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Physical activity and weight gain during pregnancy

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Lene Annette Hagen Haakstad

Summary

Background:

Studies in the general adult population demonstrate that physical activity (PA) and exercise are important to enhance weight loss and prevent weight regain. However, the effect of exercise during pregnancy on maternal weight gain is still unclear. Until the early 1980s, PA during pregnancy was discouraged primarily due to the possible risks of adverse fetal and maternal outcomes. However, results from epidemiological and clinical studies have not demonstrated risks with light and moderate exercise activities. The American College of Obstetrics and Gynecology (ACOG) published the first guidelines for exercise during pregnancy in 1985. Since then, the body of research has increased and new guidelines were issued in 1994 and in 2002. Today, the ACOG recommends that healthy, pregnant women should engage in at least 30 minutes of moderate exercise on most, and preferably all, days of the week. Moderate intensity exercise may be described by perceived exertion and ratings of 12-14 on Borg's conventional 15 point scale, equivalent to brisk walking. Both in Norway and worldwide, there is scant knowledge about PA level and exercise during pregnancy. Only a small number of studies have described the intensity, frequency, duration and exercise-mode, and possible determinants for exercise in pregnant women. In addition, few studies have aimed at preventing excessive maternal weight gain. There is a need of high quality RCTs in this area.

Aims:

The aims of the present dissertation were: 1) to assess total PA level (at work, commuting, housework and recreational exercise) in pregnant women, 2) to report pregnant women's reasons for performing or not performing regular exercise, 3) to compare self-reported PA and exercise level with data from a motion monitor (ActiReg®, PreMed AS, Oslo, Norway) and 4) to assess whether a 12-week exercise program including 60 minutes of supervised aerobic dance performed at least 2 times per week, and advice on 30 minutes of moderate self-imposed PA on the other days could prevent excessive maternal weight gain and postpartum weight retention.

Methods:

The study was conducted in three phases. Part I) 467 healthy, pregnant women answered a cross sectional survey, Physical Activity and Pregnancy Questionnaire (PAPQ), to assess total PA level and to identify the most frequently reported motives and barriers regarding exercise participation. Part II) a prospective comparison study among 77 pregnant women using the PAPQ and the ActiReg system. Part III) an assessor blinded randomized controlled trial (RCT) where 105

sedentary, primiparous women were randomized to either an exercise group (EG, n=52) or a control group (CG, n=53).

Main results:
A low level of daily PA and regular recreational exercise was shown in the present study of pregnant women in Oslo. There was a decline in exercise intensity, duration and frequency from before pregnancy and throughout the course of pregnancy. Walking was the most common exercise mode. The results of the multivariate analysis showed that women who decreased regular exercise in the 3rd trimester had higher weight gain and reported to have no social role models with respect to exercise behaviour during childhood. Pre-pregnancy physical inactivity was the strongest predictor of decreased maternal exercise in the 3rd trimester. There was no difference between exercisers and non-exercisers with respect to pre-pregnancy body mass index (BMI) and commonly reported pregnancy complaints such as pelvic girdle pain (PGP) and urinary incontinence. Comparison of the PAPQ and the ActiReg indicated only small differences between the two methods in cross-tabulation of total PA level and proportion of participants meeting the current exercise guidelines. The Bland-Altman plot of the activity patterns showed a mean difference near zero with no apparent trends and with a wide scatter of individual observations. Drop-out rates of the present RCT were 19.2% and 20.8% in the EG and CG, respectively. Only women attending regularly to the prescribed exercise program significantly reduced maternal weight gain. No women attending 24 exercise sessions exceeded the IOM recommendations. Weight retention 6-8 weeks postpartum was also significantly lower in women attending 24 exercise classes.

Key Words: adherence, determinants, exercise, PA level, portable activity monitor, pregnancy, pre-pregnancy BMI, RCT, self-reported PA, weight gain

List of papers

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

I. Haakstad LA, Voldner N, Henriksen T, Bø K. *Physical activity level and weight gain in a cohort of pregnant Norwegian women.* Acta Obstet Gynecol Scand. 2007; 86: 559-564.

II. Haakstad LA, Voldner N, Henriksen T, Bø K. *Why do pregnant women stop exercising in the 3rd trimester?* Acta Obstet Gynecol Scand. 2009;88: 1267-1275.

III. Haakstad LA, Gundersen I, Bø K. *Self report versus motion monitor in measurement of physical activity during pregnancy*. In press Acta Obstet Gynecol Scand.

IV. Haakstad LA, Bø K. *Effect of regular exercise in prevention of excessive weight gain in pregnancy*. Submitted to International Journal of Behavioral Nutrition and Physical Activity.

Abbreviations

ACOG	American College of Obstetrics and Gynecology
BMI	Body Mass Index
CI	Confidence Interval
CG	Control Group
EG	Exercise Group
IOM	Institute Of Medicine
ITT	Intention To Treat
LGA	Large for Gestational Age
LTPA	Leisure Time Physical Activity
MET	Metabolic Equivalent of Task
OR	Odds Ratios
PA	Physical Activity
PAL	Physical Activity Level
PAPQ	Physical Activity and Pregnancy Questionnaire
PAR	Physical Activity Rate
PGP	Pelvic Girdle Pain
RCT	Randomized Controlled Trial
SD	Standard Deviation
SGA	Small for Gestational Age
WHO	World Health Organization

STORK: Is not an abbreviation, but a bird (Ciconia ciconia). In the fairy-tale of HC Anderssen, the STORK brings the baby. The Norwegian project title for STORK is: Maternelt ”metabolsk syndrom”, store barn og svangerskapskomplikasjoner.

Contents

Introduction

Adults who are physically active at a sufficient level may benefit from a reduced risk of common chronic diseases compared to those who are inactive [1-5]. However, PA during pregnancy has previously been discouraged. The reasons given were mainly safety precautions and the theoretical possibility of competition between the fetus and skeletal muscles for oxygenated blood flow (leading to fetal hypoxia) and essential substrates (leading to fetal growth restrictions) [6]. Worry was also expressed that exercise might lead to fetal hyperthermia with potential teratogenic effects [6] and miscarriage [7]. To date, reports point to favourable physiological and health benefits associated with regular exercise of moderate intensity during pregnancy. The effects of intervention studies are an enhanced feeling of wellbeing [8], improved self-image [9] and fitness [8], prevention of low back pain [10;11], PGP [12] and urinary incontinence [13], as well as decreased risk of pregnancy depression [9]. Some observational studies have also reported prevention of gestational diabetes [14;15], preeclampsia [16;17], shorter labor in women who started labor spontaneously [18;19], fewer birth complications [18;20] and fewer caesarean sections [21].

Provided that pregnancy is normal and healthy, the current American College of Obstetrics and Gynecology (ACOG) guidelines promote continuation of pre-pregnancy exercise activities and recommend that sedentary women start exercising during pregnancy [22]. According to the present guidelines, all pregnant woman are encouraged to be physically active for at least 30 minutes on most days of the week and /or exercise moderately for a minimum of 15 minutes, 3-5 times a week [6;22], in the absence of medical or obstetrical contraindications (Table 1) [22;23]. However, the optimal dose for recreational PA during pregnancy remains to be determined, and the impact of prolonged and repeated aerobic exercise on clinical outcome for mother and infant is unknown [24;25]. A systematic review has associated physically demanding work with increased risk of premature birth [26], whereas increased risk of early spontaneous abortion has been reported with > 7 h/wk of high impact exercise [7].

Table 1 Guidelines for exercise during pregnancy after thorough clinical evaluation excluding other significant medical conditions associated with non-exercising[22;23]

Absolute Contraindications to Exercise	**Relative Contraindications to Exercise**
Incompetent cervix	Intrauterine growth restriction
Multiple gestation	Previous spontaneous abortion
Persistent 2nd or 3rd trimester bleeding	Severe anemia
Placenta previa after 26 weeks of gestation	Poorly controlled diabetes type 1 or hypertension
Risk for premature labour or a history of premature labor	Poorly controlled seizure disorder or hyperthyroidism
Rupture of membranes	Extreme morbid obesity or underweight (BMI<12)
Pre-eclampsia or pregnancy induced hypertension	History of extreme sedentary lifestyle or heavy smoker

In Norway there is scant knowledge about weight gain and level of PA and exercise during pregnancy. Studies from other countries have shown that PA during pregnancy differs widely, but generally in studies from other countries, there is a decline in exercise frequency before and throughout the course of pregnancy [27-29]. Hence, pregnant women may have a great potential to increase PA and reduce the risk of inactivity related complications and illness for both mother and fetus. In addition, pregnancy is often considered an ideal time for behaviour modification [30;31]. Antenatal care is a common routine health care activity, with pregnant women advised to attend between 5-8 visits throughout pregnancy [32]. Consequently, health care providers are in the position to encourage pregnant women to enrol in a structured exercise program that may also help to promote long-term PA habits. To understand why pregnant women reduce or stop exercising and further promote exercise participation, knowledge about their reasons for performing or not performing regular exercise is important.

RCTs generally support PA and exercise as means to prevent overweight /obesity and enhance weight loss in the general adult population [33;34]. However, the effect of exercise during pregnancy on maternal weight gain is still unclear. A recent Cochrane review found no difference in maternal weight gain between exercisers and non-exercisers [24]. This is in agreement with the systematic reviews of Siega-Riz et al [35] and Birdsall [36], all concluding that few studies have examined exercise as a determinant of maternal weight gain and emphasizing the need for high quality RCTs in this area. The authors list limitations of the previous trials to be small sample sizes, lack of randomization, high drop-out rates and no blinding of assessors. Hence, more knowledge about the effect of exercise interventions to prevent excessive weight gain is warranted.

Review of the literature

Pregnancy and childbirth statistics

In Norway, birth rates are now increasing again, following a steady decline for nearly a decade. According to statistics from the Norwegian Institute of Public Health (NIPH), 60 881 babies were born in Norway in 2008; about 17% in the city of Oslo. The distribution of boys and girls is quite stable, with about 51% of all newborns being boys and 49% girls. The birth rate for twins or triplets has somewhat declined, and in Norway less than 1.8% of all pregnancies now result in multiple births. The proportion of women undergoing In Vitro Fertilisation (IVF) has rapidly increased from only five babies born in 1984 to 1719 babies in 2008.

Since 1967, mean birth weight has gradually increased with a peak in 2000. This may be explained by better health status among women and fewer daily smokers [37]. To date, mean birth weight is 3 475 g with a SD of 631 g (NIPH 2008). This is almost 60 grams lower than the years 1997 to 2002. Similarly, a smaller number of newborn are weighing ≥ 4000 g and fewer are defined as high birth weight babies (≥ 4500), with a reduction from 21.9% in 2000 to 17.5% in 2008 and 4.7% in 2000 to 3.2% in 2008, respectively.

Of 60 881 births, 37.5% had one or more instrumental interventions, with 17.1 %, 7.9% and 1.4% caesarean, vacuum and forceps deliveries, respectively (NIPH 2008).

Since 1970, the mean age for women having their first baby has increased by five years. Mean age in Norway in 2008 was 28 (SD 5.1) years and 30.1 (SD 4.6) years in the city of Oslo. In addition, birth rates for women 35 to 39 years (16.2%) and 40 to 44 years (2.8%) were the highest ever registered. The birth rate for teenagers in Norway continues to decrease. In 2008, 2.5% of babies were born to mothers aged 15- 19 years compared to 10.2% in 1970.

In 2008, preterm birth rates (less than 37 weeks) and the number of low birth weight babies (less than 2.5 kilos) remained at 5-6%.

Fewer women are daily smokers during pregnancy. In 2008, 15.9% were smoking at the start and 7.6% at the end of pregnancy, compared to the year 2000 when 21.3% and 15% were registered as daily smokers, respectively.

Gestational diabetes is formally defined as "any degree of glucose intolerance with onset or first recognition during pregnancy". In 2008, 12.6 per 1000 women in Norway had the diagnosis. The

rates for pregnancy induced hypertension and pre-eclampsia were 20.3 and 33.7 per 1000 women, respectively.

Until 1995 antenatal care in Norway was provided solely by general practitioners. Today each municipality offers antenatal care for its residents by midwives in community health centers [38]. However, many women still visit their doctor, and the new antenatal care system may have led to an increase in the number of antenatal visits. Backe [39] found that the mean number of antenatal visits was 12.0, which is substantially higher than the guidelines [32]. The difference between primiparous (mean 12.4) and multiparous women (mean 11.7) was minor. Midwives provided 44% and doctors 56% of the antenatal visits. Only three of the 1 780 women (0.2%) delivered without any previous antenatal care [39]. Hence, the Norwegian antenatal healthcare system reaches almost 100% of pregnant women. The antenatal and delivery care is free of charge.

Definitions

Physical activity

PA has shown to be a significant and independent factor with respect to health and functional status [40-42], and the Leading Health Indicators from Healthy People 2010, recommend that increasing PA is one of the greatest priorities for enhancing women's health [43]. In the literature PA has been defined as "any bodily movement produced by contraction of skeletal muscles that results in a substantial increase in energy expenditure" [41]. Hence, PA comprises occupational work and associated active commuting (e.g. walking, bicycling), exercise and other everyday physical activities during leisure time. Leisure time physical activity (LTPA) is any activity performed in a person's discretionary time, and it is chosen on the basis of individual interests and needs [41]. Exercise and/or training is a component of LTPA and has been defined as "repetitive, planned and structured bouts of PA, conducted over a period of weeks or months, with the intention of improvement or maintenance of one or more components of physiological and/or physical fitness" [44]. Despite the genetic component [45], physical fitness is, to some extent, a physiological indicator of PA behaviour, defined as a set of attributes that individuals achieve relating to the ability to perform PA. Physical fitness can be related to both health and performance, and acknowledged markers of physical fitness include cardio-respiratory endurance (maximal oxygen uptake, $V0_2max$), muscular strength, flexibility and motor fitness including postural control [44]. According to Armstrong and Welsman [46], $V0_2max$ may indicate the capacity to transport oxygen to the muscles and the use of it for the production of energy during exercise.

Since individuals with higher body weight usually have larger muscle mass, absolute $V0_2$ ($1 \cdot min^{-1}$) may be higher. Hence, $V0_2max$ relative to body weight ($ml \cdot min^{-1} \cdot kg^{-1}$) may give a more correct evaluation between individuals of different body weight [46]. The effect of any exercise program on physical fitness depends on the mode of activity, intensity, frequency and duration of the training [47]. Whereas PA may vary from day to day and weekdays to weekends, physical fitness (i.e. $V0_2max$) is more constant and takes time to alter [47].

Measurement of physical activity during pregnancy

PA is a complex behaviour, and identifying the most accurate way to measure total PA level is a challenge, as different methods have their strengths and limitations regarding responsiveness, reliability, validity, expense, and feasibility [48-50]. Numerous field methods have been developed, ranging from behavioural observation and written information (e.g. diaries, logs, questionnaires, and interviews) to more direct assessment of movement via pedometers and electronic motion monitors [48]. There seems to be consensus that no single assessment device adequately measures total PA level [51].

Few of the methods available have been validated in pregnant women and most pregnancy studies have relied on retrospective, cross sectional surveys to measure PA level [25]. Additionally, surveys that primarily focus on exercise and use few or just a single dimension (e.g. walking) to identify the association between PA and health, may misclassify women who spend much more time in housework and family care activities. Hence, Ainsworth [52] has recommended that PA surveys should reflect the complex nature of women's lives, including the context in which activities are performed. Besides, few questionnaires are designed specifically, and have been validated for the pregnant population [50]. The PAPQ used in the present study (papers I, II & III) and an ongoing cohort study (STORK) of pregnant women in Norway [53;54], was developed in 2001 and followed recommendations given at that time. This questionnaire includes questions on trimester-specific PA and measures PA within four arenas, accounting for commuting, occupation, housework and childcare activities, as well as sport/exercise [41;55;56].

Questionnaires are cost-effective, yet validity of the data may be questionable [48]. The main criticism has been that questionnaires do not provide accurate estimates of the absolute amounts of PA [48]. Hence, motion monitors, or accelerometers, have been suggested as useful methods to objectively assess PA [57]. In Norway, a motion monitor, the ActiReg system, has been developed and validated against indirect caliometri and doubly labelled water, with acceptable results [58-60].

The advantage of ActiReg over other activity monitors is that it can combine information about both body position and movement, and that it is sensitive to low intensity activities.

Gestational weight gain

Obesity is a significant health problem in the Western World, and is a risk factor for many diseases, including coronary heart diseases, diabetes, depression and breast and colon cancer [61;62]. Hence, prevention of weight gain is an important public health issue [63]. Pregnancy may be a risk period for significant weight gain in women, and maternal weight gain greater than recommended by the Institute of Medicine (IOM)[64] seems to be an important contributor to later obesity amongst women [65;66].

In addition, excessive weight gain during pregnancy is a risk factor for hypertension, gestational diabetes, pre-eclampsia, macrosomia, stillbirth and delivery complications [67;68]. The economic cost of hospital prenatal and postnatal care is increased for overweight mothers compared to normal weight mothers. In addition, infants of overweight mothers are more often in need of neonatal intensive care than infants of normal weight mothers [69]. New data of US women show that approximately 40% of normal-weight and 60% of overweight women gain excessive weight during pregnancy [70]. Unfortunately, these proportions may in general be underestimated due to self-reported data on weight and height [71].

Management of obesity is complicated, since most people may have difficulty maintaining achieved weight loss in the long term [72-74]. In addition, treatment of obesity is costly and health care providers may not be able to give the required help to all. Hence, for women, controlling pregnancy weight gain may be an important approach to prevent obesity, given that 15-25% of women retain at least 5 kilos after giving birth [75;76].

IOM recommendations for gestational weight gain

During the past decades, recommendations for optimal gestational weight gain have varied, and the 1990 IOM guidelines for weight gain in pregnancy implied a clear increase in weight gain over prior guidelines. For normal weight and underweight women, the maximum recommended target weight gain at term was 4.6 kg and 6.9 kg higher than in 1985, respectively. The evidence for proposing greater weight gain came from several studies associating low weight gain during pregnancy with increased risk of a low birth weight infant, and subsequent elevated risk of fetal

morbidity and death. On the other hand, high weight gain increases the risk of gestational diabetes and hypertensive disorders, prolonged labour, caesarean section and a high birth weight infant (≥4000 g) [69]. The 1990 IOM guidelines have been criticized for being too liberal and, as a result, predisposing women to maternal complications and postpartum obesity [77;78]. In addition, a significant proportion of pregnant women exceed these weight gain recommendations.

The current guidelines, issued in May 2009 (Table 2), differ from the previous ones in two aspects. Firstly, they now include a detailed range of recommended weight gain for obese women, and secondly, they refer to the BMI categories initiated by the WHO [79]. Hence, not only the baby's health, but also the welfare of the mother is considered in the new weight gain recommendations from the IOM [80].

According to IOM [80], the present guidelines need to be used together with proper clinical evaluation and dialogue about diet and exercise, between the pregnant woman and her physician/midwife. The weight gain range for pregnant teenagers and ethnic groups is similar to that for the general population. However, women pregnant with twins are given separate recommendations, ranging from 16.8-24.5 kg for normal weight women, 14.1-22.7 kg for overweight women and 11.4-19.1 kg for obese women.

Table 2 IOM recommendations for range of total gestational weight gain in singleton pregnancies, by pre-pregnancy BMI [80]

Category	**Pre-pregnancy BMI range (kg/m^2)**	**Total weight gain range (kg)**
Underweight	<18.5	12.7-18.2
Normal weight	18.5-24.9	11.4-15.9
Overweight	25.0-29.9	6.8-11.4
Obese*	≥ 30	5.0-9.1

* Includes class I (30-34.9), II (35-39.9) and III (>40)

Description of gestational weight gain

The rate of weight gain is usually lowest (0.5-2 kg) in the first 12 weeks (1st trimester), highest in the 2nd trimester (just below 0.50 kg /wk) and relatively constant or somewhat decreasing towards the end of the 3rd trimester [80;81].

Extra energy intake is necessary in pregnancy for the growth and development of the fetus, placenta and increased mass of metabolic active tissue [64]. Between 10 and 30 weeks of gestation the added energy costs are between 250-300 kcal daily [64]. However, because of the large individual differences in factors related to the energy cost of pregnancy (level of PA and body size), recommendations for extra energy intake during pregnancy are controversial [82;83]. PA levels often decrease during pregnancy, which at least somewhat balances the enlarged energy costs [27-29]. Therefore, it is difficult to establish extra energy needs in pregnant women, and the best indicator of sufficient energy intake may be adequate weekly gestational weight gain as suggested by IOM [80].

There are three ways to identify gestational weight gain: 1) weight gain per week, 2) total weight gain (last weight prior to delivery minus weight at last menstrual bleeding and 3) net weight gain (total weight gain after removing infant birth weight) [64]. Comparison of total gestational weight gain between studies is complicated due to different definitions of weight gain, different methods for measuring weight gain and the time period for which the total gestational weight gain is calculated. It is however unlikely, due to practical reasons, that correct body weight just before conception or delivery can be determined. In the present study gestational weight gain is defined as total weight gain, unless otherwise specified.

Since the current recommended target weight at term has just recently been published (May 2009), no studies have yet described maternal and fetal outcomes within these weight gain ranges. However, several studies have found a positive association between gestational weight gain using the 1990 IOM guidelines, and fewer pregnancy and birth complications [84-90].

Risk factors for excessive gestational weight gain

Energy intake

Energy intake is a determinant of gestational weight gain, but the reported association is weak [80]. However, there is no question that excessive energy intake may lead to additional fat storage or that restriction of energy intake can limit weight gain [64]. Olafdottir et al [91] found that drinking calorific beverages (milk) and eating more (especially sweets) were associated with excessive gestational weight gain in overweight women only. Another study [92] reported an association between increased dietary energy density (kcal/g or kJ/g) at 26-29 weeks of pregnancy and excessive weight, while glycemic load was not associated with total gestational weight gain or

weight gain ratio. In addition, weight gain has been linked to intake of protein, lipids of animal origin and total fat, whereas no association was found with intake of carbohydrates [91;93]. The IOM highlights the complexity of identifying small changes in energy intake during pregnancy while simultaneously accounting for body size and total level of PA. Hence, weight development during pregnancy is a result of many interacting factors.

Physical activity

To date, there is limited and inconsistent data available on the impact of PA on control of weight gain in pregnant women [35;94;95], and non-experimental studies yield conflicting results. In a prospective cohort study of 622 healthy women with a singleton infant, reduced PA from pre-pregnancy levels was significantly and independently related to gestational weight gain [96]. Another study from the US [97] showed that continuing a regular exercise regimen throughout pregnancy did not influence the rate of early pregnancy weight gain or subcutaneous fat deposition but decreased both in late pregnancy. Also, higher pre-pregnancy PA levels have been associated with less gestational weight gain [98]. A recently published study from the US reported that mid-pregnancy walking and vigorous PA, in accordance with ACOG guidelines (≥30 minutes per day), were inversely associated with excessive gestational weight gain [99]. Other observational studies have not found any relationship between PA and gestational weight gain at any point in pregnancy [100-104].

The methods for collecting PA data have varied from mailed questionnaires and activity recalls to accelerometry and heart rate monitoring. In addition, most of the studies have used different criteria to classify the women based on their level of PA, making a comparison of the results difficult. According to Morris & Johnson [94], assessment of PA should include the mode, frequency, duration and intensity when examining the association between gestational weight gain and PA. Despite acknowledged limitations, self-report seems to be the only method to assess context and type of PA. Variation in diet and energy intake may have biased the association between PA and gestational weight gain, as only two studies reported information on dietary intake [100;103].

Other risk factors

The prevalence of fertile women with high BMI is increasing in Norway [105;106], and several studies conclude that high pre-pregnancy BMI is an important risk factor for gaining excessive

weight in pregnancy [84;96;107-110]. However, overweight and obese women often put on less gestational weight throughout pregnancy [81;111]. IOM weight gain recommendations are lower for overweight and obese women and differences in thresholds used to define weight gain in pregnancy may result in major discrepancies. Hence, most authors agree that being overweight pre-pregnancy increases maternal and fetal complications [112;113], and that increased pre-pregnancy BMI between the first and second pregnancy increases the risk of adverse pregnancy outcome, including higher risk of large for gestational age infants (LGA) [113;114].

Quitting smoking at the beginning of pregnancy has been related to higher mean weight gain [115;116], due to dietary changes with increased energy intake [116].

Results from observational studies on gestational weight gain and maternal age are contradictory, with only one [117] out of four studies reporting higher average weight gain among women ≥25 years than women < 25 years [108;110;118]. Primiparous women seem to exceed the IOM recommendations more often than multiparous women [109;110;119;120].

With respect to level of education and ethnicity related to gestational weight gain, studies have shown different results, not allowing for any conclusions [108-110;119].

PA interventions to prevent excessive gestational weight gain

A computerized search for clinical trials on Embase, PubMed and The Cochrane Controlled Trial Register through October 2009 using the following terms: weight gain, weight loss, weight management, weight control in combination with pregnancy, pregnant women and exercise or physical activity, revealed eight non-randomized intervention studies and six RCTs evaluating exercise during pregnancy and maternal weight gain. Several checklists or scales have been developed to rate the methodological quality of intervention studies [121]. The PEDro scale is an 11 item list, giving one point for each scale item for internal validity, except from item 1 which pertains to external validity and is not used to generate the total score (range 0-10 points): eligibility criteria were specified, random allocation, concealed allocation, baseline comparability, blinded subjects, blinded therapists, blinded assessors, adequate follow-up (≥85%), data analyzed by intention to treat, between group comparison, report of point estimates and variability [121].

Herbert and Gabriel [122] have suggested that only trials with scores of at least 3 of the 10 criteria on the PEDro scale may be used to draw conclusions. The mean PEDro quality score has increased

from 2.8 in physiotherapy interventions published between 1955 and 1959 to 5.0 for interventions published between 1995 and 1999 [121]. In PA/exercise trials rating of 5-6 and 7-8 out of 10 reflects a moderate or high quality, respectively [121]. This is because it is impossible to blind the therapist and participants in most exercise trials.

