary healthcare maternity clinics in Western Finland in 2007–2009, a 1-year postpartum follow-up in 2009–2011 and the 7-year follow-up in 2014–2016.

The primary aim of the trial was to prevent GDM and excessive gestational weight gain among pregnant women with an increased risk for GDM. Maternity clinics were randomised into seven intervention and seven control clinics. Pregnant women were recruited by nurses at their first visit (8–12 weeks' gestation) in maternity clinics. Women were eligible if they had at least one of the following GDM risk factors: age  $\geq 40$  years, prepregnancy body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup>, GDM or any sign of glucose intolerance in any previous pregnancy, a macrosomic baby ( $\geq 4500$  g) in any previous pregnancy or diabetes in first-degree or second-degree relatives. The main exclusion criteria were age  $< 18$  years, a GDM diagnosis at 8–12 weeks' gestation, twin pregnancy, physical restrictions that precluded exercise or a clinical history of chronic disease. A diagnosis of GDM was based on a 2-hour 75 g oral glucose tolerance test (OGTT) according to at least one of the following criteria: fasting plasma glucose of

$\geq 5.3$  mmol/L,  $> 10.0$  mmol/L at 1 hour or  $> 8.6$  mmol/L at 2 hours.<sup>33</sup>

The original intervention included individual counselling on weight gain, diet and physical activity by public health nurses during five routine visits to maternity clinics. The women in the control clinics received usual maternal care, which also included some lifestyle advice.

Of 888 pregnant women who participated in the baseline assessments at 8–12 weeks' gestation, 442 (50%) were eligible for the original study (intervention and usual care group) (figure 1). Further, 374 were excluded, of whom 174 due to a GDM diagnosis at 8–12 weeks' gestation (early GDM group). The healthy control group consisted of 176 women who did not meet the inclusion criteria.

Seven hundred and eighty-eight women were invited to participate in the follow-up study 7 years (mean 7.2, range 5.6–8.3) after delivery, and 289 women participated.

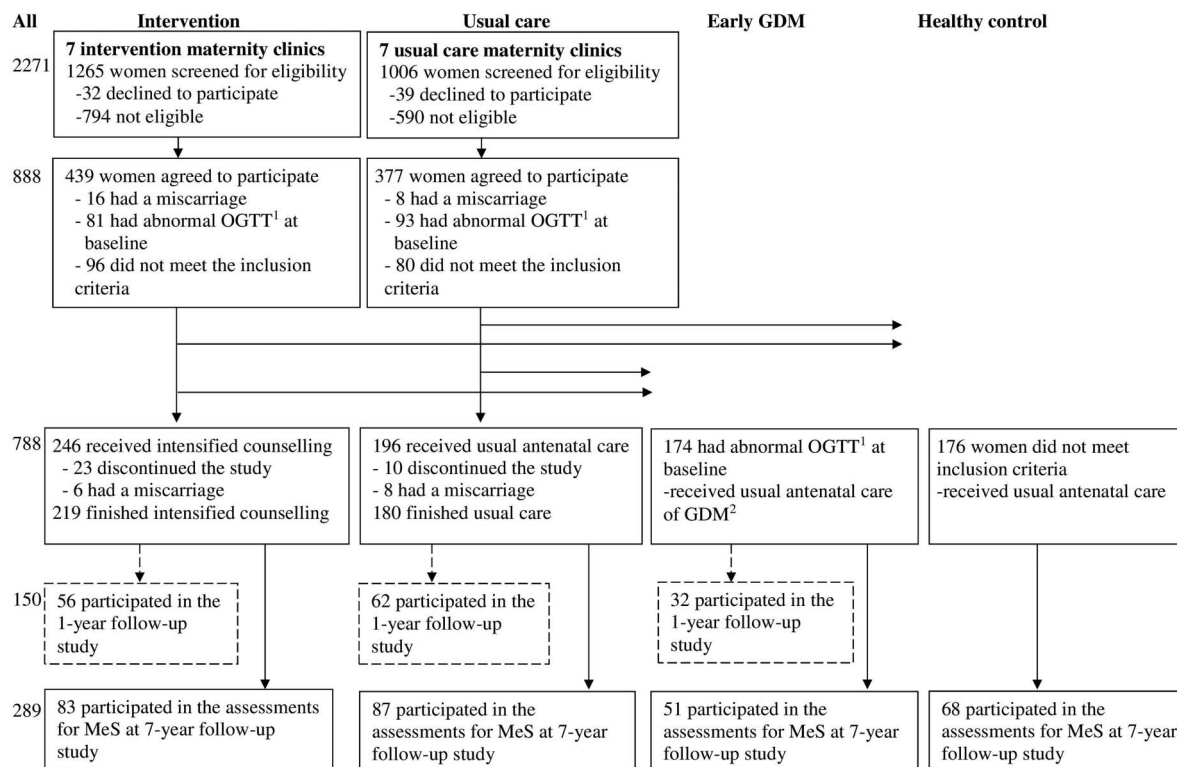
The study was conducted in accordance with the Declaration of Helsinki (2000), and it was approved by Pirkanmaa University Hospital District Ethics (Ref. number R14039). The participants completed a written informed consent before participation.

