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What is the effect of supervised group exercise on maternal psychological outcomes and common pregnancy complaints? A randomized controlled trial

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Preface

First I want to thank my two beautiful girls, Mira and Alva, who behaved so well in my stomach that I could exercise throughout both my pregnancies. This inspired me to want to explore if other pregnant women could derive the same good effects from maternal exercise as I did.

Next I want to thank my supervisor Lene Annette Hagen Haakstad for tempting me to take up my studies, and for accepting me as a student on this project. Also, I'm very thankful for all the shared knowledge, as well as for thorough reading of all editions. I've learned a lot, especially about what scientifically writing is all about. Many thanks for motivational words throughout the process!

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Abstract

Background: Being pregnant is followed by several physiological changes and pregnancy symptoms, which have the potential to reduce quality of life and well-being for pregnant women. To date, there is scant knowledge about the effect of regular exercise in relation to maternal psychological outcomes and common pregnancy complaints. Hence, the purpose of the present study was to assess the effects of supervised group exercise on psychological outcomes including well-being, quality of life, body-image and pregnancy depression, as well as on commonly reported pregnancy complaints.

Method: This was a single-blind randomized controlled trial. One hundred and five previously sedentary primiparous women, mean age 30.7 ± 4 years, were randomized to an exercise group (n=52) or a control group (n=53). The exercise intervention consisted of twelve weeks of supervised group exercise including cardiovascular and strength training, performed twice a week for 12 weeks, starting at mean gestation week 17.7 (SD 4.2). Women in the exercise group were also asked to include 30 minutes of self-imposed physical activity on the remaining weekdays. The control group received usual pre-natal care and was neither encouraged to nor discouraged from exercising. Outcome measures were assessed through standardized interviews pre- and post-intervention, and included psychological variables related to well-being, quality of life, body image and pregnancy depression, as well as number of women reporting of common pregnancy complaints.

Results: Significant differences regarding psychological outcomes in favor of the exercise group were found for fatigue, health satisfaction and negative feelings (sadness, despair, anxiety or depression). Contrary, the control group reported higher enjoyment with life. With respect to pregnancy complaints, fewer women in the exercise group reported nausea/vomiting and numbness/circulation problems, compared to the control group. Adherence rates showed that it was difficult to motivate sedentary pregnant women to participate in regular exercise.

Conclusion: Participation in supervised group exercise contributed to improvements in some variables related to maternal well-being and quality of life, as well as reductions in two common pregnancy complaints.

Key words: Pregnancy, physical activity, exercise, pregnancy depression, well-being, quality of life, body-image, pregnancy complaints.

1. Introduction

According to the literature, pregnancy is considered a unique time for behavior modification, and habits adopted during pregnancy may have the potential to affect a woman's health for the rest of her life (1;2). The period might offer enhanced health focus as it is a time of bodily changes, and also because many women feel a responsibility for the health of the unborn baby (1). Thus, pregnancy has been proposed to be an optimal time to introduce lifestyle changes through advice about exercise, as well as nutritional and weight gain counseling (3).

Several physical symptoms related to pregnancy are common, and pregnancy discomforts may have large impact on pregnant women's well-being (4). A recent study on the Norwegian population showed that by week 32 of gestation, 63% of pregnant women were on sick leave, with fatigue/sleep problems (34.7%), pelvic girdle pain (31.8%) and nausea/vomiting (23.1%) being the largest contributors with respect to total weeks away from work on the population level (5). A strong association was found between sick leave and among others; not meeting exercise recommendation (exercising less than once a week) and previous depression (5). According to ACSM (6), negative mood symptoms are commonly reported during pregnancy. Dorheim et al. (5) found that women who reported depression/anxiety as main reasons for their sick-leave (2.1%) had the longest duration of sick leave. In addition, sick leave during pregnancy has been found to be a strong predictor of postpartum depressive symptoms (7). Hence, maternal sick leave has large direct and indirect cost on a societal level, as well as large impact on quality of life for the woman both during pregnancy and post-partum.

In the general adult population, studies show that physical activity and exercise may give a number of major health benefits, including general fitness (8) and reduced risk of cardiovascular disease, type 2 diabetes, osteoporosis, obesity and some types of cancer (9). Exercise is also associated with improvements in mild to moderate depression symptoms (8;9), and has positive effects on the individual's well-being and quality of life (10). Few studies have reported on these outcomes in a pregnant population, as well as on commonly reported pregnancy complaints. Hence, there is a need for high quality studies to evaluate if regular exercise has the potential to increase well-being, quality of life and body-image, reduce pregnancy depression, as well as relieve common pregnancy complaints. To establish the causality in this field, randomized controlled trials (RCT) are especially warranted.

1.1 Maternal adaptations to pregnancy

1.1.1 Physiological changes

During pregnancy the female body goes through various anatomic and physiologic changes to create a suitable environment for the fetus, meet the increased maternal and fetal metabolic demands and to prepare the mother for parturition (11). The most obvious changes are the enlarged abdomen and increased body weight, but there are also important changes in the cardiovascular and respiratory system (11), e.g. affecting cardiac output, resting heart rate, blood volume and minute ventilation (1). Table 1 shows a brief summary of physiologic adaptations to pregnancy, including cardiovascular, respiratory, musculoskeletal and endocrine/metabolic changes.

Table 1 *Physiologic adaption to pregnancy. From Artal & O'Toole (1)*

Cardiovascular	Increased blood volume Increased heart rate Increased stroke volume Increased cardiac output Decreased systemic vascular resistance (5-10 mmHg)
Respiratory	Increased minute ventilation (50%) Increased tidal volume Increased baseline oxygen consumption (10-20%) More labored breathing
Musculoskeletal	Increased joint laxity Weight gain Increased lumbar lordosis
Endocrine/metabolic	Increased energy requirements 300 kcal/day Carbohydrates preferred as fuel

Some of the maternal adaptations to pregnancy may also impact pregnant women's ability to participate in and perform physical activity and exercise. According to Artal & O'Toole (1), anatomical changes due to weight gain increases the forces around the hip- and knee joint, especially during weightbearing activities. An increased lumbar lordosis and a shift in the center of gravity may affect posture and balance, and potentially increase the risk of falling (1). Also, increased levels of pregnancy hormones causes increased ligamentous laxity (1;12), which may result in more unstable joints and thereby increased risk of injuries (1) and discomforts (12).

Moreover, maternal response to exercise is affected by endocrine changes that alter the regulation of the cardiopulmonary and metabolic function (1). Hemodynamic changes, including increased blood volume, heart rate, stroke volume and cardiac output, as well as

reduced blood pressure, appear to establish a circulatory reserve necessary to fulfill maternal and fetal oxygen and nutrition requirements both at rest and during moderate physical activity (1). A reduced maximum heart rate and increased resting heart rate results in a reduced maximum heart rate reserve (13). Due to the increased plasma volume, the hemoglobin concentration is reduced, and thus also the capacity for oxygen delivery (13). Moreover, cardiovascular changes apply some considerations to maternal body positions both during exercise and at rest (1). Supine positions results in a relative obstruction of the vena cava, thus a reduced venous return, decreased cardiac output and orthostatic hypotension (1). In addition, motionless standing is associated with a significantly decreased cardiac output (1).

Basal metabolic rate and heat production are increased during pregnancy compared to non-pregnant levels (1). Due to the increased resting metabolic rate, less energy is available for muscle contractions (13). The increased heat production affects body temperature which during physical activity is directly related to exercise intensity, and the extra heat is dissipated through the cardiovascular system and through the evaporative cooling through sweat (1). For non-pregnant women, moderate intensity aerobic exercise in thermoneutral conditions results in a rise in core temperature of approximately 1.5 degrees, but data on the effects during pregnancy are limited (1). Moreover, as a result of the increased oxygen requirements during rest and because breathing is more labored due to the enlarged uterus adding pressure on the diaphragm, there is a decrease in oxygen available for aerobic exercise (1). Also, maternal weight gain due to increased adipose tissue and blood volume, as well as growth of the placenta, fetus and uterus, results in increased cost of energy during weightbearing activities, and a reduced relative oxygen uptake (13). Hence, subjective work load and maximum exercise performance is decreased (1).

The physiological changes during pregnancy may affect women's psychological health, and pregnancy complaints are also common.

1.1.2 Psychological changes

General mood fluctuations are common during pregnancy, and negative mood symptoms are often reported, especially during the first and last trimester (6). In addition, clinically defined mood disorders (depression and anxiety) are more common during the perinatal period (6). Proposed risk factors for mood disturbances are hormonal influences and psychosocial factors such as weight gain and body-image, maternal stress, sleep difficulties etc. (6).

Pregnancy depression

According to Gaynes et al. (14), perinatal and pregnancy depression is defined as minor and mayor depressive episodes that occur either during pregnancy or within the first 12 months postpartum. Symptoms of depression include sadness and anxiety, loss of interest in activities, fatigue and decreased energy, insomnia, changes in eating patterns, as well as aches and pains (15). In the literature, depression or depressive symptoms is often measured by the Center for Epidemiological Studies Depression Scale (CES-D), the Edinburgh Postnatal Depression Scale (EPDS) or the Beck Depression Inventory (BDI). These self-report instruments consist of 20-21 items and assess depressive mood through e.g.; feelings of pessimism, guilt, helplessness and sadness, sense of failure, suicidal thoughts, fatigue, and weight loss (16-19). Studies suggest a prevalence of depression of between 7.4% and 12.8% at different times during pregnancy (14;20). As for depressive symptomes, Haas et al. (21) reported an increase from 11.7% prior to pregnancy to 25.2% during the first trimester. Moreover, Mckee and colleagues (16) found that half of the healthy pregnant women in the study sample showed elevated levels of depressive symptoms.

The risk factors for perinatal depression include e.g.; family history of depression, previous depressive episodes, social isolation, chronic health conditions and life stress (6). Pregnancy depression may increase the risk of adverse pregnancy outcomes, e.g. reduced physical functioning including poor sleep, reduced psychosocial functioning, reduced quality of life and increased suicide risk (20;22). In addition, a recent study on the Norwegian population (MoBa) found that pregnancy depression increased the risk of alcohol consumption during pregnancy (23). Moreover, postnatal depression has been found to be a common outcome of pregnancy depression (20;22).

Well-being, quality of life and body-image

The construct well-being or “psychological well-being” can be associated with affect, emotion, mood, enjoyment and self-esteem (24), and is in medical dictionary defined as “achievement of a good and satisfactory existence as recognized by the individual” (25). Well-being is generally linked to functional assets like positive emotions and psychological resources, and can also be described as “judging life positively and feeling good” (26). According to the World Health Organization (WHO), measuring quality of life (QOL) is an important assessment of well-being (27). WHO describes quality of life as a complex construction involving the interrelated relationship between the environment and individual

physical and psychological aspects, social relationships and personal beliefs (27). In the literature, the health-related aspect of quality of life (HR-QOL) is often measured using the WHOQOL-bref or the Medical Outcome Study 36-Item Short Form Health Survey (SF-36). The WHOQOL-bref was developed by WHO and is a 26 item questionnaire on self-perceptions related to e.g. physical health, psychological aspects and social relationships (27). The SF-36 assesses health-concepts like physical or social limitations due to health problems, social limitations because of physical or emotional problem, bodily pain, general mental health, vitality, and general health perceptions (28). According to Biddle & Mutrie (24), mood is related to well-being. In the literature that was reviewed for the present RCT (22;29), mood was measured through the Profile of Mood States (POMS). This instrument assesses 6 mood states: tension, depression, anger, vigor, fatigue, and confusion (29).

Body-image could be defined as "The picture or mental image we form in our minds as a tridimensional unity involving physiologic, psychological and social factors" (Schilder, as cited in Strang & Sullivan (30)). Body-image can also be described as "the feelings and beliefs that people have about their bodies" (Ogden, as cited in Fox & Yamaguchi (31)). Previous studies that have measured body-image often refer to the Body Cathexis Scale or the Body Attitudes Questionnaire. The Body Cathexis Scale is a 46-item domain-specific scale (ranked 1-5) that assesses the degree of a person's satisfaction or dissatisfaction with various parts (e.g. weight, bust, waist, abdomen etc.) or processes of the body (32). Likewise, the Body Attitudes Questionnaire measures body dissatisfaction across four dimensions: feeling fat, attractiveness, salience of weight and shape, and strength and fitness (33).

Previous studies have shown that one or more of the health-related quality of life-factors (e.g. physical and social functioning, bodily pain, vitality and general health) tend to change from pre-pregnancy to pregnancy, and also throughout pregnancy (21;34;35). For instance, Otchet and colleagues (35) found that pregnant women had significantly poorer level of function on these subscales compared to community controls, and also higher levels of emotional distress. This is in accordance with Mckee et al. (16), who also claimed that depressive symptoms were strongly connected to reduced health-related functional status, and emotional well-being. More recently, Montoya Arizabaleta et al. (36) reported that limitations in physical and social functioning increased as pregnancy progressed. This is consistent with the findings from Tendais and colleagues (37). Moreover, Nascimento et al. (3) found a significant decrease in mean scores of perceptions of quality of life during pregnancy.

