Antenatal lifestyle intervention for limitation of gestational weight gain:

The Norwegian Fit for Delivery Trial

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1. Preface

1.1 Acknowledgements

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Linda Reme Sagedal

1.2 Summary of thesis

Background: The rising prevalence of overweight and obesity over the last decades, both in Norway and around the globe, has increased focus on lifestyle and weight gain during pregnancy (1-3). Large gestational weight gain is associated with increased risk of obstetrical complications and increased risk of later obesity for both mother and child (1-3). Prior to 2009, there were few trials published that tested the effectiveness of an antenatal lifestyle intervention in limiting gestational weight gain and improving obstetrical outcomes. The Norwegian Fit for Delivery trial was therefore initiated.

Aims: The overall aim of the NFFD trial was to examine the results of providing an antenatal lifestyle intervention combining diet and physical activity elements to a general population in a "real-world" setting, starting in the first half of pregnancy. The endpoints that are presented in the current thesis include gestational weight gain, the proportion of large newborns, obstetrical outcomes, markers of glucose metabolism, and weight retention at 12 months postpartum.

Methods and Materials: The NFFD trial was performed in southern Norway from 2009-2014, including healthy nulliparous women with a singleton pregnancy of ≤20 weeks of gestation, pre-pregnancy BMI ≥ 19 kg/m^2, and age ≥ 18 years. The intervention included dietary counseling based on ten recommendations, delivered twice by telephone, and access to twice-weekly supervised exercise sessions of 60 minutes at local gyms. There was individual, blinded randomization of participants to intervention or routine prenatal care, with a one-to-one ratio. Participants were monitored with weighing, blood tests, ultrasound examinations and questionnaires. Offspring were weighed at delivery. Data at delivery was analyzed according to the principles of Intention to treat, using Chi square and Student t-test, as well as multiple logistic regression analysis, and linear mixed models analysis to assess weight change over time. Analyses of glucose metabolism and postpartum weight retention were adjusted to account for missing participants, using multiple linear regression analysis, logistic regression analysis and linear mixed models analysis.

Results: Of 606 women included in the NFFD trial, 591 were analyzed at delivery, 557 were analyzed at 30 weeks gestation, and 391 were analyzed at 12 months postpartum. The intervention resulted in a significant reduction of gestational weight gain (1.3 kg from pre-pregnancy to term delivery, p=0.009), and significantly higher self-reported diet score and physical activity level in late pregnancy compared to routine prenatal care, but no reduction in the proportion of large newborns or the incidence of obstetrical complications. There was a trend toward decreased weight retention at 12 months postpartum for women who received the intervention compared to women who received routine care, but the effect of intervention was only statistically significant among women who were

compliant with the intervention. At 30 weeks of gestation, the NFFD intervention resulted in significantly lower leptin values for the whole intervention group compared to routine care, and a trend toward lower insulin resistance among normal-weight intervention participants compared to normal-weight controls. Overweight/obese participants showed no positive effect of intervention on glucose metabolism.

Conclusions and Future Perspectives: The NFFD antenatal lifestyle intervention successfully modified diet and physical activity habits in pregnancy, reduced gestational weight gain and lowered leptin levels compared to routine prenatal care. Similar to the findings of several recent antenatal lifestyle trials, the NFFD intervention demonstrated little measurable effect on the other outcomes measured. Particularly for women who enter pregnancy overweight or obese, early first trimester or pre-conception intervention may provide greater effect. Intervention strength and intervention compliance are also important considerations when planning future trials. The antenatal period is a "window of opportunity" for improving the health of two individuals, but should be seen in a continuum along with care of non-pregnant young women and continued care post-partum. Although there was no effect of intervention on size of the newborns, small changes to the intrauterine environment may have a lasting influence on their future health.

1.3 List of Abbreviations

ACOG = American College of Obstetricians and Gynecologists

ADA = American Diabetes Association

BMI = Body Mass Index

CARDDIP = Cardiovascular Risk Reduction Diet in Pregnancy

CI = Confidence Interval

CONSORT = Consolidation of the Standards of Reporting Trials

CRP = C - reactive protein

DEXA = Dual-Energy X-ray Absorptiometry

ETIP = Exercise Training in Obese Pregnant Women

HAPO = Hyperglycemia and Adverse Pregnancy Outcomes

HOMA-IR = Homeostatic Model Assessment of Insulin Resistance

HUNT = Helse Undersøkelsen i Nord Trøndelag

IADPSG = International Association of Diabetes and Pregnancy Study Groups

IOM= National Academy of Sciences Institute of Medicine (United States)

IPAQ = International Physical Activity Questionnaire

IPD = Individual Patient Data

iWIP = International Weight Management in Pregnancy

LiP = Lifestyle in Pregnancy

MET = Metabolic Equivalent of Task

MoBa = Norwegian Mother and Child Cohort Study

MODY = Maturity-onset diabetes of the young

mTOR = mammalian Target of Rapamycin

NFFD =Norwegian Fit for Delivery

NHANES = National Health and Nutrition Examination Survey

NICE = National Institute for Health and Care Excellence (United Kingdom)

OR = Odds Ratio

PEARS = Pregnancy, exercise and nutrition research study

REK = Regional Committee for Medical Research Ethics

RR = Relative Risk

UPBEAT = UK Pregnancies Better Eating and Activity Trial

WHO = World Health Organization

2. Introduction

2.1 Background for the Norwegian Fit for Delivery Trial

The Norwegian Fit for Delivery (NFFD) trial was conceived in response to two population trends that affected clinical practice in Norway during the early 2000´s: an increased proportion of overweight and obese women of reproductive age (3) and a greater proportion of large newborns compared to earlier decades (4). Concurrently, there was evidence that Norwegian pregnant women were less physically active than recommended, and greatly reduced their activity levels as pregnancy progressed (5, 6). The idea arose that by providing pregnant women with the opportunity to improve diet and increase physical activity, gestational weight gain could be modified and pregnancy health could be improved. Ideally, a successful intervention would be an aid in abating the obesity epidemic, as population studies show that excessive gestational weight gain is associated with later obesity for both mother and child (2).

2.2 Overweight and obesity

The World Health Organization (WHO) has defined weight classes based on body mass index (BMI), kg/m^2, with BMI of 18.5-24.9 kg/m^2 classified as normal weight, BMI of 25-29.9 kg/m^2 classified as overweight and BMI >30 kg/m^2 classified as obesity (7). According to the WHO, more than 1.4 billion of the world's inhabitants over the age of 20 were overweight in 2008, when the protocol for the NFFD trial was written, and 65% of the world's population lived in a country where mortality was greater from overweight and obesity than from underweight (7). In Norway, the Helse Undersøkelsen i Nord-Trøndelag (HUNT) study found that the proportion of women with BMI ≥25 kg/m^2 increased from 43% in 1984-1986 to 61% in 2006-2008 and the proportion of obese women increased from 13% to 23% during the same period (8). Importantly, the youngest age groups had the greatest increase in obesity (8, 9). The findings in Norway matched the global trends that were found in the same period, with an increase in mean BMI for women worldwide of 0.5 kg/m^2 per decade during the period 1980-2008, and a near-doubling of the prevalence of obesity among women during the same period, from 7.9 to 13.8% (10). According to this global survey, the United States was the developed country with the highest prevalence of overweight and obesity in 2008 (10). Disturbingly, the prevalence rates found in HUNT in 2006-2008 were similar to those found for women in the United States during the same period in the National Health and Nutrition Examination Survey (NHANES): 64.1% and 35.5% for overweight and obesity respectively (11).

Overweight and obesity are important contributors to lifetime risk of non-communicable diseases, such as diabetes, cardiovascular disease, musculoskeletal disorders, and some forms of cancer (7,

12). For women of reproductive age, overweight and obesity increase the risk of pregnancy complications such as gestational diabetes mellitus, thromboembolism, stillbirth, and hypertensive disorders including preeclampsia, a serious and complex disorder usually characterized by hypertension and proteinuria (13). Population studies demonstrate an association between overweight/obesity and delivery complications, particularly the risk of cesarean section (13, 14). There is also a strong association between increased maternal pre-pregnancy BMI and higher birth weight of the newborn (13, 14).

2.3 Gestational weight gain

The high prevalence of overweight and obesity has resulted in an increased interest in maternal weight gain during pregnancy. Several authorities have concluded that preventive efforts among pregnant women are required in order to make a lasting impact on the obesity epidemic, and limit the associated burden of non-communicable diseases (2, 15, 16). For the expectant mother, excessive gestational weight gain is associated with an increased risk of postpartum weight retention and later obesity (17, 18). For the fetus, gestational weight gain, independent of maternal pre-pregnancy weight status, has been shown to influence birth weight, (19-21) and adiposity (21), and to affect the risk of later obesity (2, 22, 23). This suggests that limitation of maternal weight gain has the potential to alter fetal metabolism and reduce the lifetime risk of obesity and disease (2, 24).

Gestational weight gain consists of several components, estimated as follows for a pregnancy at term with a hypothetical 12.5 kg weight increase: the fetus (3.4 kg), the placenta (0.7 kg), amniotic fluid (0.8 kg), increased size of the uterus (1.0 kg), breast enlargement (0. 4 kg), increased blood volume (1.4 kg), extracellular fluid (1.5 kg), and maternal fat deposition (3.3 kg) (25). Historically, limited gestational weight gain (approximately 7 kg) was encouraged from the 1930's, largely in an effort to reduce the risk of preeclampsia (26). This shifted during the 1960's and 1970's, due to the observed association between low gestational weight gain and prematurity and low birth weight (27). In 1990, the US National Academy of Sciences Institute of Medicine (IOM) issued guidelines for recommended gestational weight gain that were designed to optimize fetal outcome. The guidelines were, for the first time, differentiated according to maternal pre-pregnancy BMI status (28). In 2009, these recommendations were updated, with specified weight gain targets for obese women, and BMI categories adjusted to fit WHO classifications. The current gestational weight gain recommendations are 12.5-18 kg (0.5-0.6 kg/week) for underweight, 11.5-16 kg (0.4-0.5 kg/week) for normal-weight, 7-11.5 kg (0.2-0.3 kg/week) for overweight, and 5-9 kg (0.2-0.3 kg/week) for obese women, where rates are specified for the second and third pregnancy trimesters (29). The recommendations are not without controversy, with suggestions that weight gain limits for normal-weight women may be

unnecessarily low (30) and some evidence that obese women can benefit from even tighter control of weight gain (31, 32) while other evidence supports the need for modest weight gain also in this group (33). Several large cohort studies have shown that weight gain above IOM limits is associated with increased risk of pregnancy complications such as gestational diabetes and preeclampsia, delivery by cesarean, delivery of a large newborn (34-36), and postpartum weight retention (36). Nevertheless there is evidence that a large proportion of pregnant women exceed recommended weight gain limits, both in the United States (37) and in Norway (38, 39), and that recommendations alone have little effect on weight gain patterns (40).

2.4 Large Newborns

Large newborns are classified using several definitions. Infants exceeding weight thresholds of 4 or 4.5 kg at birth are defined as macrosomic, literally meaning "big bodied" (41). Additionally, infants with weight at the highest end of a population distribution for a given gestational length, usually the upper tenth percentile, are classified as large for gestational age. Size for gestational age can be further differentiated based on the neonate's sex and the particular population studied, as both sex and ethnicity affect fetal growth (42, 43). Ponderal index (g/m^3) is analogous to BMI and has been used to identify infants with greater adiposity at birth (44). There is currently no consensus as to which classification of large newborns has greatest clinical relevance. For the purpose of this thesis, the term macrosomia will be used when describing findings related to large newborn.

The Medical Birth Registry of Norway processes data from all births in Norway, including birth weight. Data shows that average birth weight (see figure 1) and the proportion of infants with weight

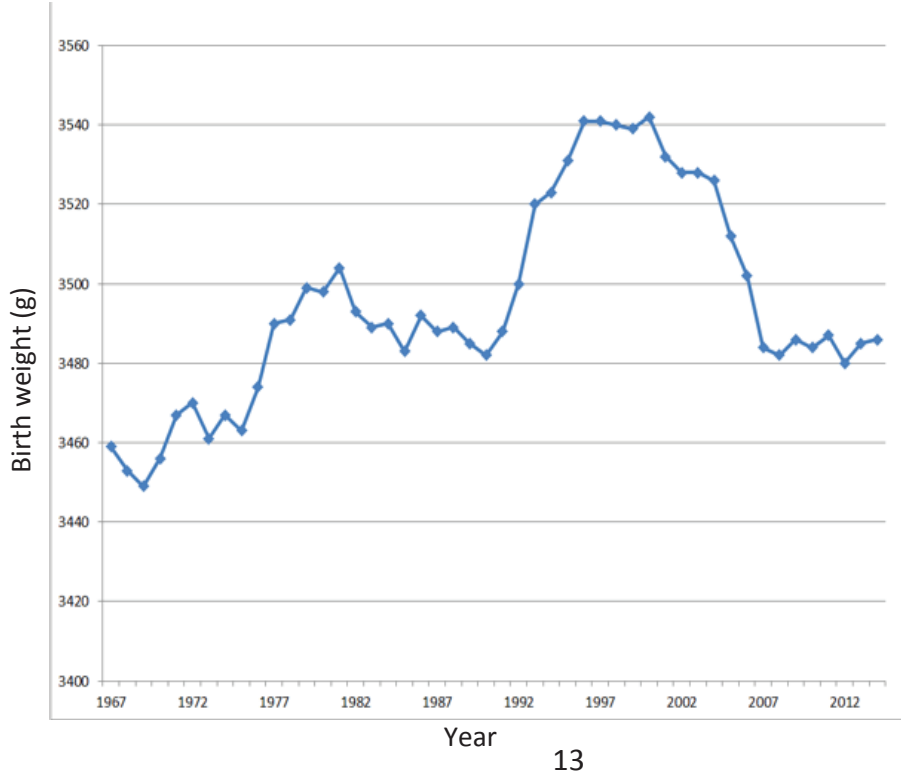

Figure 1: Average birth weight, 1967-2014. (Source: Norwegian Institute of Public Health, 2016)

exceeding 4000 g and 4500 g (see figure 2) all increased from 1990 to 2000 and thereafter began to decline, eventually returning to levels found during the 1980's. Although theories have been offered to explain these fluctuations (45), the underlying causes remain unknown. In 2008, when the NFFD study was being planned, information was available for births up until 2005, at which time 19.6% of newborns had a birth weight >4000 g and 3.9% had a birth weight >4500 g (4).

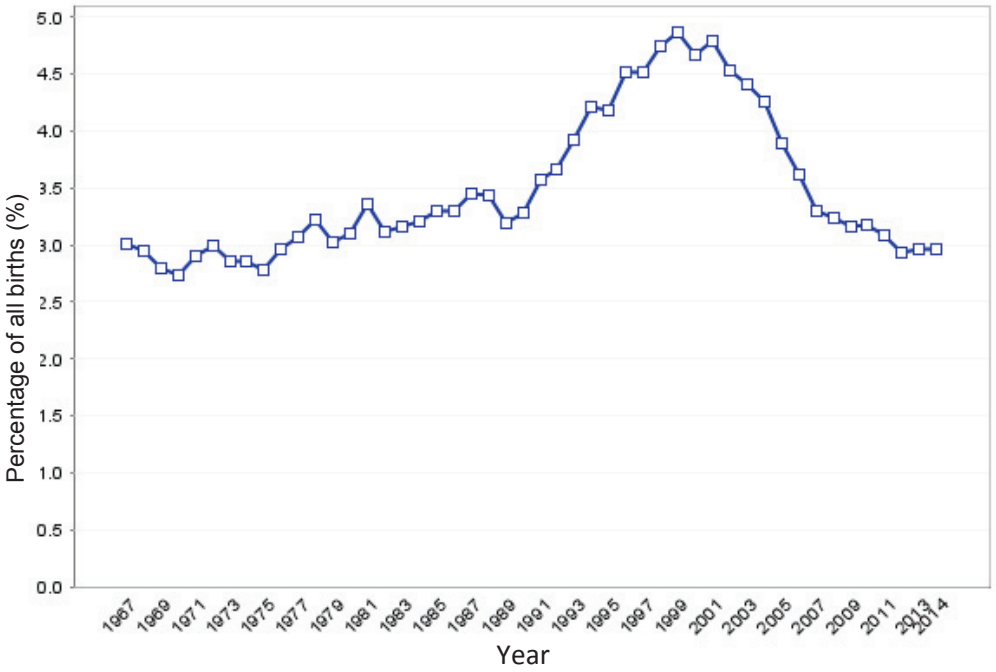

Figure 2: Percentage of newborns with birth weight >4.5 kg (Source: Medical birth registry of Norway, 2016)

Macrosomia is associated with adverse maternal and neonatal outcomes. At delivery there is increased risk of shoulder dystocia, vaginal tearing, hemorrhage and cesarean section (41). For the child there is immediate risk of birth trauma, hypoglycemia, respiratory distress syndrome, and admission to the neonatal intensive care unit (46). Later in life, there is increased risk of obesity (47), cardiovascular and metabolic disease (48), and certain forms of cancer (49). Macrosomia at birth is proposed as a component of the trans-generational transmission of obesity risk.

Elevated maternal pre-pregnancy BMI appears to be the strongest predisposing factor for large weight of the newborn (46, 50). Diabetes mellitus, both pre-gestational (type 1 and 2) and gestational, is also a known risk factor for macrosomia (46). Maternal glucose levels are shown to have a linear association with fetal growth and risk of large newborns (51, 52) and treatment of hyperglycemia has been proven to reduce risk of macrosomia at delivery (53). Although maternal overweight and hyperglycemia often coincide, these elements are found to be independently positively correlated with macrosomia and fetal adiposity (54). The increased prevalence of both obesity and diabetes are proposed to explain the observed global increase in macrosomia (43).

Other known risk factors for macrosomia are prior delivery of a macrosomic newborn, ethnicity, parity, male fetal sex, parental height, and maternal age (41, 46), none of which are amenable to intervention. However, gestational weight gain, dietary intake, and physical activity level are all known to affect fetal growth (46, 55) and are all potentially modifiable. Theoretically, by influencing weight gain, diet and physical activity, maternal glucose levels may also be affected--and thereby risk of diabetes in the present and subsequent pregnancies. Limitation of gestational weight gain also has the potential to reduce inter-pregnancy weight gain, and thereby prevent an increase in maternal pre-pregnancy BMI in subsequent pregnancies (56).

2.5 The Randomized Controlled Trial

A randomized controlled trial is a study in which participants are randomly allocated to receive one of several interventions (57). An intervention may consist of treatment, such as medication, but it may be more broadly defined as any "clinical maneuver" that affects health (57, 58). The group receiving the intervention is compared to a control group, which receives placebo, standard care or simply no intervention (57, 59). By randomly assigning a sufficiently large number of participants to intervention or control groups, it is expected that any differences in outcome between groups can be explained by the intervention, rather than by the characteristics of the participants (58). The randomized controlled trial has been described as "one of the simplest, most powerful, and revolutionary tools of research" (57), and forms the basis for evidence-based medicine (60). The highest level of evidence (Level 1) is reserved for findings demonstrated by several large randomized controlled trials (61).

2.6 Diet in pregnancy

The word "diet" is derived from the Greek "diaita", meaning "to lead one's life" (62), indicating an age-old acknowledgement of the link between nutrition and health. Available food and drink have changed dramatically over the past decades, both in content and quantity, and in both high-income and low-income countries. Industrialized foods high in calories, sugar, and fat have become widely available, and are considered an important element of the obesity epidemic (1). This can be demonstrated in the reports of the Global Burden of Disease Study, performed between 1990 and 2015. In 1990, the leading risk for disability-years was childhood under-nutrition, while this fell to fifth place in 2015 (63). Conversely, in 2015, three of the largest contributors to disability-years were conditions associated with over-nutrition: high systolic blood pressure, high fasting glucose, and high BMI (63, 64). These changes have also affected the Norwegian population, as evidenced by the increase in overweight and obesity already described, and by the increase in sale of sugar and sugar-

containing soft drinks that was documented between the late 1980's and the first decade of the 2000's (3, 45).

Diet has long been recognized to affect obstetrical risk, and the first Norwegian textbook of obstetrics, published in 1911, included a recommendation from Brandt that "… overeating is as harmful for the woman as it is for the fetus" (65). The evidence of diet's importance for maternal pregnancy health has increased dramatically in recent years, mostly based on epidemiological studies (66). For example, dietary patterns high in vegetables, fruits and water are linked to a reduction in obstetrical complications such as gestational diabetes, preterm birth and preeclampsia (66-69). Prior to the NFFD trial, there was evidence from a Norwegian randomized controlled trial that a cholesterol-lowering diet might reduce the risk of preterm birth (68), a finding which has later been confirmed by additional trials (70).

Although there was limited information on maternal dietary factors associated with excessive gestational weight gain at the start of the NFFD trial, it was logical to assume that women with excessive gestational weight gain were over-nourished in pregnancy relative to their energy requirements, determined by their basal metabolic rate, gestational length and physical activity level; population data now confirm that women with excessive gestational weight gain have higher energy intake than those with lower gestational weight gain (71). There is evidence from population studies that certain dietary patterns are associated with increased gestational weight gain, such as the "fast food" pattern (72) and high intake of sweets snacks and soft drinks (73), while others, such as the New Nordic diet, have recently been associated with reduced risk of excessive gestational weight gain (38).

Prior to the start of the NFFD trial, only three small randomized controlled trials of dietary interventions to limit gestational weight gain had been published (74-76) , excluding interventions provided to women with known diabetes, pre-gestational (77) or gestational (78) (See Appendix). Wolff, in a Danish study of 50 obese women, found reduced gestational weight gain following an intensive dietary intervention (76), while two smaller studies of young and low-income Afro-American women showed no effect of dietary counseling on gestational weight gain (74, 75).

The effect of maternal diet on fetal growth and health may be even more complex. The fetus is dependent on nutrients transported across the placenta, the supply of which is influenced by maternal intake (79). Randomized, controlled trials of dietary interventions in populations with under-nutrition have demonstrated effect in increasing birth weight and reducing the risk of low

birth weight (80). Prior to the start of the NFFD trial, there was evidence from randomized trials that diet combined with glucose monitoring and insulin could reduce birth weight and macrosomia risk in diabetic mothers (78), but very limited information on the ability of diet alone to modify macrosomia risk. The trial described by Wolf et al. showed no effect on offspring birth weight despite reduced gestational weight gain (76).

2.7 Physical activity in pregnancy

Physical activity is defined as any bodily movement produced by the contraction of skeletal muscles, while exercise is physical activity consisting of planned, structured and repetitive bodily movements done to improve one or more components of physical fitness (81). Aerobic exercise is physical activity that stimulates breathing and blood circulation (82), while resistance exercise develops muscle strength (83). Inadequate physical activity is an integral part of the obesity epidemic, and an underlying cause of non-communicable diseases such as type 2 diabetes and cardiovascular disease (84). It is estimated that sedentary lifestyle was responsible for >5.3 of the 57 million premature deaths that occurred in 2008 (84). Physical inactivity appears to be increasing world-wide, particularly in high-income countries, and rates are higher among women than men (85). In a global report from 2012, 45% (95% CI 18.9, 76.6) of Norwegian women over the age of 15 are described as inactive, higher than the mean for the European region (85).

Recommendations regarding physical activity in pregnancy have changed substantially over the last decades. Brandt's "Lærebok I Fødselshjelp" from 1911 advised that "… bicycling, dance, swimming, tennis, skiing, etc., are forbidden" during pregnancy (65). During the 1950's, American physicians recommended that pregnant women limit their activity to walking one mile (1.6 km) per day, divided into smaller lengths, while recommendation in the 1980's had evolved to allow aerobic exercise as long as it was limited to 15 minutes and did not cause a rise in heart rate above 140 beats/minute (86). These restrictions were based on concerns that physical activity could be harmful, particularly for the fetus. Active muscle use might compete with the uterus for supply of blood and glucose, causing growth restriction; exercise might lead to preterm labor; and aerobic activity might increase core temperature, which is potentially teratogenic in early pregnancy (86). However, there are also dangers associated with inactivity in pregnancy, including increased risk of venous thromboembolism, bone demineralization, loss of muscle mass and excessive gestational weight gain (81). Since 2002, the American College of Obstetricians and Gynecologists (ACOG) has advocated regular physical activity in pregnancy, citing the failure of epidemiologic studies to show a consistent association between physical activity and either preterm birth or growth retardation (87).

A 2006 Cochrane review of randomized controlled trials examining aerobic exercise in pregnancy concluded that such physical activity increased fitness, although there was insufficient evidence to conclude on other risks or benefits for either mother or child (82). Prior to the start of the NFFD trial, several randomized controlled trials demonstrated the protective effect of antenatal pelvic floor exercises in preventing later urinary incontinence (88). Kardel et al. demonstrated that duration of the second stage of labor in a population of 59 nulliparous women was inversely associated with their aerobic fitness in late pregnancy (89).There was also epidemiological evidence suggesting that regular physical activity could reduce risk of gestational diabetes (90, 91), lower the risk of delivering a large newborn (55, 90), and limit gestational weight gain (90, 91). Despite these benefits, population studies showed that Norwegian women were largely sedentary during pregnancy and that the frequency and intensity of physical activity decreased as pregnancy progressed (5, 6).

Physical activity of moderate intensity for at least 30 minutes of each day is now routinely encouraged in healthy pregnancies, both in Norway and internationally (81, 92, 93). There are a limited number of medical conditions that are cited as contraindications to moderate-intensity aerobic exercise in pregnancy (see Table 1). The recommendations were also in place in 2005, when the Norwegian Directorate of Health called for "randomized, controlled and longitudinal studies which control for the effect of different activities in pregnant women with different activity

Table 1: Contraindications to aerobic exercise in pregnancy

Pre-pregnancy conditions	**Pregnancy conditions**
Absolute contraindications	**Absolute contraindications**
Hemodynamically significant heart disease	Incompetent cervix
Restrictive lung disease	Multiple gestation at risk of premature labor
	Persistent second- or third-trimester bleeding
Relative contraindications	Placenta previa after 26 weeks gestation
Anemia	Premature labor
Unevaluated maternal cardiac arrhythmia	Ruptured membranes
Chronic bronchitis	Severe anemia
Poorly controlled type 1 diabetes	Preeclampsia or pregnancy-induced hypertension
Extreme morbid obesity	
Extreme underweight (BMI<12 kg/m^2)	
History of extremely sedentary lifestyle	**Relative contraindications**
Poorly controlled hypertension	Intrauterine growth restriction
Orthopedic limitations	
Poorly controlled seizure disorder	
Poorly controlled hyperthyroidism	
Heavy smoker	

Adapted from ACOG Committee Opinion nr 650: Physical activity and exercise during pregnancy and the postpartum period, 2015

backgrounds" and explicitly stated that there was "a need for effective interventions in physical activity that can be offered to pregnant women" (94).

At the time of preparing the NFFD trial there were five published randomized controlled trials that studied the effect of an exercise intervention and measured gestational weight gain (see Appendix). The largest of these, with results from 212 Iranian women, was designed to assess back pain, but reported on gestational weight gain as well (95). None of the studies, the others ranging in size from 20-92 participants, reported a difference in gestational weight gain following intervention, or a reduction of birth weight or macrosomia risk (95-99). Interestingly, two experimental studies by Clapp et al. showed that initiating regular physical activity in early pregnancy resulted in higher birth weight of offspring compared with routine care (97), and that both maternal gestational weight gain and newborn birth weight were significantly affected by the intensity and timing of physical activity (early vs. late in pregnancy) (100).

2.8 Glucose metabolism, normal changes in pregnancy

Glucose is an essential energy substrate for the growing fetus during pregnancy, and is known to pass the placenta using facilitated diffusion (79). Normal pregnancy is characterized by progressive insulin resistance and compensatory hyperinsulinemia during the second and third trimesters (101). These physiological changes create exaggerated and prolonged post-prandial glucose levels, allowing shunting of nutrients to the fetus during the period of pregnancy that is characterized by greatest growth (101). Women who are overweight and obese often enter pregnancy with greater insulin resistance than those who are normal weight, thereby exposing the fetus to an excess of nutrients from early gestation (102). The mechanisms regulating maternal insulin resistance and pancreatic insulin production are only partially understood, but are related to maternal levels of inflammatory proteins and hormones such as progesterone, as well as placental production of proteins such as tumor necrosis factor α and growth hormone (103, 104). Adipokines such as leptin may also play a role, as leptin is known to have an important function in modulating pancreatic beta-cells in non-pregnant adults (105).

2.9 Leptin

Leptin is an adipokine, a protein hormone synthesized predominantly by fat cells, and is essential for metabolism, appetite control, weight regulation and energy balance (106, 107). Leptin plays a role in glucose metabolism, acting both at the level of the hypothalamus and at the level of pancreatic beta cells to influence insulin production (105, 106), and is also positively correlated with insulin

resistance (106, 108) (see figure 3, section 2.10). Leptin levels are increased when adipose tissue is increased, but there appears to be a relative resistance to leptin signaling associated with obesity (107). In non-pregnant individuals it is postulated that adipokines such as leptin modulate the risk for diabetes and cardiovascular disease associated with increasing adiposity (106, 107).

In pregnancy, leptin is also produced by the placenta, leading to increasing maternal levels over the course of gestation, with reductions postpartum (107). For the mother, pregnancy is associated with a degree of resistance to leptin signaling (109). Nonetheless, leptin levels have been positively, linearly correlated with risk for both gestational diabetes and preeclampsia. In longitudinal studies, increased levels of leptin pre-date increased risk of these conditions, suggesting a role for leptin in their pathogenesis (109). The extent to which maternal leptin crosses the placenta is unknown, but at least a portion of the placental production of leptin appears to be supplied to the fetus (110). The effect of maternal serum leptin on fetal growth is unclear (102, 111, 112), but there is some evidence that maternal leptin levels, particularly in early pregnancy, may be predictive of fetal growth patterns (111).

2.10 Gestational Diabetes

Gestational diabetes is now defined by the American Diabetes Association (ADA) as “diabetes diagnosed in the second or third trimester of pregnancy that is not clearly overt diabetes”(113). The diagnosis is made when plasma glucose levels, measured after fasting and/or after a glucose challenge, exceed a given threshold level. There has been no international agreement on the dose of the challenge (75 g or 100 g of glucose), the duration of the testing (2-hour or 3-hour), the number of measurements taken (2, 3 or 4), the number of abnormal measurement required (1 or 2), or the thresholds for gestational diabetes diagnosis (114). Glucose thresholds for gestational diabetes were historically based on a United States study of 752 pregnant women performed in 1964 (115, 116), or derived from thresholds used for non-gestational diabetes (117). In 2008, the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study was published, a blinded, multi-national, multi-center trial with information on glucose levels, maternal characteristics and pregnancy outcomes from almost 25,000 participants (51, 118). The study found a linear relationship between maternal glucose levels and pre-defined pregnancy outcomes, specifically large for gestational age newborns and primary cesarean section, also after adjusting for potential confounders such as maternal BMI (51). In 2010, the International Association of Diabetes and Pregnancy Study Group (IADPSG) published recommendations for gestational diabetes diagnostic criteria based on HAPO findings, assigning thresholds based on glucose values that were associated with a 1.75 adjusted odds ratio (OR) of

adverse outcomes relative to the frequencies associated with mean glucose values (119); these recommendations have since been adopted by the American Diabetes Association and the WHO. HAPO findings have also been used to create other guidelines, such as those currently used in Denmark (120) and proposed in Norway (121), reducing the number of tests and using glucose values that were associated with a 2.0 adjusted odds ratio of adverse outcomes relative to the frequencies associated with mean glucose values (see Table 2). There remains debate as whether the lower IADPSG thresholds will reduce adverse outcomes (122, 123), and there is as yet no international consensus. Importantly, studies reporting the incidence of gestational diabetes employ differing criteria and not all report the criteria used (103). This makes it difficult to compare studies, and to perform an aggregated analysis of study results. Some of the recent and current guidelines are displayed in Table 2.

Table 2: Diagnostic criteria for gestational diabetes, recent and current

	Glucose challenge	Threshold values for glucose (mmol)				Criteria
		Fasting	1-hour	2-hour	3-hour	
IADPSG, 2010 (119)	75-g	5.1	10.0	8.5		1 abnormal value
WHO, 1999 (117) and 2006 (124)	75-g	7.0		7.8		1 abnormal value
National Diabetes Data Group, 1979 (US) (116)	100-g	5.8	10.6	9.2	8.1	2 abnormal values (after elevated 50-g challenge)
Carpenter-Coustan, 1982 (US) (116)	100-g	5.3	10.0	8.6	7.8	2 abnormal values (after elevated 50-g challenge)
NICE (UK), 2015 (125)	75-g	5.6		7.8		1 abnormal value
Canadian Diabetes Association, 2013 (126)	75-g	5.3	10.6	8.9		1 abnormal value (after elevated 50-g challenge)
Danish Society of Obstetrics and Gynecology (120)	75-g			9.0		
Norwegian Directorate of Health, proposed 2016 (121)	75-g	5.3		9.0		1 abnormal value

Regardless of criteria used, hyperglycemia sufficient to be diagnostic of gestational diabetes arises when pancreatic insulin production is insufficient to compensate for increased insulin resistance (104). The underlying pathophysiology of gestational diabetes may vary (see figure 3), with some

cases caused by β-cell dysfunction, representing an early phase of Type 1 diabetes or maturity-onset diabetes of the young (MODY) (shown in the figure as the grey arrow), but it is estimated that these women together represent <20% of all cases of gestational diabetes (127). For the majority of women with gestational diabetes, exaggerated insulin resistance underlies the disorder (shown on the figure as the green arrow), similar to the etiology of Type 2 diabetes (127). Consistent with this, longitudinal studies have shown increased insulin resistance to be a precursor to hyperglycemia in women who develop gestational diabetes (103). Women who are overweight or obese are more likely to enter pregnancy with elevated insulin resistance, which when coupled with the insulin resistance of pregnancy is believed to account for their observed increased risk of gestational diabetes (127, 128).

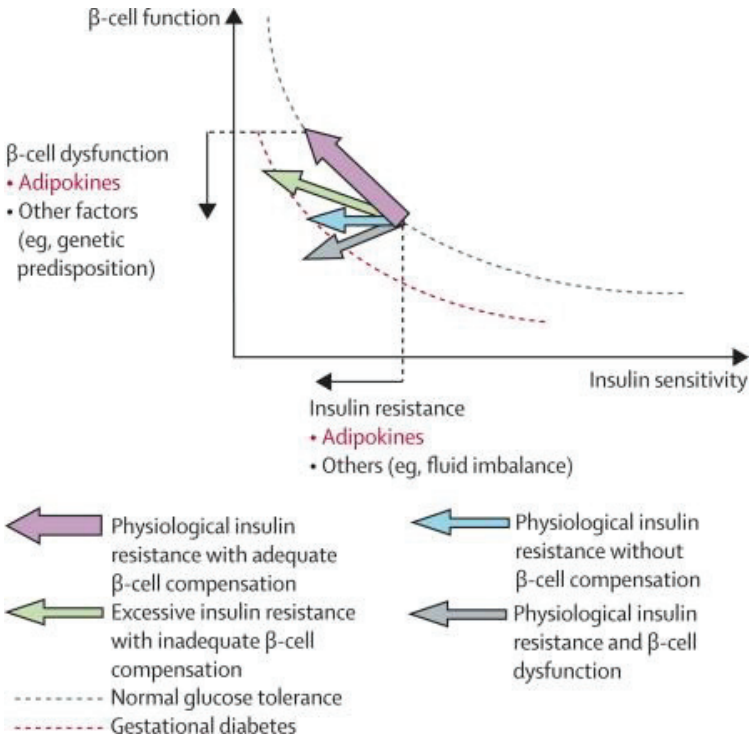

Figure 3:
Pathogenesis of gestational diabetes

Depiction of the increasing insulin resistance of pregnancy, with compensatory increased β-cell function in normal pregnancy such that gestational diabetes (purple dotted line) is avoided. Gestational diabetes develops in the case of excessive insulin resistance, insufficient β-cell compensation, or β-cell dysfunction.
Leptin influences both insulin resistance and β-cell function.

Source: Fasshauser M, Bluher M, Stumvoll M, Apidokines in gestational diabetes, The Lancet Diabetes &Endocrinology, Volume 2, Issue 6, 2014, 488-499 (119). Reprinted with permission from Elsevier Publishing.

Other known risk factors for gestational diabetes are South Asian, Asian and African ethnicity, age >35 years, and polycystic ovarian syndrome (103). Women diagnosed with gestational diabetes are at increased risk of gestational hypertensive disorders, preeclampsia, cesarean delivery and delivery of a large newborn (129, 130). According to a large, multi-national meta-analysis, women with gestational diabetes (diagnosed with varied criteria) have a seven-fold increased risk of developing type 2 diabetes later in life, compared to women who are normoglycemic in pregnancy (131).

2.11 Effects of diet and exercise on glucose metabolism and gestational diabetes risk

In non-pregnant individuals, studies suggest that diets with reduced glycemic load, diets rich in fiber, and diet patterns such as the Mediterranean diet may decrease insulin resistance (132), lower levels of leptin (132), and decrease glucose (133-135). Prior to the start of the NFFD trial there was also evidence from small, randomized, experimental trials with pregnant subjects, though without control groups, that diets with low glycemic index might lower fasting glucose levels (136) and that high-fiber diets might decrease insulin resistance (137). The randomized controlled trial by Wolff et al. demonstrated that dietary counseling in an exclusively obese population resulted in a significantly smaller increase in insulin levels from inclusion to mid- and late pregnancy, and lower levels of leptin in mid-to late pregnancy compared to control care (76).

Physical activity reduces glucose levels both by stimulating uptake of glucose into active muscle cells and by reducing skeletal muscle insulin resistance through up-regulation of Glucose transporter type 4 (GLUT4) expression (138). In pregnancy, the effect of physical activity on glucose levels appears to be influenced by type of activity performed, duration of exercise, gestational length and maternal BMI (100, 139). Specifically, exercise of at least 30 minutes duration may be required to produce a significant decline in glucose levels (139). To my knowledge, no randomized trials of physical activity interventions in pregnancy to reduce GDM risk or lower glucose levels were published prior to 2009 (140, 141). Looking beyond pregnancy, a Cochrane meta-analysis concluded in 2008 that exercise interventions alone had not demonstrated effect in reducing the incidence of Type 2 diabetes, but that interventions combining diet and exercise significantly reduced diabetes risk (142).

2.12 Lifestyle interventions combining diet and exercise

A combination of diet and physical activity is an integral element of treatment for both gestational diabetes (129, 130) and Type 2 diabetes (143), and, at the individual level, is the recommended antidote to the obesity epidemic (144). Moreover, it is reasonable to assume that combining diet and exercise elements in an intervention will allow for a combination of risk-reducing effects, as earlier described.

At the start of the NFFD trial, two randomized controlled trials of limited size were published using a combination intervention to limit gestational weight gain and improve pregnancy outcome. Polley et al. studied a counseling intervention with written and oral information on diet and exercise, including 110 women from a low-income community in the United States, and found a significant decrease in the proportion of normal-weight women exceeding IOM guidelines, but a significant increase in gestational weight gain for overweight women who received the intervention (145). There was no difference between groups in newborn birth weight or complications of pregnancy. Hui

et al. published a Canadian study of an intervention combining supervised exercise groups and diet counseling, but had limited findings in this pilot study of only 45 participants (146). In addition, in Finland, Kinnunen et al. (147) performed a non-randomized controlled trial with a total of 196 participants, providing nutritional counseling and the option of participating in group exercise sessions. There was no significant difference in gestational weight gain between the groups, but while the control group had a 15% incidence of newborns with birth weight >4 kg, there were no babies >4 kg in the intervention group (147). Based on the potential benefit of a lifestyle intervention and the scarcity of experimental evidence, the need for a large, randomized, controlled trial of high quality seemed apparent, and the Norwegian Fit for Delivery Trial was created.

2.13 Developmental origins of health and disease

The early stages of life and development are now regarded as pivotal periods for later health, and potentially the health of the next generation. The antenatal environment, and particularly nutritional supply, appears to program the developing fetus for later growth and predisposition for disease (1, 148, 149). In 1976, Ravelli published a historical cohort study of young Dutch military recruits, finding significantly higher obesity rates among those exposed to famine during the first half of gestation, and hypothesizing that hypothalamic regulation of food intake and growth had been affected by this early deprivation (150). In 1989, David Barker proposed that intrauterine growth retardation and low birth weight have a causal relationship with cardiovascular disease and type 2 diabetes in middle age (151). There is evidence that risk of cardiovascular disease, diabetes and obesity may be associated with birth weight in a u-shaped pattern, with increased risk at both high and low ends of the spectrum (152). There is now substantial evidence to suggest that gestation is a critical period of "developmental plasticity", when organs and systems are sensitive to their environment, and functional phenotype is in many cases established for the duration of life (153). In this setting, maternal diet habits and patterns of physical activity may have far-reaching consequences for the developing fetus, also beyond what can be measured by weight at delivery (2, 148).

3. The current study: Aims

The overall aim of the Norwegian Fit for Delivery (NFFD) trial was to examine if providing a combined lifestyle intervention, consisting of dietary counseling and supervised exercise sessions, to a general population in a real-world setting, starting in the first half of pregnancy, would results in health benefit to mother and newborn, measured by specific outcomes during pregnancy, delivery, and the first year postpartum.

Aim of paper I: To document the background for the NFFD trial, to record trial endpoints, and to provide a detailed description of the methods to be employed in the trial.

Aims of paper II: To assess the effect of the NFFD intervention on the outcomes of gestational weight gain, birth weight of the newborn and the proportion of large newborns, the proportion of pregnancy complications, the proportion of delivery complications, and the proportion of operative deliveries.

Aim of paper III: To assess the effect of the NFFD intervention on the outcome of weight retention at 12 months postpartum.

Aim of paper IV: To assess the effect of the NFFD intervention on glucose metabolism, by examining the levels of specific markers at gestational week 30: glucose, insulin, insulin resistance as expressed by the homeostatic model assessment of insulin resistance (HOMA-IR), and leptin.

4. The current study: Design

4.1 Trial Design, an overview

All papers included in the present study report the findings of the NFFD trial. The NFFD trial is a randomized controlled trial: a prospective, quantitative, comparative, experimental study with randomization of participants to one of two parallel arms: intervention group or control group. The intervention studied is a combined, lifestyle intervention consisting of dietary counseling and access to supervised exercise sessions; the control is standard prenatal care. The NFFD study was planned as a pragmatic trial, designed to determine whether providing the intervention would provide measurable health benefits in a setting that approximates conditions of the real world. Women were recruited from healthcare clinics, since most pregnant women in Norway attend healthcare clinics, with the intention of reducing selection bias. It was determined that results would primarily to be analyzed by the principle of "Intention to Treat", measuring the effectiveness of providing this extra treatment in pregnancy, with varying compliance. This reflects the realities of health care, where patients are free to decide if they wish to partake of the treatments which are available to them.

After randomization, participants were followed through pregnancy, to delivery, and 12 months postpartum, collecting data on health outcomes for each participant and her newborn. Outcome data was amassed using measurements of weight gain, blood tests, prenatal complications, delivery outcomes, newborn birth weight and postpartum weight retention. Data was collected in cooperation between healthcare clinics and Sørlandet Sykehus, including the Department of Obstetrics and Gynecology and the department of Laboratory Medicine. The protocol for the trial was written in 2008 and modified in 2009.

Details of the trial design are provided in Paper I. By making the protocol freely available in this manner, other researchers would be able to perform similar interventions and test the reproducibility of findings. In addition, separate publication allowed more detailed description of both the background and the NFFD intervention than would be possible in the papers detailing trial results. The trial was registered in Clinical Trials, ClinicalTrials.gov ID: NCT01001689. Reporting of trial outcomes was performed following CONSORT guidelines (154, 155).

The design of the trial is summarized in the following diagram (Figure 4):

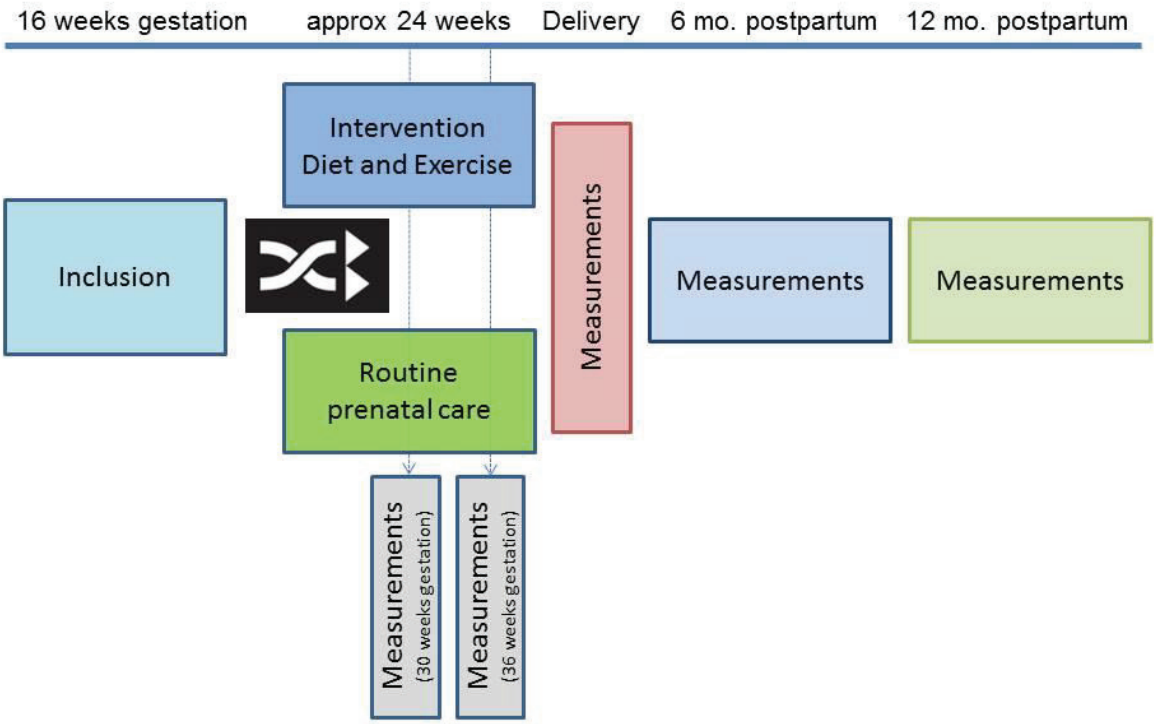

Figure 4: Design of the Norwegian Fit for Delivery Randomized Controlled Trial

4.2 Setting

Participants were recruited from eight public health care clinics in Southern Norway, all within a 45 minute driving radius of Sørlandet Hospital Kristiansand. Clinics were located in the towns of Kristiansand (three clinics), Mandal, and Lillesand, and the communities of Songdalen, Søgne and Grimstad. The clinics drew participants from urban, suburban and rural settings. Participants were included between September 2009 and February 2013. Postpartum follow-up was completed in September 2014.