Table 3 describes the *8 non-randomized intervention studies* identified. Using the PEDro rating scale, 6 of the trials scored ≤4 and may be defined as having low methodological quality [121]. The studies of Davenport et al [123] and Artal et al [124] both received a PEDro score of 5. Only the latter was successful in preventing excessive weight gain during pregnancy. However , the participants in the studies selected their own treatment (exercise + diet or diet alone), and the results may be influenced by allocation bias. The acknowledged method to obtain intervention and control groups that will give a high probability of comparable samples, is to randomize subjects to the groups [121]. However, RCTs can also be susceptible to bias and, as described previously, it is necessary to apply additional quality criteria. Table 4 shows the *6 RCTs* published before and after the present project was initiated. Five [10;125-128] and 1[8] of the RCTs received a PEDro score of 6 and 5, respectively (moderate quality). However, the study by Marquez-Sterling [8] is limited by a small sample size, involving only 20 participants. Sample size is a crucial factor in RCTs, as a small sample size may cause type II error, meaning that a possible effect is not revealed because of low power. Hence, estimation of the required sample size is essential to the planning of an RCT. In the present overview, only three RCTs reported a-priori sample size calculations [125;126;128]. Another concern is the report of high drop-out rates in two studies [8;128] and/or no report of adherence to the intervention/exercise program [8;10;127;128]. If the participants are not following the protocol, we cannot correctly evaluate whether the program prevents excessive weight gain in pregnancy. Conclusion can only be drawn on the feasibility of the intervention, which is another research question.

Clinically relevant and statistically significant effects of the interventions were documented in three RCTs [126-128], with Polley et al [127] finding reduced risk of excessive weight gain in a low income subgroup and among normal weight women only. However, a comparison of results is difficult because only the studies of Asbee et al [128] and Polley et al [127] were conducted primarily to prevent excessive gestational weight gain. In addition, there are differences in the populations studied and the intervention prescribed, including whether they used a controlled exercise program [126] or lifestyle counselling, combining diet and exercise [127;128]. Advice about healthy eating is also a factor that may affect total weight gain [33], and it is difficult to evaluate which of the two aspects is more important. Besides, insufficient PA data on the lifestyle interventions are

of great concern when judging the impact of exercise on maternal weight gain. There is scant information regarding both data collection and statistical analyzes. Hence, a possible dose-response relationship is difficult to determine. In addition, information regarding whether the women accomplished the recommended levels of exercise and intensity during the study period is often lacking.

Of the RCTs with a controlled exercise program, only Clapp et al [126] demonstrated an effect of exercise on maternal weight gain, with women who gradually increased the exercise volume to 60 min/5 days per week, weighing 2.6 kg and 3.5 kg less than women with moderate exercise regimes (40 min/5 days per week) and women with low exercise regimes i late pregnancy (20 min/5 days per week ($p<0.02$), respectively. As opposed to the other RCTs including supervised training [8;10;125], the participants in the Clapp et al's [126] study were women who exercised regularly before pregnancy. It may be difficult to get previously sedentary women to fulfil such a high training dosage.

The RCT and successful intervention programs of Asbee et al [128] comprised frequent visits to the health care provider. Also, in the RCT of Polley [127] the women exceeding weight-gain goals received more intensive counselling. This type of intervention offers both advantages and disadvantages. Weekly individual counselling is time consuming and needs highly qualified health professionals to provide patient education. Hence, it is both difficult and expensive to manage, and is hard to introduce into obstetrical practice, as opposed to a group training setting. Mottola [129] has suggested that interventions for pregnant women need to be behaviour-based because education programs increase knowledge, but do not change behaviour. Because walking is the most popular activity for pregnant women [130;131], the use of pedometers may aid compliance to exercise prescription in interventions and clinical practice. In addition, initiating a walking-program during pregnancy may be better than a supervised exercise group, because of its nearly universal use and because it allows for individual time management. However, the participants are then left to exercise on their own, and studies have shown that few women exercise regularly with a recommended dosage during pregnancy [29;130;131].

In conclusion, poorly designed and reported trials may bias the results and mislead treatment decisions from the individual level to national public health policies [121;132]. To date, the effect of exercise during pregnancy on gestational weight gain is still unclear. As shown in Table 4, only two RCTs have been conducted with the primary aim of preventing excessive gestational weight gain [127;128]. So far, no well-designed RCT has been conducted to investigate the effect of a

supervised structured exercise program (according to ACOG guidelines [22]) on maternal weight gain.

Table 3 Overview of non-randomized intervention studies during pregnancy using exercise to prevent excessive gestational weight gain (N=8)

Study	Participants	Primary aim to prevent weight gain	Intervention	Results
Collings et al. (1983) [133]	20 US women in 2nd trimester. 12 participated in an aerobic exercise program while eight women did not perform any regular exercise and served as a control group. Power calculation: Not stated Drop-out: 0	No	Three times per week aerobic exercise (cycle ergometer for a mean of 13 weeks). Control: No exercise Adherence: Not stated	No difference between groups in gestational weight gain.
Gray-Donald et al. (2000) [134]	219 Aboriginal Cree women, Canada. Power calculation: Yes Drop-out: 8 of 112 and 11 of 107 in intervention and control group, respectively. Hence, measures of key outcomes obtained from 91.3%.	Yes	PA sessions and dietary education. Control: Standard prenatal care. Adherence: Self reported levels of PA were low, with 61% and 23% in intervention and control group reporting sedentary behaviour, respectively.	No difference between groups in gestational weight gain.
Olson et al. (2004) [135]	560 US women with normal and overweight BMI. Power calculation: Yes Drop-out: 0 of 179 and 7 of 381 in intervention and control group, respectively. Hence, measures of key outcomes obtained from 98.8%.	Yes	Guidance about gestational weight gain and by-mail patient education program including tips for healthy eating and exercise in pregnancy. Control: Standard prenatal care Adherence: Not clear. Only 36% returned all 5 postcards with information about PA and diet.	Effective among low-income women only.
Kardel (2005) [136]	41 healthy Norwegian athletes who exercised regularly before pregnancy. The participants were given the choice to select between two different exercise regimens. Power calculation: Not stated Drop-out: 0	No	Hi-volume (n=20): muscle strength (2 d/week of 72 min), aerobic interval (2 d/week of 35 min) and endurance training (2 d/week of 150 min) Med-volume (n=21): muscle strength (2 d/week of 72 min), aerobic interval (2 d/week of 35 min) and endurance training (2 d/week of 90 min) Adherence: All subjects followed exercise protocol as close to labour as possible.	No difference between groups in gestational weight gain.
Artal et al. (2007) [31]	96 overweight (BMI>25) US women with gestational diabetes mellitus selected their own treatment. Power calculation: Not stated Drop-out: 2 of 39 and 8 of 57 in the exercise+diet and diet group, respectively. Hence, measures of key outcomes obtained from 89.6%.	No	Exercise + diet (n=39), included supervised exercise once a week by walking on a treadmill or by cycle ergometer, while maintaining unsupervised exercise at home on the remaining weekdays. Control: Diet alone (n=57) Adherence: 50% of the exercise group ≥150 min/week at moderate intensity (60% of $V0_{2max}$).	Lower weight gain in the exercise+ diet group compared to diet only.

Kinnunen et al. (2007) [137]	132 primiparous women recruited by six maternity clinics in Finland. Power calculation: Not stated Drop-out: 20 of 69 and 7 of 63 in the intervention and control group, respectively. Hence, measures of key outcomes obtained from 79.5%.	Yes	Counselling on gestational weight gain, diet and PA. In addition to supervised exercise sessions once a week for 45-60 min. Control: Standard prenatal care. Adherence: 88% participated in all five PA and dietary counselling sessions.	No difference between groups in gestational weight gain.
Claesson et al. (2008) [138]	368 obese (BMI≥30) women in Sweden. Power calculation: Not stated Drop-out: 5 of 160 and 15 of 208 in the intervention and control group, respectively. Hence, measures of key outcomes obtained from 94.6%.	Yes	Weekly motivational talks about weight control, eating habits and aqua aerobic once or twice a week. Control: Standard prenatal care. Adherence: Not stated	The intervention group had a significantly lower weight gain compared to the control group.
Davenport et al. (2008) [123]	30 overweight (BMI≥25) women from Canada with gestational diabetes were recruited to intervention (n=10) or control (n=20). Power calculation: Not stated Drop-out: 0	No	Walking program (3-4 d/week of 25-40 min) + diet. Control: Diet alone. Adherence: Numbers of sessions per week was 3.6 (SD 0.8), taking an average of 2629(SD 724) steps at the start of the program and 4230 (SD899) at the end of the program.	No difference between groups in gestational weight gain.

Table 4 Overview of randomized controlled trials during pregnancy using exercise to prevent excessive gestational weight gain (N=6)

Study	Participants	Primary aim to prevent weight gain	Intervention	Results
Clapp et al. (2000) [125]	50 US women who did not exercise regularly before pregnancy. Power calculation: Yes Drop-out: 3 of 25 and 1 of 25 in the intervention and control group, respectively. Hence, measures of key outcomes obtained from 92.0%.	No	20 min of aerobic exercise 3-5 times per week beginning at 8-9 weeks and continuing until delivery. Control: No exercise Adherence: All participants completed between 12 and 20 sessions of appropriate length and intensity each month.	No difference between groups in gestational weight gain
Marquez-Sterling et al. (2000) [8]	20 sedentary primiparous US women in 2nd trimester. Power calculation: Not stated Drop-out: Not clear. 9 and 6 participants were analyzed as intervention or control group, respectively. Hence, measures of key outcomes obtained from 75%.	No	Aerobic exercise 1 h 3 d/week for 15 weeks. Control: No exercise Adherence: Not stated	No difference between groups in gestational weight gain.
Clapp et al. (2002) [126]	80 US women who exercised regularly (<3 times/week) before pregnancy participated in three different weight-bearing exercise regimen. Power calculation: Yes Drop-out: Not clear. 26, 24 and 25 participants were analyzed as Lo-Hi, Mod-Mod or Hi-Low, respectively. Hence, measures of key outcomes obtained from 93.8%.	No	Lo-Hi: 20 min 5 d/week, gradually increasing to 60 min 5 d/week Mod-Mod: 40 min 5 d/week Hi-Low: 60 min 5 d/week, gradually decreasing to 20 min 5 d/week Adherence: All participants completed 18 of 20 sessions of appropriate length and intensity each month.	Pregnancy weight gain was significantly lower in the Lo-Hi group compared to the other exercise regimen.
Polley et al. (2002) [127]	120 low-income US women. Power calculation: Not stated Drop-out: 4 of 61 and 6 of 59 in the intervention and control group, respectively. Hence, measures of key outcomes obtained from 91.7%.	Yes	A stepped-care intervention including dietary and PA counselling. Control: Standard prenatal care Adherence: Not stated	Effective among normal-weight women only.
Garshasbi & Faghih (2005) [10]	266 primiparous women from Iran. Power calculation: Not stated Drop-out: 44 of 161 and 0 of 105 in the intervention and control group, respectively. Hence, measures of key outcomes obtained from 83.5%.	No	60 min of supervised exercise by midwife 3d/week. Control: No exercise Adherence: Not stated	No difference between groups in gestational weight gain.
Asbee et al. (2009) [128]	144 US women. Power calculation: Yes Drop-out: Not clear. 43 and 57 participants were analyzed as intervention or control group, respectively. Hence, measures of key outcomes obtained from 69.5%.	Yes	Organized program of intensive dietary and lifestyle counselling, including instructions to engage in moderate intensity exercise >3times/week. Control: Standard prenatal care Adherence: Not stated	The intervention group had a significantly lower weight gain compared to the control group.

Table 5 Studies assessing the effect of exercise during pregnancy to prevent excessive gestational weight gain. PEDro quality score is determined by counting the number of criteria that are satisfied, except that scale item one is not used to generate the total score. Total scores are out of 10. + = criterion was clearly satisfied, - = criterion was not satisfied, ? = not clear if the criterion was satisfied

Study	**Eligibility criteria specified**	**Subjects randomly allocated to groups**	**Allocation was concealed**	**Groups were similar at baseline**	**Subjects were blinded**	**Therapist administrating the treatment was blinded**	**Assessors were blinded**	**Measures of key outcomes obtained from > 85 % of subjects**	**Data analyzed by intention to treat**	**Statistical comparison between groups were conducted**	**Point measures and measures of variability provided**	**Total score**
Collins et al. (1983) [133]	+	-	-	+	-	-	-	+	-	+	+	4/10
Clapp et al. (2000) [125]	+	+	+	+	-	-	?	+	?	+	+	6/10
(Gray-Donald et al. (2000) [134]	+	-	-	+	-	-	-	+	-	+	+	4/10
Marquez-Sterling et al. (2000) [8]	+	+	?	+	-	-	-	-	+	+	+	5/10
Clapp et al. (2002) [126]	+	+	+	+	-	-	?	+	?	+	+	6/10
Polley et al. (2002) [127]	+	+	?	+	-	-	-	+	+	+	+	6/10
Olson et al. (2004) [135]	+	-	-	+	-	-	-	+	-	+	+	4/10

Garshasbi & Faghih (2005) [10]	+	+	+	+	-	-	-	-	+	+	+	6/10
Kardel (2005) [136]	+	-	-	-	-	-	-	+	-	+	+	3/10
Artal et al. (2007) [31]	+	-	-	+	-	-	-	+	+	+	+	5/10
Kinnunen et al. (2007) [137]	+	-	-	-	-	-	-	-	-	+	+	2/10
Claesson et al. (2008) [138]	+	-	-	+	-	-	-	+	-	+	+	4/10
Davenport et al. (2008) [123]	+	-	-	+	-	-	-	+	+	+	+	5/10
Asbee et al. (2009) [128]	+	+	+	+	-	-	-	-	+	+	+	6/10

Basis for the aims of the dissertation

Pregnancy has been recognized as an unique time for behaviour modification [30] and, in the absence of contraindications, pregnant women are now advised to participate in regular, moderately intensive PA to derive the same associated health benefits as non-pregnant women. Hence, information about exercise patterns during pregnancy and possible determinants for exercise in pregnant women is important when planning health promotion and preventative programs. However, there is scant knowledge about the effect of level of PA and exercise during pregnancy on weight gain. There is a lack of description of intensity, frequency, duration and exercise-mode among pregnant women, and it is mainly reported on recreational exercise and not other arenas activities such as housework, occupation and commuting. It is also not clear what characteristics are associated with exercise during pregnancy. Reasons why pregnant women are more sedentary than non-pregnant women have largely been understudied. Additionally, only a small number of studies have used motion monitors to assess women's PA during pregnancy and few questionnaires or interviews are designed specifically and have been validated in a pregnant population. There is limited evidence on the effect of exercise interventions designed to prevent excessive gestational weight gain. No RCTs were found where the main outcome was to investigate the effect of a supervised structured exercise program to reduce 1) mean maternal weight gain, and 2) the proportion of women with a higher that optimal weight gain.

Aims of the dissertation

There is insufficient knowledge on weight gain and level of PA and exercise during pregnancy, especially amongst women of Scandinavian origin. Before this project was initiated, no studies were available describing PA habits among pregnant women in Norway. Hence, the specific aims of the present doctoral thesis were as follows:

- To describe total PA level (at work, in movement, housework and recreational exercise) in pregnant women and investigate the association between weight gain, PA and exercise during pregnancy (Paper I).
- To report pregnant women's reasons for performing or not performing regular exercise, and to compare demographic, pregnancy related health factors and social modelling in Norwegian women exercising and not exercising in the 3rd trimester (Paper II).
- To compare self-reported PA level and activity patterns with a portable activity monitor (ActiReg®, PreMed AS, Oslo, Norway) (Paper III).
- To assess whether a 12-week pregnancy exercise program - including 60 minutes of supervised aerobic dance performed at least 2 times per week and advice of 30 minutes of moderate self-imposed PA on the remaining week-days - can prevent excessive gestational weight gain (Paper IV).

Methods

Study designs

The different aims of this dissertation required various study designs.

Papers I and II

Papers I and II are based on a cross sectional study, using the PAPQ to examine total PA level during pregnancy and pregnant women's reasons for performing or not performing regular exercise in the 3rd trimester.

Paper III

Paper III is a comparison study of PA level amongst pregnant women using the PAPQ and the ActiReg system.

Paper IV

Paper IV is an assessor blinded RCT to evaluate the effects of supervised aerobic dance exercise and advice of moderate self-imposed PA in prevention of excessive gestational weight gain**.**

Participants

Papers I and II

The first two papers were part of STORK, a study on determinants of high birth weight infants in Norway [54]. Healthy pregnant women giving birth at Rikshospitalet University Hospital, Oslo were invited to participate. The women were successively allocated from the application form for birth at Rikshospitalet University Hospital. Inclusion criteria were being of Scandinavian origin, having a singleton baby, recruitment to the project before week 12-14 of gestation and ability to answer the questionnaire in the 3rd trimester. Exclusion criteria were inability to understand and read instructions given in Norwegian and pre-gestational diabetes.

The recruitment of participants took place between 2002 and 2005. Figure 1 shows the selection process. Of the 2145 women who were invited to participate in STORK, 678 accepted the invitation. However, 90 withdrew before inclusion. Fourteen women were excluded after routine ultrasound at gestation week 17-18, due to congenital disorders (n=8) and twin births (n= 6). Further exclusions were two stillbirths, eleven relocations and births at another hospital, and eight participants chose to withdraw, leaving 553 women being invited to participate in our study. Of

these, 467 (84.4%) pregnant women answered the PAPQ at home between gestation week 32-36, and returned it at the last consultation with the midwife (NV).

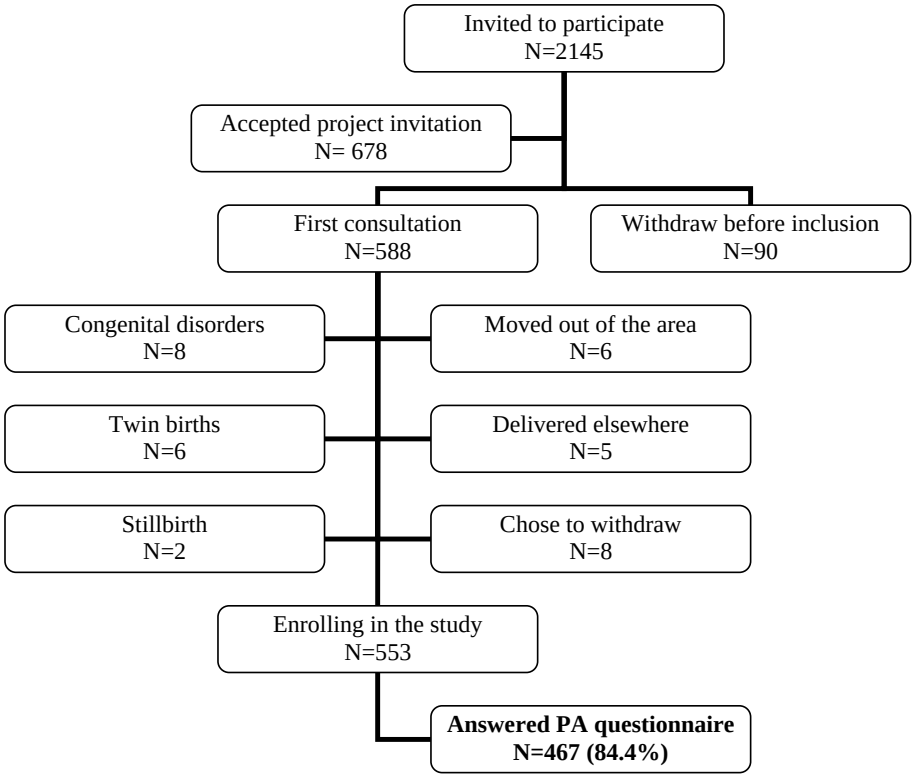

Figure 1 Flow chart showing the selection process

Paper III

In paper III sample size considerations were performed using mean values with SD from the first 15 participants. The calculations showed that a 95% CI of 0.55-0.85 would require at least 68 participants. We recruited participants across a wide range of sites and settings, varying from Rikshospitalet University Hospital, to flyers placed at pregnancy clinics and within the university and surrounding community. Over a 10-month period, a total of eighty-two pregnant women volunteered to participate in the study. Data collection began in March 2007 and concluded in January 2008.

Before completing the study, five women dropped out due to problems with the ActiReg-sensors (n=2) time constraints (n=1), acute illness (n=1) and miscarriage (n=1). No data were obtained from these women.

Paper IV

In paper IV we aimed to recruit 50 women in each group, giving 85% power and alfa=5% to detect a standardized difference in maternal weight gain of 0.6. Assuming that the SD of weight gain was 5 kg, the actual weight gain had to be Δ= 3 kg. These figures were conservatively based on findings in paper 1 [53].

Participants were recruited via health practitioners (physicians, midwives), articles and advertisement in newspapers, websites for pregnant women, flyers and word of mouth. Interested women telephoned or mailed the principal investigator (LH). At the first phone contact, the aims and implications of the study were explained and the eligibility criteria checked. Primiparous women whose pre-pregnancy exercise levels did not include participation in a structured exercise program (> 60 minutes once per week), including significant amounts of walking for the past six months (> 120 minutes per week), were eligible for the trial. Other inclusion criteria were ability to read, understand and speak Norwegian, and to be within their first 24 weeks of pregnancy. Exclusion criteria were severe heart disease, pregnancy induced hypertension, history of more than two miscarriages, persistent bleeding after week 12 of gestation and poorly controlled thyroid disease, pre-eclampsia and other diseases that could interfere with participation [22]. In addition, all women not able to attend weekly exercise classes were ineligible.

In total, 105 women from the city of Oslo were recruited to the trial from September 2007 to March 2008. All follow-up procedures were completed by November 2008. Figure 2 illustrates the flow chart, including exclusions and loss to follow-up. Some women who were lost to the test after the intervention may have re-entered the study at the postpartum examination.

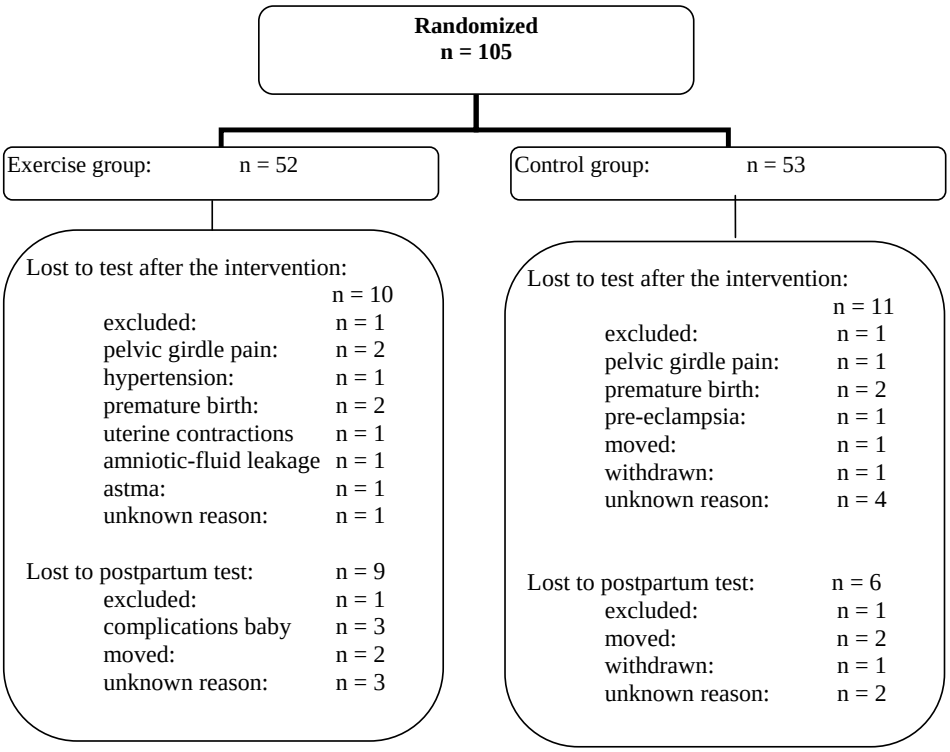

Figure 2 Trial profile showing the flow of participants through the randomized controlled trial

Ethics

In all four papers, every participant gave written consent to participate, and the studies were approved by The National Committee for Medical Research Ethics, Southern Norway, Oslo (Appendix 1). In addition, the Norwegian Social Sciences Data Services (NNT) provided licence to store and register individual health information (Appendix 2). Paper IV is listed in the ClinicalTrials.gov Protocol Registration System (NCT00617149) and the procedures followed the World Medical Association Declaration of Helsinki.

Assessments procedures and outcome measures

Paper 1

The PAPQ is a self-administered twelve-page questionnaire designed to obtain information about PA behaviour in pregnant women. The survey contains 53 questions and requires 10-15 minutes to complete (Appendix 3). The questions about total PA level were grouped into five sections titled: 1) sedentary activities; 2) occupational activities; 3) commuting activities; 4) housework and family care activities and 5) sports/exercise, which included the mode of activity, duration, frequency and perceived intensity. The same questions were asked retrospectively; pre-pregnancy and at 1st and 2nd trimester: 1) How often do you exercise? 2) For how long do you usually exercise (not included changing clothes, shower, and travelling)? 3) At what intensity do you regularly exercise? Low intensity was defined as without sweating or out of breath, moderate intensity as modestly sweating and light breathing and high intensity as sweating and breathing heavily. Regular exercise was defined as vigorous recreational PA for at least 20 minutes once a week [47].

In addition, the PAPQ contained questions about background variables, including age, weight, height, occupation, education, health status and complaints.