With respect to body-image, pregnancy results in rapid changes of maternal body weight and shape. These changes may influence the women's perceived body-image satisfaction (BIS) (31;38) due to conflicting feelings about body-image (e.g. increased self-consciousness, decreased feelings of physical attractiveness and increased concerns about body weight) (31;39). A study by Strang & Sullivan (30) reported that the sample of pregnant women felt more negative about their bodies during the third trimester than pre-pregnancy. Likewise, Goodwin et al. (38) found significant changes in a negative direction from pre-pregnancy to gestation week 17, measured by the Body Cathexis Scale. The researchers (38) also reported that a small positive improvement occurred from early to late pregnancy (week 30). Moreover, Downs et al. (39) found that body-image satisfaction during pregnancy was inversely associated to depressive symptoms, and further that depressive symptoms and body-image satisfaction were main determinants of later depression in pregnancy and post-partum. The latter was supported by a study by Rauff & Downs (40). Hence, depressive symptoms and body-image satisfaction are important factors related to women's psychological health during pregnancy and post-partum (39), and a healthy body-image may be a non-pharmacologic treatment that could protect against depressive symptoms during pregnancy (40). As concluded by Prather, Spitznagle & Hunt (41), maternal body-image satisfaction may be an important determinant of psychological well-being during pregnancy.

Based on the explored literature, in the present study well-being, quality of life and body-image are regarded as interrelated concepts, all of which may have a relation to pregnancy depression.

1.1.3 Common pregnancy complaints

Due to the physiological changes of pregnancy, many of them triggered by pregnancy hormones, physical symptoms are common and normal (42). Table 2 shows a list of pregnancy symptoms that are to be expected, as well as proposed mechanisms.

Table 2 *Common physical changes with pregnancy. From ACOG (42)*

Physical symptom	Proposed reasons
Bach ache	Strain on back muscles from extra weight Changed posture Stretched and weakened abdominal muscles
Congestion and nosebleed	Hormone levels and increased blood volume makes mucus membranes swell, dry out and bleed easily
Constipation and gas	Infrequent bowel movements Slowed digestion due to progesterone Extra weight from uterus adding pressure on the rectum
Leg cramps	Reasons are not clear
Frequent urination	Kidneys work harder to flush waste product out Uterine growth adds pressure to the bladder Fetus moving against the bladder
Hemorrhoids	Extra blood in the pelvic area Pressure of the growing uterus on the lower body
Headache	Pregnancy hormones, hunger, stress, caffeine withdrawal symptoms
Mouth and tooth changes	Pregnancy hormones causes swelling and bleeding Mouth watering Increased risk for cavities
Heartburn	Burning feeling in throat and chest due to pregnancy hormones relaxing the muscle valve between the stomach and esophagus
Insomnia	Uncomfortable because of growing stomach
Lower abdominal pain	Pulling of ligaments around the uterus
Fatigue	Pregnancy hormones, body works harder to create and support a new life
Nausea and vomiting	Increased levels of hormones, other, unknown reasons
Numbness and tingling	Uterine growth and swelling adds pressure to nerves Hyperventilation
Shortness of breath	Increased progesterone Growing uterus adds pressure to the diaphragm
Skin and hair changes	Increased melanin
Varicose veins	Slowed venous return due to weight of the uterus pressing down on the vena cava

Back pain, pelvic girdle pain and urinary incontinence are considered to be three severe pregnancy complaints. According to a Cochrane review by Pennick & Young (43), as many as two-thirds of pregnant women experienced back pain and one-fifth experienced pelvic girdle pain. An increased lumbar lordosis is likely to contribute to the high prevalence of low back pain (1). Pelvic girdle pain may be caused by increased maternal weight, as well as

increased ligamentous laxity caused by pregnancy hormones to prepare the musculoskeletal system for delivery (1;12). Moreover, Boyle et al. (44) stated that about 33% of women suffer from urinary incontinence after childbirth. The condition is associated with anatomical changes in pregnancy and after delivery, including nerve and soft tissue injury (6;11).

According to Poudevigne & O'Connor (45), fatigue appears to be one of the most common symptoms during pregnancy. Studies have found that as many as 87% of pregnant women were affected (46;47). Proposed reasons for fatigue are physiological changes with pregnancy, e.g. rapidly increased energy requirement, weight gain, increased cost of energy for moving and hormonal changes (45). In addition, age, diet, child care, work, alcohol and tobacco consumption, and pre-pregnancy physical activity-levels are probable coexisting factors (45). Moreover, studies (48;49) report that nausea and vomiting of pregnancy (NVP) occurs in approximately 80% of pregnant women during the first trimester, while 40% continues into the second trimester (49). The severity of the syndrome vary, from mild symptoms often called "morning sickness" (although it may occur at any time of the day) to the more severe diagnosis "hyperemesis gravidarum" (49;50). The latter is characterized by prolonged and severe nausea and vomiting, dehydration and weigh loss (50;51). The causes of nausea and vomiting of pregnancy are unknown, with theories ranging from endocrine changes related to pregnancy (50;52), to psychological factors (50;51). To date, treatment options range from dietary and lifestyle changes to vitamins, and if needed, hospitalization for intravenous therapy (48).

Older studies (17;53;54) measured minor pregnancy symptoms by the Physical Discomfort Checklist containing 29 different symptoms identified through literature searches as well as expert and practitioner's advice. In addition to fatigue, nausea and vomiting, pelvic girdle pain, back pain and urinary incontinence, examples of symptoms include heartburn, constipation, headache, vaginal discharge, leg cramps, varicose veins, hemorrhoids, edemas and insomnia (53). Later Zib and colleagues (46) identified 38 different symptoms occurring with higher frequency in pregnant women than controls. The authors (46) found that in mean, pregnant women reported 24.2 symptoms, compared to 11.2 in the non-pregnant sample. During pregnancy, the five most frequently reported symptoms were: frequency of micturition, fatigue, pelvic pressure, insomnia and low back pain (46). Recently, Foxcroft et al. (47) designed a Pregnancy Symptoms Inventory aimed to assess a wide range of pregnancy symptoms, as well as determine their impact on quality of life. The Pregnancy

Symptoms Inventory consists of 41 items, with the top four most common complaints being: urinary frequency (52.2%), tiredness (45.5%), poor sleep (27.5%) and back pain (19.5%) (47). Tiredness (76.3%), poor sleep (54.5%), back pain (52%), headache (50.9%) and nausea (30.1%) were the symptoms reported to considerably limit activities of daily life (47).

In the present study, pregnancy complaints were defined as less severe common complaints associated with pregnancy, including one or more of the following: poor sleep, unusual tiredness, numbness/reduced circulation, leg cramps, heartburn/acid reflux, nausea/vomiting, coordination and/or balance problems, problems with intestinal function, swollen legs/edemas, headache/migraine, varicosities, hemorrhoids and/or hernia. Low back pain, pelvic girdle pain and urinary incontinence were also measured. Results from the latter have been published previously (55), and low back pain and pelvic girdle pain was submitted as a separate article in October 2013. Hence, the results will not be included in this study.

1.2 Physical activity and exercise

In the literature, physical activity is defined as any bodily movement produced by skeletal muscles that results in a substantial energy expenditure, e.g. leisure time, household and job-related activities (56). Exercise is a subset of physical activity: planned, structured and repetitive physical activity with a purpose of improving or maintaining physical fitness (56). The terms are used interchangeably in the literature, and will be used according to the cited articles in the following text.

1.2.1 General exercise recommendations

To date, the exercise recommendation for the healthy adult population is to include 30 minutes of moderate intensity activity on most, preferably all, days of the week, vigorous-intensity aerobic physical activity for a minimum of 20 minutes on three days a week, or a combination of moderate- and vigorous intensity (57). Moderate intensity is defined as physical activity with an energy requirement of 3-6 metabolic equivalents (METs), and vigorous intensity is physical activity at >6 METs (57). Adults are also recommended to perform activities to maintain or increase muscular strength and endurance at least twice a week, e.g. weight training (57).

According to Haskell et al. (57), the minimum dose of physical activity can be obtained by performing bouts of activity, each lasting a minimum of 10 minutes. The recommended dose

should be performed in addition to the light intensity activities of daily life such as household and occupational activities (57). Moreover, due to the dose-response relationship between physical activity and health, the recommended amount of physical activity should be regarded as a minimum (57). Additional health effects and higher levels of fitness may be obtained by increasing the dose and intensity (57).

1.2.2 Exercise recommendations during pregnancy

The traditional medical advice for pregnant women was to reduce exercise levels or refrain from initiating strenuous exercise programs, to avoid the potential risk of adverse pregnancy outcomes (58). According to the most recent recommendations by the American College of Obstetricians and Gyneocologists (ACOG) (59) as well as the Canadian guidelines (58), exercise prescription for pregnant women should consist of the same elements as for the non-pregnant adult population, including activities to maintain or improve both cardiovascular and musculoskeletal fitness (1;2;58;60). To date, all pregnant women with no medical or obstetrical complications are advised to participate in 30 minutes or more of moderate intensity exercise on most or all days of the week (59). Previously sedentary women should begin with 15 minutes of continuous exercise three times a week, increasing gradually to 30-minute sessions four times a week (2;58). Athletes and very active pregnant women may continue their activities (1;2;58;59), but may need to alter intensity and frequency, as well as mode of activity throughout the pregnancy (61). Durations exceeding 45 minutes offer two concerns: thermoregulation and energy balance (1). Therefore, pregnant women should insure to be properly hydrated, maintain appropriate energy intake and exercise in a thermo-neutral environment (1).

According to Nascimento et al. (61), pregnant women should engage in activities they are familiar with and be careful not to overexert and overstretch, to avoid injury to connective or muscle tissue. In addition, some types of activities should be avoided. Contact sports and sports with a potential increased risk of falling propose a risk of abdominal trauma (2;58;59). Supine positions should be avoided after the first trimester due to a relative obstruction of venous return (58;59). Also, pregnant women should refrain from motionless standing (59). Last, scuba diving is not advisable as the fetus has a higher risk of decompression illness (1;2;58-60). The aim of exercising should be to maintain physical fitness, not to reach peak values (58). No matter the purpose – basic health, recreational pursuits or competition - type, intensity, duration and frequency of exercise should be considered to balance potential benefit

and harmful effects (1). Women with previous high fitness levels should be cautious to engage in higher levels of activities, and also expect a small decline in total activity and fitness level throughout pregnancy (1).

Concerning aerobic exercise, ASCM recommends intensities at target heart rate of 60-70% of maximal heart rate for priory sedentary pregnant women, and 60-90% of maximal heart rate for women with a history of pre-pregnancy regular exercise who wish to maintain fitness during pregnancy (1;2). However, conventional heart rate target zones for aerobic intensity is less dependable and accurate during pregnancy due to reduced maximum heart rate reserve (12) and the variability in maternal heart rate response to exercise (1). Measuring perceived exertion is recommended as an efficient alternative, and intensities with a perceived exertion of 12-14 (somewhat hard) on the 6-20 Borg scale is considered to be an optimal level for most pregnant women (1;2;58). In addition, the "talk test" (exercising at a level where one is able to keep a conversation) is suggested as a final check to avoid overexertion (2;12). However, a clinical opinion based on review of literature and clinical recommendations for exercise prescriptions during pregnancy recently critiqued the current exercise guidelines for pregnant women (62). The ACOG recommendations from 2002 were based on general public health recommendations from 1995 (62). According to Zavorsky & Longo (62), these recommendations were unclear on the definition of moderate intensity, as well as the recommended amount of weekly energy expenditure from physical activity. The authors (62) argue that as research has enhanced the understanding of the necessary dose of physical activity to improve health and quality of life, there is a need for a revision of the exercise guidelines for pregnant women.

In addition to aerobic exercise, activities that promote musculoskeletal fitness should be included in exercise prescriptions, i.e. resistance and flexibility training (1). Recommendations include the use of relatively low weights with multiple dynamic repetitions, to limit static work and exercises that result in a large pressor-effect (1;60), to ensure safe technique and to use proper breathing techniques (avoid breath-holding and valsalva manouver) (60). The Canadian guidelines for exercise in pregnancy (12) provides recommendations for muscular strengthening (Table 3).