### Laboratory measurements

Information on maternal measurements by the nurses was obtained from the standard maternity cards. Height was measured at the first maternity care visit (8–12 weeks' gestation), and weight was measured at each maternity care visit, and at 1 and 7 years postpartum. Waist circumference was measured at 1 and 7 years postpartum, and the average of three measurements was used in the analysis. Blood pressure was measured in duplicate at each maternity care visit and at 1 and 7 years postpartum.

Blood samples for glucose, cholesterol, HDL cholesterol and triglyceride analysis after a 12-hour fast, and a 2-hour OGTT were collected at baseline and at 1 and 7 years postpartum. All blood analyses were performed at the UKK Institute. During the OGTT, the participants drank 75 g glucose in 330 mL water (Glucodyn, Ultimed, Finland), and the samples were taken after 60 and 120 min. Plasma glucose concentrations were measured fresh within 24 hours after the OGTT. Plasma samples for lipid analysis were stored frozen at  $-80^{\circ}\text{C}$  until analysed. Citric acid/fluoride and EDTA tubes were used for glucose and lipid analysis of venous blood. Glucose, total cholesterol, HDL cholesterol and triglyceride concentrations were determined in enzymatic assays using a Roche Cobas Mira Plus analyser. All testing was performed in duplicate.

MeS was diagnosed according to International Diabetes Federation (IDF) criteria.<sup>1</sup> The diagnosis was set if any three of the five criteria were present: increased waist circumference ( $> 80$  cm); elevated triglycerides ( $\geq 1.7$  mmol/L), or specific medication; reduced HDL cholesterol ( $< 1.3$  mmol/L), or specific medication, elevated fasting glucose ( $\geq 5.6$  mmol/L), or specific



**Figure 1** Flow diagram of the study. The two intervention groups (intervention and usual care), early gestational diabetes mellitus and healthy control groups were invited for follow-up measurements 7 years after intervention.

medication, and elevated blood pressure ( $\geq 130$  or 85 mm Hg), or specific medication.

### Statistical analyses

The background characteristics and descriptive information on components and the prevalence of MeS are reported as means and SDs or frequencies and proportions. The Wilson score method without continuity correction was used to calculate 95% CIs for prevalence. A  $\chi^2$  test was used to investigate whether distributions of categorical variables differed from one another. Continuous variables were normally distributed. We used one-way analysis of variance to compare means across groups. Differences in continuous variables between the healthy control or the early GDM group compared with the other three groups merged together were tested by independent samples t-test. Binary logistic regression models were used to obtain ORs and their 95% CIs to study associations between MeS and its explanatory variables. Explanatory variables were group (the intervention, the usual care, the early GDM and the healthy control as a reference group), age (continuous), BMI (continuous) and the five GDM risk factors which were used in entrance criteria to the original study: BMI  $\geq 25$  kg/m<sup>2</sup>, age  $\geq 40$  years, GDM or any sign of glucose intolerance in any previous pregnancy, a macrosomic baby ( $\geq 4500$  g) in any previous pregnancy, and diabetes in first-degree or second-degree relatives. Based on the rule of 10 events per variable, multivariable logistic

regression models were adjusted only for BMI and GDM or any sign of glucose intolerance in any previous pregnancy. The results were considered to be statistically significant if  $p < 0.05$ . All analyses were performed with SPSS software (V.20.0).