Overweight was defined as BMI ≥25[79], and excessive weight gain during gestation as ≥16 kg. Maternal pre-pregnant weight was self-reported. The participant's weight gain was assessed electronically at the last clinic visit prior to delivery (week 37.0; SD 1.1). The responders were divided into groups according to pre-pregnancy BMI using body mass groupings recommended by the IOM [64].

Paper II

In addition to detailed questions about PA level at work, commuting, at home and during leisure time, the PAPQ contained questions about symptoms of urinary and fecal incontinence, and PGP. The questions related to urinary and fecal incontinence were: " Do you experience problems with urinary incontinence?" and "Do you experience problems with flatus or fecal incontinence?" [139]. The questions on PGP were: "During this pregnancy, have you been bothered by pain in the pelvic area" and "During previous pregnancies, did you experience any PGP?" In addition we asked about severe PGP: "Did you have problems walking, with the need for crutches?

To identify the most frequently reported motives and barriers regarding exercise participation during pregnancy, we performed a qualitative interview among 12 pregnant women, asking "Why

are you /or why aren't you participating in regular exercise during the current pregnancy?" [41]. The answers from the individual interviews were combined with a number of responses on barriers/motives from a previous study in Norway [140]. Hence, the 12 response options to the question in the present study "If you engage in regular exercise at present, what are the two main reasons?" were: enjoyment; appearance; relaxation/recreation; sports competitions; prevention of health complaints/increasing physical fitness; well-being and happiness; prevention of weight gain; increase self-confidence; decrease pregnancy complaints; decrease stress/depression; obligation, and for social reasons.

The question related to exercise barriers was "If you do not engage in regular exercise at present, what are the two main reasons?" Possible responses were: "insufficient time, lack of interest, get sufficient exercise at work/home, too much effort to get started, difficulties due to children and childcare, lack of exercise companion, difficulty combining with work/studies, lack of availability of exercise options, negative experience with exercise, obstetric complications, no experience/never exercised, disease/handicap, fear of harm to the baby and advice from health professional to avoid".

Social modelling

To obtain information regarding social modelling, two questions were asked about family exercise behaviour (mother, father or siblings) during childhood, and how common exercising was amongst the participants` friends and colleagues [141]. Furthermore, we asked if the women usually exercised alone or with others. If with others, she was asked with whom. The provided responses were: family/spouse/partner; friends; colleagues; in a sports club, gym/fitness centre, or walking the dog. Selection of more than one response was allowed.

Anxiety about the fetus

Anxiety is recognized as a barrier towards exercise participation by non-pregnant samples [142]. Since women may feel uncertain about how exercise will affect the fetus [143], we included the following question. "Do you worry about the health of your unborn baby when participating in exercise activities?" with four alternatives for answering (yes, no, sometimes or do not exercise). To obtain information about specific barriers during pregnancy, the participants were also asked to specify the reasons for their concern, and whether the midwife, physician and/or other health care providers had given any advice about PA and exercise during pregnancy.

Paper III

In order to compare associations between activity levels indicated by the PAPQ and the ActiReg system, we needed to compute an activity score for each domain of PA section, by giving the specific categorical response a value ranging from 1 to 4 (1=inactivity, 2=low activity, 3= moderate activity, 4= high activity). Detailed information is given in Table 6.
In addition, a total activity index for each participant was calculated as the sum of all four areas divided by four. For women reporting no occupational activity (e.g. sick listed), the occupational index was assigned a value of 1 (seldom or never). The values and classification groups are based upon a IOM's quartered categorization of PAL-values [144] and the current ACOG guidelines, which advises the continuation of pre-pregnancy exercise activities of three to five times per week, providing pregnancy is normal and healthy[22].

Moreover, daily and weekly summary scores of minutes spent in non-occupational walking and exercise activities of light, medium and high intensity were used to compare associations between the activity levels indicated by the questionnaire and the ActiReg system. Low intensity was defined as any activity performed without sweating or being out of breath. Moderate intensity during activity was defined as moderate sweating and light breathing, and high intensity was defined as sweating and breathing heavily. Finally we calculated total hours of sedentary activities and reported sleeping time.

Table 6 Activity scores computed for each domain of physical activity sections, ranging from 1 to 4 (1=inactivity, 2=low activity, 3=moderate activity, 4= high activity)

Occupational activities	*Do you work standing and/or walking?*					
	Seldom or never	Sometimes, but not daily	Yes, but less than 50% of my working day		Yes, 50% or more of my working day	
	1	2	3		4	
Commuting activities	*Please specify how much you walk on daily basis (non-occupational walking) (e.g. to and back from work, deliver and pick up children, to the grocery shop)?*					
	Seldom or never	Less than 5 min	5-14 min	15-29 min	30-60 min	More than 60 min
	1	1	1	2	3	4
Housework and family care activities	*How often do you do light to moderate intensity housework tasks?*					
	Seldom or never	Once per week	2-3 times weekly	4-5 times weekly	6 times weekly	Every day or more than once every day
	1	2	3	4	4	4
Sports/exercise	*How often do you exercise (vigorous leisure-time physical activity ≥ 20 minutes)?*					
	Seldom or never	Once per week	2-3 times weekly	4-5 times weekly	6 times weekly	Every day or more than once every day
	1	2	3	4	4	4

ActiReg®

The ActiReg system comprises two pairs of motion and position sensors connected by cables to a battery-operated storage unit fixed to a waist belt. A computer program (ActiCalc) is used for processing and presenting the ActiReg data and calculation of energy expenditure [58]. During measurement, each pair of sensors was attached by medical tape to the front of the right thigh (midway between knee and hip) and chest (on the sternum between the breasts). The sensors discriminate between the positions: lying, sitting, standing and bending forward, and changes in these positions, from movement or not in each pair of sensors. In total, this provided 16 possible codes, one code for each combination. The ActiCalc data is obtainable as PAL-values ranging from 1.0 to 2.5. Inactivity is classified as $1.0 < PAL \leq 1.4$, low activity as $1.4 < PAL \leq 1.6$, moderate activity as $1.6 < PAL \leq 1.9$, and high activity as $1.9 < PAL \leq 2.5$. In addition, to calculate energy expenditure, ActiReg estimates a Physical Activity Rate (PAR-value), which may be categorized as sedentary (0.9-1.4), light (1.5-3.0), moderate (3.1-6.0) or high activity (>6.0) corresponding to the Compendium-based MET intensities [58;145].

The ActiReg was attached to the woman's body during all waking hours for seven consecutive days, except when showering, bathing or swimming. The participants were told to engage in their normal level of PA and to remove the ActiReg sensors at night. They were given a brief log to record when they applied and removed the device. In addition, the participants received written instructions about the use of ActiReg (Appendix 4). All the participants completed the PAPQ at the end of the seven days of ActiReg monitoring. The registration period was in mean pregnancy week 35.0 (SD 2.1).

Paper IV

The participants were examined three times during the intervention period (Appendix 5). The first visit was between 12 and 24 weeks of gestation (baseline test), the second at week 36-38 (after the intervention) and the last 6-12 weeks after delivery (postpartum test). Each visit lasted about 60-75 minutes. The main outcome measures were maternal weight gain and the proportion of women exceeding the IOM recommendations [80]. Maternal weight gain was defined as the difference between self-reported pre-pregnancy weight and the weight measured after the intervention period. Height and body weight were measured in light clothing and without shoes using a digital beam scale. Classification of maternal weight gain and pre-pregnancy BMI (kg/m^2) was done according to recommendations from the IOM [80]: 12.7-18.2 kg weight gain for underweight women (pre-pregnancy BMI<18.5), 11.4-15.9 kg weight gain for normal weight women (pre-preg BMI of 18.5- 24.9), 6.8-11.4 kg weight gain for overweight women (pre-preg BMI of 25.0-29.9)

and 5.0-9.1 kg weight gain for obese women (pre-preg BMI≥30). In the present study, two women had a pre-pregnancy BMI<18.5 and 11 women had a pre-pregnancy BMI ≥30. These women were classified as either normal weight or overweight, and corresponding weight gain recommendations were used [127;135].

Secondary outcome measures were the mean of skin-fold thickness and the women's postpartum weight. Skin-fold thickness was assessed by Holtain Caliper (Holtain Ltd., Crymych, UK), measuring left side skinfold thickness of the triceps, abdomen and thigh. Each measurement was done twice and held for 5-10 seconds. A mean value of the two was computed. If the two skinfold assessments differed by more than 2 mm, the skinfold was measured a third time and the mean of the three values was calculated [146]. Postpartum weight measured at the postpartum test was compared with self-reported pre-pregnancy weight to compute weight retention.

Other pregnancy data were obtained from a maternity card (pregnancy week, term-date) and interviews with the participants. The baseline questionnaire covered demographic information (e.g. age, pregnancy week, smoking habits, education, occupation), assessment of daily life, PA and sedentary behaviour (at work, commuting and housework). In addition, pregnancy complications such as pelvic girdle and low back pain, urinary and fecal incontinence, high blood pressure, pre-eclampsia, nausea and fatigue were recorded.

The participants completed two sub maximal lactate profile step tests, walking on the treadmill. One test immediately after randomization and the second test at after the intervention. The lactate profile test may be an indicator of fitness level, and is considered appropriate for monitoring the effects of aerobic exercise training [147]. Other outcome variables were heart rate and blood pressure. Following the recommendation of ACOG [22], the sub maximal test was chosen because of the limited documentation of the safety of maximal exercise testing in pregnancy, especially if the fetus is not monitored [148].

After adjustments to the treadmill, nose clip and mouthpiece, all participants started walking at an initial speed of 4.5 km/h. The inclination increased each fourth minutes by exactly 4%. Blood pressure, heart rate and rating of perceived exertion (6-20 scale) [149] were measured during the last two minutes of every stage after a steady state was reached based on stable oxygen uptake measurements. A capillary blood sample to measure blood lactate concentration was assessed in the 30 second pause between each stage. The test ended after 12-20 minutes (3-5 stages) when the subject's blood lactate concentration rose about 1.5 $mMol \cdot L^{-1}$ above resting level or perceived

physical exertion was between 15-17 (Borg scale) and/or a heart rate > 85% of expected maximal heart rate. Results are not presented in this dissertation [150].

Exercise program

The exercise program consisted of supervised exercise for 60 minutes, performed at least twice a week, for a minimum of 12 weeks. The women had the opportunity to participate in aerobic dance exercise classes three times a week. Since most participants were working full time, the exercise groups were arranged in the evening. Each session started with 5 minutes warm up, followed by 35 minutes of aerobic dance, including cool down. This was followed by 15 minutes of strength training with a special focus on the deep abdominal stabilization muscles (internal oblique and the transverse abdominal muscle), pelvic floor and back muscles, following the ACOG recommendations[22]. Exercises in the supine position were avoided because venous return to the heart may be compromised [151;152]. The last 5 minutes included stretching, relaxation and body awareness exercises. The aerobic dance routine included low impact exercises (no jumping or running) and step training. Step length and body rotations were reduced to a minimum, and crossing of legs and sharp and abrupt changes of position were avoided. The exercise program followed the ACOG exercise prescription [22], and all aerobic activities were performed at moderate intensity measured by ratings of perceived exertion at 12-14 (somewhat hard) on the 6-20 Borg's rating scale [22]. The exercise program was choreographed and led by certified aerobic instructors, and each session included a maximum of 25 participants.

In addition to joining the scheduled aerobic classes, all women were asked to include 30 minutes of moderate self-imposed PA on the remaining days of the week. They were also advised to incorporate short bouts of activity into their daily schedules (e.g. walk instead of drive short distances and to use stairs instead of elevators). Adherence to the exercise classes was controlled by the instructors, and the self imposed daily activity was registered in a personal training diary. Control participants were asked to continue their usual PA habits and were neither encouraged to, nor discouraged from exercising.

Randomization

An independent person involved in neither the assessment nor exercise classes assigned the participants to either an exercise group (EG) or a control group (CG) by simple randomization procedure (not block) following a computerised randomization program. The women were not stratified by BMI before randomization. The participants were requested not to reveal group allocation to the principal investigator (LH). The principal investigator was not involved in

training the women and was blinded to group allocation while assessing the outcome measures, plotting and analyzing the data.

Statistical analyses

Except from calculation of energy expenditure and time, computation of PA was done using ActiCalc (paper III). All other statistical analyses were conducted with SPSS Statistical Software version 11.5 (paper I), version 14.0 (paper II) and version 15.0 for Windows (papers III and IV). In all analyses level of statistical significance was set at $p<0.05$.

Paper I

The difference between two means was calculated by t-test. The X^2 test was used to analyse the relationship between categorical variables, correlations by Spearman tests. The women were divided into two weight gain groups: <16 and ≥16 kilograms. In addition, weight gain was analysed by pre-pregnancy BMI, using body mass groupings recommended by the IOM [64]. Trend analyses for PA levels across the different weight gain groups were done using the X^2 trend-test.

Paper II

The relationship between the women's exercise behaviour and selected variables was assessed by independent t-tests or X^2 as appropriate. The X^2 was used for cross-table analyses of categorical data, whereas correlations on ordinal scaled variables were evaluated by Spearman test. To address factors associated with engaging or not in recreational exercise in the 3rd trimester, univariate and multivariate odds ratios (OR) with 95% CI were estimated using binary logistic regression analysis. Age and pre-pregnancy BMI were chosen as fixed factors. Then, six relevant variables with univariate p-values less than 0.25 were entered by a forward variable selection process. Probability for exclusion was chosen as 0.05.

Paper III

The strength of agreement between the two methods was analysed by Bland & Altman plot [153]. Additionally, to enable comparison of these results with other studies, the Spearman correlation coefficient was used to evaluate the PAPQ and ActiReg data of activity estimates. The correlation values were interpreted as "good"= 0.50-1.0, "moderate"= 0.30-0.49 and "fair"= 0.10 to 0.29 [154;155]. To assess the concordance of PAPQ and ActiReg measures in classifying the women into

inactivity, low activity, moderate activity and high activity level, cross-classification and percentage agreement were calculated.

Paper IV

The principal analysis was done on an intention to treat basis (ITT). Missing values were replaced with the mean value (maternal weight gain) or the percentage change in the mean value (skinfold thickness and weight postpartum) in the EG and CG, respectively. Mean maternal weight gain was compared between the two groups and the possible difference was tested using a two-sided independent sample t-test. The group differences in proportion of participants gaining weight above the IOM guidelines was tested by using two-sided X^2-test. Spearman's rho was used for correlations on ordinal scaled variables. According to Irwin et al [156], per protocol analysis was based on adherence to ≥ 80% of the recommended exercise sessions (≥19 exercise sessions). In addition, we compared women attending 24 exercise sessions (exercise twice a week) with the CG.

Main results

Physical activity level and weight gain in a cohort of pregnant Norwegian women (paper I)
Fifty-five percent of the participants, mean age 31.6 years, pre-pregnancy BMI 23.5 reported to be working in a sitting position. Most women drove (52.9%) or used public transport (31.7%) to work. Low to moderate intensity childcare was the main housework activity in addition to vacuum-cleaning, housework and shopping. Thirty-nine percent reported sedentary activities of ≥4 hours (watching television and reading) daily. Nineteen percent were defined as non-exercisers before pregnancy, 30% in the 1st trimester, 36% in the 2nd trimester and 53% in the 3rd trimester. There was a reduction in frequency, duration and intensity of exercise before and throughout pregnancy. Walking was the most common exercise mode, but the mode of exercise tended to change throughout pregnancy. The prevalence of swimming tended to increase from pre-pregnancy to the 3rd trimester.

Mean weight gain was 13.8 kg (SD 5.2). Of the normal weight women (pre-pregnancy BMI<26) and overweight women (pre-pregnancy BMI≥26), 32% and 51% had weight gain above accepted recommendations, respectively. In total, 31.7% of the participants had gained ≥ 16 kilos. Women who exercised regularly had significantly lower weight gain than inactive women in the 3rd trimester only (p=0.023). Among women with high exercise frequency (≥ 4 times per week) in 3rd trimester, 16.0% had gained ≥ 16 kilos. Thirty-one percent in the other two exercise frequency groups (≤1 time per week and 2-3 times per week) had increased their weight by 16 kilos or more. The difference was borderline statistically significant (p=0.045).

Why do pregnant women stop exercising in the 3rd trimester? (paper II)
Fifty women (11%) were defined as regular exercisers according to ACOG recommendations in the 3rd trimester. The most common reasons cited for performing regular exercise in the 3rd trimester were a positive impact on health complaints and increase in physical fitness. A number of women also believed that performing regular exercise would improve their feeling of well-being, contribute to the reduction of pregnancy complaints, and help prevent excessive weight gain. The most frequently reported barriers towards exercise were: pregnancy complaints; lack of time; too much effort to get started and childcare difficulties. Of 262 women reporting to be non-exercisers pre-pregnancy, 9 started a regular exercise program and were defined as regular exercisers in the 3rd trimester. Overall, 19% of the women (n=467) reported to have become more physically active in the 3rd trimester compared to pre-gestational exercise levels.

The results of the multivariate analysis showed that women who decreased regular exercise in the 3rd trimester had a higher weight gain and reported having no good social role models with regard to exercise behaviour during childhood. Pre-pregnancy physical inactivity was the strongest predictor of decreased maternal exercise in the 3rd trimester. Not receiving advice about PA from health professionals and PGP were not found to be statistically significant factors. There was no difference between exercisers and non-exercisers with respect to pre-pregnancy BMI and commonly reported pregnancy complaints such as PGP and urinary incontinence. Neither was working status, including number of women reporting to be on sick leave, associated with regular exercise.

Self report versus motion monitor in measurement of physical activity during pregnancy (*paper III)*

Table 7 shows percentage distribution of total PA level estimated with PAPQ and measured with ActiReg. Both methods classified few women to be physically inactive or having a high activity level. Cross-tabulation of participants according to self-report and objectively measured PAL-values, showed that 94.8%, 92.2%, 100% and 97.4% were correctly classified as inactive, having low activity, moderate activity and high activity respectively. Twelve participants were misclassified, giving a total percent agreement of 84.5%.

Table 7 Percentage distribution of total PA level (PAPQ and ActiReg), and the proportion of women for each domain of PA group estimated with PAPQ (n=77)

	Inactivity	**Low activity**	**Moderate activity**	**High activity**
PAPQ	9.1%(n=7)	50.6% (n=39)	37.7% (n=29)	2.6% (n=2)
ActiReg	14.3% (n=11)	42.9% (n=33)	37.7% (n= 29)	5.2% (n=4)

In the PAPQ 23.4% reported that they had exercised for 30 minutes or more daily and 24.7% did so according to ActiReg data. Cross-tabulation of proportion of regular exercisers and participants meeting the ACOG guidelines, showed that 6 and 2 participants were misclassified in each group. Hence, the accuracy of the PAPQ against the ActiReg in correctly classifying participants was 92.2% and 97.4%, respectively.

The correlation between the methods was good for activities with high intensity ($r=0.586$, $p<0.01$). Associations with minutes spent in the two lower MET intensities were weaker and non-significant. When comparing activity patterns from PAPQ with crude ActiReg information

categorizing two main activity positions (time spent standing/moving and sitting/lying), the correlations with questionnaire responses were moderate for standing activities ($r=0.358$, $p<0.01$) and fair for sitting/lying ($r=0.288$, $p<0.05$). The Bland-Altman plot of the activity patterns showed a mean difference near zero with no apparent trends and with wide scatter of individual observations.

Effect of regular exercise in prevention of excessive weight gain in pregnancy (*paper IV)*
One hundred and five primiparous women were randomized to EG (n=52) or CG (n= 53). There were no statistically significant differences in background variables between the EG and CG prior to the intervention, at mean gestation week 17.7 (SD 4.2). Ten women in the EG (19.2%) and 11 women in the CG (20.8%) were lost to the test after the intervention. Two were excluded, due to twin pregnancy and poorly controlled thyroid disease after the first assessment. Others lost to follow up (n=11) were primarily due to pregnancy-related diseases (Fig 2).

Adherence rates are based on registrations taken by the aerobic instructors, and the total number of women randomized to the EG. However, four women never attended and one woman was excluded because of twins. Hence, the mean adherence to the exercise classes was 17.0 (± 12.5) out of 24 prescribed exercise sessions, with 21 women (40.4%) attending ≥ 80% of the recommended exercise sessions (≥ 19 supervised exercise sessions). Fourteen women had 100% exercise adherence and completed two exercise sessions per week with a total of 24 exercise sessions. Adherence to exercise classes was not associated with pre- pregnancy BMI or commonly reported pregnancy complaints such as nausea, fatigue, urinary incontinence, pelvic-girdle pain or low-back pain.

At the completion of the intervention (pregnancy week 36.6, SD 0.95), no difference in maternal weight gain was seen between the EC and the CG in the ITT analyses. Women attending 24 exercise sessions reduced maternal weight gain compared to women attending fewer exercise sessions and compared to the CG. Similarly, the proportion of women gaining more weight than recommended by the IOM did not differ between the EG and CG in the ITT analyses. No women attending 24 exercise sessions exceeded the IOM recommendations. After the intervention period, mean of skin-fold thickness at 3 sites did not differ between the EG (from 23.17 ± 5.14 to 22.97 ±4.82) and CG (from 23.23 ± 5.48 to 23.50 ± 5.55) ($p=0.38$). Per protocol and analysis of attendance to all 24 exercise sessions did not change the ITT results.

Postpartum weights were available for 90 of the 105 women (85.7%). According to ITT analyses, mean weight retention was 3.3 (SD 3.9) and 3.3 (SD 4.1) (p=0.93) in the EG and CG, respectively. The results were statistically significant when comparing women attending 24 exercise sessions (0.8 kg ± 1.7) with the CG (3.3±4.1) (p=0.001).

General discussion

Methodological considerations

Study designs

In the present cross-sectional survey of pregnant women in Oslo, Norway the aims were to describe total PA level (at work, commuting, housework and recreational exercise) and investigate the association between weight gain, PA and exercise during pregnancy (paper I). In addition we wanted to study pregnant women's reasons for performing or not performing regular exercise, and to compare demographics, pregnancy related health factors and social modelling in Norwegian women exercising and not exercising in the 3rd trimester (paper II).

An obvious limitation of cross sectional surveys is that the results consist simply of what the participants say they do (e.g. PA) and do not measure the activity directly. Also, it is only a snapshot of the situation and may be biased by socially desirable responses, which refers to the psychological tendency of respondents to provide socially acceptable survey responses rather than ones that reflect their own true behaviour or opinions [63]. Finally, cross sectional surveys cannot identify cause-and-effect relationships [157].

However, with carefully designed questions, cross sectional surveys are undoubtedly a practical assessment tool due to low cost, the opportunity to assess several outcomes and risk factors at the same time and because they are less time consuming for the participants [158]. In addition, the procedure does not influence participants' activities to the extent that can occur with observation, diary keeping or use of motion monitors. Hence, it may be useful for the generation of hypotheses and public health planning [158].

Because they are relatively inexpensive and more easy to use in large-scale studies, surveys will probably continue to be the most widely used type of PA measure, making it essential to continue to strive to improve their quality [48;159]. Hence evaluating and comparing the PAPQ with other more quantifiable measurement methods is important, as the questionnaire may be used in future studies [50]. For the purpose of this study, the PAPQ was compared to the ActiReg system, considered to be an acceptable criterion-related method to assess PA [58;60]. The ActiReg sensors record both body position and movement, and have summary measures which are easily comparable to activity patterns and indices (PAL-values) from the PAPQ.

Motion monitors like the ActiReg system may not be considered the best indicator of PA level. However, the preferable criterion-related measure and gold standard to validate a PA questionnaire, the doubly labelled water method, is rather costly and involves technical expertise. Besides, the method does not measure the activity patterns, indicating that no single assessment device appears to adequately measure total PA [58].

The strength of paper III is that the PAPQ was specially designed for use in a pregnant population and that we conducted 7 days of ActiReg registrations. When the present study was initiated, with the exception of the Schmidt et al study [160] which evaluated a women's questionnaire (KPAS) with ActiGraph accelerometer in a pregnant population, only one other study compared outcome variables from a pregnancy PA questionnaire (PPAQ) with a portable activity monitor [50].

Well designed randomised controlled trials (RCTs) are considered the best scientific study design to detect whether a cause-effect relation exists between intervention and outcome and for assessing the efficacy of an intervention [132;161]. As far as we can ascertain this is the first RCT investigating the effect of a supervised structured exercise program and self-imposed PA (following ACOG guidelines [22]) on maternal weight gain.

Clinical trials can be administered well or badly, and a survey describing the quantity and quality of RCTs reported that at least 25 different scales have been used [121]. As described previously, the PEDro quality scale includes items known to reduce bias in clinical trials such as randomization, concealed allocation, blinding, and that all intervention groups should be treated identically apart from for the experimental intervention. In addition, the participants should be studied within the group to which they were allocated, independent of whether they received treatment as allocated (intention to treat analysis, ITT) [121]. The PEDro scale has been shown to have acceptable inter-rater reliability [162] and is intended to improve the reporting of an RCT, enabling readers to understand a trial's conduct and to assess the validity of its results.

In the present study, as for most exercise trials, it was not possible to satisfy the criteria of blinding participants or the aerobic dance instructors. Hence, the RCT was assessor blinded only. However, we fulfilled most of the other items included in the PEDro quality scale, and scored 7 of the 8 criteria, with 8 being the maximum possible score of RCTs evaluating the effect of regular exercise. Unfortunately, key outcomes were not obtained from > 85 % of the participants.

It was not considered unethical to use a control group not receiving treatment in the present study. However, control participants were neither encouraged to, nor discouraged from, exercising, as we considered asking the CG not to exercise to be against current guidelines. In order to treat the two groups identically apart from for the experimental intervention, the CG underwent all tests and completed the same interview as the EG. However, awareness of being randomized to the CG, may have influenced the "usual-care" intervention [163]. We know that some participants may have been disappointed by not being randomized to the EG and therefore initiated exercise regimens comparable to the RCT intervention. This type of bias has been referred to as the "Avis effect" [164]. Hence, to obtain information about the PA habits in the CG, the CG underwent the same follow-up questions about PA and exercise after the intervention period as the EG. This was also done to ensure that the primary investigator was "blind" to the treatment received. The CG did not complete a training diary. In contrast to the EG, none of the exercises performed by the CG were supervised. Following the CONSORT statement for reporting RCTs [132], all analyses were based on assigned treatment (EG or CG) at the time of the randomization, regardless of adherence or compliance status.