Table 3 *Recommendations for muscular strengthening. From Wolfe & Davies (12)*

Target area	Effect
Upper and lower back	Promote good posture
Abdomen	Promote good posture, prevent low back pain, prevent diastasis recti and strengthen the muscles of labor
Upper body	To support the breasts
Buttocks and lower limbs	Facilitate weightbearing and prevent varicose veins
Pelvic floor exercises	Strengthen pelvic floor muscles and prevent urinary incontinence

In addition, warm up and cool down including range of motion exercises for all major joints and muscle groups should be incorporated (12). Flexibility exercises should focus on maintaining normal range of motion, taking in consideration the increased relaxation of ligaments during pregnancy (1).

1.2.3 Potential risks of exercise during pregnancy

There are some potential risk factors associated with strenuous exercise during pregnancy, including fetal hyperthermia, hypoxia, growth restrictions due to insufficient nutrition, and abdominal trauma (1), as well as early pregnancy loss (63). In the case of hyperthermia, research indicates that pregnant women may have enhanced thermoregulatory capacity explained by increased plasma volume, improved heat storage capacity, enhanced heat loss by radiation, a lower sweating threshold and a greater ventilator heat loss (13). There are also some protective mechanisms concerning hypoxia (13). Studies show that the fetus compensate for the reduced placental blood flow either by increasing or decreasing heart rate, and reducing unnecessary movement (13). Hence, uterine and umbilical oxygen uptake remains unchanged during exercise (13). As for early pregnancy loss, a Danish study by Madsen et al. (63) found an increased risk of miscarriage in early pregnancy (< week 18) for women who exercised more than 7 hrs./weekly, and especially for high impact exercise. Though, the researchers (63) commented that potential research bias may explain part of the association, and that it is too early to draw public inferences based on the data. Further, a literature review exploring the potential relationship between physical activity and preterm birth concluded that no studies had found a detrimental effect of recreational activities for this outcome (64).

Hence, to date the benefits of exercise during pregnancy are considered much greater than the potential risks, and no reports of negative effects of low to moderate intensity aerobic exercise are found in a healthy pregnant population (2;6;58;60). Table 4 shows an overview of absolute and relative contraindications, and warning signs that exercise should be terminated.

Table 4 *Contraindications and warning signs related to aerobic exercise during pregnancy. From ACOG (59)*

Absolute contraindications	**Relative contraindications**	**Warnings signs to terminate exercise**
Hemodynamically significant heart disease	Severe anemia	Vaginal bleeding
Restrictive lung disease	Unevaluated maternal cardiac arrhythmia	Dyspnea prior to exertion
Incompetent cervix/cerclage	Chronic bronchitis	Dizziness
Multiple gestation at risk for premature labor	Poorly controlled type 1 diabetes	Headache
Persistent second- or third-trimester bleeding	Extreme morbid obesity	Chest pain
Placenta previa after 26 weeks of gestation	Extreme underweight (BMI <12)	Muscle weakness
Premature labor during current pregnancy	History of extremely sedentary lifestyle	Calf pain of swelling
Ruptured membranes	Intrauterine growth restriction in current pregnancy	Preterm labor
Preeclampsia / pregnancy-induced hypertension	Poorly controlled hypertension	Decreased fetal movement
	Orthopedic limitations	Amniotic fluid leakage
	Poorly controlled seizure disorder	
	Poorly controlled hyperthyroidism	
	Heavy smoker	

1.3 Physical activity among pregnant woman

A systematic review by Melzer et al. (65) found that activity-induced energy expenditure for pregnant women (gestation week 25-38) decreased by 13% to 23%, compared to non-pregnant women. The majority of the pregnant women had shorter duration of physical activity, and tended to shift towards less intense physical activity with lower risk of maternal and fetal injury (e.g. from running/jogging to swimming or walking) (65). This corresponds with findings in other studies (45;61). Likewise, Tendais and colleagues (37) found a prevalence of recommended physical activity (ACOG guidelines) of 39.3% in the first

trimester and 12.5% in second trimester of pregnancy. The authors (37) also reported a significant decrease in vigorous and total leisure time physical activity (37). As for the Norwegian population, two studies have shown that pregnant women reported low levels of regular exercise, and that there was a decline in physical activity and exercise from pre-pregnancy and throughout late gestation (66;67). Owe et al. (67) reported that the proportion of women being regular exercisers decreased from 46.4% before pregnancy to 28% and 20% by gestation week 17 and 30, respectively.

Poudevigne & O'Connor (45) proposed that a mix of biological, psychological, social and environmental factors explain the changes in pregnant women's leisure time physical activity, e.g. adaptation to the increased energy demands of pregnancy and cultural pressure. Also, fatigue and nausea are probable barriers to physical activity, especially during the first trimester (45). Difficulties in moving due to the enlarged body mass, as well as discomforts related to anatomical and physiological changes, might explain some of the shift towards less activity in the last trimester (45;65). Further, Foxcroft et al. (4) found that health-related variables (history of miscarriage, lower pre-pregnancy BMI, fewer pregnancy complaints) tended to predict exercise in early pregnancy, while sociodemographic variables like higher education were predictors in late pregnancy. In a sample of Norwegian pregnant women, Haakstad et al. (66) found that high gestational weight gain and a lack of social role models for exercise during childhood were inversely related to exercise in the third trimester. Pre-pregnancy exercise was the strongest predictor of regular exercise in late pregnancy (66). Owe et al. (67) reported that pregnant women experiencing multiple pregnancies, pelvic girdle pain or nausea (week 17), musculoskeletal pain and uterine contractions (week 30), as well as sick-leave, were less likely to exercise regularly.

1.4 Positive effects of maternal exercise

There are numerous beneficial health effects of physical activity in the general population (9), including cardiovascular and musculoskeletal fitness (8). In addition, a positive association has been established between regular physical activity and cardiovascular disease, type 2 diabetes, osteoporosis, obesity, some types of cancer and levels of anxiety and depression (9). Moreover, recent research have shown an association between time spent sedentary (1-1.5 METs) and increased risk of cardio-metabolic disease and all-cause mortality, independent of leisure-time physical activity levels (68;69).

There is nothing to imply that healthy pregnant women will not derive the same health benefits from regular physical activity as the general population (1;59;70). Moreover, as shown in Table 10 (Appendix 1), several studies have documented positive effects of regular maternal exercise in relation to pregnancy-related outcome measures. Proposed benefits include improved or maintained maternal fitness (41;52;65;71), prevention of gestational diabetes mellitus (GDM) (41;52;70;72-74), pregnancy-induced hypertensive disorders (52;61;70;72-74) and reduced excessive gestational weight gain (EGWG) (41;61;70;72;74).

In addition, the research hypothesis in the present study is that regular exercise may have a positive effect on maternal psychological variables and common pregnancy complaints.

1.4.1 Exercise and psychological variables

In the general population, studies suggest that physical activity has the potential to improve psychological well-being, mood, depressive symptoms and quality of life-outcomes (24;75-77). Results from a systematic review showed a consistent positive association between physical activity level and health-related quality of life (78). Likewise, improved mental health and general well-being are proposed maternal benefits of regular physical activity during pregnancy (6;60;65). However, a limited amount of RCTs exploring this area has been performed in a pregnant population, and there is little knowledge about the psychological effects of exercise during pregnancy.

Pregnancy depression

There is some evidence of an inverse relation between physical activity and pregnancy depression. A quasi-experimental study on pregnant adolescents observed a significant decrease in symptoms of depression from pre- to post-test in the exercise group (17). Pottinger and colleagues (18) reported that occational exercise was one out of five protective factors against a depressive disorder in a population of pregnant women (the others being planned pregnancy, not smoking, being married and support from physician and family). Moreover, an observational study by Haas et al. (21) found that lack of exercise both prior to and during pregnancy was associated with higher depressive symptoms. This corresponds with findings in other studies: A cohort study by Demissie et al. (79) found that active women ($\leq$ 2.67 hrs. physical activity/wk.) had almost half the odds of having high depressive symptoms compared to pregnant women with no moderate-vigorous physical activity. Also, a cross-sectional study measuring physical activity by accelerometer reported that women

classified as not having depressive symptoms spent significantly more time in moderate-intensity physical activity than women with depression symptoms (80). This is in contrast to two longitudinal studies that found no significant group differences for depression (37;38). In the Norwegian population, a study by Nordhagen & Sundgot-Borgen (81) found that physically active pregnant women had lower levels of pregnancy depression.

Search on Pubmed throughout August 2013 revealed only one RCT evaluating the effect of a supervised exercise program on pregnancy depression. Robledo-Colonia et al. (19) reported reduced symptoms of depression measured by the CES-D in a group of pregnant women attending a supervised exercise program for three months, compared to the control group (Table 11, Appendix 2). However, the authors (19) commented that there was some uncertainty related to the estimate of a significant effect due to that a CES-D threshold-score has not been established for the pregnant population.

Well-being, quality of life and body-image

According to ACSM (6), there is evidence of a beneficial effect of physical activity on body-image and general well-being for pregnant women. A review by Prather et al. (41) found that maternal benefits of exercise during pregnancy among others included improved sense of well-being. The authors (41) also reported that exercise interventions combining stretching and strengthening claimed to increase quality of life in pregnant women. Another review by Poudevigne & O'Connor (22), claimed that evidence suggested that inactivity is associated with worse mood in pregnant women. This is supported by Haas et al. (21), who reported that being sedentary was associated with poor or fair self-rated health, poor physical function and vitality. According to a cross-sectional by Da Costa et al. (82), there was a consistent relationship between enhanced psychological well-being and leisure time physical activity. The authors (82) found that women who exercised reported significantly less depressed mood, daily hassles, state-anxiety and pregnancy-spesific stress than non-exercisers. This is consistent with the results from a prospective longitudional study by Goodwin et al. (38). The researchers (38) found that the exercise group reported a significantly higher level of psychological well-being, as well as lower frequency of somatic symptoms, anxiety and insomnia, compared to the non-exercise group (38). According to Polman and colleagues (29), even a single bout of exercise has been shown to result in enhanced mood in pregnant women. Contrary, in a longitudinal study, Tendais and colleagues (37) reported that the physical quality of life-scores decreased during pregnancy, independent of physical activity

status. Likewise, an observational study by Poudevigne & O'Connor (22) reported that there were no correlation between changes in physical activity and changes is mood for neither pregnant nor non-pregnant women.

Regarding body-image, Goodwin and colleagues (38) did not find significant differences between exercisers and non-exercisers, measured by self-report. Nevertheless, women in the exercise group retained a more positive attitude towards some of the growing body-parts (38). Also, attitude towards body-image moved in a positive direction in the exercise group and in a negative direction in the control group (38). The authors (38) suggested that a small sample size (n=65) may have contributed to the lack of significant differences for total body-image. Boscaglia and colleagues (83) reported that at 15-22 weeks' gestation, women with weekly exercise levels of at least 90 minutes of moderate exercise reported higher levels of body-image satisfaction than women with no or a minimum of exercise. According to the authors (83), the results suggest a positive relationship between body-image satisfaction and increased exercise behavior.

To date, only six RCTs have investigated the effect of regular exercise during pregnancy on the psychological outcomes included in the present study. As shown in Table 11 (Appendix 2), suggested effects include increased preception of health status (84;85), favorably changes in well-being and body-image (85) and improved health-related quality of life (36). Montoya Arizabaleta et al. (36) reported that the physical components of health-related quality of life (physical function, role-physical, bodily pain and general health) seemed to be more affected by physical activity than the mental aspects (vitality, social functioning, role-emotional and mental health). Barakat et al. (84) commented that regular physical activity could minimize the negative changes is pregnant women's psychological health, and thereby contribute to a healthy pregnancy. This is supported by Marquez-Sterling et al. (85), who claimed that exercise may have positive contributions to maternal health and psychological well-being. Other studies found no effect of exercise on quality of life (3;86). According to Nascimento et al. (3), the lack of effect could be explained by inconveniences that are typical at the end of pregnancies, e.g. weight gain, pain and fatigue. Vallim et al. (86) commented that both the exercise group and the control group scored high on the different quality of life-domains at all points of measurement, and that this, in addition to a small sample size, may explain the lack of association between exercise and quality of life.

As shown, the results from former exercise interventions vary, and the effect of exercise during pregnancy on well-being, quality of life, body-image and pregnancy depression is still unclear. Hence, there is a need for prospective longitudinal studies, as well as RCTs investigating the causality in the present field.