4.3 Study population

Antenatal health care is free of charge in Norway, provided by primary care physicians and midwives at healthcare clinics, working in cooperation. Nulliparous women attending participating clinics received information about the trial as a routine part of their first prenatal consultation. The inclusion and exclusion criteria for participation in the NFFD trial are presented in Table 3.

Table 3: Inclusion and exclusion criteria for the NFFD trial

Inclusion criteria:
Nulliparity
Age 18 years or older*
Planning to deliver at Sørlandet Hospital
Able to read and understand Norwegian and/or English
Signed informed consent
Exclusion criteria:
Known twin gestation
Pre-gestational diabetes
Substance abuse
Physical disability precluding moderate aerobic physical activity (see table 1)
BMI <19 kg/m^2
Failure to complete blood tests and questionnaire at inclusion*

*Criteria which were not in place for the first 20 participants

The first 20 participants, included between September and December 2009, comprised a feasibility study. Their results were not assessed before the conclusion of the trial and were included with those of later participants. Based on findings from the feasibility study, the protocol was modified to include a lower age limit of 18 years and randomization was delayed until after initial questionnaires and blood tests were completed, in order to ensure that the participants were sufficiently motivated and to avoid missing data (these elements are marked with * in Table 3). All changes to the protocol were approved by the Regional Ethics Committee.

Midwives reported weekly on the number of women who agreed to participate and the number who declined participation. Based on weekly reporting, and confirmed by detailed examination of attendance at four clinics, 4245 women attended the participating clinics during the inclusion period, of which 1610 were nulliparous.

4.4 Randomization and blinding

After receiving signed, informed consent and confirming that blood tests and questionnaires were completed, a research nurse assigned participants consecutively to the intervention or control arm of the study using a computer-generated list with a 1 : 1 allocation ratio in blocks of 20. The research

nurse never met the participants, had no role in recruitment or measurements, and had no knowledge of questionnaire responses.

Participants were necessarily un-blinded as to their group allocation. It was the intention that measurements should be performed blinded to group allocation, and participants were instructed not to reveal their group status to those who weighed them. However, it is unlikely that this "blinded-ness" was complete. Assessment of questionnaire responses and hospital record review for delivery weight, newborn birth weight, and obstetrical and neonatal outcomes was performed by assessors blinded to participant group allocation.

4.5 Intervention

4.5.1 Dietary Component of the NFFD trial

The dietary portion of the NFFD intervention was designed by members of the NFFD team at the Nutrition division of the Department of Public Health, Sport and Nutrition at the University of Agder. Ten dietary recommendations were specifically created for the NFFD trial (see Table 4), and form the basis for this portion of the intervention. The recommendations were designed to be simple, direct, and to increase awareness of food choices by targeting specific behaviors. The background for the recommendations is previously published (156).

Table 4: The Ten Dietary Recommendations for the NFFD trial

NFFD Dietary Recommendations
Eat regular meals
In between meals—choose fruits and vegetables
Drink water when thirsty
Eat vegetables with dinner every day
Eat sweets and snacks only when you really appreciate them
Don't eat beyond satiety
Buy small portion sizes of unhealthy foods
Limit your intake of added sugar
Limit your intake of salt
Read nutritional labels of foods before buying

The NFFD diet recommendations were intended to supplement dietary information all pregnant women receive from the Norwegian Directorate of Health in the form of a brochure. These

brochures inform women that they should eat a varied diet, increase intake of whole grains, vegetables, fruits and fish, and reduce the intake of high-fat dairy products, sugar and salt (92). "Gravid" ("Pregnant", 2009-present) also advises pregnant women to avoid unhealthy snacks such as potato chips and soft drinks, and gives specific recommendations for increased food intake based on gestational length (92).

Delivery of the dietary portion of the NFFD intervention was designed to be suitable for more wide-spread use at moderate cost should the intervention prove effective in improving maternal and newborn health. Information was provided to intervention participants in a brochure entitled "Fit for Fødsel: Kost-og treningsråd for deg som venter baby" (see Appendix, 11.2). Intervention participants also received two telephone consultations, the first shortly after assignment to the intervention group, and the second six to eight weeks later, each of approximately 20 minutes. Consultation was performed either by experienced clinical dieticians or graduate students in public health who were trained and supervised by the NFFD team. In addition, intervention participants were given access to a password-encoded internet site (http://blogg.fitforfodsel.no) with recipes and tips for healthy eating. They were also invited to one evening meeting, with information on the NFFD intervention and its components, and one cooking class; attendance was recorded.

4.5.2 Physical activity component of the NFFD trial

The physical activity portion of the NFFD intervention was designed by members of the NFFD team at the Sports Medicine division of the Department of Public Health, Sport and Nutrition at the University of Agder. A 60 minute session of physical activity appropriate for an indoor fitness center was designed for the trial. Sessions consisted of 10 minutes of warm-up, 40 minutes of resistance training and aerobic exercise of moderate intensity (including calisthenics and weight training), and 10 minutes of stretching/cool down. The exercise elements were designed to be modified according to participant fitness level. Pelvic floor exercises were included at each session. Pregnancy is associated with an increase in resting heart rate and a variable heart rate response to exercise (139). Participants were therefore instructed to gauge their intensity level using the subjective measurement of exertion known as Borg's scale (157), with moderate intensity quantified as 12-14 on the range from 6-20 (see figure 5). Borg's scale is recommended for use in pregnancy both nationally and internationally (81, 94) and is often employed in antenatal interventions including exercise (158).

Level	Description
6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	**Somewhat hard**
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	Maximum

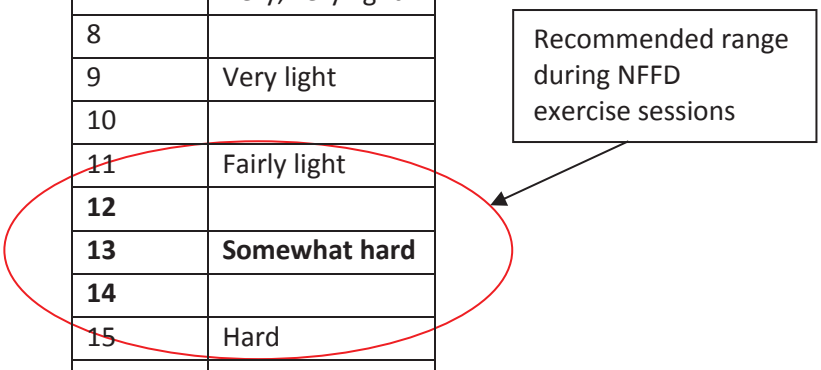

Figure 5: Borg's scale of perceived exertion, with recommended range during NFFD exercise sessions

Participants were instructed to increase weekly physical activity gradually if they were unaccustomed to exercise, progressing to individual moderate physical activity at least 30 minutes per day on two-three days each week, in addition to two NFFD 60-minute training sessions. They were given recommendations regarding individual physical activity (see NFFD brochure, Appendix, 11.2). Participants were informed of the importance of hydration, to compensate for fluid losses during exercise. They were advised to adjust their dress to avoid hyperthermia. Both participants and instructors were informed of warning signs for discontinuing physical activity (See Table 5).

Table 5: Warning Signs to Discontinue Exercise While Pregnant

• Vaginal bleeding
• Regular painful contractions
• Amniotic fluid leakage
• Dyspnea before exertion
• Dizziness
• Headache
• Chest pain
• Muscle weakness affecting balance
• Calf pain or swelling

Source: ACOG Committee Opinion nr 650: Physical activity and exercise during pregnancy and the postpartum period, 2015

Twice-weekly sessions were provided at a total of five fitness centers, and participants chose the center they wished to attend when they were randomized to the intervention. Exercise sessions were supervised either by physiotherapists or graduate students in Sports science at the University of Agder, trained and quality-controlled by the NFFD team. Attendance at each session was recorded. In addition, information on physical activity was available to intervention participants in the NFFD brochure (see Appendix, 11.2), on the password-encoded web-site (http://blogg.fitforfodsel.no), and during the evening information meeting.

4.5.3 Intervention compliance

In the assessment of women who provided postpartum measurements, attendance at exercise classes was dichotomized according to the median (14 classes), and those receiving at least one dietary consultation and attending ≥14 exercise classes were defined as "compliant" with the intervention (Paper III).

4.6 Routine care

Women in the control arm of the study received routine prenatal care following the Norwegian standard, which is eight prenatal appointments including one second-trimester ultrasound examination, with additional care as needed. In Norway, pregnant women routinely receive an informational booklet from their healthcare clinic. The booklet "Gravid" was available from the spring of 2009, and was presumably provided to all control participants. A similar booklet entitled "Ernæring" ("Nutrition") was available from 2005-2009. "Gravid" contains advice on prenatal nutrition and physical activity, including recommendations for weight gain based on IOM guidelines (92). Control group women received no additional counseling, access to exercise classes or written information from the NFFD team.

4.7 Measurements

4.7.1 Weight and height

Pre-pregnancy weight was self-reported. Participants were weighed at their healthcare clinic upon inclusion in the study using class III scales with a 0.1 kg accuracy that were calibrated at the start of the trial. Pre-pregnancy weight and inclusion weight were recorded in whole kg by midwives at the time of inclusion. All participants were weighed at Sørlandet Hospital at 30 and 36 weeks of gestation using a Tanita BC 418 (Tokyo, Japan) bioimpedance scale which also recorded body fat and water. Participants were measured wearing light indoor clothing but without socks and shoes, subtracting one kg for the weight of clothing. Participants were weighed by hospital staff on admission to the

delivery ward using a Seca class III scale with a 0.1 kg accuracy, and results were entered into the patient's electronic hospital record for later retrieval. If weight at delivery was missing, the last weight in the prenatal record was recorded along with corresponding date. Gestational weight gain was calculated both according to self-reported pre-pregnancy weight and measured weight at inclusion. Gestational weight gain at term was calculated for women delivering at ≥37 gestational-weeks with recorded weight within two weeks of admission.

Feasibility study participants reported their height. Later participants measured their height to the nearest centimeter (cm) at their first follow-up appointment at 30 weeks gestation using a Seca Leicester portable stadiometer (Hamburg, Germany) with an accuracy of 0.1 cm. Pre-pregnancy BMI (kg/m^2) was calculated using self-reported pre-pregnancy weight and measured height, or self-reported height if measured height was missing.

Newborns were weighed immediately following delivery using either a Seca or Solotop infant scale, each with a 0.01 kg accuracy, and measured using a Seca pediatric measuring rod, with a 5 mm precision. Measurements were performed by labor floor personnel, as usual following delivery, and results were later retrieved from the electronic hospital record. Weight percentile was calculated according to sex and gestational age using a z-score derived from Medical Birth Registry of Norway data (159). The proportion of large newborns was calculated using the definitions >4000 g, >4500 g, and ≥90th percentile. "Small for gestational age" was defined as ≤10^{th} percentile. Ponderal index was calculated as weight in grams (g) multiplied by 100 and divided by length in centimeters (cm) cubed.

Gestational weight gain was also calculated as a rate (Paper II). Gestational weight gain rate from pre-pregnancy was calculated as the difference between last available weight prior to delivery and pre-pregnancy weight, divided by gestational length at last measurement. Gestational weight gain rate from inclusion was calculated as the difference between last available weight prior to delivery and weight at inclusion, divided by interval between last measurement and date of inclusion. Compliance with IOM guidelines for gestational weight gain was assessed by comparing gestational weight gain from pre-pregnancy to term with the upper limit of recommended total gain for each pre-pregnancy BMI category (normal-weight: 16 kg, overweight: 11.5 kg, obese: 9 kg). Third-trimester weekly weight gain rate (difference between weight at first follow-up, at 30 weeks of gestation, and last weight measured, divided by interval between measurements) was compared with the upper limit of IOM recommendations for third-trimester weekly weight gain rate (normal-weight: 0.5 kg/week, overweight: 0.33 kg/week, obese: 0.27 kg/week).

Weighing at 6- and 12 months postpartum was performed at healthcare clinics using scales calibrated at the start of the trial and reported in whole kg (Paper III). Postpartum weight retention was defined as the difference between measured weight postpartum and self-reported pre-pregnancy weight.

4.7.2 Ultrasound measurements

During first and second follow-up assessments at Sørlandet Hospital, at gestational weeks 30 and 36 respectively, ultrasound measurements of the fetus were routinely performed. Fetal growth was assessed by measuring biparietal diameter and mean abdominal diameter. The amniotic fluid index was measured, summing up the deepest pockets in the four quadrants of the uterus. Abnormal findings were reported to the Department of Obstetrics of Sørlandet Hospital for additional assessment.

4.7.3 Blood tests

Paper II: Fasting levels of glucose and C - reactive protein (CRP) were measured shortly after consenting to trial participation, using blood samples obtained at the office of the participant's primary care physician and analyzed at Sørlandet Hospital. At gestational-week 30, plasma glucose was obtained and analyzed at Sørlandet Hospital after overnight fast and again two hours after 75 g glucose load. All analyses were performed using a Cobas 6000 c501 chemistry analyzer (Roche Diagnostics). Glucose levels ≥7.0 mmol/l at fasting and/or ≥7.8 mmol/l at 2-hours were classified as elevated, based on contemporary national and WHO 1999/2006 criteria and participants and their primary care physicians were informed.

Paper IV: At gestational-week 30, plasma glucose was measured as described above. In addition, fasting serum samples were frozen and stored at -80°C. Frozen samples were analyzed at Aker Hormone laboratory using a Modular E170 analyzer (Roche), batched to decrease inter-assay variation. Insulin was analyzed using non-competitive electrochemoluminescence immunoassay (Roche Diagnostics), with coefficient of variance of 4%. Leptin was analyzed using competitive radioimmunoassay (Millipore), with coefficient of variance of 7%. HOMA-IR was calculated as: (insulin (mU/l) x fasting glucose (mmol/l)) / 22.5. Leptin, insulin and HOMA-IR were missing for eight participants (3 intervention, 5 control), due to errors in freezing or transport. All missing values were considered missing completely at random. Three insulin and HOMA-IR values (one intervention, two controls) were excluded from analysis as outliers. Glucose values were assessed according to newer gestational diabetes criteria, including IADPSG criteria and proposed-revised Norwegian criteria derived from HAPO findings.

4.7.4 Questionnaires

Papers II-IV: All participants were requested to complete questionnaires at inclusion, gestational-week 36, 6 months postpartum and 12 months postpartum (see Appendix). No questionnaires were completed at gestational week 30, when glucose testing was performed. The questionnaires were available electronically in Norwegian, and in a printed version in Norwegian and English. The questionnaires consisted of three sections: demographics, diet and physical activity. The demographic section included questions on income, highest attained education level, and smoking status, but had no entries on race or ethnicity.

Paper III: The questionnaires administered postpartum included questions on breastfeeding. At both 6 and 12 months postpartum women were asked if they were currently breastfeeding, either exclusively or in addition to other food/drink, and the duration of breastfeeding. The postpartum questionnaires did not include questions about new pregnancy.

4.7.4.1 Diet section of the NFFD questionnaire

Dietary intake was assessed using a 43-item Food Frequency Questionnaire (FFQ), designed to assess compliance with the NFFD diet intervention. Each of the 10 recommendations was assessed using from one to nine of the FFQ questions, with replies compiled to form a number on a subscale. For example, the recommendation “Eat regular meals” was assessed by four questions, with a subscale ranging from 0 to 28. Results for each subscale were dichotomized using the median value as cut-off, such that results at the median or higher gave a subscale score of 1 while results below the median gave a score of 0. The subscale scores were summed to create the NFFD diet score, which ranged from 0 to 10, with a higher score indicating healthier eating behavior according to NFFD principles. A detailed description of the score is published (156). The score has also been tested and found to have acceptable test-retest reliability, with a Spearman’s rank order correlation of 0.68 ($p<0.001$) (156).

Papers II, III: The questionnaire completed at inclusion contained two sets of diet-FFQ questions: one for the present time and one for the period immediately pre-pregnancy.

4.7.4.2 Physical activity section of the NFFD questionnaire

Physical activity was assessed using International Physical Activity Questionnaire, short version (IPAQ-short) which quantifies physical activity during the last seven days divided into the categories of vigorous intensity, moderate intensity and walking (160). The questionnaire summarizes the activities of daily living, recreational activity or work-related activity. The number of days in which

activity has been performed and the average length of time that has been spent on activity on those days is recorded. It was anticipated that intervention participant responses would include the time spent in NFFD exercise classes as well as individual physical activity, while control participants would report their individual activity level. The Metabolic Equivalent of Task (METs) in each category was calculated as MET-level (3.3 for walking, 4.0 for moderate activity, 8.0 for vigorous activity) x minutes per day x days per week. The METs for the three categories were summed, after excluding all cases with "don't know" as a response, according to IPAQ analysis guidelines (161). The IPAQ-short is validated in a Scandinavian non-pregnant population (160). At the time of initiating the NFFD trial, no questionnaires specifically designed and validated for pregnancy were available for a Scandinavian population. Since then, both the Physical Activity in Pregnancy Questionnaire (162) and the Norwegian Mother and Child Cohort Study physical activity questionnaire (163) have been validated among Norwegian women. The IPAQ-short was originally designed to be completed either as a printed questionnaire or as a telephone-based interview. The electronic version which was used for the current study was not validated prior to use in the trial, but a validation study has since been performed by members of the NFFD team at the division of Sports Medicine at the University of Agder, and results will be published following completion.

Paper II: The questionnaire completed at inclusion contained two sets of IPAQ-short questions: one for the present time and one for the period immediately pre-pregnancy. IPAQ is designed and tested to describe activity for the last seven days, and use for more retrospective reporting is not validated.

4.7.5 Hospital record review

Paper II: In addition to retrieval of participant and newborn measurements at delivery, as described above under "Weight and height"(section 6A), labor floor records were reviewed to determine mode of delivery, the specific delivery complications of shoulder dystocia and postpartum hemorrhage, and APGAR scores of the newborn. Admissions to the neonatal intensive care unit with diagnosis and duration of stay were recorded. Prenatal records and labor floor records were examined for the diagnosis of preeclampsia or gestational diabetes (insulin-requiring or non-insulin requiring), with gestational length at diagnosis. Record review was performed by physicians and midwives blinded to participant group allocation.

Paper III: Record review was performed to detect new pregnancy. In the event of pregnancy at the time of postpartum follow-up, gestational length was calculated based on recorded date of confinement.

4.8 Trial withdrawal

Women were informed at trial inclusion that they were free to withdraw from participation at any time. Intervention participants who failed to receive dietary consultation or attend exercise classes were not required to withdraw from the trial. All participants who discontinued trial participation were asked if they would consent to review of labor floor and hospital records following delivery. Some consented to the use of delivery information only (date and mode of delivery and newborn measurements), while others consented to complete hospital record review.

4.9 Sample size

There was scant data on gestational weight gain among Norwegian women at the time of trial planning, as neither maternal weight nor weight gain were routinely recorded by the Medical Birth Registry (164) and data was not yet available from the Mother and Child (MoBa) cohort (165). Power calculations were therefore based on the variable of large newborns, for which there was more information available. We expected a 20% prevalence of newborns with birth weight >4000 g in the control group based on 2005 statistics from the Norwegian birth registry (166), which was the most recent data available at the time of trial preparation. We determined empirically that a reduction to 10% in the intervention group would be clinically relevant. We calculated that we required 198 women in each study arm to demonstrate statistical significance with a power of 80%. To allow for participant drop-out and premature deliveries, and to allow for evaluation of subgroups such as overweight and obese women, it was determined that we would randomize 600 participants.

4.10 Statistical analysis

Paper II: Data was analyzed according to the principles of “intention to treat”, retrieving information on as complete a population as possible, including women who withdrew from participation over the course of the trial. In the case of continuous outcomes, the study groups were compared using a student t-test after confirming normal distribution. Categorical outcomes were compared using chi-square tests and results were expressed as mean difference and odds ratio. Mixed-effects model analysis (linear mixed models) was used to assess the influence of age, education, income, occupation, smoking, and pre-pregnancy BMI on the primary outcome of gestational weight gain measured at three time points. Mixed-effects model analysis is an extension of linear regression that allows analysis of repeated measures, such as weight, without excluding cases with missing data. Time (gestational week) was modeled as a categorical variable and data was allowed to define the covariance structure given that time intervals were uneven (unstructured covariance matrix). All selected covariates were treated as fixed effects while time (gestational week) was fitted as a repeated variable. P-values <0.05 were considered statistically significant, with no adjustment for

multiple comparisons. All tests were two-sided. SPSS for Windows version 21.0 was used for all statistical analyses.

Paper II, results not published: The binary categorical outcome of exceeding IOM recommendations for gestational weight gain was assessed using multiple logistic regression analysis, including the possible confounding variables of pre-pregnancy BMI category, and age, educational level, occupation, income, and smoking status at inclusion. P-values <0.05 were considered statistically significant, with no adjustment for multiple comparisons. Tests were two-sided. SPSS for Windows version 21.0 was used for statistical analysis.

Paper III: Results were primarily analyzed for participants with measured weight available postpartum, and after excluding new pregnancies. Missing participants were compared with included intervention and control participants, both separately and together, using student T-test and chi-square test after confirming normal distribution. Postpartum weight retention in the two study groups was compared as a continuous variable using a student t-test. Relative risk and chi-square test were used for the binary outcome of postpartum weight retention > 0 or ≤ 0. Compliant vs. non-compliant intervention participants were compared using student T-test and chi-square test after confirming normal distribution. The effect of compliance with the NFFD intervention on postpartum weight retention was assessed using ANOVA with Bonferroni post-hoc testing, and adjusted for age, pre-pregnancy BMI category, education, income, and occupation using multiple linear regression analysis. P-values <0.05 were considered statistically significant, with no adjustment for multiple comparisons. All tests were two-sided. SPSS for Windows version 21.0 was used for all statistical analyses.

Paper IV: Unadjusted comparison of intervention and control groups was performed using student t-test or chi-square test as appropriate. Difference between the randomized groups for continuous or binary variables was assessed using multiple linear or logistic regression models adjusted for age, education, income level and smoking at inclusion, pre-pregnancy BMI category and gestational age at measurement. Variables included in the adjusted analysis were chosen based on clinical relevance (pre-pregnancy BMI category and smoking) and/or measured differences between intervention and control group (gestational age at measurement) and/or measured differences between included and missing participants (age, education and income). Effect modification between randomized groups and patient characteristics on continuous outcomes was assessed by an interaction term in the multiple linear regression models. For binary outcomes, effect modification was assessed by the Breslow-Day test of homogeneity of odds ratios. No further adjustment for BMI category was

performed when analysis was stratified according to pre-pregnancy BMI. P-values <0.05 were considered statistically significant. All tests were two-sided. SPSS for Windows version 21.0 was used for all statistical analyses.

4.11 Ethics

The NFFD study was performed in accordance with the Helsinki Declaration, and all participation was based on informed, written consent. Participants were informed that they could withdraw from the study at any time, without the need for further explanation. Intervention elements were designed and performed according to contemporary national and international guidelines (87, 167). The NFFD study has been approved by the Regional Committee for Medical Research Ethics South-East C (REK reference 2009/429).

5. Results

5.1 Flow chart of participation through the Norwegian Fit for Delivery trial

The Norwegian Fit for Delivery trial is the focus of all of the papers included in the present study. The first paper describes the protocol, while the remaining three papers contain results from the NFFD trial. A schematic depiction of participation in the trial in its entirety, including the portions that are described by each individual paper, is provided in Figure 6.

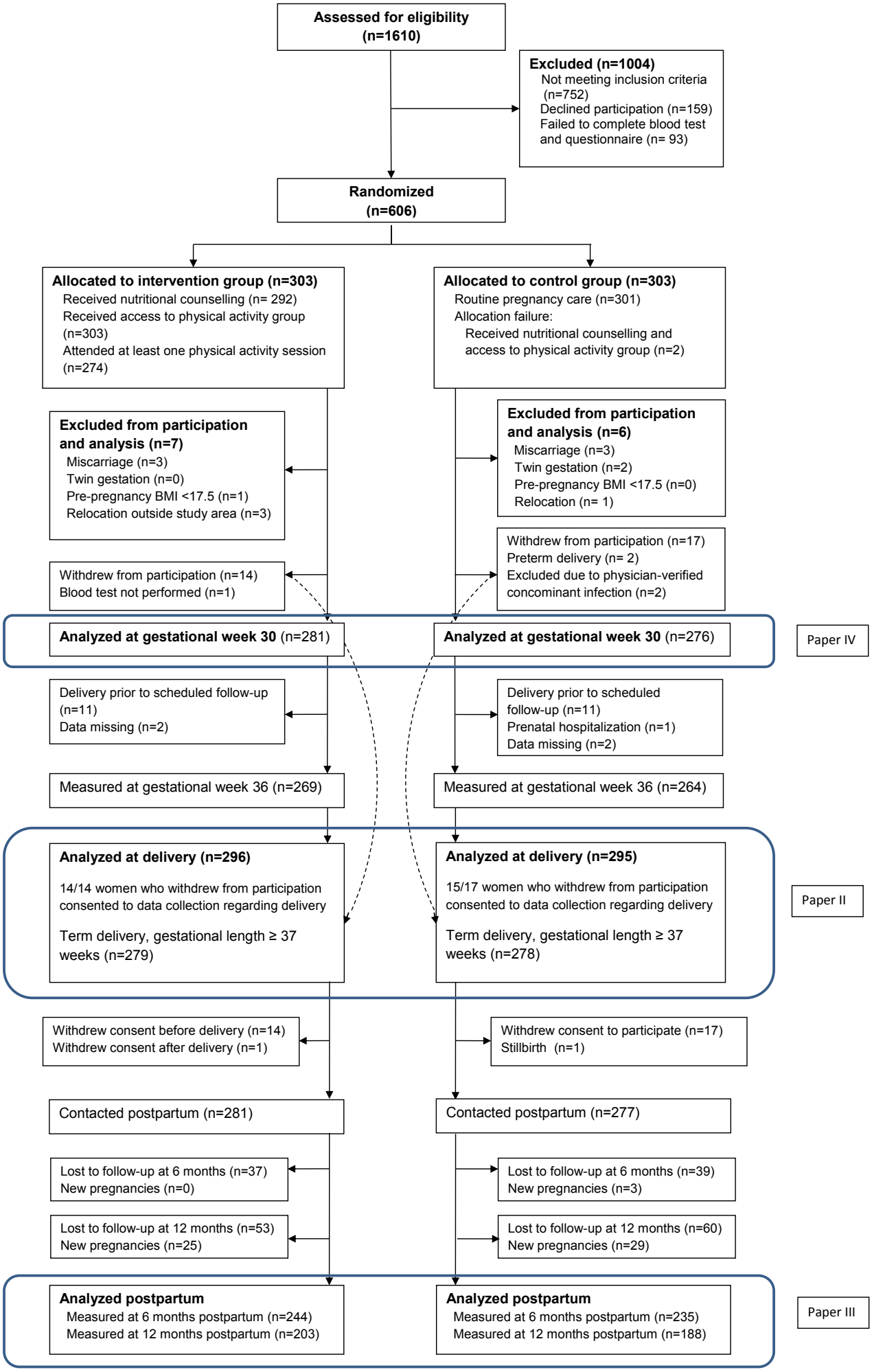

Figure 6: Flow chart of participation in the NFFD trial

5.2 Paper II: A total of 606 women consented to participation in the NFFD trial, of which 591 women (296 in the intervention group and 295 in the control group) were included in an intention to treat analysis of the effect of intervention on gestational weight gain, newborn birth weight, and rates of pregnancy and delivery complications. The two groups were similar at baseline, but both groups were notable for a high level of education (only 32% of both groups were without some form of higher education), and a predominance of normal-weight participants (68% and 74% for intervention and control groups respectively). Participants were included at a mean of 16 weeks gestation.
Comparison of intervention and control groups showed a modest reduction of gestational weight gain to term, measured both from pre-pregnancy (14.4 kg vs. 15.8 kg for intervention and control groups respectively, mean difference -1.3 kg, 95% CI -2.3, -0.3, p=0.009) and from trial inclusion (12.2 vs. 13.1 kg for intervention and control groups respectively, mean difference -0.90 kg, 95% CI -1.70, -0.03, p=0.043). For all pregnancies, gestational weight gain rate from trial inclusion was significantly lower for intervention vs. control group: mean difference -0.03 kg/week from inclusion to last weight, 95% CI -0.07, -0.00, p=0.040. A large proportion of women in both groups exceeded IOM recommendations for gestational weight gain (41.6% and 50% for intervention and control groups respectively) and the effect of intervention on this outcome with unadjusted analysis was not statistically significant (p=0.056).
At 36 weeks of gestation, intervention participants had significantly higher mean diet scores (5.05 vs. 4.60 for intervention and control groups respectively, p=0.018) and mean IPAQ scores (1560 vs. 1254 MET-minutes/week for intervention and control groups respectively, p=0.009) than women in the control group.
There was, however, no significant effect of intervention on newborn birth weight at term (3470 vs. 3516 g for intervention and control group respectively, p=0.204) or the proportion of large newborns (newborns >4000 g: 11.8% vs. 14.0% for intervention and control group respectively, p= 0.451).
There was no difference between groups in the frequency of pregnancy complications, operative deliveries or delivery complications.

5.3 Paper II, Results not published: Multiple logistic regression analysis including the possible confounding variables of age, pre-pregnancy BMI category, educational level, occupation, income and smoking status demonstrated significantly reduced risk of exceeding IOM recommendations in the intervention group compared to the control group: adj. OR 0.61, 95% CI 0.42, 0.89, p=0.011 when assessing total gestational weight gain; adj. OR 0.67, 95% CI 0.46, 0.98 p=0.039 when assessing third trimester weight gain rate.

5.4 Paper III: Of the 606 women who were randomized to the NFFD trial, 391 were analyzed at 12 months postpartum. In addition to women who withdrew from the trial or were lost to follow-up, 54 women who were measured at 12 months were excluded due to new pregnancy. Missing participants were significantly younger (27.5 vs. 28.3 years, p=0.036), had lower education level (p=0.003), lower income (p=0.018) and tended to have a higher pre-pregnancy BMI (24.1 vs. 23.5 kg/m^2, p=0.059) than those who were included in the post-partum analysis.

Postpartum weight retention was not significantly different in the intervention group compared to the control group: 0.66 kg vs. 1.42 kg for intervention and control groups respectively, mean difference -0.77 kg, 95% CI -1.81, 0.28, p=0.149). Mixed effects model analysis confirmed lack of intervention effect after adjusting for variables associated with missing participants. Unadjusted analysis of the proportion of women returning to pre-pregnancy weight showed a possible effect of the intervention (53% vs. 43% return to pre-pregnancy weight for intervention and control groups respectively, OR 1.5, 95% CI 1.0, 2.2, p=0.045) but the effect was not significant when logistic mixed-effects models analysis was used to adjust for missing data (adjusted OR 2.23, p=0.067).

Compliance with intervention was associated with significantly lower weight retention at 12 months, compared with both non-compliant intervention participants and control participants, also using adjusted analysis: 2.25 vs. 3.79 kg for compliant intervention participants and control participants respectively, mean difference -1.54 kg, 95% CI -3.02, -0.05, p=0.013.

Evaluating diet scores and IPAQ scores showed that there was no difference between the intervention group, either the whole group or the compliant subgroup, and the control group postpartum.

5.5 Paper IV: Of the 606 women who were randomized to the NFFD trial, 557 (91.9%) provided blood tests at 30 weeks gestation and were analyzed. Missing participants in the intervention group were significantly younger (24.9 vs. 28.0, p=0.005), had lower education levels (p=0.004) and lower income (p=0.034) compared to those who were measured, while missing participants in the control group were not significantly different from those who were tested.

For the total group, intervention resulted in reduced insulin (adj. mean diff -0.91 mU/l, p=0.045) and leptin levels (adj. mean diff -207pmol/l, p=0.021) compared to routine care, while glucose levels after fasting and 2 hours after glucose challenge were unchanged.

Evaluation of glucose, insulin, HOMA-IR and leptin levels was also performed after dividing the participants into normal-weight (pre-pregnancy BMI<25 kg/m^2, n=399) and overweight/obese (pre-pregnancy BMI≥25 kg/m^2, n=158) subgroups. Analysis showed that pre-pregnancy BMI category significantly modified intervention effect on glucose levels at both time points (p=0.030 for fasting glucose, p=0.039 for 2-hour glucose). For normal-weight participants, the intervention had a weak positive effect on glucose metabolism, evidenced by a trend (p<0.1) toward reduced insulin and HOMA-IR levels and significantly lower leptin values, although there was no change in mean glucose levels or the proportion of women exceeding thresholds for gestational diabetes diagnosis. Among overweight/obese women, there was a trend toward slightly higher fasting glucose levels for those receiving intervention compared to controls, and no change in the other metabolic parameters. Employing thresholds for gestational diabetes diagnosis recommended by the IADPSG showed a higher proportion of overweight/obese intervention participants with elevated glucose levels compared to overweight/obese controls (33.7% vs. 13.9% for intervention and control group respectively, adj. OR 3.9, 95% CI 1.6, 9.7, p=0.004), whereas when using 1999/2006 WHO criteria there was no significant difference between groups. There was no significant difference between overweight/obese intervention and overweight/obese control participants in newborn birth weight or the proportion of large newborns (>4 kg: 18.3% vs. 13.6% for intervention and control subgroup respectively, OR 1.41, 95% CI 0.58, 4.48, p=0.44).

6. General methodical considerations

6.1 Randomized controlled trial

The NFFD trial studied the effects of a lifestyle intervention in pregnancy using the form of a randomized controlled trial. It was the goal of the team who created the NFFD trial that the trial would have high methodological quality, and that the results would be useful in a real-world setting. The quality of a randomized trial has been defined as "the confidence that the trial design, conduct and analysis has minimized or avoided biases in its treatment comparisons" (168). Bias is created by elements that deviate information to one side or the other of the analysis (57). In a clinical trial, bias can be created in the selection of participants, in the measurement of outcomes, in missing outcomes, in the analysis of data, and in the reporting of results (57). Bias impacts the extent to which trial results reflect the "truth" for the studied population, known as the internal validity of a trial (169). The extent to which trial results can be generalized to other populations is the external validity of a trial. Assessment of external validity includes an evaluation of the context of the trial: the setting, population, and outcomes reported (170).

In the NFFD trial, the intervention studied was a "lifestyle package" randomly provided to one half of the women included, while women in the control group received routine Norwegian prenatal care. Women were recruited from healthcare clinics attended by almost all pregnant women living in the geographical area, and inclusion and exclusion criteria were not restrictive. All participants in both groups were analyzed, to the best of our ability, regardless of their degree of participation. This approximates the realities of clinical practice. The NFFD trial was therefore performed under conditions approximating the real-world, and results of the trial reflect the effectiveness of the NFFD intervention in modifying the outcomes measured, as opposed to the efficacy the NFFD intervention might have in modifying outcomes under ideal conditions and with full compliance (171). It is important that the results not be interpreted as an evaluation of the effects of exercising regularly in pregnancy, or the effects of eating a diet consistent with the NFFD recommendations. Women in the control group were not instructed to refrain from physical activity, or to eat unhealthy snacks and drink sugary soft-drinks; such measures would be unethical.

6.2 Individual randomization

The NFFD randomized controlled trial was performed with individual randomization of participants. This allowed a balanced distribution of effect-modifying factors and confounders (elements that can influence outcome but that are unrelated to the effect of intervention) (57) between the two groups, as confirmed by the assessment of baseline characteristics at trial inclusion. However, individual randomization also meant that women who lived in the same area and attended the same clinic were randomized to different groups. It is possible that control group women were influenced (or "contaminated") by intervention group women, but also by clinic midwives who were informed of the background for the trial and therefore conceivably more apt to address diet, physical activity and weight gain when providing prenatal care than they would have been without the trial. Cluster randomization of healthcare clinics was considered in order to reduce this potential contamination of control participants. As there were only eight clinics involved in the trial, which differed in size and cultural context, it would have been difficult to balance the distribution of clinics such that the resulting groups were equivalent at baseline regarding socioeconomic characteristics, geographical factors and other elements that may affect lifestyle habits. Cluster randomization would therefore have introduced new and potentially more serious forms of bias into the trial. Another consideration was to perform a clinical trial using historical controls, for example comparing results from women attending health care clinics and receiving intervention in 2010-2011 with those attending in 2008-2009, before initiating intervention. This would, however, have removed the element of randomization, and introduced new forms of bias into the analysis. Historical control trials have been found to favor interventions, presumably through bias in selection of controls (172) . In addition, time periods can also affect outcomes, as can be demonstrated by the curve describing birth weight of newborns over the period 1980-2015 (see Figures 1 and 2). Women delivering in the later period would have been prone to deliver babies of lower weight based on population changes of unknown etiology (45) , but unrelated to intervention effect. The result could conceivably have been that a null hypothesis (that NFFD intervention does not affect the proportion of large newborns) was incorrectly rejected, also known as a Type I error.

6.3 The NFFD Population

When planning the NFFD trial it was decided that only nulliparous women would be invited to participate. This assured greater homogeneity of groups when assessing outcomes, as both gestational weight gain and newborn birth weight are related to parity, and risk of delivery by cesarean section is influenced by earlier deliveries. Women who had not delivered previously were also without "pregnancy habits" based on earlier experiences, and their lifestyle might therefore be

easier to influence. Influencing lifestyle before the birth of the first child also had the potential to influence the new family from its start. In practical terms, nulliparous women were more likely to be at work or at school during the day, such that intervention elements were scheduled during the afternoon and evenings.

The NFFD trial included women of normal weight and above. This was based on findings suggesting that excessive gestational weight gain is an independent risk factor for obstetric morbidity independent of BMI (173-175). Normal-weight women may, in fact, be more prone to later obesity based on large gestational weight gain than women who are overweight or obese pre-pregnancy (17, 176). However, the subgroup of overweight and obese women was to be analyzed separately after study completion, based on the increased risk of obstetrical morbidity, delivery by cesarean section, and macrosomic offspring associated with entering pregnancy with excess weight (14, 173, 177, 178).

6.4 Missing participants

When planning the NFFD trial, a short questionnaire was constructed for women who were offered participation but declined. Only 60 of 159 (38%) women who declined participation completed the questionnaire, limiting its validity for analyzing the missing population, but it may nonetheless provide some information. Women who completed the "Decline participation" questionnaire were significantly younger (mean difference 1.48 years, $p=0.01$), more often smokers (12.5% vs. 4.2%, $p=0.01$) and fewer had ≥4 years higher education (9.4% vs. 35.6%, $p<0.001$) than those who participated in the trial, although the two groups were similar in self-reported pre-pregnancy weight, height and BMI (179). In addition, 93 women were not randomized in the NFFD trial because they failed to complete initial blood tests and questionnaires. It was proposed that these women be sent a similar questionnaire, but this proposal was rejected by the Regional Ethics Committee.

Comparing the NFFD participants to the population of southern Norway shows that they were older than average for nulliparous women giving birth in the region at the time (mean age 28.0 years for NFFD vs. 26.8 years for southern Norway in 2011 (180)), and had a higher level of education (35.5% with ≥4 years higher education in NFFD vs. 25.5% in 2014 survey of Agder region(181)). In addition, there were more normal-weight women than anticipated. Based on HUNT data, which is stated to be "fairly representative" of Norway (8), it was anticipated that 38-58% of participants would be overweight/obese (8). In fact, <30% of the NFFD population were above normal weight. This suggests that women of higher weight chose to abstain from participation.

After randomization, 32 women (32/591, 5.4%) withdrew consent to participation in the NFFD trial before delivery. This is a low rate of non-completion for a trial of an antenatal lifestyle intervention. In comparison, the Lifestyle in Pregnancy study published by Vinter et al, which studied the effect of a lifestyle intervention in a population of obese Danish women, had a 15.6% dropout rate (182), while the UK Pregnancies Better Eating and Activity Trial (UPBEAT), a large, multicenter study of a lifestyle intervention offered to obese women in the UK, reported that 11.3% discontinued participation (183). This may be a reflection of the mature and well-educated population that comprised the NFFD trial, but may also be affected by the randomization of women after the completion of initial testing, which assured a high degree of participant motivation. Comparing the NFFD non-completers to the 559 women included in the intention to treat analysis who completed the trial, showed that women who withdrew from the intervention group were significantly younger (24.9 vs. 28.0 years, p=0.005), more often without higher education (71.4% vs. 30.0%, p=0.004) and reported lower income (p=0.034), but had a similar distribution of occupations, pre-pregnancy BMI categories, and healthcare clinics compared with those who continued. Women who withdrew from the control group were not significantly different than those who continued.

Continuation of participation is important in a clinical trial, in order to accurately assess intervention effect (184). The NFFD trial was designed to make participation uncomplicated, allowing for completion of questionnaires from home using electronic forms available on the internet, and scheduling weight measurements on the same day as blood tests when possible. Information to intervention participants at evening meetings on the importance of the trial may have had more impact on those with higher education. While this was not specifically explored in the NFFD trial, a lifestyle intervention trial performed in an older, non-pregnant population demonstrated that adequate comprehension of the provided information was significantly associated with higher education (185).

6.5 Intervention considerations

The NFFD intervention was designed to limit gestational weight gain. All weight gain, in the absence of disease, is regulated by the balance of energy intake and energy expenditure (144, 186), and the obesity epidemic is largely fueled by the intake of energy-dense foods combined with decreased physical activity (12, 144). In keeping with WHO recommendations for obesity prevention (144), it was determined that the NFFD intervention would consist of both a dietary and a physical activity component. The goal was to create an intervention that would be feasible in a real-world setting: an

intervention that could be reproduced at reasonable cost, that could be applicable in both an urban and rural environment, and with which pregnant women would be able to comply.

Given the limited effect of the NFFD intervention on obstetrical and neonatal outcomes, it is appropriate to consider if other modalities could have generated more effect. The population studied was highly-educated and received written information on healthy lifestyle as part of routine prenatal care. In addition, there was considerable media attention directed at gestational lifestyle habits during the time of the trial (187). It may be that the NFFD lifestyle recommendations were too similar to standard information to produce detectable health changes. The dietary recommendations had no calorie limitation, an element which is known to be essential for weight restriction (186), and lacked information on increasing fiber and reducing intake of carbohydrates, elements that may influence maternal glucose levels (188). It is also possible that dietary advice could have been misconstrued, such as interpreting the recommendation to increase intake of fruits and vegetables as advice to increase intake of sugar-laden fruit juices. Providing additional consultations would have allowed detection and correction of such misunderstandings. The telephone consultations could also have been improved using the technique of "motivational interviewing". This technique, which emphasizes the user's needs and preferences before providing recommendations, has shown to be effective in weight loss interventions among non-pregnant adults (189). It is plausible that motivational interviewing is well-suited to use during pregnancy, a period when women are uniquely inclined to improve their health in order to protect their new baby (16).

Regular, supervised physical activity sessions formed the basis of the physical activity portion of the intervention, designed to be provided uniformly throughout the course of the trial and at all participating centers. The components of each session were designed to be modifiable, to fit varying fitness levels and gestational length. There was, however, lower attendance at exercise sessions than anticipated. While there was a mean of 21 weeks between randomization and delivery, women in the intervention group attended a median of 14 sessions (range 0-38). Acknowledging that classes were not held during 6 weeks of each calendar year (due to Christmas, Easter and summer holidays), most intervention women attended less than half of the exercise sessions that were available to them. It is possible that the uniformity of the sessions discouraged continued participation. It is also possible that by attempting to suit all needs, there were few who were completely satisfied. Practical considerations may also have determined participation: all classes were scheduled in the afternoon/evening, but some women worked during this time. Fitness centers were spread throughout the trial area, but some participants had closer access than others. Women participating in the feasibility study were asked for their feed-back, as were attendants at NFFD evening meetings, and both groups expressed their satisfaction with the exercise intervention. User-involvement could

have been further stressed by including pregnant women of different BMI categories in the design of the exercise portion of the intervention.

In Paper III, the outcome of postpartum weight retention was assessed according to compliance with the intervention. Intervention compliance was defined after trial completion, while ideally it should have been defined when designing the trial. However, one counseling session was deemed adequate to convey diet advice, and use of the median value for exercise sessions allowed a simple comparison of participants with greater adherence to the exercise portion of the intervention with those with lower adherence. Participants thus defined as non-compliant were found to have lower educational levels (p=0.029) and were less often employed outside the home (p=0.043) than those who attended ≥14 sessions. European women of lower socioeconomic status are at increased risk of overweight and obesity (190), and effective interventions are therefore especially important in this group. Assuring that exercise classes were accessible by public transportation and that written information was in language appropriate for all educational levels, might have improved compliance in this group.

A behavior-monitoring strategy, such as a food diary or physical activity log, is now a recommended element of lifestyle intervention to prevent obesity in non-pregnant adults (191). A diary or log might have improved NFFD intervention compliance by making participants more aware of their own lifestyle habits, and also provided researchers with additional information. The disadvantage is that participants may have perceived the registration as burdensome, leading to a higher drop-out rate, particularly among participants with lower education levels. Regular weighing with feed-back on results might also have been a useful supplement to the NFFD intervention, although this modality has shown varied results on gestational weight gain when used alone (192, 193). Conversely, the repeated measurement of control participants in the NFFD trial may have stimulated them to limit their weight gain in pregnancy.

6.6 Randomization and Blinding

Randomization was performed using a computer-generated list, with blocks of 20 to assure that women would be equally distributed to the two groups also in relation to time. There was no stratification of pre-pregnancy BMI groups, but analysis at trial completion showed that this was not significantly different between groups. Selection bias was avoided by physically separating the inclusion and randomization processes, with mail communication between healthcare clinics and the research nurse. Postponing randomization until after the initial blood test and questionnaire were completed may have contributed to the low proportion of non-completers and missing data in the

NFFD trial, thereby reducing another potential source of bias. However, by taking this step to assure that participants were sufficiently motivated before joining the trial, the population had already undergone a selection process, and the external validity of the findings—the degree to which the NFFD results apply to other populations—may have been weakened. It can be argued that as women who failed to complete initial testing constituted only 9.3% of the total number of women who were excluded from participation (see flow chart), their absence is not of crucial significance. Although women could not be blinded to their group allocation, blinding of assessors who weighed participants and gathered data through chart review reduced the risk of ascertainment bias.