Participants

Every year approximately 2000 women give birth at the Department of Obstetrics and Gynecology, Rikshospitalet University Hospital, and from 2002- 2005, a total of 2145 women were randomly invited to participate in the STORK project. Unfortunately, due to logistic limitations, not all eligible women were approached. About one third of the women approached accepted the invitation. Thus approximately five participants were included each week. Of these women (n=553), a total of 467 (84.4%) answered the PAPQ (Fig 1)

In general, there may be selection bias in a study population if the drop-outs differ from participants completing the study or if the participants differ from non-participants. The response-rate of eligible women to our study may be considered high. In addition, the population in STORK was similar in marital status, educational level, mean maternal age, parity, gestational age at delivery and the baby's birth weight as compared to non-participants giving birth at Rikshospitalet University Hospital. However, mean weight pre-pregnancy was significantly higher in the STORK group (67.2 kg versus 64.5 kg, $p<0.01$) [54]. When compared to the general Scandinavian pregnant population giving birth at Ullevål University Hospital, another major hospital in Oslo, the STORK participants included more non-smokers, but were otherwise similar

[54]. Hence, the survey participants in the present study may be considered to be fairly representative for an urban Norwegian population of Scandinavian origin.

A strength of paper III is that an a-priori power calculation estimated a recruitment of 68 participants, and data were obtained from 77 women who completed both the self-administrated questionnaire and the ActiReg assessment. Validation studies are often time consuming and involve considerable cooperation from the participants. Hence, most of the previous studies comparing a questionnaire with a portable activity monitor, as well as two validation studies among pregnant women, included selected samples of volunteers [50;160]. Even though efforts were made to include participants with a range of demographic characteristics, the study population in paper III consisted of motivated, educated women with sedentary occupations. All these are markers that may characterize individuals with high socioeconomic status, not being representative of all Norwegian women. This group is also recognized as more likely to be engaged in PA than non-participants. In the present study, the PA level of the participants was relatively high, as more than 79% reported to exercise regularly in the 3rd trimester. Regular exercise was defined as vigorous recreational PA at least 20 minutes once a week. In comparison, paper I including pregnant women at Rikshospitalet University Hospital, found that 45% were exercising regularly at late gestation, and that only 10% met the current ACOG exercise guidelines [22]. Hence, in paper III, about 23% were following the exercise recommendations. Additionally, pre-pregnancy BMI and maternal weight gain was significantly lower, and there were a higher proportion of primiparous women compared to the participants in STORK. However, across several characteristics (age, marital status, daily smokers, common pregnancy complaints), the present sample appears to be fairly similar to other pregnant women in Oslo, Norway [54].

As long as the numbers of participants are sufficient and that the loss of participants is not different between the groups, randomization is an effective method for balancing known and unknown confounding factors between treatment groups [165]. Paper IV was based on power calculations from the cross-sectional survey (paper I), and estimation of sufficient power to detect a statistically significant treatment effect. Estimation of a required sample size was also an ethical question, considering that Committees for Medical Research Ethics may not want to approve oversized trials due to unnecessary costs and involvement of additional participants, nor trials that are too small to be able to observe clinically important differences [166].

A limitation of the present RCT is that ten women in the EG (19.2%) and 11 women in the CG (20.8%) were lost to the test after the intervention. Many of the drop-out reasons (Fig 2) were pregnancy-related, so could be expected e.g. premature birth, pelvic girdle pain, uterine contractions, preeclampsia or pregnancy induced hypertension. Hence, these reasons should be accounted for when future studies and power calculations are considered. On the other hand, the possible bias associated with the drop-outs was probably minor, as there was only a small difference in reasons for drop-out, or drop-out rates between the EG and CG. In addition, there were no statistically significant differences in background variables between the EG and CG prior to the intervention, at mean gestation week 17.7 (SD 4.2). Withdrawals and drop-outs make an ideal ITT analysis impossible, and missing data of 20% may have reduced the power of the study and the ability to draw clear conclusions. Herbert et al [167] stated that measures of key outcomes should be obtained from >85% of the participants, as imputation techniques can never compensate for, or exactly reproduce, missing data. However, as recommended by Armijo-Olivo et al [168] and to complement the pragmatic approach provided by ITT, we also performed "per protocol" analyses (≥ 80% of the recommended exercise sessions) and analyses of "women attending 24 exercise sessions". This type of analysis may provide an answer to the efficacy of the treatment, but on the other hand may also overestimate the effect size due to selection bias, meaning that those exercising as prescribed differ from those who did not. Hence, conclusions from the "per protocol" analysis cannot be generalized to other pregnant women or settings.

Primiparous women whose pre-pregnancy exercise levels did not include participation in a structured exercise program (> 60 minutes once per week), including brisk walking (>120 minutes per week) for the past six months, were eligible for the trial. It could be questioned whether we randomized only sedentary woman (one of the main inclusion criteria) in the study. However, we believe that this was the case, since the baseline assessments of physical fitness showed a low level of oxygen uptake (VO_2) at anaerobe threshold (=critical power) [169], in both groups (EG: 25,3 ± 3,7 and CG: 24,9 ± 3,7). Anaerobe threshold reflects about 75-80% of $V0_2max$ [170], giving a mean value of 33.7 $ml \cdot min^{-1} \cdot kg^{-1}$ and 33.2 $ml \cdot min^{-1} \cdot kg^{-1}$ in the EG and CG respectively, compared to 37.5 $ml \cdot min^{-1} \cdot kg^{-1}$ in the general Norwegian female adult population (20-40 years) [171].

Although results of RCT designs are acknowledged as the highest level of evidence, their use may be limited by practical concerns, as they are generally expensive to conduct and time consuming for the participants. Furthermore, the extent to which results from RCTs are generalizable is always debatable. The participants in the present study volunteered for a study on exercise and

maternal weight gain. Thus, they may have had more of an interest in, and been more attentive to, these aspects than non-participants. The pregnant women in this study were healthy primiparous with a high educational level. Hence, the results can only be generalized to this group. As noted by Calfas and Marcus [172], a woman expecting her first child probably has more time and motivation to participate in a research study of regular exercise than a woman with one or more children. Hence, interventions for multiparous women must pay special attention to exercise barriers. As shown in paper II, one of the most frequently perceived barriers were factors related to time available to exercise, including difficulties with child care and competing priorities.

Assessments procedures and outcome measures

To our knowledge, no validated self-reporting questionnaire on PA and pregnancy existed when the data collection of paper I started in 2001. There was also scant knowledge about weight gain and level of PA and exercise during pregnancy. Only a small number of studies had described the intensity, frequency, duration and exercise-mode amongst pregnant women, and trimester-specific exercise is not reported [29;56;101]. Additionally, it was mainly reported on recreational exercise, and different definitions of exercise have been used. Especially for women, Ainsworth [52] recommend that studies on PA level should account for the full range of PA including commuting, occupation, housework and childcare activities. Daily activities may comprise a substantial portion of the total PA level during pregnancy [50;55]. The strength of paper I is inclusion of questions about housework activities, commuting and work related PA in addition to regular recreational exercise, along with trimester specific exercise level. A general limitation of PA questionnaires is the actual definitions and interpretations of the term "PA", despite the attempts of investigators to provide a clear definition. In the present study regular exercise was defined as performing vigorous recreational PA for at least 20 minutes once a week. This definition is based on the ASCM [47] guidelines for exercise testing and prescription, suggesting that the duration of an exercise session should include 20-60 minutes of continuous or intermittent activity. Significant gains to achieve health and fitness goals such as improved body composition have been demonstrated with a minimum of 20 minutes of cardiovascular exercise of medium intensity [47]. We did not want to exclude several women from answering the upcoming exercise questions - as may have been the consequence if we had defined regular exercisers as women who trained 3-5 times per week. In the PAPQ we wanted to be sure that all women who performed regular exercise once a week were included, to answer the questions about how long they had been exercising regularly and their three preferred activities. We also wanted to be able to classify all exercising women as being at low, moderate or high exercise level. We asked questions about exercise frequency, duration and

intensity prior to and throughout pregnancy, since activity levels may change with advanced gestation [173].

In paper II we have analysed both motivational factors, barriers and social modelling, in combination with demographic and pregnancy related health variables associated with participation in recreational exercise in the 3rd trimester. Choosing the 3rd trimester, we have data on the women who are most likely to be true regular exercisers, maintaining a regular exercise pattern throughout pregnancy. The majority of studies on the topic "exercise in pregnancy" have been in non-European cohorts. Hence, it is important to undertake a study in Nordic-Caucasians, as one might expect cultural differences in attitude towards exercising during pregnancy between countries. However, there are some measurement errors that need to be considered. First of all, the survey design chosen was a questionnaire with closed questions. Answers to these may be easier to code and analyze, but they do not give room for any answers outside the alternatives given [174]. This means that the women were not given any opportunity to comment on their replies. Such comments concerning barriers/motives and exercise during pregnancy would have been most interesting. However, answers from open-ended questions are difficult to encode and analyze using powerful statistical methods. Also, such questions take more time to answer and demand that the participants write full sentences instead of marking a cross [174]. It can be considered a strength of paper I and II that a well-qualified midwife (NV) was available to answer questions when the participants handed in the questionnaire. This may have avoided misinterpretations of the questions.

The PAPQ was distributed at gestation week 32, and returned at 36 weeks of pregnancy. Limitations are retrospective self-reporting on pre-pregnancy, 1st and 2nd trimester activity level. Hence, exercise questions about frequency, duration and intensity may have been difficult to report correctly as they have to be remembered many months back in time. However, as the pre-pregnancy data of total PA had to be obtained retrospectively, we chose a retrospective design for 1st and 2nd trimester as well. Third trimester PA data was obtained cross-sectionally. To our knowledge, there have been no studies where PA was assessed prospectively, before pregnancy. In addition, when planning the study, it was important that the PAPQ should not be too time consuming, because PA was only one of several exposure variables (maternal body mass index, fat mass, food frequency, fasting plasma glucose and insulin, newborn birth weight) assessed in the STORK project [20]. Hence, distributing the PAPQ in all three trimesters was not considered feasible and would have placed more burden on the participants.

Validation studies face many challenges and previous studies using motion monitors as an objective measure for comparison with a PA questionnaire in non-pregnant adults generally show relatively low validity. This may be a reflection of the difficulty in addressing the individual differences in energy use associated with a given activity, by asking questions [175]. Many of the low intensity activities may be hard to remember and are often carried out routinely with no reflection of time and intensity (housework and child-care activities). Additionally, because of social desirability, over-reporting of time spent in exercise activities may have occurred [63]. The pregnant women may also have had difficulty estimating the intensity of exercise and it is not certain that they all share the same understanding and definition of "high, moderate and low intensity"[159]. Thirty-five percent of the pregnant women were sick listed, and for that reason given the lowest value for the occupational activity index. However, it is possible that this group is more active in their every day life activities, and that the current categorization is incorrect. In addition, while occupational and housework activities tend to be consistent across seasons, there may be seasonal variation in exercise activities [50]. Although each pregnant woman in the present study answered the PAPQ and wore the ActiReg during one specific season only, our data collection period included all four seasons.

Several studies have been conducted to explore how many days of recording is optimal to consistently assess PA level with a portable activity monitor. In these investigations, the number of days has varied from 3 to 12 [176]. To keep the withdrawal and drop-out low, it is also important to consider what is practical and reasonable for the participants. In agreement with Schmidt et al [160] and to include both weekdays and weekends, we assumed that 7 days recording with the ActiReg system was appropriate. However, more studies are needed to determine the optimal length for measurement of PA behaviour and how this parameter varies with subject characteristics, such as being pregnant [177].

A limitation of our study is that wearing an activity monitor may have increased the awareness of PA, and therefore overestimated the results due to a more precise report of total PA level [160]. Additionally, as has been shown in other portable activity monitors, there may be errors and inaccuracies at the individual level [58;178]. In its present form, ActiReg is known to miscalculate total PA level in very active persons, and it is not well adapted to cover high to very high intensity exercise activities [58]. For example uphill walking, swimming, weight lifting, and activities involving arm-work are not properly accounted for [58]. Hence, combining the ActiReg with a heart rate monitor is suggested to improve the results for those individuals with high to very high activity level [58]. Such an approach would have been complicated with the participants in our study

because of the reduced maximal heart rate reserve in pregnant women. Use of conventional heart rate target ranges for aerobic exercise is less dependable and precise during pregnancy compared with the non-pregnant state [6]. A heart rate monitor is also easily influenced by other electronic equipment, and some individuals may even find it difficult to handle, due to the somewhat advanced technique. However, the majority of women are not very active during pregnancy [29;179], and results from paper I showed that both exercise frequency, intensity and duration were reduced in the 3rd trimester compared to 1st trimester, 2nd trimester and pre-pregnancy exercise levels [53]. The participants in the present study had a moderate PA level, with a group mean PAL-value of 1.59 and 1.58, using ActiReg and PAPQ registrations, respectively. Hence, the ActiReg system may be well suited to measure PA levels in pregnant women.

The ActiReg system is still rather expensive, puts a heavier workload on the participants and is somewhat impractical. Handling the data file is also relatively time consuming, making the method less feasible for a surveillance system. So, while these devices are an advance, and useful in research studies, the need for high quality PA questionnaires is not reduced [57]. Besides, as questionnaires and portable activity monitors measure different aspects of PA, there may be several advantages in combining these two instruments for the measurement of PA level during pregnancy [180].

The PAPQ is not evaluated for test-retest reliability. However, such studies are planned in a random sample of pregnant women, with the objective to estimate the 4 week test-retest of the PAPQ of total activity, accounting for commuting, occupation, housework and childcare activities, as well as sport/exercise.

A major strength of the RCT was that all the interviews and assessments of outcome variables were done by the main investigator only (LH). Therefore no extra study personnel were needed for the counselling, and the possible bias concerning the data collection of outcome variables is assumed to be small. In addition, we used a standardized interview guide and all women were asked the questions in the same order and manner, as was the case for the clinical outcome measures. All visits were accomplished during daytime and at normal working hours, and the women were examined three times during the study period. Hence, due to hectic time schedules, the duration of the interviews needed to be kept to a minimum (about 60 minutes). At the third and last visit (6-8 weeks postpartum), a majority of the women brought their newborns. A possible limitation of this approach was that the presence of the baby may have interfered with the interviews at this time.

To calculate gestational weight gain and weight retention postpartum, valid information about pre-pregnancy weight is required. However, in the present study as in most other pregnancy studies, this information was based on self-report. It is acknowledged that self-reported data on body weight may be underreported, particularly in overweight women [181]. Hence, if the proportion of overweight women differs between the two groups being compared, incorrect reporting of lower pre-pregnancy body weight may bias the results. In this study there were no baseline differences in number of women with normal weight and overweight. Gestational weight gain may also be inaccurately calculated if a woman has not weighed herself for a long time prior to pregnancy. Among our participants, only one woman did not know her pre-pregnancy body weight. Given that most women only gain little weight during the 1st trimester and to reduce possible bias regarding self-reported pre-pregnancy weight, the early pregnancy weight, measured at the first visit, was used as a control variable [182].

Because total body fluid during pregnancy increases, weight alone may not be a proper estimate of actual weight gain during pregnancy. Hence, we included measures of skinfold thickness to estimate body composition at late gestation (fat mass and fat-free mass) [146]. Compared to underwater weighing and isotope dilution, the method is inexpensive and can be mastered after a brief training period [146]. In addition, measuring skinfold thickness poses no risk for the mother or fetus and can be completed in less than 10 minutes. A disadvantage of the method is that inaccuracy increases with obesity and among individuals with firm subcutaneous tissue [146]. Eleven of 105 participants (10.5%) had a pre-pregnancy BMI ≥30 and were defined as obese.

Information on dietary habits that could potentially affect maternal weight gain was not collected. However, the reported association is weak and the IOM emphasizes the complexity of identifying changes in energy intake in pregnant women [64]. In addition, to complete consistent measures of average intake of macronutrients and energy, food records of 3-10 days may be needed [183]. Hence, food records are often very detailed and time consuming for the participants to fill in and for the researchers to process. To our knowledge when this study started, only one such questionnaire was evaluated for a Norwegian population and found suitable, although not tested in a pregnant population [184].

Moreover, we did not introduce individual weight gain charts as have been used in some previous studies [127;135]. It might have been easier for the participants to keep their weight gain within the IOM recommendations if such counselling had been given. However, the main focus of the RCT

was increasing exercise and PA level in EG rather than guidance on appropriate gestational weight gain.

In the interviews we asked questions about PGP and low back pain. Unfortunately, no clinical tests were carried out. More detailed questions on history of pain, body charts and an opportunity for the participants to give more details about the location and extent of pain would have made it easier to correctly classify the women and accordingly compare the EG and CG [185]. Similarly, we did not assess pelvic floor muscle function before and after the intervention, as we wanted to examine whether training of the pelvic floor muscles taught in a general fitness class without such testing could be effective in preventing and reducing urinary incontinence during pregnancy. From a health promotion and prevention point of view it would be excellent if such a program achieved this, as it would be less time consuming, more cost-effective and maybe more motivating than one to one exercise with a health care professional. Results on pelvic floor muscle dysfunction (urinary and fecal incontinence) are published separately [186].

According to the current exercise guidelines, pregnant woman are encouraged to exercise moderately 3-5 times a week [6;22;187]. We assumed that, in a group of previously sedentary women, it would be easier to allocate and achieve high adherence with an exercise program of 2 days a week. The participants were, however, in addition to joining the scheduled aerobic classes, asked to include 30 minutes of moderate self-imposed PA e.g. brisk walking on the rest of the days of the week. Unfortunately, we have no data on whether or not they fulfilled the criteria of 30 min of PA a day, as few reported adherence in their exercise diary. In the general adult population 60 minutes of daily moderate intensity activity may be needed to prevent unhealthy weight gain [188;189]. Hence, higher levels of PA than recommended in this RCT may also be necessary to prevent excessive weight gain in pregnancy.

Skilled aerobic instructors led the exercise groups, gave instructions on intensity and emphasized the importance of adherence to the exercise protocol. All the aerobic sessions were accompanied by music, choreographed specifically for previously inactive and pregnant women with only low impact exercise, and a maximum of 25 participants attended in an airy, modern exercise room. Still, only 40% attended the recommended number of exercise sessions. Why the women in the present study did not adhere is difficult to understand, and information on the reason for the low participation rate is not available. A fitness class of 60 minutes prescribed twice a week, including endurance training of 40 minutes may be considered demanding. Thus, the sedentary women who were the target group for this study may have been less motivated to adhere to this specific

program. In addition, finding time to exercise is vital if an exercise program is to be adhered to. Even though the exercise groups were arranged in the evenings, previously sedentary women may have had problems getting into a weekly exercise routine, as well as possibly lacking the necessary social support from family and friends. It is not unlikely that sedentary women have a sedentary partner [141]. Hence, to maximize exercise adherence, the spouse, in particular, needs to be cooperative by avoiding events which may interfere with the scheduled exercise time [190].

Also previous trials in sedentary pregnant women have reported low adherence to the exercise program or not reported it at all [8;191;192]. Despite the fact that there are physiological and anatomical adjustments during pregnancy that may influence activity level, there is little evidence that should discourage otherwise healthy, pregnant females from exercising [30]. In the present study, adherence to the exercise protocol was not affected by commonly reported pregnancy complaints such as nausea, fatigue, urinary incontinence, pelvic-girdle pain or low-back pain. Further studies on adherence strategies to improve compliance are warranted.

Results

A low exercise level was shown in the present study of pregnant women in Oslo, and there was a decline in exercise frequency before and throughout the course of pregnancy. This corresponds with other studies [101;179;193;194], and may be an expected development as weight increases and many women may experience musculoskeletal pain and discomfort during exercise. Additionally, the reduction in exercise level may be due to inadequate knowledge about recommendations both amongst health personnel advising pregnant women, and the pregnant women themselves.

Leiferman and Evenson [193] and Eliasson et al [179] found that 33% and 47% of pregnant women respectively, reported that they continued exercising during pregnancy. In the 3rd trimester; more than 45% of the Norwegian women were still exercising regularly. These data indicate that Norwegian women may be more comparable to their Swedish counterparts than American pregnant women. One explanation for this may be that more women in both Norway (81%) and Sweden (62%) exercised before pregnancy and therefore already had regular exercise routines as a part of their lifestyles. Additionally, ACOG exercise recommendations were not published until 2002. Earlier studies and data collections might have been influenced by the older guidelines and, as a result, contributed to higher prevalence of non-exercising women during pregnancy [29].

Exercise guidelines for pregnant women recommend walking, stationary bicycling, swimming, aerobics and strength training [22]. These were the five most frequently observed activities found in our study. Walking has also been reported as the most frequent exercise in other studies, alone or in combination with other exercise regimes [29;179]. This is reasonable as walking is a suitable exercise mode for most adults due to its nearly universal use and low impact on the skeleton [195]. For sedentary pregnant women walking at moderate intensity may increase maximal oxygen uptake, whereas walking programs may not be intense enough to increase $V0_2$max in fit pregnant women [147;170].

About 50% of the women reported that they undertook low to moderate intensity childcare and/or housework activities three times per week or more during pregnancy. However, no association was seen between excessive weight gain and daily activities in and around the house, or physically demanding work. Hence, such activities may not demand enough energy expenditure to prevent excessive weight gain during pregnancy. This finding is also inconsistent with literature suggesting that women as a group are very active in their everyday life, and that family care and housework activities may be sufficient to obtain health benefits [50;55].

A substantial number of the participants were overweight before pregnancy. This corresponds with another study showing increasing prevalence of fertile women with high BMI in Norway [196]. Overweight women often underestimate their weight [197;198]. The strength of our study is that these variables are based on final weighing completed by a midwife. However, as pre-pregnancy weight is based on women's self-report, underreporting of weight prior to pregnancy may cause an overestimation of maternal weight gain [65;199].

In the literature, results on weight gain during pregnancy in overweight women are inconsistent. In the present study, 51% of the women with pre-pregnancy BMI>26, had put on more weight than optimal (≥11.3 kg). This is a much higher percentage than found in the normal pre-pregnancy BMI group. However, when comparing pregnancy weight gain according to WHO, the results showed that mean weight gain was 14.8 kilos (SD 4.8) and 12.9 kilos (SD 5.8) in pre-pregnant BMI group<25 and ≥ 25, respectively. This finding corresponds with other studies reporting that females with a high BMI before pregnancy did not gain more weight than their slimmer counterparts [81;111]. Differences in thresholds used to define weight gain in pregnancy may result in major discrepancies. However, most authors agree that being overweight pre-pregnancy increases maternal and fetal complications, and that excessive weight gain in pregnancy enhances the risk for gestational diabetes and macrosomnia, as well as hypertension and preterm delivery [69;77;199].

Paper I demonstrated a significant negative correlation between weight gain and exercise level only during the 3rd trimester. These results correspond with Clapp and Little [97], showing that continuing a regular exercise regimen throughout pregnancy did not influence the rate of early pregnancy weight gain or subcutaneous fat deposition.

The results of paper II found that prevention of health complaints and improving physical fitness were stronger motivators for regular exercise during pregnancy than mental and social factors. None reported meeting people to be a main reason for performing regular exercise in the 3rd trimester. This is consistent with research amongst other populations, ranking socialization as a less important motivator for PA than staying fit [200]. Downs and Hausenblas [201] found that the most common exercise advantage during pregnancy was that exercise improved mood. In our study about 52% reported well-being and happiness as an important factor influencing exercise participation.

A previous study by Sallis et al [202] has found that factors such as lack of time, lack of interest, lack of enjoyment from exercise and lack of self-discipline are significant predictors of exercise

behaviour in the general population. A recent study from Norway demonstrated that more women than men seem to intend to be physically active without being able to establish a regular PA pattern [203]. In the present study on pregnant women the most frequently reported barriers towards maternal exercise were: pregnancy complaints, lack of time, and difficulties related to childcare. Surprisingly, but consistent with findings in the RCT, pregnancy complaints reported as a main cause for not exercising were not associated with prevalence of either urinary incontinence or PGP, and neither was sick-leave. Unfortunately, we do not have information about other common pregnancy complaints e.g. fatigue, back pain, leg cramps, vomiting and nausea, which may limit pregnant women's participation in regular exercise.

Clarke & Gross [143] reported that rest and relaxation were perceived as being more important during pregnancy than performing regular exercise or maintenance of an active lifestyle. In addition, it has been suggested that if the women are sedentary before onset of pregnancy, this habit is established and very difficult to modify [130]. Our results support a positive association between pre-pregnancy PA and maternal exercise in the 3rd trimester. Only 3.4% of the pre-pregnancy inactive women started an exercise program after becoming pregnant. Zhang and Savitz, reported that 7% began exercise during pregnancy [194]. Hinton and Olson [56] reported that 20% of the inactive participants started to exercise during pregnancy. The low prevalence in the present study may be due to the fact that only 36% of those surveyed reported that they had received advice from a physician or midwife about PA at least once during their pregnancy. We do not know if this information was initiated by the doctor or the pregnant woman herself. It may be that it was the women who asked the doctor about exercise, rather than the opposite. Considering that roughly 70% of adults are examined by a health care provider at least once per year, researchers have suggested that health professionals play a valuable future role in encouraging exercise behaviour with their patient [204]. In particular, pregnant women visit their health care provider on a regular basis throughout pregnancy, and this may be an open gate for providing information on the benefits of regular exercise during pregnancy [22].