1.4.2 Exercise and common pregnancy complaints

To the author's knowledge, no RCT has explored the effect of exercise on a wide range of common pregnancy complaints. The search for literature for this study revealed two literature reviews that included this outcome: Melzer et al. (65) reported that maternal benefits of regular physical activity included reduced incidence of muscle cramps and lower limb edemas, while Prather et al. (41) reported the same for enhanced sleep. Also, some studies of lower quality were found. Older observational and pre-experimental studies reported that active pregnant women experienced fewer discomforts compared to sedentary pregnant women (53;54). Wallace et al. (53) found that the exercise group reported significantly less fatigue, backache, headache, shortness of breath and hot flashes, and that there was an inverse relationship between the amount of exercise and reported discomforts during the last trimester. In addition, the exercise group had lower scores on all but one discomfort (increase of appetite), compared to the control group (53). The authors (53) suggested that possible explanations might be that women exercise because they feel better. On the other hand, it might be that women who exercise are more used to minor symptoms in general, and therefore complain less about discomforts like shortness of breath and sensation of heat (53). Consistent with Wallace et al. (53), Horns and colleagues (54) found that women in the active group reported less discomforts than women in the sedentary group. Significant differences were found for vaginal discharge, swelling, leg cramps, fatigue and shortness of breath (54). Similarly, a quasiexperimental study by Hall & Kaufmann (87) found that pregnant women who attended an exercise program reported a decrease in common pregnancy discomforts as long as they participated. Moreover, Koniak-Griffin (17) found that the control group experienced a statistically significant increase in total discomforts and number of discomforts from pre- to post-test, assessed by self-report. Although both variables increased also in the exercise group, the change was not significant, suggesting that exercise might reduce the progression of minor pregnancy complaints (17).

Concerning nausea and vomiting of pregnancy, according to Foxcroft et al. (4) in a study to explore the correlates of exercise during pregnancy, results suggested that exercise helped

alleviate this complaint. Though, the authors (4) emphasized that it may also be that the women who chose to exercise during pregnancy were those who experienced less nausea and vomiting. On the other hand, a prospective study on the epidemiology of nausea and vomiting of pregnancy reported that exercise during the first trimester of pregnancy was significantly associated with a decreased likelihood of reporting nausea and vomiting in the second trimester (49).

Consistent with psychological outcomes, there is a need for high quality studies to explore the relationship between regular exercise in accordance with current exercise guidelines and common pregnancy complaints.

2. Aims of this study

Search on Pubmed throughout August 2013 revealed a few relevant RCTs exploring the effects of regular supervised exercise on psychological variables, but the evidence is conflicting and population sizes are small (n=15-82). In addition, the identified relevant literature include studies with differences in; study population (e.g. age, primi-/multiparas, obese/normal weight, gestation week, ethnicity and social-economic status), primary and secondary outcomes, types of exercise and dosage (intensity, frequency and duration), as well as duration of exercise interventions. Hence, comparison of results is difficult. Another concern is the report of high drop-out rates and a lack of reports of adherence to the intervention. If the participants are not following the protocol, we cannot correctly evaluate the overall effects. Moreover, Pubmed searches did not identify any RCTs exploring the effect of regular supervised exercise on a wide range of commonly reported pregnancy complaints, including poor sleep, unusual tiredness, numbness/reduced circulation, leg cramps, heartburn/acid reflux, nausea/vomiting, coordination and/or balance problems, problems with intestinal function, swollen legs/edemas, headache/migraine, varicosities, hemorrhoids and/or hernia.

Hence, there is limited knowledge about the effect of interventions following current recommendations of exercise on psychological outcomes and common pregnancy complaints, and none has been done in a population of pregnant women of Scandinavian origin. The present RCT is therefore the first to evaluate the effect of regular supervised exercise on both psychological outcomes and physiological pregnancy complaints, and includes the following specific aims:

1) What is the effect of 12-week supervised group exercise on self-reported well-being, quality of life, body-image and pregnancy depression?

2) What is the effect of 12-week supervised group exercise on commonly reported pregnancy complaints?

3. Methods

3.1 Study design

This study is the secondary analysis of a RCT with the primary aim to evaluate the effect of regular exercise on maternal weight gain (88). Project manager of the original intervention was Lene A. H. Haakstad (LAHH) at the Norwegian School of Sports Sciences, and the RCT was part of her doctoral dissertation "Physical activity and weight gain during pregnancy" in 2010. Assessment of psychological outcomes and common pregnancy complaints was done by analyzing questionnaire data collected through standardized interviews at baseline and post intervention.

Due to that the present project was based on already assembled data, all necessary approvals have been provided. All participants gave written consent to participate, and the study was approved by The National Committee for Medical Research Ethics, Southern Norway, Oslo (Appendix 3). The Norwegian Social Sciences Data Services (NNT) provided license to store and register individual health information (Appendix 4). The data is listed in the ClinicalTrials.gov Protocol Registration System (NCT00617149) and the procedures followed the World Medical Association Declaration of Helsinki. The complete study (included this secondary analysis) was conducted in agreement with the most recent Consort Statement (http://www.consort-statement.org).

3.2 Participants

Healthy, pregnant women were recruited to the trial from September 2007 to March 2008, mainly through health practitioners (pre-natal care clinics, midwives, physicians). In addition, newspaper articles and advertisement, websites for pregnant, flyers and word of mouth was used to spread information about the project and connect with eligible women. After a first phone contact explaining aims and implications of the study and checking eligibility criteria, 105 pregnant women from Oslo and nearby areas were invited to participate in the study. All participants received written and oral information about the purpose of the study and expectations, as far as exercise adherence, test-meetings etc. (Appendix 5). No economic compensation was given.

3.2.1 Inclusion criteria

Being healthy was defined as not having cardiovascular disease, diabetes mellitus, pregnancy-induced hypertension or pre-eclampsia by the time of inclusion. Health status was recorded through a health survey questionnaire (Appendix 6). In addition, participants should be previously sedentary, defined as pre-pregnancy exercise levels that did not include participation in a structured exercise program (> 60 minutes once per week) or significant amount of walking (>120 minutes per week) for the past six months. Other inclusion criteria were: pregnant with first child (primiparous), ability to read, understand and speak Norwegian and gestational age of 12-24 weeks.

3.2.2 Exclusion criteria

Exclusion criteria were set according to the most recent exercise guidelines at that time from ACOG (59), and included: severe heart disease, pregnancy induced hypertension, history of more than two miscarriages, persistent bleeding after week 12 of gestation, poorly controlled thyroid disease, pre-eclampsia and other diseases that could interfere with exercise participation (Table 4). Additional exclusion criteria were: not being able to attend 2-3 weekly exercise classes and lower limb ailments that could prevent exercise participation.

3.3 Procedures

The intervention was performed in a university setting at the Norwegian School of Sport Sciences, Department of Sport Medicine. The participants were examined three times during the study period: at baseline between 12-24 weeks of gestation, after the intervention at week 36-38 and postpartum, 6-12 weeks after delivery. Each visit lasted 60-75 minutes and started with individual interviews and registration of data from maternity cards, followed by measurements of weight and skin fold thickness and finally a submaximal treadmill test to measure cardiorespiratory fitness. Data collection was finished by September 2008. The present results were based on data from the standardized interview performed at the baseline and post-intervention tests. Data from the post-partum visit as well as physiologic measurements (oxygen uptake, work load, heard rate), are not included in this master thesis.

3.3.1 Sample size calculation

As this study was part of a RCT investigating the effect of exercise on weight gain during pregnancy, a priori power calculation was done according to this outcome measure only. Hence, we do not have a priori sample size calculation for psychological outcomes nor

common pregnancy complaints. Results from previous studies on psychological factors have shown that at the 0.05 level with a power of 0.80, a total sample size of 64 (31-33 per group) was required to detect a 3-point difference between the intervention group and the control group for quality of life measured by the 12-item Colombian version of the Medical Outcome Study Short-Form Health Survey (SF12v2) (36). Similarly, Robledo-Colonia et al. (19) assumed that a sample size of 74 (37 per group) would provide 80% power to detect a difference of 4 points at the 20-item CES-D scale. As no RCT reporting on well-being, body-image or common pregnancy complaints has been found, there were no comparable sample size calculations for these outcomes. The aim of the original study performed by Haakstad & Bo (88) was to recruit 100 primiparous women, 50 for the exercise group and 50 for the control group, which should also be sufficient to detect an effect for the primary and secondary outcomes in the present intervention.

3.3.2 Randomization

The participants were assigned to either an exercise group or a control group by an independent person not involved in either the assessment procedure or the exercise classes. Randomization was conducted by simple randomization, with no stratification, following a computerized randomization program and sealed envelope system.

3.3.3 Blinding

All testers, including the primary investigator (LAHH), were blinded to group allocation during the entire process, including plotting and analyzing the data. Besides, LAHH was not involved in the exercise classes. Participants in both the exercise group and the control group were emphasized not to reveal group allocation to LAHH during interviews.

3.4 Intervention

The exercise program included 60 minutes of supervised aerobic dance (Appendix 7), following the ACOG (59) exercise prescription. It was aimed that the program should be performed at least twice a week, with an option of a third session. Since most participants had full time employment, the exercise classes took place in the afternoon and evenings. In addition to participating in the aerobic dance classes, all participants in the exercise group were given advice of 30 minutes of moderate self-imposed physical activity on the remaining weekdays. This was in accordance with the recommendations for physical activity during

pregnancy (59). Moreover, they were asked to incorporate short bouts of activity in their daily schedule (active transportation on short distances, use of stairs instead of elevator etc.).

The exercise classes were choreographed and led by certified aerobics instructors, and each session included a maximum of 20-25 participants. Adherence was controlled by the instructors, and reported to the primary investigator weekly. The self-imposed daily activity was registered in a personal training diary, including reports of exercise activity, duration and intensity. Exercise intensity was initiated to be moderate, and was evaluated using Borg's rating of perceived exertion scale (89). Posters of the scale hang in the exercise room, and explanations of how it was used were given to the participants at each exercise session.

The women in the control group were asked to continue their usual physical activity habits, and were neither encouraged to nor discouraged from exercising, as this was considered unethical considering current physical activity guidelines (59).

3.5 Outcome measures

The baseline interview covered demographic information (e.g. age, gestation week, marital status, education and occupation, ethnicity and smoking habits), information about daily life, physical activity and sedentary behavior (e.g. household activities, active or passive transportation, work).

The primary and secondary outcomes were recorded at baseline and post-intervention through standardized interviews. Primary outcome measures were four psychological variables: well-being, quality of life, body-image and pregnancy depression. No instrument measuring these outcomes in a pregnant population was found. Hence, the questions used were primarily based on different existing questionnaires for the general adult population (90;91). Secondary outcomes were reported pregnancy complaints. Development and design of the interview guide was done in discussions with general physicians following what they perceived to be the most commonly reported pregnancy complaints, as well as different physical symptoms identified in the literature (11).

3.5.1 Primary outcomes; psychological variables

Well-being, quality of life and body-image were assessed by 16 questions (Appendix 8). The participants rated their "feelings" regarding different statements (the last 4 weeks) on a 6 item

scale (from 1 to 6), where 1 was negative and 6 was positive. Based on their nature, the questions were categorized in three different sub-groups: well-being, quality of life and body-image.

Well-being:

1. *To what extent do you feel your life is meaningful? 1 (not at all) – 6 (very much)*
2. *How satisfied are you with yourself? 1 (not satisfied) – 6 (very satisfied)*
3. *How often do you have negative feelings such as sadness, despair, anxiety or depression? 1 (always) – 6 (never)*
4. *How much do you enjoy life?1 (not at all) – 6 (very much)*
5. *How safe do you feel in your daily life? 1 (not at all) – 6 (very much)*

Quality of life:

6. *How would you rate the quality of your life?1 (very bad) –6 (very good)*
7. *How satisfied are you with your health?1 (not satisfied) – 6 (very satisfied)*
8. *Do you have enough energy for your everyday life activities?1 (not at all) – 6 (completely)*
9. *How satisfied are you with your sleep? 1 (not satisfied) – 6 (very satisfied)*
10. *How satisfied are you with your capacity for work? 1 (not satisfied) – 6 (very satisfied)*
11. *How satisfied are you with your personal relationships? 1 (not satisfied) – 6 (very satisfied)*
12. *How often do you feel worn out?1 (all the time) – 6 (not at all)*
13. *How satisfied are you with the support you get from others? 1 (not at all) – 6 (completely)*
14. *Do you feel lonely? 1 (always) – 6 (never)*
15. *To what degree are you able to participate in leisure-time activities? 1 (not at all) – 6 (completely)*

Body-image:

16. *Are you able to accept your bodily appearance? 1 (not at all) – 6 (completely)*

All variables were analyzed both separately and as a mean sum-score for each sub-variable. Sum-scores were computed by combining the scores from the related questions (well-being

and quality of life). The sum-scores were divided by the number of questions included in each sub-variable to create a mean sum-score. Example: if the mean scores for the questions included in a sub-variable were 5+4+4+5+3, the sum-score would be 21. The mean sum-score was then found by dividing the sum by the number of included variables (in this case 5), and the mean sum-score would be 4.2. In addition, a mean sum-score for the psychological variables was calculated by combining the scores from all the questions and dividing the sum by the number of questions (total 16).