6.7 Measurements

6.7.1 Weight

The primary outcome of the NFFD trial was gestational weight gain, making measurement of weight of central importance. Prior to the analysis of data, it was planned that gestational weight gain would be measured from pre-pregnancy to term delivery, limited to those with weight recorded within two weeks of delivery. This would allow comparison of groups that were equivalent in gestational length and results could be assessed according to compliance with IOM guidelines. Correspondingly, postpartum weight retention would be measured according to pre-pregnancy weight. Although measured pre-pregnancy weight was not available, self-reported pre-pregnancy weight has been validated in earlier studies (194) and has frequently been used in both epidemiological studies (19, 195) and randomized controlled trials (76, 196) evaluating gestational weight gain. Gestational weight gain measured from inclusion was included as a sensitivity analysis, to assure that the findings were robust. Weighing at inclusion was performed on the scales of healthcare clinics; possible inaccuracies should not have introduced bias as there was a similar distribution of clinics in both groups (p=0.177). In paper II, in response to a reviewer query, gestational weight gain was also assessed as a rate, using the last weight available for all participants. Comparing this rate to IOM recommendations posed a difficulty, as IOM rates for weekly weight gain are for second and third trimesters (with upper limit of total first trimester weight gain set to two kg), and 95 (16%) NFFD participants were included before the second trimester. This was resolved by comparing the rate of weight gain between first follow-up at week 30 and date of last weighing to IOM recommendations.

6.7.2 Body composition

At inclusion, there was no measurement of adiposity other than BMI. BMI is easily calculated, and widely used both in research and clinical practice, including in pregnancy (29, 197), but does not differentiate between lean and fat mass. Weights measured at weeks 30 and 36 included calculations of fat mass and fat percent by electrical bioimpedance. These results have so far not been analyzed, but may give additional information on intervention effect. Although bioimpedance measurements are not available at baseline, unbiased randomization of participants should allow comparison of groups. A recent study found that electrical bioimpedance measurement of fat mass in the third trimester correlated well with dual-energy X-ray absorptiometry (DEXA) scan administered two weeks postpartum (Deming regression slope 0.91, Pearson's r=0.95), although there was a trend toward overestimation of fat mass at higher values (197). DEXA is considered a reliable method for determining body composition, but contains small doses of radiation, making it unsafe for use in pregnancy (198). Other modalities that may be used in pregnancy are magnetic resonance imaging, underwater weighing and air-displacement plethysmography (197, 198), all of which were rejected as expensive and impractical for use in the NFFD trial. Measurement of skin fold thickness was also considered, but rejected as it requires extensive training (198) and has been described as prone to error in older Scandinavian studies of pregnant women (199, 200). However, a newer study found skin fold thickness to correlate well with DEXA results in late pregnancy (197).

For the newborn, there were no measurements of body composition other than those derived from weight and length at birth. These are inaccurate measures of fat mass, as has recently been demonstrated by a study comparing weight, weight for gestational age and ponderal index with a sum of skin fold measurements (201). Neonatal morbidity may be more closely associated with body fat mass than with birth weight percentile alone (201). Body composition in the neonate can be assessed using the same modalities as described above for adults—multiple skin fold thickness measurements, DEXA scan, air displacement plethysmography and MRI. Due to practical and economic considerations, these modalities were not employed in the NFFD trial. "Large for gestational age" and "small for gestational age" status were determined using a z-score based on singletons born in Norway during the period of 1987-1998 (159). Variations in birth weight during the period from 1980 to the completion of the trial (see Figure 1) may have made the comparison of NFFD neonates, born 2010-2013, with this reference population less accurate than intended.

6.7.3 Ultrasound measurements

All participants were monitored using abdominal fetal ultrasound measurements, primarily to assure that the intervention was safe, and perceived as safe, for women and their offspring. Results may

later be used to compare fetal growth based on group allocation. It may also be relevant to evaluate growth relative to intervention compliance, gestational weight gain and IOM compliance.

6.7.4 Blood tests

Blood tests were measured at inclusion and at gestational week 30. In addition to the measurement of proteins involved in glucose metabolism, included in papers II and IV, C-reactive protein and lipoproteins were measured at both time points. At the initiation of the NFFD trial, there was an underlying hypothesis that maternal glucose regulation would be modified by intervention, with corresponding modulation of fetal insulin levels (51) , and limitation of fetal overgrowth and adiposity (50, 202). Cord-blood levels of c-peptide, approximating the levels of insulin (51), have been measured, but results have yet to be analyzed. Fetal growth regulation is a multi-faceted process that remains largely unexplained, but there is evidence that maternal triglycerides, free fatty acids, and inflammatory proteins may have an important role in mediating fetal nutritional supply across the placenta, and fat deposition in the fetus (2, 102). Future papers are planned to examine the levels of maternal lipoproteins and C-reactive protein relative to intervention, BMI and gestational weight gain in the NFFD population. Baseline levels of insulin, and thereby a measure of baseline insulin resistance, may also be assessed at a later date using frozen stored samples from trial inclusion.

In the NFFD trial, homeostatic model assessment of insulin resistance (HOMA-IR) was used to assess insulin resistance. The gold standard for measuring insulin resistance is the euglycemic insulin clamp, measuring the amount of glucose infusion required to maintain a constant plasma glucose level in response to a constant infusion of insulin (203). The clamp test is invasive and time-consuming, and not suited for clinical practice (203). Surrogate tests have therefore been devised to measure insulin resistance. Measurement of fasting insulin alone is a measurement of insulin resistance and has shown significant correlation with euglycemic clamp findings, particularly in normoglycemic subjects (204). HOMA-IR was developed to include the interaction between glucose and insulin (205), and is calculated as described in section 4.7.3.

HOMA-IR has demonstrated acceptable correlation with the euglycemic insulin clamp (205, 206), but as it is performed in the fasting state it may more accurately reflect hepatic insulin resistance than skeletal muscle insulin resistance (203). Other surrogates for measuring insulin resistance, such as the oral glucose insulin sensitivity test (203) and the Matsuda index (207), are derived using multiple measurements of glucose and insulin during an oral glucose tolerance test, and may more accurately

reflect skeletal muscle insulin sensitivity (203). There is evidence that the oral glucose insulin sensitivity test may have the best correlation with the euglycemic insulin clamp in pregnant women (208). However, HOMA-IR has also demonstrated significant correlation with euglycemic clamp in pregnant women (208) and testing has shown a strong association between insulin resistance in liver and skeletal muscle, albeit in non-pregnant subjects (207, 209). Moreover, HOMA-IR is frequently reported in clinical trials of lifestyle interventions in pregnancy (76, 210-212).

6.7.5 Questionnaires

Questionnaires were most often completed electronically, as almost all participants had access to computers and the internet. There was excellent compliance with this measurement form, as 87% (515/591) of participants in the intention to treat analysis completed questionnaires at week 36, 81% (478/591) completed at 6 months, and 73% (431/591) completed at 12 months postpartum. Questionnaires supplied important information to the NFFD trial, but had several short-comings. They were designed to be completed within 25 minutes, thereby limiting the number of items included. There were no questions regarding race or ethnicity, information that would have been particularly valuable in the assessment of fetal growth and glucose metabolism. They gathered no information on family medical history, specifically history of diabetes. There were no questions on quality of life. This would have been of interest, to determine whether the intervention increased the subjective perception of well-being, or alternatively was perceived as a source of stress during pregnancy. Most participants (96 %) reported living with the father of their child. While information on partner health was limited, participants reported their partner's height and weight at inclusion and at gestational-week 36. It may be interesting to explore whether partners was indirectly affected by intervention, as weight loss intervention among non-pregnant participants has demonstrated positive effect on spouses (213). The Fit for Delivery study from the United States reported that partner weight was not affected by antenatal lifestyle intervention (214), although there was a limitation of gestational weight gain among normal-weight participants (196).

Additionally, the absence of questionnaire responses or other forms of reporting between inclusion and gestational week 36 meant that there was no information on participant lifestyle at the time of glucose testing at gestational-week 30. Responses at gestational-week 36 may have been affected by the results of glucose testing, as women informed of elevated glucose levels would have received additional impetus to eat a healthy diet and engage in regular physical activity. To eliminate the possibility of reverse causation, questionnaires in late pregnancy were not analyzed in the evaluation of week-30 glucose metabolism findings.

Finally, it is important to note that all questionnaire data is self-reported, and therefore has limitations. Self-reporting has been shown to favor over-reporting of behavior that is considered desirable, both for diet and physical activity (215, 216). This may have particularly affected the intervention group, where participants received additional information about healthy lifestyle, potentially creating reporting bias. Furthermore, the diet questions were specifically designed to measure compliance with the ten NFFD diet recommendations (see section 4.7.4.1). Questions were therefore not designed to address either the general quality of the diet, its caloric content, or the composition of fat, carbohydrates and proteins. The questionnaire was tested for reliability in a pregnant population but not validated prior to use. Objective measurement of diet is difficult, but supplementing questionnaires with food diaries at regular intervals would have provided additional information. Physical activity was assessed using IPAQ questions and scored according to IPAQ guidelines (161), as was done in the recent UK Pregnancies Better Eating and Activity Trial (UPBEAT) (discussed further in section 7.3) (183). The IPAQ analysis guidelines require that all cases with "don't know" as a response to one or more questions be excluded. In the NFFD trial, this resulted in discarding between 10.7% and 18.8% of responses (at 12 months postpartum and baseline, respectively). While this may reduce the accuracy of responses, it should not introduce bias into the comparison of the two groups. Physical activity could have been objectively measured using step-counters or accelerometers, in addition to self-reported levels.

6.8 Sample size

As described in Section 4.9, the NFFD trial was powered to detect a decrease in the proportion of macrosomic infants, and a decrease in the proportion of women diagnosed with gestational diabetes according to 1999 WHO criteria. As the primary outcome of the NFFD trial was gestational weight gain, using this outcome to determine sample size would have been more correct. In retrospect, in order to have 80% statistical power to detect a significant difference between groups with a reduction in the proportion of women exceeding IOM guidelines from 50% (as observed in the NFFD control group) to 40%, 390 women would be required in each arm of the analysis. Although it is difficult to determine whether there is a reduction in absolute gestational weight gain that is clinically significant, with 295 women in each arm of the trial, there was 75% statistical power to detect a statistically significant effect with a mean difference in weight gain between groups of 1.3 kg and SD 6.0, as was found in the NFFD trial. These calculations demonstrate that large trials, or a summation of several trials, are necessary to adequately assess the effect of intervention on gestational weight gain.

6.9 Statistics

The NFFD trial was a large trial with properly performed randomization, a similar distribution of baseline characteristics between groups, and with few missing data. Evaluation of the effect of the NFFD intervention on gestational weight gain, and obstetrical and neonatal outcomes was primarily performed using unadjusted analyses, with Chi square test for categorical outcomes such as mode of delivery and two-sided student t-test for continuous variables such as birth weight. Proper randomization does not exclude chance imbalance between groups that can have effect on outcome, such that analysis adjusted for baseline characteristics may also be performed. Adjusted analysis has been reported in randomized controlled trials of gestational weight gain interventions, such as the previously mentioned UPBEAT trial (183) and the Finnish RADIEL trial (217), which will be discussed in more detail in the next section. In the NFFD trial, unadjusted analysis was combined with adjusted analysis for the outcome of gestational weight gain. Each participant had multiple weights, but not all participants were weighed at all time-points. Linear mixed models analysis was used in Papers II and III to allow the comparison between groups of a series of repeated weight measures over time. This approach provided a more robust statistical analysis with missing data, and included assessment of the effects of others variables known to influence gestational weight gain such as age and pre-pregnancy BMI category. In addition, an adjusted analysis of IOM exceedance is included in the present thesis. In the NFFD trial, gestational weight gain was significantly different between groups both with adjusted and unadjusted analysis, confirming the effect of intervention on this outcome. The effect of intervention on the proportion of women exceeding IOM guidelines was statistically significant only when adjusted analysis was used. In contrast, the effect of intervention on postpartum weight retention was attenuated when the mixed model was applied.

The NFFD trial followed the method of intention to treat analysis, including women who withdrew from the intervention, women who were incorrectly included, and those who were incorrectly allocated (two control participants received the intervention). In addition to two participants who withdrew from the trial and did not consent to data use, only those who were excluded from participation were removed from the analysis: due to miscarriage (n=6), re-location to another part of the country (n=4), twin gestation (n=2), or very low BMI (n=1). In this way, the effectiveness of providing the NFFD intervention was tested. An assessment of the effect of the intervention per protocol, and an assessment of the effect of compliance with intervention, may be of interest for later analysis. However, these evaluations remove the random allocation of participants that forms the basis of a randomized controlled trial, and may introduce bias into the analysis. For example, in

the trial by Garshasbi et al. of Iranian women who received an exercise intervention in pregnancy (see Appendix, 11.1), the authors concluded that the intervention resulted in less lower back pain in the latter half of pregnancy (95). However, of 266 participants who were randomized, only 212 were analyzed, as those who missed three or more exercise sessions were excluded. It is conceivable that women with back pain ceased to attend exercise sessions, thus biasing the results in favor of the intervention.

As this example illustrates, missing participants are an important consideration in the analysis of randomized controlled trials (184). In the NFFD trial, it was possible to include obstetrical data from women who discontinued participation through record retrieval, but it was not possible to obtain other data, such as postpartum weights. In the case of missing data, baseline data on missing participants, dichotomized according to group allocation, was described as accurately as possible. Our assessment was that women in the NFFD trial were missing either completely at random (for example, those who moved out of the region), or missing at random (those with lower socioeconomic levels at baseline who withdrew consent). Adjusted analysis incorporated variables associated with "missingness" into evaluation of intervention effect (Paper III). For repeated measures, mixed models analysis was employed (Paper II, II), as it has been described as a statistical analysis that estimates unbiased treatment effects with missing participants, given that they are missing at random(184).

6.10 Reporting

Papers II-IV have reported findings using the standards described in the Consolidation of the Standards of Reporting Trials (CONSORT) statement (154, 155). Each paper has been accompanied by a completed CONSORT checklist when submitted for consideration for publication.

6.11 Ethics

In order for a randomized trial of an intervention to be ethically sound, there must be a condition of equipoise at the initiation of the study: genuine doubt about whether it is better to be in one group or the other (57). At the time the NFFD trial was planned, there was limited information on the safety of an intervention to limit maternal weight gain in pregnancy. Information about the benefits of exercise and moderate weight gain was largely from observational studies, which may not be transferrable to an intervention. It was deemed important to assess if the NFFD intervention had any

positive, or potentially negative, effects before recommending broader use in a general population. The conditions for an ethical randomized interventional trial were thereby fulfilled.

Due to the limited information available about the effects of an intervention to limit gestational weight gain, there were two extra ultrasound examinations performed during pregnancy. These were performed on all participants, so that the extra care would not be a confounding factor when comparing groups. Abnormal findings were reported to the obstetric department for further observation and treatment. Had we found suboptimal fetal growth in several participants, group allocations would have been un-blinded, to assess if this were predominantly in the intervention group. Had this been the case, the intervention would have been discontinued. Abnormal findings on blood tests were reported to the primary physician for further care. Elevated glucose levels using alternative thresholds for gestational diabetes diagnosis were not disclosed to participants or their physicians, as these thresholds do not reflect current Norwegian practice.

7. Discussion of Main findings

As described in Paper I, the current study is an evaluation of the effect of the NFFD antenatal combined lifestyle intervention on maternal and newborn health, with specific endpoints during pregnancy, delivery and the first year postpartum.

7.1 Gestational weight gain

Gestational weight gain was the primary endpoint for the NFFD trial. As presented in Paper II, intervention resulted in a small but significant reduction in gestational weight gain. Women in all pre-pregnancy BMI categories appeared to reduce gestational weight gain following intervention, but the effect was not significant in smaller BMI-category subgroups (see figure 7). Statistical analysis confirmed that pre-pregnancy BMI category did not affect gestational weight gain effect, as detailed in paper IV.

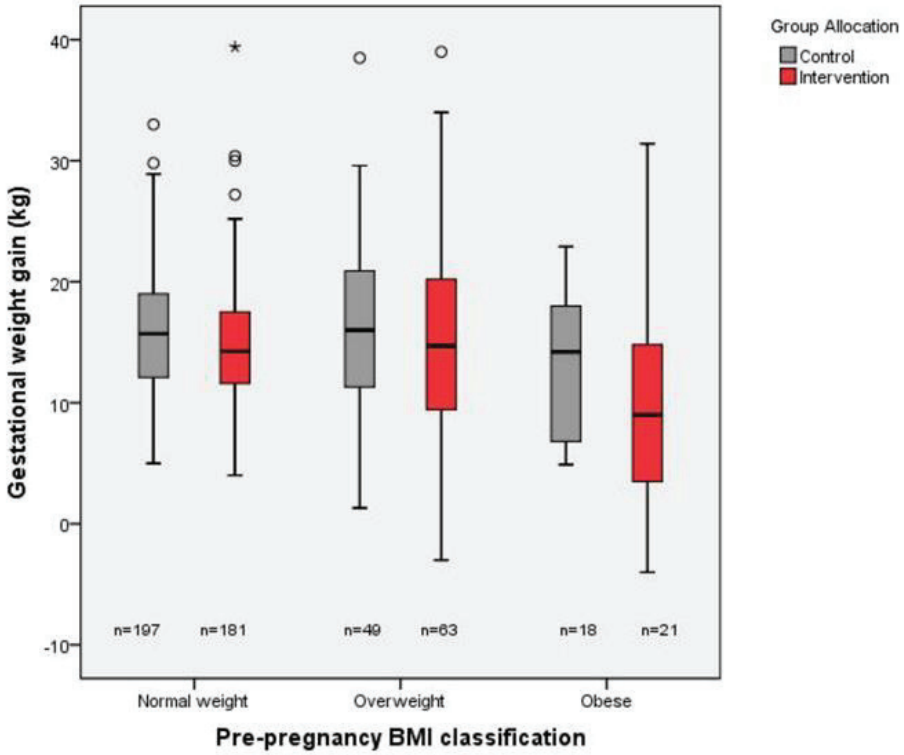

Figure 7: NFFD Intervention effect on gestational weight gain according to pre-pregnancy BMI category (measured from pre-pregnancy self-report)

A large proportion of both intervention and control group women exceeded IOM guidelines for gestational weight gain (42% in the intervention group, 50% in the control group) but there was a

trend toward reduced risk of exceeding recommendations following intervention using unadjusted analysis (Paper II), which was statistically significant in adjusted analysis (see section 5.3, unpublished results). The proportion of women exceeding IOM recommendations for gestational weight gain in the NFFD control group corresponded closely with findings from the Norwegian Mother and Child Cohort Study (MoBa). In the MoBa cohort of 56,101 women, 49.5% of nulliparous women with pre-pregnancy BMI ≥ 18.5 kg/m^2 exceeded IOM recommendations, based on self-reported weights (56).

Since the initiation of the NFFD trial, the literature regarding antenatal lifestyle interventions has grown exponentially. A 2015 Cochrane review of diet, exercise, or combined interventions for preventing excessive gestational weight gain by Muktabhant et al., included 65 randomized controlled trials published before November 2014 (218). My own search of Medline and Embase, performed in November 2016, using the terms ("diet or nutrition") or ("exercise or physical activity") or ("lifestyle or life style or life-style") and "weight" and ("antenat* or prenat*or pregnan*"), limited to randomized controlled trials or combined with the term "random* control* trial", produced 1230 citations, and identified an additional 32 relevant randomized controlled trials. Although it is outside the scope of this thesis to provide a thorough review of all available data, these numbers indicate the actuality of the topic and the breadth of the information available.

Antenatal lifestyle intervention trials published to date have employed a variety of interventions and included a variety of populations, making systematic review challenging. Nevertheless, several meta-analyses have now concluded that antenatal lifestyle intervention can effectively reduce gestational weight gain, whether the intervention is provided as diet alone, physical activity alone, or a combination of the two (218-223). However, consistent with the findings of the NFFD trial, intervention effect on gestational weight gain appears to be modest. The systematic review by Thangaratinam et al. reported a mean 1.42 kg (95% CI 0.95, 1.89, p<0.001) reduction in weight gain following lifestyle intervention compared with control care (219), and the Cochrane review by Muchtabhant et al. reported a 20% reduction in risk of IOM exceedence (RR 0.80, 95% CI 0.73, 0.87) (218). Unlike the NFFD trial, where women of all BMI categories appeared to reduce gestational weight gain (see figure 7), reduction of gestational weight gain has in several trials been more difficult to demonstrate in women who are overweight or obese pre-pregnancy (145, 196, 224). The largest trial of an antenatal intervention designed to limit gestational weight gain published to date, the LIMIT trial from Australia, employed a combination intervention, using the form of counseling. The LIMIT trial included 2212 overweight and obese women and provided six individual face-to-face meetings, with advice on physical activity and a personalized meal plan. Intervention participants showed no reduction in gestational weight gain or change in IOM compliance (225, 226).

Similar to LIMIT, most combined antenatal lifestyle interventions published to date have employed counseling (183, 218, 219, 227). Women may be reluctant to exercise in pregnancy, especially if they are previously sedentary, and counseling may be inadequate to stimulate this behavior change (103). The NFFD trial can best be compared to the Lifestyle in Pregnancy (LiP) study from Denmark (182) and the two randomized controlled trials published by Hui et al. from Mannitoba Canada (224, 228), all three of which have provided a combination of dietary counseling and supervised exercise. The LiP study included 360 obese women and provided four face-to-face sessions with a dietician, weekly supervised exercise classes, and free gym membership to intervention participants. The intervention resulted in reduced gestational weight gain and a trend toward reduced IOM exceedance, but the evaluation was not "intention to treat". Hui et al. provided an intervention with two diet consultations and weekly local exercise sessions plus a DVD for home exercise, and reported a reduction in IOM exceedance in two independent studies, both including normal-weight and overweight/obese women (224, 228). However, the Canadian studies may have included a highly selected population, reported to be recruited through advertisements. The rates of several obstetrical outcomes were very low in the Canadian populations described, particularly cesarean section: 2.0% for intervention group and 3.2% for control group in the 2011 study (228) and 0% cesarean section rate in all but the overweight control group in the 2014 study (224). Cesarean section rates for Ontario Canada (data from Mannitoba not found) are described as 19.6% for 2003-2006 and 21.1% for 2007-2010, the period of the studies (229). This may limit the external validity of the findings. Combining the NFFD findings with that of the three other trials combining dietary counseling with supervised exercise appears to confirm that this intervention form is effective for reducing gestational weight gain and IOM exceedance.

Both reduction of gestational weight gain and reduction of IOM exceedance may have clinical implications. For overweight and obese women, excess gestational weight gain has been found to consist of adipose tissue rather than lean body mass, consistent with the link between excess gestational weight gain and later obesity (230). For offspring, longitudinal studies have demonstrated that gestational weight gain exceeding IOM limits is associated with a 50% increase in the probability of obesity in childhood (2). Large gestational weight gain in the second and third trimester has also been associated with adverse lipid and inflammatory profiles in the offspring at nine years of age (231). Reduction in gestational weight gain may therefore have effects beyond what can be measured within the scope of the present study.

7.2 Diet and Physical Activity

Women in the intervention arm of the NFFD trial reported significantly higher diet scores and physical activity levels than control participants in late pregnancy (Paper II). This finding was based on questionnaire responses, and was without food diaries or activity logs to improve reliability, or objective measurements such as fitness testing or accelerometers. However, the finding of reduced gestational weight gain would seem to corroborate these reports. In the NFFD trial we found no effects on newborn birth weight (Paper II). However, changes in maternal diet and physical activity patterns can affect the intrauterine environment and have effects on the growing fetus that are not captured using the coarse measures of weight and length (232, 233). For example, maternal dietary patterns during pregnancy have been found to correlate with offspring diet in childhood to a greater degree than both maternal and paternal postnatal diet (234). This suggests that offspring appetite, and thereby later risk of obesity and disease, may be programmed by maternal intake while in-utero.

As reported in Paper III, there was no difference between groups in diet scores or physical activity levels at 6 or 12 months postpartum. The absence of effect was also seen among women who were defined as compliant with the intervention. This suggests that women failed to adopt their improved dietary habits and physical activity patterns as long-term changes. It is possible that supervised exercise sessions may, for some women, be a hinder to developing personal physical activity habits, with the result that they are less active when the sessions are no longer available. In an older US trial of 40 non-pregnant obese women, diet combined with supervised exercise was compared with diet combined with lifestyle counseling; both groups had equivalent weight loss during the 16 week intervention, but at one year follow-up the supervised exercise sessions group had regained significantly greater weight (235).

It is also possible that the NFFD intervention was interpreted as pregnancy-specific. Among women with new pregnancies at follow-up 12 month postpartum (n=54), there was a trend toward lower gestational weight gain in the new pregnancy for the intervention group compared to the control group (adj. mean difference -2.79 kg, p=0.069) (Paper III). This may indicate that intervention women with new pregnancies employed the habits that were acquired through NFFD participation. Examining the outcome of later pregnancies is a planned future investigation for the NFFD trial.

The first year postpartum is a time of radical change for first-time mothers, such that information on diet and physical activity collected during this period may not accurately reflect lifestyle over time. Further investigation at two and four years postpartum may give additional information on long-term lifestyle changes. In retrospect, information provided to participants should have explicitly addressed the period after delivery, informing them of the benefits of continuing good dietary and physical activity habits in their new role as mothers.

7.3 Large Newborns

Birth weight of term newborns and the proportion of newborns >4 kg were primary endpoints of the NFFD trial, while the proportion of newborns ≥90th percentile was a secondary endpoint. As described in Paper II, the NFFD intervention resulted in no measurable difference in any of these outcomes. However, there was a lower than expected proportion of large newborns in both groups, limiting the ability to demonstrate significant effect. Only 2.4% and 3.7% of newborns, in the intervention and control groups respectively, were in the 90th percentile for weight, based on population-specific z-scores differentiated according to sex and gestational age (159). The NFFD trial demonstrated no increase in the incidence of small for gestational age newborns or adverse neonatal events, but it was not powered to assess these outcomes adequately.

The three studies combining diet and supervised exercise published prior to the NFFD trial demonstrated mixed results on newborn birth weight. The LiP study, with a high-risk population, found an increase in mean birth weight without an increase in large for gestational age newborns, despite a reduction in gestational weight gain (182). The Canadian studies reported no effect of intervention on the proportion of large for gestational age newborns in either trial (224, 228), but noted reduced mean birth weight among normal-weight intervention participants compared to normal-weight controls in the second trial (224).

The Cochrane review of antenatal lifestyle interventions from 2015 stated that, although there was no clear reduction in macrosomia following lifestyle intervention overall, high-risk women (those with overweight/obesity or at high risk for gestational diabetes) receiving combined diet and exercise counseling interventions appeared to have a 15% decreased risk of infant macrosomia (218). The analysis included the results of the LIMIT study, that demonstrated a small but significant reduction in newborns >4 kg (from 19% to 15%), although gestational length at birth was not reported and there was no reduction in large for gestational age newborns (226). It also included the NELLI study from Finland, a cluster-randomized trial with 399 women at risk for gestational diabetes, where intervention participants received five antenatal counseling sessions (236). Intervention was associated with a significant decrease in large for gestational age newborns despite no improvement in glucose metabolism or gestational diabetes risk (236). Of note, several newer trials were not included in the Cochrane analysis, including the NFFD, UPBEAT (183), and RADIEL trials (217). The UPBEAT trial from the United Kingdom included 1555 obese women, provided eight weekly sessions with a health trainer to improve diet and physical activity, and found a small but significant reduction in gestational weight gain, but no effect on birth weight or neonatal outcomes (183). The RADIEL trial

from Finland included 293 women at high risk of gestational diabetes, either due to gestational diabetes in a previous pregnancy or pre-pregnancy BMI ≥ 30 kg/m^2, and found no effect of intervention on mean birth weight or the proportion of infants >4.5 kg (macrosomia not otherwise reported), despite reporting a significant reduction in gestational diabetes incidence (217).

Currently, the evidence for effect of lifestyle counseling in the prevention of macrosomia in high-risk women is uncertain. Interventions targeting diet alone, specifically those employing a low glycemic index, have shown effect on macrosomia risk in some trials (136, 237) but not in others (238, 239). Interventions employing exercise alone have demonstrated the potential to influence fetal growth (100, 140), but several large randomized controlled trials of supervised exercise interventions have shown little effect on macrosomia risk (218, 240-242). A recent meta-analysis concluded that supervised exercise (with or without additional nutritional counseling) significantly reduced the odds of delivering a macrosomic newborn (OR 0.69, 95% CI 0.55, 0.86, p<0.01), but the preventive effect was only seen in trials with low-risk populations (243). Also of note, the meta-analysis did not include the LiP study (182), which filled criteria for inclusion, thereby raising the possibility that the analysis was incomplete. Although they are beyond the scope of the present study of lifestyle intervention, dietary supplementation and pharmacological agents such as metformin, an oral hypoglycemic medication, are also studied for the prevention of macrosomia (103, 244). In a large trial of non-diabetic obese women recently performed in the United Kingdom, metformin administered starting at 12-18 weeks of gestation was found to have no effect on the incidence of macrosomia despite a significant reduction in gestational weight gain when compared with placebo (244).

Macrosomia has been described as a component in the trans-generational risk of obesity (245), but the risk of excess fetal growth appears to be difficult to affect by antenatal intervention, particularly for overweight and obese women. This may, at least in part, be explained by the modulating influence of the placenta, whose function is in turn determined by pre-pregnancy and early pregnancy conditions, including maternal BMI, nutritional status, and physical activity levels (246-248). The placenta is itself an endocrine organ with production of an array of hormones and proteins that influence fetal growth, such as human chorionic gonadotropin, human placental growth factor, and leptin (202). Maternal diet at a given time influences availability of nutrients in the maternal circulation, but maternal metabolic and hormonal status and placental function, all determined by earlier health, affect the transport of nutrients across the placenta (103, 202, 248). For example, placental mammalian target of rapamycin (mTOR) signaling regulates amino acid transport across the placenta and promotes protein synthesis and fetal growth (249). Insulin and leptin have both been found to up-regulate mTOR expression in placental trophoblastic cells (250), and both have been demonstrated to be elevated in obese women already in the first trimester (251). Transport of

triglycerides across the placenta also appears to be important for fetal growth, and may be altered by maternal over-nutrition, although the cellular mechanisms are largely unknown (249). In the NFFD trial, mean gestational age at randomization was 18 weeks (Paper II), and only 4.2% (25/591) of participants were randomized during the first trimester (result not previously published). Intervention may therefore have been initiated too late to affect the early processes that exert a powerful influence on fetal growth.

While large, observational studies have demonstrated a positive, linear correlation between glucose levels and fetal size (51, 118), the same association has not always been found in the antenatal lifestyle interventions published to date. For example, both the NELLI and the RADIEL studies demonstrated discordant results of intervention on maternal glucose levels and fetal growth outcomes (217, 236). The effects of triglycerides on fetal growth appear to be independent of maternal glucose levels (102), and intervention participants in the NELLI trial reported decreased intake of saturated fatty acids (236). In addition, women who exercise regularly have been found to have larger placental size (100) and may have improved placental circulation (139). This may explain the finding of larger newborns in the intervention group in the LiP trial despite limitation of gestational weight gain (182). The effects of NFFD intervention on lipid levels and placental size have thus far not been explored. Finally, the fetus also produces hormones that regulate growth and respond to the intrauterine environment, such as insulin, insulin-like growth factor and thyroid hormones (202). It is plausible that this will affect growth also after delivery. In the NFFD trial, the weight and length of offspring were measured at six and 12 months postpartum, but analysis is incomplete and results have not been published. In addition, participants have been asked to report the weight and length of offspring at two and four years after delivery. These results may provide additional information regarding intervention effect.

7.4 Obstetrical complications

The incidence of operative deliveries was a secondary endpoint of the NFFD trial. The trial protocol specified that hospital record review would include an evaluation of obstetrical complications, and the results were included in Paper II. The NFFD trial resulted in no change in the incidence of obstetrical or neonatal complications, specifically no reduction in the incidence of preterm delivery, preeclampsia, or delivery by cesarean section; the effect of the NFFD intervention on incidence of gestational diabetes will be discussed separately.

The MoBa cohort study mentioned earlier found a significant association for nulliparous women between excessive gestational weight gain and gestational hypertension, preeclampsia and emergency cesarean section (56). The NFFD trial found no effect of intervention on these outcomes, despite a significant reduction in weight gain. One explanation for this discrepancy is that the increased risk of adverse events associated with IOM exceedance is modest (for example OR 1.4 for acute cesarean section in the MoBa cohort), such that a small reduction in exceedance coupled with a modest reduction in risk of adverse events creates a summed effect of intervention on adverse events that is too small to identify in a trial of only 600 participants. However, meta-analysis of combined antenatal interventions, both those employing counseling and those with supervised exercise, have also shown little effect on obstetrical outcomes such as preeclampsia, preterm delivery and cesarean section rate (1, 218, 252). It should also be noted that the association between gestational weight gain and preeclampsia is very unclear, as preeclampsia is a condition characterized by changes in plasma volume and extracellular fluid leading to weight changes (29).

The NFFD intervention may have been initiated too late in pregnancy, as discussed earlier, or been too weak to produce measurable effect on the obstetrical health outcomes. The Cardiovascular Risk Reduction Diet in Pregnancy (CARDDIP) study, also performed in Norway, demonstrated a significant reduction in preterm birth, enrolling participants up until 20 weeks of gestation, similar to the NFFD trial. The CARDDIP intervention group was placed on a cholesterol-lowering diet that mandated large changes in diet composition (meat only twice per week and large intake of oils and vegetables), and required participants to weigh and record all dietary intake one day per week for 16 weeks, facilitated by four face-to-face visits with a dietician (68). In contrast, the NFFD intervention was designed to be feasible in a clinical setting, both regarding demands on participant time and effort and regarding cost. As a result, the intervention “dose” may have been inadequate to produce effect. Although women receiving the NFFD intervention were recommended to increase intake of fruits and vegetables and limit added sugar, they were given no other specific advice on the fat or carbohydrate content of their diet. In addition, the NFFD diet intervention contained no calorie limitations. Calorie restriction, preferably adjusted to participant weight status, is an important feature of weight-loss interventions in non-pregnant women, and may be an important component to include in an intervention targeting GWG (253). In addition, dietary advice in the NFFD trial could have been reinforced with additional consultations, preferably combined with feed-back based on participant food diaries.

The physical activity portion of the NFFD intervention may also have been of inadequate intensity. In addition to two one-hour sessions per week, women were encouraged to be physically active at moderate intensity for at least 30 minutes on two to three additional days each week, complying

with the Norwegian Directory of Health recommendation of 150 minutes of moderate activity per week (94). Some authors have argued that these recommendations are too low, and advised that all healthy women expend 16-28 MET hours/week on physical activity during pregnancy (approximately 4-7 hours/week of moderate-intensity exercise), and advocated use of interval training to meet these goals (254). Consistent with this, Kardel et al. reported that fitness level was significantly and inversely associated with the length of the second stage of labor, albeit in a population that also had high levels of pre-pregnancy physical activity (89). In addition, Aune et al. reported in a systematic review of cohort studies that physical activity level in early pregnancy was inversely associated with preeclampsia risk (255). However, when antenatal exercise interventions were reviewed, there was no pattern of intensity, frequency or duration that was associated with successful reduction in gestational weight gain (256). Similarly, the most recent Cochrane review evaluating exercise for overweight or obesity (not in pregnancy), published in 2006, found that for interventions combining exercise and diet, there was no significant difference in weight loss between high-intensity exercise and low-intensity exercise (257). While ideal level of physical activity in pregnancy is uncertain, providing pedometers or journals for recording daily physical activity might have given NFFD intervention participants additional motivation to be physically active outside of the scheduled sessions. In addition, earlier and more frequent assessments of weight gain, combined with feedback to participants, may have further reduced gestational weight gain.

Finally, the element of intervention compliance must be considered. Most women received at least one telephone diet consultation but attended less than half of available exercise classes. Low compliance with intervention has been cited as a limiting element in several antenatal lifestyle trials (226, 242, 258) Motivation is a key factor in all lifestyle intervention (259), and could have been improved in the NFFD trial by using motivational interviewing at the start of intervention and providing frequent follow-up. NFFD participants demonstrated ready access to the internet by choosing to complete questionnaires electronically. Use of the internet and mobile technology may be a helpful supplement to personal contact during the course of intervention. This is currently being tested in the Pregnancy, exercise and nutrition research study (PEARS) (260).

7.5 Glucose Metabolism

There was no significant difference between intervention and control group in the incidence of gestational diabetes using WHO 1999/2006 criteria, which remains in use in Norway as of 1. December 2016 (167). Analysis of indicators of glucose metabolism at gestational week 30 showed divergent effects of NFFD intervention based on participant pre-pregnancy BMI. The larger subgroup

of normal-weight women (BMI <25 kg/m^2) showed a small, positive effect of intervention on elements of glucose regulation. Participants with pre-pregnancy BMI ≥25 kg/m^2 demonstrated no positive effects of intervention on glucose metabolism, with trends toward higher glucose levels and a significantly greater proportion of intervention participants exceeding IADPSG thresholds for gestational diabetes diagnosis compared to overweight/obese controls. The trends for the two subgroups, normal-weight and overweight/obese, using an unadjusted analysis of data can be summarized as seen in Figure 8. When analysis was adjusted to control for possible confounding factors, particularly those associated with missing participants, results were similar but without trends for 2-hour glucose values.

Intervention effect on metabolic parameters according to BMI

BMI	Fasting glucose	2 h glucose	Insulin	HOMAR-IR	Leptin
<25	no change	↓ (trend)*	↓ (trend)*	↓ (trend)*	↓**
≥ 25	↑ (trend)*	↑ (trend)*	no change	no change	no change

*p<0.1 **p<0.05

Trends:
BMI <25: 4 out of 5 parameters altered in a metabolically favorable direction
BMI ≥25: 2 out of 5 parameters altered in a metabolically adverse direction

Figure 8: Effect of NFFD intervention on metabolic parameters according to BMI

Women who are overweight or obese have been shown to enter pregnancy with higher levels of inflammation, lipolysis, lipogenesis, and insulin resistance than those who are normal-weight (248). Metabolic improvements in response to lifestyle changes in pregnancy may be more difficult to achieve in this context (261). A low-intensity lifestyle intervention may therefore be insufficient to produce measurable changes in glucose homeostasis, particularly during the short span of the second half of pregnancy. This may account for the divergent findings found in normal-weight and overweight/obese women, displayed in Figure 8.

The intervention group as a whole demonstrated a significant reduction in serum leptin compared to the control group (adj. mean diff -208 pmol/l, 95% CI -383, -32, p=0.021). There were similar reductions in both the normal-weight and overweight/obese subgroups, but only the normal-weight subgroup demonstrated intervention effect due to a greater number of participants (Paper IV). Among normal-weight women, the reduction in leptin was associated with a trend toward lower insulin resistance (Figure 8), consistent with the known positive association between leptin and

insulin resistance (106, 108), but without reduction of glucose levels in adjusted analysis. It is plausible that the NFFD intervention affected energy balance, as gestational weight gain to term was significantly lower in the intervention group. Reduction of the mean leptin level may express this subtle change in metabolism, although the effect of intervention was not of sufficient strength and/or duration to result in measurable changes in glucose metabolism.

The increased proportion of overweight/obese women in the intervention group who exceeded IADPSG thresholds for GDM diagnosis compared with control women was unexpected, and is so far unexplained. Elements that have been analyzed thus far are intervention compliance, weight gain prior to testing, compliance with IOM recommendations for gestational weight gain prior to testing (results not published), self-reported pre-pregnancy lifestyle, and glucose level at inclusion. Family history of diabetes, participant ethnicity, and participant history of polycystic ovarian syndrome are unknown elements that may influence gestational diabetes risk, and are therefore possible sources of residual confounding in the NFFD population.

The intervention group was only found to have a significantly greater proportion of elevated glucose values when IADPSG thresholds were used. IADPSG criteria were established based on risk for high birth weight and newborn adiposity (119) and have been shown to best predict fetal overgrowth, while older and more restrictive gestational diabetes criteria have also been associated with hypertensive disorders of pregnancy, preterm birth and cesarean section (123). We found no significant difference in birth weight or the incidence of macrosomia among overweight/obese intervention participants compared with overweight/obese controls, but the subgroup analysis was not powered to assess this endpoint adequately (Paper IV).

Effective prenatal lifestyle intervention to prevent gestational diabetes is in high demand, but results to date have been modest and conflicting. A meta-analysis published in 2012 concluded that interventions consisting of dietary elements alone resulted in the greatest improvement in pregnancy outcomes, including a 61% reduction in risk of gestational diabetes ($p<0.001$) (219). In 2015, another meta-analysis published with many of the same authors found a non-significant reduction of gestational diabetes risk with diet-based interventions (RR 0.67, 95% CI 0.39, 1.15) and concluded that “Nutritional manipulation in pregnancy based on diet or mixed approach does not appear to reduce the risk of gestational diabetes” (262). The heterogeneity of dietary interventions may have made effect difficult to demonstrate (263). In 2012, A Cochrane meta-analysis by Han et al. found no effect of exercise intervention of incidence of gestational diabetes, based on three trials (141). In 2015, two new meta-analyses both concluded that exercise interventions result in a small but significant reduction in gestational diabetes risk: Russo et al. reported RR 0.75, $p<0.005$ based on

10 trials (264) and Sanabria-Martin et al. reported RR 0.69, p= 0.009 based on 13 trials (221). Two large trials of supervised exercise have since been published, with conflicting results. Nobles et al. found no effect of intervention on the incidence of gestational diabetes in a high-risk population in the United States (258), while the Exercise Training in Obese Pregnant Women (ETIP) trial demonstrated a significant reduction in gestational diabetes incidence based on WHO 2006 criteria in a population of Norwegian women with BMI >28 kg/m^2 (210). Exercise may be particularly suited to reduce serum glucose levels in overweight and obese women with increased insulin resistance, as contraction-induced mobilization of GLUT4 to the cell membrane, and thereby increased uptake of glucose into muscle cells, is independent from insulin-induced GLUT4 mobilization and glucose uptake (139). However, the ETIP trial did not demonstrate a change in mean glucose, insulin or insulin resistance in late pregnancy (210)

Combined interventions have demonstrated little effect on glucose metabolism and gestational diabetes incidence. To date, only two trials of combined interventions have demonstrated an effect on gestational diabetes: that reported by Petrella et al. in 2014 and the RADIEL study from 2016. Petrella et al. included 61 Italian women with BMI≥25 kg/m^2 and provided a strict diet plan of 1500-1800 kcal/day, advice on moderate physical activity, and pedometers. The trial demonstrated no effect of intervention on the primary outcome of gestational weight gain, but reduced incidence of gestational diabetes and gestational hypertension (265). The larger RADIEL trial also demonstrated a significant reduction of gestational diabetes incidence in high-risk women, although effect was only found using adjusted analysis in a randomized trial with similar groups at baseline (217). Both trials included only high-risk women and were aggressive in their intervention, with the RADIEL trial advising no weight gain in the first and second trimester for obese participants. Also important, the RADIEL trial included participants pre-conception or in early pregnancy. In addition to creating a longer intervention interval, this may also have allowed for improvement in maternal metabolic profile before gestation.

Intervention initiated before the start of pregnancy, particularly if it leads to a decrease in adipose tissue in women who are overweight or obese, may improve the maternal level of cytokines, adipokines, insulin, glucose and triglycerides in early gestation (266). This may, in turn, enhance the functioning of the complex interaction of maternal, placental and fetal elements that characterizes later pregnancy, allowing lifestyle intervention continued during pregnancy to have enhanced effect on glucose metabolism (261, 267). Consistent with this supposition, cohort studies examining physical activity and risk of gestational diabetes have demonstrated that pre-pregnancy physical activity is associated with greatest risk reduction (268, 269). While pre-conception intervention is

now a field of considerable interest, there are notably few trials to date that have addressed its effectiveness in improving obstetrical outcome (1, 270).

There are many diagnostic criteria in use for diagnosis of gestational diabetes, and trial findings can vary based on criteria used, as demonstrated by both the NFFD trial (Paper IV) and the ETIP study (210). Reporting of glucose, insulin and HOMA-IR levels may provide additional information and allow more accurate comparison between trials. The NFFD trial data, including glucose levels, is also to be incorporated in the international Weight management in Pregnancy (iWIP) collaborative network data-bank, for use in a systematic review of individual patient data, which may provide additional information on gestational weight gain, gestational diabetes and intervention effect.

7.6 Postpartum weight retention

Postpartum weight retention was a secondary endpoint of the NFFD trial. As described in Paper III, women in the NFFD intervention group had a trend toward greater return to pre-pregnancy weight (53% vs. 43%, adj. OR 2.23, p=0.067) and women compliant with the intervention had significantly lower postpartum weight retention than control participants (p=0.039) at 12 months postpartum.

The postpartum analysis of weight retention was limited by the number of participants who were missing, or excluded due to new pregnancy. Detection of a significant difference between groups with a risk difference of 10%, as here found, would have required 400 women in each group postpartum. The study would then have required 1000-1500 participants initially, in order to allow for loss to follow-up and new pregnancies. The return of an additional 10% of women to pre-pregnancy weight within the first year post-partum may be clinically significant in the public health goal of reducing lifetime obesity risk, and illustrates the need for large studies, or combined analysis of several studies, in order to adequately assess this outcome. To date, to the best of my knowledge, the NFFD trial is one of only four randomized controlled trials of interventions to limit gestational weight gain that have followed participant weight as long as 12 months postpartum (271-273).

Weight retention at 12 months postpartum was low in both groups in the NFFD trial. For example, the Norwegian MoBa cohort of 19,604 nulliparous women described 2.1 kg weight retention at 18 months, while the intervention and control group in the NFFD trial had mean weight retention of 0.7 and 1.4 kg at 12 months postpartum. This suggests that both groups may have been affected by trial participation, as does the low incidence of macrosomia in both groups, as earlier described. Control participants may have been "contaminated" by intervention elements (see section 6.2). Alternatively, all trial participants may have been influenced by being observed. Improved behavior

while under scientific observation has been termed the “Hawthorne effect” (274). There is evidence that participation in a randomized trial has a positive effect on the outcome of all participants (274), thereby making it more difficult to measure effect of a particular intervention. The control group in the NFFD trial received good-quality, free prenatal care including literature with information on healthy lifestyle in pregnancy (92), such that the additional motivation of trial participation might have led to positive changes also in this group.