Our univariate analysis confers that multiparous women were less likely than their primiparous counterparts to be engaged in recreational exercise in the 3rd trimester [56;194]. However, unlike other investigators [56;130] we did not find an association between exercise in the 3rd trimester and sociodemographic correlates like age, maternal education, working status, smoking habits and pre-pregnancy BMI. This may be due to the fact that the majority of the participants in our study were middle to upper class and well educated women. Studies in the general population are

consistent in this area, showing that higher education levels reflect healthier living habits, including participation in regular exercise [205].

In paper II we defined regular exercise as performing moderate intensity leisure time PA >3 times a week. This definition was based on current exercise guidelines, encouraging pregnant women to exercise a minimum of 3 times per week throughout the pregnancy [6;22]. However, several studies have shown that physically active pregnant women exercise less frequently [29], and as shown in paper I, most women were regularly active only once per week in the 3rd trimester. Hence, the relationship between exercise behaviour in the 3rd trimester and potential predictors may show different results in exercise populations where a different frequency of exercise cut-off is applied.

The study population was from a single hospital in Oslo and the investigation was carried out in the Norwegian language only. Accordingly, we have excluded women from ethnic non-Norwegian groups who might have an increased risk of inactivity during pregnancy. Our results demonstrated that the majority of the participants had high education, smoked less and were older than women giving birth in Oslo, Norway [54]. Because motivational factors and barriers towards exercise may vary with social status, the generalizability of the present findings should be considered with caution. Additionally, the power was also limited since only 50 of 467 women were defined as regular exercisers in the 3rd trimester. Post hoc power analysis showed that because of only small differences in e.g. pre-pregnancy BMI, at least 1430 women should have been included in each group to show a difference between exercisers and non-exercisers. Similar numbers for PGP were 630 women in each group.

To date, few research groups have used motion monitors to assess PA level during pregnancy [206-208] and as far we have ascertained, only three published studies have compared outcome variables from a PA questionnaire with a portable activity monitor in pregnant women [50;160;209]. We used the ActiReg system, developed in Norway, as did Brantsæter [209], whereas the other two studies used the ActiGraph accelerometer. The study of Schmidt et al [160] showed that the r-values were homogeneous across the trimesters of pregnancy, but varied considerably assessing domain specific activity, with the highest Spearman correlations for sport/exercise and vigorous activity (r=0.12-0.51). These findings are supported by the study of Chasan-Taber et al [50], showing Spearman correlation coefficients ranging from 0.08-0.43 for total activity, 0.25 to 0.34 for vigorous activity, 0.20 to 0.49 for moderate activity and -0.08 to 0.22 for light intensity activity. In Brantsæter et al's study [209], Spearman correlations between frequency of weekly exercise and objectively assessed variables were r=0.16 for total energy expenditure, r= 0.24 for PA energy

expenditure, r=0.26 for PAL and r= vigorous PA. Our estimates for the validity of the PAPQ in this sample of pregnant women are comparable with Smith et al [160] and slightly higher than those observed for the PPAQ by Chasan-Taber et al [50] and Brantsæter et al [209].

Exact matches of two methods to assess PA level are not possible and, as shown above, self-report measures compared with an objective measure of PA generally show low to moderate validity correlations among pregnant women, especially in measurement of low intensity activity. One explanation for this may be that many of the low intensity activities are hard to remember and are often carried out routinely with no reflection of time and intensity (e.g. housework and child-care activities) [52]. Additionally, over-reporting of time spent in exercise activities is common and may have occurred [48]. However, as demonstrated in paper I, pre-pregnancy exercise declined in pregnancy. Thus a low level of PA could reduce the validity of a questionnaire. On the other hand and as discussed earlier, the present study included a higher proportion of regular exercisers in the 3rd trimester than demonstrated in paper I. Studies have shown that recreational PA may be easier to assess and validate than occupational and daily life activities [51]. Hence, the present results may indicate a better case scenario than is correct, and may not actually reflect the population of STORK for which the PAPQ was developed.

The ActiReg addressed 7 days in mean pregnancy week 34.7 (SD 2.1), and the PAPQ reported PA in the 3rd trimester. Hence, the correlations reflecting validity in this study may be underestimated due to different time periods assessed by the PAPQ and the ActiReg system. Thus a questionnaire reporting the past week would probably have given higher correlation estimates as the time periods would have been the same length (7 days). However, for pregnant women PA in the distant past, including pre-pregnancy exercise, is of great interest as many pregnancy-related diseases develop over time [210].

The results of paper IV showed that only women attending the prescribed exercise program regularly significantly reduced maternal weight gain. No women attending 24 exercise sessions exceeded the IOM recommendations. Weight retention 6-8 weeks postpartum was also significantly lower in women attending 24 exercise classes.

As shown in Table 4 and 5 (page 18-19), results from previous trials evaluating exercise during pregnancy and maternal weight gain are inconsistent and comparisons of results are difficult due to use of different designs, study populations, measurement methods to assess maternal weight gain and dosage of the exercise program.

The high quality RCT by Clapp et al [126] demonstrated a positive effect of exercise on reducing maternal weight gain, with women who gradually increased the exercise volume to 60 min/5 days per week, weighing less than women with moderate or low exercise regimes in late pregnancy. The exercise volume of our study was lower than in Clapp's [126] study, suggesting that a less demanding exercise program may be effective for previously sedentary women. Both studies focused on weight-bearing moderate intensity exercise for about 60 min, which has higher energy costs than other modes of activities (e.g. cycling) and exercise of less duration and intensity. The present study also focused on integration of exercises into daily activities.

Availability is the first and most important factor when advocating PA and exercise. Hence, establishing specific exercise classes for pregnant women as a part of a public health policy to prevent excessive weight gain during pregnancy may be a good prevention strategy. The moderate intensity of the exercise classes in the present study followed the ACOG guidelines [22] and can easily be achieved in most aerobic classes or by brisk walking. However, as discussed previously, and shown in this study, it is difficult to get previously sedentary women to fulfil the ACOG exercise recommendations.

Interviews after the intervention period revealed that some women in the CG had started regular exercise after the baseline test. Low adherence in the EG and increased PA level in the CG may have confounded our findings and resulted in a smaller difference in maternal weight gain between the two groups than expected. To date, reports clearly point to favourable physiological and health benefits associated with regular exercise of moderate intensity during pregnancy. Hence, we assumed it to be unethical to say that the CG was not allowed to exercise.

Excessive weight gain during pregnancy may be a significant predictor of long term weight gain [211;212]. In the present study weight retention 6-8 weeks postpartum was significantly lower in women attending 24 exercise classes. These women also had lower maternal weight gain. Six weeks postpartum may be too soon to study the impact of exercise during pregnancy on long term weight change. Early postpartum weight loss mainly represents loss of non-adipose tissue, including loss of placenta, amniotic fluid and maternal blood volume [212] . Whether the EG would continue to exercise, and thus control their weight in the long term, remains to be investigated. There is some evidence that participants of interventions tend to return to old habits [72-74]. Hence a long term follow-up of the participants is warranted.

Conclusions

The main conclusions from this dissertation are:

- The PAPQ may be considered an acceptable method for assessing habitual PA and exercise among pregnant women at group level.
- In the cross sectional study, using the PAPQ, we found that:
    - there is a low level of daily PA and an increase in the number of non-exercising women throughout pregnancy
    - a high percentage of women are exceeding recommended weight gain
    - being physically active in housework and childcare-giving did not reduce the rate of maternal weight gain
    - women who decreased regular exercise in the 3rd trimester had higher weight gain and reported to have no social role models with respect to exercise behaviour, during childhood
    - pre-pregnancy physical inactivity was the strongest predictor of decreased maternal exercise in the 3rd trimester
    - there was no difference between exercisers and non-exercisers with respect to pre-pregnancy BMI and commonly reported pregnancy complaints such as PGP and urinary incontinence
- It is difficult to motivate previously sedentary women to participate regularly in an exercise program, and only women participating in 24 exercise sessions of 60 min moderate intensity aerobic dance during the 2nd and 3rd trimesters of pregnancy reduced maternal weight gain, and none exceeded the IOM recommendations compared to the control group.

Further research

Many new questions have arisen from the present dissertation and should lead to future research:

- The PAPQ is not evaluated for test-retest reliability. Hence, it is important to carry out a test-retest reliability study of the PAPQ on total activity, including commuting, occupation, housework and childcare activities, as well as sport/exercise.
- Considering the low prevalence of exercise in the present study and the many health benefits from performing regular exercise during pregnancy, more research and interventions aiming to help women maintain or increase PA level during pregnancy are warranted, including studies on adherence strategies to enhance motivation for participation in regular exercise.
- The present study showed that regular attendance at aerobic dance exercise can significantly reduce maternal weight gain. Further RCTs with larger numbers of participants are needed to replicate this finding, in addition to a long term follow-up of the participants in the present study investigating whether they have changed PA habits.
- An RCT with four arms (exercise, diet, exercise + diet, control) is indicated, to determine whether a lifestyle intervention can prevent excessive maternal weight gain and postpartum weight retention in obese pregnant women.
- More RCTs are needed to evaluate how exercise influences gestational diabetes and pre-eclampsia.
- More RCTs to investigate the effect of exercise on birth outcome and the health of the infant (e.g. birth weight, Apgar score)
- Studies investigating the knowledge and to what extent health care providers use the ACOG exercise guidelines to advise and encourage pregnant women to exercise regularly are needed.

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PAPER I

PAPER II

PAPER III

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MAIN RESEARCH ARTICLE

Self-reporting compared to motion monitor in the measurement of physical activity during pregnancy

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Abstract

Most pregnancy-studies have relied on retrospective, cross-sectional surveys to measure physical activity level. Questionnaires are cost-effective, but validity of the data may be questionable. *Objective.* The aim of the present study was to validate a physical activity and pregnancy questionnaire (PAPQ) with a portable activity monitor (ActiReg®). *Design.* Prospective comparison study. *Setting.* Healthy pregnant women recruited in a capital area. *Population.* Seventy-seven pregnant women wore the ActiReg® sensors during waking hours for seven consecutive days and answered the PAPQ. *Main outcome measures.* Agreement between the two methods was analyzed by Bland–Altman plots and Spearman correlation coefficients. *Results.* The results indicated only small differences between the PAPQ and the ActiReg® in cross-tabulation of total physical activity level and proportion of participants meeting the current exercise guidelines. The correlation between the methods was good ($r = 0.59$) for time spent in activities with high intensity (METS > 6), moderate for time spent standing/moving ($r = 0.36$) and fair for sitting/lying ($r = 0.29$). The Bland–Altman plot of the activity patterns, showed a mean difference near zero with no apparent trends and wide scatter of individual observations. *Conclusions.* The PAPQ may be considered an acceptable method for assessing habitual physical activity and exercise among pregnant women at group level. However, as questionnaires and portable activity monitors have their strengths in measuring different aspects of physical activity, there may be advantages in combining these two types of instruments for registrations of physical activity level during pregnancy.

Key words: *Pregnancy, physical activity, physiology, motion*

Introduction

The health benefits of regular physical activity are well established (1,2). Current recommendations for all adults, including pregnant women, encourage at least 30 minutes of moderate activity on most days of the week (3,4). Physical activity entails complex behavior, and identifying the most accurate way to measure total physical activity level is a challenge, as different methods have their strengths and limitations regarding responsiveness, reliability, expense and feasibility (5–7). Numerous field methods have been developed, ranging from behavioral observation and written information (such as diaries, logbooks, questionnaires and interviews) to more direct assessment of movement via pedometers and electronic motion sensors (5).

Few of the methods available have been validated in pregnant women and most pregnancy-studies have relied on retrospective, cross-sectional surveys to measure physical activity level (8). Additionally, few questionnaires or interviews are designed specifically or have been validated for the pregnant population (7). The physical activity and pregnancy questionnaire (PAPQ) was developed in 2001, and is used in an ongoing cohort study (STORK) of pregnant women in Norway (9,10). This questionnaire includes questions on trimester-specific physical activity and measures physical activity within four arenas, accounting for transportation, occupation,

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household and child-care activities, as well as sport/exercise (11,12). Questionnaires are cost-effective, but validity of the data may be questionable (5). The main criticism has been that questionnaires do not provide accurate estimates of the absolute amounts of physical activity (5). Hence, it is important to evaluate and compare the PAPQ with other more quantifiable measurement methods.

Motion monitors, or accelerometers, have been suggested as useful methods to objectively assess physical activity during pregnancy (13). In Norway, a motion monitor, the ActiReg® system (PreMed AS, Oslo, Norway), has been developed and validated against indirect caliometry and doubly labeled water, with acceptable results (14–16). The advantage of ActiReg® over other activity monitors is that it can combine information about both body position and movement, and that it is sensitive to low intensity activities. The aim of the present study was to compare self-reported physical activity and exercise level, reported with PAPQ, with data from the ActiReg® system in pregnant women.

Material and methods

We compared physical activity level among pregnant women using the PAPQ and the ActiReg® system. Sample size considerations were done using data from the first 15 participants. The calculations showed that a 95% confidence interval of 0.55–0.85 would require at least 68 participants. Over a 10-month period, a total of 82 pregnant women volunteered to participate. We recruited participants across a wide range of sites and settings, varying from Rikshospitalet University Hospital, to flyers placed at pregnancy clinics and within the university and surrounding community. Data collection began in March 2007 and concluded in January 2008. The study was approved by the Regional Medical Ethics Committee and the Norwegian Social Sciences Data Services (NNT), and all participants gave written consent for participation.

Before completing the study, five women dropped out due to problems with the sensors (n = 2), time constraints (n = 1), acute illness (n = 1) and loss of the baby (n = 1). No data were obtained from these women.

The PAPQ is a self-administered 12-page questionnaire designed to obtain information about physical activity behavior in pregnant women. The survey contains 53 questions and requires 10–15 minutes to complete. The questions about total physical activity level were grouped into four sections titled: (i) occupational activities; (ii) commuting activities; (iii) household and family care activities and (iv) sports/exercise, which included the mode of activity, duration, frequency and perceived intensity (9).

All participants completed the PAPQ at the end of 7 days of ActiReg® monitoring. The mean registration period was at 34.7 weeks gestation (SD 2.1).

We computed an activity score for each domain of physical activity section, by giving the specific categorical response a value ranging from 1 to 4 (1 = inactivity, 2 = low activity, 3 = moderate activity, 4 = high activity) (Table 1). In addition, a total activity index for each participant was calculated as the sum of all four areas divided by four. For women reporting no occupational activity (such as being sick listed), the occupational index was assigned a value of 1 (seldom or never). The values and classification groups are based upon a Institute of Medicine's (IOM) quartered categorization of physical activity levels (PAL-values) (17) and the current American College of Obstetricians and Gynecologists guidelines, which give advice on the continuation of pre-pregnancy exercise activities of 3–5 times/week, provided the pregnancy is normal and the woman healthy (3). PAL is an index of total energy expenditure (TEE) adjusted for basal metabolic rate (BMR).

Daily and weekly summary scores of minutes spent in non-occupational walking and exercise activities of light, medium and high intensity were used to compare associations between the activity levels indicated by the questionnaire and the ActiReg® system. Low intensity was defined as any activity performed without sweating or being out of breath. Moderate intensity was defined as moderate sweating and light breathing, and high intensity was defined as sweating and breathing heavily. Finally, we calculated total hours of sedentary activities and reported sleeping time.

The ActiReg® system contains two pairs of motion and position sensors connected by cables to a battery-operated storage unit fixed to a waist belt. A computer program (ActiCalc®, PreMed AS, Oslo, Norway) is used for processing and presenting the ActiReg® data and calculation of energy expenditure (14). During measurement, each pair of sensors was attached by medical tape to the front of the right thigh (midway between knee and hip) and chest (on the top of the sternum between the breasts). The sensors discriminate between the positions: lying, sitting, standing and bending forward, and changes in these positions from movement or not in each pair of sensors. In total, this provided 16 possible codes, one code for each combination. The ActiCalc® data are obtainable as PAL-values ranging from 1.0 to 2.5. Inactivity is classified as $1.0 < \text{PAL} \leq 1.4$, low activity as $1.4 < \text{PAL} \leq 1.6$, moderate activity as $1.6 < \text{PAL} \leq 1.9$ and high

Table 1. Activity scores computed for each domain of physical activity sections, ranging from 1 to 4 (1 = inactivity, 2 = low activity, 3 = moderate activity, 4 = high activity).

Occupational activities	*Do you work standing and/or walking?*			
	Seldom or never	Sometimes, but not daily	Yes, but less than 50% of my working day	Yes, 50% or more of my working day
	1	2	3	4
Commuting activities	*Please specify how much you walk on daily basis (non-occupational walking) (e.g. to and back from work, drop and pick up children, to the grocery or store)?*			
	Seldom or never	Less than 5 minutes	5–14 minutes	15–29 minutes	30–60 minutes	More than 60 minutes
	1	1	1	2	3	4
Household and family care activities	*How often do you do light to moderate intensity household tasks?*					
	Seldom or never	Once per week	2–3 times weekly	4–5 times weekly	6 times weekly	Every day or more than once every day
	1	2	3	4	4	4
Sports/exercise	*How often do you exercise (vigorous laisure-time physical activity ≥ 20 minutes)?*					
	Seldom or never	Once per week	2–3 times weekly	4–5 times weekly	6 times weekly	Every day or more than once every day
	1	2	3	4	4	4

activity as $1.9 < \text{PAL} \leq 2.5$. In addition, to calculate energy expenditure, ActiReg® estimates a physical activity rate (PAR-value), which may be categorized as sedentary (0.9–1.4), light (1.5–3.0), moderate (3.1–6.0) or high activity (> 6.0) corresponding to the compendium-based metabolic equivalent of task (MET) intensities (14,18), where MET is defined as the energy cost of physical activities as the ratio of work metabolic rate to a standard resting metabolic rate (RMR), set by convention to 3.5 ml $O_2 \cdot kg^{-1} \cdot min^{-1}$. One MET is considered as the resting metabolic rate obtained during quiet sitting.

The participants visited the principal researcher twice. At the first visit, all procedures were explained to the women by the project-leader, the participants read and signed the informed consent and were instructed in how to wear the ActiReg® system.

The ActiReg® was calibrated before each measurement and the sensors checked to avoid incorrect functioning. Prior to mounting the sensors on the body, the sensors were wrapped in sports tape. The sensors were marked with arrows and colors to assist correct placement of the equipment. In addition, the participants received written instructions and a memory list about the use of ActiReg®. The sensors were attached to the woman's body during all waking hours for seven consecutive days, except when showering, bathing or swimming. The participants were told to engage in their normal level of physical activity and to remove the sensors at night. They were given a brief log to record when they applied and removed the device. If the sensors were removed during daytime for a total of 3 h or more, the day was excluded.

Statistical analysis

Energy expenditure and time computation of physical activity was done using ActiCalc®. All other analyses were conducted with SPSS Statistical Software version 15.0 for Windows. Background variables are presented as frequencies, percentages or means with standard deviations (SD). The strength of agreement between the two methods was analyzed by Bland–Altman plotting (19). Additionally, to enable comparison of these results with other studies, the Spearman correlation coefficient was used to evaluate the PAPQ and sensor data of activity estimates. The correlation values were interpreted as 'good' = 0.50–1.0, 'moderate' = 0.30–0.49 and 'fair' = 0.10–0.29 (20,21). To assess the concordance of PAPQ and ActiReg® measures in classifying the women into inactivity, low activity, moderate activity and high activity levels, cross-classification and percentage agreement were calculated. Level of significance was set at $p < 0.05$.

Results

Based on registrations in an activity log, all women had adequate data collection, defined as 10 h or more per day of wear-time. Demographic characteristics of the participants are shown in Table 2, whereas Table 3 shows the percentage distribution of total physical activity level estimated with PAPQ and measured with the sensor. Both methods classified few women to be physically inactive or having a high activity level. Cross-tabulation according to self-reporting and objectively measured PAL-values, showed that 94.8, 92.2, 100 and 97.4% were similarly classified as inactive, having low activity, moderate activity and high activity, respectively. Twelve participants were misclassified, giving a total agreement of 84.5%. The Spearman correlation coefficient between each pair of variables listed, were moderate, with $r = 0.388$ ($p = 0.019$). The proportion of women in each domain of physical activity group estimated with PAPQ is also presented in Table 3. It was not possible to measure a corresponding classification from the sensors.

As shown in Table 4, the ActiReg® data were in agreement with respect to classifying the participants as sufficiently or insufficiently physically active both in numbers (n) and PAL-values in all four sections as defined by self-reporting in PAPQ.

Table 5 shows the associations of self-reported time (PAPQ) spent on three different MET intensities and in two main activity positions (standing/moving and sitting/lying) with measures from the sensors. The correlation was good for activities with high intensity ($r = 0.586$, $p < 0.01$). Associations with minutes spent in the two lower MET intensities were weaker and non-significant. When comparing activity patterns from PAPQ with crude sensor information categorizing two main activity positions (time spent standing/moving and sitting/lying), the correlations with questionnaire responses were moderate for standing activities ($r = 0.358$, $p < 0.01$) and fair for sitting/lying ($r = 0.288$, $p < 0.05$).

Figure 1 shows the agreement between the two methods for the significant associations analyzed by Bland–Altman plotting. The plot illustrates that the mean differences between the two methods were 0.2 + 118.1 minutes/week for high intensity activities, −11.4 + 149.6 minutes/day for standing/moving and 3.0 + 159.5 minutes/day for sedentary activities. The 95% confidence limits of agreement varied from +231.8 to −231.4 minutes/week, +281.9 to −304.7 minutes/day and +315.5 to −309.6 minutes/day in variable 1, 2 and 3, with 4, 4 and 5 participants being outliers of the 95% limits of agreement, respectively.

According to the PAPQ, 23.4% reported exercising for 30 minutes or more daily and 24.7% did so according to the ActiReg® data. Cross-tabulation of the proportion of regular exercisers (moderate exercise at least 20 min once a week) and participants meeting the American College of Obstetricians and Gynecologists guidelines (moderate exercise at least 20 min 4 times a week or more) showed that six and two participants were misclassified in each group. Hence, the accuracy of the PAPQ against the sensor in correctly classifying participants was 92.2 and 97.4%, respectively. The Spearman correlation coefficients were moderate, with $r = 0.449$ ($p = 0.000$) and $r = 0.467$ ($p = 0.000$).

Table 2. Background and health variables of study population ($n = 77$).

Age (years)	32.3 (SD 3.6)
Married/living together	97.4%
College/university education	94.8%
Parity	0.47 (SD 0.6)
Pre-pregnancy BMI (kg/m^2)	22.3 (SD 2.2)
Pre-pregnancy BMI ≥ 25	6.6%
Weight gain (kg)	12.4 (SD 3.5)
Daily smokers in pregnancy	0%
Previous smokers	30.7%
Sick-listed in third trimester	35.1%
Pelvic girdle pain	62.3%
Urinary incontinence	27.3%
Regular exercisers third trimester[a]	79.2%
Sedentary occupations	67.2%

[a]Vigorous recreational physical activity ≥ 20 minutes once a week.

Table 3. Percentage distribution of total physical activity level (PAPQ and ActiReg), and the proportion of women for each domain of physical activity group estimated with PAPQ ($n = 77$).

	Inactivity	Low activity	Moderate activity	High activity
PAPQ	9.1% ($n = 7$)	50.6% ($n = 39$)	37.7% ($n = 29$)	2.6% ($n = 2$)
ActiReg (PAL-values)	14.3% ($n = 11$)	42.9% ($n = 33$)	37.7% ($n = 29$)	5.2% ($n = 4$)
Physical activity arenas				
Commuting	10.4% ($n = 8$)	23.4% ($n = 18$)	35.1% ($n = 27$)	31.2% ($n = 24$)
Occupation	64.9% ($n = 50$)	10.4% ($n = 8$)	5.2% ($n = 4$)	19.5% ($n = 15$)
Household/child-care	10.5% ($n = 8$)	40.8% ($n = 31$)	13.2% ($n = 10$)	35.5% ($n = 27$)
Sport/exercise	36.4% ($n = 28$)	32.5% ($n = 25$)	13.0% ($n = 10$)	18.2% ($n = 14$)

Table 4. PAL-values and number of participants classified as sufficiently or insufficiently physically active in the four arenas of physical activity by PAPQ and ActiReg (n = 77).

	PAPQ		ActiReg	
	Insufficient	Sufficient	Insufficient	Sufficient
Commuting	1.47 (n = 26)	1.64 (n = 51)	1.52 (n = 26)	1.62 (n = 51)
Occupation	1.54 (n = 62)	1.78 (n = 15)	1.57 (n = 62)	1.66 (n = 15)
Household/child-care	1.52 (n = 39)	1.60 (n = 37)	1.59 (n = 39)	1.67 (n = 37)
Sport/exercise	1.52 (n = 53)	1.74 (n = 24)	1.54 (n = 53)	1.70 (n = 24)

Table 5. The association of self-reported time (PAPQ) spent on three different MET intensities and in two main activity positions with measures from ActiReg (n = 77) using Spearman's correlation coefficient.

	PAPQ	ActiReg	
Intensity	Minute/week	Minute/week	
High (MET > 6)	134.2 (SD 123.2)	134.0 (SD 129.4)	r = 0.586 (p = 0.000)
Moderate (MET > 3–6.0)	705.0 (SD 122.5)	953.0 (379.8)	r = 0.153 (p = 0.183)
Low /inactive (MET = 0.9–3.0)	7,855.7 (SD 782.1)	8,933.0 (SD 719.9)	r = 0.202 (p = 0.080)
Main activity positions	Minute/day	Minute/day	
Standing and moving	249.9 minutes (SD 128.5)	264.9 minutes (SD 115.2)	r = 0.358 (p = 0.002)
Sitting and lying (sedentary activities)	1,122.2 (SD 111.7)	1,117.2 (SD 144.5)	r = 0.288 (p = 0.013)

Discussion

The strength of the present study is that the PAPQ covers the four arenas of physical activity (9) and that we conducted 7 days of sensor registrations. In addition, the sensors record both body position and movement, and provide summary measures which are easily comparable to activity patterns and scores (PAL-values) from the PAPQ. Our power calculations estimated that fewer participants were needed than those from whom the data were obtained.