Pregnancy depression was assessed through one yes or no question in the health and lifestyle-section of the interview guide (Appendix 9): *Have you in previous pregnancy weeks and/or in current pregnancy week experienced depression and/or psychological problems?*

3.5.2 Secondary outcomes; pregnancy complaints

Assessment of pregnancy complaints was obtained as part of the interview guide concerning "health and lifestyle", and included a yes or no response to 13 separate questions for each specific condition, as well as one overall question about pregnancy complaints. The following questions about specific physical symptoms were included (Appendix 9): *Have you in previous pregnancy weeks and/or in current pregnancy week experienced: poor sleep, unusual tiredness, numbness/reduced circulation, leg cramps, heartburn/acid reflux, nausea/vomiting, coordination- and/or balance problems, problems with intestinal function, swollen legs/edemas, pregnancy-related headache/migraine and/or hemorrhoids/varicosities/hernia?* In addition, all participants answered an overall question regarding physical changes and pregnancy complaints: *Have you in previous pregnancy weeks and/or in current pregnancy week experienced any pregnancy complaints? (yes/no).*

3.6 Statistical analyses

The statistical analyses were done using The Statistical Package for the Social Sciences (SPSS, SPSS Inc., Chicago, IL, U.S.A.), release version 18 for Windows.

Pearson's Chi-square for categorical variables and independent sample t-test for continuous variables were used to analyze if the exercise group and the control group were comparable with respect to background variables and outcome measures at baseline.

To evaluate the normal distribution of the primary outcome data, the Kolmogorov-Smirnov (Shapiro Wilks) test was used. A post-hoc estimation of effect size for the primary outcome measures was done using Cohen's *d*.

Post-intervention mean-scores for the psychological variables well-being, quality of life and body-image were compared between the two groups and the possible differences were tested using a two-sided independent sample t-test. Group differences in proportion of pregnancy depression and commonly reported pregnancy complaints were tested by Pearson's chi-square test. Data are presented as means with standard deviation (SD) and numbers with percentage.

The principal analysis was done on an intention to treat basis (ITT), and involved all women who were randomly assigned to either the exercise group or the control group. Missing values in the post-intervention test were replaced using Last Value Carried Forward (LVCF), by extending baseline values to the post-test. In addition to ITT, per protocol analysis based on ≥80% (≥ 19 exercise sessions, n =21) and 100% (24 exercise sessions, n=14) adherence have been done.

P-values less than 0.05 were considered to be statistically significant.

3.7 Research group

Master student on this project was Beate Torset. Primary supervisor was PhD, Associate Professor Lene A. H. Haakstad. This project was organized under the Department of Sports Medicine at the Norwegian School of Sport Sciences (NSSS).

4. Results

4.1 Description of participants

In total, 105 pregnant women (mean age 30.7) gave written consent to participate, attended the baseline interview and were randomized to the exercise group (n=52) or the control group (n=53). The majority was ethnic Norwegians (89.5%) and the remaining were from Sweden, Russia, Poland, Uganda, Iran, Chile and Burundi. As shown in Table 5, there were no statistically significant differences between the two groups on background variables at mean gestation week 17.7 (SD 4.1).

Table 5 *Background variables at baseline presented as means with standard deviation (SD) and numbers (n) with percentage (%) for the exercise group and the control group, respectively (n=105).*

Background variable	Exercise n=52	Control n=53	Missing
Age	31.2 (3.7)	30.3 (4.4)	
Gestation week	17.3 (4.1)	18.0 (4.3)	
Maternal weight (kg)	71.8 (11.4)	72.7 (14.3)	
Maternal height (m)	1.69 (0.1)	1.69 (0.1)	
Married/cohabiting	51 (98.1%)	52 (98.1%)	4
Daily smokers	2 (3.8%)	1 (1.9%)	
College/university	44 (84.6%)	45 (84.9%)	
Sick listed	10 (21.3%)	13 (27.7%)	11

4.2 Primary and secondary outcomes at baseline

One woman from the control group did not complete the interview on psychological outcomes at baseline. In addition, not all the participants answered every question and therefore individual questions had varying response rate. Due to that some women did not work at the time and that others did not feel comfortable answering all questions, three women in the exercise group and five women in the control group had missing values in five different questions (feeling safe, energy for activities of daily life, satisfaction with work capacity, fatigue and social support) (Table 5).

Except on the primary outcome variable *How often do you feel worn out?,* where the exercise group reported less fatigue than the controls (p=0.04), there were no significant differences between the groups on primary outcome variables including well-being, quality of life and body-image at baseline (Table 6). Overall, most of the mean scores for the primary outcomes were in the upper end of the scale (>4 on the 1-6 scale) in both the exercise and the control

group. Moreover, there were no significant difference between the exercise and the control group for pregnancy depression (Table 7).

Table 6 *Primary outcome measures, including well-being, quality of life and body-image at baseline (mean gestation week 17.3), rated on a standardized scale from 1(negative)* to *6 (positive). Results are presented as means with standard deviation (SD) (n=104)*

Primary outcomes	**Exercise n=52**		**Missing**	**Control n=52**		**Missing**	**p-value**
Primary outcome sum-score*	4.7	(0.5)		4.63	(0.6)		0.5
Well-being (sum-score)	4.94	(0.5)		4.98	(0.5)		0.7
Meaningful life	5.56	(0.7)		5.38	(0.8)		0.3
Satisfaction with self	4.67	(0.7)		4.71	(0.8)		0.8
Negative feelings (mood)	4.19	(1.0)		4.23	(1.0)		0.8
Enjoyment with life	5.31	(0.8)	2	5.40	(0.7)	2	0.5
Feeling safe in everyday life	5.18	(0.8)		5.36	(0.7)		0.2
Body-image (accept bodily appearance)	4.81	(1.0)		4.94	(1.0)		0.5
Quality of life (sum-score)	4.56	(0.6)		4.42	(0.7)		0.3
Quality of life	5.08	(0.9)		5.12	(0.7)		0.8
Health satisfaction	4.33	(0.9)		3.96	(1.3)	1	0.09
Energy for daily life	4.04	(1.3)		3.86	(1.2)		0.5
Sleep satisfaction	4.38	(1.4)	1	4.38	(1.4)		1.0
Work capacity	4.27	(1.2)		3.87	(1.4)		0.1
Personal relationships	4.96	(0.8)		5.02	(0.8)	1	0.7
Worn out (fatigue)	3.52	(1.1)		3.08	(1.0)	1	0.04
Support from friends	5.25	(1.0)		5.27	(0.8)		0.9
Feeling lonely	5.1	(0.9)		5.19	(0.9)		0.6
Able to participate in leisure time activities	4.79	(1.2)		4.77	(1.2)		0.9

** Mean score for all psychological variables combined*

Regarding the secondary outcome measures, one woman in the exercise group did not answer the question regarding poor sleep (Table 7). There were no significant differences between the groups on sum of pregnancy complaints or specific pregnancy complaints at baseline.

Table 7 *Secondary outcomes (common pregnancy complaints) and pregnancy depression at baseline (mean gestation week 17.3). Apart from report of total pregnancy complaints, which is presented as mean values with standard deviation (SD), the results are presented as observed cases and percentage (%) (n=105)*

Secondary outcomes	**Exercise n=52**	**Missing**	**Control n=53**	**p-value**
Sum of pregnancy complaints (total13)	3.8 (1.8)		4.1 (1.6)	0.4
Poor sleep	18 (34.6%)	1	19 (36.5%)	0.8
Unusual tiredness	38 (73.1%)		44 (83%)	0.2
Numbness/reduced circulation	6 (11.5%)		11 (20.8%)	0.2
Leg cramp	10 (19.2%)		11 (20.8%)	0.8
Heartburn/acid reflux	20 (38.5%)		20 (37.7%)	0.9
Nausea/vomiting	32 (61.5%)		31 (58.5%)	0.8
Coordination/balance problems	4 (7.7%)		5 (9.4%)	0.8
Intestinal function	36 (69.2%)		39 (73.6%)	0.6
Swollen legs/edemas	9 (17.3%)		7 (13.2%)	0.6
Head ache/migraine	20 (38.5%)		27 (50.9%)	0.2
Hemorrhoids	3 (5.8%)		3 (5.7%)	1.0
Varicosities	2 (3.8%)		1 (1.9%)	0.5
Hernia	2 (3.8%)		0	0.2
Overall pregnancy complaints*	20 (38.6%)		20 (37.7%)	0.9
Pregnancy depression	6 (11.5%)		11 (20.8%)	0.2

**Overall question: Have you in previous pregnancy weeks and/or in current pregnancy week experienced any pregnancy complaints?*

4.3 Lost to test

Figure 1 illustrates the flow diagram of the participants with losses to follow-up and reasons for drop-out in the exercise and the control group, respectively.

Overall, 21 women were lost to the test, 10 (19.2%) in the exercise group and 11 (20.8%) in the control group. One woman in the exercise group was excluded due to twin pregnancy and one woman in the control group was excluded due to thyroid disease. The rest dropped out due to pregnancy-related complications (pelvic girdle pain, possible pre-eclampsia, leakage of amniotic fluid, uterine contractions), premature birth, relocations, withdrawals and other unknown reasons. According to analysis done by Haakstad & Bø (88), there were no significant differences between the women who dropped out and those who completed the post-intervention tests.

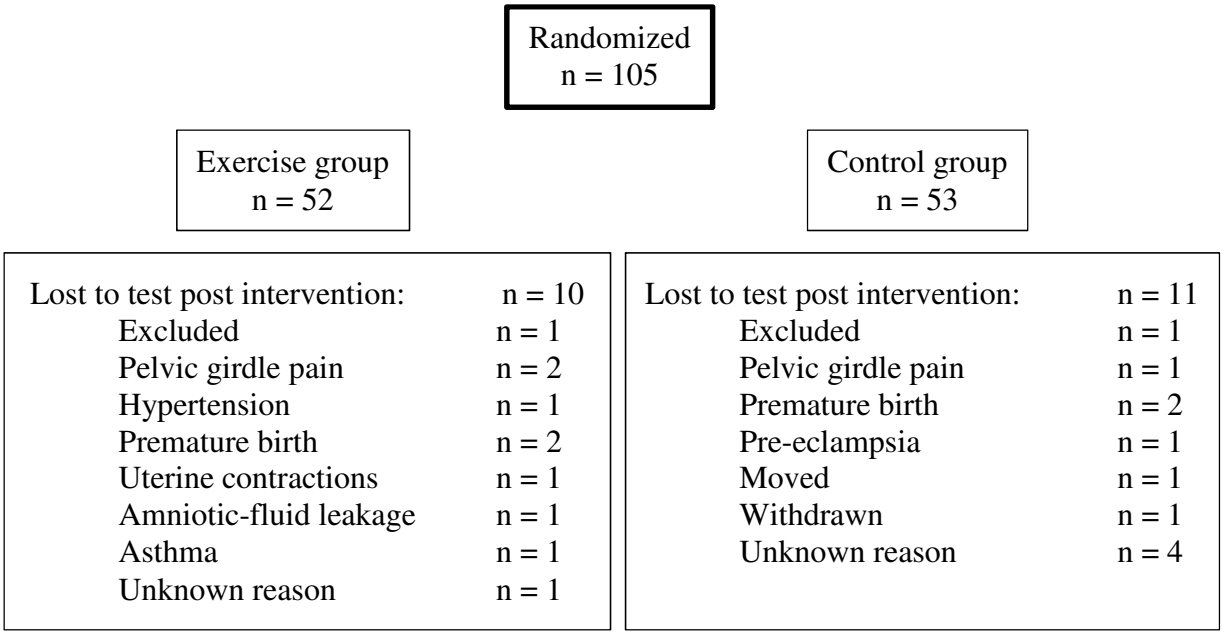

Figure 1 *Flow of participants through the RCT*

4.4 Adherence to exercise protocol

The recommendation of at least 19 exercise classes (80% exercise adherence) was followed by 21 women (40.4%). A total of 24 exercise sessions (100% exercise adherence) were completed by 14 women (26.9%). This represents in mean two exercise sessions per week over a period of 12 weeks. Four women randomized to exercise never showed up for the scheduled exercise classes. Hence, out of a total of 24 exercise sessions, mean adherence rate was 17.2 (SD 12.5).

4.5 Primary and secondary outcomes post intervention

At mean gestation week 36.6 (SD 1.0), a total of 84 women (42 in both groups) completed assessment of primary and secondary outcomes. Results from the Kolmogorov-Smirnov (Shapiro Wilks) test showed that scores related to the primary outcome (well-being, quality of life and body-image) were not normally distributed. For most questions, there were negative skewness values with scores clustered at the right side of the graph (high end), and few plots on the lower end of the scale.