7.7 Intervention directed at a general population

Our findings suggest that a broad lifestyle intervention offered to the general population may be less beneficial for overweight/obese women. While women of all BMI categories reduced gestational weight gain following NFFD intervention (see Figure 7 and Papers II and IV), intervention effect on glucose metabolism was modified based on pre-pregnancy BMI category (Paper IV). Similarly, the trial reported by Hui et al. in 2014 (223), studying a combined intervention of diet and supervised exercise, found no effect of intervention on overweight/obese participants, while normal-weight participants demonstrated reduced weight gain, lower gestational diabetes risk and reduced mean birth weight of offspring. In the NFFD population, approximately 70% of participants were normal-weight pre-pregnancy, such that larger women may have felt out of place, particularly at exercise classes. Although not a statistically significant difference, overweight/obese women participated in a median of 11 classes, while normal-weight women participated in a median of 14 (Mann Whitney U test: p=0.240, result not previously published). Frequent monitoring of weight may be especially important for overweight and obese women, who have lower gestational weight gain recommendations than normal-weight women (29), and the NFFD intervention might have demonstrated greater effect had this element been provided. In contrast to the strict diet and gestational weight gain recommendations of the two trials (RADIEL and that of Petrella et al.) that demonstrated reduced gestational diabetes risk following combination intervention (217, 265), obese women in the NFFD trial received information that was also meant to be relevant to normal-weight women. While antenatal lifestyle and gestational weight gain are important for both normal-weight and overweight/obese women, the form of intervention that leads to the best outcome for mother and child may differ based on pre-pregnancy BMI category.

7.8 Combination intervention

While effects of antenatal lifestyle interventions trials have been modest, similar interventions among non-pregnant individuals have shown to be effective in reducing weight, preventing type 2 diabetes, and decreasing the incidence of metabolic syndrome (275-277). As both overweight and sedentary behavior are public health epidemics related to a long list of chronic diseases, improvements in both diet and physical activity levels are desirable in a long-term perspective, beyond the boundaries of pregnancy. Both diet quality and physical activity levels are important considerations for the new family as well. Exploring elements that can improve motivation and increase compliance, particularly in high-risk groups, such as those with low socioeconomic status and those with pre-pregnancy overweight and obesity, are important avenues for further research. Providing supervised exercise may improve intervention compliance (103), and appears to decrease the risk of macrosomia, at least in low-risk populations (243). For women who are overweight or obese, pairing supervised exercise and diet counseling with other elements, such as electronic reminders and frequent follow-up, may be required in order to achieve compliance. An element of counseling may also be necessary in order to continue lifestyle changes after the discontinuation of supervised sessions.

7.9 Antenatal intervention, a moment of opportunity

The antenatal period is characterized by heightened interest in health and lifestyle, motivated by the responsibility of caring for a new life (16). In addition, pregnant women have frequent contact with health care providers during pregnancy, and prenatal health care is free of charge. It is therefore important that health care professionals continue to use this “moment of opportunity” to influence women to improve lifestyle. While antenatal lifestyle interventional trials may have modest results to date, they do not reflect the effects of improving diet and increasing physical activity for the individual. It may also be necessary to look beyond the individual in order to target societal and cultural elements that can be modified in order to assist women in achieving and maintaining a healthy lifestyle (1).

For women who are planning pregnancy, it is important to inform of the benefits of achieving normal weight and improving metabolic status before conception. However, pregnancy is often unplanned, and this ideal state may be difficult to reach. I maintain that attention to the antenatal period remains justified. Healthy lifestyle should be addressed as early as possible in a new pregnancy and attention should be given to continuing lifestyle changes in the post-partum period. Most Norwegian women deliver more than one child, so that improvements in diet and physical activity in one

pregnancy may affect the metabolic state in which the next pregnancy is begun. Small changes may therefore have incremental benefits over time, for both the woman and the new family.

8. Conclusions and summarizing remarks

Overweight and obesity continue to be health challenges around the globe, with continued increases since the NFFD trial was initiated in 2009 (12). Effective interventions to prevent the development of obesity are therefore still in high demand.

The NFFD intervention resulted in a moderate reduction in gestational weight gain, and a significant improvement in self-reported diet quality and physical activity level, compared with routine prenatal care. Over-nutrition and sedentary lifestyle fuel the current obesity epidemic, and small improvements in these outcomes may therefore plausibly improve health and reduce the risk of later obesity for both mother and child.

Similar to the findings of most antenatal lifestyle intervention trials published to date, the NFFD trial failed to demonstrate significant improvements in obstetrical outcomes following intervention. Further, evaluation of findings from the NFFD trial suggest that overweight and obese women require more intensive intervention, ideally initiated pre-pregnancy, in order to achieve reduced risk of obstetrical complications. Exploring factors that can motivate overweight women to partake in interventions, and to comply with the intervention elements provided, are important areas for future study.

For the individual patient, improving diet and increasing physical activity may have far greater effect than what is demonstrated by the findings of a large trial evaluated according to the stringent principles of intention to treat. Providers of antenatal healthcare are in a unique position to influence the health of two individuals, and small improvements in the intrauterine environment during the period of “developmental plasticity” may have far-reaching consequences. Although antenatal intervention is best seen in a life-course perspective, accompanied by efforts to improve lifestyle both before and after gestation, pregnancy remains a “window of opportunity” for improving the health of the current and the next generation.

9. References

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10. Errata

Abbreviations for different types of corrections:
Cor – correction of language
Cpltf – change of page layout or text format

Page	Original text	(Type of Correction) Corrected text
74	4. Hånes H. Birth weight in Norway-- fact sheet with statistics. Health NIoP; 2014.	(Cor/Cpltf) 4.Hånes H. Birth weight in Norway-- fact sheet with statistics. National Institute of Public Health; 2014.
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79	121. Mehre K. Eksternt høringsutkast--Nasjonal faglig retningslinje for svangerskapsdiabetes. In: Health) HNDo, editor. 2016. p. 263.	(Cor/Cpltf) 121. Mehre K. Eksternt høringsutkast--Nasjonal faglig retningslinje for svangerskapsdiabetes. Oslo: Helsedirektoratet;2016. p. 263.
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STUDY PROTOCOL Open Access

Study protocol: fit for delivery - can a lifestyle intervention in pregnancy result in measurable health benefits for mothers and newborns? A randomized controlled trial

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Abstract

Background: The global obesity epidemic has led to increased attention on pregnancy, a period when women are at risk of gaining excessive weight. Excessive gestational weight gain is associated with numerous complications, for both mother and child. Though the problem is widespread, few studies have examined the effect of a lifestyle intervention in pregnancy designed to limit maternal weight gain. The Fit for Delivery study will explore the effectiveness of nutritional counseling coupled with exercise classes compared with standard prenatal care. The aims of the study are to examine the effect of the intervention on maternal weight gain, newborn birth weight, glucose regulation, complications of pregnancy and delivery, and maternal weight retention up to 12 months postpartum.

Methods/design: Fit for Delivery is a randomized controlled trial that will include 600 women expecting their first child. To be eligible, women must be 18 years of age or older, of less than 20 weeks gestational age, with a singleton pregnancy, and have a Body Mass Index (BMI) ≥ 19 kg/m^2. The women will be randomly allocated to either an intervention group or a control group. The control group will receive standard prenatal care. The intervention group will, in addition, receive nutritional counseling by phone, access to twice-weekly exercise sessions, and information on healthy eating and physical activity provided in pamphlets, evening meetings and an interactive website. Both groups will be monitored by weighing (including bioimpedance measurements of percent body fat), blood tests, self-report questionnaires and hospital record review.

Discussion: Weight gained in pregnancy affects the health of both the mother and her unborn child, and simple models for efficient intervention are in high demand. The Fit for Delivery intervention provides concrete advice on limiting energy intake and practical training in increasing physical activity. This lifestyle intervention is simple, reproducible, and inexpensive. The design of the study reflects the realities of clinical practice, where patients are free to choose whether or not they respond to health initiatives. If we find measurable health benefits associated with the intervention, it may be an easily adopted supplement to routine prenatal care, in the prevention of obesity.

Trial registration: ClinicalTrial.gov, NCT01001689

Keywords: Pregnancy, Gestational weight gain, Nutrition, Exercise, Large for gestational age, Gestational diabetes, Weight retention, Randomized controlled trial

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Background

The health consequences of overweight and obesity have resulted in an increased interest in maternal weight gain during pregnancy. Several authorities, including the World Health Organization, have concluded that preventive efforts among pregnant women are required to make a long-term effect on the obesity epidemic [1,2]. The American Institute of Medicine (IOM) first suggested guidelines for weight gain during pregnancy in 1990, based on a woman's pre-pregnancy BMI [3]. Specifically, it recommended that normal weight women (BMI 19.8-26 kg/m^2) gain 11.5-16 kg, underweight women (BMI < 19.8 kg/m^2) gain 12.5-18 kg, overweight women (BMI 26.1-29 kg/m^2) gain 7–11.5 kg, and obese women (BMI > 29 kg/m^2) gain at least 6.8 kg. Research suggests that weight gain at or below these recommendations is associated with an optimal delivery outcome for both mother and child [4,5]. These guidelines were modified in 2009, and the BMI ranges now correspond with WHO definitions of normal weight (18.5-24.9 kg/m^2), underweight (<18.5 kg/m^2) and overweight (25–29.9 kg/m^2), and the recommended weight gain for obese women is now 5–9 kg [6].

The effects of excessive gestational weight gain

For the pregnant woman, excessive gestational weight gain is associated with an increased risk of complications during the prenatal period, such as gestational diabetes, gestational hypertension, and pre-eclampsia, a potentially life-threatening combination of hypertension and increased renal excretion of protein [5]. At the time of delivery, maternal overweight is associated with an increased incidence of complications, such as operative vaginal delivery, shoulder dystocia, cesarean section, and postpartum hemorrhage [7]. Excessive weight gain during pregnancy is also associated with an increased risk of weight retention after delivery [8]. In studies of obese women, as many as 73% describe pregnancy as an important trigger for a significant (>10 kilo) increase in weight [9]. Excessive gestational weight gain may also be a risk factor for the development of disease later in life, such as diabetes, hypertension, and breast cancer [10].

Excessive gestational weight gain is clearly associated with an increased incidence of large for gestational age babies [4] and has been linked with an increased incidence of overweight in childhood [11]. The large for gestational age newborn is at increased risk of birth trauma, respiratory distress syndrome, hypoglycemia, hyperbilirubinemia and admission to the neonatal intensive care unit, compared to newborns of appropriate weight [12]. Later in life, high birth weight is associated with an increased risk of overweight and obesity, along with diabetes and certain forms of cancer [13,14].

The effect of maternal weight gain on pregnancy outcome and fetal growth is at least partly moderated by maternal glucose levels. Maternal energy intake has a direct effect on serum glucose, while exercise moderates serum glucose levels by increasing skeletal muscle glucose uptake and improving insulin sensitivity [15]. Maternal plasma glucose levels have been shown to have a linear correlation with newborn birth weight [16] and the incidence of caesarean section [17]. Maternal glycemia has a direct correlation with fetal blood levels of insulin and c-peptide, which in turn regulate the growth of the fetus. Maternal dietary intake and physical activity level also have an influence on fetal levels of hormones such as leptin [18] and insulin-like growth hormone [19], the development of the fetal hypothalamus[20], the proportion of lean and fat body mass, and even gene expression [21]–all of which will affect fetal growth and energy regulation later in life.

The current literature on interventions to limit gestational weight gain

Several recent review articles have summarized the current literature regarding interventions to limit weight gain in pregnancy [22-26]. Muktabhant et al. (2012) for the Cochrane collaboration [26] examined the results of a total of 27 randomized controlled trials, and divided interventions into those which recruited women from a general population and those that were designed for women in high risk groups. The interventions ranged from regular weighing to the use of appetite suppressants, with sample sizes of 20 to 327 participants. Only 9 studies provided some element of both diet and exercise in their intervention. Of these, five [27-31] provided behavioral counseling with recommendations for diet and exercise, one of them through an interactive computer program [30]. An additional three studies provided counseling on diet and exercise, but limited their population to overweight or obese women [32-34]. Of the 27 reported studies, only that of Hui et al. (2006) [35] provided an intervention consisting of both nutritional counseling and exercise groups. This was, however, a pilot study with only 45 participants. Hui et al. have since reported on the effects of the same intervention on a population of 190 women, and found a decreased prevalence of excessive gestational weight gain in the intervention group [36].

Postpartum weight retention was rarely reported in these interventional studies, but the Cochrane review found two studies with a combined intervention in a general population [28,29] both of which showed a significantly higher probability of returning to pregestational weight in the intervention arm of the study at 6 months postpartum. No studies reported on the effect of the intervention at 12 months postpartum or

later. Three studies [27,29,31] reported on the effect of a combined intervention on the incidence of caesarean section, and all showed a trend toward decreased prevalence but this was not large enough to be statistically significant.

Four studies of lifestyle interventions performed in a high-risk population [29,31,33,34] and three performed on a general population [29,31,35] reported the incidence of high birth weight. Luoto et al. (2011) [33], who reported on the effect of diet and exercise counseling among women at risk for gestational diabetes, found a lower incidence of birth weight above the 90% percentile in the intervention group, but the result was not large enough to be significant in their group of 93 participants. The Cochrane review concludes that there is no evidence to date that interventions in pregnancy result in a significant reduction in excessive gestational weight gain or in the incidence of high birth weight, and calls for high quality randomized controlled trials of adequate sample size to assess potential interventions for restricting maternal weight gain [26].

Another recent meta-analysis, by Thangaratinam et al. (2012) [25], included 34 studies that examined gestational weight gain and divided interventions into three categories: diet, physical activity and mixed approach. Thangaratinam's group found that interventions based on exercise alone showed a small but statistically significant reduction in birth weight and maternal weight gain. Interventions based on diet alone resulted in a larger decrease in maternal weight gain and a statistically significant decrease in the incidence of gestational diabetes, pre-eclampsia, gestational hypertension and preterm delivery compared with controls, but had no effect on birth weight. Mixed interventions showed a decrease in maternal weight gain compared with controls, but less than with diet alone, and no significant effect on pregnancy complications or birth weight [25]. As in the Cochrane review, the lifestyle interventions analyzed by Thangaratinam's group consisted almost exclusively of counseling, with the exception of those reported by Hui et al. (2012) [36] and Vinter et al. (2011) [37].

Hui et al., (2012) [36] examined the effects of a lifestyle intervention with group exercise once a week and nutritional counseling in a population of 190 women in Canada, and found that fewer women in the intervention group exceeded IOM guidelines for weight gain, but found no effect on birth weight, the incidence of gestational diabetes or the frequency of caesarean section. The "Lifestyle in Pregnancy" study, published by Vinter et al. (2011) [37], included 360 obese Danish women and provided physical training once a week and dietary guidance. Vinter et al. found significantly lower gestational weight gain in the intervention group, but no difference in the incidence of gestational diabetes or caesarean section. Surprisingly, there was a significant increase in birth weight in the intervention group compared to the control group, without an increased incidence of LGA babies. Neither of these studies followed participants postpartum.

The Fit for Delivery study

In contrast to previously published trials of interventions to limit gestational weight gain, the Fit for Delivery study combines access to twice-weekly supervised exercise sessions with counseling on nutrition and appropriate gestational weight gain, and is designed for a general population. The study is to include 600 participants, and is therefore larger than other interventions that have been published. The study is also unique in that it includes only nulliparous patients and follows all participants until 12 months after the completion of the intervention. The aim of the Fit for Delivery study is to examine if this mixed, lifestyle intervention results in a measurable decrease in maternal weight gain in pregnancy, maternal weight retention postpartum, newborn birth weight and the incidence of large for gestational age newborns, maternal hyperglycemia, and the incidence of caesarean section and operative vaginal delivery. In this article we describe the protocol for our study.

Methods

Study design

Fit for Delivery is a randomized controlled trial with participants allocated either to an arm which receives a lifestyle intervention in pregnancy or a control arm which receives standard care. All participants in the study will be monitored at the time of inclusion in the study, at 30 and 36 weeks of gestation, at the time of delivery and at 6 and 12 months postpartum.

Setting

Health care during pregnancy in Norway is free of charge, and almost 100% of women receive prenatal care. Most women alternate between visits with their general practitioner and with a midwife at a local clinic. Fit for Delivery is to be conducted in the cities and towns of southern Norway, with participants from both urban and rural settings.

Participants

All women expecting their first child and attending antenatal clinics in the included districts will be asked to participate. Midwives at the local antenatal clinics will provide information about the trial and take the initial measurement of each participant. To be eligible, women must be 18 years or older, have a BMI of 19 or higher, have a singleton pregnancy of less than 20 gestational weeks, and be fluent in either Norwegian or English.

Exclusion criteria are pre-existing diabetes, physical disabilities which preclude participation in a physical fitness program (based on the recommendations of the American College of Obstetricians and Gynecologists) [38], ongoing substance abuse, and planned relocation outside the study area before delivery. Those who choose to participate will be asked to read and sign a consent form, take blood tests and answer an initial questionnaire. The participants will not receive any compensation for participation in the trial, but all examinations and interventions will be free of charge. Women who choose not to participate in the trial will be asked to answer a short questionnaire (see description below), anonymously, to learn why they are not interested in participation. Participating clinics will be asked to report each week how many women were enrolled in the trial, how many completed a non-participation questionnaire and how many declined participation without completing questionnaires.

All participants will receive two additional prenatal care visits, including ultrasound examinations, in the third trimester. Blood pressure will be examined at each visit using an Omron electronic sphygmomanometer, HEM-7301 (www.omron.com) following a recommended protocol for pregnant women [39].

Intervention

The Fit for Delivery lifestyle intervention is composed of nutrition and physical activity elements.

1. Dietary counselling will consist of an initial telephone consultation with a doctor, clinical nutritionist or graduate student in public health. Counselling will be focused on ten recommendations, designed to assist in establishing good nutritional habits. Specific attention will be given to selected key behaviors: intake of fruits and vegetables, drinking water instead of drinks containing energy, regular meal patterns, and limiting consumption of snack foods and foods/drinks containing added sugar. The Fit for Delivery nutritional advice is based on recommendations from the Norwegian Directorate for Health [40], but is more specific and action-oriented. A complete discussion of the advice and its background is published elsewhere [41]. A follow-up consultation will take place 4–6 weeks after the first consultation. Participants in the intervention group will receive a pamphlet containing the 10 specific dietary recommendations. They will also have password-protected access to an interactive internet site, with information on nutrition and physical activity during pregnancy. Participants in the intervention group will be invited to two evening meetings, one with additional information about the trial and one with a hands-on cooking class, focused on the Fit for Delivery recommendations.
2. The physical activity component of the intervention is based on national [40] and international [38] guidelines and will consist of two exercise sessions each week, each lasting one hour. The groups will meet at local fitness centers, and attendance will be registered. All groups will have the same exercise plan. Exercise will be supervised either by physiotherapists or graduate students in sports science at the University of Agder. Each session will consist of 40 minutes of strength training and cardiovascular exercises of moderate intensity, measured using the Borg scale of perceived exertion [42] with 20 minutes of warm-up and stretching. Pelvic floor exercises will be performed during each session. In addition, all women in the intervention group will be encouraged to have at least one unsupervised exercise session each week, increasing to a total of 5 days each week of moderate physical activity lasting 30 minutes. Information about safe physical activity in pregnancy is provided in the pamphlet created for the trial and on the web site.

Endpoints

The Fit for Delivery study has several endpoints.

1. Maternal weight gain and weight retention postpartum.
2. Maternal body composition at 36 weeks of gestation
3. Infant birth weight and the percent of newborns with birth weight above the 90th percentile for gestational age.
4. Maternal glucose levels and measurement of hormones related to glucose metabolism.
5. Incidence of operative deliveries and delivery complications.

Outcome measures

1. Weight and height measurements
   Pre-pregnancy weight will be self-reported. Women will be weighed at their health care clinic at the time of enrollment in the study. All scales used in the project are class III with a 0.1 kg accuracy, calibrated at the initiation of the study. All participants will be weighed at Sorlandet Hospital at gestational weeks 30 and 36, wearing light indoor clothing and without shoes or socks, using a Tanita bioimpedance scale which measures weight with an accuracy of 0.1 kg and percent body fat (www.tanita.com/en/bc-418). The assessor will be blinded as to the woman's group allocation. Height will be measured to the nearest centimetre (cm) at the 30 week assessment, using a Seca Leicester portable stadiometer with an accuracy of 0.1 cm. Weight at the time of delivery will be

measured by labor floor staff on arrival at the labor floor using a Seca weight with a 0.1 kg graduation. Labor floor midwives will not be otherwise engaged in the study, and will be blinded as to which arm of the study her patient belongs.
The newborn will be weighed immediately following delivery on either a Seca or Solotop infant scale, each with 0.01 kg accuracy, and measured using a Seca pediatric measuring rod, with a 5 mm precision.
Mother and child will be weighed at their local healthcare clinic using a class III scale, when the child has his/her 6 month and 12 month wellness examination.

2. Blood tests
Participants will be instructed to take a fasting blood sample at the office of their primary physician as soon as possible after agreeing to participate in the study, which will be analyzed at Sorlandet Hospital. Glucose will be measured, in addition to C-reactive protein, cholesterol, and triglycerides. At gestational week 30, a glucose tolerance test will be performed at Sorlandet Hospital, where serum glucose level will be measured fasting and 2 hours after intake of 75 grams of glucose. A glucose level of 7.8 mmol/l or higher at 2 hours will be defined as gestational diabetes. Positive results will be reported to the woman's primary physician, so that the patient can be appropriately treated. Serum samples will be collected from participants at inclusion and at gestational week 30, and from the umbilical cord of babies born to women in the study, and frozen for later analysis.
3. Questionnaire
All participants in the study will complete a questionnaire at the time of inclusion in the study (approximately week 14) [see Additional file 1], toward the end of pregnancy (week 36) [see Additional file 2], 6 months post-partum [see Additional file 3] and 12 months post-partum [see Additional file 4]. Women will be encouraged to answer the questionnaire electronically, with access from the Fit for Delivery web site, but a written version will also be available in both Norwegian and English. The questionnaires will include demographic variables, the short version of the International Physical Activity Questionnaire (IPAQ) [43] and a questionnaire specially designed to assess the key nutritional behaviors which are highlighted in Fit for Delivery [41]. At the time of inclusion, women will be asked to report on both current status and status before pregnancy. Subsequent questionnaires will only measure current status.
The short version of the IPAQ measures physical activity and consists of 36 questions. It has been validated in a Swedish population (both genders), where the questionnaire showed acceptable criterion validity in Swedish adults [44]. The IPAQ has been modified for the purpose of our study, in order to be answered electronically. Additional questions have been added to identify motivating factors for participation and non-participation in physical activity. The nutritional questionnaire is created for the purpose of this study and consists of 82 questions, with a food frequency section and a 24 hour recall section. The questions are designed to test selected nutritional behaviors which are emphasized during the consultation sessions. The test-retest reliability of the questionnaire was evaluated and found to be acceptable in a study including 154 pregnant women who filled out the questionnaire two weeks apart [41]. Employment information and partner's weight will also be included. Post-partum questionnaires will contain questions about the duration and frequency of breast-feeding, as this may have an impact on post-partum weight retention.
Women who decline to participate in the study will be asked to complete a short non-response questionnaire, which consists of age, height (self-reported), pre-pregnancy weight (self-reported), smoking history, education level and reason for non-participation. This questionnaire is written and anonymous.
4. Hospital chart review
Hospital records directly related to pregnancy and delivery will be reviewed. All documented pregnancy complications will be recorded. The duration of labor and mode of delivery will be documented, as well as APGAR scores and eventual delivery complications. All admissions to the neonatal care unit will also be recorded, along with diagnosis for admission.
Women who choose to withdraw from the study will be asked if they will allow review of their hospital records, for the purpose of comparing "drop-outs" with women who remain in the study. Information regarding labor and delivery and newborn measurements will be recorded with their permission.

Statistical analysis

A p-value of < 0.05 will be considered statistically significant. Data from each patient will be analyzed according to the principle of "intention to treat." We will also analyze results based on the degree of attendance at exercise classes and other interventional elements. Comparisons between the endpoints and the two arms of the study will be performed using multivariate regression models; i.e. bivariate and multinominal logistic regressions, linear regression and repeated measures procedures.

Sample size

We predicted a 20% prevalence of birth weight over 4 kg in the control group, based on 2005 statistics from the Norwegian birth registry, and claim that a reduction in prevalence of birth weight over 4 kg in the intervention group to 10% would be clinically significant. In order to demonstrate a statistical difference, we calculated that we would need 198 women in each arm of the study. Further, we expected a 10% prevalence of 2 hour glucose challenge test results ≥7.8 mmol/l in the control group, based on the findings of the Norwegian STORK study [45]. We hope to achieve a reduction to 3% prevalence of glucose ≥7.8 mmol/l in the intervention group, and maintain that this would be a clinically significant reduction. Using an alpha of 0.05 and a power of 80%, we calculated that we would need 200 women in each arm of the study in order to demonstrate a statistical difference.

We wish to examine subgroups within our participant population, specifically women with BMI >25 and women who report low levels of physical activity on their first questionnaire. We expect that our study will have a drop-out rate of approximately 25%. To compensate for these factors, we plan to recruit 300 women in each arm, in total 600 women.

Randomization

To ensure that participants are sufficiently motivated to complete the study, they are asked to provide blood samples and answer questionnaires before enrolment, after giving informed consent. A study nurse will confirm that there is a signed consent form, blood test and completed questionnaire, and will then randomize the participant. The nurse will not check the results of either the blood test or questionnaire before randomization. A physician will check that the fasting glucose level does not indicate diabetes, which would exclude the woman from enrolment in the trial. The women will be individually randomly assigned to either the control or intervention group, based on a computer-generated list with groups of 20. Women will be randomized consecutively, based on the time of completion of all three elements needed for participation. The staff involved with providing and assessing the intervention will have no influence on the randomization procedure.

Ethical considerations

Nutritional information and physical activity programs provided in Fit for Delivery follow national and international recommendations for safety in pregnancy. The study has been approved by the Norwegian Regional Committee for Medical Research Ethics South-East C (REK reference 2009/429). This is an independent committee, appointed by the Norwegian Ministry of Education, IRB 00001870. The study will be performed in accordance with the Helsinki Declaration, and all participation will be based on informed, written consent. At the completion of the trial, all participants in the control arm of the study will be sent the written information that was provided to the intervention arm during pregnancy.

Discussion

There is evidence in the medical literature that excessive gestational weight gain is associated with a higher incidence of pregnancy and delivery complications, also for the woman of normal pre-pregnancy weight [5]. For women who begin pregnancy with overweight or obesity, the risks associated with excessive weight gain during gestation may be even greater [46]. Norway is a country with nationalized health care, where almost 100% of pregnant women receive prenatal care. Information about nutrition and physical activity is a part of routine pregnancy care provided by midwives. Nonetheless, there is good evidence that Norwegian women are less physically active in pregnancy than is recommended and that they gain more weight than recommended during pregnancy [47], not unlike their counterparts in Great Britain [48] and the United States [49]. The rates of overweight and obesity among young Norwegian women are also comparable to those of other developed countries. Population studies performed in the Trøndelag area of Norway (HUNT) in 2006–2008 show that 24% of women over the age of 20 are now obese, and an additional 37% are classified as overweight [50]. This is not unlike the results of the 2007–2008 National Health and Nutrition Examination Survey (NHANES) from the United States, where the corresponding figures were 35% and 29% [51].

Several authors have expressed the need for prospective, randomized studies to examine the effects of interventions to limit maternal weight gain in pregnancy [26,52]. Our hypothesis is that a lifestyle intervention in pregnancy will result in significant, measurable changes in maternal weight gain, newborn birth weight, glucose levels, and maternal weight retention the first year postpartum. We have here detailed the protocol for our randomized, controlled trial to test this hypothesis. There are several reports published to date of interventions designed to limit weight gain in pregnancy [25,26], but few studies have combined supervised group exercise sessions with clear nutritional guidelines. Thangaratinam et al. reported inferior results with mixed, lifestyle interventions compared to interventions composed of diet alone. They speculate that the inferior results of mixed interventions may be because a combined program results in less vigorous delivery of the components of

the intervention, and also that it may be easier to comply with a dietary intervention alone [25]. Another element to consider is that almost all mixed interventions reported in their meta-analysis consisted of counseling alone. Other studies have found that compliance and energy expenditure are higher with group training sessions than with individual unsupervised physical activity in middle-aged women [53] and that exercise groups are associated with a greater improvement in glycemic control for diabetic patient than exercise advice [54]. A mixed intervention which includes supervised, group training may therefore be more effective in regulating weight gain and glucose levels than mixed interventions consisting of counseling alone.

The Fit for Delivery intervention combines exercise classes with nutritional counseling, and is designed for both normal-weight and overweight pregnant women. By including a general population, there is no stigma involved with participation. The intervention is also designed so that both women who have previously been sedentary and those with an active lifestyle will be able to perform the exercises and follow the nutritional advice, albeit at different levels. By recruiting all first-time mothers at local health care clinics, we hope to include a broad and diverse population that will reflect a standard population of pregnant women. Results are primarily to be analyzed by the principle of "intention to treat", so that we will measure the effect of providing this extra treatment in pregnancy, with varying compliance. This reflects the realities of health care, where patients are free to decide if they wish to partake of the treatments which are available to them. We have emphasized a simple and inexpensive design for the Fit for Delivery intervention that can easily be adopted by health authorities should it be proven effective.

Pregnancy is a unique opportunity to affect the health of both mother and child. Other authors have described pregnancy as a "teachable moment": women have a new awareness of their body and the responsibility of a new life, and are therefore more responsive to healthcare information than at other times [55]. The WHO has listed both pregnancy and the prenatal period as key moments for lifetime risk of obesity [2]. By preventing excessive weight gain during pregnancy, there will be less risk of the mother developing obesity later in life. Perhaps more important, a lifestyle change during pregnancy has the potential to affect the health of the newborn at the earliest possible stage—while still in the uterus. By teaching women new habits, the intervention will also influence the environment the child will enter after birth. Should our Fit for Delivery intervention demonstrate measurable health benefits for mother and child, it may be of use in the important goal of curbing the obesity epidemic.

Additional files

Additional file 1: The written, English version of the questionnaire which is completed at inclusion in the study.

Additional file 2: The written, English version of the questionnaire which is completed at approximately gestational week 36.

Additional file 3: The written, English version of the questionnaire which is completed at 6 months postpartum.

Additional file 4: The written, English version of the questionnaire which is completed at 6 months postpartum.

Competing interest

The authors declare that they have no competing interests. The authors have no conflict of interest with the fitness centers which will provide training facilities for the study.

Authors' contributions

LRS, NØ, EB, HLS, TH and IV designed the study. HLS and LRS have developed the physical activity information for Fit for Delivery, MT and HLS supervise the physical activity portion of the intervention, while NØ and EB have developed the nutritional counseling and nutritional questionnaires included in Fit for Delivery study. LRS will manage the obstetrical care (examination and ultrasound) of participants, supervised by IV and TH. All authors read and approved the final manuscript.

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Lifestyle intervention to limit gestational weight gain: the Norwegian Fit for Delivery randomised controlled trial

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Objective To examine whether a lifestyle intervention in pregnancy limits gestational weight gain (GWG) and provides measurable health benefits for mother and newborn.

Design Randomised controlled trial.

Setting Healthcare clinics of southern Norway.

Population Healthy, non-diabetic, nulliparous women, aged ≥18 years, with a body mass index of ≥19 kg/m^2, and with a singleton pregnancy at ≤20 weeks of gestation.

Methods Women were randomised to an intervention group (with dietary counselling twice by telephone and access to twice-weekly exercise groups) or to a control group (with standard prenatal care). Participants were measured three times during pregnancy and at delivery, and newborns were measured at delivery. Hospital records were reviewed for outcomes of pregnancy and delivery. Assessors were blinded to group allocation. Analysis was performed by intention to treat, assessing GWG using the Student's *t*–test and linear mixed models, and comparing proportions using the chi-square test.

Main outcome measures GWG, rates of pregnancy complications and operative deliveries, and newborn birthweight.

Results A total of 606 women were randomised. Of these, 591 were analysed, with 296 in the intervention group and 295 in the control group. At term, the mean GWG from pre-pregnancy was 14.4 kg for the intervention group and 15.8 kg for the control group (mean difference 1.3 kg; 95% confidence interval, 95% CI 0.3–2.3 kg; $P = 0.009$). There was no significant difference between groups in the frequency of pregnancy complications or operative deliveries. The intervention demonstrated no effect on the mean birthweight of term infants, or on the proportion of large newborns.

Conclusions The Norwegian Fit for Delivery lifestyle intervention in pregnancy had no measurable effect on obstetrical or neonatal outcomes, despite a modest but significant decrease in GWG.

Keywords Birthweight, diet, intervention, lifestyle, physical activity, pregnancy, weight gain.

Tweetable abstract Norwegian Fit for Delivery RCT: reduced gestational weight gain, unchanged birthweight and obstetric outcomes.

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Introduction

Obesity has become a pressing public health issue around the globe. Although the aetiology is complex, there is no doubt about the role of over-nutrition and sedentary lifestyle in fuelling the epidemic.[1] Preventive efforts may be more effective than the treatment of individuals who are already overweight or obese,[2] and might be particularly timely in pregnancy, when two lives are affected.[3,4] Observational studies show that large gestational weight gain (GWG) is associated with postpartum weight retention and with the development of obesity later in the mother's life.[5,6] Excess GWG has been associated with complications of pregnancy, such as pre-eclampsia and gestational diabetes,[7–9] and with

an increased incidence of caesarean section.[7,10] For the child, large GWG is associated with an increased birthweight.[11,12] Both large GWG and high birthweight are associated with an increased risk of obesity in childhood and adolescence.[13,14]

These observational studies have prompted a variety of trials of prenatal interventions to limit GWG through improving diet and/or increasing physical activity. Assessing the efficacy of interventions has been difficult, in part because of the heterogeneity of interventions and study populations, and because of the small size of most trials.[15,16] There is now evidence that exercise interventions limit GWG,[15–18] and may reduce the risk of gestational diabetes.[19] Interventions targeting diet alone have demonstrated a greater limitation of GWG,[15,20] and a decreased risk of both gestational diabetes and pre-eclampsia.[15] Combining diet and exercise could potentially increase the intervention strength, but meta-analyses of combined/lifestyle interventions have shown less effect on GWG than dietary interventions alone,[15] and no effect on other pregnancy outcomes.[15,21] To our knowledge, however, the published lifestyle interventions have provided counselling alone, with just two exceptions.[22,23] Many women are reluctant to exercise, particularly in pregnancy, and providing exercise classes rather than counselling may improve compliance.[18]

As excessive GWG is associated with an increased risk of obstetrical complications and postpartum weight retention for both women who are normal weight and women who are overweight,[7,24] a population-based health initiative to limit GWG should be suitable for women of all sizes. Many trials published to date have only included women who were overweight or obese.[18,20,23,25,26] The Norwegian Fit for Delivery (NFFD) intervention consists of dietary counselling and supervised exercise groups, and was designed to be feasible in a clinical setting for a general population and to be easily reproducible. The aim of the NFFD randomised trial was to examine whether the intervention resulted in measurable health benefits for both mother and infant. Here we report the effects of the intervention on GWG, newborn birthweight, obstetrical outcomes, and neonatal outcomes.

Methods

Study design and participants

The NFFD study is a randomised, blinded, controlled trial with two parallel groups performed in southern Norway, encompassing the cities of Kristiansand and Mandal, as well as the more rural surrounding areas. The protocol for the trial has already been published.[27] Midwives at eight healthcare clinics enrolled participants between September 2009 and February 2013. All healthcare clinics received the same information regarding study participation. Women were eligible if they were nulliparous, with a singleton pregnancy at ≤20 weeks of gestation, had a pre-pregnancy body mass index (BMI) of ≥19 kg/m^2, were literate in Norwegian or English, and provided signed, informed consent. Exclusion criteria were pre-existing diabetes, disabilities precluding participation in a physical fitness programme (based on national and international recommendations),[28] continued substance abuse, or planned relocation outside of the study area before delivery. The first 20 participants comprised a feasibility study. The protocol was modified to include a lower age limit of 18 years and to allow randomisation after initial questionnaires and blood tests were completed, in order to ensure that the participants were sufficiently motivated and to avoid missing data. The Norwegian Regional Committee for Medical Research Ethics South-East–C approved the trial and modifications (REK reference 2009/429).

Participating clinics documented the attendance of 4245 women during the inclusion period. We approximate that 1610 were nulliparous (Figure 1), based on detailed data from four participating clinics.

Randomisation and blinding

After receiving signed consent forms and confirming that blood tests and questionnaires were completed, a research nurse assigned participants consecutively to the intervention or control arm of the study using a computer-generated list with 1 : 1 allocation ratio in blocks of 20. The research nurse never met the participants, had no role in recruitment or measurements, and had no knowledge of questionnaire responses. All examinations, blood test evaluations, record reviews, and scoring of questionnaire responses were performed by assessors blinded to group allocation.

Intervention

Details of the dietary and physical activity components of the NFFD, and the rationale behind them, were published previously.[27,29] The dietary component consisted of ten recommendations designed to increase awareness of food choices, with specific advice on portion sizes, regular meal patterns, limiting the consumption of snack foods, and increasing the intake of water, fruits, and vegetables. Dietary counselling was performed by telephone, with an initial consultation and then a follow-up 4–6 weeks later, each of approximately 20 minutes. Counsellors were either experienced clinical dieticians or graduate students in public health who were trained and supervised by the NFFD team. Intervention participants were informed of the recommended GWG based on pre-pregnancy BMI and current Institute of Medicine (IOM) guidelines (GWG: normal weight, 11.5–16.0 kg; overweight, 7.0–11.5 kg; obese, 5.0–9.0 kg).[24] The physical activity component consisted of access to twice-weekly exercise classes at a local gym facil-

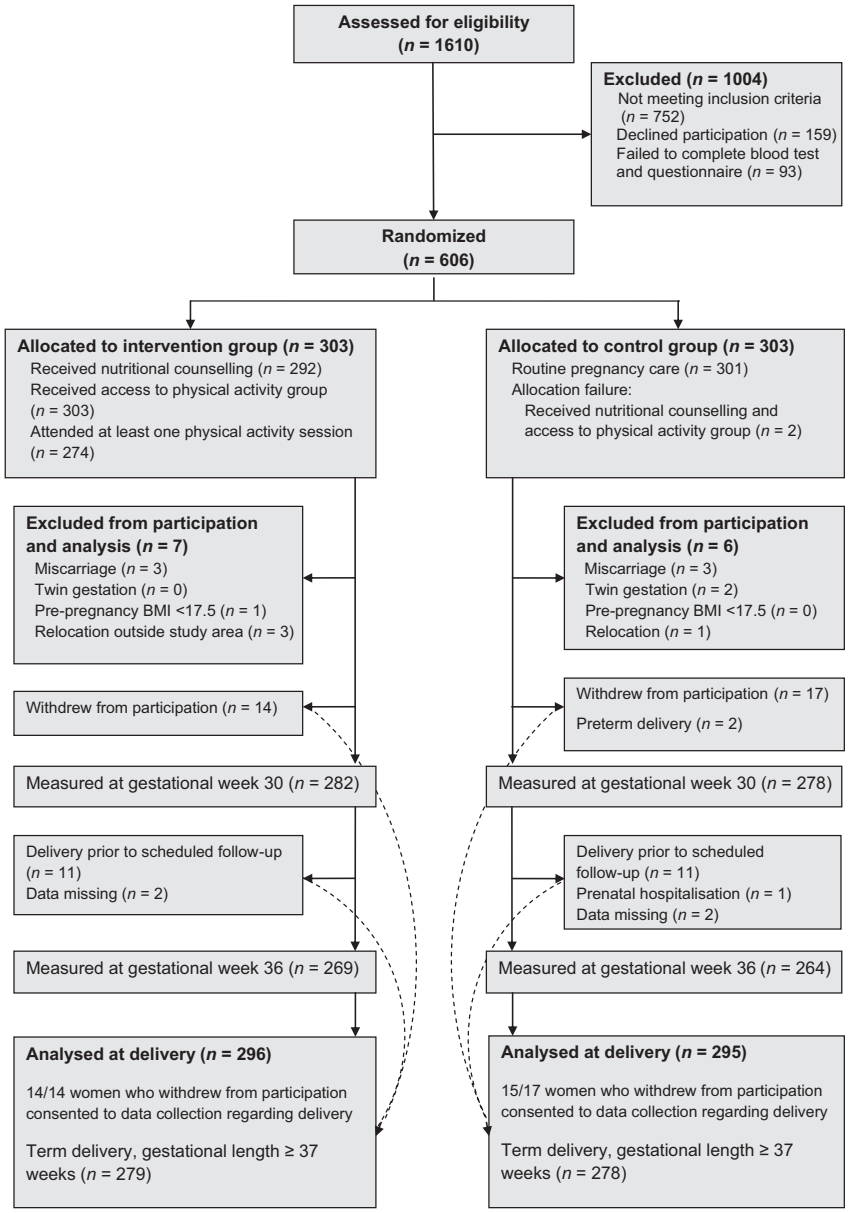

Figure 1. Trial profile. Measurements at 30 weeks of gestation included the glucose challenge test and weight. Measurements at 36 weeks of gestation included weight and the completion of the questionnaire. Four women who moved to another region of the country were considered 'missing completely at random', and were excluded. Fourteen participants in the intervention group withdrew consent to participation, six without receiving any form of intervention, and all prior to the first scheduled follow-up. All 14 consented to an examination of hospital records pertaining to delivery. Seventeen participants in the control arm withdrew consent to participation, all prior to the first scheduled follow-up. Of these, 15 consented to the use of stored data and to an examination of hospital records pertaining to delivery.

ity, all following the same pattern: 10 minutes of warm-up, 40 minutes of strength training and cardiovascular exercise at moderate intensity (using aerobics, calisthenics, and weight training), and 10 minutes of stretching. The intensity of the exercise was self-monitored using Borg's scale for perceived exertion,[30] which is widely recommended in pregnancy because of the variations in maternal heart-rate responses to exercise,[28] with a target intensity of 12–14 on the 6–20 scale. Classes were led by physical therapists or students in sports science who were trained and quality-controlled by the NFFD team. Attendance was recorded. Although practical and economic considerations limited classes to two per week, participants were encouraged to be physically active at moderate intensity on three additional

days per week, and activity was assessed using questionnaire responses in late pregnancy. Lifestyle recommendations were reinforced with booklets, access to an NFFD internet site, and with an invitation to one cooking class and to an evening meeting, which provided information on the NFFD trial and on the value of regular exercise and a healthy diet in pregnancy.

Participants in the control group received routine prenatal care in accordance with Norwegian standards: eight prenatal appointments, including one second-trimester ultrasound examination, with additional care as needed. All pregnant women receive a booklet with advice on prenatal nutrition and physical activity, including recommendations for weight gain based on IOM guidelines.[24] Prenatal care is free of charge and is provided through alternating visits with midwives and doctors.

Measurements

The primary aims of the NFFD trial were to examine whether the intervention resulted in differences in GWG, birthweight of term infants, the proportion of term infants weighing >4000 g, maternal fasting glucose levels at 30 weeks of gestation, maternal percentage of fat at 36 weeks of gestation, and the incidence of operative deliveries. The proportion of newborns of birthweight ≥90th percentile, the proportion of women with elevated 2-hour glucose tolerance tests, the levels of hormones related to glucose metabolism, the incidence of delivery complications, and postpartum weight retention were secondary end points.

Pre-pregnancy weight was self-reported. Participants were weighed at their healthcare clinic upon inclusion in the study using scales that were calibrated at the start of the trial, and also at Sørlandet Hospital at 30 and 36 weeks of gestation (Tanita BC 418, Tokyo, Japan). Pre-pregnancy and inclusion weight were reported in whole kg. Pre-pregnancy weight was compared with measured weight for women included before 13 weeks of gestation ($N = 95$). No pre-pregnancy weights were discarded for implausibility, defined as a GWG exceeding 9 kg.[31] Participants in the feasibility study self-reported their heights; later participants were measured using a stadiometer (Seca Leicester, Hamburg, Germany). Blood pressure and fetal ultrasound measurements were recorded. Abnormal findings were reported to the antenatal unit for further management.

Participants were weighed on admission to the delivery ward. If missing, the last weight in the prenatal record was recorded along with corresponding date. GWG at term was calculated for women delivering at ≥37 weeks of gestation, with weight recorded within 2 weeks of admission. The rate of GWG was calculated as weight gain from either pre-pregnancy or inclusion weight to last available weight prior to delivery, divided by gestational length at last measurement (for pre-pregnancy weight), or by the interval between date of inclusion and last measurement (for inclusion weight). Compliance with IOM guidelines for GWG was assessed by comparing GWG from pre-pregnancy to term with the upper limit of recommended total gain for each pre-pregnancy BMI category (normal weight, 16 kg; overweight, 11.5 kg; obese, 9 kg). Third-trimester weekly weight gain (difference between weight at first follow-up and last weight measured, divided by interval between measurements) was compared with the upper limit of IOM recommendations for third-trimester weekly weight gain (normal weight, 0.5 kg/week; overweight, 0.33 kg/week; obese, 0.27 kg/week). The weight, length, head circumference, and Apgar score of the newborn were recorded by delivery ward staff. Weight percentile was calculated according to sex and gestational age using a *z*–score derived from data in the Medical Birth Registry of Norway, which was determined to be appropriate for the trial population.[32] The proportion of large newborns was calculated using the definitions >4000, >4500 g, and ≥90th percentile. Small for gestational age (SGA) was defined as ≤10th percentile. Hospital records related to pregnancy and delivery were reviewed. Neonatal records were reviewed in case of admission to a neonatal intensive care unit.

Prior to randomisation, fasting blood tests were assessed for evidence of pre-existing diabetes. No participants were excluded on this basis. A glucose tolerance test was performed at 30 weeks of gestation, measuring serum glucose after fasting and at 2 hours after an intake of 75 grams of glucose. Glucose levels ≥7.8 mmol/L at 2 hours were classified as elevated, based on both national and WHO criteria,[33,34] and participants and their primary care doctors were informed.