A limitation of the study is that wearing an activity monitor may have increased the awareness of physical activity, and therefore overestimated the results due to a more precise report of total physical activity levels in PAPQ (22). Additionally, as shown in other portable activity monitors, there may be errors and inaccuracies at the individual level (14,23). A general limitation of activity monitors is the inability to correctly assess upper body activities such as lifting and carrying (14,23). Hence, the sensor system may also underestimate physical activity and energy expenditure of common daily activities.

Validation studies are often time consuming and involve considerable cooperation from the participants. Hence, participants may be more likely to have an interest and engagement in physical activity than non-participants. In the present study, the physical activity level of the participants was relatively high, as more than 79% reported to exercise regularly in the third trimester. Regular exercise was defined as vigorous recreational physical activity at least 20 minutes once a week. In comparison, a previous study of pregnant women in Norway (9), found that 45% were exercising regularly by late gestation, and that only 10% met the current American College of Obstetricians and Gynecologists guidelines (3). Hence, in the present study, about 23% were following the exercise recommendations. However, across several characteristics (age, marital status, working status, daily smokers, common pregnancy complaints), the present sample appears to be fairly similar to other pregnant women in Oslo, Norway (9,10).

To date, few research groups have used motion sensors to assess physical activity level during pregnancy (24–26) and as far we have ascertained, only two published studies have compared outcome variables from a physical activity questionnaire with a portable activity monitor in pregnant women (7,22). We used the ActiReg® system, developed in Norway, and similar validation coefficients were observed. The study of Schmidt et al. (22) showed that the r-values were homogeneous across the pregnancy trimesters, but varied considerably assessing domain specific activity, with the highest

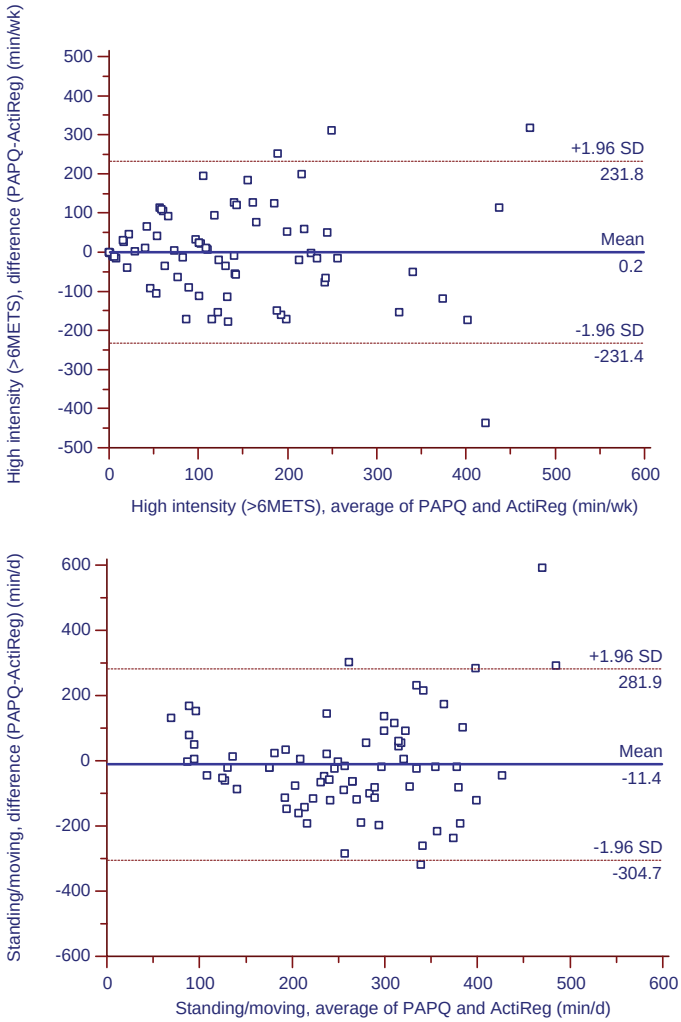

Figure 1. Bland–Altman plot showing the difference among high intensity activity (> 6 METS), standing/moving (minutes) and sitting/lying (minutes) plotted against the mean of the two estimates, assessed with PAPQ and measured with ActiReg. (——) mean difference between the two methods; (– – –) limits of agreement (SD2).

Spearman correlations for sport/exercise and vigorous activity (r = 0.12–0.51). These findings are supported by the study of Chasan-Taber et al. (7), showing correlation coefficients ranging from 0.08 to 0.43 for total activity, 0.25 to 0.34 for vigorous activity, 0.20 to 0.49 for moderate activity and −0.08 to 0.22 for light intensity activity. Our estimates for the validity of the PAPQ in this sample of pregnant women are comparable with Smith et al. (22) and slightly higher than those observed for the PPAQ by Chasan-Taber et al. (7).

Except for the time spent in exercising and sedentary activities, the PAPQ reported less time spent in the two lower MET intensities and standing compared with the sensors. Many of the low intensity activities may be hard to remember and

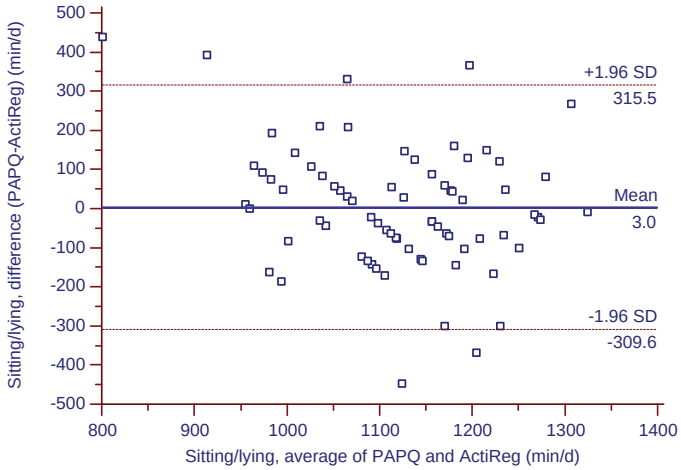

Figure 1. (Continued).

are often carried out routinely with no reflection of time and intensity (household and child-care activities) (27). Additionally, over-reporting of time spent in exercise activities is common and may have occurred (5).

The ActiReg® system registers the combination of body position and movement every second and covers all waking hours. However, in its present form, it may miscalculate total physical activity level in very active persons, and it is not well adapted to cover high to very high intensity exercise activities (14). For example, running, uphill walking, swimming, weight lifting and activities involving arm-work are not properly accounted for (14). Combining the sensor with a heart rate monitor may improve the results for individuals with high to very high activity levels (14). However, several studies have shown that the majority of women are not very active during pregnancy (9,12,28,29). The participants in the present study demonstrated a moderate physical activity level, with a group mean PAL-value of 1.59 and 1.58 using ActiReg® and PAPQ registrations, respectively. Hence, the sensors may be well suited to measure physical activity levels in pregnant women.

To date, there seems to be consensus that no single assessment device adequately measures total physical activity level (30). Different methods have varying strengths and limitations, and used together, they may compliment one another. Self-reporting seems to be the only method to assess context and type of physical activity. The strength of the sensors is the registration of time spent in different physical activity levels, defined according to three MET intensities and in the two main activity positions (standing/moving and sitting/lying). Hence, multiple assessments, such as motion monitoring along with physical activity questionnaires, may be needed to give detailed information on total physical activity level.

Conclusions

The PAPQ provided a close estimate of total physical activity level and was concurrent with the ActiReg® system in classifying the participants as sufficiently or insufficiently physically active. Additionally, we found that PAPQ correctly grouped the participants according to current exercise guidelines. However, as questionnaires and portable activity monitors measure different aspects of physical activity, there may be several advantages in combining these two instruments for the registration of physical activity level during pregnancy.

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PAPER IV

Effect of regular exercise on prevention of excessive weight gain in pregnancy

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Exercise to prevent weight gain in pregnancy

The results of the present study do not have any competing interests or financial disclosure.

Abstract

Purpose: The aim of the present study was to assess whether a 12-week supervised exercise-program plus advice of 30 minutes of moderate self-imposed physical activity on the non-supervised week days could prevent excessive weight gain in pregnancy, as well as postpartum weight retention. **Methods:** 105 sedentary, primiparous women, mean age 30.7(±4.0) years, pre-pregnancy BMI (kg/m^2) 23.8 (±4.3) were randomized to either an exercise group (EG, n=52) or a control group (CG, n=53). The exercise program consisted of supervised aerobic dance and strength training for 60 minutes, performed at least twice per week for a minimum of 12 weeks. In addition, the EG was asked to include 30 minutes of moderate self-imposed physical activity on the remaining week-days. Primary outcome measures were maternal weight gain (kg) and the proportion of women exceeding the Institute of Medicine (IOM) recommendations (2009). Secondary outcomes were skin-fold thickness and postpartum weight retention. Differences between the two groups were tested using independent sample and X^2-tests. The principal analysis was done on an intention to treat basis (ITT). The assessor was blinded to group allocation. **Results:** Drop-out rates were 19.2% and 20.8% in the EG and CG, respectively. The EG participated in mean 17.0 (± 12.5) out of a possible 24 exercise sessions. Fewer women in the EG than the CG exceeded the IOM recommendations, however a between-group significance was found only between CG and EG particpants attending 24 exercise sessions (p=0.006). In addition, only EG women attending 24 exercise sessions (n=14) reduced maternal weight gain (kg) (11.0±2.3 vs. 13.8±3.8, p<0.01) and postpartum weight retention (kg) (0.8±1.7 vs. 3.3±4.1, p<0.01), compared to the control group. **Conclusion:** Regular attendance to aerobic dance exercise can significantly reduce excessive maternal weight gain.

Key Words: adherence, aerobic exercise, obesity, overweight, randomized controlled trial

Introduction

Paragraph nr 1 Obesity is a significant health problem in the Western World, and the known risks of morbidity associated with being overweight - such as coronary heart disease, diabetes, breast and colon cancer - emphasise prevention of weight gain an important public health issue (26,38). Pregnancy is a risk period for significant weight gain in women, and maternal weight gain greater than that recommended by the Institute of Medicine (IOM) seems to be an important contributor to later obesity among women (15,30).

Paragraph nr 2 Excessive weight gain during pregnancy is a risk factor for hypertension, gestational diabetes, pre-eclampsia, macrosomia, stillbirth and delivery complications (12,32). In a recent study Haakstad et al (16) found that 32% of normal weight women (pre-pregnancy BMI≤ 26) and 51% of the overweight women (pre-pregnancy BMI > 26) gained more weight during pregnancy than current recommendations. This is in accordance with new data of US women, which showed that approximately 40% of normal-weight and 60% of overweight women gained excessive weight during pregnancy (9).

Paragraph nr 3 Currently, the recommendation for all healthy pregnant women is to be physically active at a moderate intensity for a minimum of 15 minutes, 3-5 times a week (1,40). Randomized controlled trials (RCTs) generally support that physical activity and exercise are important to enhance weight loss and prevent weight regain in the general adult population (21,33). However, the effect of exercise during pregnancy on maternal weight gain is still unclear. A recent Cochrane review found no difference in maternal weight gain between exercisers and non-exercisers (24). This is in agreement with the systematic reviews of Siega-Riz et al (35) and Birdsall (8), both concluding that few studies have examined exercise as a determinant of maternal weight gain. These authors emphasized the need for

high quality RCTs in this area. The authors listed limitations of the previous trials to include small sample sizes, lack of randomization, high drop-out rates and non-blinding of assessors.

Paragraph nr 4 The research hypothesis of the present study was: Regular attendance at aerobic dance exercise twice a week and unsupervised moderate physical activity on the remaining week-days can significantly reduce excessive maternal weight gain in previously inactive pregnant women. The 0-hypothesis was: There are no differences in excessive maternal weight gain between previously inactive pregnant women attending regular aerobic dance exercise and unsupervised moderate physical activity on the remaining week-days and controls.

Methods

Design

Paragraph nr 5 This study was an assessor blinded randomized controlled trial to evaluate the effects of a 12-week exercise program including 60 minutes of supervised aerobic dance performed at least 2 times per week, plus advice to conduct 30 minutes of moderate self-imposed physical activity on the remaining week-days, on weight gain in primiparous pregnant women.

Participants

Paragraph nr 6 Participants were recruited via health practitioners (physicians, midwives), articles and advertisement in newspapers, websites for pregnant women, flyers and word of mouth. Interested women telephoned or mailed the principal investigator (LH). At the first phone contact, the aims and implications of the study were explained and the eligibility criteria checked. Primiparous women whose pre-pregnancy exercise levels did not include participation in a structured exercise program (> 60 minutes once per week), including brisk walking (>120 minutes per week) for the past six months, were eligible for the trial. Other inclusion criteria were ability to read, understand and speak Norwegian, and to be within their first 24 weeks of pregnancy. Exclusion criteria were severe heart disease, pregnancy induced hypertension, history of more than two miscarriages, persistent bleeding after week 12 of gestation and poorly controlled thyroid disease, pre-eclampsia and other diseases that could interfere with participation (5). In addition, all women not able to attend weekly exercise classes were ineligible.

Paragraph nr 7 We aimed to recruit 50 women in each group, giving 85% power and alfa=5% to detect a standardized difference in maternal weight gain of 0.6. Assuming that the

standard deviation of weight gain was 5 kg, the actual weight gain had to be Δ= 3 kg. These figures were conservatively based on findings in a previous study (16). The participants came from the city of Oslo. In total, 105 women were recruited to the trial from September 2007 to March 2008. All follow-up procedures were completed by November 2008. There was no financial compensation to the participants. Figure 1 illustrates the flow chart, including drop-outs and reasons for withdrawals. Some women who did not meet for assessment after the intervention, met at the postpartum examination.

Paragraph nr 8 All participants gave written consent to participate and the procedures followed the World Medical Association Declaration of Helsinki. The project was approved by The National Committee for Medical Research Ethics, Southern Norway, Oslo, Norway (reference number S-05208). The Norwegian Social Sciences Data Services (NNT) provided licence to store and register individual health information (reference number 17804/2/KH). The study is listed in the ClinicalTrials.gov Protocol Registration System (NCT00617149).

Randomization

Paragraph nr 9 An independent person not involved in the assessment nor exercise classes, assigned the participants to either an exercise group (EG) or a control group (CG) following a simple (not block) computerised randomization program. The women were not stratified by BMI before randomization. The participants were requested not to reveal group allocation to the principal investigator (LH). The principal investigator was not involved in training the women and was blinded to group allocation while assessing the outcome measures, plotting and analyzing the data.

Exercise program

Paragraph nr 10 The exercise program consisted of supervised exercise for 60 minutes, performed at least twice a week, for a minimum of 12 weeks. In addition, the women had the opportunity to participate in aerobic dance exercise classes three times a week. Since most participants were working full time, the exercise groups were arranged in the evening. Each session started with 5 minutes warm up, followed by 35 minutes of aerobic dance, including cool down. This was followed by 15 minutes of strength training with a special focus on the deep abdominal stabilization muscles (internal oblique and the transverse abdominal muscle), pelvic floor and back muscles. The last 5 minutes included stretching, relaxation and body awareness exercises. The aerobic dance routine included low impact exercise (no jumping or running) and step training. Step length and body rotations were reduced to a minimum, and crossings of legs and sharp and abrupt changes of position were avoided. The exercise-program followed the ACOG exercise prescription (1), and all aerobic activities were performed at moderate intensity measured by ratings of perceived exertion at 12-14 (somewhat hard) on the 6-20 Borg's rating scale (1). The exercise program was choreographed and led by certified aerobic instructors, and each session included a maximum of 25 participants.

Paragraph nr 11 In addition to joining the scheduled aerobic classes, all women in the EG were asked to include 30 minutes of moderate self-imposed physical activity on the remaining week-days. They were also advised to incorporate short bouts of activity into their daily schedules (e.g. walk instead of drive short distances and to use stairs instead of elevators). Adherence to the exercise classes was controlled by the instructors, and the self imposed daily activity was registered in a personal training diary. Control participants were asked to continue their usual physical activity habits and were neither encouraged nor discouraged

from exercising. To obtain information about the PA habits in the CG, the CG underwent the same follow-up questions about PA and exercise after the intervention period as the EG. This was also done to ensure that the primary investigator was “blind” to the treatment received. The CG did not complete a training diary.

Outcome measure

Paragraph nr 12 The participants were examined three times during the study period. The first visit was between 12 and 24 weeks of gestation (baseline test), the second at week 36-38 (after the intervention) and the last 6-12 weeks after delivery (postpartum test). Each visit lasted about 60-75 minutes. The main outcome measures were maternal weight gain (kg) and the proportion of women exceeding the IOM recommendations (19). Maternal weight gain was defined as the difference between self-reported pre-pregnancy weight and the weight measured after the intervention period (pregnancy week 36.6 ±0.95). Height (m) and body weight (kg) were measured in light clothing and without shoes using a digital beam scale. Classification of maternal weight gain and pre-pregnancy BMI (kg/m^2) was done according to recommendations from the Institute of Medicine (19): 12.7-18.2 kg weight gain for underweight women (pre-pregnancy BMI<18.5), 11.4-15.9 kg weight gain for normal weight women (pre-preg BMI of 18.5- 24.9), 6.8-11.4 kg weight gain for overweight women (pre-preg BMI of 25.0-29.9) and 5.0-9.1 kg weight gain for obese women (pre-preg BMI≥30). In the present study, two women had a pre-pregnancy BMI<18.5 and 11 women had a pre-pregnancy BMI ≥30. These women were classified as either normal weight or overweight, and corresponding weight gain recommendations were used in the statistical analysis (28,29).

Paragraph nr 13 Secondary outcome measures were the mean of skin-fold thickness and the womens’ postpartum weight retention (kg). Skin-fold thickness was assessed by Holtain

Caliper (Holtain Ltd., Crymych, UK), measuring left side skinfold thickness of the triceps, abdomen and thigh. Each measurement was done twice and held for 5-10 seconds. A mean value of the two was computed. If the two skinfold assessments differed by more than 2 mm, the skinfold was measured a third time and the mean of the three values was calculated (17). Postpartum weight measured at the postpartum test was compared with self-reported pre-pregnancy weight to compute weight retention.

Paragraph nr 14 Other pregnancy data were obtained from a maternity card and interviews with the participants. The baseline questionnaire covered demographic information (e.g. age, pregnancy week, smoking habits, education, occupation), assessment of daily life, physical activity and sedentary behaviour (at work, transportation and household). The questionnaire has been validated with a portable activity monitor (ActiReg®, PreMed AS, Oslo, Norway) with acceptable results in a pregnant population (Haakstad et al, submitted to Acta Obstetrica et Gynecologica Scandinavia). In addition, pregnancy complications such as pelvic girdle and low back pain, urinary and fecal incontinence, high blood pressure, pre-eclampsia, nausea and fatigue were recorded (16).

Statistical analysis

Paragraph nr 15 The principal analysis was done on an intention to treat basis (ITT). Missing values were replaced with the mean value (maternal weight gain) or the percentage change in the mean value (skinfold thickness and weight postpartum) in the EG and CG, respectively. Average maternal weight gain was compared between the two groups and the possible difference was tested using a two-sided independent sample t-test. The group differences in proportion of participants gaining weight above the IOM guidelines was tested by using two-sided X^2-test. Spearman's rho was used for correlations on ordinal scaled variables.

According to Irwin et al (20), per protocol analysis was based on adherence to ≥ 80% of the recommended exercise sessions (≥19 exercise sessions). In addition, we compared women attending 24 exercise sessions (exercise twice a week) with the CG. Level of statistical significance was set at $p<0.05$.

Results

Paragraph nr 16 One hundred and five primiparous women were randomized to EG (n=52) or CG (n= 53). The majority of the participants were from Norway (n=94). The remaining were from Sweden, Burundi, Chile, Iran, Poland, Russia and Uganda. There were no statistically significant differences in background variables between the EG and CG prior to the intervention, at mean gestation week 17.7 (±4.2) (Table 1).

Paragraph nr 17 Ten women in the EG (19.2%) and 11 women in the CG (20.8%) were lost to the test after the intervention. Two were excluded due to twin birth and poorly controlled thyroid disease after the first assessment. Other drop-outs (n=11) were primarily due to pregnancy-related diseases (Fig 1).

Paragraph nr 18 Mean adherence rates are based on registrations done by the aerobic instructors and all the women in the EG. However, four women never showed up and one woman was excluded because of twins. Hence, the mean adherence to the exercise classes was 17.0 (± 12.5) out of 24 prescribed exercise sessions, with 21 women (40.4%) attending to ≥ 80% of the recommended exercise sessions (≥ 19 supervised exercise sessions). The remaining 31 women (59.6%) participated in less than 80% of the exercise sessions. Fourteen women had 100% exercise adherence and completed two exercise sessions per week with a total of 24 exercise sessions. Adherence to exercise classes was not associated with pre-pregnancy BMI. Sixty-two percent of the EG returned their training diaries and reported daily minutes with physical activity and exercise. Excluding low intensity activity and the scheduled aerobic classes, the results showed a mean weekly exercise time of 90 minutes (±73) of moderate exercise, with sixteen women (30.8%) following the pregnancy exercise guidelines of a minimum of 15 minutes moderately intense exercise, 3-5 times a week. In

addition to participation in the aerobic exercise classes, walking was the most common exercise mode, followed by cross-country skiing, bicycling, strength training, swimming and aerobic dance. Adherence to the exercise protocol was not affected by commonly reported pregnancy complaints such as nausea, fatigue, urinary incontinence, pelvic-girdle pain or low-back pain.

Paragraph nr 19 Eighteen of 53 women (34%) in the CG reported to have started to exercise regularly, defined as moderately intense recreational physical activity of at least 20 minutes duration once per week, after the baseline test. Six CG women were exercising at moderate intensity ≥ 2 times per week for 60 minutes, which was the prescribed intervention dosage for the EG. None of the exercises performed by the CG were supervised as opposed to the EG.

Maternal weight gain

Paragraph nr 20 At the completion of the intervention (pregnancy week 36.6 ± 0.95), no difference in maternal weight gain (kg) was seen between the EC and the CG. Women attending 24 exercise sessions reduced maternal weight gain compared to women attending less exercise sessions and compared to the CG. Table 2 summarizes the results of maternal weight gain of the ITT, per protocol analysis and analyzes of women attending 24 exercise sessions. Analysing the data, excluding the women who exercised regularly in the CG (n=6) did not change the ITT results. EG, *n=52*: (13.0 ±4.0) and CG, *n=47*: 13.9 ±3.5 (p=0.21).

IOM recommendations

Paragraph nr 21 As shown in Table 3, the proportion of women gaining more weight than recommended by the IOM did not differ between the EG and CG. No women attending 24 exercise sessions exceeded the IOM recommendations.

Paragraph nr 22 Analyses of pre-pregnancy BMI categories and weight gain after the intervention period showed a significant difference between EG and CG among normal weight women attending all 24 exercise sessions, only ($p<0.01$). In both groups, there was a trend towards pre-pregnancy overweight women (BMI≥25) gained less weight than normal weight women (BMI<25) ($p=0.06$).

Skin-fold thickness

Paragraph nr 23 At baseline, measures of skin-fold thickness from 9 women were not taken. Four participants were uncomfortable with the measurements and 5 women were overweight or obese, and estimation of skin-fold thickness of the thigh was not done due to the limitation of the size of the caliper. After the intervention period, mean of skin-fold thickness at 3 sites did not differ between the EG (from 23.17 ± 5.14 to 22.97 ±4.82) and CG (from 23.23 ± 5.48 to 23,50 ± 5.55) ($p=0.38$). Per protocol and analysis of attendance to all 24 exercise sessions did not change the ITT results.

Postpartum weight retention

Paragraph nr 24 Postpartum weights were available for 90 of the 105 women (85.7%). According to ITT analysis, mean postpartum weight was 71.1 kg (± 11.9) and 71.7 kg (±14.4), and mean weight retention was 3.3 kg (±3.9) and 3.3 kg (±4.1) ($p=0.93$) in the EG and CG, respectively. The results were statistically significant when comparing women attending 24 exercise sessions (0.8 kg ± 1.7) with the CG, only (3.3±4.1) ($p=0.001$). Weight gain during pregnancy was positively correlated with weight retention in the EG ($r=0.60$, $p<0.001$) and CG ($r=0.75$, $p<0.001$), respectively. The average postpartum weight loss was similar in both groups, ranging from 10.1 kg to 11.9 kg, with no effect of pre-pregnancy BMI

category or group allocation. Removing infant birth weight to assess the amount of weight change attributed to maternal body weight did not change the overall results, nor did adjusting for numbers of weeks postpartum.

Paragraph nr 25 No side effects or injuries of the exercise program were reported. One women in the CG gave birth <37 pregnancy week. There were no reports of misfalls, including spontaneous or missed abortions in either group during this study.

Discussion

Paragraph nr 26 Only women attending the prescribed exercise program significantly reduced maternal weight gain compared to the control group. No women attending 24 exercise sessions exceeded the IOM weight gain recommendations. Weight retention 6-8 weeks postpartum was also significantly lower in women attending 24 exercise classes. The difference between the groups in mean of skin-fold thickness was not statistically significant.

Paragraph nr 27 Results from previous trials evaluating exercise during pregnancy and maternal weight gain are inconsistent and comparisons of results are difficult due to use of different designs, study populations, measurement methods to assess maternal weight gain and dosage of the exercise program. In addition, previous trials using supervised exercise have focused on primary outcome measures other than maternal weight gain e.g. maintenance of fitness, fetoplacental growth and low back pain (10,11,13,14,22,27). In the few intervention studies with maternal weight gain as the main outcome measure, there are only two RCTs and the focus in these has been on lifestyle counselling and combining diet and exercise, rather than supervised training (6,29). Hence, as far as we can ascertain this is one of the first RCTs where the primary outcome was to investigate the effect of a supervised structured exercise program and self-imposed physical activity according to ACOG guidelines (1) on maternal weight gain.