## RESULTS

### Background characteristics

**Table 1** shows the characteristics of the 289 women who participated in the follow-up study 7 years postpartum. The mean age of the participants was 37.8 years (range 25–52 years) and the mean number of deliveries was 2.5 (range 1–9). Twenty-nine (10%) women smoked frequently or occasionally. The most common inclusion criteria for the study were prepregnancy overweight or obesity, and diabetes in first-degree or second-degree relatives. Women with early GDM fulfil the inclusion criteria of being overweight ( $p < 0.001$ ) and having a history of GDM ( $p = 0.002$ ) more often than others. Healthy controls did not meet inclusion criteria (GDM risk factors) at baseline. The prevalence of overweight and obesity 7 years postpartum (53%, 69%, 80%) had stayed around the same level, or slightly increased, compared with early pregnancy (48%, 68%, 78%) among women in the intervention, usual care and early GDM group, respectively. Four women (2 in the early GDM and 2 in the healthy control group) had medication for type 2 diabetes. Sixteen (5%) women had medication for dyslipidaemias and eight (3%) for hypertension, with no



**Table 1** Background characteristics of women at 7 years postpartum

	Intervention (n=83)	Usual care (n=87)	Early GDM (n=51)	Healthy control (n=68)	All (n=289)
Age (years)	37.7±4.5	38.0±4.9	38.6±4.3	37.0±5.2	37.8±4.8
Weight (kg)	75.6±17.3	76.9±13.1	84.5±16.3	62.9±7.6	74.6±15.7
BMI (kg/m <sup>2</sup> )	27.2±5.5	28.1±5.1	30.1±5.6	22.7±2.5	26.9±5.4
BMI 25–29.9 kg/m <sup>2</sup>	17 (20)	39 (45)	41 (35)	12 (18)	86 (29)
BMI ≥30 kg/m <sup>2</sup>	27 (33)	21 (24)	23 (45)	0 (0)	71 (25)
Smoking					
No	73 (91)	77 (91)	45 (94)	57 (84)	252 (90)
Occasionally or daily	7 (9)	8 (9)	3 (6)	11 (16)	29 (10)
Education					
Basic or secondary education	25 (31)	25 (28)	19 (37)	20 (31)	89 (31)
Polytechnic education	28 (34)	40 (46)	20 (39)	29 (45)	117 (41)
University degree	29 (35)	23 (26)	13 (25)	16 (25)	81 (28)
Parity	2.4±1.0	2.6±1.2	2.6±1.6	2.5±1.0	2.5±1.2
1	8 (10)	12 (14)	6 (13)	6 (9)	32 (12)
2–3	66 (84)	60 (71)	35 (74)	50 (75)	211 (76)
≥4	5 (6)	12 (14)	6 (13)	11 (16)	34 (12)
GDM risk criteria (at 8–12 weeks' pregnancy)					
BMI ≥25 kg/m <sup>2</sup>	40 (48)	59 (68)	39 (78)	NA	138 (48)
Macrosomic child in any previous pregnancy	3 (4)	3 (3)	5 (10)	NA	11 (4)
GDM in any previous pregnancy	13 (16)	7 (8)	13 (39)	NA	33 (12)
Diabetes in first-degree or second-degree relatives	53 (64)	43 (49)	25 (50)	NA	121 (42)
Age ≥40 years	3 (4)	5 (6)	0 (0)	NA	8 (3)

Means and SDs or frequencies (and proportions) of participants (n=289). BMI, body mass index; GDM, gestational diabetes mellitus.

difference between groups. Eighty-one (28%) women reported hormonal contraception.

Women with early GDM had higher mean weight ( $p<0.001$ ) and BMI ( $p<0.001$ ) compared with women in the other three groups. Significant association between group and overweight ( $p<0.001$ ) and obesity ( $p<0.001$ ) was found, so that women with early GDM were more often overweight and obese than women in the other groups. Healthy controls, on the other hand, had lower mean weight ( $p<0.001$ ) and lower BMI ( $p<0.001$ ). They were less often overweight or obese compared with women in the other three groups, both of the associations being significant ( $p<0.001$ ). There were no other between-group differences in the background characteristics. Compared with baseline (at 8–12 weeks' pregnancy), the women had gained weight on average 3.1 kg (SD 7.0, range –33.2 to 25.1 kg). The groups did not differ statistically significantly from each other. The healthy control group seemed to have had gained less weight than the other three groups (1.8 vs 3.5,  $p=0.13$ ). Twelve (9%) women of the intervention group and seven (5%) women of the usual care group and none of the healthy control group had been diagnosed for GDM at 26–28 weeks' pregnancy.