Participants in both groups completed questionnaires at inclusion and at 36 weeks of gestation, either electronically (in Norwegian) or in print (in English or Norwegian). The questionnaire had three sections: demographics, diet, and physical activity. Diet was assessed by 43 food-frequency questions analysed using a predetermined score built from ten subscales corresponding to NFFD recommendations. Each subscale was dichotomised using the median value as a cut-off: a value of '0' or '1' was assigned for each subscale, with '1' being the healthier behaviour. The total NFFD diet score thus ranged from 0 to 10, with a higher score indicating healthier behaviour. A detailed description has been published previously.[29] The dietary score has demonstrated acceptable test–retest reliability.[27] Physical activity was assessed with the International Physical Activity Questionnaire, short version (IPAQ-short), which quantifies physical activity during the last 7 days divided into the categories of vigorous intensity, moderate intensity, and walking.[35] Responses from the intervention group included participation in both scheduled and self-initiated physical activity, whereas the control group reported self-initiated

physical activity. Responses were scored according to IPAQ analysis algorithms, both as weekly energy expenditure (METs) and as physical activity categories. The IPAQ-short has been validated in a Scandinavian population.[35]

Sample size

As there were scant data on GWG among Norwegian women at the time of planning the trial, power calculations were not based on this variable. We expected a 20% prevalence of newborns with birthweight >4000 g in the control group based on 2005 statistics from the Norwegian birth registry,[36] which were the most recent data available at the time of trial preparation. We determined empirically that a reduction to 10% in the intervention group would be clinically relevant. We calculated that we required 198 women in each study arm to demonstrate statistical significance with a power of 80%. To allow for participant dropout and premature deliveries, we chose to randomise 600 participants.

Statistical analysis

Data were analysed according to the principles of intention to treat (ITT). We compared the study groups regarding continuous outcomes using a Student's *t*–test after confirming normal distribution. Categorical outcomes were compared using chi-square tests and the results were expressed as mean differences and odds ratios. We used mixed-effects model analysis (linear mixed models), an extension of linear regression that allows for the analysis of repeated measures such as weight without excluding cases with missing data, to assess the influence of age, education, income, occupation, smoking, and pre-pregnancy BMI on the primary outcome of GWG, measured at three time points. Time (gestational week) was modelled as a categorical variable, and the relationship between the levels of the repeated effects was modelled using an unstructured covariance matrix given that time intervals were of different lengths. Thus the covariance of random effects was unstructured and conditional on the random effect, and the within-subject error was assumed to be independent. All selected covariates were treated as fixed effects, whereas time (gestational week) was fitted as a repeated variable. $P < 0.05$ was considered statistically significant, with no adjustment for multiple comparisons. All tests were two-sided. We used SPSS 21.0 for WINDOWS for all statistical analyses.

Results

The 606 women included in the NFFD trial were equally distributed into intervention and control groups (Figure 1). Thirty-one participants withdrew from the study: five women could not/did not wish to exercise; two declined to participate in a control group; two declined testing; and the rest gave no reason for their withdrawal. Among the withdrawals, 29 consented to the use of inclusion data and review of delivery ward records, and 21 consented to the use of all hospital records. The baseline characteristics of the 591 participants included in our analysis were similar in the two groups (Table 1). There was a trend towards a difference in occupational background, based on a larger proportion of students in the intervention group (35/295, 11.9%) compared with the control group (16/294, 5.4%). Participants were predominantly white, of European descent. There were similar proportions of control and intervention participants from each clinic ($P = 0.177$). Randomisation was performed at a mean of 16 days after inclusion for both groups. Among women in the intervention arm, 259 (87.5%) received both dietary consultations, 28 (9.5%) received one, and nine (3%) received none. All received access to physical fitness classes and 274 (92.6%) attended at least one class. The number of classes attended varied between 0 and 38, with a median of 14.

Gestational weight gain

Weight recorded at delivery was available for 466/591 (78.8%) women; 114 (19.2%) women had a weight available in the prenatal records (mean 9.8 days before admission) and 11 women had no measurements available after inclusion. The availability of weight at delivery was evenly distributed between the intervention and the control groups ($P = 0.904$). GWG was calculated using both pre-pregnancy weight (self-reported) and inclusion weight (measured) as the baseline. Analysis of GWG from pre-pregnancy to term ($n = 557$, 94.2%), showed a mean difference between intervention and control group (between-group difference) of 1.3 kg ($P = 0.009$; Table 2). Subgroup analyses according to pre-pregnancy BMI category revealed a greater between-group mean difference in GWG with increasing BMI (Figure S2; Table 2), but only the normal-weight subgroup was of sufficient size to reach statistical significance. Analysing GWG from inclusion to term delivery showed a smaller but significant between-group difference of 0.9 kg ($P = 0.043$). Here there was no significant intervention effect found when examining subgroups according to pre-pregnancy BMI. The intervention group tended to have a smaller weight increase from pre-pregnancy to inclusion than the control group: 2.2 versus 2.7 kg (mean difference −0.44 kg; 95% confidence interval, 95% CI −0.93 to 0.05 kg; $P = 0.079$).

The rate of GWG was calculated for all pregnancies using the last available weight measured before delivery (Table 2). Analysis showed a significantly lower rate of GWG in the intervention group compared with the control group using both pre-pregnancy weight (0.36 kg/week for the intervention group, versus 0.39 kg/week for the control group; mean difference of −0.03 kg/week; 95% CI −0.06

Table 1. Baseline characteristics of participants

	Intervention (n = 296)		Control (n = 295)		P*
	Mean	**SD**	**Mean**	**SD**	
Age (years)	27.9	4.2	28.1	4.5	0.56
Length of gestation (weeks)	15.4	2.6	15.6	2.4	0.53
Prepregnancy weight (kg)**	67.7	12.2	67.3	12.3	0.75
Height (cm)	168.5	5.7	168.9	6.7	0.37
Prepregnancy BMI (kg/m²)	23.8	4.1	23.5	3.7	0.36
Inclusion weight (kg)	69.9	12.5	70.0	12.5	0.93
Glucose, fasting (mmol/litre)***	4.4	0.4	4.4	0.4	0.54
C-Reactive Protein (mg/litre)****	4.4	4.3	4.3	4.0	0.77
	N	**%**	***N***	**%**	
BMI category, pre-pregnancy					
Underweight (inclusion error)	2	0.7	3	1.0	0.42
Normal weight	201	67.9	217	73.6	
Overweight	69	23.3	54	18.3	
Obese	24	8.1	21	7.1	
Educational level***					
12 years or less	94	31.8	93	31.5	0.26
<4 years of higher education	104	35.1	88	29.8	
≥4 years of higher education	96	32.4	113	38.3	
Occupation***					
Employed outside the home	240	81.1	256	86.8	0.06
Student	35	11.8	16	5.4	
Unemployed	9	3.0	14	4.7	
Long-term sick leave	6	2.0	5	1.7	
Homemaker	5	1.7	3	1.0	
Cohabitation***					
Husband/boyfriend/partner	286	96.6	281	95.3	0.38
Live alone	6	2.0	7	2.4	
Parents	3	1.0	6	2.0	
Household income (NKR/year)****					
≤400 000	95	32.1	88	29.8	0.83
401 000–700 000	82	27.7	81	27.5	
>700 000	101	34.1	101	34.2	
Refrained from response	17	5.7	22	7.5	
Smoking status***					
Never smoked	204	68.9	194	65.8	0.30
Ex-smoker	83	28.0	85	28.8	
Current smoker	8	2.7	15	5.1	

*Weight at inclusion was missing for eight participants (two in the control group and six in the intervention group).
**Glucose was missing for 14 participants (eight in the control group and six in the intervention group).
***C–reactive protein was missing for 18 participants (ten in the control group and eight in the intervention group).
****Two participants failed to complete the questionnaire on socio-economic status.
*****Four participants failed to provide information on household income.

to −0.01 kg/week; $P = 0.008$) and inclusion weight (0.50 kg/week for the intervention group versus 0.54 kg/week for the control group; mean difference of −0.03 kg/week; 95% CI −0.07 to −0.00 kg/week; $P = 0.040$) as baseline.

A mixed-models analysis using weight measured at gestational weeks 30 and 36, and at term, with pre-pregnancy weight as baseline (Figure S2), revealed a between-group mean difference in GWG of 1.7 kg (95% CI 0.91–2.57 kg; $P < 0.001$) when adjusted for age, income, education, occu-

Table 2. Gestational weight gain

	Intervention (n = 296)		Control (n = 295)		Intervention effect		
	Mean	SD	Mean	SD	Mean diff.	95% CI	P†
Gestational weight gain (GWG) from pre-pregnancy (kg)							
For term deliveries*	(n = 279)		(n = 278)		−1.3	−2.4, −0.3	0.009
n = 267 (i), 266 (c)	14.4	6.2	15.8	5.7			
Normal weight pre-pregnancy	(n = 189)		(n = 206)		−1.1	−2.2, −0.1	0.036
n = 181 (i), 197 (c)	14.7	5.1	15.8	5.4			
Overweight pre-pregnancy	(n = 65)		(n = 51)		−1.4	−4.1, 1.4	0.321
n = 63 (i), 49 (c)	15.3	7.4	16.7	7.1			
Obese pre-pregnancy	(n = 23)		(n = 18)		−3.1	−8.0, 1.9	0.221
n = 21 (i), 18 (c)	10.3	9.0	13.4	5.8			
For all pregnancies, GWG rate, pre-pregnancy to last measurement (kg/week)**	0.36	0.15	0.39	0.14	−0.03	−0.06, −0.01	0.008
n = 291 (i), 289 (c)							
Gestational weight gain from inclusion (kg)							
For term deliveries***	(n = 279)		(n = 278)		−0.9	−1.7, −0.03	0.043
n = 262 (i), 265 (c)	12.2	4.3	13.1	4.9			
Normal weight pre-pregnancy	(n = 189)		(n = 206)		−0.7	−1.6, 0.3	0.153
n = 176 (i), 196 (c)	12.3	4.4	13.0	4.8			
Overweight pre-pregnancy	(n = 65)		(n = 51)		−1.1	−3.2, 1.1	0.320
n = 63 (i), 49 (c)	12.8	5.8	13.9	5.3			
Obese pre-pregnancy	(n = 23)		(n = 18)		−2.2	−6.3, 1.9	0.287
n = 21 (i), 18 (c)	9.8	7.8	12.0	3.9			
For all pregnancies GWG rate, inclusion to last measurement (kg/week)****	0.50	0.21	0.54	0.20	−0.03	−0.07, −0.00	0.040
n = 285 (i), 287 (c)							
	N	***%***	***N***	***%***	***OR***	***95% CI***	***P*‡**
Exceeding IOM recommendations							
Based on total weight gain range for term pregnancies*****	(n = 279) 111	41.6	(n = 278) 133	50.0	0.71	0.51, 1.00	0.056
n = 267 (i), 266 (c)							
Based on range for weekly weight gain, third trimester******	(n = 296) 154	55.4	(n = 295) 173	62.5	0.75	0.53. 1.04	0.091
n = 277 (i), 278 (c)							

For analyses not performed on the whole group, the n for each subgroup is presented over the corresponding result. The number of participants with available data is presented to the left, for both the intervention group (i) and the control group (c). Proportions are calculated according to the data available.

*Weight measurements for term deliveries (at or within 14 days of admission) missing for 24 participants (12 in the intervention group and 12 in the control group).

**Rate of GWG calculated as last available weight before delivery minus pre-pregnancy weight divided by gestational length at time of last measurement.

***Weight at inclusion missing for eight participants (six in the intervention group and two in the control group).

****Rate of GWG calculated as last available weight before delivery minus inclusion weight divided by interval between measurements.

*****Exceeding IOM recommendations analysed as total weight gain from pre-pregnancy to term in excess of upper limit of IOM range for corresponding pre-pregnancy BMI group (16 kg for normal weight, 11.5 kg for overweight, and 9 kg for obese).

******Exceeding IOM recommendations analysed as weekly weight gain in third trimester (last available weight minus weight at 30 weeks of gestation, divided by interval between weights, kg/week) in excess of IOM range for corresponding pre-pregnancy BMI group (0.5 kg/week for normal weight, 0.33 kg/week for overweight, and 0.27 kg/week for obese).

†P value calculated with Student's t-test.

‡P value calculated with chi-square test.

pation, smoking, and pre-pregnancy BMI category. All covariates except for income and age were statistically significantly associated with GWG (all $P < 0.001$). The same analysis performed using inclusion weight as baseline demonstrated a between-group mean difference of 1.8 kg (95% CI 0.96–2.58 kg; $P < 0.001$). All covariates were statistically significant except for income (all $P < 0.001$).

A secondary analysis of compliance with the IOM guidelines (Table 2), comparing total weight gain (between pre-pregnancy and term) with the upper limit of the IOM ranges, showed a strong trend towards a lower proportion of participants in the intervention group exceeding the guidelines (41.6% of the intervention group versus 50.0% of the control group; OR 0.71; 95% CI 0.51–1.00; $P = 0.056$). This trend was less evident when the measured rate of weekly weight gain in the third trimester was compared with the IOM recommendations (55.4% exceeded guidelines in the intervention group versus 62.5% in the control group; OR 0.75; 95% CI 0.53–1.04; $P = 0.091$).

Obstetrical outcomes

The NFFD intervention did not result in a reduction in the proportion of women with gestational diabetes: 12.9% of those tested in the intervention group had an elevated 2-hour glucose tolerance test, versus 9.1% of the control group (OR 1.33; 95% CI 0.77–2.32; $P = 0.330$; Table 3). Record review showed that five intervention participants required insulin for glucose regulation, compared with just one woman in the control group (OR not calculated because of the small numbers). There was no statistically significant difference between groups in the proportion of women with pre-eclampsia (3.4 versus 5.2% for intervention and control groups, respectively; OR 0.65; 95% CI 0.29–1.47; $P = 0.31$) or premature delivery (5.7 versus 5.8% for intervention and control groups, respectively). The two groups were almost identical in the proportion of women who experienced operative deliveries, including both operative vaginal deliveries (15.9% for intervention group versus 15.6% for control group) and caesarean sections (12.8% for the intervention group versus 12.2% for the control group). There was no difference in the incidence of pre-defined delivery complications: shoulder dystocia (two cases in the intervention group versus three in the control group, OR not calculated because of small numbers), deep perineal lacerations (3.5% in both groups), or postpartum haemorrhage (20.3% for the intervention group versus 19.3% for the control group).

Neonatal outcomes

There was no significant difference between newborns in the two study groups regarding gestational age at delivery, birthweight, length, ponderal index, or head circumference (Table 3). The mean weight for term infants was 3470 g in the intervention group and 3516 g in the control group, with a mean difference of −47 g (95% CI −119 to 25 g; $P = 0.20$). The proportion of term newborns >4000 g was not significantly lower in the intervention group compared with the control group: 33 (11.8%) versus 39 (14.0%) (OR 0.82; 95% CI 0.50–1.35; $P = 0.45$). Few NFFD babies were ≥90th percentile: seven (2.4%) in the intervention group versus 11 (3.7%) in the control group. The proportion of SGA infants was equivalent between groups (10.5 versus 9.2% for the intervention and the control groups, respectively). We found no increase in adverse neonatal outcomes as a result of the NFFD intervention.

Lifestyle changes

Intervention and control groups had equivalent dietary scores (mean of 4.92 for both groups) and reported similar weekly energy expenditure (with a mean of 1515 METs for the intervention group versus 1485 METs for the control group; $P = 0.828$) at inclusion (Table S1). At 36 weeks of gestation there was a statistically significant difference between groups in both mean dietary score (5.05 versus 4.60, $P = 0.018$) and mean reported weekly energy expenditure (1560 versus 1254 METs for the intervention and the control groups, respectively; $P = 0.009$).

Discussion

Main findings

The NFFD intervention resulted in a modest but significant decrease in GWG in the intervention group compared with the standard prenatal care group. The NFFD intervention did not decrease the incidence of pregnancy complications or operative delivery, and had no effect on fetal weight or neonatal outcomes. NFFD intervention participants reported significantly increased levels of physical activity and improved nutritional habits in late pregnancy, compared with women in the control group.

Strengths and limitations

A major strength of the NFFD trial is its pragmatic design, particularly, in including women attending healthcare clinics rather than examining a highly selected sample recruited through advertisement. ITT analysis further enhanced the pragmatic nature of the trial. Few women discontinued participation and there was little missing data. The blinding of assessors reduced the risk of bias.

The NFFD trial has several limitations. Although there was a high participation rate, recruitment may have been subject to selection bias: our population was older than the mean found for nulliparous women who delivered in southern Norway in 2011 (28.0 versus 26.8 years),[37] and had a higher proportion of highly educated women than

Table 3. Obstetrical and neonatal outcomes

Obstetrical outcomes	Intervention (*n* = 296)		Control (*n* = 295)		Intervention effect		
	n	%	*n*	%	OR	95% CI	*P*
Gestational diabetes							
Elevated 2-hour glucose tolerance test*	32	11.8	25	9.1	1.33	0.77, 2.32	0.330
Insulin-treated gestational diabetes**	5	1.7	1	0.3	–	–	–
Pre-eclampsia**							
All cases	10	3.4	15	5.2	0.65	0.29, 1.47	0.314
Severe pre-eclampsia/HELLP/eclampsia	7	2.4	8	2.8	0.87	0.31, 2.41	0.800
Premature delivery***							
Prior to 30 weeks	0		2	0.7	–	–	–
30–34 weeks	3	1.0	2	0.7	–	–	–
34–37 weeks	14	4.7	13	4.4	1.08	0.50, 2.33	1.00
Operative delivery***							
Elective cesarean section	8	2.7	7	2.4	1.03	0.63, 1.68	1.00
Acute cesarean section	30	10.1	29	9.8	1.04	0.61, 1.78	1.00
Forcep-assisted delivery	18	6.1	17	5.8	1.06	0.54, 2.11	1.00
Vacuum-assisted delivery	29	9.8	29	9.8	1.00	0.58, 1.72	1.00
Delivery complications							
Shoulder dystocia***	2	0.9	3	1.9	–	–	–
Perineal laceration, grade 3 or 4***	9	3.5	9	3.5	1.00	0.39, 2.55	1.00
Postpartum haemorrhage, ≥500 ml***	60	20.3	57	19.3	1.06	0.71, 1.59	0.837
Neonatal outcomes***	**Mean**	**SD**	**Mean**	**SD**	**Mean diff.**	**95% CI**	***P***
All gestations							
Length of gestation (days)	279	12.5	280	13.5	−0.4	−2.53, 1.66	0.684
Birthweight (g)	3411	485	3450	538	−38	−121, 44	0.361
Length (cm)	50.0	2.1	49.9	2.7	0.03	−0.36, 0.43	0.867
Head circumference (cm)	34.9	1.6	34.9	1.7	−0.08	−0.34, 0.18	0.547
Ponderal index (gm/m³)*****	2.74	0.23	2.75	0.25	−0.01	−0.05, 0.03	0.610
Term gestations****							
Birthweight (g)	3470	416	3516	449	−47	−119, 25	0.204
Length (cm)	50.2	1.7	50.2	2.1	0.0	−0.37, 0.28	0.792
Head circumference (cm)	35.0	1.3	35.1	1.5	−0.1	−0.32, 0.16	0.503
Ponderal index (gm/m^3)*****	2.75	0.22	2.77	0.23	−0.02	−0.05, 0.02	0.434
	n	%	*n*	%	OR	95% CI	*P*
Sex							
Male	164	55.4	155	52.5	1.12	0.81, 1.55	0.510
Female	132	44.6	140	47.2			
Large for gestational age (LGA)							
>4000 g at term	33	11.8	39	14.0	0.82	0.50, 1.35	0.451
>4500 g at term	2	0.7	5	1.8	–	–	–
≥90th percentile for GA******	7	2.4	11	3.7	0.63	0.24, 1.64	0.351
Small for gestational age (SGA)							
≤10th percentile for GA******	31	10.5	27	9.2	1.16	0.68, 2.00	0.679

was found in a 2014 survey of the region (35.5 versus 25.5%).[38] Furthermore, the population was narrowed to those sufficiently motivated to complete testing before randomisation. The women included in the study were predominantly white, European, and highly educated, with relatively few participants who were overweight or obese,

Table 3. (Continued)

	n	%	*n*	%	OR	95% CI	*P*
Adverse outcomes							
Admission NICU‡	38	12.8	38	12.9	0.99	0.61, 1.61	1.00
Admission NICU, >24 hours	31	10.4	35	11.9	0.87	0.52, 1.44	0.603
Apgar at 5 min <7	1	0.3	6	2.0	–	–	–
Stillbirth	0		1	0.3	–	–	–

The intervention effect is expressed as an odds ratio (OR) with 95% confidence interval (95% CI) and *P* value calculated with the chi-square test, or as a mean difference with 95% CI and *P* value calculated with Student's *t*–test. (–, not calculated because of small numbers).
*Glucose tolerance test not performed for the following participants: 29 withdrew from study; two delivered preterm; and 12 failed to complete because of vomiting or other complication. One test (control) discarded because of concurrent influenza and elevated C–reactive protein (CRP); *n* = 275 (i), 272 (c).
**Data based on complete medical record review. Eight participants (three in the intervention group and five in the control group) not included, who withdrew from the study and gave consent to a review of maternity ward records alone; *n* = 293 (i), 290 (c).
***Data based on review of maternity ward records for all participants.
****Term gestations: *n* = 279 (i), 278 (c).
*****Ponderal index = 100 × weight/length^3.
******Birthweight percentile calculated according to sex and gestational age, based on data from the Medical Birth Registry of Norway.
‡NICU, Neonatal Intensive Care Unit.

which may limit the reproducibility and external validity of our results. Although it is among the largest trials of its kind to be published, the results demonstrate trends that might have been statistically significant in a larger population. Although we found no differences in SGA and adverse outcomes, the trial had limited power to detect such effects. Combining NFFD results with those of other relevant intervention studies may provide additional information.

Self-reported pre-pregnancy weight was used to calculate pre-pregnancy BMI and to define the baseline in some analyses. Although it has demonstrated strong validity in earlier GWG studies,[14,39] self-reported weight remains subjective. Registering pre-pregnancy and inclusion weight in whole kg may have made small changes in weight difficult to measure. The degree of exertion during exercise classes was subjectively measured using Borg's scale, and levels of dietary compliance and physical activity were self-reported using questionnaires. Although diet is difficult to measure objectively, the use of accelerometers might have allowed for a more objective evaluation of physical activity.

As a result of individual randomisation, women living in close proximity and attending the same clinic were often in different trial groups. Midwives at the participating clinics were also informed about the purpose of the trial. It is therefore possible that control participants were influenced to some extent, and that analysis underestimates the effect of intervention. Alternately, we can conjecture that the NFFD intervention could have demonstrated a greater effect had the intervention elements been stronger, with more intensive activity sessions or more restrictive dietary advice, for example with calorie limitations.

Interpretation

Gestational weight gain

The NFFD intervention resulted in a 0.9 kg reduction in GWG using objectively measured weight and unadjusted calculations, and a slightly greater effect using self-reported pre-pregnancy weights. Although subgroups based on pre-pregnancy BMI category had limited statistical power to demonstrate effect of the intervention, the results suggest that the NFFD intervention resulted in lower GWG for women in all BMI subgroups. Our findings correspond well with the two trials to date that have compared a combination of dietary counselling and supervised exercise groups with standard prenatal care: that of Hui from Canada and Vinter from Denmark, both of which found a 1.1–1.2 kg reduction in GWG as a result of intervention.[22,23]

A large proportion of NFFD participants exceeded the IOM recommendations for GWG, consistent with recently published data on self-reported GWG for 29 931 nulliparous Norwegian women.[40] NFFD intervention participants received individual information about recommended GWG early in the study, but were not given any feedback when they were later measured, as assessors were blinded to group allocation. Ronnberg et al.[41] have recently reported a significant reduction in GWG using personalised weight graphs and regular weight monitoring. Combining the NFFD intervention with interim evaluation of weight gain might have further improved IOM compliance.

Obstetrical outcomes

The NFFD intervention reduced GWG without a corresponding reduction in obstetric complications. This is consistent with the meta-analysis of Thangaratinam et al., which showed that interventions combining dietary and physical activity elements, usually in the form of counselling, reduced GWG without affecting the risk of pregnancy complications or caesarean section.[15] The more recent UK Pregnancies Better Eating and Activity Trial (UPBEAT) study, a large, multi-centre study of behavioural intervention, showed the same outcome pattern.[26] The use of supervised exercise groups in the NFFD trial did not result in a measurably greater effect; however, the NFFD trial had limited power to detect changes in pre-eclampsia and preterm delivery risk, and results show trends that may have been significant in a much larger group. Observational studies have found that the development of gestational diabetes is closely linked with weight gain and fat deposition during the first trimester.[8,9] The NFFD intervention was initiated in the second trimester, perhaps too late to affect the complex metabolic processes regulating the development of glucose intolerance. Future studies of lifestyle interventions should focus on early pregnancy, or on the inter-pregnancy period,[42] particularly for the women who are overweight or obese, who are most at risk for pregnancy complications. To date, dietary interventions have shown the greatest effect on obstetrical outcomes.[15] Research is needed to define which elements are of most consequence: specific dietary patterns; calorie restriction; micronutrient availability; or carbohydrate, fat, and fibre content.

Neonatal outcomes

We failed to detect a decrease in the proportion of large neonates. This is consistent with the findings of several systemic reviews of GWG interventions, which have reported little or no effect on fetal weight and the proportion of large newborns, regardless of the type of intervention.[15,16,20] The NFFD trial had fewer babies of >4000 g than had been predicted: 14% rather than the anticipated 20% in the control group. The proportion of macrosomic infants decreased yearly in Norway from 2005 to 2012, when 17.2% of infants were ≥4000 g.[43] Including only first-born infants in the trial may explain further reductions. To achieve a power of 80% to demonstrate statistical significance with the difference in proportion of large newborns seen here, over 1000 women would be needed in each arm of the study. Of note, the LIMIT trial from Australia demonstrated a small but statistically significant decrease in newborns >4000 g in a population of 2152 women who were obese, without change in GWG.[25]

Lifestyle changes

Questionnaire responses suggest that both intervention elements have created behaviour change. In late pregnancy, the intervention group had a higher diet score compared with the control group, and an increased physical activity level compared with their baseline at inclusion. The control group reported decreased physical activity in late pregnancy, corresponding well with earlier findings that most women decrease or stop exercising by the third trimester.[44] Intervention group responses are plausible given the measurable result of decreased GWG. Maternal dietary and physical activity patterns affect the intrauterine environment, which may in turn affect the child's later health.[3,45,46] Improving the new mother's habits may also positively influence the lifestyle of the new family.[47,48]

Conclusion

The NFFD lifestyle intervention did not demonstrate any measurable effect on the proportion of large newborns or the incidence of obstetrical complications, but did result in a significant reduction in GWG.

Disclosure of interests

Full disclosure of interests available to view online as supporting information.

Contribution to authorship

LRS and IV conceived the idea for the trial. LRS, NØ, EB, HLS, TH, and IV wrote the protocol. NØ, EB, MT, HLS, and ERH supervised the intervention. LRS, ERH, and IV supervised participant follow-up and data collection. LRS and MS performed the data analysis. The article was written by LRS, with input from all co-authors. All authors read and approved the final version.

Details of ethics approval

The Norwegian Regional Committee for Medical Research Ethics South-East–C approved the NFFD trial protocol and modifications (REK reference 2009/429). Initial approval: 8 December 2008 and 28 July 2009. Approval of modification: 23 August 2010. ClinicalTrials.gov ID: NCT01001689.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Weight gain, from pre-pregnancy to delivery.

Figure S2. Gestational weight gain, according to pre-pregnancy BMI category.

Table S1. Self-reported lifestyle.■

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III

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The effect of prenatal lifestyle intervention on weight retention 12 months postpartum: results of the Norwegian Fit for Delivery randomised controlled trial

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Objective To examine the effect of a prenatal lifestyle intervention on postpartum weight retention (PPWR).

Design Randomised controlled trial.

Setting Healthcare clinics in southern Norway.

Population Healthy, nulliparous women with body mass index ≥19 kg/m^2, age ≥18 years, and singleton pregnancy of ≤20 gestational weeks.

Methods Women were randomised to intervention (dietary counselling twice by phone and access to twice-weekly exercise groups during pregnancy) or control group (standard prenatal care). Intervention compliance was defined post-factum as attending dietary counselling and ≥14 exercise classes.

Main outcome measures PPWR (weight measured postpartum minus self-reported pre-pregnancy weight) and the proportion of women returning to pre-pregnancy weight.

Results Of 606 women randomised, 591 were included in an intention-to-treat analysis of pregnancy outcomes and 391 (64.5%) were analysed 12 months postpartum. Mean PPWR was not significantly different between groups (0.66 kg for intervention versus 1.42 kg for control group, mean difference −0.77 kg, 95% CI −1.81, 0.28; P = 0.149). An increased proportion of intervention participants achieved pre-pregnancy weight (53% versus 43%, OR 1.50, 95% CI 1.003, 1.471; P = 0.045). However, the difference was not statistically significant when we adjusted for missing data (adjusted odds ratio (OR) 2.23, P = 0.067) using logistic mixed-effects models analysis. Women compliant with intervention had significantly lower PPWR than control participants, also after adjusting for potential confounders (adjusted mean diff −1.54 kg, 95% CI −3.02, −0.05; P = 0.039).

Conclusions The Norwegian Fit for Delivery intervention had little effect on PPWR, although women who were compliant with the intervention demonstrated significantly lower PPWR at 12 months.

Keywords Lifestyle, postpartum, pregnancy, weight gain, weight retention.

Tweetable abstract Norwegian Fit for Delivery RCT: little effect of lifestyle intervention on weight retention 1 year postpartum.

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Introduction

Weight gained during pregnancy and retained in the postpartum period has importance for a woman's lifetime risk of obesity, and may increase her subsequent risk of chronic diseases such as type 2 diabetes and cardiovascular disease.[1–4] Weight retained postpartum also has significance for future pregnancies, as an inter-pregnancy weight increase is associated with increased risk of pregnancy complications,[5] large newborns,[6] and caesarean section.[7] Observational studies have shown that excessive gestational weight gain (GWG) is closely associated with postpartum weight retention (PPWR).[1,8,9] However, there are few data from clinical trials to assess whether interventions to limit GWG will facilitate the return to pre-pregnancy weight, as few trials of pregnancy interventions published to date have reported maternal weight outcomes beyond the first weeks after delivery.[10–14] The clinically relevant question of whether efforts in pregnancy to limit GWG can affect maternal weight 1 year postpartum remains largely unanswered.

The Norwegian Fit for Delivery (NFFD) lifestyle intervention consists of dietary counselling and supervised exercise groups, and was designed to be feasible in a clinical setting, appropriate for both normal-weight and overweight women, and easily reproducible. The principal aim of the NFFD randomised trial was to examine whether the intervention could reduce GWG, obstetrical complications and the proportion of macrosomic infants. Postpartum weight retention at 6 and 12 months after delivery were secondary endpoints. We have previously reported that the NFFD intervention resulted in a 1.3-kg reduction in GWG from pre-pregnancy to term ($P = 0.009$), without statistically significant changes in obstetrical outcomes, infant birthweight or the incidence of large newborns. We hypothesised that the NFFD intervention would have an effect on the amount of weight retained postpartum or the probability of returning to pre-pregnancy weight within the 1st year after delivery. We here present the findings of postpartum follow up of maternal weight, performed 6 and 12 months after delivery.

Methods

Study design and participants

NFFD was a randomised, blinded, controlled trial with two parallel groups performed in southern Norway, encompassing the cities of Kristiansand and Mandal, and the more rural surrounding areas. The protocol for the trial has been published previously.[15] Norwegian healthcare clinics provide both pregnancy care and standardised health evaluations of all infants at regular intervals and free of charge. Midwives at eight healthcare clinics enrolled participants between September 2009 and February 2013. Women were eligible if they were nulliparous, with a singleton pregnancy of ≤20 gestational weeks, had a pre-pregnancy body mass index (BMI) ≥19 kg/m^2, were literate in Norwegian or English, and provided signed, informed consent. Exclusion criteria were pre-existing diabetes, disabilities precluding participation in a physical fitness programme (based on national and international recommendations[16]), on-going substance abuse, or planned relocation outside the study area before delivery. The first 20 participants made up a feasibility study. The trial protocol was then modified to include an age limit of ≥18 years and to allow randomisation after the completion of initial blood tests and questionnaires. The Norwegian Regional Committee for Medical Research Ethics South-East-C approved the trial and modifications (REK reference 2009/429). The trial was registered at ClinicalTrials.gov with ID NCT01001689.

Randomisation and blinding

After receiving signed consent forms and confirming that blood tests and questionnaires were completed, a research nurse assigned participants consecutively to the intervention or control arm of the study utilising a computer-generated list with a 1:1 allocation ratio and blocks of 20. The research nurse never met participants, had no role in recruitment or measurements, and had no knowledge of questionnaire responses. It was not feasible to blind participants to their group allocation, but they were instructed to refrain from revealing this to assessors. Assessors blinded to group allocation performed record reviews, recording of data and scoring of questionnaire responses.

Intervention

Details of the NFFD dietary and physical activity components and the rationale behind them have been published previously.[15,17] The dietary component consisted of ten recommendations designed to increase awareness of food choices, with specific advice on portion sizes, limiting snacks, and increasing intake of water, fruit and vegetables. Dietary counselling was performed using two telephone consultations with counsellors who were trained and supervised by the NFFD team. Intervention participants were informed of recommended GWG based on pre-pregnancy BMI and current Institute of Medicine (IOM) guidelines for term pregnancies (normal-weight 11.5–16 kg, overweight 7–11.5 kg, obese 5–9 kg)[1] but were not instructed as to how quickly they were expected to return to pre-pregnancy weight. The physical activity component consisted of access to twice-weekly exercise classes at a local gym facility from randomisation to delivery. All classes followed the same 60-minute programme, led by instructors who were trained and quality-controlled by the NFFD team. Attendance was recorded. Participants were encouraged to be physically active at moderate intensity on an additional 3 days/week. Lifestyle recommendations were reinforced

with booklets, access to a NFFD internet site, and invitation to one cooking class, and one evening meeting with information on the NFFD trial and the value of regular exercise and healthy diet in pregnancy. The postpartum period was not specifically addressed in the information provided during pregnancy and there was no intervention performed after delivery.

Among intervention participants (Figure 1, $n = 296$), 259 (87.5%) received both dietary consultations, 28 (9.5%) received one, and nine (3%) received none. All received access to physical fitness classes and 274 (92.6%) attended at least one class. The number of classes attended varied between 0 and 38, with a median of 14. Compliance with the intervention was defined as receiving one or both of the dietary consultations in addition to participating in 14 or more exercise classes.

Participants in the control group received routine prenatal care following Norwegian standards: eight prenatal appointments including one-second-trimester ultrasound examination, with additional care as needed. All pregnant women receive a booklet with advice on prenatal nutrition and physical activity, including recommendations for weight gain based on IOM guidelines.[1] Prenatal care is free of charge and provided as a co-operation between midwives and physicians. Participants in both arms of the study received routine postpartum care, which includes an appointment with a general practitioner at 6–8 weeks postpartum and a home visit from a healthcare nurse, both free of charge.

Measurements

The primary aims of the NFFD trial were to examine whether intervention resulted in differences in the following pregnancy outcomes: GWG, birthweight of term infants, the proportion of term infants >4000 g, maternal fasting glucose levels at 30 weeks gestation, maternal fat percent at 36 weeks' gestation, and the incidence of operative deliveries. PPWR was a secondary endpoint. Pre-pregnancy weight was self-reported. Participants were weighed at their healthcare clinic at inclusion using scales calibrated at trial initiation. Participants' height was measured to the nearest centimetre (cm) using a stadiometer (Seca Leicester, Hamburg, Germany) at gestational week 30. Pre-pregnancy BMI was calculated based on self-reported pre-pregnancy weight and measured height. Participants were weighed on admission to the delivery ward. If missing, the last weight in the antenatal record along with the corresponding date were recorded. Review of maternity records determined gestational age at delivery. Women were weighed by healthcare clinic staff at the time of their infants' routine assessments at 6 and 12 months of age, using healthcare clinic scales. All weights were reported to the nearest whole kilogram, as prescribed by trial protocol. Participants also had the option to be weighed postpartum at Sørlandet Hospital, but few chose this location. Postpartum measurements were collected between September 2010 and September 2014.

Participants completed questionnaires at trial inclusion, gestational week 36, and 6 and 12 months postpartum, either electronically (in Norwegian) or in print (in English or Norwegian). At both 6 and 12 months postpartum the questionnaires included three questions on initiation, duration and exclusivity of breastfeeding.[18] Diet was assessed by 43 food-frequency questions, analysed using a pre-determined score built from 10 subscales corresponding to NFFD recommendations. Total NFFD diet score ranged from 0 to 10 with higher scores indicating healthier behaviour. A detailed description has been published previously.[17] The dietary score has demonstrated acceptable test–retest reliability.[15] Physical activity was assessed with the International Physical Activity Questionnaire (IPAQ) short version, which quantifies physical activity during the last 7 days divided into categories of vigorous intensity, moderate intensity and walking. Responses were scored using IPAQ analysis algorithms as weekly energy expenditure (MET).[19] The IPAQ has been validated in a Scandinavian population.[19] The postpartum questionnaires did not include questions about new pregnancy.

Electronic hospital records, encompassing the southeastern region of Norway, were reviewed from November 2014 to January 2015, to determine subsequent pregnancy. In the event of pregnancy at the time of postpartum follow up, gestational length was calculated based on recorded date-of-confinement.

Sample size

The sample size of the current study was determined based on power calculations for delivery outcomes, rather than on postpartum weight retention. While there were few data on GWG among Norwegian women when planning the trial, reliable data on newborn birthweight were available through the Norwegian birth registry. We expected a 20% prevalence of newborns with a birthweight >4000 g in the control group based on 2005 statistics,[20] and determined that a reduction to 10% in the intervention group would be clinically relevant. We calculated that we required 198 women in each study arm to demonstrate statistical significance with a power of 80%. To allow for participant drop-out and premature deliveries, we decided to randomise 600 participants.

Statistical analysis

PPWR was defined as the difference between measured weight postpartum and self-reported pre-pregnancy weight. Assessment of randomisation groups was performed according to the study protocol using Student's *t*-test for PPWR or chi-squared test and logistic regression analysis

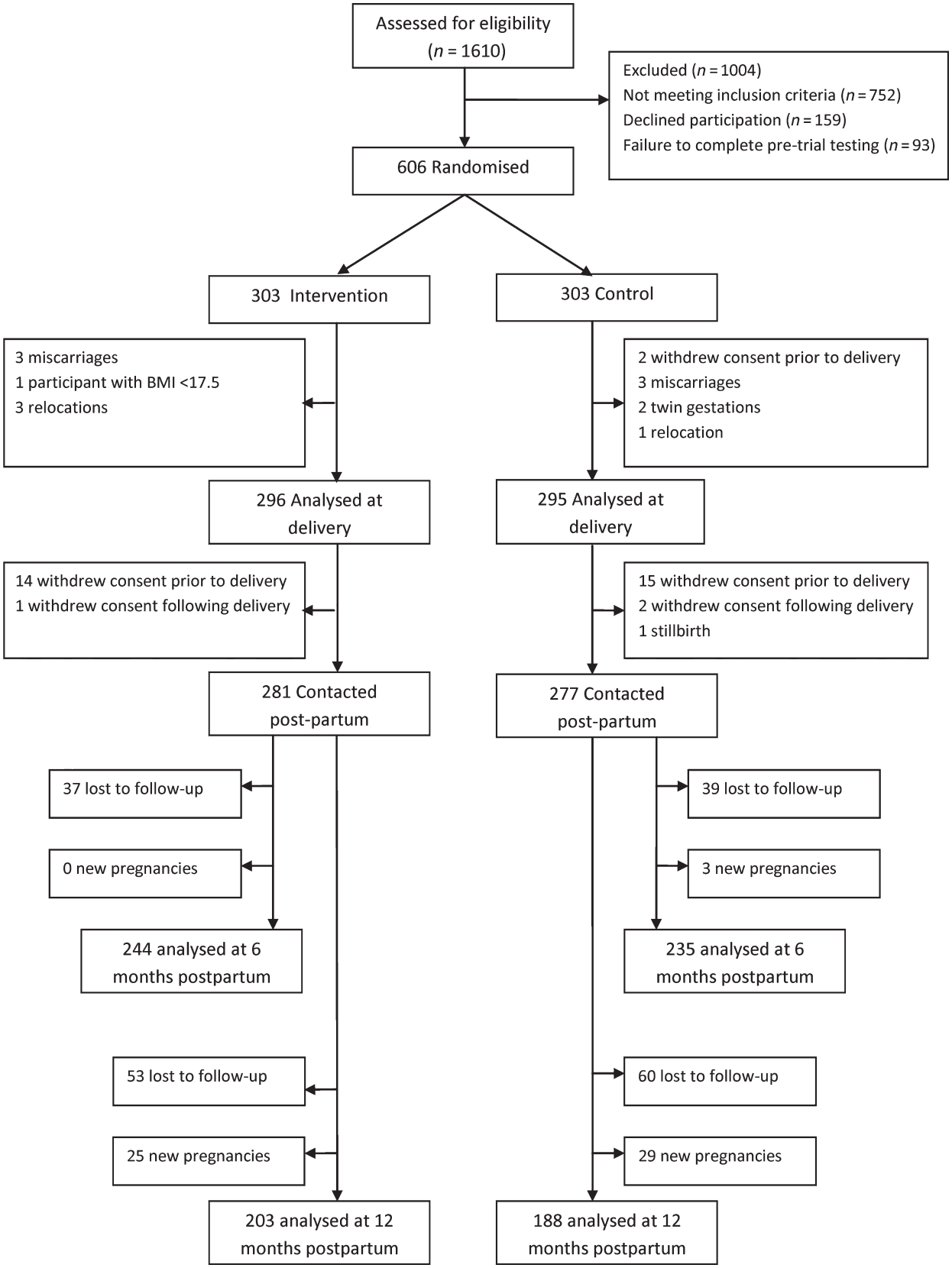

Figure 1. Flow chart of trial participation. After randomisation, seven women in the intervention arm and six in the control arm were excluded from the intervention, including four women who moved to another region of the country and were considered 'missing completely at random'. Two women in the control group withdrew from the trial and did not consent to analysis of delivery ward records. An additional 29 women (14 intervention group, 15 control group) withdrew from the trial but allowed analysis of delivery records, and three women withdrew from the trial after delivery. In all, 558 women were contacted at 6 months postpartum and again at 12 months postpartum.

for the binary outcome of exceeding pre-pregnancy weight (PPWR >0 or ≤ 0). These statistical tests were also used to assess missing and compliant versus non-compliant intervention participants. Further, a linear mixed-effects model adjusted for time, age, education, income and pre-pregnancy BMI group and with the repeated measurements (i.e. delivery, 6 months postpartum and 12 months postpartum) and randomisation group both as main effects and as an interaction term was estimated. This model contained a random intercept and an AR1 residual matrix and used a robust estimation of standard errors. Exceeding pre-pregnancy weight as a binary outcome was also modelled using a logistic mixed-effects model with a random intercept and the same set of fixed independent variables as for the linear mixed-effect model. The effect of randomisation groups at each repeated measurement was estimated using a linear combination. The effect of compliance with the NFFD intervention on PPWR, diet score and physical activity levels was assessed using a general linear model with Bonferroni post-hoc testing and was adjusted for age, pre-pregnancy BMI category, education, income and occupation using multiple linear regression analysis. *P*-values <0.05 were considered statistically significant. All tests were two-sided. Statistical analyses were performed using SPSS for Windows version 21.0 (IBM Corp, Armonk, NY, USA) and STATA 13 for Windows (StataCorp, College Station, TX, USA).

Results

Participant enrollment and demographics

Participating clinics documented attendance of 4245 women during the inclusion period. We approximate that 1610 were nulliparous, based on detailed data from four participating clinics. The NFFD trial included 606 women (Figure 1), equally randomised into intervention and control groups, 591 of whom (97.5%) were included in the intention-to-treat (ITT) analysis of pregnancy outcomes. Of these, 32 women withdrew consent and one control participant delivered a stillborn, such that 558 women (92.4%) remained in the NFFD trial after delivery. A total of 516 women (85.1%) were weighed at least once postpartum: 482 (79.5%) at 6 months and 445 (73.4%) at 12 months postpartum. Questionnaires were completed by 479 participants (79%) at 6 months and 431 participants (71.1%) at 12 months postpartum.

Hospital record review showed 54 pregnancies among those measured 12 months postpartum (25 intervention, 29 control). When new pregnancies were excluded, 201 women (66.3%) remained in the intervention arm and 188 (63.0%) in the control arm of the trial at 12 months postpartum. These women were the primary focus of our analysis and their baseline characteristics are presented in Table 1. Participants were predominantly white, of European descent. Intervention and control group participants were similar in all categories. Among intervention participants in the present analysis, 115 (56.7%) were defined as compliant and 88 (43.3%) non-compliant with the intervention.

At 12 months postpartum, measurements were missing or excluded for 200 women included in the ITT analysis of pregnancy outcomes: 93 (93/296, 31.31.4%) in the intervention group and 107 (107/295, 36.3%) in the control group (Figure 1). Compared with measured participants, missing participants were somewhat younger (27.5 versus 28.3 years, mean difference −0.8 years, $P = 0.036$), had lower educational level ($P = 0.003$), lower income ($P = 0.018$), and tended to have a higher pre-pregnancy BMI (24.1 versus 23.5 kg/m^2, mean difference 0.65 kg/m^2, $P = 0.059$) at trial inclusion. Women with missing postpartum data had similar GWG to those measured (15.3 versus 14.8 kg, mean difference 0.6 kg, $P = 0.279$). Examining intervention and control groups separately showed that low educational level ($P = 0.001$) and low income level ($P = 0.040$) were significantly associated with missingness in the intervention group, whereas age was significantly lower only in the control group (mean difference −1.07 years, $P = 0.048$).