Paragraph nr 28 Strengths of the present study were use of a randomized controlled design, blinding of the assessor, and use of a standardized exercise program following ACOG recommendations (1). In addition, this study was based on power calculations from a previous study (16) and applied clinical outcome measures. The particpants' adherence to the exercise protocol was monitored both by the instructors and via recordings in a training diary. A

limitation of the study is that ten women in the EG (19.2%) and 11 women in the CG (20.8%) were lost to follow- up immediately following the intervention. In addition, unfortunately only 40% in the EG attended the recommended exercise sessions. Moreover, information on dietary habits that could potentially affect maternal weight gain was not collected, although the observed association is weak and the IOM emphasizes the complexity of identifying changes in energy intake in pregnant women (18).

Paragraph nr 29 The present RCT had withdrawals and drop-outs. Hence, missing data due to participants` refusal to complete outcome assessments and missed appointments of 20% may have reduced the power of the study and the ability to draw clear conclusions. Imputation techniques can never compensate for or exactly reproduce missing data. On the other hand, the possible bias associated with the drop-outs were probably minor, because there was only small difference in reasons for or drop-out rates between the EG or CG. In addition, there were no statistically significant differences in background variables between the EG and CG prior to the intervention, at mean gestation week 17.7 (SD 4.2).

Paragraph nr 30 As recommended by Armijo-Olivo et al (4), we also performed "per protocol" analyses (≥ 80% of the recommended exercise sessions) and analyses of "women attending 24 exercise sessions". This type of analysis may provide an answer to the efficacy of the treatment, but on the other hand may also overestimate the effect size due to selection bias, meaning that those exercising as prescribed may differ from those who did not. Hence, conclusions from the "per protocol" analysis cannot be generalized to other pregnant women or settings.

Paragraph nr 31 According to the current exercise guidelines, pregnant woman are encouraged to exercise moderately 3-5 times a week (1,31,40). We assumed that it was easier

to recruit and achieve high adherence with an exercise program 2 days a week in a group of previously sedentary women. However, all women in the EG had the opportunity to attend three exercise classes per week. Additionally, the EG was asked to include 30 minutes of moderate self-imposed PA on the rest of the week-days e.g. brisk walking. Unfortunately, we have no data whether they fulfilled the criteria of 30 min of PA a day, as only few reported adherence in their exercise diaries. In the general adult population 60 minutes of daily moderate intensity activity is needed to prevent unhealthy weight gain (37). Hence, higher levels of PA than recommended in this RCT may be necessary to prevent excessive weight gain also in pregnancy.

Paragraph nr 32 Certified aerobic instructors were leading the class, gave instructions on intensity and emphasized the importance of adherence to the exercise protocol. Despite this, only 40% attended the recommended exercise sessions. Why the women in the present study did not adhere is difficult to understand, and information on the reason for the low participation rate is not available. A fitness class of 60 minutes prescribed twice a week, including endurance training of 40 minutes may be considered demanding. Thus, the sedentary women being the target group for this study may have been less motivated to adhere to this specific program. In addition, finding time to exercise is vital if an exercise program is to be adhered to. Even though the exercise groups were arranged in the evenings, previously sedentary women may have had problems with getting into a weekly exercise routine. Previous studies in sedentary pregnant women have also reported low adherence to the exercise program or not reported it at all (7,25,27). In addition, the interviews after the intervention period revealed that some women in the CG had started regular exercise after the baseline test. This type of bias has been referred to as the “Avis effect” (36). Low adherence in the EG and increased physical activity level in the CG may have confounded our findings and

resulted in a minimised difference in maternal weight gain between the two groups than expected.

Paragraph nr 33 Clapp et al (11) demonstrated a positive effect of exercise on reducing maternal weight gain, with women gradually increasing the exercise volume to 60 minutes/5 days per week, weighing less than women with moderate or low exercise regimes at late pregnancy. The exercise volume of our study was lower than in the study of Clapp (11), suggesting that a less demanding exercise program may be effective for previously sedentary women. Both studies focused on weight-bearing moderate intensity exercise of about 60 minutes, which have higher energy costs than other mode of activities (e.g. cycling) and exercise of less duration and intensity. The moderate intensity of the exercise classes in the present study, followed the ACOG guidelines (1) and can easily be achieved in most aerobic classes or by walking briskly. However, the present study showed that it is difficult to motivate former sedentary women to fulfil the ACOG exercise recommendations. Hence, further studies on adherence strategies to improve compliance in a pregnant population are warranted.

Paragraph nr 34 Excessive weight gain during pregnancy is a significant predictor of long term weight gain (23,30). In the present study weight retention 6-8 weeks postpartum was significantly lower in women attending 24 exercise classes. These women also had lower maternal weight gain. Six weeks postpartum may be too soon to study the impact of exercise during pregnancy on long term weight change. Early postpartum weight loss mainly represents loss of non-adipose tissue, including loss of placenta, amniotic fluid and maternal blood volume (30) . Whether an EG would continue to exercise and thus control their weight in the long term, remains to be investigated. There is some evidence that participants of

interventions tend to return to old habits (3,34,39). Hence a long term follow-up of the participants is now being planned.

Paragraph nr 35 RCT's are time consuming and involve cooperation from the participants. Hence, pregnant women who volunteer for a study on exercise and maternal weight gain may have an interest and be more attentive to these aspects than non-participants. The pregnant women in this study were healthy primiparous with a high educational level. Hence, the results can only be generalized to this group.

Paragraph nr 36 In conclusion, only women in the EG attending to 24 exercise sessions of moderate intensity during 2nd and 3rd trimester of pregnancy, reduced maternal weight gain, and non exceeded the IOM recommendations compared to the CG. Further studies on the effect of adherence strategies to enhance motivation for regular participation in general fitness classes during pregnancy are warranted.

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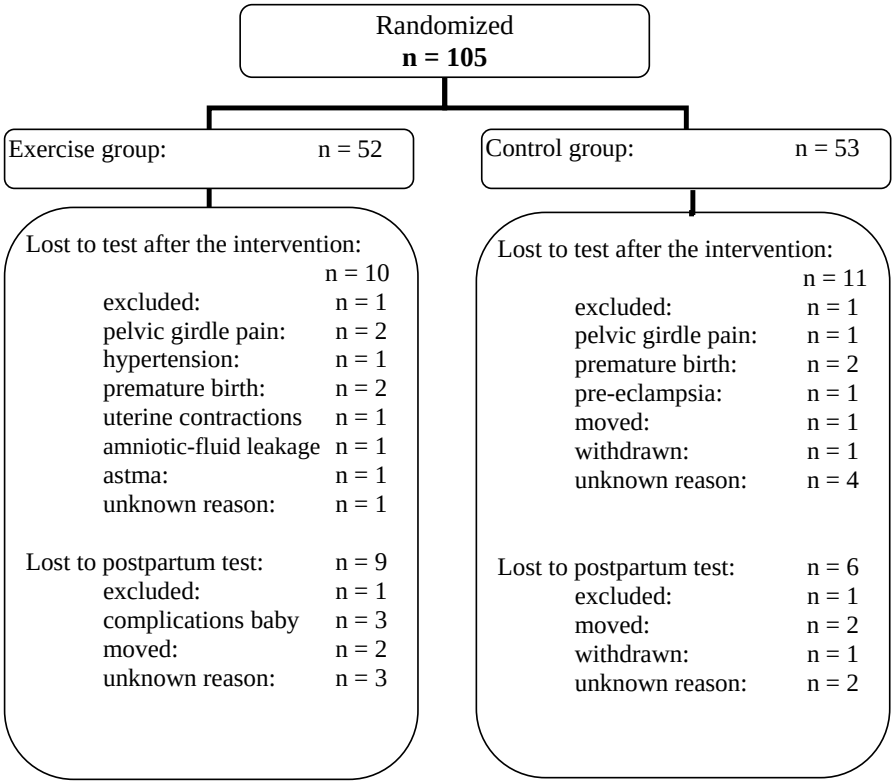

FIGURE 1. Trial profile showing the flow of participants through the randomized controlled trial

TABLE 1. Background variables in the exercise and control groups. Means with standard deviation (SD) and N (%) (n=105). No statistically significant differences between groups at baseline

Detail	Exercise n= 52		Control n= 53	
Age	31.2	(3.7)	30.3	(4.4)
Gestational wk	17.3	(4.1)	18,0	(4.3)
Married/living together	51	(98.1)	52	(98.1)
College/university education	44	(84.6)	45	(84.9)
Sedentary occupations	37	(71.2)	36	(67.9)
Sicklisted	10	(19.2)	13	(24.5)
Daily smokers	2	(3.8)	1	(1.9)
Pregnancy complaints	20	(38.5)	20	(37.7)
Height (m)	1.69	(0.1)	1.69	(0.1)
Pre-preg weight (kg)	67.9	(11.4)	68.4	(14.6)
Weight (kg)*	71.8	(11.4)	72.7	(14.3)
Pre-preg BMI (kg/m^2)	23.8	(3.8)	23.9	(4.7)
Pre-preg BMI≥25	13	(25.0)	14	(26.4)

* At baseline test, pregnancy weight was measured using a digital beam scale

TABLE 2. Maternal weight gain during pregnancy in the exercise and control groups (mean and SD), analyzed by intention to treat (ITT), per protocol (≥80% of exercise sessions) and analyses of attendance at 24 exercise sessions

	ITT –analysis			
	Exercise (n= 52)	*Control (n=53)*	*Difference (kg)*	*p-value*
Maternal weight gain (kg)*	13.0 (4.0)	13.8 (3.8)	0.8	0.31
	Per protocol analysis			
	Exercise (n= 21)	*Control (n=53)*	*Difference (kg)*	*p-value*
Maternal weight gain (kg)	12.5 (4.2)	13.8 (3.8)	1.3	0.23
	Attendance at 24 exercise sessions			
	Exercise (n= 14)	*Control (n=53)*	*Difference (kg)*	*p-value*
Maternal weight gain (kg)	11.0 (2.3)	13.8 (3.8)	2.8	0.01

* Maternal weight gain based on weight measured after the intervention (pregnancy week 36.6 ± 0.95) minus self reported pre-pregnancy weight at last menstrual bleeding

TABLE 3. Institute of Medicine (IOM) categories of maternal weight gain after the intervention in the exercise and control groups (N and %), analyzed by intention to treat (ITT), per protocol (≥80% of exercise sessions) and analyses of attendance at 24 exercise sessions

	ITT–analysis		
	Exercise (n= 52)	*Control (n=53)*	*p-value*
Exceeded IOM recommendations	17 (32.7)	20 (37.7)	p=0.59
Within IOM recommendations	35 (67.3)	33 (62.3)	
	Per protocol analysis		
	Exercise (n= 21)	*Control (n=53)*	
Exceeded IOM recommendations	4 (19.0)	20 (37.7)	p= 0.12
Within IOM recommendations	17 (81.0)	33 (62.3)	
	Attendance at 24 exercise sessions		
	Exercise (n= 14)	*Control (n=53)*	
Exceeded IOM recommendations	-	20 (37.7)	p=0.006
Within IOM recommendations	14 (100)	33 (62.3)	

APPENDIX 1:

Approval letters from the Regional Committees
for Medical Research Ethics

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

To whom it may concern

Regional komité for medisinsk forskningsetikk
Sør- Norge (REK Sør)
Postboks 1130 Blindern
NO-0318 Oslo

Telefon: 228 44 666
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Dato: 14.12.06
Deres ref.:
Vår ref.: S-01191 - approval

Title of protocol:

S-01191 Maternal metabolic syndrome, macrosomic newborn and pregnancy complications

Principal investigator: Chief physician dr.med. Tore Henriksen, Rikshospitalet.

The protocol was reviewed and approved by The Regional Committee for Medical Research Ethics, Southern Norway, Oslo, Norway, on 30 August 2001.

Sincerely yours

Kristian Hagestad
Fylkeslege cand.med., spes. i samf.med
Chairman

Jørgen Hardang
Secretary

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

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Dato: 20.06.2005
Deres ref.:
Vår ref.: S-05208

S-05208 **Graviditet, fysisk aktivitet og overvekt - Et randomisert, kontrollert treningsforsøk (RCT) som ser på effekt av moderat, regelmessig fysisk aktivitet for stabilisering av vekt hos overvektige gravide**

Komiteen behandlet søknaden i sitt møte torsdag 16. juni 2005.

Komiteen har følgende merknader til prosjektsøknaden:

1. Pkt 10: På hvilken måte skulle man kunne tilby behandling (trening) til placebogruppen dersom behandlingen virker fordelaktig ettersom dette ikke er mulig, da endepunktene er blant annet knyttet til svangerskapsutfallene, dvs. at det ikke lenger er mulig å intervenere for de kvinnene som allerede har født? Komiteen har ikke etiske motforestillinger til designet, så lenge det ikke er vitenskapelig vist at trening har noen positiv effekt på de parametrene en ønsker å måle.
2. I punkt 10 opplyses det om jordmorstipendiat på Ullevål Universitetssykehus, menes det Rikshospitalet, siden studien utgår derfra?
3. Pkt 8: Det er uklart hvilket primært endepunkt statistikken er beregnet ut fra. Er dette en pilotstudie der utfallsvariasjonen er ukjent, slik at det derfor er vanskelig med styrkeberegning på forhånd? Menes det BMI>25 (ikke bare de med BMI=25), og alder <40 år (ikke bare førstegangsfødende som =40 år, hvilket det ville være vanskelig å rekruttere nok av)?

Komiteen har følgende merknader til informasjonsskrivet:

1. Forkortelse som UiO bør forklares.
2. Informasjonsskrivet informerer ikke om at ikke alle kvinner får tilbud om enten Actireg eller trening. Er det korrekt at kun 50 gravide får Actireg-tilbud, mens det er kun 100 kvinner med overvekt (BMI>25 før svangerskapet) som får tilbud om treningsforsøket?
3. Vil dette skjemaet kun gå til kvinner som allerede har samtykket til å delta i STORK-undersøkelsen? I så fall bør dette komme klarere frem.
4. Det er ikke informert om 6-ukers postpartumkontroll som er angitt på side 6 i prosedyreboken, denne informasjonen må inkluderes.
5. Det må angis tid for alle ekstraundersøkelsene som studien innebærer i forhold til dersom de ikke deltar.
6. Det må informeres om at de ikke behøver å delta i denne studien selv om de deltar i STORK-studien, hvis dette medfører riktighet.
7. Informasjonsskrivet opplyser at undersøkelse av fysioterapeut gjøres før og etter treningsintervensjonen. Det opplyses ikke om at det også spørres om urin- og avføringslekkasje ved samme anledninger, dette bør tas med i informasjonsskrivet.

Vedtak:
"Ved tilfredsstillende svar på merknader og revidert informasjonsskriv vil komiteen tilrå at prosjektet gjennomføres. Leder og sekretær tar stilling til dette ved ettersendt informasjon fra prosjektleder."

Med vennlig hilsen

Sigurd Nitter-Hauge
Professor dr.med.
Leder

Tone Haug
Rådgiver
Sekretær

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Dato: 20.02.2006
Deres ref.:
Vår ref.: S-05208

S-05208 **Graviditet, fysisk aktivitet og overvekt - Et randomisert, kontrollert treningsforsøk (RCT) som ser på effekt av moderat, regelmessig fysisk aktivitet for stabilisering av vekt hos overvektige gravide**

Vi viser til e-post 09.08.05 med vedlegg: revidert informasjonsskriv og samtykkeerklæring.

Komiteen tar svar på merknader til etterretning.

Komiteen har ingen merknader til revidert informasjonsskriv og samtykkeerklæring.

Komiteen tilrår at prosjektet gjennomføres

Vi ønsker lykke til med prosjektet!

Pga en inkurie har henvendelsen ikke blitt besvart tidligere.

Med vennlig hilsen

Kristian Hagestad
Fylkeslege cand.med., spes. i samf.med
Fungerende leder

Tone Haug
Rådgiver
Sekretær

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Dato: 12.09.2006
Deres ref.:
Vår ref.: S-05208

S-05208 **Graviditet, fysisk aktivitet og overvekt - Et randomisert, kontrollert treningsforsøk (RCT) som ser på effekt av moderat, regelmessig fysisk aktivitet for stabilisering av vekt hos overvektige gravide**

Vi viser til e-post 24.08.06 med vedlegg: revidert informasjonsskriv med samtykkeerklæring.

Komitéen har ingen innvendinger mot forslaget om å rekruttere fra et bredere inklusjonsområde slik det er beskrevet.

Komiteen har ingen merknader til revidert informasjonsskriv og samtykkeerklæring.

Vi ønsker fortsatt lykke til med prosjektet!

Med vennlig hilsen

Kristian Hagestad
Fylkeslege cand.med., spes. i samf.med
Fungerende leder

Jørgen Hardang
Sekretær

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Dato: 18.12.2007
Deres ref.:
Vår ref.: S-05208

S-05208 **Graviditet, fysisk aktivitet og overvekt - Et randomisert, kontrollert treningsforsøk (RCT) som ser på effekt av moderat, regelmessig fysisk aktivitet for stabilisering av vekt hos overvektige gravide**

Vi viser til e-post 30.11.07 fra Lene Anette Hagen Haakstad,med følgende vedlegg: prosedyrebok: Et randomisert, kontrollert treningsforsøk 2007 og Tredemølleprotokoll ved Testing av gravide.

Bruk av opplysninger fra helsekort for gravide godkjennes, forutsatt at kvinnene samtykker til dette.

Komiteen forutsetter at merknaden ovenfor tas til etterretning og godkjenner at prosjektet videreføres med de endringene som er beskrevet..

Med vennlig hilsen

Kristian Hagestad
Fylkeslege cand.med., spes. i samf.med
Fungerende leder

Jørgen Hardang
Sekretær

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Dato: 17.3.08
Deres ref.:
Vår ref.: S-05208

S-05208 **Graviditet, fysisk aktivitet og overvekt - Et randomisert, kontrollert treningsforsøk (RCT) som ser på effekt av moderat, regelmessig fysisk aktivitet for stabilisering av vekt hos overvektige gravide**

Vi viser til e-post av 18.2.08 fra Lene Anette Hagen Haakstad.

Inklusjon av informasjon om fødselsvekt og svangerskapsuke for fødsel godkjennes på vilkår av at kvinnene samtykker til registrering av slik informasjon.

Med vennlig hilsen

Kristian Hagestad
Fylkeslege cand.med., spes. i samf.med
Fungerende leder

Jørgen Hardang
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Dato: 1.4.08
Deres ref.:
Vår ref.: S-05208

S-05208 **Graviditet, fysisk aktivitet og overvekt - Et randomisert, kontrollert treningsforsøk (RCT) som ser på effekt av moderat, regelmessig fysisk aktivitet for stabilisering av vekt hos overvektige gravide**

Vi viser til e-post av 26.3.08 med følgende vedlegg: skjema for protokolltillegg og endringer og revidert informasjonsskriv med samtykkeerklæring.

Komiteen har ingen merknader til revidert informasjonsskriv med samtykkeerklæring.

Komiteen godkjenner at prosjektet videreføres med de endringer som er beskrevet i skjema for protokolltillegg og endringer.

Med vennlig hilsen

Kristian Hagestad
Fylkeslege cand.med., spes. i samf.med
Fungerende leder

Jørgen Hardang
Sekretær

APPENDIX 2:

Approval letters from the Norwegian Social Science Data Services

Datatilsynet

Rikshospitalet Universitetssykehuset
Kvinneklinikken
V/ Dr. med. Tore Henriksen
0027 OSLO

Deres ref	Vår ref (bes oppgitt ved svar)	Dato
	2001/4061-7 ACM/-	07.05.02

KONSESJON TIL Å BEHANDLE HELSEOPPLYSNINGER

Datatilsynet viser til Deres søknad av 16.01.2002 om konsesjon til å behandle helseopplysninger. Vi beklager den lange saksbehandlingstiden som skyldes tolkningstvil med hensyn til helseregisterlovens regler om konsesjonsplikt.

Datatilsynet har vurdert søknaden og gir Dem med hjemmel i helseregisterloven § 5, jf. personopplysningsloven § 33, jf. § 34, konsesjon til å behandle helseopplysninger til følgende formål: "STORK-prosjektet, maternelt metabolsk syndrom, store barn og svangerskapskomplikasjoner".

Konsesjonen er gitt under forutsetning av at behandlingen foretas i henhold til søknaden og de bestemmelser som følger av helseregisterloven med forskrifter, samt vedlagte merknader.

Dersom det skjer endringer i behandlingen i forhold til de opplysninger som er gitt i søknaden, må dette fremmes i ny konsesjonssøknad.

I medhold av helseregisterloven § 5, jf. § 36, jf. personopplysningsloven § 35, fastsettes i tillegg følgende vilkår for behandlingen:

1. Den databehandlingsansvarlige skal hvert tredje år sende Datatilsynet bekreftelse på at behandlingen skjer i overensstemmelse med søknaden og helseregisterlovens regler.
2. Det må søkes om ny konsesjon for oppbevaring av personopplysningene utover planlagt prosjektslutt, hvor behovet for slik oppbevaring begrunnes nærmere.

Med hilsen

Svein Engelschiøn (e f)
rådgiver

Ann-Cathrin Marcussen
rådgiver

Postadresse: Postboks 8177 Dep 0034 OSLO | Kontoradresse: Tollbugt 3 | Telefon: 22 39 69 00 | Telefaks: 22 42 23 50 | Org.nr: 974 761 467 | Hjemmeside: www.datatilsynet.no

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

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Lene A.H. Haakstad
Seksjon for idrettsmedisinske fag
Norges idrettshøgskole
Postboks 4014 Ullevål Stadion
0806 OSLO

Vår dato: 17.12.2007 Vår ref: 17804 / 2 / KH Deres dato: Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 30.10.2007. All nødvendig informasjon om prosjektet forelå i sin helhet 17.12.2007. Meldingen gjelder prosjektet:

17804	*Graviditet, fysisk aktivitet og overvekt*
Behandlingsansvarlig	*Norges idrettshøgskole, ved institusjonens øverste leder*
Daglig ansvarlig	*Lene A.H. Haakstad*

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/melding/pvo_endringsskjema.cfm. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/register/.

Personvernombudet vil ved prosjektets avslutning, 30.03.2009, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Bjørn Henrichsen

Kjersti Håvardstun

Kontaktperson:Kjersti Håvardstun tlf: 55 58 29 53
Vedlegg: Prosjektvurdering

Personvernombudet for forskning

Prosjektvurdering - Kommentar

17804

Prosjektleder beklager at prosjektet ikke ble meldt ved oppstart. Datainnsamlingen startet i juni 2006, og pågår fremdeles.

Personvernombudet finner at informasjonsskrivet til utvalget ikke inneholder opplysninger om at prosjektavslutning er planlagt til 30.03.2009 og at datamaterialet anonymiseres ved prosjektslutt, og slik sett ikke tilfredsstiller lovens krav til informasjon, jf. personopplysningsloven § 19 og merknader. Personvernombudet forutsetter at det er informert om tidspunkt for prosjektavslutning og anonymisering (jf. e-post fra prosjektleder 06.12.06), eventuelt at det gis supplerende informasjon til samtlige deltakere.

Det er beklagelig at prosjektleder har oppgitt til deltakerne at studien har konsesjon fra Datatilsynet, uten at den har vært meldt.

Personvernombudet forstår det slik at 14 pasienter ble rekruttert fra STORK-prosjektet ved Rikshospitalet, men at det ikke foregår noe samarbeid mellom de to prosjektene utover dette, jf. telefonsamtale 17.12.07. Ombudet forutsetter at taushetplikten ikke har vært til hinder for rekrutteringen av pasientene fra STORK-prosjektet.

Veileder Kari Bø og student Ingvild Gundersen, som skal skrive masteroppgave på en del av materialet fra ActiReg studien, vil ha tilgang til datamaterialet.

Datamaterialet anonymiseres ved prosjektslutt 30.03.2009 ved at verken direkte eller indirekte personidentifiserbare opplysninger fremgår. Koblingsnøkkelen og samtykkeerklæringer slettes/makuleres.

Prosjektet er tilrådd av Regional komité for medisinsk forskningsetikk, Sør-Norge.

APPENDIX 3:

Physical Activity and Pregnancy Questionnaire (PAPQ)

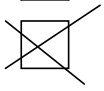
Kode _____

SPØRRESKJEMA OM GRAVIDITET OG FYSISK AKTIVITET

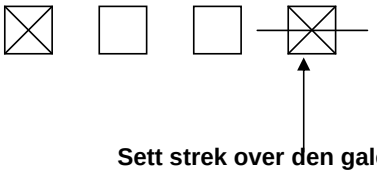
Vi vet for lite i dag om gravide kvinners aktivitets- og mosjonsvaner, og hva som gjør at noen er fysisk aktive og andre ikke. Ved å besvare dette spørreskjemaet bidrar du til å få frem nyttig kunnskap uansett om du er fysisk aktiv eller ikke. En liten oppfordring før du starter – vær ærlig. Her er det ingen riktige eller gale svar

Det tar ca 15 minutter å fylle ut skjemaet. Velg den svarkategorien som passer best for deg og sett kryss.

Marker slik: 

IKKE slik:  **eller** 

Dersom du markerer feil:



Sett strek over den gale markeringen

På forhånd takk for at du tar deg tid til å fylle ut skjemaet.