As shown in Table 8, women in the exercise group scored significantly better on two questions regarding quality of life: *How often do you feel worn out?* (p=0.04) and *How satisfied are you with your health?* (p=0.02). The latter was also significant for the per

protocol analysis (p=0.01) and 100% exercise adherence (p=0.001). In addition, women with 100% exercise adherence (24 sessions) had a significantly better score compared to the control group on one question related to measurement of well-being: *How often do you have negative feelings such as sadness, despair, anxiety or depression?* (p=0.01). In contrast, the control group had a more favorable score on the question: *How much do you enjoy life?* (p=0.01). Otherwise there were no significant between-group differences on any of the primary outcome variables analyzed as sum-scores nor each variable separately, but scores related to the questions about fatigue (feel worn out) and energy for activities of daily life were borderline significant for women attending 24 exercise sessions (100% adherent) (p=0,05 and 0.06 respectively).

In addition, although not significant, all levels of analysis showed that fewer women in the exercise group reported to have experienced pregnancy depression, compared to women being controls (Table 9).

Table 8 *Primary outcome measures including well-being, quality of life and body-image post intervention, rated on a standardized scale from 1 (negative)* to *6 (positive). Results are presented as means with standard deviation (SD), analyzed by intention to treat (ITT), per protocol (≥80% exercise adherence) and 100% exercise adherence*

	ITT					**Per protocol**					**100% exercise adherence**				
Primary outcome variables	Exercise n=52		Control n=52		p-value	Exercise n=21		Control n=52		p-value	Exercise n=14		Control n=52		p-value
Primary outcome sum-score*	4.64	(0.6)	4.53	(0.6)	0.4	4.54	(0.6)	4.53	(0.6)	0.9	4.67	(0.4)	4.54	(0.6)	0.4
Well-being (sum-score)	5.01	(0.6)	5.0	(0.6)	0.6	4.90	(0.6)	5.0	(0.6)	0.7	5.0	(0.3)	5.0	(0.6)	0.7
Meaningful life	5.56	(0.6)	5,52	(0.6)	0.7	5.48	(0.6)	5,52	(0.6)	0.8	5.5	(0.7)	5,52	(0.6)	0.9
Satisfaction with self	4.71	(0.8)	4.73	(0.6)	0.9	4.62	(0.8)	4.73	(0.6)	0.5	4.64	(0.7)	4.73	(0.6)	0.7
Negative feelings (mood)	4.31	(0.9)	4.15	(1.0)	0.4	4.24	(0.9)	4.15	(1.0)	0.7	4.64	(0.5)	4.15	(1.0)	0.01
Enjoyment with life	5.27	(0.8)	5.37	(0.7)	0.5	5.05	(0.8)	5.37	(0.7)	0.08	5.07	(0.3)	5.37	(0.7)	0.01
Feeling safe in everyday life^	5.31	(0.8)	5.29	(0.7)	0.9	5.10	(1.0)	5.29	(0.7)	0.4	5.14	(0.5)	5.29	(0.7)	0.4
Body-image (accept bodily appearance)	4.92	(0.8)	4.98	(0.9)	0.7	4.95	(0.7)	4.98	(0.9)	0.9	4.86	(0.8)	4.98	(0.9)	0.6
Quality of life (sum-score)	4.43	(0.6)	4.28	(0.7)	0.3	4.32	(0.7)	4.28	(0.7)	0.8	4.48	(0.4)	4.28	(0.7)	0.2
Quality of life	5.25	(0.7)	5.10	(0.8)	0.3	5.14	(0.7)	5.10	(0.8)	0.8	5.14	(0.5)	5.10	(0.8)	0.8
Health satisfaction	4.63	(1.0)	4.15	(1.2)	0.02	4.90	(1.0)	4.15	(1.2)	0.01	5.14	(0.8)	4.15	(1.2)	0.001
Energy for daily life	4.00	(1.0)	3.73	(1.0)	0.2	3.95	(1.0)	3.73	(1.0)	0.4	4.29	(0.8)	3.73	(1.0)	0.06
Sleep satisfaction	3.67	(1.3)	3.87	(1.5)	0.5	3.48	(1.2)	3.87	(1.5)	0.3	3.64	(1.2)	3.87	(1.5)	0.6
Work capacity^^	3.92	(1.3)	3.90	(1.2)	0.9	3.90	(1.2)	3.90	(1.2)	1.0	4.15	(0.8)	3.90	(1.2)	0.5
Personal relationships	4.87	(1.0)	4.94	(0.8)	0.7	4.71	(0.8)	4.94	(0.8)	0.3	4.71	(0.6)	4.94	(0.8)	0.3
Worn out (fatigue)	3.44	(1.0)	3.04	(0.9)	0.04	3.29	(0.9)	3.04	(0.9)	0.3	3.57	(0.6)	3.04	(0.9)	0.05
Support from friends	5.21	(1.0)	5.0	(0.9)	0.2	4.90	(1.2)	5.0	(0.9)	0.7	5.00	(1.0)	5.0	(0.9)	1.0
Feeling lonely	5.04	(1.0)	4.98	(1.0)	0.8	4.76	(1.1)	4.98	(1.0)	0.4	4.93	(0.8)	4.98	(1.0)	0.9
Able to participate in leisure time activities	4.35	(1.1)	4.29	(1.1)	0.8	4.43	(0.7)	4.29	(1.1)	0.5	4.50	(0.7)	4.29	(1.1)	0.4

** Mean score for all psychological variables combined*
^Missing. Exercise group: n=51, CG: n=49
^^Missing. Exercise group: n=51, CG: n=50

Table 9 shows secondary outcomes including total number of reported pregnancy complaints, specific pregnancy complaints and the overall question "*Have you in previous pregnancy weeks and/or in current pregnancy week experienced any pregnancy complaints?"* There were no significant differences between the groups according to ITT analysis. As for per protocol and 100% exercise adherence, significantly fewer women in the exercise group reported episodes of nausea/vomiting, compared to the control group: 0 vs. 12 (p=0.02 and 0.049). In addition, fewer women with 100% exercise adherence reported of numbness/reduced circulation compared to women in the control group (p=0.02).

For women with 100% exercise adherence, there was a tendency that total number of reported pregnancy complaints was less than for controls. Mean number of reported complaints was 3.0, compared to 4.0 reported by women in the control group (p=0.07) (Table 9).

Table 9 *Prevalence of secondary outcome measures (common pregnancy complaints) and pregnancy depression post intervention. Apart from reports of total pregnancy complaints, which are presented as mean values with standard deviation (SD), the results are presented as observed cases and percentage (%). All variables are analyzed by intention to treat (ITT), per protocol (≥80% adherence) and 100% adherence*

	ITT			**Per protocol**			**100% exercise adherence**		
Secondary outcome variable	Exercise group n=52	Control group n=53	p-value	Exercise group n=21	Control group n=53	p-value	Exercise group n=14	Control group n=53	p-value
Sum of pregnancy complaints (total13)	3.8 (1.9)	4.0 (1.7)	0.5	3.4 (1.8)	4.0 (1.7)	0.2	3.0 (0.5)	4.0 (0.2)	0.07
Poor sleep	24 (46.2%)	28 (52.8%)	0.5	13 (61.9%)	28 (52.8%)	0.5	8 (57.1%)	28 (52.8%)	0.8
Unusual tiredness	25 (48.1%)	28 (52.8%)	0.6	9 (42.9%)	28 (52.8%)	0.4	5 (35.7%)	28 (52.8%)	0.3
Numbness/reduced circulation^	15 (29.4%)	16 (30.2%)	0.9	5 (25%)	16 (30.2%)	0.7	0	16 (30.2%)	0.02
Leg cramp	21 (40.4%)	23 (43.4%)	0.8	9 (42.9%)	23 (43.4%)	1.0	7 (50%)	23 (43.4%)	0.7
Heartburn/acid reflux	29 (55.8%)	31 (58.5%)	0.8	12 (57.1%)	31 (58.5%)	0.9	7 (64.3%)	31 (58.5%)	0.7
Nausea/vomiting	8 (15.4%)	12 (22.6%)	0.3	0	12 (22.6%)	0.02	0	12 (22.6%)	0.049
Coordination problems	6 (11.5%)	8 (15.1%)	0.6	3 (14.3%)	8 (15.1%)	0.9	2 (14.3%)	8 (15.1%)	0.9
Intestinal function	19 (36.5%)	21 (39.6%)	0.7	5 (23.8%)	21 (39.6%)	0.2	3 (21.4%)	21 (39.6%)	0.2
Swollen legs/edemas	24 (46.2%)	26 (49.1%)	0.8	10 (47.6%)	26 (49.1%)	0.9	3 (28.6%)	26 (49.1%)	0.2
Head ache/migraine	9 (17.3%)	10 (18.9%)	0.8	2 (9.5%)	10 (18.9%)	0.3	1 (7.1%)	10 (18.9%)	0.3
Hemorrhoids	11 (21.2%)	8 (15.1%)	0.4	4 (19%)	8 (15.1%)	0.7	4 (28.6%)	8 (15.1%)	0.2
Varicosities	4 (7.7%)	3 (5.7%)	0.7	0	3 (5.7%)	0.3	0	3 (5.7%)	0.4
Hernia	3 (5.8%)	0	0.07	0	0	-	0	0	-
Overall pregnancy complaints*	28 (53.8%)	32 (60.4%)	0.5	14 (66.7%)	32 (60.4%)	0.6	7 (50%)	32 (60.4%)	0.5
Pregnancy depression	3 (5.8%)	9 (17%)	0.07	3 (14.3%)	9 (17%)	0.8	1 (7.1%)	9 (17%)	0.4

**Overall question: Have you in previous pregnancy weeks and/or in current pregnancy week experienced any pregnancy complaints?*

^One reply missing from the exercise group

5. Discussion

5.1 Methodological considerations

5.1.1 Study design

To the author's knowledge, this is the first RCT to assess the effect of a structured and supervised exercise program following ACOG (59) guidelines on both psychological factors and commonly reported pregnancy complaints, in a group of sedentary primiparous women. The results showed that regular exercise had positive effects on well-being, quality of life and prevalence of some common pregnancy complaints. According to the CONSORT statement (CONSORT), well-designed RCTs are considered the best scientific study design to detect whether a cause-effect relation exists between the intervention and the outcomes, as well as for assessing the efficacy of the intervention (92). CONSORT was published in 1996 with an objective to guide authors on how to improve reporting of RCTs, and includes a checklist of important items that should be included in trail reports, as well as a flow diagram to document the flow of participants through a trial (92).

The Pedro-scale (Physiotherapist Evidence Database) was developed in 1999 to improve the reporting of study results and aid readers to identify valid studies and interpret their results (93). PEDro includes 11-items to reduce research bias in clinical trials, such as blinding, specification of eligibility criteria, concealed allocation and equal treatment of groups except from the experimental intervention (93). Item 1 through 10 is related to internal validity, and helps the researcher to determine if the observed effect can be related to the treatment (92). Item number 11 is about external validity, which refers to the ability to generalize the results to other participants and settings (94). External validity can be controlled by selecting participants, experimental situation and intervention that can be generalized to a larger population (94). According to PEDro, participants should be studied within the group they were randomized to independent of whether they received the treatment (intention to treat analysis, ITT), and outcome measures should be obtained from more than 85% of the subjects originally allocated to the groups (93).

The present RCT fulfills eight of the 11 items on the PEDro quality scale. As for all the intervention studies that includes exercise, blinding was possible for the primary investigator (LH) only, as both the participants and the aerobics instructors knew who were randomized to the exercise group. Also, the study did not fulfill the criteria of 85% measurement of the key outcomes in either the exercise group (81%) or the control group (79%).

5.1.2 Participants

According to CONSORT, randomization is a crucial component of RCTs (92). Randomization controls for many of the existing threats to internal validity, e.g. history before intervention, maturation, statistical regression, selection biases and selection-maturation interaction (94). With random allocation, each participant has a known probability of being allocated to the exercise group or the control group, but the final allocation cannot be predicted as it is a result of chance (92). The aim of randomization is to generate unbiased comparison groups not affected by selection or confounding biases (95), that allows the assumption that the groups are equal at baseline (94). The strengths of the present study include randomization of participants to an exercise group and a control group. As the randomization was conducted by a person not involved in the intervention, neither the researchers nor the participants could influence the process. Also, the randomization was conducted after baseline test: hence the results from this test were not affected by group assignment.