Weight retention

Assessing weight gain patterns for women measured at 12 months postpartum (Table 2) confirmed that GWG (pre-pregnancy to term) was lower in the intervention group than the control group (mean difference −1.3 kg, $P = 0.043$). Timing of postpartum measurements was equivalent between groups. Measuring weight change from delivery showed no between-group difference. There was wide variation in PPWR in both randomisation groups, with a range of −15 to 28 kg (Figure S1). There was no significant difference in mean PPWR between intervention and control groups (0.66 versus 1.42 kg, mean difference −0.77 kg, 95% CI −1.81, 0.28; $P = 0.149$). Mixed-effect model analysis was used to assess weight change at delivery, and 6 and 12 months postpartum, adjusting for age, education, income and pre-pregnancy BMI group at inclusion and assuming that data were missing at random. Analysis showed no significant effect of intervention (mean differ-

Table 1. Baseline characteristics of participants

	Intervention (n = 203)		Control (n = 188)	
	Mean	**SD**	**Mean**	**SD**
Age at trial inclusion (years)	28.0	4.0	28.5	4.2
Gestational age at inclusion (weeks)	15.4	2.6	15.7	2.3
Pre-pregnancy weight (kg)	67.1	11.9	67.0	11.2
Height (cm)	168.7	5.8	169.0	6.9
Pre-pregnancy BMI (kg/m²)	23.6	4.0	23.4	3.3
Inclusion weight (kg)*	69.4	12.2	69.5	11.4
NFFD diet score	4.99	2.09	5.01	2.01
IPAQ score (MET)	1521	1328	1482	1481
	N	**%**	***N***	**%**
BMI category, pre-pregnancy				
Underweight	1	0.5	2	1.1
Normal-weight	144	70.9	142	75.5
Overweight	43	21.2	37	19.7
Obese	15	7.4	7	3.7
Education level**				
12 years or less	52	25.7	55	29.3
<4 years of higher education	74	36.3	56	29.8
≥4 years of higher education	76	37.6	77	41.1
Occupation				
Employed outside the home	166	81.8	163	86.7
Student	25	12.3	14	7.4
Unemployed	6	3.0	6	3.2
Long-term sick leave	5	2.5	3	1.6
Homemaker	1	0.5	2	1.1
Cohabitation				
Husband/boyfriend/partner	200	98.5	180	95.7
Other	3	2.3	11	4.3
Household Income (NKR)**				
≤400,000	63	31.0	55	29.4
401-700,000	57	28.1	52	27.8
>700,000	76	37.4	69	36.9
Refrained from response	7	3.4	11	5.9
Smoking status				
Smoker	6	3.0	7	3.7
Non-smoker	197	97.0	181	96.3

BMI, Body Mass Index. IPAQ, International Physical Activity Questionnaire.
Baseline characteristics of participants included in analysis of weight retention 12 months postpartum: 228 intervention participants measured, 25 excluded due to new pregnancy; 217 control participants measured, 29 excluded due to new pregnancy.
*Weight at inclusion was missing for eight (two control and six intervention) participants.
**Education and income information missing for one control participant.

ence −0.75 kg at 12 months postpartum, $P = 0.122$). Examining the proportion of measured women who returned to pre-pregnancy weight at 12 months showed a significant increase in the intervention group compared with the control group: 108 (53%) versus 81 (43%), OR 1.50, 95% CI 1.00, 1.47 ($P = 0.045$) but the difference was not statistically significant when using logistic mixed-effects models analysis to adjust for missing data (adjusted OR 2.23, $P = 0.067$).

Record review showed that women measured at 12 months postpartum with new pregnancies had an equivalent gestational length in the two groups: 14.5 versus 15.0 weeks for intervention and control groups, respectively ($P = 0.80$). There was a trend toward less weight gain in the intervention group ($n = 25$) compared with the control group ($n = 29$): 3.16 versus 6.10 kg, mean difference −2.94 kg, 95% CI −6.29, 0.80 ($P = 0.074$). The trend remained after adjusting for gestational length (adjusted mean difference −2.79 kg, $P = 0.069$).

Compliance with intervention

A secondary analysis was performed, dividing the intervention group into compliant and non-compliant participants. Women who were compliant with the intervention had higher educational levels than those who were non-compliant ($P = 0.029$) and they were more often employed outside the home ($P = 0.043$); however, they were of equivalent age, with equivalent income, pre-pregnancy weight and pre-pregnancy BMI compared with non-compliant intervention participants. Although the two intervention subgroups had equivalent GWG, they had different patterns of PPWR (Figure 2). Intervention compliance was associated with significantly lower mean weight retention at 12 months, compared with both non-compliant intervention participants (−0.34 versus 1.95 kg, mean difference −2.29 kg, 95% CI −4.06, −0.53; $P = 0.006$) and control participants (−0.34 versus 1.42 kg, mean difference −1.76 kg, 95% CI −3.23, −0.29, $P = 0.013$). The difference in PPWR between women who complied with the intervention and women in the control group remained significant when adjusted for age, pre-pregnancy BMI category, education, income and occupation (2.25 versus 3.79 kg, mean difference −1.54 kg, 95% CI −3.02, −0.05; $P = 0.013$). There was no significant difference in duration of breastfeeding between women compliant with the intervention and those in the control group (37.3 versus 34.2 weeks, mean difference 3.0 weeks, 95% CI −1.3, 7.5; $P = 0.294$).

Compliance, physical activity and diet

At inclusion, all participants reported equivalent activity levels as measured by IPAQ scores (Table 1), with compliant intervention participants recalling slightly lower pre-pregnancy physical activity levels than the other partici-

Table 2. Weight gain patterns for NFFD participants measured at 12 months postpartum

	Intervention $n = 203$		Control $n = 188$		Intervention Effect		
	Mean	SD	Mean	SD	Mean diff.	95% CI	*P*-value
At delivery							
Weight at delivery*, kg	81.12	13.71	82.40	12.86	−1.28	−3.94, 1.37	0.342
GWG pre-pregnancy to term**, kg	14.26	6.31	15.55	5.65	−1.29	−2.54, −0.04	0.043
GWG rate*** pre-pregnancy to delivery*, kg/week	0.35	0.15	0.39	0.14	−0.04	−0.06, −0.01	0.019
12 months postpartum							
Interval since delivery, days	374.00	21.51	375.06	21.90	−1.08	−5.41, 3.24	0.623
Weight, kg	67.73	13,46	68.38	12.42	−0.64	−3.22, 1.94	0.624
Weight loss from delivery*, kg	13.34	6.23	14.00	5.91	−0.65	−1.86, 0.56	0.292
Weight retention from pre-pregnancy, kg	0.66	5.48	1.42	4.96	−0.77	−1.81, 0.28	0.149
	N	%	*N*	%	OR	95% CI	*P*-value
Return to pre-pregnancy weight	108	53.2	81	43.1	1.50	1.01, 2.24	0.045

GWG, Gestational weight gain.
Weight measurements at delivery and at 12 months postpartum.
*Weight measurement at or before delivery available for 389/391 participants.
**Weight measurement within 2 weeks of term delivery available for 183/203 women in intervention group and 173/188 women in control group.
***GWG rate = (last available weight prior to delivery – pre-pregnancy weight)/gestational length at date of last measurement.

pants (Figure 2). Both intervention subgroups reported a significantly higher physical activity level in late pregnancy compared with the control group, but postpartum physical activity levels showed little difference between all three groups.

The NFFD dietary scores at inclusion were slightly higher for the compliant intervention group than for the control and non-compliant intervention groups, but the difference between groups was only significant in late pregnancy. Postpartum, there was no significant difference between the three groups, although the group compliant with intervention consistently scored highest.

Discussion

Main findings

This large randomised controlled trial showed that the NFFD lifestyle intervention had little effect on PPWR, although there was a trend toward greater return to pre-pregnancy weight in the intervention group. Compliance with the NFFD intervention was associated with a significantly lower PPWR compared with the control group, also when adjusted for socioeconomic factors. While intervention participants (both the whole group and the compliant subgroup) reported significantly higher dietary scores and physical activity levels in late pregnancy compared with control participants, these differences were no longer found postpartum.

Strengths and limitations

Prospective randomised controlled design is a major strength of the NFFD trial. It is also among the largest published, and among the few trials of lifestyle interventions to limit GWG that has followed its participants 12 months postpartum. The trial was pragmatic in nature, including women attending routine antenatal appointments rather than a potentially more selected population recruited through advertising.

Despite the size of the NFFD trial, an even greater sample size may be needed to assess PPWR. To detect a 1.0-kg difference in mean PPWR with the degree of variation here found, approximately 400 participants would be needed in each arm. To allow for loss to follow up, conservatively estimated at 30–40% when new pregnancies are included, an adequately powered trial would require 1000–1500 participants. PPWR is a clinically important outcome, and highly relevant in an assessment of GWG interventions, but adequate evaluation may require combining findings with those of other trials.

NFFD participants were older and had higher educational levels compared with the background population,[21,22] and data from women with lower socioeconomic status and higher BMI were more likely to be missing from postpartum follow up. The women included in the study were predominantly white, European, and highly educated, with relatively few overweight and obese participants. Trial par-

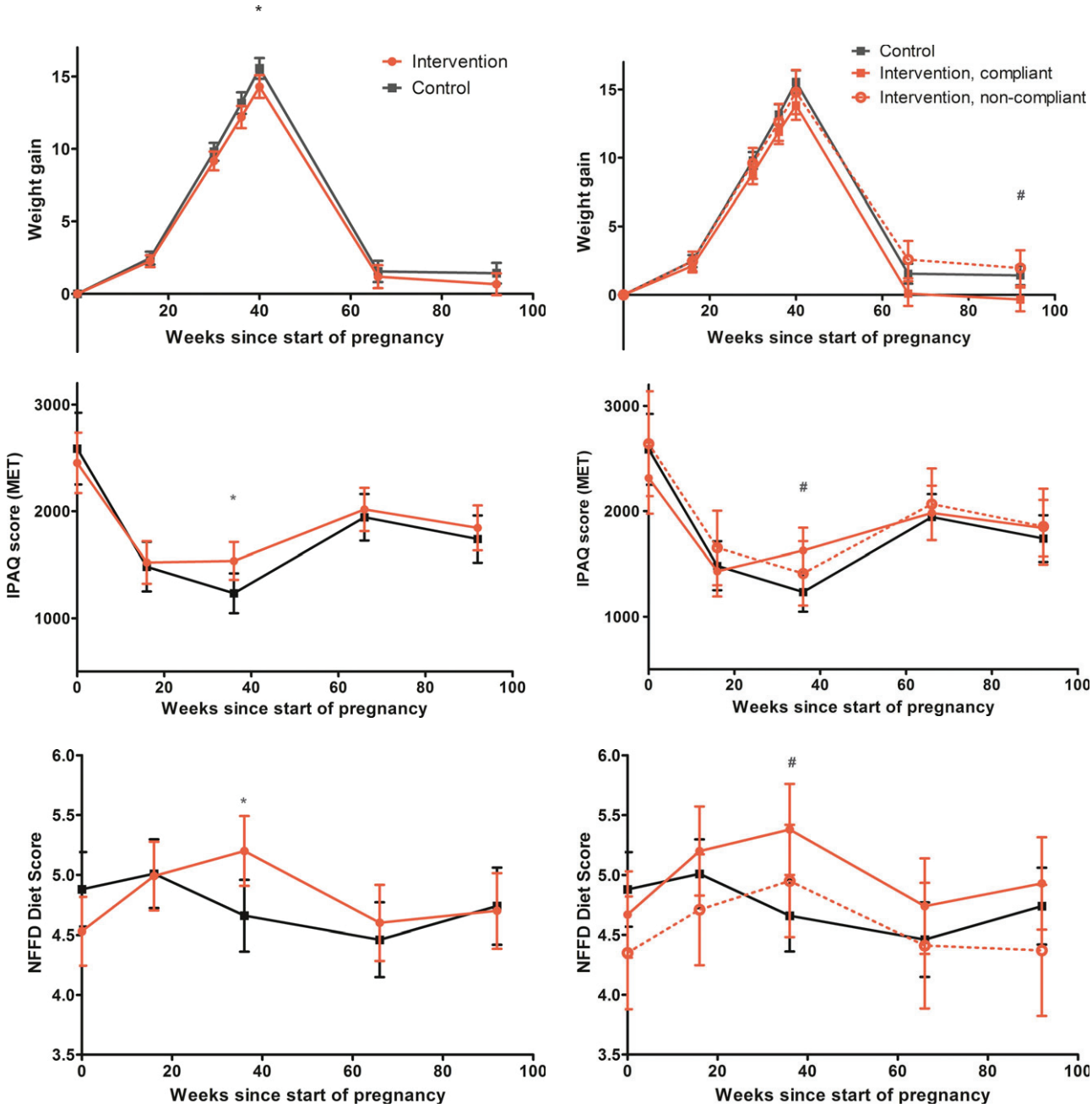

Figure 2. Comparison of groups over time, based on randomisation and compliance: weight change, IPAQ score and dietary score. Weight change from pre-pregnancy (week 0) measured at gestational weeks 16 (inclusion), 30 and 36, at term delivery (week 40), and 6 and 12 months postpartum (weeks 66 and 92). *Statistically significant difference between intervention and control groups. #Statistically significant difference between compliant intervention subgroup and both non-compliant intervention subgroup and control group.

ticipation required that women were sufficiently motivated to complete testing before randomisation, and postpartum follow up was further limited to those motivated enough to continue participation. Although we have attempted to adjust for these factors in our analysis, they may limit the reproducibility and validity of results.

Self-reported pre-pregnancy weight was used to calculate pre-pregnancy BMI and define baseline in calculating PPWR. Although it has demonstrated strong validity in earlier studies,[11,23] self-reported weight remains subjective. Information on breastfeeding was also self-reported, but similar questions have been shown previously to

provide an accurate estimation of the duration of breastfeeding.[24] Dietary patterns and physical activity levels were also self-reported using questionnaires. Although diet is difficult to measure objectively, use of accelerometers might have allowed more objective evaluation of physical activity.

Interpretation

Few published trials have studied the effect of GWG interventions performed during pregnancy on weight retention beyond the first weeks after delivery. Two randomised trials have reported the effects of prenatal lifestyle counselling on PPWR at 12 months. Phelan et al. found no effect of intervention using an intention-to-treat analysis, but a significant reduction in PPWR among those who completed follow up (n = 261, 1.4 versus 3.0 kg, P = 0.046),[12] whereas Althuzien et al. found no effect of intervention on PPWR (n = 188, 2.5 versus 2.3 kg) despite including one counselling session after delivery.[25] Vinter et al.[14] reported no effect of intervention on PPWR at 6 months (n = 238, exclusively obese) in a randomised trial that previously demonstrated significant reduction in GWG. Olson et al.[26] compared prenatal dietary counselling and weight monitoring (n = 155) with historical controls (n = 348) and found no effect on PPWR at 1 year; however, they reported decreased risk of substantial PPWR in a subgroup of low-income, overweight women who received intervention. These trials were all limited in size but suggest that modifying PPWR is difficult, and that limiting GWG may not reduce PPWR.

At 12 months postpartum, data were missing or excluded for over 30% of NFFD participants. Other gestational interventions have reported similar loss to follow-up postpartum.[12,14] The NFFD trial was designed to facilitate compliance by performing measurements at the time of infant healthcare clinic appointments, but many women are fully employed at 1 year postpartum and may not attend themselves. Missing data is accounted for in our presentation, and statistical analysis is used to compensate for losses, but incomplete data nonetheless limit our ability to draw conclusions from our findings.

In the NFFD trial, mean PPWR was low in both the control and intervention group, compared both with other trials that have assessed PPWR[12,25,27] and with a published cohort of 19 604 nulliparous Norwegian women that described a mean PPWR of 2.1 kg at 18 months (not measured at 12 months).[28] The Norwegian cohort was similar to our population in age, pre-pregnancy BMI and educational status. This suggests that control participants could be influenced by trial participation. Women in both arms of the study lived in the same geographical area and attended the same healthcare clinics, where performing the trial focused attention on healthy diet, prenatal physical activity and GWG. Repeated weighing during pregnancy and postpartum may also have increased awareness of weight change in both groups.[29]

Analysis of compliance demonstrated that participation in the intervention elements was associated with lower PPWR. However, we cannot conclude that these findings are the result of intervention, as this population is self-selected and random assignment is set aside. Analysing factors associated with compliance may be informative, as motivation and compliance are central to the evaluation of healthcare interventions.[30,31] We found that women with lower educational levels were underrepresented in the compliant sub-group. Low educational levels have been linked to obesity prevalence throughout Europe, particularly among women.[32] Our findings expose a major challenge, as effective interventions that decrease the risk of developing obesity are particularly needed in this group. Analysis of obesity-prevention interventions has suggested that interventions which rely solely on education and individual choice place women with lower socioeconomic status at a disadvantage.[33] The use of structural intervention elements, such as exercise classes in the NFFD intervention, would be expected to increase effectiveness in this group. Making classes easily accessible by public transportation and allowing for participation in exercise classes during work hours might have improved attendance. Language assessment, to assure that intervention elements and questionnaires were appropriate for women of all educational levels, would also have been useful.

The effect of the NFFD intervention on PPWR appeared to be achieved through lifestyle changes in pregnancy rather than postpartum, as both diet scores and physical activity levels for the intervention group approached those of the control group postpartum. This was also true for women who complied with the intervention, suggesting that participants interpreted the intervention as a lifestyle to be adopted during pregnancy rather than maintained indefinitely. This may explain the trend toward lower GWG observed among women in the intervention group who were pregnant again, compared with the control group. All participant groups reported a decline in physical activity level postpartum compared with pre-pregnancy, probably reflecting the radical change in daily life experienced by first-time mothers caring for an infant. The intervention might have been improved by explicitly incorporating information on the postpartum period and beyond.

Conclusion

Providing the NFFD intervention had little measurable effect on the outcome of PPWR, although women who were compliant with the intervention demonstrated significantly lower weight retention 12 months postpartum. Combining results with those of other relevant studies may

provide additional information about the effect of gestational lifestyle intervention. At the present time, lifestyle interventions provided during pregnancy have demonstrated little effect on maternal weight postpartum and therefore highlight the need for more long-term, preferably pre-pregnancy, initiatives to prevent overweight and obesity among young women.

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Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

LRS and IV conceived the idea for the trial. LRS, NØ, EB, HLS, TH and IV wrote the protocol. NØ, EB, MT, HLS and ERH supervised the intervention. LRS, ERH and IV supervised participant follow up and data collection. LRS and AHP performed the data analysis. The article was written by LRS, with input from all co-authors. All authors read and approved the final version.

Details of ethics approval

The Norwegian Regional Committee for Medical Research Ethics South-East-C approved the NFFD trial protocol and modifications (REK reference 2009/429). Initial approval 8 December 2008 and 28 July 2009; approval of modifications 23 August 2010.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Postpartum weight retention at 12 months. ■

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IV

The effect of a prenatal lifestyle intervention on glucose metabolism: results of the Norwegian Fit for Delivery randomized controlled trial

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Abstract

Background

Effective prenatal lifestyle intervention to prevent gestational diabetes (GDM) remains to be established. Intervention in pregnancy may, however, have effects on glucose metabolism that are not revealed by GDM incidence alone. The Norwegian Fit for Delivery (NFFD) randomized, controlled trial studied the effect of a combined lifestyle intervention provided to a general population, and found significantly lower gestational weight gain among intervention participants but no improvement in obstetrical outcomes or the proportion of large infants. The aim of the present study is to examine the effect of the NFFD intervention on levels of glucose, insulin, insulin resistance and leptin.

Methods

Healthy, non-diabetic women expecting their first child, with pre-pregnancy body mass index (BMI) ≥19 kg/m2, age ≥18 years and a singleton pregnancy of ≤20 gestational-weeks were enrolled from healthcare clinics in southern Norway. Gestational weight gain was the primary endpoint. Participants (n=606) were individually randomized to intervention (two dietary consultations and access to twice-weekly exercise groups) or control group (routine prenatal care). The effect of intervention on glucose metabolism was a secondary endpoint, measuring glucose (fasting and 2-hour following 75-g glucose load), insulin, homeostatic assessment of insulin resistance (HOMA-IR) and leptin levels at gestational-week 30.

Results

Blood samples from 557 (91.9%) women were analyzed. For the total group, intervention resulted in reduced insulin (adj. mean diff -0.91 mU/l, p=0.045) and leptin levels (adj. mean diff -207pmol/l, p=0.021) compared to routine care, while glucose levels were unchanged. However, the effect of intervention on both fasting and 2-hr glucose was modified by pre-pregnancy BMI (interaction p=0.030 and p=0.039, respectively). For overweight/obese women (n=158), intervention was associated with increased risk of at least one glucose measurement exceeding International Association of Pregnancy and Diabetes Study Group thresholds (33.7% vs. 13.9%, adj. OR 3.89, p=0.004).

Conclusions

The Norwegian Fit for Delivery intervention lowered neither glucose levels nor GDM incidence, despite reductions in insulin and leptin. Prenatal combined lifestyle interventions designed for a general population may be unsuited to reduce GDM risk, particularly among overweight/obese women, who may require earlier and more targeted interventions.

Trial registration: ClinicalTrials.gov ID NCT01001689, https://clinicaltrials.gov, registered July 2, 2009, confirmed completed October 26, 2009

Keywords: gestational diabetes, intervention, lifestyle, overweight, obesity

Background

Maternal glucose regulation appears to be fundamentally important for fetal growth and pregnancy health. Observational studies demonstrate a linear relationship between maternal glucose levels and adverse obstetrical outcomes, particularly fetal macrosomia [1, 2], and randomized trials demonstrate that treatment of mild hyperglycemia reduces the incidence of these same outcomes [3, 4]. Gestational diabetes mellitus (GDM) is defined as hyperglycemia first detected during pregnancy, ultimately due to insufficient insulin production relative to the physiologic insulin resistance of pregnancy [5]. The level of maternal glucose that constitutes a risk for mother and fetus is much debated, and there is currently no international consensus on glucose thresholds for the diagnosis of GDM [6-8]. Effective antenatal lifestyle intervention to improve maternal glucose metabolism and reduce GDM risk is in high demand [9]. Trials published to date indicate that prenatal interventions combining diet and exercise reduce gestational weight gain but not GDM risk [10-13]. Few trials of antenatal diet and exercise have reported levels of glucose, insulin and insulin resistance [8]. These levels may give information about alterations in maternal metabolism that are not disclosed by simply reporting the incidence of GDM. Women who are overweight or obese often enter pregnancy with increased insulin resistance, and examination of glucose metabolism for this subgroup of women is therefore of particular interest [5, 14]. Leptin levels are also relevant to interventions affecting weight gain, as this adipocyte appears to play a role in glucose regulation [15].

The Norwegian Fit for Delivery (NFFD) randomized controlled trial tested the effect of a prenatal lifestyle intervention consisting of dietary counseling and supervised exercise groups on a general population including normal-weight, overweight and obese women. We have previously reported that the NFFD intervention resulted in a significant reduction in gestational weight gain (GWG) of 1.3 kg from pre-pregnancy to term but showed no significant effect of intervention on the incidence of GDM based on 2006 World Health Organization (WHO) criteria or on the proportion of large newborns [16]. The aim of the present paper is to examine the effect of intervention on levels of glucose, insulin, homeostatic assessment of insulin resistance (HOMA-IR) and leptin measured at gestational-week 30, including an assessment of intervention effect on the subgroups of normal-weight and overweight/obese women.

Methods

NFFD is a randomized, blinded, controlled trial with two parallel groups performed in southern Norway, encompassing the cities of Kristiansand and Mandal and the more rural surrounding areas. The protocol for the trial is previously published [17]. Midwives at eight healthcare clinics enrolled participants between September 2009 and February 2013. Women were eligible if they were nulliparous, with a singleton pregnancy of ≤20 gestational

weeks, had a pre-pregnancy body mass index (BMI) ≥19 kg/m^2, were literate in Norwegian or English, and provided signed, informed consent. Exclusion criteria were pre-existing diabetes, disabilities precluding participation in a physical fitness program (based on national and international recommendations) [18], on-going substance abuse, or planned relocation outside the study area before delivery. The first 20 participants comprised a feasibility study. The protocol was modified to include a lower age limit of 18 years and to allow randomisation after initial questionnaires and blood tests were completed, in order to assure that participants were sufficiently motivated and avoid missing data. Participating clinics documented attendance of 4245 women during the inclusion period, of whom we estimate that 1610 were nulliparous (Figure 1)[16].

Ethics, consent and permissions

The trial was performed in accordance with the Declaration of Helsinki. The Norwegian Regional Committee for Medical Research Ethics South-East-C approved the trial and modifications (REK reference 2009/429). Signed, informed consent was obtained from all participants.

Randomisation and Blinding

After receiving signed consent forms and confirming that blood tests and questionnaires were completed, a research nurse assigned participants consecutively to the intervention or control arm of the study utilising a computer-generated list with 1:1 allocation ratio and blocks of 20. All examinations, blood test evaluations and scoring of questionnaires were performed by assessors blinded to group allocation.

Intervention

Details of NFFD's dietary and physical activity components and the rationale behind them are previously published [17] [19]. The dietary component was based on ten recommendations designed to increase awareness of food choices, with advice to increase intake of water, vegetables and fruit and reduce snack food consumption. There was no calorie restriction or specific limitation of fats or carbohydrates. Counselling was performed twice, by phone, with a four to six week interval. Counsellors were either experienced clinical dieticians or graduate students in public health, trained and supervised by the NFFD team. The physical activity component consisted of access to twice-weekly exercise classes at a local gym facility, led by physical therapists or students in sports science, trained and quality-controlled by the NFFD team. Attendance was recorded. Participants were encouraged to engage in 30 minutes of moderate-intensity physical activity on three

additional days per week. Lifestyle recommendations were reinforced with booklets, access to a NFFD internet site, and invitation to one cooking class and one evening meeting with information on the NFFD trial and the value of regular exercise and healthy diet in pregnancy.

Participants in the control group received routine prenatal care following Norwegian standard: eight prenatal appointments, including one second-trimester ultrasound examination, with additional care as needed, provided free of charge. Routine cares includes a booklet with advice on prenatal nutrition, physical activity and recommendations for weight gain based on current Institute of Medicine (IOM) guidelines (normal-weight: 11.5-16 kg, overweight: 7-11.5 kg, obese: 5-9 kg) [20].

Measurements

The primary aims of the NFFD trial were to examine if intervention resulted in differences in GWG, birth weight of term infants, the proportion of term infants >4000 g, maternal fat percent at 36 gestational-weeks, and the incidence of operative deliveries. Maternal glucose levels at 30 gestational-weeks was a primary endpoint, while the proportion of women with elevated 2-hour glucose tolerance tests and measurement of hormones related to glucose metabolism were secondary endpoints of the trial. Assessment of the subgroup of overweight/obese women was specified in the trial protocol.

Pre-pregnancy weight was self-reported. Participants were weighed at their healthcare clinic at inclusion, and at Sørlandet Hospital at 30 gestational-weeks (Tanita BC 418, Tokyo, Japan). Feasibility study participants reported their height; later participants were measured using a stadiometer (Seca Leicester, Hamburg, Germany). Pre-pregnancy BMI was calculated based on self-reported pre-pregnancy weight and measured height when available. Participants were weighed on admission to the delivery ward. If missing, last weight in the prenatal record was recorded with corresponding date. GWG at term was calculated for women delivering at ≥37 gestational-weeks with weight available within two weeks of admission.

Participants completed questionnaires at trial inclusion and at gestational-week 36, either electronically or in print. No questionnaires were completed at gestational-week 30. Diet was assessed by 43 food-frequency questions, analyzed using a pre-determined score (range 0-10, with higher score denoting healthier eating behavior). The score is previously described in detail, and has demonstrated acceptable test-retest reliability [19]. Physical activity was assessed with the International Physical Activity Questionnaire (IPAQ) short version, scored using IPAQ analysis algorithms. The IPAQ is validated in a Scandinavian population [21].

Prior to randomisation, fasting blood tests were assessed for evidence of pre-existing diabetes (defined as glucose ≥7.1 mmol/l) [22]. No participants were excluded on this basis.

At gestational-week 30, plasma glucose was measured after overnight fast and again at 2-hours after 75 g glucose load. All tests were performed at Sørlandet Sykehus using a Cobas 6000 c501 chemistry analyzer (Roche Diagnostics). Glucose levels ≥7.1 mmol/l at fasting and/or ≥7.8 mmol/l at 2-hours were classified as elevated, based on contemporary national [23] and WHO 2006 criteria [22], and participants and their primary care physicians were informed. Glucose at 2-hours was missing for 12 participants (9 intervention, 3 control), primarily due to vomiting. Fasting serum samples were frozen and stored at -80°C. Frozen samples were analyzed at Aker Hormone laboratory using a Modular E170 analyzer (Roche), batched to decrease interassay variation. Insulin was analyzed using non-competitive electrochemoluminescence immunoassay (Roche Diagnostics), with coefficient of variance of 4%. Leptin was analyzed using competitive radioimmunoassay (Millipore), with coefficient of variance of 7%. HOMA-IR was calculated as: (insulin(mU/l) x fasting glucose(mmol/l))/22.5. Leptin, insulin and HOMA-IR were missing for eight participants (3 intervention, 5 control), due to errors in freezing or transport. All missing values were considered missing completely at random. Three insulin and HOMA-IR values (1 intervention, 2 control) were excluded from analysis as outliers.

Sample size

We predicted a 20% prevalence of newborns with birth-weight >4000 g in the control group based on 2005 statistics from the Norwegian birth registry [24], and determined empirically that a reduction to 10% in the intervention group would be clinically relevant. We calculated that 198 women were required in each study arm to demonstrate statistical significance with a power of 80%. We also expected a 10% incidence of GDM (based on 2-hour glucose ≥7.8 mmol/l)[22, 23] in the control group, and determined that a reduction to 3% in the intervention group would be clinically significant. We calculated that we would have 80% power to detect a statistically significant difference between groups with 200 participants in each arm. To allow for participant drop-out and premature deliveries and to allow for analysis of subgroups, we planned to randomize 600 participants.

Statistics

Unadjusted comparison of intervention and control groups was performed using student t-test or chi-square test as appropriate. Difference between the randomized groups for continuous or binary variables was assessed using multiple linear or logistic regression models adjusted for age, education, income level and smoking at inclusion, pre-pregnancy BMI category and gestational age at measurement. Variables included in the adjusted analysis were chosen based on clinical relevance (pre-pregnancy BMI category and smoking) and/or measured differences between intervention and control group (gestational age at measurement) and/or measured differences between included and missing participants (age, education and income). Effect modification between randomized groups and patient

characteristics on continuous outcomes was assessed by an interaction term in the multiple linear regression models. For binary outcomes, effect modification was assessed by the Breslow-Day test of homogeneity of odds ratios. No further adjustment for BMI category was performed when analysis was stratified according to pre-pregnancy BMI. P-values <0.05 were considered statistically significant. All tests were two-sided. We used SPSS for Windows version 21.0 for all statistical analyses.

Results

The 606 women included in the NFFD trial were equally distributed into intervention and control groups (Figure 1), of which 591 (97.5%) were included in a previously-published intention-to-treat (ITT) analysis of intervention effect on obstetrical outcomes [16]. An additional 34 women withdrew or were excluded from participation (Figure 1) such that 557 (91.9%) women were included in the present analysis. Compared to the ITT analysis, missing participants in the intervention group (15/296, 5.1%) were younger (24.9 vs. 28.0 years, p=0.005), more often without higher education (71.4% vs. 30.0%, p=0.004) and reported lower income (p=0.034), but had a similar distribution of occupations, pre-pregnancy BMI categories, and healthcare clinics compared with intervention participants who were tested. Missing participants in the control group (19/295, 6.4%) were not significantly different from those who were tested.

Among women in the intervention arm, 253/281 (90.0%) received both dietary consultations, 25/281 (8.9%) received one, and 3/281 (1.1%) received none. All received access to exercise classes and 267/281 (95.0%) attended at least one class. The number of classes attended prior to glucose-testing varied from 0 to 24, with median 10. The baseline characteristics of the 557 participants included in the present analysis were similar in the two groups (Table 1). Participants were predominantly white, of European descent. The majority of women in both groups were normal-weight pre-pregnancy. Five participants with pre-pregnancy BMI ≤18.5 kg/m^2 (inclusion failures; 2 intervention and 3 control participants) were included in the normal-weight BMI category for statistical analyses. There was a similar proportion of control and intervention participants from each clinic (p=0.196). Glucose-testing was performed slightly earlier in the intervention group (29.9 vs. 30.1 gestational-weeks, p=0.036), such that gestational length at glucose-testing was included in adjusted analyses.

Table 1: Baseline characteristics of participants

		Intervention (n=281)		Control (n=276)	
		Mean	**SD**	**Mean**	**SD**
Age at trial inclusion (years)		28.0	4.2	28.0	4.5
Gestational age at inclusion (weeks)		15.4	2.7	15.6	2.5
Pre-pregnancy weight (kg)		67.5	11.9	67.3	12.4
Height (cm)		168.7	5.6	168.9	6.7
Pre-pregnancy BMI (kg/m²)		23.7	4.0	23.6	3.8
Inclusion weight (kg)[*]		69.8	12.2	70.1	12.6
Glucose, fasting (mmol/l)		4.43	0.38	4.45	0.40
C-Reactive Protein (mg/l)		4.38	4.26	4.36	4.04
		N	**%**	**N**	**%**
BMI category, pre-pregnancy	Underweight	2	0.7	3	1.1
	Normal-weight	193	68.7	201	72.8
	Overweight	64	22.8	52	18.8
	Obese	22	7.8	20	7.2
Education level[†]	12 years or less	84	30.0	89	32.4
	<4 years of higher education	101	36.1	84	30.5
	≥4 years of higher education	95	35.5	102	37.1
Occupation[‡]	Employed outside the home	230	81.9	239	86.9
	Student	33	11.7	16	5.8
	Unemployed	7	2.5	13	4.7
	Long-term sick leave	6	2.1	4	1.4
	Homemaker	5	1.8	3	1.1
Cohabitation[‡]	Husband/boyfriend/partner	274	97.5	263	95.6
	Other	7	2.5	12	4.4
Household Income (NKR)[§]	≤400,000	89	31.7	84	30.8
	401-700,000	79	28.1	76	27.8
	>700,000	99	35.2	93	34.1
	Refrained from response	14	5.0	20	7.3
Smoking status[‡]	Smoker	8	2.8	13	4.7
	Non-smoker	273	97.2	262	95.3

[*]Weight at inclusion was missing for 8 (2 control and 6 intervention) participants. [†]Education information missing for 1 intervention and 1 control participant. [‡]Information on occupation, cohabitation and smoking missing for 1 control participant. [§]Income information missing for 3 control participants.

The intervention group showed a statistically significant reduction of GWG to term compared to controls, but GWG prior to glucose-testing was not significantly different between intervention and control groups (Table 2). There was no modification of intervention effect on GWG based on pre-pregnancy BMI category.

Table 2: Gestational weight gain, NFFD population

	Intervention (n=281)		Control (n=276)		Intervention effect Unadjusted			Adjusted		
	Mean	*SD*	*Mean*	*SD*	*Mean diff.*	*95% CI*	*p-value*	*Adj. Mean diff.*	*95% CI*	*p-value*
Gestational weight gain to term (kg)										
From pre-pregnancy [*]	14.41	6.26	15.66	5.54	-1.25	-2.28, -0.22	0.017	-1.2	-2.2, -0.2	0.021
From trial inclusion[†]	12.11	5.17	12.99	4.68	-0.89	-1.75, -0.02	0.044	-1.0	-1.8, -0.1	0.025
Gestational weight gain prior to glucose testing (kg)										
From pre-pregnancy[‡]	9.22	4.67	9.86	4.37	-0.64	-0.11, 1.40	0.096	-0.52	-1.28, 0.20	0.170
From trial inclusion[§]	6.96	3.24	7.18	2.96	-0.22	-0.72, 0.30	0.407	-0.24	-0.74, 0.27	0.359

Gestational weight gain analyzed as continuous outcome variables using Student's t-test for unadjusted comparison of intervention and control groups, and multiple regression analysis including age, smoking status, educational level and income at trial inclusion. Analysis of weight gain prior to glucose testing also included gestational length at time of measurement (analysis from pre-pregnancy) or interval between measurements (analysis from trial inclusion).

[*]Gestational weight gain to term missing for 47 participants: 31 who delivered at <37 gestational-weeks (16 intervention, 15 control) and 16 without measured weight at or within 2 weeks of delivery (9 intervention, 7 control). [†]An additional 6 participants were without measured weight at trial inclusion (5 intervention, 1 control). [‡]Weight gain prior to glucose testing missing for 1 participant (intervention) without weight measured at glucose testing. [§]An additional 8 participants were without weight measured at inclusion (6 intervention, 2 control).

The effect of NFFD intervention on biochemical elements of glucose metabolism was assessed for the whole population and for the subgroups of normal-weight (BMI<25, n=399) and overweight/obese participants (BMI≥25 kg/m^2, n=158), see Table 3.

Table 3: Effect of NFFD intervention on glucose regulation

		Intervention (n=281)		Control (n=276)		Intervention effect Unadjusted			Adjusted		
		Mean	*SD*	*Mean*	*SD*	*Mean diff.*	*95% CI*	*p-value*	*Adj. Mean diff.*	*95% CI*	*p-value*
Glucose, fasting (mmol/L)	Whole population	4.66	0.40	4.65	0.34	0.01	-0.05, 0.07	0.724	-0.00	-0.06, 0.06	0.912
	BMI<25 kg/m^2 *	4.56	0.34	4.61	0.32	-0.05	-0.11, 0.02	0.142	-0.04	-0.10, 0.03	0.239
	BMI≥25 kg/m^2 #	4.87	0.45	4.74	0.37	0.13	-0.01, 0.26	0.059	0.11	-0.02, 0.25	0.094
Glucose, 2 hour (mmol/L)	Whole population	6.07	1.34	6.08	1.16	-0.01	-0.22, 0.21	0.964	0.030	-0.18, 0.24	0.776
	BMI<25 kg/m^2	5.84	1.15	6.03	1.09	-0.19	-0.42, 0.03	0.089	-0.16	-0.38, 0.07	0.175
	BMI≥25 kg/m^2	6.59	1.57	6.20	1.32	0.39	-0.07, 0.85	0.099	0.30	-0.18, 0.77	0.217
Insulin (mU/l)	Whole population	11.06	5.54	11.69	6.19	-0.63	-1.62, 0.36	0.210	-0.91	-1.79, -0.02	0.045
	BMI<25 kg/m^2	9.37	4.20	10.28	5.25	-0.91	-1.86, 0.04	0.060	-0.93	-0.03, 1.88	0.056
	BMI≥25 kg/m^2	14.81	6.28	15.62	6.91	-0.80	-2.89, 1.28	0.446	-0.83	-2.97, 1.31	0.468
HOMA-IR‡	Whole population	2.34	1.30	2.45	1.41	-0.11	-0.34, 0.11	0.332	-0.18	-0.38, 0.03	0.089
	BMI<25 kg/m^2	1.92	0.94	2.13	1.35	-0.20	-0.41, 0.01	0.056	-0.21	-0.41, 0.01	0.056
	BMI≥25 kg/m^2	3.25	1.50	3.35	1.70	-0.09	-0.60, 0.41	0.712	-0.11	-0.63, 0.42	0.692
Leptin (pmol/l)	Whole population	2471.1	1254.1	2606.7	1215.1	-135.6	-342.7, 71.5	0.199	-207.8	-383.4, -32.1	0.021
	BMI<25 kg/m^2	2048.0	982.9	2251.7	971.4	-203.7	-398.0, -9.3	0.040	-201.7	-395.4, -7.9	0.041
	BMI≥25 kg/m^2	3415.7	1283.7	3587.9	1286.0	-172.3	-577.7, 233.1	0.403	-256.9	-662.2, 148.4	0.212

Hormone levels and HOMA-IR analyzed as continuous outcome variables using Student's t-test for unadjusted comparison of intervention and control groups, and multiple regression analysis including age, smoking status, educational level and income at trial inclusion, and gestational length at time of testing. *Subpopulation with pre-pregnancy BMI<25 kg/m^2: intervention group n=195, control group n=204. #Subpopulation with pre-pregnancy BMI≥25 kg/m^2: intervention group n=86, control group n=72. ‡HOMA-IR calculated as (insulin x fasting glucose)/22.5.

The NFFD intervention resulted in lower insulin levels for the intervention group vs. the control group (Table 3) and a strong trend toward lower insulin levels among normal-weight women (adj. mean diff. -0.91 mU/l, (95%CI -1.86, 0.04), p=0.056). Normal-weight women also had a trend toward reduced insulin resistance as demonstrated by lower HOMA-IR (adj. mean diff. -0.21, (95%CI -0.041, 0.01), p=0.056). Further, the intervention was associated

with a significant reduction of leptin for both the whole intervention population and the subgroup of normal-weight women. For the smaller subgroup of overweight/obese women, there was no significant reduction in leptin, insulin or HOMA-IR levels as a result of intervention.

The intervention had no effect on glucose levels for the group as a whole, either fasting or two hours after glucose challenge (Table 3). However, analysis showed a significant interaction (effect modification) between pre-pregnancy BMI category and intervention effect on glucose levels at both time points (p=0.030 for fasting glucose, p=0.039 for 2-hour glucose), which is illustrated in Figure 2. Among overweight/obese women, there was a trend toward slightly higher fasting glucose levels for those receiving intervention compared to controls.

As previously reported, there was no significant difference between intervention and control groups in the proportion of glucose values exceeding 2006 WHO thresholds for GDM, which are still in use in Norway. Applying proposed-revised Norwegian thresholds (fasting glucose ≥5.3 mmol/l and/or 2-hour glucose ≥9.0 mmol/l), there was a trend toward a greater proportion of intervention participants with elevated glucose (8.8% vs 4.8%, adj. OR 2.01, 95%CI 0.95, 4.26, p=0.069). Using thresholds recommended by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) (fasting glucose ≥5.1 mmol/l and/or 2-hour glucose ≥8.6 mmol/l), the intervention group had a significantly larger proportion of women with one or more elevated glucose levels compared to the control group (17.4 vs. 10.5%, adj. OR 1.8 (95%CI 1.1, 3.0) p=0.029).

Assessing risk of exceeding IADPSG thresholds showed a significant modification of intervention effect by pre-pregnancy BMI category, stratified as normal-weight and overweight/obese (interaction p=0.048). While the proportion of normal-weight women with glucose levels exceeding IADPSG thresholds was similar in the intervention and control groups (10.3% and 9.3% respectively, adj. OR 1.1 (95%CI 0.6, 2.2) p=0.71), among overweight/obese women there was a significantly larger proportion of intervention participants with elevated glucose levels (33.7% vs. 13.9% for intervention and control group respectively, adj. OR 3.9 (95%CI 1.6, 9.7) p=0.004).

Focusing on overweight/obese women in the intervention group showed that those with glucose levels exceeding IADPSG thresholds had similar GWG prior to testing, both when measured from pre-pregnancy and from trial inclusion, and attended a similar number of exercise classes (median 8 vs. 9 classes, p=0.283) compared to those who had lower glucose levels. There was no association between dietary score or IPAQ score at inclusion and risk of exceeding IADPSG thresholds at gestational-week 30 (p>0.05), for either the intervention or control group. Glucose levels at trial inclusion were strongly associated with exceeding IADPSG thresholds at gestational-week 30 for both intervention and control groups, also after adjusting for pre-pregnancy BMI category, and age, income and educational level (p<0.001). However, overweight/obese intervention participants had increased risk of

exceeding IADPG thresholds also after controlling for glucose levels at inclusion in the adjusted analysis (adj. OR 4.24, p=0.004).

Despite the increased proportion of intervention group women with glucose levels exceeding IADPSG thresholds, the intervention group showed no significant increase in newborn birth-weight or the proportion of large newborns, either for the group as a whole [16] or for the overweight/obese subgroup (Table 4).

Table 4: Neonatal outcomes for overweight/obese NFFD participants

	Intervention (n=86)		Control (n=72)		Intervention effect Unadjusted			Adjusted		
	Mean	*SD*	*Mean*	*SD*	*Mean diff.*	*95% CI*	*p-value*	*Adj. Mean diff.*	*95% CI*	*p-value*
Birth Weight (g)	3485	484	3466	506	19	-134, 172	0.81	-24	-138, 91	0.68
Length at birth (cm)	50.2	2.1	50.0	2.5	0.2	-0.5, 0.9	0.57	-0.2	-0.7, 0.3	0.51
Ponderal index	2.76	0.20	2.77	0.23	-0.01	-0.07, 0.06	0.86	0.01	-0.06, 0.08	0.83
	N	*%*	*N*	*%*	*OR*	*95%CI*	*p-value*	*Adj. OR*	*95%CI*	*p-value*
>4 kg at term	15	18.3	9	13.6	1.41	0.58, 4.48	0.44	1.30	0.46, 3.70	0.61
>4,5 kg at term	0	0	1	1.2	*	*	0.88	*	*	1.00
>10th percentile	4	4.9	3	4.5	*	*	0.95	*1.58*	*0.31, 8.13*	0.58

Unadjusted analysis by Student t-test for continuous values and chi-square for binary outcomes. Adjusted analysis with additional variables of age, educational level, income and smoking status at inclusion, gestational length at delivery and child's sex. *Analysis not performed due to small numbers.

Discussion

Main Findings

Overall, there was little beneficial effect of the NFFD lifestyle intervention on participant glucose levels, although there was a small but significant reduction of insulin and leptin levels. The intervention appeared to have divergent effect on glucose metabolism dependent on participants' pre-pregnancy BMI status. For normal-weight women, the

intervention had a weak positive effect on glucose metabolism, as evidenced by a trend ($p<0.1$) toward reduced insulin and insulin-resistance and significantly lower leptin values, although there was no change in mean glucose levels or the proportion exceeding thresholds for GDM diagnosis. For overweight and obese women this picture was different, with a trend towards higher fasting glucose, but without any change in the other metabolic parameters. The effect of these trends on the prevalence of GDM varied depending on criteria used. When IADPSG thresholds were employed an increase in GDM was observed, whereas when using older WHO criteria there was no difference between groups.

Interpretation

There is little information available to date on the effect of prenatal combined lifestyle interventions on glucose, insulin and leptin levels, as most trials report the effect of intervention on GDM incidence rather than biochemical parameters. The effect of NFFD intervention on the glucose metabolism of normal-weight women is consistent with the findings of Vinter et al, who reported significantly lower insulin and HOMA-IR levels at gestational-week 28-30 following lifestyle intervention, but no significant differences in glucose levels or the incidence of GDM, albeit in an exclusively overweight/obese population [25]. Among non-pregnant individuals, exercise is well documented to improve glycemic control through improved insulin sensitivity [26]. It is plausible that a combination of exercise and diet can lessen insulin resistance, without being of sufficient intensity and/or duration to change plasma glucose levels. In the NFFD intervention group, women attended a median of 10 exercise classes (9 for overweight/obese participants) over a mean of 14 weeks between inclusion and testing, while the intended attendance was twice per week. Although we lack information about total physical activity level during this period of pregnancy, it is reasonable to suppose that greater compliance might have resulted in greater intervention effect.