BAKGRUNNSOPPLYSNINGER

1. Alder: ☐ år

2. Svangerskapsuke: ☐

3. Hvilken sivilstand har du nå?

☐ Gift/samboer ☐ Enslig

☐ Skilt/separert ☐ Enke

4. Hva er din høyeste fullførte utdannelse?

☐ Grunnskole ☐ Høgskole/universitet inntil 4 år

☐ Videregående yrkesfaglig ☐ Høgskole/universitet mer enn 4 år

☐ Videregående allmennfaglig ☐ Annen utdannelse

5. Yrke/stilling: .....

6. Hvor stor stillingsprosent har du?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3.trimester)**
100%				
Mer enn 50%				
Mindre enn 50%				
Arbeidsledig				
Sykemeldt				
Jobber ikke (f.eks. student)				

7. Hvilken arbeidstid har du på nåværende tidspunkt?

☐ Fast dagtid ☐ Skiftarbeid eller turnusordning

☐ Fast ettermiddag/kveld ☐ Ingen fast ordning *(ekstrahjelp, vikar o.l.)*

☐ Fast nattarbeid ☐ Jobber ikke *(arbeidsledig, sykemeldt, student o.l)*

HELSE OG LIVSSTIL

8. Høyde: ☐ m

9. Vekt før graviditet: ☐ kg

10. Er du tilfreds med vektøkningen du har hatt så langt?

☐ JA ☐ NEI ☐ Vet ikke

11. Hvor mange kg har du lagt på deg? ☐ kg

12. Hvordan vil du karakterisere kostvanene dine?

	Svært bra	**Bra**	**Middels**	**Dårlig**	**Svært dårlig**
Før graviditet					
I dag					

13 a) Røyker du daglig?

☐ JA ☐ NEI

b) Hvis JA bes du svare så nøyaktig som mulig på antall sigaretter

..... pr. dag

c) Hvis NEI, har du røykt tidligere?

☐ JA ☐ NEI

d) Er du utsatt for passiv røyking hjemme eller på arbeid?

☐ JA ☐ NEI

14. Hvor ofte drikker du alkohol?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Sjelden eller aldri				
Mindre enn 1 gang per måned				
1-3 ganger per måned				
1 gang i uka				
Flere dager i uken				
Hver dag				

HELSEPLAGER

15 a) Har du problemer urin-lekkasje?

☐ JA ☐ NEI

b) Hvis JA, når skjer dette?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Når jeg er fysisk aktiv				
Når jeg hoster og/eller nyser				
Når jeg ler				
Ved sterk vannlatingstrang				

16 a) Har du problemer med å holde på luft eller avføring?

☐ JA ☐ NEI

b) Hvis JA, når skjer dette?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Når jeg er fysisk aktiv				
Når jeg hoster og/eller nyser				
Når jeg ler				
Når jeg må veldig på do				

17 a) Hvor ofte har du avføring?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Mindre enn 2 ganger per uke				
Annenhver dag				
Hver dag Flere ganger per dag				

b) Må du ”trykke” for å få ut avføring?

☐ Sjelden eller aldri ☐ Ofte

☐ Av og til ☐ Alltid

18 a) Har du i løpet av dette svangerskapet vært plaget med smerter i ryggen?

☐ JA ☐ NEI

b) Har du i løpet av dette svangerskapet vært plaget med smerter i bekkenområdet?

☐ JA ☐ NEI

c) Hvis JA på spørsmål om bekkensmerter, har du hatt så store vansker med å gå at du må bruke stokk eller krykker?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Ikke i det hele tatt				
Ikke så ofte				
I perioder				
Mesteparten av tiden				

19 a) Har du i tidligere svangerskap vært plaget med smerter i bekkenområdet?

☐ JA ☐ NEI

b) Hvis JA, når sluttet plagene?

☐ Mindre 6 uker etter fødselen ☐ 5-10 måneder etter fødsel

☐ 6-20 uker etter fødselen ☐ Har fortsatt vedvarende plager

JOBBAKTIVITETER

Dersom du i dag ikke har jobb eller betalt arbeid utenfor hjemmet, vennligst gå videre til spørsmål nr. 26 a)

20. Arbeider du stående og/eller gående?

☐ Sjelden eller aldri ☐ JA, mindre enn 50% av tiden

☐ Av og til, men ikke daglig ☐ JA, mer enn 50% av tiden

21. Arbeider du med armene løftet i skulderhøyde eller høyere?

☐ Av og til, men ikke daglig ☐ JA, mer enn 50% av tiden

22. Må du vri eller bøye deg mange ganger i løpet av en arbeidsdag?

☐ Sjelden eller aldri ☐ JA, mindre enn 50% av tiden

☐ Av og til, men ikke daglig ☐ JA, mer enn 50% av tiden

23. Hvor ofte opplever du belastende løft på arbeidsplassen?

☐ Sjelden eller aldri ☐ 10-20 ganger daglig

☐ Mindre enn 20 ganger ukentlig ☐ Mer enn 20 ganger daglig

☐ Mer enn 20 ganger ukentlig

24. Vil du karakterisere jobben din som fysisk krevende?

☐ JA, spesifiser .....

☐ Av og til, spesifiser .....

☐ NEI, spesifiser .....

TRANSPORTAKTIVITETER

25 a) Hvordan kommer du deg vanligvis til jobb nå som du er gravid?

(*Sett gjerne flere kryss dersom mer enn et av alternativene passer)*

☐ Kjører bil ☐ Går

☐ Offentlig kommunikasjon ☐ Annet, spesifiser .....

☐ Sykler

b) Hvor lang tid bruker du til og fra hjem og arbeidssted *(en vei)*?

☐ Mindre enn 5 min ☐ 30-60 min

☐ 5-15 min ☐ Mer enn 60 min

☐ 15-30 min ☐ Annet, spesifiser .....

26 a) Har du barn du skal bringe/hente?

☐ JA, daglig ☐ JA, av og til

☐ JA, annenhver dag ☐ NEI

b) Hvis JA, hvordan bringer/henter du vanligvis barna nå som du er gravid?
(*Sett gjerne flere kryss dersom mer enn et av alternativene passer)*

☐ Kjører bil ☐ Går

☐ Offentlig kommunikasjon ☐ Annet, spesifiser .....

☐ Sykler

27 a) Kan du angi hvor mye du totalt **går** (bruker bena) i løpet av en dag (utenom arbeidstid)?

(F.eks. til og fra arbeid, hente/bringe barn, til og fra butikken, osv.)

☐ Mindre enn 5 min ☐ 30-60 min

☐ 5-15 min ☐ Mer enn 60 min

☐ 15-30 min ☐ Går sjelden eller aldri

b) Er dette mindre tid enn du normalt ville brukt bena (gått) dersom du ikke var gravid?

☐ JA ☐ NEI

28 a) Kan du angi hvor mye du totalt **sykler** i løpet av en dag?

(F.eks. til og fra arbeid, hente/bringe barn, til og fra butikken, osv.)

☐ Mindre enn 5 min ☐ 30-60 min

☐ 5-15 min ☐ Mer enn 60 min

☐ 15-30 min ☐ Sykler sjelden eller aldri

b) Er dette mindre tid enn du normalt ville brukt dersom du ikke var gravid?

☐ JA ☐ NEI

29 a) Bruker du trapper fremfor heis/rulletrapp?

☐ JA ☐ Av og til ☐ NEI

b) Ville du brukt mer trapper dersom du ikke var gravid?

☐ JA ☐ NEI

AKTIVITET I HJEM OG NÆRMILJØ

30 a) Har du barn fra før?

☐ JA ☐ NEI

b) Hvis JA, hvor mange barn under 18 år har du omsorg for?

☐ 1 ☐ 2 ☐ 3 ☐ 4 eller flere

31 a) Har du hage/gårdsplass?

☐ JA ☐ NEI

b) Hvis JA, hvor ofte i en vanlig uke gjør du **tungt fysisk** hagearbeid eller tilsvarende?
(F.eks. snømåking, klippe plenen, løfte tunge steiner, hugge ved, gravearbeid, oppussingsarbeid)

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3.trimester)**
Aldri				
Mindre enn 1 gang i uka				
1-3 ganger i uka				
3-5 ganger i uka				
Hver dag				
Mer enn 1 gang per dag				

c) Hvis JA, hvor ofte i en vanlig uke gjør du **lett til middels anstrengende** hagearbeid eller tilsvarende?
(F.eks. bære lette ting, rydde, vedlikeholdsarbeid, luke i blomsterbed, koste og rake)

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3.trimester)**
Aldri				
Mindre enn 1 gang i uka				
1-3 ganger i uka				
3-5 ganger i uka				
Hver dag				
Mer enn 1 gang per dag				

32. Hvor ofte i en vanlig uke gjør du med **lett til middels anstrengende** arbeid i hjemmet?
(F.eks. støvsuge, vaske gulv, trappevask, innkjøp av mat, pleie og omsorgsoppgaver)

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3.trimester)**
Aldri				
Mindre enn 1 gang i uka				
1-3 ganger i uka				
3-5 ganger i uka				
Hver dag				
Mer enn 1 gang per dag				

33. Hvor fysisk anstrengende er dine daglige omsorgsoppgaver og gjøremål i og rundt hjemmet?

- ☐ Veldig lett
- ☐ Lett
- ☐ Litt anstrengende
- ☐ Anstrengende
- ☐ Svært anstrengende

FRITIDSAKTIVITETER; SPORT OG REKREASJON

MERK: *Fysisk aktivitet* defineres som 1 eller flere treningsaktiviteter per uke med minst 20 minutters varighet per gang

34. Var du regelmessig fysisk aktiv før graviditet?

(1 eller flere mosjonsaktiviteter per uke med minst 20 minutters varighet per gang)

☐ JA ☐ NEI

35. Er du som gravid regelmessig fysisk aktiv?

(1 eller flere mosjonsaktiviteter per uke med minst 20 minutters varighet per gang)

	JA	**NEI**
1-12 svangerskapsuke (1. trimester)		
13-27 svangerskapsuke (2. trimester)		
28-40 svangerskapsuke (3. trimester)		

Dersom du har svart NEI på både spørsmål 34 og 35, vennligst gå videre til spørsmål nr. 43

36. Hvor lenge har du drevet med regelmessig fysisk aktivitet før nåværende svangerskap?

(1 eller flere mosjonsaktiviteter per uke med minst 20 minutters varighet per gang)

☐ Mindre enn 6 måneder
☐ 6 mnd -1 år
☐ 1-4 år
☐ 5-10 år
☐ Mer enn 10 år

37. Har du opprettholdt samme fysisk aktivitetsnivå som før graviditet?

	Mer aktiv nå	**Like aktiv som før**	**Mindre aktiv nå**
1-12 svangerskapsuke (1. trimester)			
13-27 svangerskapsuke (2. trimester)			
28-40 svangerskapsuke (3. trimester)			

38. Hva slags type fysisk aktivitet driver du vanligvis? (*Sett maks tre kryss*)

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Går tur				
Jogger / løper				
Svømmer				
Sykler				
Styrke / vekttrening				
Ballsport				
Langrenn / rulleski				
Skøyter / rollerblades				
Kampsport				
Aerobic				
Aerobic for gravide				
Bevegelighetstrening / avspenning				
Dans				
Annet				

39. Hvor ofte driver du med fysisk aktivitet?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
1 gang i uka				
2-3 ganger i uka				
4-5 ganger i uka				
5-6 ganger i uka				
Hver dag				
Mer enn 1.gang per dag				

40. Hvor lang tid bruker du i gjennomsnitt når du trener?

(Ikke medregnet tid til skift, dusj, reisevei osv.)

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Mindre enn 30 min				
30-60 min				
1-2 timer				
Over 2 timer				

41. På hvilken intensitet trener du vanligvis?

	Før graviditet	**Uke 1-12 (1. trimester)**	**Uke 13- 27 (2. trimester)**	**Uke 28-40 (3. trimester)**
Uten å bli svett eller andpusten *(oppleves lite anstrengende)*				
Blir svett og lett andpusten *(oppleves anstrengende)*				
Blir veldig svett og puster tungt *(oppleves svært anstrengende)*				

42 a) Gjør du 1 gang i uken eller mer styrkeøvelser på egenhånd hjemme?

☐ JA ☐ NEI

b) Hvis JA, gjør du øvelser for disse musklene?

	Magemusklene	**Ryggmusklene**	**Bekkenbunns-musklene**
Før graviditet			
1-12 svangerskapsuke (1. trimester)			
13-27 svangerskapsuke (2. trimester)			
28-40 svangerskapsuke (3. trimester)			

STØTTE, BARRIERER OG MOTIVASJON

43. Var det noen i din nære familie (mor, far eller søsken) som drev regelmessig fysisk aktivitet under din oppvekst (før du fylte 18 år)?

☐ JA ☐ NEI

44. Hvor vanlig er det å drive fysisk aktivitet i din nærmeste omgangskrets?

☐ Ikke vanlig ☐ Forekommer ☐ Svært vanlig

45. Hvilket av disse alternativene passer best for deg?

☐ Jeg trener ikke, og jeg har ikke tenkt til å begynne
☐ Jeg trener ikke, men det er mulig jeg begynner
☐ Jeg trener noen ganger, men ikke regelmessig
☐ Jeg trener regelmessig, men har akkurat startet
☐ Jeg har trent regelmessig mer enn 6 måneder

46 a) Trener du sammen med noen?

☐ Aldri ☐ Av og til ☐ Alltid ☐ Trener ikke

b) Hvis du har svart alltid eller av og til, hvem trener du vanligvis med?

(*Sett gjerne flere kryss dersom mer enn et av alternativene passer)*

- ☐ Familie/ektefelle/partner
- ☐ Venner
- ☐ Arbeidskollegaer
- ☐ Idrettsklubb
- ☐ Helsestudio/aerobic (mennesker jeg møter der)
- ☐ Hund

47. Dersom du i dag **ikke er** regelmessig fysisk aktiv, hva er de to viktigste grunnene til dette?

(*Sett maks to kryss*)

- ☐ Har ikke tid
- ☐ Er ikke interessert
- ☐ Får nok mosjon gjennom min jobb og/eller i hjemmet
- ☐ Det krever for mye å komme i gang
- ☐ Passer ikke med barn/omsorg
- ☐ Har ingen å trene sammen med
- ☐ Vanskelig å kombinere med arbeid/utdanning
- ☐ Dårlige treningsmuligheter
- ☐ Negative opplevelser i forbindelse med fysisk aktivitet
- ☐ Svangerskapskomplikasjoner
- ☐ Har aldri trent, ingen erfaring
- ☐ Sykdom/handikap
- ☐ Frykt/redsel for mitt ufødte barn
- ☐ Helsepersonell råder meg til ikke å være fysisk aktiv

48. Dersom du i dag **er** regelmessig fysisk aktiv, hva er de to viktigste grunnene til dette?

(*Sett maks to kryss*)

- ☐ Det er gøy/opplevelse
- ☐ Gir bedre utseende/kropp
- ☐ Avreagere/avkobling
- ☐ Trener til større eller mindre konkurranser
- ☐ Gir bedre fysisk form/forebygger helseplager
- ☐ Gir psykisk overskudd/velvære/glede
- ☐ Holde vekta nede (slik at jeg ikke legger for mye på meg under graviditeten)
- ☐ Øker selvtilliten/selvfølelsen
- ☐ Reduserer svangerskapsplager
- ☐ Motvirker angst og depresjon
- ☐ Fordi jeg føler at jeg bør
- ☐ Det er sosialt

49. Bekymrer du deg for barnet inne i magen når du driver med fysisk aktivitet?

☐ JA ☐ Av og til ☐ NEI ☐ Trener ikke

50 a) Har lege/jordmor gitt deg råd om hvordan drive fysisk aktivitet i svangerskapet?

☐ JA ☐ NEI

b) Hvis JA, hvilke råd fikk du, vennligst spesifiser nærmere?

……

.....

.....

.....

ROLIGE AKTIVITETER

51. Hvor mange timer ser du på TV?

	Hverdag	**Helg/fridag**
Mindre enn 1 time		
1-2 timer		
2-3 timer		
3-4 timer		
4-5 timer		
Mer enn 5 timer		

52. Hvor lang tid bruker du på å lese bøker/aviser/blader, løse kryssord eller lignende?

	Hverdag	**Helg/fridag**
Mindre enn 1 time		
1-2 timer		
2-3 timer		
3-4 timer		
4-5 timer		
Mer enn 5 timer		

53 a) Hvor mange timer sover du vanligvis i løpet av et døgn?

	Hverdag	**Helg/fridag**
Mindre enn 4 timer		
4-6 timer		
6-8 timer		
8-10 timer		
10-12 timer		
Mer enn 12 timer		

b) Er dette mer tid enn du normalt ville sovet dersom du ikke var gravid?

☐ JA ☐ NEI

TUSEN TAKK FOR HJELPEN 

APPENDIX 4:

Informed Consent and written instructions about the use of ActiReg

Til deg som er gravid i Oslo-området!

Forespørsel om å delta i direkte måling av fysisk aktivitet med Actireg®

Det har vært en økning i forekomsten av overvekt hos kvinner og en kraftig parallell økning i andelen barn med høy fødselsvekt (> 4000 g) de siste 10 år i Norge. Denne utviklingen er knyttet til økt forekomst av svangerskaps- og fødselskomplikasjoner både for mor og barn. I tillegg synes høy fødselsvekt å gi økt risiko for overvekt og diabetes senere i livet for mor og barn.

I Norge mangler vi data vedrørende totalt fysisk aktivitetsnivå (arbeid, transport, nærmiljø og fritid) blant gravide, og om fysisk aktive har en mer gunstig vektøkning i svangerskapet. Få studier har sammenlignet data på fødselsvekt hos barnet og grad av fysisk aktivitet hos gravide.

Prosjektet "Graviditet, fysisk aktivitet og overvekt" er et faglig samarbeid og en utvidelse av det allerede pågående prosjektet STORK (Store barn og svangerskapskomplikasjoner) ved Kvinneklinikken på Rikshospitalet. Resultatene fra undersøkelsen vil danne grunnlag for helsefremmende og forebyggende tiltak for gravide, samt være viktig i videre planlegging av helsetjenester for denne gruppen.

Hensikten med dette forskningsprosjektet er å undersøke grad og omfang av fysisk aktivitet under svangerskap. Ca 80 kvinner vil bli forespurt om å delta i studien.

Hva vil det innebære å delta i prosjektet?
Actireg er en bærbar posisjons- og bevegelsesmåler utviklet av forskere ved Institutt for Ernæringsforskning, Universitetet i Oslo (UiO). Apparatet består av to sensor-par. Et par er festet til brystbenet og et er festet på framsiden av høyre lår. Sensorene registrerer kroppens hovedposisjoner (ligge, sitte, stå) og bevegelser i disse posisjonene minutt for minutt gjennom døgnet.

Actireg skal være på kroppen i arbeid og fritid, en periode på **7 døgn** (ca 170 timer), kun avbrutt ved søvn og dusj. Brukerveiledning for Actireg vil belyses med praktisk demonstrasjon og montering av apparatene.

Deltagelse er helt frivillig, og du har anledning til å trekke deg fra prosjektet når du måtte ønske det, uten å måtte oppgi grunn for dette. Alle resultater vil bli behandlet konfidensielt, og kun kodenummer, ikke navn, vil bli lagt inn på datamaskin for videre analyser. Prosjektet er vurdert av Regional komité for medisinsk forskningsetikk og Datatilsynet.

Kari Bø, professor dr.scient, fysioterapeut	Lene Haakstad, cand.scient, dr. grads stipendiat	Ingvild Gundersen, mastergradsstudent

Kontaktperson:

Lene Haakstad
Stipendiat /PhD student
Seksjon for idrettsmedisinske fag
Norges idrettshøgskole
P.b 4014, Ullevål Stadion
0806 OSLO
e-post: lene. haakstad@nih.no
Tlf: 23 26 23 90/45 48 99 02

Klipp

Jeg har mottatt skriftlig informasjon om studien, og samtykker i å delta.

Dato:_____ Underskrift:_____

Vennligst skriv ned følgende opplysninger:

Navn:

……

***Adresse:*……**

……

***Tlf.nr:*……**

***e-post:*……**

Brukerveiledning til Actireg®

Actireg skal bæres i 7 sammenhengende døgn. Det er viktig at av/på knappen ikke røres i løpet av registreringsperioden. Apparatet vil bli startet og stoppet av prosjektleder ved konsultasjon på Norges idrettshøgskole eller Rikshospitalet.

Før påmontering: Pass på at huden er ren og tørr.

Påmontering: Den smale sensoren (med rød pil) festes med medisinsk tape på brystbenet, midt i mellom brystene. Pilen skal peke **OPP** mot hodet. Pass på at ledningen kommer **under** BH eller lignende.

Den brede sensoren (med blå pil) festes midt på **HØYRE** lår. Pilen skal peke **OPP** mot magen. Pass på at ledningen kommer **under** trusestrikken.

Avmontering: Apparatet er **ikke vanntett**, og må derfor tas av i forbindelse med dusjing og bading.

Apparatet skal tas av om natten, og sensorene skal da plasseres på et **flatt underlag**. Ta det på deg så fort som mulig etter at du har våknet.

For at registreringen skal bli så korrekt som mulig, er det veldig viktig at du påmonterer Actireg så snar du kan etter at du har hatt det av deg!

Aktivitetsdagbok: Det er viktig at du registrerer hvor mange ganger du tar av og på dag ActiReg daglig, samt at du noterer eventuelle mosjonsaktiviteter i vann. Eventuelle problemer eller vanskeligheter underveis registreres også.

Etterpå: Du vil få tilsendt din aktivitetsprofil for registreringsperioden i etterkant.

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Tusen takk for at du deltar i Actireg-prosjektet!

APPENDIX 5:

The RCT - Informed Consent

NORGES IDRETTSHØGSKOLE

Til deg som er gravid
Forespørsel om å delta i et treningsforsøk

Det har vært en økning i forekomsten av overvekt hos kvinner og en kraftig parallell økning i andelen barn med høy fødselsvekt (> 4000 g) de siste 10 år i Norge. Denne utviklingen er knyttet til økt forekomst av svangerskaps- og fødselskomplikasjoner både for mor og barn. I tillegg synes høy fødselsvekt å gi økt risiko for overvekt og diabetes senere i livet for mor og barn.

I Norge mangler vi data vedrørende totalt fysisk aktivitetsnivå (arbeid, transport, nærmiljø og fritid) blant gravide, og om fysisk aktive har en mer gunstig vektøkning i svangerskapet. Få studier har sammenlignet data på fødselsvekt hos barnet og grad av fysisk aktivitet hos gravide.

Hensikten med dette forskningsprosjektet er å undersøke sammenhengen mellom fysisk aktivitetsnivå, vektøkningen hos mor, barnets fødselsvekt, samt svangerskaps- og fødselskomplikasjoner.

Treningsforsøk
Ca 100 gravide kvinner blir tilfeldig delt inn i en treningsgruppe (50) eller kontrollgruppe (50). Begge gruppene skal gjennomgå følgende prosedyre:

Svangerskapsuke 12-24 (test 1) og 32-38 (test 2)
- Helsekartlegging og spørreskjema om fysisk aktivitet, livskvalitet og helse
- Måle vekt og høyde, samt hudfoldtykkelse på triceps, subscapular og lår
- Gjennomføre arbeidsbelastning og kartlegging av fysiologisk respons mht bl.a laktatproduksjon, hjertefrekvens, VO_2 og blodtrykksrespons. Arbeidsbelastningen foregår ved gjennomføring av laktatprofil på submaksimale belastninger ved gange på tredemølle

6-12 uker postpartum
- Helsekartlegging og spørreskjema om livskvalitet og helse
- Registrering av barnets fødselsvekt og eventuelle fødselskomplikasjoner
- Måle vekt og høyde, samt hudfoldtykkelse på triceps, subscapular og lår
- Gjennomføre arbeidsbelastning og kartlegging av fysiologisk respons mht bl.a laktatproduksjon, hjertefrekvens, VO_2 og blodtrykksrespons.

Dersom du loddtrekkes til å være med i treningsgruppen får du i tillegg tilbud om spesielt tilrettelagt treningsprogram til musikk og rask gange. Programmet inkluderer 30 minutter med utholdenhetstrening, resten av timen (del 2) vil bli brukt til: styrketrening, ergonomi og avspenning.

Målsettingen er du deltar på trening hos oss to til tre kvelder i uken, og videre oppfordres til selvvalgt fysisk aktivitet hjemme (30 minutter, for eksempel rask gange) de dagene det ikke tilbys organisert trening ved Norges idrettshøgskole.

Testene og/eller treningene medfører ikke noen risiko eller negativ påvirkning for deg eller barnet ditt.

NORGES IDRETTSHØGSKOLE

Ekstraundersøkelsene på Norges idrettshøgskole vil ta ca **1 time og 30 minutter** hver gang (totalt 3 ganger).

Alle tester og trening er selvsagt gratis i de ukene prosjektet foregår.

Deltagelse er helt frivillig, og du har anledning til å trekke deg fra prosjektet når du måtte ønske det, uten å måtte oppgi grunn for dette. Alle resultater vil bli behandlet konfidensielt, og kun kodenummer, ikke navn, vil bli lagt inn på datamaskin for videre analyser. Prosjektet er vurdert av Regional komité for medisinsk forskningsetikk og Datatilsynet.

Kari Bø, professor dr.scient,
fysioterapeut

Lene Haakstad, cand. scient
dr. grads stipendiat

Skjema 1

Helsevurdering

KODE:

Vennligst svar på alle spørsmålene

	JA	NEI
1) Har du hjertesykdom/hjertefeil?	☐	☐
2) Har du høyt blodtrykk?	☐	☐
3) Røyker du nå?	☐	☐
4) Har du hatt mer enn to tidligere aborter?	☐	☐
5) Har du blødninger (etter uke 12)?	☐	☐
6) Har du ubalansert stoffskiftesykdom?	☐	☐
7) Har du svangerskapsforgiftning?	☐	☐
8) Har du noen andre sykdommer du vil nevne _____	☐	☐
9) Tar du noen form for medisiner? Hvilke?_____	☐	☐

Hvis du svarte NEI på alle spørsmålene kan du trygt delta i treningsprogrammet. Svarte du JA på et eller flere av tilfredsstiller du dessverre ikke inklusjonskriterine for prosjektet (kontraindikasjoner for trening under graviditeten)

Jeg har mottatt skriftlig og muntlig informasjon om studien og samtykker i å delta?

☐ JA ☐ NEI

Signatur

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