Due to that the present study included a secondary analysis of data from a RCT on maternal weight gain (96), a priori power calculations was done for this outcome only. A post-hoc evaluation of power revealed that the included number of participants gave small to medium effect size (< 0.44) for the primary outcomes in the present RCT. Hence, the sample size may not have been sufficient to detect all the hypothesized effects of exercise on the primary and secondary outcome variables in the present RCT (type II error). In accordance with CONSORT, all analysis were based on original group assignment (exercise group and control group), regardless of adherence or compliance of each participant (ITT). One requirement for an ideal ITT-analysis is a complete dataset on all participants, as noncompliance with the assigned treatment may increase the risk of underestimating the treatment effect (type II error) (92). Hence, in the present study the number of losses to follow-up might have represented a limitation and reduced

the ability to draw conclusions based on an ITT-analysis. However, although drop out may have reduced the power of the study, the between-group differences in number of women lost to the post-test and also the reasons for the drop-outs, were minor. Neither were there any significant differences on background variables at baseline (mean gestations week 17.7). Hence, it is likely that the exercise group and the control group were relatively balanced with respect to known and unknown confounding factors.

To overcome the missing values in the dataset and be able to perform ITT-analysis, the imputation technique last value carried forward (LVCF) was used. LVCF is a simple imputation strategy that has shown to be common in articles discussing quality of life outcomes (97), as well as physical functioning and health (98) in the general population. According to researchers (97;98), the method has been critiqued as it assumes that the outcomes does not change with time, which is unlikely in quality of life situations (97), as well as when physical health is concerned (98). Revicki et al. (98) found that LVCF was acceptable when missing data was low. When missing values exceeded 15%, more complex imputation techniques provided better estimates of the between-group differences, as LVCF tended to underestimate the effect of the interventions (98). In the present study, the use of LVCF meant carrying forward an off-treatment score (baseline) to an on-treatment missing value (post-intervention), thus assuming that outcome scores were not affected by exercise or by gestation week. According to researchers (97), this is unlikely to reflect the truth. Hence, as missing data represented about 20% in the present study, the application of baseline values to the post-intervention test may have contributed to underestimate the effect of the exercise intervention for the primary and secondary outcomes (type II error). On the other hand, the effect of the intervention may have been overestimated (type I error): Both psychological variables and pregnancy complaints are likely to change according to gestation week, and some variables might be expected to change in a negative direction (21;34;35;45). An alternative method to deal with missing data is to report on completers only (97). The disadvantage of this method is a reduced sample size and power of the study, and thus less ability to draw conclusions (97). Moreover, excluding drop-outs could give reduced control with the randomization of participants, and may produce biased results unless the reasons for the missing data are completely random (97).

A common challenge for interventions involving exercise is to motivate participants to attend all the recommended exercise sessions. In the present study mean adherence was 17.2 out of 24 sessions. In comparison, Montoya Arizabaleta and colleagues (36) reported that 75% of the participants attended ≥ 25 of the 36 sessions. Robledo-Colonia et al. (19) reported higher adherence rates. Women in the exercise group attended an average of 28.9 out of 36 sessions (19). To adjust for the low adherence in the present study, per protocol analysis (≥80% exercise adherence to exercise sessions) and analysis of 100% exercise adherence were done. These methods may be helpful to assess the effect of the exercise intervention, but may also overestimate the effect due to selection bias (type I error). Hence, because the participants who follow the prescribed exercise may differ from those who do not, the ability to generalize the results is limited. In addition, in the present study these analyses are limited by small numbers.

Being previously sedentary, defined as pre-pregnancy exercise levels that not included participation in a structured exercise program (>60 minutes once per week) or significant amount of walking (>120 minutes per week) for the past six months, was one of the eligibility criteria for the present study. It could be questioned whether only sedentary women were randomized to the trial. A positive relationship between exercise and psychological outcomes like depression and quality of life has been found both in the general population and among pregnant women. In the present study, the population of pregnant women had high ratings on most psychological variables at admission point, and results could have been affected if the subjects were already participating in regular physical activity. However, measurements of baseline oxygen uptake on the same population done by Halvorsen et al. (99), suggested that the study population could be categorized as sedentary. The reported levels of oxygen uptake were below mean values for the general adult female population of the same age (96).

To be able to generalize results, the population of a study needs to be representative for the population at large. As exercise interventions relies on cooperation from the participants with respect to following exercise protocol and attending tests and interviews, there may be a risk of selection bias if the volunteers are more interested in physical activity and health-related outcomes than the average population. On the other hand, voluntary participation is necessary to be able to conduct such interventions. Moreover, a limitation to RCT designs is that they are relatively expensive and

somewhat time-consuming for the study group, exercise interventions in particular. Because the population in the present study was primiparous women, it was expected that they would have more time and motivation to exercise compared to multiparous women with child care responsibilities. Also, because the exercise sessions took place in the afternoons and evenings, it was assumed that the women randomized to exercise would be able to adhere to two out of three possible exercise sessions weekly. However, only 40% and 27% of the women did follow ≥80% or 100% of the exercise sessions, respectively. Follow-up phone calls to the women who did not attend the exercise sessions revealed that lack of time was the main reason for not exercising. This is in accordance with findings by Haakstad et al. (66), who reported that insufficient time and difficulties due to children and childcare were among top four reasons for not performing regular exercise.

The average age of the participants in the present study was higher than the average age of Norwegian primiparous women, 30.7 years vs. 28.5 years (100), and 84% had completed tertiary education. Higher education has been found to be a correlation to physical activity (101), as also demonstrated in the study by Foxcroft and colleagues (4). Hence, the population in the present study might represent a limitation to external validity as it was a group of healthy primiparous women with a high education level. Therefore, this sample may not be representative of the pregnant population at large.

It was not considered unethical to offer the treatment only to the exercise group. The control group was neither encouraged to or discouraged from exercising, as this would be against the present guidelines (59). Both groups were treated equal except from the experimental intervention, including undergoing the same tests and interviews. Nevertheless, the post intervention interview revealed that some of the participants in the control group were disappointed with group allocation, and had started exercise routines similar to the exercise group (96). This bias is referred to as the AVIS-effect (94). Hence, the between-group differences concerning the intervention might have been smaller than planned. Therefore, it is likely that the expected treatment effect related to the supervised exercise program was difficult to detect.

5.1.3 Study intervention

Current exercise guidelines for pregnant women (12;59) include an advice of participation in 30 minutes or more of moderate intensity exercise on most or all days of the week. When planning this intervention, it was assumed that it would be easier to recruit a study population of previously sedentary pregnant women if the required amount of exercise classes was limited to two days a week, with an option of a third day. It could be speculated if the recommended amount of exercise sessions was too low to see an effect on the outcomes of the present study. Other studies reporting effects of exercise on psychological outcomes included recommendations of three weekly exercise sessions (19;36;84;85), although only two of these reported adherence rates (19;36). In the present study, the fact that exercise adherence was recorded by the group exercise instructors represents a strength. Unfortunately, adherence rates showed that the participants were not able to fulfill to the recommendation of two weekly exercise sessions. Hence, it is unlikely that an advice of three weekly exercise sessions would have yielded a higher exercise adherence. Moreover, women in the exercise group were advised to include 30-minutes of moderate self-imposed physical activity on the days without participation in supervised exercise sessions. Although participants were encouraged to record their self-imposed physical activity in their personal training dairy, few actually completed this recording. Hence, there is no data on whether the participants fulfilled the advice of physical activity on the remaining week-days.

According to Thomas & Nelson (94), research in physical activity can be placed on a continuum with applied and basic research on opposite ends. In general, applied research is conducted in a real-world setting and has direct value to the practitioners, while basic research is a typical laboratory setting (94). Likewise, the term “ecological validity” refers to whether the research setting can be transferred to the real world (94). The present study could be seen as an example of applied research with good ecological validity, as the intervention contained elements similar to what can be found at most fitness clubs. The exercise classes included 35 minutes of endurance exercise planned to fit inactive pregnant women, performed as easy-to-follow choreography with low-impact exercises. In addition, the program included 15 minutes of strength training and 10 minutes of warm-up and cool-down exercises. The classes were led by qualified aerobics instructors who gave instructions on intensity following the Borg scale, and also emphasized the importance of adherence to the exercise protocol. Classes were

performed in a modern group exercise room with air-conditioning, had a limited number of participants (20-25), and were accompanied by music. Hence, a similar exercise program can also be obtained in the real world.

The cardiovascular part of the exercise program was aimed to have an exertion level of 12-14 (somewhat hard). Researchers (62) have argued that increasing the amount of vigorous exercise would give additional benefits to maternal health compared to less vigorous exercise. Hence, the intensity in the exercise classes in the present study may not have been optimal to assess the potential effects of the exercise intervention. Moreover, due to the long recruitment period, new participants joined the exercise sessions throughout the intervention. This limited the aerobics instructors' possibility to include a gradual progression of the program, as well as the intensity. On the other hand, due to that women with regular participation could learn the choreography better, and in addition that the Borg scale was used to guide intensity, it might have been easier for each participant to achieve the recommended intensity. However, in a pregnant population, there are some limitations to guiding intensity based on the participant's perceived exertion level. As pregnancy progresses, the women gain weight and might experience discomforts related to movement. Hence, they might feel that they are exercising at a higher level than they really are. It could be speculated if an objective evaluation of intensity in addition to the Borg scale, would have resulted in higher actual exercise intensity in the present study. In comparison, other studies (19;36;84;85) reported to have guided the intensity through the use of heart rate monitoring. On the other hand, heart rate monitoring is found to have some limitations in the pregnant population due to the variability in maternal heart rate response to exercise (1).

Information about the reasons for the low adherence to exercise in the present study was not available. It could be questioned if performing 60 minutes of exercise twice a week was too demanding for the target group of sedentary pregnant women, and that the motivation to adhere to the program was low. Zavorsky & Longo (62) recently claimed that with more vigorous exercise, less total time of exercise is required per week due to that physical activity energy expenditure is increased both during and after exercise. Taking into account that lack of time has been rated as an important reason for not undertaking regular exercise, a program of shorter and/or fewer exercise sessions with higher intensity might have made it easier for the population of previously sedentary

pregnant women to incorporate regular exercise into their schedule. However, there are some proposed risks related to high-intensity maternal exercise (13;63) . Although it appears that the mother and the fetus have sufficient physiological reserve to tolerate short periods of high intensity exercise (13), further research on safety and efficiency is necessary to evaluate the possible additional effects of increased exercise intensity on maternal fitness and health.

5.1.4 Assessment procedures and outcomes

Measurement of validity and reliability is important in research. Validity refers to whether the test-instrument measures what it is supposed to measure, and reliability is the repeatability of the measurement (94). In the present study, except from one day, all interviews were done by the primary investigator. This reduced the need for counseling of extra personnel, as well as the risk of bias due to differences in the data collection. In addition, the interviews were conducted following a standardized interview guide, ensuring that all women were asked the same questions in th e same order. All intervention visits took place during normal work hours and therefore the duration of the interviews were kept to a minimum. Consequently, the control group underwent the same follow-up questions about physical activity habits post-intervention as the exercise group. This also ensured that the primary investigator was blinded to group allocation during the study period.

The current study measured psychological outcomes based on an interview guide specifically constructed for this intervention, including questions about self-perception of well-being, quality of life and body-image. The interview guide was comparable to the existing questionnaires: the WHOQOL-bref and the SF-36, but included fewer questions. Part of the explanation for the limited number of statistically significant between-group differences for well-being and quality of life in the present study may be less sensitive tools for detection of changes in the psychological variables. This is in consistency with comments by researchers assessing quality of life by the WHOQOL-bref (86). Likewise, assessing self-reported pregnancy depression through only one question was probably not sensitive enough, compared to clinical tools like the CES-D. In contrast, both Koniak-Griffin (17) and Robledo-Colonia et al. (19) found reduced depressive symptoms measured by CES-D after a supervised exercise program. Consistent with pregnancy depression, the present study measured body-image through

one specific question about satisfaction with body appearance. Other studies (33;38) reporting on body-image in a pregnant population have used the Body Cathexis Scale, or the Body Attitudes questionnaire. As both these questionnaires measure a wider range of factors related to body-image and well-being, results are probably not comparable to the single question about appearance included in the current study.

At the time of planning the original intervention, neither the WHOQOL-bref nor the SF-36 were found to have been validated for the pregnant population. Nevertheless, it could be questioned if the study could have used one of these existing questionnaires, which would have made the results more comparable to other studies. The disadvantage of using questionnaires designed for other populations is that they may not account for or measure accurately enough all pregnancy-specific symptoms and psychological changes. In addition, due to that the primary outcome of the original study was maternal weight gain, each meeting with the participants included measurement of weight and skinfold thickness, in addition to the interviews. Hence, there was a need to keep time spent on interviews to a minimum. This limited the number of questions that could be included in the interview guide. Moreover, the participants of the original RCT volunteered for a study on a different outcome than reported in the present study. The participants' responses to the questions related to psychological variables and pregnancy complaints could have been affected if the participants were less motivated to fully consider these aspects and answering "truthfully". On the other hand, the data was collected through personal interviews in contrast to questionnaires based on self-report. This is likely to have contributed to more reliable responses.