### MeS and its components 7 years postpartum

The prevalence of MeS among all women was 19% (95% CI 15% to 25%) (table 2). Among women with

GDM risk factors, the prevalence was 14% (95% CI 9% to 21%), with no difference between the intervention (14%, 95% CI 8% to 25%) and the usual care group (15%, 95% CI 8% to 25%). The prevalence was highest among the early GDM group (50%, 95% CI 35% to 65%) and lowest among the healthy control group (7%, 95% CI 2% to 18%). Two (11%) of the 19 women with the GDM diagnosis at 26–28 weeks' gestation had MeS at 7 years postpartum.

Seventy-two per cent of the women exceeded the waist circumference limit of 80 cm (increased waist circumference) and almost half exceeded the limit of 88 cm (abdominal obesity). HDL was reduced ( $\leq 1.3$  mmol/L) among half of the women. All women with the MeS diagnosis exceeded the waist circumference of 80 cm. Women in the early GDM group had a larger mean waist circumference ( $p<0.001$ ), higher fasting glucose ( $p<0.001$ ), higher systolic blood pressure ( $p=0.047$ ) and higher TG ( $p<0.0001$ ). They more often exceeded the limits for increased waist circumference and abdominal obesity ( $p<0.001$  and  $p=0.002$ ), impaired fasting glucose ( $p<0.001$ ) and increased TG ( $p<0.001$ ) compared with the three other groups. Healthy controls had a smaller mean waist circumference ( $p<0.001$ ), lower systolic ( $p=0.01$ ) and diastolic ( $p=0.03$ ) blood pressure and higher HDL ( $p=0.02$ ), and they less often exceed the limits for increased waist circumference ( $p<0.001$ ) and decreased HDL ( $p=0.03$ ) compared with the other

**Table 2** Components of metabolic syndrome (MeS) and the prevalence of MeS according to International Diabetes Federation criteria

	Intervention (n=64–74)	Usual care (n=66–78)	Early GDM (n=40–45)	Healthy control (n=44–51)	All (n=217–248)	Missing values (N)*
Waist circumference (cm)*	89.9±13.0	90.9±12.8	97.9±14.6	79.5±6.5	89.5±13.5	0, 3, 0, 0
Waist ≥80 cm	52 (70)	59 (79)	42 (93)	24 (47)	177 (72)	
Waist ≥88 cm	41 (55)	42 (56)	32 (71)	6 (12)	121 (49)	
Fasting glucose (mmol/L)	5.2±0.5	5.2±0.4	5.6±0.5	5.2±0.4	5.3±0.5	5, 12, 3, 6
Fasting glucose ≥5.6 mmol/L or medication	10 (15)	7 (11)	21 (49)	4 (9)	42 (19)	
Systolic pressure (mm Hg)	119±13	118±12	122±11	114±14	118±12	2, 3, 1, 4
Diastolic pressure (mm Hg)	77±10	78±10	79±7	75±10	77±10	2, 3, 1, 4
Blood pressure ≥130 or ≥85 mm Hg or medication	10 (14)	13 (17)	8 (18)	6 (13)	37 (16)	
HDL cholesterol (mmol/L)	1.30±0.27	1.28±0.38	1.28±0.36	1.41±0.30	1.32±0.34	10, 0, 2, 1
HDL cholesterol ≤1.3 mmol/L or medication	33 (52)	41 (53)	25 (58)	18 (36)	117 (50)	
Triglycerides (mmol/L)	0.91±0.34	1.05±0.67	1.36±0.88	0.95±0.38	1.05±0.61	10, 0, 2, 1
Triglycerides ≥1.7 mmol/L	1 (2)	9 (12)	12 (28)	5 (10)	27 (12)	
Metabolic syndrome	9 (14)	10 (15)	20 (50)	3 (7)	42 (19)	10, 7, 5, 7

Means and SDs or frequencies (and proportions) of participants. GDM, gestational diabetes mellitus.

\*Number of missing values in the intervention, usual care, early GDM, healthy control groups, respectively.

groups. There were no differences in the components MeS between the intervention and usual care groups.

Fifty-five (27%) women did not meet the criteria for any MeS component: 14 (23%) women in the intervention group, 14 (22%) in the usual care group, 7 (18%) in the early GDM group and 20 (46%) in the healthy control group. Most women (n=115, 56%) met one or two MeS components.