The temporal sequence of changes in the biochemical and clinical parameters following lifestyle intervention in pregnancy are not well known. In the current study, the reduction of leptin found in the total NFFD intervention group may indicate that adipokines are sensitive to interventions affecting energy metabolism. Leptin is essential in energy regulation and glucose metabolism [27, 28], and is secreted by both maternal adipocytes and placental trophoblasts during pregnancy [15]. Others have found that lower mid-pregnancy leptin levels are associated with reduced insulin resistance [28]. For the child, there is evidence that maternal mid-pregnancy leptin may be an indicator of fetal growth, with lower levels associated with reduced birth weight adjusted for gestational age [29]. Adipokines such as leptin may therefore be particularly sensitive to interventions affecting energy metabolism and may precede changes in glucose levels or clinical endpoints.

The divergent effect of lifestyle intervention on glucose metabolism based on pre-pregnancy BMI has, to our knowledge, not previously been reported. However, earlier trials have

shown that women with higher pre-pregnancy BMI demonstrate resistance to intervention effect. Polley et al. reported that behavioural intervention reduced excessive GWG among normal-weight women, while overweight and obese women had a trend in the opposite direction [30]. Hui et al. [31] and Phelan et al. [32] both reported that a lifestyle intervention performed in a mixed population only reduced GWG among normal-weight women, and Phelan also reported a significant treatment-by-weight interaction for gestational hypertension [32]. The BMI-modified effects of lifestyle intervention have several possible explanations, which may be synergistic. Larger women may differ from normal-weight women in their understanding of and compliance with intervention. Additionally, overweight and obese women may enter trials with a metabolic state that is less sensitive to intervention than that of normal-weight women.

For overweight/obese women participating in the NFFD trial, assignment to exercise classes may have inadvertently discouraged further leisure-time physical activity, particularly among sedentary women. Exercise routines were designed to adjust to varied fitness levels, possibly allowing larger women to limit their exertion. Larger women may also have been intimidated by classes where normal-weight women were in the majority, perhaps explaining why overweight/obese women had lower attendance than normal-weight participants. In addition, NFFD dietary recommendations were not specifically designed to reduce GDM risk and contained no advice on restriction of calories, carbohydrates or fat.

Our finding of an increased proportion of elevated glucose levels among intervention participants compared to controls was unexpected, and its significance is unclear. Reassuringly, we found no increase in large newborns among intervention participants, an outcome that is closely associated with elevated maternal glucose. Several meta-analyses have concluded that combined lifestyle interventions in pregnancy have no effect on risk of GDM, with approximately half of the included trials demonstrating a non-significant increase in risk of GDM using varied criteria [12, 13]. The recently published RADIEL study is one of only two trials, to our knowledge, to report a significant reduction in the incidence of GDM following a combined lifestyle intervention [11, 33]. While results from individual trials must be assessed with caution, comparison may provide some insight. In contrast to the NFFD trial, RADIEL participants were included pre-gestation or in early pregnancy, which may be of critical importance. There is evidence that disposition for GDM is determined prior to pregnancy, with subclinical metabolic dysfunction before conception [14, 34]. RADIEL participants were also presumably highly motivated, as they were included in the trial based on their high-risk status. In contrast, including overweight/obese women with a normal-weight population, as was done in the NFFD trial, may have undermined the potentially greater importance of lifestyle changes for this more high-risk group.

Acknowledging that the effect of intervention may vary significantly among groups and individuals is important in planning future studies. Also important, in the current analysis, the effect of intervention on GDM risk was dependent on the thresholds used. This finding

illustrates the difficulty of assessing trials that employ varying criteria for GDM diagnosis, and suggests that systematic review of individual patient data (IPD analysis) may be more suitable than standard meta-analysis for exploring the effect of prenatal interventions on glucose metabolism and gestational diabetes risk.

Strengths and Limitations

The major strengths of the NFFD trial are its randomized, controlled design and the large size of the population studied, with relatively few missing values. Measured weight at inclusion and at the time of testing make it possible to accurately assess GWG and its association with metabolic findings. A major limitation of the current analysis is that, although examination of the subgroup of overweight/obese women was detailed in the trial protocol, <30% of participants were overweight/obese and the trial was not adequately powered to detect changes in smaller subgroups. Intervention effect of equivalent size may therefore be more easily detectable in the large subgroup of normal-weight women, as in the analysis of leptin. Another limitation is that due to individual randomization, women living in close proximity and attending the same clinic were often in different trial groups; it is possible that control participants were influenced by both intervention participants and clinic personnel who were informed of the purpose of the trial. While cluster randomization of clinics would have reduced such "contamination", it would have introduced within-clinic correlations such as familial/genetic distribution, and likely required larger sample size in order to demonstrate intervention effect [35]. Due to practical and financial constraints, insulin resistance was assessed using HOMA-IR, which has shown significant correlation in pregnancy with the gold standard of the euglycemic insulin clamp [36], although an index incorporating multiple insulin measurements during glucose-testing might more accurately reflect skeletal muscle insulin resistance [37, 38]. Information regarding lifestyle at the time of glucose-testing is not available, limiting our assessment of the impact of diet and physical activity on biochemical results. In addition, lack of information on participants' ethnic background and family history, both of which can affect glucose metabolism, may contribute to residual confounding. Also important, NFFD trial participants were predominantly white, European and highly educated, which may limit the external validity of results.

Conclusion

The findings of the NFFD trial contribute to the growing evidence that GDM is difficult to prevent using combined lifestyle interventions administered during the second and third trimesters of pregnancy. Interventions aimed at a general population may miss the mark, particularly for overweight and obese women. Future research should focus on the efficacy of early intervention, preferably starting pre-pregnancy, and on methods for increasing participant motivation and compliance.

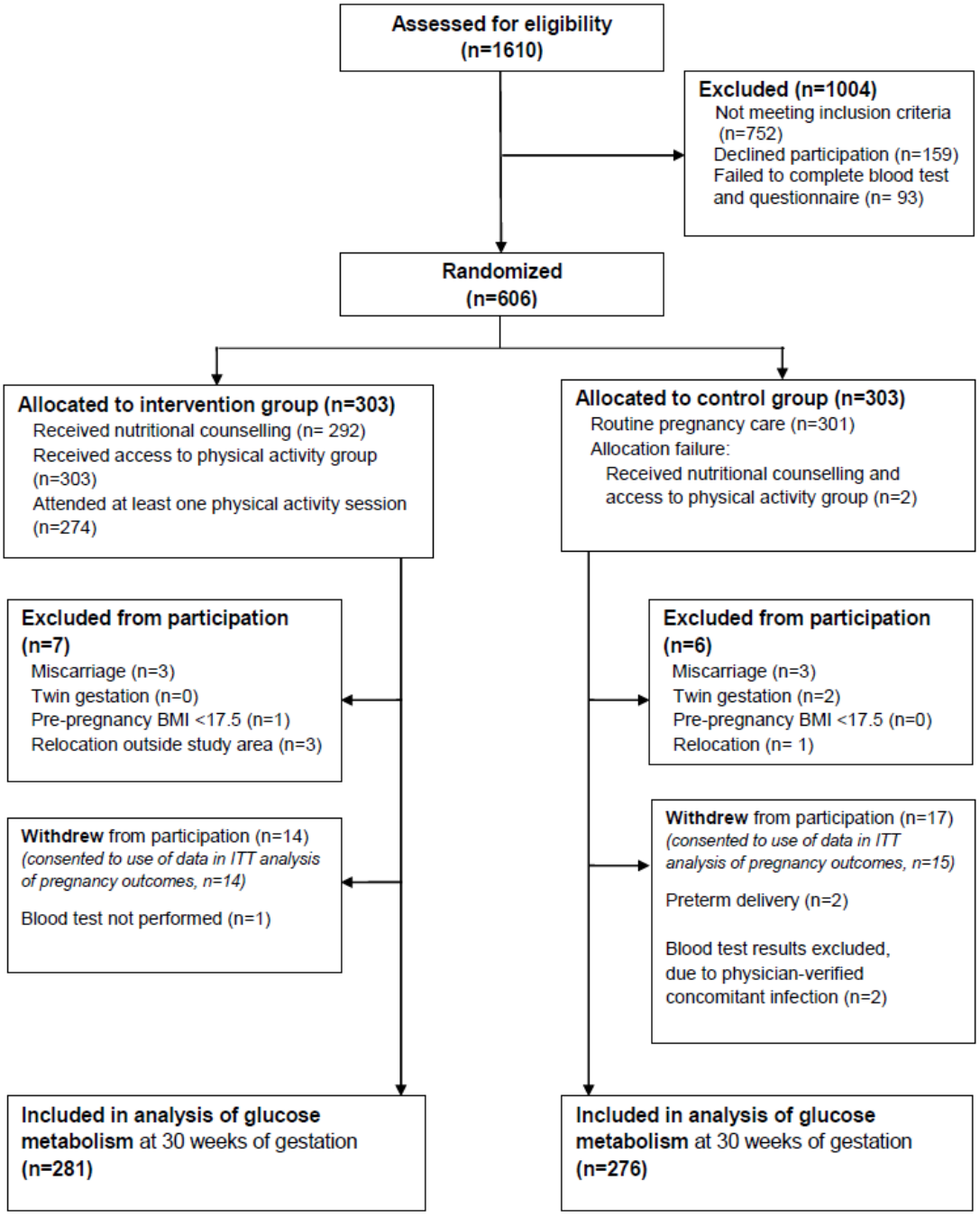

Figure Legend:

Figure 1: Trial profile for analysis of glucose metabolism, Norwegian Fit for Delivery trial Blood tests were collected after fasting and two hours after glucose challenge at 30 weeks of gestation. Of 606 women randomised, 557 (91.9%) provided blood samples for analysis. An ITT analysis of pregnancy outcomes included 591 women, excluding 13 from trial participation as described above and two of 31 who withdrew from trial participation due to lack of consent for use of data.

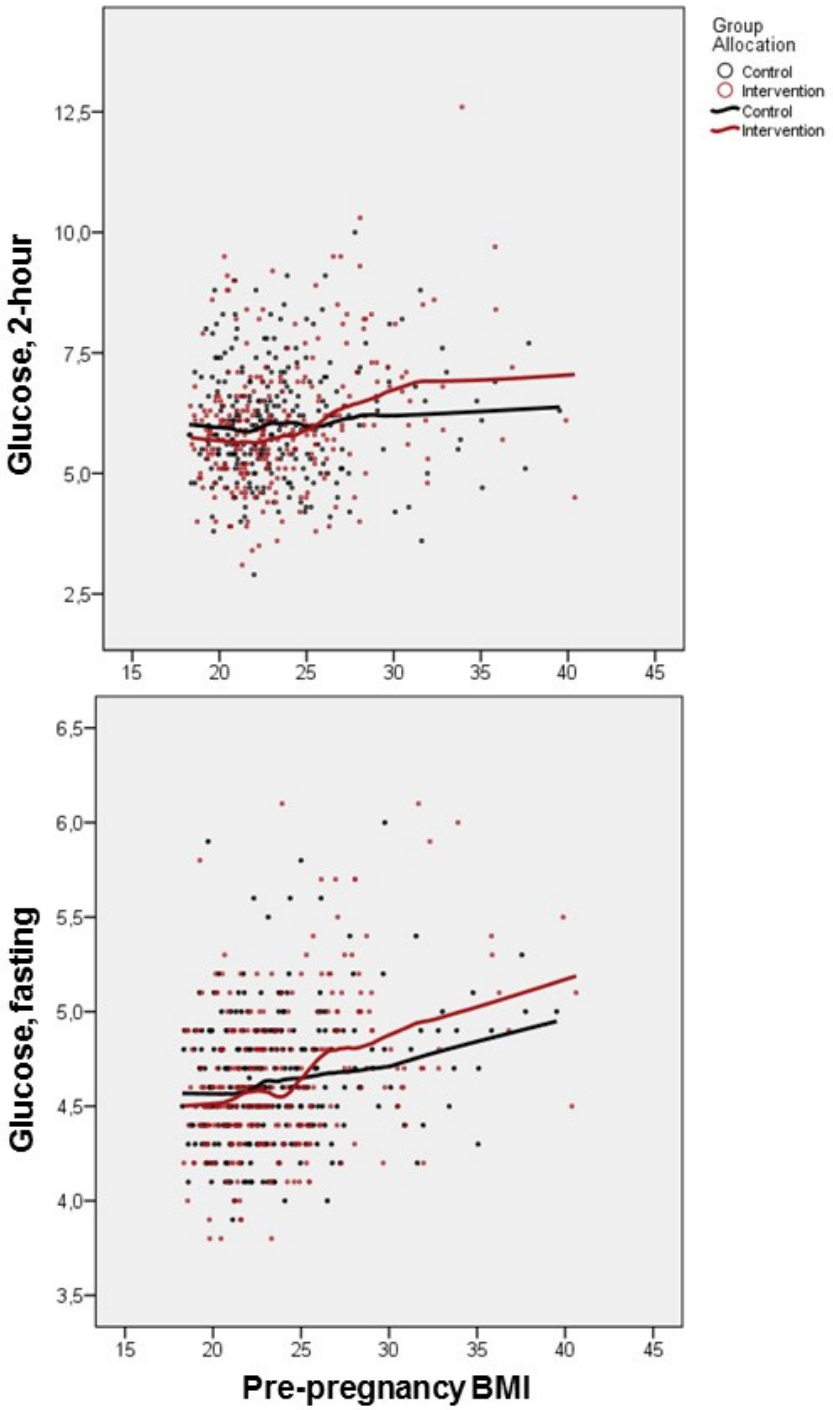

Figure Legend:

Figure 2: Interaction of NFFD intervention and pre-pregnancy BMI on glucose levels measured after fasting and at 2-hours after 75 g glucose load.

List of abbreviations

BMI	Body mass index
GDM	Gestational diabetes mellitus
GWG	Gestational weight gain
HOMA-IR	Homeostatic assessment of insulin resistance
IADPSG	International Association of Diabetes and Pregnancy Study Groups
IOM	Institute of Medicine
IPAQ	International Physical Activity Questionnaire
ITT	Intention to treat
NFFD	Norwegian Fit for Delivery
WHO	World Health Organization

Declarations

Ethics approval and consent to participate
The Norwegian Regional Committee for Medical Research Ethics South-East-C approved the NFFD trial protocol and modifications (REK reference 2009/429). Initial approval December 8, 2008 and July 28, 2009; approval of modification August 23, 2010. All participants provided informed written consent to participation.

Consent for publication
Not applicable.

Availability of data and material
The dataset generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests
LRS received a research grant from the South-Eastern Norway Regional Health Authority in order to perform the NFFD trial. The authors declare that they have no conflict of interests.

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Authors' contributions
LRS and IV conceived the idea for the trial. LRS, NØ, EB, HLS, TH and IV wrote the protocol. NØ, EB, MT, HLS, and ERH supervised the intervention. LRS, ERH, and IV supervised participant follow-up and data collection. LRS and AHP performed the data analysis. The article was written by LRS, with input from all co-authors. All authors read and approved the final version.

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APPENDIX Antenatal trials evaluating gestational weight gain prior to 2009

Author/ Publication Date	Title	Country of origin	Population studied	N	Intervention	GWG Results	Neonatal weight and Postpartum weight retention
Bechtel-Blackwell (1) 2002	Computer assisted self-interview and nutrition education in pregnant teens	USA	Afro-american teenagers, <18 years	46	**Diet** counseling 3 20-minute group sessions	Less GWG in intervention group first trimester, total GWG not reported	Offspring not measured. Less weight retention at 6 weeks postpartum (11.9 vs. 13.9 pounds)
Briley, Flanagan, Lewis (2) 2002	In-home prenatal nutrition intervention increased dietary iron intakes and reduced low birth weight in low-income African-American women	USA	Low-income Afro-American women <24 weeks gestation	27	**Diet** counseling 6 in-home visits	GWG 11.9 kg intervention group, 15.2 kg control group, difference not stat. significant	Significantly higher birth weight of offspring in the intervention group.
Khoury, Henriksen, Christopher-sen, Tonstad (3) 2005	Effect of a cholesterol-lowering diet on maternal, cord, and neonatal lipids, and pregnancy outcome: a randomized clinical trial	Norway	General population, non-smoking, 21-38 years old, 17-20 weeks gestation	290	**Diet** counseling: 4 visits with dietician Control: usual diet	GWG not measured	No difference between groups in birth weight of offspring. Also: reduction in preterm delivery: (0.7% vs. 7.4% for intervention and control groups respectively)
Wolff, Legarth, Vangsgaard, Toubro, Astrup (4) 2008	A randomized trial of the effects of dietary counseling on gestational weight gain and glucose metabolism in obese pregnant women	Denmark	Obese women, 15 weeks gestation	50 (66 en-rolled)	**Diet** counseling 10 1-hour meetings with dietician.	Reduced GWG : 6.6 vs. 13.3 kg for intervention and control group respectively	No sig. difference in birth weight of offspring. Significantly less weight retention at 4 weeks postpartum for intervention group (mean diff 6.9 kg).

Baciuk, Pereira, Cecatti, Braga, Cavalcante (5) 2008	Water aerobics in pregnancy: cardiovascular response, labor, and neonatal outcomes	Brazil	General population, not exercising regularly <20 weeks gestation	70	**Exercise**: 50 min water aerobics 3 times/week	GWG not reported	No sig. difference in birth weight of offspring
Clapp, Kim, Burciu, Lopez (6) 2000	Beginning regular exercise in early pregnancy: effect on fetoplacetal growth	USA	General population, not regularly exercising, 8 weeks gestation	46	Weight bearing **exercise** 3-5 times/week	No difference between groups in GWG: 15.7 vs. 16.6 for intervention and control respectively	Significantly higher birth weight of offspring to women in exercise intervention group (3.7 vs. 3.4 kg)
Clapp, Kim, Burciu, Schmidt, Petry, Lopez (7) 2002	Continuing regular exercise during pregnancy: effect of exercise volume on fetoplacental growth	USA	Women who exercised regularly pre-pregnancy 8 weeks gestation	75	High-and low-volume of **exercise**, switching at 20 gestational weeks : Lo-Hi, Mod-Mod, Hi-Lo. No control group.	Sig lower GWG for the Lo-Hi group (12.0 kg) vs. Mod-Mod (14.6) and Hi-Lo (15.5 kg) groups	Offspring of women assigned to Hi-Lo group were sig. heavier (3.8 vs. 3.4 kg) with higher fat % (8.3 vs. 12.1%)
Garshasbi, Faghih (8) 2005	The effect of exercise on the intensity of low back pain in pregnant women	Iran	General population, 17-22 weeks gestation	212 (266 en-rolled)	**Exercise** groups 3 times/week for 12 weeks Intervention part. excluded if ≥3 sessions missed	No significant difference in GWG	No difference in birth weight of offspring
Marquez-Sterling, Perry, Kaplan, Halberstein, Signorile (9) 2000	Physical and psychological changes with vigorous exercise I sedentary primigravidae	USA	Sedentary women recruited from advertise-ment	20	**Exercise** sessions 3 times/week for 15 weeks	No difference in GWG (16.2 vs. 15.7 kg for exercise and control group respectively)	No significant difference in offspring birth weight (3.5 vs. 3.7 kg for exercise and control group respectively)

Santos, Stein, Fuchs, Duncan, Ribeiro, Kroeff, et al(10) 2005	Aerobic exercise and submaximal functional capacity in overweight pregnant women: a randomized controlled trial	Brazil	Women with BMI 26-31 kg/m2 <20 weeks gestation	72 (92 random-ized)	E**xercise** sessions 3 times per week for 12 weeks Control group with relaxation sessions	No difference in GWG	No difference in birth weight of offspring, or proportion of SGA newborns. No sig. difference in GDM, preeclampsia, cesarean section
Hui, Ludwig, Gardiner, Seven-huysen, Murray, Morris, et al (11) 2006	Community-based exercise and dietary intervention during pregnancy	Canada	General population, <26 weeks gestation	45	**Combined intervention**: Group exercise and home-based exercise with diet counseling	No change in GWG (mean 14.2 kg for both groups)	2/24 vs. 4/21 offspring with birth weight > 4 kg, for intervention and control groups respectively , not stat. significant
Polley, Wing, Sims (12) 2002	Randomized controlled trial to prevent excessive weight gain in pregnant women	USA	General population, low income, <20 gestational weeks	110 (120 random-ized)	**Combined intervention**: Written and oral information on diet and exercise, weight gain graphs	No sig. change in GWG for normal-weight women, but sig decrease % exceeding IOM recommendations. Sig. increase in GWG for overweight women in intervention group.	No difference between groups in birth weight of offspring or proportion defined as LGA or SGA. No difference between groups in pregnancy complications. No difference between groups in weight retention at 8 weeks postpartum.

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NFFD
Brochure

Kost- og treningsråd

for deg som venter

baby

Kjære deltaker i Fit for Fødsel,

Gratulerer med graviditeten!

Vi håper at du og ditt barn får et flott svangerskap og fødsel. Vi vet at det du spiser og hvordan du tar vare på kroppen din i løpet av de neste månedene kan ha stor betydning både for deg og for barnet ditt, også etter fødselen.

Du får mange gode råd hos din fastlege og på helsestasjonen, og vi vil ikke erstatte disse rådene. Helsemyndighetene har også laget nyttig informasjon for gravide. Vi legger derfor med brosjyren "Gravid" fra helsedirektoratet, som vi ønsker at du også leser. Fit for Fødsel rådene som kommer i dette heftet er i samsvar med anbefalingene til helsedirektoratet, bare mer konkrete og rettet mot sunn vektøkning i svangerskap.

Vårt mål er å gi deg ekstra hjelp underveis, når det gjelder å spise sunt og å holde deg i fysisk aktivitet, slik at du er "Fit for Fødsel"!

Hilsen

Fit for Fødsel
-teamet

Fit for Fødsel-teamet presenteres på baksiden av heftet

HVA SKAL DU SPISE?

Vi ønsker at alle deltagere i Fit for fødsel spiser i samsvar med de rådene som helsemyndighetene har gitt. Les mer om dette i den vedlagte brosjyren "Gravid", eller på Helsedirektoratets nettsider: helsedirektoratet.no/gravid. Her finner du nyttig informasjon om blant annet vitaminer og mineraler og mat du bør unngå i svangerskapet.

I tillegg har vi i Fit for Fødsel teamet laget noen konkrete råd som vi tror er spesielt viktige. Disse er ikke vanskelige å følge og gir en stor grad av frihet. Husk at som deltaker i Fit for fødsel trener du flere ganger i uken. Dette gjør at du trenger litt mer mat enn hvis du ikke hadde trent.

For deg som er plaget med kvalme:
I begynnelsen av graviditeten er mange plaget med kvalme og har vanskelig for å få i seg mat og drikke. Et råd som kan hjelpe mot dette er å spise ofte og lite. Noen syns flatbrød, knekkebrød eller lignende er det som er enklest å få i seg, mens andre syns det går greiere med sterkt krydret mat.

Kvalmen går som regel over i uke 12-20. Det er viktig at du får i deg nok drikke. Når du er kommet litt lenger i svangerskapet kan du igjen begynne med regelmessige måltider, og spise mer frukt og grønt.

HVOR MYE SKAL DU LEGGE PÅ DEG?

Alle gravide skal gå opp i vekt. Svangerskap er ikke tiden for å slanke seg. Hvor mange kilo det er best at du legger på deg, avhenger av din KMI (Kropps Masse Indeks) før du ble gravid. Kvinner med KMI før svangerskap mellom 20 og 25 bør legge på seg 11-16 kg. Hvis du har en KMI under 20 før svangerskap bør du legge på deg litt mer. Hvis du har KMI mellom 25 og 30 er det ønskelig at du legger på seg litt mindre (7-11 kg) og hvis du har KMI over 30 er det optimalt å legge på deg omtrent 7 kg.
Se vår nettside for å lære hvordan du regner ut dette, fitforfodsel.no

Dette er tall basert på befolkningen som helhet, dvs at for enkelte vil det være naturlig å legge på seg mer eller mindre enn disse anbefalingene.

Uansett hvor mange kilo du veier er det viktigste at du spiser sunt og er fysisk aktiv – ikke hvor mange kilo du legger på deg under svangerskapet.

HER FØLGER VÅRE 10 KONKRETE RÅD:

1. Spis regelmessige måltider

Personer som spiser regelmessige måltider er sjeldnere overvektige enn de som spiser uregelmessige måltider. Dette kan være fordi de spiser mindre mellom måltidene.

Fit for Fødsel anbefaler at du bør spise regelmessige måltider.

Dette kan være tre - fire hovedmåltider og ev. et eller to mellommåltider i løpet av en dag.

2. Mellommåltid bør bestå av frukt eller grønnsaker

Et mellommåltid er som regel mat som spises uten at det er planlagt og når en må ha energi fort. Forskning viser at mellommåltider ofte er energitette og inneholder mye fett og sukker. Dagens mellommåltider består gjerne av snacks eller bakevarer. Hvis en spiser frukt og grønnsaker når en skal ha et mellommåltid vil en lettere unngå å legge på seg for mye, og det blir enklere å få i seg anbefalt mengde av disse matvarene.

Fit for fødsel anbefaler derfor at hvis du spiser mellom måltidene, så bør dette være frukt og/eller grønnsaker. Ha alltid med en frukt i vesken!

3. Drikk vann

Vann er den beste tørstedrikken. Annen drikke inneholder ofte energi. Man blir mindre mett av energi i form av drikke enn i form av mat, og dermed er sjansen mindre for unødvendig vektøkning hvis en unngår energirik drikke som saft og brus. Melk og juice inneholder mange næringsstoffer og kan være greit å drikke til måltider, men ikke utenom måltider og ikke i store mengder.

Drikke tilsatt kunstige søtningsstoffer anbefales ikke da disse ofte skader tennene, og en kan venne seg til at alt må være søtt.

Å drikke vann er en vanesak. Ha en mugge med vann stående framme hjemme eller på arbeidsplassen. Muggen kan gjerne smaksettes med for eksempel lime eller mynte.

Fit for Fødsel anbefaler at du bør drikke vann når du er tørst.

4. Spis grønnsaker til middag hver dag.
Personer som spiser mye grønnsaker har utsikter til god helse. Grønnsaker inneholder lite energi og er rike på vitaminer og mineraler. Det er svært ønskelig at man øker inntaket av grønnsaker i løpet av en dag. Det er enklest å inkludere grønnsaker i varme måltider, som til middag.

Fit for fødsel anbefaler derfor at du spiser grønnsaker til middag hver eneste dag.

5. Spis snop/snacks kun når du virkelig nyter det.
Snop og snacks inneholder mye energi og få nyttige næringsstoffer. Ofte spiser en snop og snacks litt ureflektert.

Fit for fødsel anbefaler at du kun spiser snacks når du virkelig nyter det.

6. Ikke spis deg overmett.
Det er livsviktig å spise, og en skal spise måltider slik at en blir mett. Fortrinnsvis bør måltidene spises ved et bord, og en bør sette av nok tid til å kunne nyte maten. Mange kaster derimot i seg maten for fort, og spiser seg mettere enn nødvendig, slik at de blir stappmette/overmette. Dette kan føre til at de spiser mer enn de trenger.

Fit for fødsel anbefaler at du ikke spiser deg overmett.

7. Velg små porsjonsstørrelser av usunne ting.
Mange matvarer, deriblant sjokolade og snacks kommer i ulike porsjonsstørrelser. Produsentene reklamerer med at det er økonomisk lurt å kjøpe store porsjoner, men du blir lurt til å spise mer av produkter du bør begrense inntaket av.

Fit for fødsel anbefaler at du velger små porsjonsstørrelser av usunne ting.

8. Begrens inntaket av tilsatt sukker.

Sukker gir bare energi og ingen andre næringsstoffer. Flere studier viser at et høyt inntak av tilsatt sukker, spesielt fra drikke, fører til overvekt. Det meste av sukkeret vi spiser kommer fra brus, saft og snop.

Fit for fødsel anbefaler derfor at du begrenser inntaket av produkter tilsatt mye sukker.

9. Begrens inntaket av salt.

Et høyt inntak av salt er lite gunstig helsemessig. Man regner med at ¾ av saltet vi spiser kommer fra industribearbeidede matvarer. Ved å lage mat fra bunnen av vil man redusere saltinntaket betraktelig. Dessuten blir man tørst av å spise mye salt. Drikker du da energiholdig drikke kan saltet du spiser indirekte føre til at du går opp i vekt!

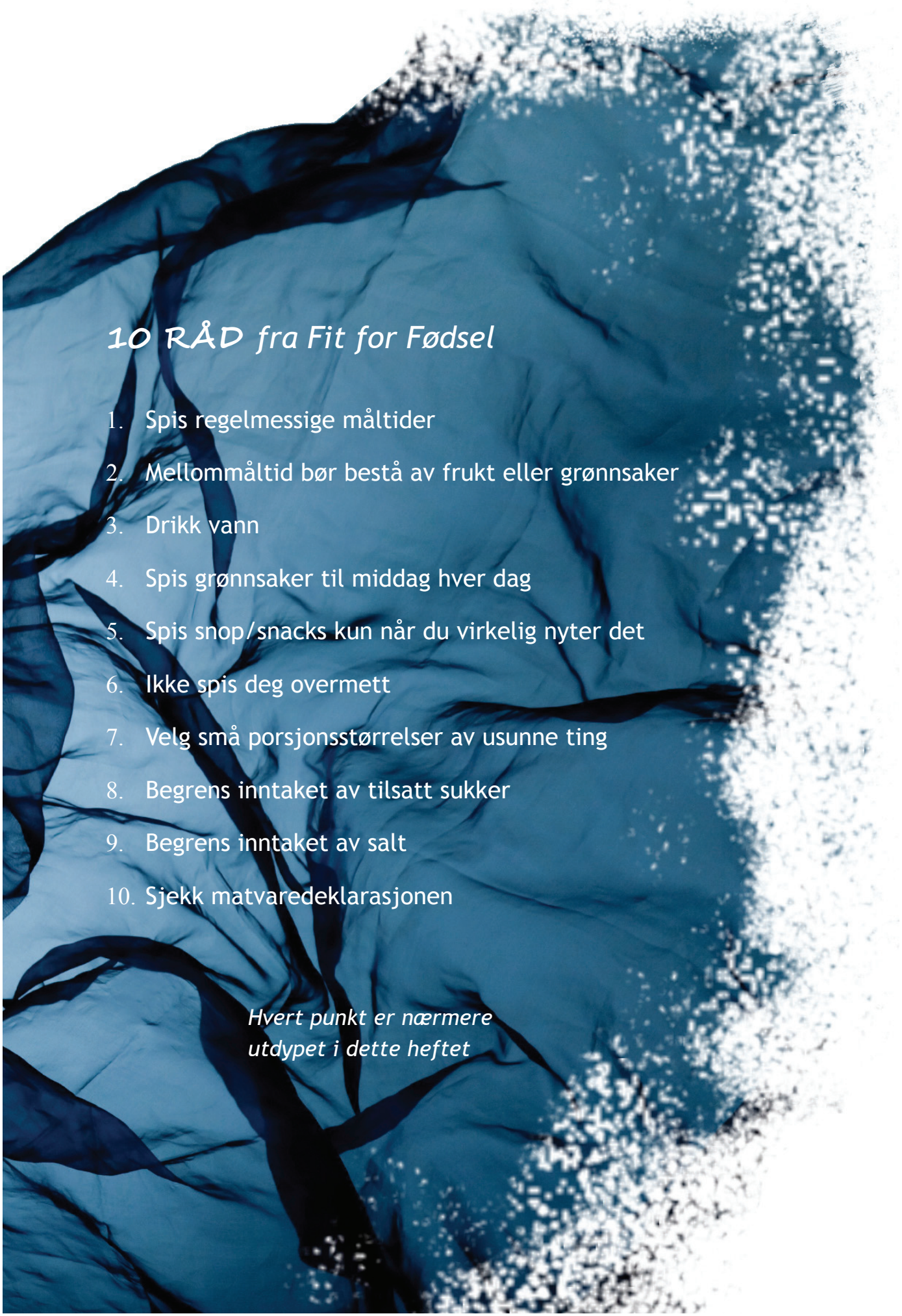
Fit for fødsel anbefaler at du begrenser inntaket av salt.

10. Sjekk matvaredeklarasjonen.

Alle matvarer skal være merket med en liste over ingredienser. Ingrediensene er alltid satt opp i fallende rekkefølge. Dette betyr at den ingrediensen det er mest av, er nevnt først. Dersom for eksempel olje, margarin, smør, salt eller sukker er oppført tidlig på listen, bør du vurdere alternative produkter.

Fit for fødsel anbefaler at du sjekker matvaredeklarasjonen.


Allerede nå
kan du påvirke
barnet ditt



10 RÅD *fra Fit for Fødsel*

1. Spis regelmessige måltider
2. Mellommåltid bør bestå av frukt eller grønnsaker
3. Drikk vann
4. Spis grønnsaker til middag hver dag
5. Spis snop/snacks kun når du virkelig nyter det
6. Ikke spis deg overmett
7. Velg små porsjonsstørrelser av usunne ting
8. Begrens inntaket av tilsatt sukker
9. Begrens inntaket av salt
10. Sjekk matvaredeklarasjonen

Hvert punkt er nærmere utdypet i dette heftet

HVORFOR TRENE?

Kroppen er skapt til å være i bevegelse, også for deg som er frisk og gravid! Trening gir sterke muskler, bedre kondisjon og mer overskudd. For deg som er gravid, gir trening noen ekstra helsegevinster. Sterke muskler i rygg og mage gjør det lettere for deg å bære den voksende magen, og en sterk bekkenbunn beskytter deg mot komplikasjoner etter fødselen. Nyere forskning har til og med vist at kvinner som trener har kortere fødsler! Og babyen får økt blodforsyning mens du er i bevegelse.

Alle Fit for Fødsel treningstimer er i samsvar med rådene til helsedirektoratet. Les mer om dette i den vedlagte brosjyren "Gravid", eller på helsedirektoratets nettsider: helsedirektoratet.no/gravid

For deg som ikke har trent før:

Svangerskap er en ypperlig tid å komme i gang! Og gjennom treningstimene i Fit for Fødsel kan du få opplæring i hvordan du skal utføre øvelser som gir deg en sterkere og mer utholdene kropp. Men vær tålmodig med deg selv—det tar tid å lære nye treningsteknikker. Ikke vær redd for å spørre etter en bedre øvelse for deg, eller erstatte en øvelse med gåing på stedet. Du og babyen nyter likevel godt av bevegelsen!

Ditt mål i begynnelsen skal være deltakelse i to Fit for Fødsel treningstimer i uken, og én ekstra treningsøkt på 15-20 minutter. Det kan være en rask spasertur, eller en kort økt i svømmehallen—du velger selv. Finn noe du synes er gøy, og få gjerne med deg en venn. Etter hvert blir du en "som har trent en del", og kan følge rådene under.

For deg som har trent en del:

Så flott! Det gir et fint grunnlag for å forsette treningen i svangerskapet. Da beholder du den gode formen og de sterke musklene, og kommer deg raskt tilbake til "den gamle kroppen" etter fødselen. Under svangerskapet skal du konsentrere deg ekstra mye om rygg- og bekkenmuskulatur. Du får veiledning til dette under treningstimene i Fit for Fødsel.

Ditt mål er deltakelse på to Fit for Fødsel treningstimer i uken, samt to-tre ekstra treningsøkter hver uke. Bruk helst en halv time hver gang og bli ”passelig sliten”. Se tabellen s 12.

For deg som er topp-trent:

Det er godt å ha deg med! For deg kan utfordringen være å senke intensiteten noe, uten å miste treningsgleden. Det er også viktig for deg å trene rygg- og bekkenmuskulatur, for å møte utfordringene med voksende mage og kommende fødsel.

Ditt mål er å fortsette med treningsmengden som før, men med moderat intensitet. Og selvfølgelig: deltakelse på to Fit for Fødsel treningstimer i uken!

Hva er riktig treningsintensitet i svangerskap?

For å få en helsegevinst, må du kjenne at du trener. Det er ikke farlig å bli sliten under eller etter trening, heller ikke for gravide. Trening med moderat intensitet anbefales for alle friske gravide, og undersøkelser viser at det er trygt for både mor og barn.

Alle gravide kvinner har både høyere puls og raskere pust enn før de ble gravide. Dette er fordi kroppen skal forsyne blod og oksygen (surstoff) til både mor og baby. Det kan derfor være vanskelig å bruke puls som mål for treningsintensitet i svangerskap.

Du kan kjenne etter hvordan du puster under trening. Hvis du trener lett, skal du kunne føre en samtale samtidig. Med litt hardere trening er det vanskelig å prate, men du kan likevel puste med lukket munn. Enda hardere, og du må puste med åpen munn. Du skal helst ikke jobbe hardere enn dette når du er gravid.

Det beste er sannsynligvis å kjenne etter hvor sliten du er under en trening. Se tabellen på neste side; Borgs skala. Du skal holde deg i område 12-14, hvor trening er litt anstrengende, men du bruker ikke alle kreftene for å fortsette.

Her skal du være under en treningsøkt

Trinn	Opplevelse
6	Ikke anstrengende
7	Svært lett
8	
9	Meget lett
10	
11	Ganske lett
12	
13	Litt anstrengende
14	
15	Anstrengende
16	
17	Meget anstrengende
18	
19	Svært anstrengende
20	Maksimal anstrengelse

Borgs skala

Her finner du noen forslag til trening på egenhånd:

- Svømming
- Skigåing
- Dans
- Yoga
- Sykling
- Spinning
- Aerobics
- Trening med lette vekter

Det er noen treningsformer som *ikke* passer for gravide:

- Dykking
- Slalåm, vannski
- Ballspill etter 3. måned (fotball, håndball, tennis)
- Ridning
- Terrengsykling
- Kampsport

Det er ikke farlig å være sliten etter en trening. Det er lurt å spise et lite måltid eller noe frukt ca. en time før trening, slik at du har energi under-veis. Pass på å drikke rikelig med vann, og spis litt rett etter treningsøkten er ferdig. Det er heller ikke farlig å føle seg støl og verke i armer og ben neste dag. Dette er bare et fint bevis på at du har jobbet under treningen.

Avslutt trening i tilfelle

- Vaginalblødning
- Regelmessige sammentrekninger av livmoren
- Lekkasje av fostervann
- Brystsmerter
- Ensidig smerter og hevelse i leggen
- Mer en lett hodepine.

Hvis du blir svimmel under trening, sett deg ned eller legg deg på siden. Ikke legg deg på ryggen, da gravide har dårligere blodforsyning i denne stillingen. Avslutt dagens trening hvis ikke svimmelheten går fort over. Husk at mange kan unngå svimmelhet ved å spise et lett måltid før trening (f. eks. en yoghurt eller en frukt).

DU SKAL ALLTID:

Ta med drikke på trening, og drikke jevnlig i løpet av treningen.
Kle deg i luftig tøy, slik at du unngår å bli veldig varm under treningen.
I kaldt vær kan du kle deg med flere lag, slik at du kan kle av og på deg etter behov.

Benytt deg av forslagene i den grønne boksen eller bruk fantasien og gjør det som stimulerer deg. Og hvis du er i tvil, send en melding til linda.sagedal@sshf.no og spør.

Vi håper at du får en god treningsopplevelse i svangerskapet, og føler deg fit for fødsel!

Egne notater:

Fit for Fødsel
-teamet består av

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Vi håper du får et godt svangerskap og føler deg *Fit for Fødsel!*

fitforfodsel.no

Foto bakside: Lennart Nilsson/Scanpix, layout: gmk.no, trykk: Stav.

NFFD
Questionnaire,
inclusion

Sørlandet sykehus HF

UNIVERSITETET I AGDER

Participant number:

Fit for Delivery

Thank you for choosing to participate in our research study "Fit for Delivery"! We look forward to following you through your pregnancy and first year as a new mother.

Please take about 30 minutes of your time and complete this survey. Read the questions carefully, and answer as best you can. Use black or blue ink, and make an "X" inside the box. Write clearly, where necessary.

The survey can be delivered in an envelope to the midwife or secretary at your healthcare clinic, or mailed to us directly (stamped, addressed envelopes are available at the healthcare clinic). In all cases, your answers will be treated confidentially—your answers can not be traced back to you.

Thank you for your help!

Sincerely,

The Fit for Delivery Team

Date of completion:_____

Some questions about you:

(ver. 090112)

001. **Participant number** (please write clearly):

_____

002. **What is your date of birth?**

_____

003. **How far along are you in your pregnancy?**

_____ weeks

004. **What was your weight immediately before becoming pregnant?**

_____ kg

005. **How tall are you?** (in cm)

_____cm

006. **With whom do you live?**

- ☐ husband/partner/ boyfriend
- ☐ parents
- ☐ friends
- ☐ live alone

007. **If you live with the baby's father, how tall is he?** (in cm)

_____ cm

008. **If you live with the baby's father, what is his weight?**

_____ kg

009. **What is your highest level of education? (Choose one)**

- ☐ Less than 7 years of primary education
- ☐ Primary education, 7-10 years
- ☐ Trade school or 1-2 years of secondary education
- ☐ 3 years of secondary education
- ☐ College/university, Less than 4 years
- ☐ College/university, 4 years or more

010. **What is your primary activity?**

- ☐ Working outside the home
- ☐ Student
- ☐ Unemployed
- ☐ Prolonged sick leave/disabled
- ☐ Homemaker

011. **What was your household's combined income last year**? Include all income from wages, disability payments, social assistance, investment dividends, etc. (in krone)

- ☐ Under 125 000
- ☐ 125 000-200 000
- ☐ 201 000-300 000
- ☐ 301 000-400 000
- ☐ 401 000-550 000
- ☐ 551 000-700 000
- ☐ 701 000 -850 000
- ☐ Over 850 000
- ☐ Do not wish to answer

012. **Have you been on a diet within the last year?**

- ☐ No, my weight is fine
- ☐ No, but I needed to lose weight
- ☐ Yes

013. **Do you smoke?**

- ☐ Never smoked
- ☐ Smoked before I became pregnant, but have stopped completely
- ☐ Smoke 1-4 cigs / day
- ☐ Smoke 5-9 cigs / day
- ☐ Smoke 10-20 cigs / day
- ☐ Smoke > 20 cigs / day

014. **Do you use snuff?**

- ☐ Have never used snuff
- ☐ Used snuff occasionally before I became pregnant, but have stopped completely
- ☐ Used snuff regularly before I became pregnant, but have stopped completely
- ☐ Use snuff occasionally
- ☐ Use snuff daily, about

015. _____ doses per day

016. **Do you use any medication daily?**

- ☐ No
- ☐ Yes

017. **If yes, which? (Name of medication):**

018. **Do you use any vitamins or supplements daily?**

- ☐ No
- ☐ Yes

019. **If yes, which? (name of supplement- iron, folate, etc.):**

020. **Have you ever used any form of drugs/narcotics?**

- ☐ Never tried
- ☐ Used drugs regularly before I became pregnant, but have stopped completely
- ☐ Have tried drugs in the past, but have stopped completely
- ☐ Use drugs occasionally
- ☐ Use drugs on a weekly basis

021. **If yes, which? (name of drug/ narcotic):**

022. **How would you describe your own health? (choose one):**

- ☐ Very good
- ☐ Good
- ☐ Neither good nor bad
- ☐ Poor
- ☐ Very poor

023. **To what extent does your health limit your activities of daily life? (choose one):**

- ☐ To a large extent
- ☐ To some extent
- ☐ Very little
- ☐ Not at all

024. **If you are employed outside the home, have you had more than 1 week of sick leave during the past month ?**

- ☐ Yes
- ☐ No

025. **If yes, how long have you had sick leave?** (choose the answer that fits best):

- ☐ 1-2 weeks, partial sick leave
- ☐ 1-2 weeks, complete sick leave
- ☐ 2-3 weeks, partial sick leave
- ☐ 2-3 weeks, complete sick leave
- ☐ 3-4 weeks, partial sick leave
- ☐ 3-4 weeks, complete sick leave
- ☐ 4+ weeks, partial sick leave
- ☐ 4+ weeks, complete sick leave

Physical activity

We would now like to ask you about the physical activities you do. We are interested in information about different kinds of physical activity that are part of women's daily lives. Please answer all questions, regardless of how active you believe yourself to be. Think of activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time (for recreation, exercise or sport). We ask two sets of questions: We would first like you to tell us about your activities during **the last seven days**. After that, we are interested in your physical situation in **the period right before you became pregnant**.

Think of all **vigorous** physical activities you have performed over the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Include only those activities that last for at least 10 minutes at a time.

026. **During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast biking?**

_____ days

☐ No vigorous physical activities: *Go to question 28.*

→

027. **How much time did you usually spend on one of those days doing vigorous physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think of all **moderate** physical activities you have done over the last 7 days. Moderate physical activities are activities that take moderate physical effort and make you breathe somewhat harder than normal. Include only those activities that last for at least 10 minutes at a time.

028. **During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or light jogging? Do not include walking.**

_____ days

☐ No moderate physical activities: *Go to question 30.*

→

029. **How much time did you usually spend on one of those days doing moderate physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think about the time you have spent walking during the last 7 days. This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

030. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?
_____ days

☐ Didn't walk: *Go to question 32.*

→

031. **How much time in total did you usually spend walking on one of those days?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

The next question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading, traveling on a bus or sitting or lying down to watch television.

032. **During the last 7 days, how much time in total did you usually spend sitting on a week day?**

Answer: _____ hours

We would now like you to think back to the time right before you became pregnant. Try to imagine a typical week during that time. Think of activities you did at work, as part of your house and yard work, to get from place to place, and in your spare time (for recreation, exercise or sport).

Think of all **vigorous** physical activities you performed during a typical week (7 days) right before you became pregnant. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Include only those activities that last for at least 10 minutes at a time.

033. **How many days during a typical week did you do vigorous physical activities like heavy lifting, digging, aerobics or fast biking?**

_____ days

☐ No vigorous physical activities: *Go to question 35.*

→

034. **How much time did you usually spend on one of those days doing vigorous physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think of all **moderate** physical activities you performed during a typical week (7 days) **right before you became pregnant**. Moderate physical activities are activities that take moderate physical effort and make you breathe somewhat harder than normal. Include only those activities that last for at least 10 minutes at a time.

035. **How many days during a typical week did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or light jogging? Do not include walking.**

_____ days

☐ No moderate physical activities: *Go to question 37.*

→

036. **How much time did you usually spend on one of those days doing moderate physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think about the time you have spent **walking** during a typical week (7 days) **right before you became pregnant**. This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

037. **How many days during a typical week did you walk for at least 10 minutes at a time?**

_____ days

☐ Didn't walk: *Go to question 39.*

→

038. **How much time in total did you usually spend walking on one of those days?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

The next question is about the time you spent **sitting** on weekdays during a typical week (7 days) before you became pregnant. Include time you spent sitting while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading, traveling on a bus or sitting or lying down to watch television.