### Risk factors of MeS

#### Univariable binary logistic regression models

In univariable logistic regression models, the OR for developing MeS 7 years postpartum among women with increased GDM risk during pregnancy (intervention and usual care) did not differ statistically significantly from the healthy control group (table 3). OR for MeS among women with early GDM was 21.0 (95% CI 4.47 to 98.7) compared with the healthy controls, and 6.0 (95% CI 2.7 to 13.2) compared with the intervention and the usual care groups (not presented). Prepregnancy BMI (OR 1.20, 95% CI 1.11 to 1.29, p<0.001), prepregnancy overweight or obesity (OR 8.06, 95% CI 3.21 to 20.2, p<0.001) and GDM or any sign of glucose intolerance in any previous pregnancy (OR 3.21, 95% CI 1.34 to 7.69, p<0.01) were associated with increased occurrence of MeS. The other GDM risk factors (macrosomic baby in any previous pregnancy, diabetes in relatives or age) were not associated with the MeS occurrence 7 years postpartum.

#### Multivariable binary logistic regression models

In a multivariable regression model 1, adjusted for prepregnancy BMI, the OR for developing MeS 7 years

postpartum among women with increased GDM risk during pregnancy (intervention and usual care) did not differ significantly from the healthy control group (table 3). Women with early pregnancy GDM had increased odds for MeS compared with the healthy control group (OR 9.18, 95% CI 1.82 to 46.20, p=0.007). Also increased prepregnancy BMI was associated with increased odds for MeS (OR 1.20, 95% CI 1.11 to 1.29, p<0.001). In a multivariable regression model 2, adjusted for BMI and GDM or any sign of glucose intolerance in any previous pregnancy, early GDM when compared with the healthy control group (OR 97.75, 95% CI 1.50 to 40.0, p=0.014), and increased prepregnancy BMI (OR 1.19, 95% CI 1.09 to 1.31, p<0.001) were associated with the MeS occurrence. GDM or any sign of glucose intolerance in any previous pregnancy was not associated with the MeS occurrence 7 years postpartum.

#### Dropout analyses

Data for 7-year follow-up for MeS were available for 37% of the women who were invited to participate after 7 years (n=788). Of the women invited to follow-up study, 17% were not willing to participate, 26% were out of reach and 20% only completed a follow-up questionnaire. Dropout analyses showed that the women participating the 7-year follow-up study were older at the baseline (30.2 vs 29.2, p<0.01), were less often frequent or occasional smokers before pregnancy (17% vs 30%, p<0.001) and were higher educated (university degree 28% vs 19%, p<0.009) compared with the non-participants. There were no differences between the groups in other background characteristic (BMI, parity

**Table 3** Logistic regression models with ORs and 95% CIs and p values (n=217) for occurrence of metabolic syndrome (according to International Diabetes Federation criteria) by its explanatory variables (group, age, body mass index and five gestational diabetes mellitus risk factors)

	Univariable logistic regression models		Multivariable logistic regression model 1		Multivariable logistic regression model 2	
	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
Group (reference=healthy control)						
Intervention	3.44 (0.71 to 16.8)	0.13	1.64 (0.31 to 8.79)	0.56	1.29 (0.23 to 7.18)	0.77
Usual care	3.15 (0.65 to 15.3)	0.16	1.39 (0.26 to 7.41)	0.70	1.17 (0.21 to 6.41)	0.85
Early GDM	21.0 (4.47 to 98.7)	<0.001	9.18 (1.82 to 46.20)	0.007	7.75 (1.50 to 40.0)	0.014
Age (early pregnancy, continuous)	1.07 (1.00 to 1.15)	0.052				
BMI (prepregnancy, continuous)	1.20 (1.11 to 1.29)	<0.001	1.17 (1.08 to 1.28)	<0.001	1.19 (1.09 to 1.31)	<0.001
GDM risk factors during early pregnancy						
BMI $\geq 25$ kg/m <sup>2</sup> (prepregnancy)	8.06 (3.21 to 20.2)	<0.001				
A macrosomic baby ( $\geq 4500$ g) in any previous pregnancy	0.74 (0.09 to 6.34)	0.78				
GDM or any sign of glucose intolerance in any previous pregnancy	3.21 (1.34 to 7.69)	<0.01			2.07 (0.74 to 5.78)	0.17
Type 1 or 2 diabetes in first-degree or second-degree relatives	1.04 (0.52 to 2.09)	0.91				
Age $\geq 40$ years	0.74 (0.09 to 6.34)	0.78				

GDM, gestational diabetes; BMI, body mass index.

Univariable logistic regression models: separate models for each explanatory variables without adjustments.

Multivariable logistic regression model 1: adjusted for one explanatory variable (BMI).

Multivariable logistic regression model 2: adjusted for two explanatory variables (BMI, and GDM or any sign of glucose intolerance in any previous pregnancy).

or GDM risk criteria), laboratory measurements or group distribution.

## DISCUSSION

Seven years postpartum, MeS was diagnosed among 14% (95% CI 9% to 21%) of the women with risk factors for GDM during pregnancy. The MeS prevalence was highest among women with a diagnosis of early GDM (50%, 95% CI 35% to 65%), and lowest among the healthy control group (7%, 95% CI 2% to 18%). Diagnosis of early GDM and increased prepregnancy BMI were the strongest risk factors for developing MeS. Prepregnancy and present overweight or obesity were common among women with GDM risk factors, and especially among those with early GDM.

In a prospective Finnish population study among women aged 36 and 39, the MeS prevalence was 18% and 23% according to the IDF definition.<sup>18</sup> Compared with these levels, the MeS prevalence in our study was somewhat lower among women with an increased risk for GDM. Therefore, increased GDM risk seemed not to be associated with a higher MeS prevalence 7 years postpartum. Compared with the women aged 35–45 and 25–60 years in a Finnish population study in 2012, however, the women with increased GDM risk were more often obese (28% vs 16%),<sup>34</sup> and abdominally obese (waist circumference  $>88$  cm) (56% vs 30%).<sup>35</sup> These differences are relevant, as especially abdominal obesity is the most important independent factor in the development of MeS.<sup>10</sup> The finding may indicate future risk in our participants. Overweight was also the most common inclusion criteria (GDM risk criteria) in our study, which apparently had an influence on the high prevalence of overweight and obesity postpartum.

However, the intervention (14%, 95% CI 8% to 25%) and usual care (15%, 95% CI 8% to 25%) group did not differ from each other in the prevalence of MeS or its components after 7 years, even though counselling had positive effects on women's weight gain and lifestyle during pregnancy.<sup>28–31</sup> However, 7 years are a long time, and several factors have affected women's lifestyle. Mothers with small children may have had lack of time and may have got tired to follow the recommended lifestyle habits which were discussed during the intervention. Further, participation in a GDM prevention study may have improved health consciousness and lifestyle habits in the intervention and the usual care group. Additionally, also usual care includes some lifestyle counselling in Finland. Dropout rate was rather high, but since it was non-differential for group, the possibility for bias in the differences between groups remains low.

Our subgroups differed in the prevalence of MeS. Women in the early GDM and women in the healthy control groups represented the extremes (50% vs 7%). Earlier studies have found that history of GDM is strongly associated with a higher risk of future MeS and other cardiometabolic disorders.<sup>36 37</sup> In a Finnish

cohort among 240 women, the risk of developing MeS 2–6 years after pregnancy complicated by GDM was 2.4-fold higher compared with normal pregnancy.<sup>21</sup> In our earlier report of the same original trial, the MeS prevalence among women with early GDM was already elevated (31%) at 1-year postpartum compared with the intervention group (11%).<sup>24</sup> Seven years postpartum, the MeS prevalence among women with early GDM had increased to 50%. Further, women with early GDM had increased odds for MeS compared with other three groups (intervention, usual care and healthy controls). The association remained after adjustment for BMI. Also history of GDM was associated with the MeS occurrence. These findings attest the later cardiometabolic risk associated with GDM. Nevertheless, GDM diagnosis at 26–28 weeks' gestation among the 19 women in the intervention and usual care group seemed not to be associated with higher MeS prevalence in our data. Therefore, our study suggests that GDM was associated with an increased MeS prevalence 7 years postpartum if it was diagnosed in early pregnancy (8–12 weeks). Women with early GDM are a special high risk group for later cardiometabolic disorders. A large meta-analysis found that women with early pregnancy GDM were at a twofold risk for future type 2 diabetes compared with women with later GDM.<sup>26</sup>