039. **How much time in total did you usually spend sitting on a week day during a typical week?**

Answer: _____ hours

(040-042) **Think further back in time. How often did you do a sport or physical activity that was so intense that you became sweaty and/or breathless when you were:** ***(Make a mark for each age group)?***

	When I was younger than 10:	When I was 10 to 14:	When I was between 15 and 20:
Never	☐	☐	☐
Less than 1 x/month	☐	☐	☐
1-3 x/month	☐	☐	☐
1 /week	☐	☐	☐
2-3 x/week	☐	☐	☐
4-6 x/week	☐	☐	☐
Every day	☐	☐	☐

How do you usually get to work/school?

	Before pregnancy: (043):	Now: (044):
Walk	☐	☐
Bike	☐	☐
Public transportation (bus, train, etc.)	☐	☐
Car	☐	☐
Motorcycle, scooter or moped	☐	☐
Not applicable (not working, going to school)	☐	☐

Below you will find a list of reasons for NOT doing physical activities.
Please mark one or more boxes for the reason(s) that are most important for you:

		Before pregnancy:	Now:
(045/065)	Don't have the time	☐	☐
(046/066)	Can't afford it	☐	☐
(047/067)	Transportation problems	☐	☐
(048/068)	Negative experiences	☐	☐
(049/069)	Problems with mobility	☐	☐
(050/070)	Don't think I can do it	☐	☐
(051/071)	Don't have the energy	☐	☐
(052/072)	Afraid to get hurt (to fall, get a sprain)	☐	☐
(053/073)	Would rather use my time on other things	☐	☐
(054/074)	Because of my physical health	☐	☐
(055/075)	Don't have anyone to do physical activities with me	☐	☐
(056/076)	Schedules don't fit for me	☐	☐
(057/077)	Don't know of anything available to me	☐	☐
(058/078)	Afraid to go out	☐	☐
(059/079)	Nothing available in my area of interest	☐	☐

(060/080)	Because of nausea	☐	☐
(061/081)	Fear of urinary incontinence	☐	☐
(062/082)	Afraid to harm the baby	☐	☐
(063/083)	Pelvic pain	☐	☐

If you have other reasons, please explain:

064. Before pregnancy: _____

085. Now: _____

What do you usually eat?

When you answer these questions, think about what you usually ate and drank before you became pregnant and what you eat and drink now. Consider what you eat at home, at work, and in your spare time. Mark the box that you feel best fits for you. Please answer every question for both before pregnancy and now.

(086-087). **How often did you/do you eat breakfast?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day

(088-089). **How often did you/do you eat lunch?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day

(090-091). **How often did you/do you eat dinner?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day

(092-093). **How often did you/do you eat a late supper (kveldsmat)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day

(094-095). **How often did you/do you eat snacks?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(096-097). **How often did you/do you drink whole milk?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(098-099). **How often did you/do you drink low-fat milk?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(100-101). **How often did you/do you drink skimmed milk?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(102-103). **How often did you/do you drink juice?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(104-105). **How often did you/do you drink fruit nectar?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(106-107). **How often did you/do you drink soda/punch - *with sugar*?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(108-109). **How often did you/do you drink soda/punch—*without sugar*?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(110-111). **How often did you/do you drink beverages that contain alcohol?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(112-113). **How often did you/do you drink tap water?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(114-115). **How often did you/do you drink bottled water (without carbonation or flavor added)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(116-117). **How often did you/do you drink bottled water with carbonation or flavor added?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(118-119). **How often did you/do you drink coffee?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(120-121). **How often did you/do you eat potatoes?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(122-123). **How often did you/do you eat vegetables at dinner?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(124-125). **How often did you/do you eat vegetables on your sandwich?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(126-127). **How often did you/do you eat other vegetables (for example, carrots at lunchtime)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(128-129). **How often did you/do you eat apples, oranges, pears or bananas?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(130-131). **How often did you/do you eat other fruits or berries (fruits or berries other than apples, oranges, pears or bananas)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(132-133). **How often did you/do you eat fruits or vegetables as snacks?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(134-135). **How often did you/do you eat cookies or crackers?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(136-137). **How often did you/do you eat sweet buns (sweet rolls, "boller", etc)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(138-139). **How often did you/do you eat cake, muffins, etc.?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(140-141). **How often did you/do you eat cereal without added sugar?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(142-143). **How often did you/do you eat cereal containing sugar?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(144-145). **How often did you/do you eat plain yogurt (yogurt without added sugar)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(146-147). **How often did you/do you eat yogurt with added sugar?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(148-149). **How often did you/do you eat instant noodles (for example, Mr. Lee)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(150-151). **How often did you/do you eat potato chips/other salty snacks?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(152-153). **How often did you/do you eat chocolate/ other sweets?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(154-155). **How often did you/do you eat hot dogs/ sausages from a gas station or kiosk?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(156-157). **How often did you/do you eat french fries from a fast-food chain?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(158-159). **How often did you/do you add sugar to the food you eat?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(160-161). **How often did you/do you add salt to the food you eat?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(162-163). **How often did you/do you eat industrially processed food for dinner? (freeze-dried instant food, og pre-cooked meals)**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day

(164-165). **How often did you/do you eat so much that you are more than full (feel that you have eaten too much)?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(166-167). **How often did you/do you eat candy, salty snacks or other unhealthy food even if you don't think it tastes very good?**

Before	Now	
☐	☐	Never
☐	☐	Less than once a week
☐	☐	Once a week
☐	☐	Twice a week
☐	☐	3 times a week
☐	☐	4 times a week
☐	☐	5 times a week
☐	☐	6 times a week
☐	☐	Every day
☐	☐	Several times each day

(168-169). **When you buy groceries, how often did you/do you check the ingredient list?**

Before	Now	
☐	☐	Never
☐	☐	Once in a while
☐	☐	Usually
☐	☐	Always

Which size did you/do you usually choose when you buy:

Before you became pregnant:

		Large	Small
(171)	Potato chips	☐ 350g	☐ 150g
(173)	chocolate	☐ ≥80g	☐<80g
(175)	Soda	☐ 1,5l	☐ 0,5l

Now:

		Large	Small
(171)	Potato chips	☐ 350g	☐ 150g
(173)	chocolate	☐ ≥80g	☐<80g
(175)	Soda	☐ 1,5l	☐ 0,5l

In this last section, we would like you to mark what you ate and drank yesterday:

	Yes	No
176. Breakfast	☐	☐
177. Lunch	☐	☐
178. Dinner	☐	☐
179. Late supper	☐	☐
180. Snack	☐	☐
181. Whole milk	☐	☐
182. Low-fat milk	☐	☐
183. Skimmed milk	☐	☐
184. Juice	☐	☐
185. Fruit nectar	☐	☐
186. Soda/punch with sugar	☐	☐
187. Soda/punch without sugar	☐	☐
188. Beverages containing alcohol	☐	☐
189. Tap water	☐	☐
190. Bottled water, plain	☐	☐
191. Bottled water with carbonation or added flavor	☐	☐
192. Potatoes	☐	☐
193. Vegetables at dinner	☐	☐
194. Vegetables on a sandwich	☐	☐
195. Other vegetables (for example, carrots at lunch)	☐	☐
196. Apple, orange, pear or banana	☐	☐
197. Other fruits or berries (other than apple, orange, pear or banana)	☐	☐
198. Sweet buns (sweet rolls, "boller", etc)	☐	☐
199. Cake, muffins, etc.	☐	☐
200. Cereal without added sugar	☐	☐
201. Cereal containing sugar	☐	☐
202. Plain yogurt/yogurt without added sugar	☐	☐
203. Yogurt with added sugar	☐	☐
204. Instant noodles (for example, Mr. Lee)	☐	☐
205. Potato chips/other salty snacks	☐	☐
206. Chocolate/other sweets	☐	☐
207. Hot dog from kiosk/gas station	☐	☐
208. French fries from fast-food chain	☐	☐
209. Industrially processed food, liked freeze-dried or pre-cooked food?	☐	☐
210. Did you add SUGAR to your food yesterday?	☐	☐
211. Did you add SALT to your food yesterday?	☐	☐

Did you buy the following yesterday? (Make a mark for each food item)

	Yes	No
(212) Potato chips	☐	☐
(213) Chocolate	☐	☐
(214) Soda	☐	☐

If you answered "yes", which size did you buy?

	Large	Small
(215) Potato chips	☐	☐
(216) Chocolate	☐	☐
(217) Soda	☐	☐

(218) **Which day of the week was it yesterday?**

☐ Monday
☐ Tuesday
☐ Wednesday
☐ Thursday
☐ Friday
☐ Saturday
☐ Sunday

(219) **Was yesterday a completely normal weekday?**

Yes ☐ No ☐

220. **If not, why not?**

Thank you for your help!

NFFD
Questionnaire,
36 weeks gestation

Sørlandet sykehus HF

UNIVERSITETET I AGDER

Fit for Delivery

Thank you for choosing to participate in our research study “Fit for Delivery”!

Please take about 20-30 minutes of your time and complete this survey. Read the questions carefully, and answer as best you can. Use black or blue ink, and make an “X” inside the box. Write clearly, where necessary.

Please write the date for completion of the survey in the box at the bottom of the page. The survey can then be delivered at the time of your “Fit for Delivery” week 36 examination, or mailed to us directly in a stamped, addressed envelope. In all cases, your answers will be treated confidentially—your answers can not be traced back to you.

Thank you for your help!

Sincerely,

The *Fit for Delivery* team

Date of completion:_____

Some questions about you:

(ver. 090112)

001. **Participant number** (please write clearly):

_____

002. **What is your date of birth?**

_____

003. **How far along are you in your pregnancy?**

_____ weeks

004. **What was your weight immediately before becoming pregnant?**

_____ kg

005. **How tall are you?** (in cm)

_____cm

006. **With whom do you live?**

- ☐ husband/partner/ boyfriend
- ☐ parents
- ☐ friends
- ☐ live alone

007. **If you live with the baby's father, how tall is he?** (in cm)

_____ cm

008. **If you live with the baby's father, what is his weight?**

_____ kg

009. **What is your highest level of education? (Choose one)**

- ☐ Less than 7 years of primary education
- ☐ Primary education, 7-10 years
- ☐ Trade school or 1-2 years of secondary education
- ☐ 3 years of secondary education
- ☐ College/university, Less than 4 years
- ☐ College/university, 4 years or more

010. **What is your primary activity?**

- ☐ Working outside the home
- ☐ Student
- ☐ Unemployed
- ☐ Prolonged sick leave/disabled
- ☐ Homemaker

011. **What was your household's combined income last year**? Include all income from wages, disability payments, social assistance, investment dividends, etc. (in kroner)

- ☐ Under 125 000
- ☐ 125 000-200 000
- ☐ 201 000-300 000
- ☐ 301 000-400 000
- ☐ 401 000-550 000
- ☐ 551 000-700 000
- ☐ 701 000 -850 000
- ☐ Over 850 000
- ☐ Do not wish to answer

012. **Have you been on a diet within the last year?**

- ☐ No, my weight is fine
- ☐ No, but I needed to lose weight
- ☐ Yes

013. **Do you smoke?**

- ☐ Never smoked
- ☐ Smoked before I became pregnant, but have stopped completely
- ☐ Smoke 1-4 cigs / day
- ☐ Smoke 5-9 cigs / day
- ☐ Smoke 10-20 cigs / day
- ☐ Smoke > 20 cigs / day

014. **Do you use snuff?**

- ☐ Have never used snuff
- ☐ Used snuff occasionally before I became pregnant, but have stopped completely
- ☐ Used snuff regularly before I became pregnant, but have stopped completely
- ☐ Use snuff occasionally
- ☐ Use snuff daily, about

015. _____ doses per day

016. **Do you use any medication daily?**

- ☐ No
- ☐ Yes

017. **If yes, which? (Name of medication):**

018. **Do you use any vitamins or supplements daily?**

- ☐ No
- ☐ Yes

019. **If yes, which? (name of supplement- iron, folate, etc.):**

020. **Have you ever used any form of drugs/narcotics?**

- ☐ Never tried
- ☐ Used drugs regularly before I became pregnant, but have stopped completely
- ☐ Have tried drugs in the past, but have stopped completely
- ☐ Use drugs occasionally
- ☐ Use drugs on a weekly basis

021. **If yes, which? (name of drug/ narcotic):**

022. **How would you describe your own health? (choose one):**

- ☐ Very good
- ☐ Good
- ☐ Neither good nor bad
- ☐ Poor
- ☐ Very poor

023. **To what extent does your health limit your activities of daily life? (choose one):**

- ☐ To a large extent
- ☐ To some extent
- ☐ Very little
- ☐ Not at all

024. **If you are employed outside the home, have you had more than 1 week of sick leave during the past month ?**

- ☐ Yes
- ☐ No

025. **If yes, how long have you had sick leave?** (choose the answer that fits best):

- ☐ 1-2 weeks, partial sick leave
- ☐ 1-2 weeks, complete sick leave
- ☐ 2-3 weeks, partial sick leave
- ☐ 2-3 weeks, complete sick leave
- ☐ 3-4 weeks, partial sick leave
- ☐ 3-4 weeks, complete sick leave
- ☐ 4+ weeks, partial sick leave
- ☐ 4+ weeks, complete sick leave

Physical activity

We would now like to ask you about the physical activities you do. We are interested in information about different kinds of physical activity that are part of women's daily lives. Please answer all questions, regardless of how active you believe yourself to be. Think of activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time (for recreation, exercise or sport).

Think of all **vigorous** physical activities you have performed over the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Include only those activities that last for at least 10 minutes at a time.

026. **During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast biking?**

_____ days

☐ No vigorous physical activities: *Go to question 28.*

→

027. **How much time did you usually spend on one of those days doing vigorous physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think of all **moderate** physical activities you have done over the last 7 days. Moderate physical activities are activities that take moderate physical effort and make you breathe somewhat harder than normal. Include only those activities that last for at least 10 minutes at a time.

028. **During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or light jogging? Do not include walking.**

_____ days

☐ No moderate physical activities: *Go to question 30.*

→

029. **How much time did you usually spend on one of those days doing moderate physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think about the time you have spent walking during the last 7 days. This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

030. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?
_____ days

☐ Didn't walk: *Go to question 32.*

→

031. **How much time in total did you usually spend walking on one of those days?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

The next question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading, traveling on a bus or sitting or lying down to watch television.

032. **During the last 7 days, how much time in total did you usually spend sitting on a week day?**

Answer: _____ hours

(040-042) **Think further back in time. How often did you do a sport or physical activity that was so intense that you became sweaty and/or breathless when you were:** ***(Make a mark for each age group)?***

	When I was younger than 10:	**When I was 10 to 14:**	**When I was between 15 and 20:**
Never	☐	☐	☐
Less than 1 x/month	☐	☐	☐
1-3 x/month	☐	☐	☐
1 /week	☐	☐	☐
2-3 x/week	☐	☐	☐
4-6 x/week	☐	☐	☐
Every day	☐	☐	☐

How do you usually get to work/school?:

	(044):
Walk	☐
Bike	☐
Public transportation (bus, train, etc.)	☐
Car	☐
Motorcycle, scooter or moped	☐
Not applicable (not working, going to school)	☐

Below you will find a list of reasons for NOT doing physical activities.
Please mark one or more boxes for the reason(s) that are most important for you:

(065)	Don't have the time	☐
(066)	Can't afford it	☐
(067)	Transportation problems	☐
(068)	Negative experiences	☐
(069)	Problems with mobility	☐
(070)	Don't think I can do it	☐
(071)	Don't have the energy	☐
(072)	Afraid to get hurt (to fall, get a sprain)	☐
(073)	Would rather use my time on other things	☐
(074)	Because of my physical health	☐
(075)	Don't have anyone to do physical activities with me	☐
(076)	Schedules don't fit for me	☐
(077)	Don't know of anything available to me	☐
(078)	Afraid to go out	☐
(079)	Nothing available in my area of interest	☐
(080)	Because of nausea	☐
(081)	Fear of urinary incontinence	☐
(082)	Afraid to harm the baby	☐
(083)	Pelvic pain	☐

If you have other reasons, please explain:

085. _____

What do you usually eat?

When you answer these questions, think about what you usually eat. Consider what you eat at home, at work, and in your spare time. Mark the box that you feel best fits for you.

087. How often do you eat breakfast?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(089). How often do you eat lunch?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(091). How often do you eat dinner?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(093). How often do you eat a late supper (kveldsmat)?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(095). How often do you eat snacks?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(097). How often do you drink whole milk?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(099). How often do you drink low-fat milk?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(101). How often do you drink skimmed milk?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(103). How often do you drink juice?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(105). How often do you drink fruit nectar?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(107). How often do you drink soda/soft drinks - *with sugar*?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(109). How often do you drink soda/soft drinks—*without sugar*?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(111). **How often do you drink beverages that contain alcohol?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(113). **How often do you drink tap water?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(115). **How often do you drink bottled water (without carbonation or flavor added)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(117). **How often do you drink bottled water with carbonation or flavor added?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(119). **How often do you drink coffee?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(121). **How often do you eat potatoes?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(123). **How often do you eat vegetables at dinner?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(125). **How often do you eat vegetables on your sandwich?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(127). **How often do you eat other vegetables (for example, carrots at lunchtime)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(129). **How often do you eat apples, oranges, pears or bananas?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(131). **How often do you eat other fruits or berries (fruits or berries other than apples, oranges, pears or bananas)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(133). **How often do you eat fruits or vegetables as snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(135). **How often do you eat cookies or crackers?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(137). **How often do you eat sweet buns (sweet rolls, "boller", etc)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(139). **How often do you eat cake, muffins, etc.?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(141). **How often do you eat cereal without added sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(143). **How often do you eat cereal containing sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(145). **How often do you eat plain yogurt (yogurt without added sugar)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(147). **How often do you eat yogurt with added sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(149). **How often do you eat instant noodles (for example, Mr. Lee)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(151). **How often do you eat potato chips/other salty snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(153). **How often do you eat chocolate/ other sweets?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(155). **How often do you eat hot dogs/ sausages from a gas station or kiosk?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(157). **How often do you eat french fries from a fast-food chain?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(159). **How often do you add sugar to the food you eat?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(161). **How often do you add salt to the food you eat?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(163). **How often do you eat industrially processed food for dinner? (freeze-dried instant food, or pre-cooked meals)**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(165). **How often do you eat so much that you are more than full (feel that you have eaten too much)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(167). **How often do you eat candy, salty snacks or other unhealthy food even if you don't think it tastes very good?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(169). **When you buy groceries, how often do you check the ingredient list?**

- ☐ Never
- ☐ Once in a while
- ☐ Usually
- ☐ Always

Which size do you usually choose when you buy:

	Large	**Small**
(171) Potato chips	☐ 350g	☐ 150g
(173) chocolate	☐ ≥80g	☐<80g
(175) Soda	☐ 1,5l	☐ 0,5l

In this last section, we would like you to mark what you ate and drank yesterday:

	Yes	No
176. Breakfast	☐	☐
177. Lunch	☐	☐
178. Dinner	☐	☐
179. Late supper	☐	☐
180. Snack	☐	☐
181. Whole milk	☐	☐
182. Low-fat milk	☐	☐
183. Skimmed milk	☐	☐
184. Juice	☐	☐
185. Fruit nectar	☐	☐
186. Soda/punch with sugar	☐	☐
187. Soda/punch without sugar	☐	☐
188. Beverages containing alcohol	☐	☐
189. Tap water	☐	☐
190. Bottled water, plain	☐	☐
191. Bottled water with carbonation or added flavor	☐	☐
192. Potatoes	☐	☐
193. Vegetables at dinner	☐	☐
194. Vegetables on a sandwich	☐	☐
195. Other vegetables (for example, carrots at lunch)	☐	☐
196. Apple, orange, pear or banana	☐	☐
197. Other fruits or berries (other than apple, orange, pear or banana)	☐	☐
198. Sweet buns (sweet rolls, "boller", etc)	☐	☐
199. Cake, muffins, etc.	☐	☐
200. Cereal without added sugar	☐	☐
201. Cereal containing sugar	☐	☐
202. Plain yogurt/yogurt without added sugar	☐	☐
203. Yogurt with added sugar	☐	☐
204. Instant noodles (for example, Mr. Lee)	☐	☐
205. Potato chips/other salty snacks	☐	☐
206. Chocolate/other sweets	☐	☐
207. Hot dog from kiosk/gas station	☐	☐
208. French fries from fast-food chain	☐	☐
209. Industrially processed food, liked freeze-dried or pre-cooked food?	☐	☐
210. Did you add SUGAR to your food yesterday?	☐	☐
211. Did you add SALT to your food yesterday?	☐	☐

Did you buy the following yesterday? (Make a mark for each food item)

	Yes	No
(212) Potato chips	☐	☐
(213) Chocolate	☐	☐
(214) Soda	☐	☐

If you answered "yes", which size did you buy?

	Large	Small
(215) Potato chips	☐	☐
(216) Chocolate	☐	☐
(217) Soda	☐	☐

(218) **Which day of the week was it yesterday?**

☐ Monday
☐ Tuesday
☐ Wednesday
☐ Thursday
☐ Friday
☐ Saturday
☐ Sunday

(219) **Was yesterday a completely normal weekday?**

Yes ☐ No ☐

220. **If not, why not?**

Thank you for your help!

NFFD
Questionnaire,
6 months
postpartum

Sørlandet sykehus HF

UNIVERSITETET I AGDER

Fit for Delivery

Thank you for choosing to participate in our research study "Fit for Delivery". We wish to learn how you are doing now, about 6 months after delivery.

Please take about 20-30 minutes of your time and complete this survey. Read the questions carefully, and answer as best you can. Use black or blue ink, and make an "X" inside the box. Write clearly, where necessary.

Please write the date for completion of the survey in the box at the bottom of the page. The survey can then be delivered to your health care station at the time of your child's 6 month examination, or mailed to us directly in a stamped, addressed envelope. In all cases, your answers will be treated confidentially—your answers can not be traced back to you.

Thank you for your help!

Sincerely,

The *Fit for Delivery* team

Date of completion:_____

001. **Participant number (please write clearly):**

_____

002. **What is your date of birth?**

_____

003. **How many months have gone since your delivery?**

_____ months

004. **What is your primary activity?**

- ☐ Working outside the home
- ☐ Student
- ☐ Unemployed
- ☐ Prolonged sick leave/disabled
- ☐ Homemaker
- ☐ Maternity leave
- ☐ Part-time employment combined with part-time maternity leave

005. **Are you currently breastfeeding?**

- ☐ No
- ☐ Yes, exclusively breastfeeding
- ☐ Yes, breastfeeding in addition to other food

006. **How long did you breastfeed EXCLUSIVELY (the baby did not get anything other than breast milk, with the possible exception of vitamins)?**

- ☐ I never breastfed exclusively
- ☐ _____ weeks
- ☐ _____ months

007. **How long have you breastfed the baby (either exclusively or in addition to formula, porridge, etc.)?**

- ☐ I never breastfed
- ☐ _____ weeks
- ☐ _____ months

We would like to ask you a little about what your child drinks in addition to or instead of breast milk.

008. **How often does your child usually drink formula in addition to or instead of breast milk?**

- ☐ never/less than once a week
- ☐ 1-3 times/week
- ☐ 4-6 times/week
- ☐ once a day
- ☐ twice a day
- ☐ 3 times/day
- ☐ 4 times/day
- ☐ 5 times/day or more

009. **How often does your child usually drink regular milk in addition to or instead of breast milk?**

- ☐ never/less than once a week
- ☐ 1-3 times/week
- ☐ 4-6 times/week
- ☐ once a day
- ☐ twice a day
- ☐ 3 times/day
- ☐ 4 times/day
- ☐ 5 times/day or more

010. **How often does your child usually drink water in addition to or instead of breast milk?**

- ☐ never/less than once a week
- ☐ 1-3 times/week
- ☐ 4-6 times/week
- ☐ once a day
- ☐ twice a day
- ☐ 3 times/day
- ☐ 4 times/day
- ☐ 5 times/day or more

011. **How often does your child usually drink soft drinks/soda in addition to or instead of breast milk?**

- ☐ never/less than once a week
- ☐ 1-3 times/week
- ☐ 4-6 times/week
- ☐ once a day
- ☐ twice a day
- ☐ 3 times/day
- ☐ 4 times/day
- ☐ 5 times/day or more

012. **How often does your child usually drink fruit juice/nectar in addition to or instead of breast milk?**

- ☐ never/less than once a week
- ☐ 1-3 times/week
- ☐ 4-6 times/week
- ☐ once a day
- ☐ twice a day
- ☐ 3 times/day
- ☐ 4 times/day
- ☐ 5 times/day or more

013. **Does your child receive Vitamin D (for example, D vitamin drops or cod liver oil/tran) or other dietary supplements?**

- ☐ Yes
- ☐ No, but the child has received Vitamin D/dietary supplements earlier
- ☐ No, the child has never received Vitamin D/dietary supplements

014. **Do you smoke?**

- ☐ Never smoked
- ☐ Smoked before I became pregnant, but have stopped completely
- ☐ Smoke 1-4 cigs / day
- ☐ Smoke 5-9 cigs / day
- ☐ Smoke 10-20 cigs / day
- ☐ Smoke > 20 cigs / day

015. **Do you use snuff?**

- ☐ Have never used snuff
- ☐ Used snuff occasionally before I became pregnant, but have stopped completely
- ☐ Used snuff regularly before I became pregnant, but have stopped completely
- ☐ Use snuff occasionally
- ☐ Use snuff daily, about

016. _____ doses per day

017. **Do you use any medication daily?**

- ☐ No
- ☐ Yes

018. **If yes, which? (Name of medication):**

_____

_____

019. **Do you use any vitamins or supplements daily?**

- ☐ No
- ☐ Yes

020. **If yes, which (name of supplement- iron, folate, etc.)?**

_____

_____

021. **Have you ever used any form of drugs/narcotics?**

- ☐ Never tried
- ☐ Used drugs regularly before I became pregnant, but have stopped completely
- ☐ Have tried drugs in the past, but have stopped completely
- ☐ Use drugs occasionally
- ☐ Use drugs on a weekly basis

022. **If yes, which? (name of drug/ narcotic):**

_____

_____

023. **How would you describe your own health? (choose one):**

(1)
- ☐ Very good
- ☐ Good
- ☐ Neither good nor bad
- ☐ Poor
- ☐ Very poor

024. **To what extent does your health limit your activities of daily life? (choose one):**

- ☐ To a large extent
- ☐ To some extent
- ☐ Very little
- ☐ Not at all

025. **If you are employed outside the home, have you had more than 1 week of sick leave during the past month ?**

- ☐ Yes
- ☐ No

026. **If yes, how long have you had sick leave? (choose the answer that fits best):**

- ☐ 1-2 weeks, partial sick leave
- ☐ 1-2 weeks, complete sick leave
- ☐ 2-3 weeks, partial sick leave
- ☐ 2-3 weeks, complete sick leave
- ☐ 3-4 weeks, partial sick leave
- ☐ 3-4 weeks, complete sick leave
- ☐ 4+ weeks, partial sick leave
- ☐ 4+ weeks, complete sick leave

Physical activity

We would now like to ask you about the physical activities you do. We are interested in information about different kinds of physical activity that are part of women's daily lives. Please answer all questions, regardless of how active you believe yourself to be. Think of activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time (for recreation, exercise or sport).

Think of all **vigorous** physical activities you have performed over the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Include only those activities that last for at least 10 minutes at a time.

027. **During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast biking?**

_____ days

☐ No vigorous physical activities: *Go to question 29.*

→

028. **How much time did you usually spend on one of those days doing vigorous physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think of all **moderate** physical activities you have done over the last 7 days. Moderate physical activities are activities that take moderate physical effort and make you breathe somewhat harder than normal. Include only those activities that last for at least 10 minutes at a time.

029. **During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or light jogging? Do not include walking.**

_____ days

☐ No moderate physical activities: *Go to question 31.*

→

030. **How much time did you usually spend on one of those days doing moderate physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think about the time you have spent walking during the last 7 days. This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

031. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?
_____ days

☐ Didn't walk: *Go to question 33.*

→

032. **How much time in total did you usually spend walking on one of those days?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

The next question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading, traveling on a bus or sitting or lying down to watch television.

033. **During the last 7 days, how much time in total did you usually spend sitting on a week day?**

Answer: _____ hours

How do you usually get to work/school?

	(044):
Walk	☐
Bike	☐
Public transportation (bus, train, etc.)	☐
Car	☐
Motorcycle, scooter or moped	☐
Not applicable (not working, going to school)	☐

Below you will find a list of reasons for NOT doing physical activities. Please mark one or more boxes for the reason(s) that are most important for you:

(065) Don't have the time	☐
(066) Can't afford it	☐
(067) Transportation problems	☐
(068) Negative experiences	☐
(069) Problems with mobility	☐
(070) Don't think I can do it	☐
(071) Don't have the energy	☐
(072) Afraid to get hurt (to fall, get a sprain)	☐
(073) Would rather use my time on other things	☐
(074) Because of my physical health	☐
(075) Don't have anyone to do physical activities with me	☐
(076) Schedules don't fit for me	☐
(077) Don't know of anything available to me	☐
(078) Afraid to go out	☐
(079) Nothing available in my area of interest	☐
(081) Fear of urinary incontinence	☐
(083) Pelvic pain	☐
(085) Other reasons	☐

If you have other reasons, please explain:

085. _____

_____

What do you usually eat?

When you answer these questions, think about what you usually eat. Consider what you eat at home, at work, and in your spare time. Mark the box that you feel best fits for you.

087. **How often do you eat breakfast?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(089). **How often do you eat lunch?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(091). **How often do you eat dinner?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(093). **How often do you eat a late supper (kveldsmat)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(095). **How often do you eat snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(097). **How often do you drink whole milk?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(099). **How often do you drink low-fat milk?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(101). **How often do you drink skimmed milk?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(103). **How often do you drink juice?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(105). **How often do you drink fruit nectar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(107). **How often do you drink soda/soft drinks - *with sugar*?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(109). **How often do you drink soda/soft drinks—*without sugar*?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(111). **How often do you drink beverages that contain alcohol?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(113). **How often do you drink tap water?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(115). **How often do you drink bottled water (without carbonation or flavor added)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(117). **How often do you drink bottled water with carbonation or flavor added?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(119). **How often do you drink coffee?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(121). **How often do you eat potatoes?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(123). **How often do you eat vegetables at dinner?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(125). **How often do you eat vegetables on your sandwich?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(127). **How often do you eat other vegetables (for example, carrots at lunchtime)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(129). **How often do you eat apples, oranges, pears or bananas?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(131). **How often do you eat other fruits or berries (fruits or berries other than apples, oranges, pears or bananas)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(133). **How often do you eat fruits or vegetables as snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(135). **How often do you eat cookies or crackers?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(137). **How often do you eat sweet buns (sweet rolls, "boller", etc)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(139). **How often do you eat cake, muffins, etc.?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(141). **How often do you eat cereal without added sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(143). **How often do you eat cereal containing sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(145). **How often do you eat plain yogurt (yogurt without added sugar)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(147). **How often do you eat yogurt with added sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(149). **How often do you eat instant noodles (for example, Mr. Lee)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(151). **How often do you eat potato chips/other salty snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(153). **How often do you eat chocolate/ other sweets?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(155). **How often do you eat hot dogs/ sausages from a gas station or kiosk?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(157). **How often do you eat french fries from a fast-food chain?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(159). **How often do you add sugar to the food you eat?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(161). **How often do you add salt to the food you eat?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(163). **How often do you eat industrially processed food for dinner? (freeze-dried instant food, or pre-cooked meals)**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(165). **How often do you eat so much that you are more than full (feel that you have eaten too much)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(167). **How often do you eat candy, salty snacks or other unhealthy food even if you don't think it tastes very good?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(169). **When you buy groceries, how often do you check the ingredient list?**

- ☐ Never
- ☐ Once in a while
- ☐ Usually
- ☐ Always

Which size do you usually choose when you buy:

	Large	**Small**
(171) Potato chips	☐ 350g	☐ 150g
(173) chocolate	☐ ≥80g	☐<80g
(175) Soda	☐ 1,5l	☐ 0,5l

In this last section, we would like you to mark what you ate and drank yesterday:

	Yes	No
176. Breakfast	☐	☐
177. Lunch	☐	☐
178. Dinner	☐	☐
179. Late supper	☐	☐
180. Snack	☐	☐
181. Whole milk	☐	☐
182. Low-fat milk	☐	☐
183. Skimmed milk	☐	☐
184. Juice	☐	☐
185. Fruit nectar	☐	☐
186. Soda/punch with sugar	☐	☐
187. Soda/punch without sugar	☐	☐
188. Beverages containing alcohol	☐	☐
189. Tap water	☐	☐
190. Bottled water, plain	☐	☐
191. Bottled water with carbonation or added flavor	☐	☐
192. Potatoes	☐	☐
193. Vegetables at dinner	☐	☐
194. Vegetables on a sandwich	☐	☐
195. Other vegetables (for example, carrots at lunch)	☐	☐
196. Apple, orange, pear or banana	☐	☐
197. Other fruits or berries (other than apple, orange, pear or banana)	☐	☐
198. Sweet buns (sweet rolls, "boller", etc)	☐	☐
199. Cake, muffins, etc.	☐	☐
200. Cereal without added sugar	☐	☐
201. Cereal containing sugar	☐	☐
202. Plain yogurt/yogurt without added sugar	☐	☐
203. Yogurt with added sugar	☐	☐
204. Instant noodles (for example, Mr. Lee)	☐	☐
205. Potato chips/other salty snacks	☐	☐
206. Chocolate/other sweets	☐	☐
207. Hot dog from kiosk/gas station	☐	☐
208. French fries from fast-food chain	☐	☐
209. Industrially processed food, liked freeze-dried or pre-cooked food?	☐	☐
210. Did you add SUGAR to your food yesterday?	☐	☐
211. Did you add SALT to your food yesterday?	☐	☐

Did you buy the following yesterday? (Make a mark for each food item)

	Yes	No
(212) Potato chips	☐	☐
(213) Chocolate	☐	☐
(214) Soda	☐	☐

If you answered "yes", which size did you buy?

	Large	Small
(215) Potato chips	☐	☐
(216) Chocolate	☐	☐
(217) Soda	☐	☐

(218) **Which day of the week was it yesterday?**

☐ Monday
☐ Tuesday
☐ Wednesday
☐ Thursday
☐ Friday
☐ Saturday
☐ Sunday

(219) **Was yesterday a completely normal weekday?**

Yes ☐ No ☐

220. **If not, why not?**

Thank you for your help!

NFFD
Questionnaire,
12 months
postpartum

Sørlandet sykehus HF

UNIVERSITETET I AGDER

Fit for Delivery

Thank you for choosing to participate in our research study "Fit for Delivery". We wish to learn how you are doing now, about 1 year after delivery.

Please take about 20-30 minutes of your time and complete this survey. Read the questions carefully, and answer as best you can. Use black or blue ink, and make an "X" inside the box. Write clearly, where necessary.

Please write the date for completion of the survey in the box at the bottom of the page. The survey can then be delivered to your health care station at the time of your child's 12 month examination, or mailed to us directly in a stamped, addressed envelope. In all cases, your answers will be treated confidentially—your answers can not be traced back to you.

Thank you for your help!

Sincerely,

The *Fit for Delivery* team

Date of completion:_____

001. **Participant number (please write clearly):**

_____

002. **What is your date of birth?**

_____

003. **How many months have gone since your delivery?**

_____ months

004. **What is your primary activity?**

- ☐ Working outside the home
- ☐ Student
- ☐ Unemployed
- ☐ Prolonged sick leave/disabled
- ☐ Homemaker
- ☐ Maternity leave
- ☐ Part-time employment combined with part-time maternity leave

005. **Are you currently breastfeeding?**

- ☐ No
- ☐ Yes, exclusively breastfeeding
- ☐ Yes, breastfeeding in addition to other food

006. **How long did you breastfeed EXCLUSIVELY (the baby did not get anything other than breast milk, with the possible exception of vitamins)?**

- ☐ I never breastfed exclusively
- ☐ _____ weeks
- ☐ _____ months

007. **How long have you breastfed the baby (either exclusively or in addition to formula, porridge, etc.)?**

- ☐ I never breastfed
- ☐ _____ weeks
- ☐ _____ months

008. **Do you smoke?**

- ☐ Never smoked
- ☐ Smoked before I became pregnant, but have stopped completely
- ☐ Smoke 1-4 cigs / day
- ☐ Smoke 5-9 cigs / day
- ☐ Smoke 10-20 cigs / day
- ☐ Smoke > 20 cigs / day

009. **Do you use snuff?**

- ☐ Have never used snuff
- ☐ Used snuff occasionally before I became pregnant, but have stopped completely
- ☐ Used snuff regularly before I became pregnant, but have stopped completely
- ☐ Use snuff occasionally
- ☐ Use snuff daily, about

010. _____ doses per day

011. **Do you use any medication daily?**

- ☐ No
- ☐ Yes

012. **If yes, which? (Name of medication):**

_____

_____

013. **Do you use any vitamins or supplements daily?**

- ☐ No
- ☐ Yes

014. **If yes, which (name of supplement- iron, folate, etc.)?**

_____

_____

015. **Have you ever used any form of drugs/narcotics?**

- ☐ Never tried
- ☐ Used drugs regularly before I became pregnant, but have stopped completely
- ☐ Have tried drugs in the past, but have stopped completely
- ☐ Use drugs occasionally
- ☐ Use drugs on a weekly basis

016. **If yes, which? (name of drug/ narcotic):**

_____

_____

017. **How would you describe your own health? (choose one):**

- ☐ Very good
- ☐ Good
- ☐ Neither good nor bad
- ☐ Poor
- ☐ Very poor

018. **To what extent does your health limit your activities of daily life? (choose one):**

- ☐ To a large extent
- ☐ To some extent
- ☐ Very little
- ☐ Not at all

019. **If you are employed outside the home, have you had more than 1 week of sick leave during the past month ?**

- ☐ Yes
- ☐ No

020. **If yes, how long have you had sick leave? (choose the answer that fits best):**

- ☐ 1-2 weeks, partial sick leave
- ☐ 1-2 weeks, complete sick leave
- ☐ 2-3 weeks, partial sick leave
- ☐ 2-3 weeks, complete sick leave
- ☐ 3-4 weeks, partial sick leave
- ☐ 3-4 weeks, complete sick leave
- ☐ 4+ weeks, partial sick leave
- ☐ 4+ weeks, complete sick leave

Physical activity

We would now like to ask you about the physical activities you do. We are interested in information about different kinds of physical activity that are part of women's daily lives. Please answer all questions, regardless of how active you believe yourself to be. Think of activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time (for recreation, exercise or sport).

Think of all **vigorous** physical activities you have performed over the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Include only those activities that last for at least 10 minutes at a time.

021. **During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast biking?**

_____ days

☐ No vigorous physical activities: *Go to question 23.*

→

022. **How much time did you usually spend on one of those days doing vigorous physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think of all **moderate** physical activities you have done over the last 7 days. Moderate physical activities are activities that take moderate physical effort and make you breathe somewhat harder than normal. Include only those activities that last for at least 10 minutes at a time.

023. **During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or light jogging? Do not include walking.**

_____ days

☐ No moderate physical activities: *Go to question 25.*

→

024. **How much time did you usually spend on one of those days doing moderate physical activities?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

Think about the time you have spent walking during the last 7 days. This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

025. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?
_____ days

☐ Didn't walk: *Go to question 27.*

→

026. **How much time in total did you usually spend walking on one of those days?**

☐ 0. Don't know
☐ 1. 10 minutes
☐ 2. 20 minutes
☐ 3. 30 minutes
☐ 4. 40 minutes
☐ 5. 50 minutes
☐ 6. 1 hour
☐ 7. 1 hour and 10 minutes
☐ 8. 1 hour and 20 minutes
☐ 9. 1 hour and 30 minutes
☐ 10. 1 hour and 40 minutes
☐ 11. 1 hour and 50 minutes
☐ 12. 2 hours or more

The next question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading, traveling on a bus or sitting or lying down to watch television.

027. **During the last 7 days, how much time in total did you usually spend sitting on a week day?**

Answer: _____ hours

How do you usually get to work/school?

	(044):
Walk	☐
Bike	☐
Public transportation (bus, train, etc.)	☐
Car	☐
Motorcycle, scooter or moped	☐
Not applicable (not working, going to school)	☐

Below you will find a list of reasons for NOT doing physical activities. Please mark one or more boxes for the reason(s) that are most important for you:

(065) Don't have the time	☐
(066) Can't afford it	☐
(067) Transportation problems	☐
(068) Negative experiences	☐
(069) Problems with mobility	☐
(070) Don't think I can do it	☐
(071) Don't have the energy	☐
(072) Afraid to get hurt (to fall, get a sprain)	☐
(073) Would rather use my time on other things	☐
(074) Because of my physical health	☐
(075) Don't have anyone to do physical activities with me	☐
(076) Schedules don't fit for me	☐
(077) Don't know of anything available to me	☐
(078) Afraid to go out	☐
(079) Nothing available in my area of interest	☐
(081) Fear of urinary incontinence	☐
(083) Pelvic pain	☐
(085) Other reasons	☐

If you have other reasons, please explain:

085. _____

_____

What do you usually eat?

When you answer these questions, think about what you usually eat. Consider what you eat at home, at work, and in your spare time. Mark the box that you feel best fits for you.

087. How often do you eat breakfast?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(089). How often do you eat lunch?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(091). How often do you eat dinner?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(093). How often do you eat a late supper (kveldsmat)?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(095). How often do you eat snacks?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(097). How often do you drink whole milk?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(099). How often do you drink low-fat milk?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(101). How often do you drink skimmed milk?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(103). How often do you drink juice?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(105). How often do you drink fruit nectar?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(107). How often do you drink soda/soft drinks - *with sugar*?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(109). How often do you drink soda/soft drinks—*without sugar*?

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(111). **How often do you drink beverages that contain alcohol?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(113). **How often do you drink tap water?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(115). **How often do you drink bottled water (without carbonation or flavor added)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(117). **How often do you drink bottled water with carbonation or flavor added?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(119). **How often do you drink coffee?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(121). **How often do you eat potatoes?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(123). **How often do you eat vegetables at dinner?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(125). **How often do you eat vegetables on your sandwich?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(127). **How often do you eat other vegetables (for example, carrots at lunchtime)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(129). **How often do you eat apples, oranges, pears or bananas?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(131). **How often do you eat other fruits or berries (fruits or berries other than apples, oranges, pears or bananas)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(133). **How often do you eat fruits or vegetables as snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(135). **How often do you eat cookies or crackers?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(137). **How often do you eat sweet buns (sweet rolls, "boller", etc)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(139). **How often do you eat cake, muffins, etc.?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(141). **How often do you eat cereal without added sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(143). **How often do you eat cereal containing sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(145). **How often do you eat plain yogurt (yogurt without added sugar)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(147). **How often do you eat yogurt with added sugar?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(149). **How often do you eat instant noodles (for example, Mr. Lee)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(151). **How often do you eat potato chips/other salty snacks?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(153). **How often do you eat chocolate/ other sweets?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(155). **How often do you eat hot dogs/ sausages from a gas station or kiosk?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(157). **How often do you eat french fries from a fast-food chain?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(159). **How often do you add sugar to the food you eat?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(161). **How often do you add salt to the food you eat?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(163). **How often do you eat industrially processed food for dinner? (freeze-dried instant food, or pre-cooked meals)**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day

(165). **How often do you eat so much that you are more than full (feel that you have eaten too much)?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(167). **How often do you eat candy, salty snacks or other unhealthy food even if you don't think it tastes very good?**

- ☐ Never
- ☐ Less than once a week
- ☐ Once a week
- ☐ Twice a week
- ☐ 3 times a week
- ☐ 4 times a week
- ☐ 5 times a week
- ☐ 6 times a week
- ☐ Every day
- ☐ Several times each day

(169). **When you buy groceries, how often do you check the ingredient list?**

- ☐ Never
- ☐ Once in a while
- ☐ Usually
- ☐ Always

Which size do you usually choose when you buy:

	Large	**Small**
(171) Potato chips	☐ 350g	☐ 150g
(173) chocolate	☐ ≥80g	☐<80g
(175) Soda	☐ 1,5l	☐ 0,5l

In this last section, we would like you to mark what you ate and drank yesterday:

	Yes	No
176. Breakfast	☐	☐
177. Lunch	☐	☐
178. Dinner	☐	☐
179. Late supper	☐	☐
180. Snack	☐	☐
181. Whole milk	☐	☐
182. Low-fat milk	☐	☐
183. Skimmed milk	☐	☐
184. Juice	☐	☐
185. Fruit nectar	☐	☐
186. Soda/punch with sugar	☐	☐
187. Soda/punch without sugar	☐	☐
188. Beverages containing alcohol	☐	☐
189. Tap water	☐	☐
190. Bottled water, plain	☐	☐
191. Bottled water with carbonation or added flavor	☐	☐
192. Potatoes	☐	☐
193. Vegetables at dinner	☐	☐
194. Vegetables on a sandwich	☐	☐
195. Other vegetables (for example, carrots at lunch)	☐	☐
196. Apple, orange, pear or banana	☐	☐
197. Other fruits or berries (other than apple, orange, pear or banana)	☐	☐
198. Sweet buns (sweet rolls, "boller", etc)	☐	☐
199. Cake, muffins, etc.	☐	☐
200. Cereal without added sugar	☐	☐
201. Cereal containing sugar	☐	☐
202. Plain yogurt/yogurt without added sugar	☐	☐
203. Yogurt with added sugar	☐	☐
204. Instant noodles (for example, Mr. Lee)	☐	☐
205. Potato chips/other salty snacks	☐	☐
206. Chocolate/other sweets	☐	☐
207. Hot dog from kiosk/gas station	☐	☐
208. French fries from fast-food chain	☐	☐
209. Industrially processed food, liked freeze-dried or pre-cooked food?	☐	☐
210. Did you add SUGAR to your food yesterday?	☐	☐
211. Did you add SALT to your food yesterday?	☐	☐

Did you buy the following yesterday? (Make a mark for each food item)

	Yes	No
(212) Potato chips	☐	☐
(213) Chocolate	☐	☐
(214) Soda	☐	☐

If you answered "yes", which size did you buy?

	Large	Small
(215) Potato chips	☐	☐
(216) Chocolate	☐	☐
(217) Soda	☐	☐

(218) **Which day of the week was it yesterday?**

☐ Monday
☐ Tuesday
☐ Wednesday
☐ Thursday
☐ Friday
☐ Saturday
☐ Sunday

(219) **Was yesterday a completely normal weekday?**

Yes ☐ No ☐

220. **If not, why not?**

Thank you for your help!