Several cardiometabolic risk factors were clustered in the women in the early GDM group. In early pregnancy, they had been more often overweight or obese, and 7 years postpartum, they still were more often overweight or obese, and had components of MeS more frequently than the other women. Further, compared with Finnish female population, the women with early GDM in our study were three times more often obese (45% vs 16%),<sup>34</sup> and over two times more often abdominally obese (waist circumference >88cm) (71% vs 30%).<sup>35</sup> Present obesity partly explains the increased MeS prevalence. Clustering of lifestyle-related risk factors is common.<sup>38–40</sup> Pregnancy-related weight retention tends to be highest among those women who have been overweight or obese before pregnancy.<sup>41 42</sup> Further, many women retain weight after pregnancy, and the mean weight gain associated with parity is around 0.5–3.2 kg, with a high personal variation.<sup>39 43 44</sup> In a Finnish population study, parity-related weight retention was associated with visceral obesity.<sup>45</sup>

High prevalence of obesity promoting insulin resistance was probably the common denominator for the increased prevalence of early pregnancy GDM and MeS after 7 years.<sup>46 47</sup> This finding clearly underlines that it is particularly important to invest in lifestyle counselling among overweight and obese pregnant women entering maternity care. Prevention of excessive weight gain during pregnancy and promoting postpartum weight reduction by individually tailored lifestyle modifications have been effective against weight retention, and in preventing further cardiometabolic disorders, such as MeS

in parous women.<sup>48–52</sup> A weight reduction of 5–10% is associated with significant decreases in cardiometabolic risk factors.<sup>53 54</sup> The possibilities for reaching pregnant women in many countries are good due to maternity care systems, but there is often lack of long-term follow-up as the healthcare providers change.<sup>55</sup> Actions to increase cooperation between different providers are needed.

Healthy controls were healthier than the other three groups with GDM risk factors, as assessed by components and the prevalence of MeS at 7 years postpartum. Also compared with the Finnish population, they represented an unexceptionally healthy group, in what comes to the prevalence of obesity (0% vs 16%), abdominal obesity (12% vs 30%) as well as MeS (7% vs 17–23%).<sup>34 35</sup> The results suggest that keeping normal weight and prevention of excessive pregnancy-related weight retention are important in not only preventing GDM, but also in preventing later MeS.

### Strengths and limitations

Our study has several strengths. It was a long-term follow-up, from early pregnancy until 7 years postpartum. It was also one of the first follow-up studies of gestational trials, in which the prevalence of MeS has been determined among women with risk factors for GDM. To the best of our knowledge, the only previous follow-up report was ours on the MeS prevalence among women with GDM risk factors at 1-year postpartum.<sup>24</sup> In general, there is a limited amount of studies of the MeS prevalence among reproductive-aged female populations, even though obesity is rapidly increasing worldwide, especially among young adults.<sup>11 56</sup> Our study results include data of the MeS prevalence among different risk groups—women with an increased GDM risk, women diagnosed with early GDM and healthy pregnant women. Also associations between risk factors assessed in early pregnancy and MeS 7 years postpartum have not been identified earlier. Our original trial<sup>32</sup> was one of the largest RCTs about preventing the development of GDM in women with GDM risk factors.

After 7 years, the recruitment of the women of the original study was difficult, and eventually, 37% of the invited women entered the measurements for analyses of MeS. Thirty-seven per cent were either not willing to participate or only completed the follow-up questionnaire. Dropout analyses showed that the results may have been affected by a healthy selection bias, as the women who participated in the follow-up study were less often smokers and were higher educated. On the other hand, the bias affected all four subgroups entering the follow-up study, as they did not differ from each other regarding to the participation rate. The subgroups were relatively small, which weakened the power to compare the subgroups. The study was implemented among Finnish women, and thus, the results can only be generalised to Caucasian populations.

## CONCLUSIONS

Seven years postpartum, MeS was diagnosed among 14% of the women with risk factors for GDM during pregnancy, which is less than average. The MeS prevalence was the highest among women with a diagnosis of early GDM (50%), and the lowest among the healthy control group (7%). Early GDM diagnosis and increased pre-pregnancy BMI were the strongest risk factors for developing MeS. Prepregnancy and present overweight or obesity were common among women with GDM risk factors, and especially among those with early GDM. Overweight and obese women and especially those with early GDM should be monitored and counselled for cardiometabolic risk factors after delivery. Prevention of pregnancy-related weight retention, including excessive gestational and postpartum weight gain, is important for the prevention of MeS. Overweight and obesity among reproductive-aged women is increasing, which represents even a greater challenge in monitoring and managing risk factors for chronic diseases. Larger population studies on the MeS prevalence and evaluation of prevention strategies are needed among reproductive-aged women, especially among those with GDM risk factors.

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