The grouping of the psychological factors into sub-variables for well-being, quality of life and body-image in the present study was done according to which factor was regarded to be most related to each sub-variable. The original questionnaire was not set up accordingly, and neither has this grouping been found elsewhere in the literature. Hence, the value of the different sub-variables is questionable. In addition, well-being, quality of life and body-image are subjective and complex concepts and therefore difficult to measure. However, the interview questions were focused on individual perceptions and not only clinical evaluation, and included 16 different underlying concepts as well as pregnancy depression. This should be considered strengths as far as measuring overall psychological health in the population of pregnant women.

Regarding the secondary outcome, the present study evaluated 13 minor pregnancy complaints that may cause limitations to well-being and quality of life for pregnant women. At the time of planning the original intervention, these specific complaints were considered to be the most commonly reported, in addition to the more severe complications like pelvic girdle pain, low back pain and urinary incontinence. In comparison, previous studies have listed a wider range of minor and major complaints (17;46;53;54). The 41-item Pregnancy Symptoms Inventory by Foxcroft et al. (47) provides a comprehensive view of pregnancy-related symptoms and their effect on the daily life of pregnant women. Hence, it could have been beneficial to include a wider range of physical symptoms in the present study.

5.2 Results

Although the Kolmogorov-Smirnov (Shapiro Wilks) test showed that the data related to the primary outcomes were not normally distributed, the data were analyzed according to student's t-test for continuous variables. This is a violation of one assumption connected to the student t-test (102). According to Pallant (102), most analyzing techniques for continuous variables are tolerant of this violation with large enough sample sizes (30+), which was the case in the present RCT. In addition, the range of the scores for the primary outcomes was limited to 1-6, also reducing the risk of problems related to the use of the student's t-test.

The results of the present study showed that women in the exercise group had some positive psychological effect of the exercise intervention, regardless of adherence to exercise sessions. With respect to the between-group differences for fatigue in favor of the exercise group, it is worth noting that the women randomized to exercise reported less fatigue also at the baseline test. This might point to favorable values for the exercise group concerning this variable. Hence, it is uncertain if the significant between-group difference was related to the exercise intervention. Concerning the question regarding negative feelings (sadness, despair, anxiety or depression), the results showed that the exercise group had a significantly better rating of this variable. This is consistent with previous studies evaluating the effect of maternal exercise on mood (29;38;82). Moreover, the results of the present study demonstrated that the exercise group had a higher rating of health satisfaction, compared to the control group. This is in accordance with another study on the pregnant population: Barakat and colleagues

(84) reported increased health status in the exercise group after a 12-week exercise program, measured by self-report

As shown in Table 11 (Appendix 2), results from previous RCTs evaluating the relationship between exercise during pregnancy and psychological variables are inconsistent, and comparison of results was difficult due to the use of different outcome measures, study populations and exercise dosage (mode, intensity and duration). The results from the present study demonstrated that both the exercise group and the control group had a high perception of quality of life, well-being and body-image, as well as overall psychological health, both at the baseline test (Table 6) and post-intervention (Table 8). Hence, the results may indicate that the pregnant women in the present population were generally satisfied with their psychological health. This is consistent with reports from the RCT by Vallim et al. (86), and may be a fundamental explanation for the limited number of significant differences between the exercise and the control group for the primary outcomes in this study.

With respect to body-image, no statistically between-group differences were found. This is consistent with the study by Goodwin et al (38), although the researcher (38) reported that significant differences in favor of the exercise group were found for some items on the Body Cathexis Scale. This is in agreement with the study by Marquez-Sterling and colleagues (85), assessing body-image through the same instrument. Hence, the Body Cathexis Scale might be a more sensitive tool to measure body-image than the single question in the present study. As for changes in body-image throughout pregnancy, it could be expected that women would have the most negative feelings about their physical appearance during the last trimester. The discrepancy between the ideal body and the actual pregnant body is generally at the largest at the end of the pregnancy. Contrary, the present results showed that the scores for acceptance of bodily appearance were higher towards the end of the pregnancy (mean gestation week 36) than at baseline (mean gestation week 17.7). Clark et al. (33) found similar results and reported that pregnant women felt the least fat in the last trimester, compared to both pre- and early pregnancy, as well as post-partum. According to the authors (33), the reasons might be that pregnant women appreciate the functionality of their body and move away from self-objectification. In addition, pregnancy is generally considered a time when weight gain is acceptable (33).

All levels of analysis showed that the number of women reporting pregnancy depression post-intervention was higher in the control group, compared to the exercise group. However, between-group differences were not statistically significant (Table 9). This is in contrast to the study by Robledo-Colonia and colleagues (19). It is not unlikely that a lower adherence to exercise and possibly a less sensitive measurement instrument, contributed to less effect in the present study. In addition, in the intervention by Robledo-Colonia et al. (19) each exercise session included only 3-5 women. This allows a more individualized follow-up and possibly also contributed to the high adherence rate in the study. Nevertheless, results from the current RCT showed a small decline in number of women reporting pregnancy depression post-intervention both in the exercise and the control group, compared to baseline numbers. This is in contrast to previous research reporting higher levels of depressive symptoms in late pregnancy (33).

As for the secondary outcomes, consistent with Foxcroft et al. (47), tiredness (78.1%) and poor sleep (35.6%) were among the most frequently reported symptoms, along with problems with intestinal function (73.6%), nausea/vomiting (58.5%) and headache (44.8%). The present study found significant between-group differences in favor of the exercise group for two common pregnancy complaints: nausea/vomiting and numbness/reduced circulation. However, it should be noted that the total number of women reporting nausea/vomiting post-test was low (19% vs. 60% at baseline). This could be explained by the fact that these symptoms generally decrease throughout pregnancy (49). On the other hand, the study by Foxcroft et al. (4) reported an association between exercise and nausea/vomiting. Similarly, evidence from a prospective study by Lacasse and colleagues (49) suggested that exercise during early pregnancy decreased the likelihood of reporting nausea/vomiting in the second trimester. In the present study, the between-group difference concerning problems with numbness/reduced circulation might be explained by that physical activity has the potential to increase the blood flow to and from the extremities, especially when involving large muscle groups.

Some of the complaints measured in the present RCT were reported by very few participants. Less than 8% reported of varicosities and hernia. This was possibly due to that the population was primiparous women, and these conditions are more common among multiparous women. Similarly, few women reported of coordination problems.

Although it could be expected that the exercise group would report less coordination problems compared to the control group, results did not support this. Hence, due to low prevalence of some of the complaints measured, it would have been difficult to detect any potential between-group differences.

The low adherence in the present study may indicate that it is difficult to motivate previously sedentary women to exercise. It might be that exercise adherence could have been increased through individual follow-up, either personal (by phone or email), through virtual tools (computer programs or phone apps) or active lifestyle counseling. In addition, it might be that small group training would have increased the women's motivation and commitment to exercise. Nevertheless, results showed that the pregnant women included in the RCT reported that regular participation in a 12-week group exercise program had some positive effects considering well-being and quality of life, as well as for pregnancy complaints. As physical activity also has a number of physiological health benefits, results should be used to encourage pregnant women to participate in regular exercise. Also, these findings should motivate further studies with larger sample sizes and an additional emphasis on exercise adherence.

6. Conclusion

Supervised group exercise with focus on endurance training, performed twice a week for 12 weeks, had some positive effects on well-being and quality of life through reduced fatigue and negative feelings, as well as increased health satisfaction. Regular exercise also reduced the prevalence of nausea/vomiting, as well as the proportion of women reporting reduced circulation and numbness. Low adherence to exercise, a relatively small sample size, insensitive measuring tools as well as an increased physical activity level in the control group is likely to have limited the effects of the exercise intervention in the present study. Hence, future studies and public health interventions for pregnant women should take into account that it is difficult to motivate previously sedentary pregnant women to regularly participate in maternal exercise. Moreover, an interview guide for measuring psychological variables that is validated for the pregnant population is warranted.

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Tables

Figures

Appendixes

Appendix 1

Table 10 *Brief overview of effects of exercise interventions on maternal fitness and adverse maternal outcomes*

Authors	Study design	Sample size*	Purpose/outcome	Result/conclusion
Weissgerber et al. (74)	Review	Not stated	Examine evidence of regular exercise on preventing and treating GDM, pre-eclampsia and maternal obesity	• Exercise in combination with nutritional control helps women at risk for GDM control blood glucose and prevent EGWG. • Exercise is an adjunctive therapy for women with GDM • Protective effect of exercise on pre-eclampsia • Regular exercise may prevent EGWG, and thus prevent obesity-related complications
Kramer & McDonald (71)	Review of acceptably controlled trials	14, n=1014	Assess effects of regular aerobic exercise 2-3 times/wk on fitness, course of labour and delivery, and pregnancy outcomes	• Regular exercise appears for improve or maintain physical fitness. Insufficient data to infer maternal and fetal risks or benefits.
Gavard & Artal (73)	Review	Not stated	Evaluate scientific literature for effects of exercise on pregnancy outcome	• Exercise is protective against GDM and pre-ecplampsia (especially for vigorous exercise).
Olson et al. (52)	Review	Not stated	Review recommendations for exercise in pregnancy and associated risks	• Same cardiovascular benefits as for non-pregnant women • Potential risk reduction for GDM for obese women • One study suggests that exercise levels exceeding current recommendations may increase the risk of pre-eclampsia
Melzer et al. (65)	Review	Not stated	Review knowledge on cardiovascular adaptations to PA in pregnant and non-pregnant, compliance to PA recommendations and effects of PA on pregnancy outcomes.	• Improved cardiovascular function: lower resting heart rate, higher stroke volume and greater VO2 response at a given heart rate t than sedentary pregnant women. • Reduced gestational weight gain • Attenuation of GDM and gestational hypertension • Decreased musculoskeletal discomfort

Ferraro et al. (70)	Review	212	Overview of maternal-fetal exercise physiology, summarize effects of PA during pregnancy on maternal-fetal outcomes	• Improved insulin sensitivity with aerobic exercise • PA before and during pregnancy, especially at a moderate-to-vigorous intensity level, have a lower risk of developing GDM. • Protective affect against development of GDM. 50% risk reduction for developing GDM for physically active women with increased BMI, compared to sedentary controls. • Moderate-to-vigorous physical activity before and during pregnancy protect against hypertensive disorders, e.g. pre-eclampsia, and propose a 40% risk reduction. One study suggests that extreme amounts of aerobic exercise in the first trimester may increase the risk of developing preeclampsia.
Prather et al. (41)	Review of original studies and systematic reviews	86	Briefly summarize known maternal benefits of exercise	• Improved cardiovascular function • Lower risk for GDM in both obese and not obese women • Reduced need for insulin with strength training for women with GDM • Improved strength and lean muscle mass • Beneficial for weight management for both normal-weight, overweight and obese women • Reduced low back pain with individualizes exercise
Nascimento et al. (61)	Review of RCTs on healthy women undergoing physical exercise.	19	Update on recent evidence on effect of exercise during pregnancy	• PA prevents EGWG • PA is a recommended intervention for GDM control, although conflicting findings in the literature (no effects in one study (low adherence), others find improvements in maternal glucose tolerance, reduced number of women requiring insulin and no cases of GDM). • Strength training was found to improve glycemic control and reduce the number of women in need of insulin. • PA could prevent pre-eclampsia. • Conflicting findings on musculoskeletal discomforts and urinary incontinence.

Appendix 2

Table 11 *Effects of exercise on maternal psychological outcomes*

Authors	Study design	Sample size (n)	Purpose/outcome	Result/conclusion
Robledo-Colonia (19)	RCT. Intervention: 60 min., aerobic, stretching and relaxation.	80	Examine effect of aerobic exercise on depressive symptoms (CES-D, measured at baseline and after intervention).	Significant reduced depressive symptoms in EG compared to CG (between group difference 4 points on the CES-D scale).
Nascimento et al. (3)	RCT. Intervention: weekly supervised 40min. classes w. light to moderate intensity exercises + home exercise counseling.	82	To evaluate the effective of exercise on maternal /perinatal outcomes and the perception of quality of life (QoL) in pregnant obese and overweight women.	Exercise did not affect variation in the perception of QoL between EG and CG. Significant decrease in mean score of physical and social domains of WHOQOL-bref over time for both groups.
Barakat et al. (84)	RCT. Intervention: 35-45 min., 3 t/wk, appr. 30 wks.	80	To assess the effect of moderate exercise on maternal perceptions of health and other pregnancy outcomes.	Increased perception of health status in EG. 54.5% and 27.3% of women perceived their health status as “very good”, in the EG and CG respectively (p=0.03).
Vallim et al (86)	Comparative study performed in conjunction with a RCT. Intervention: 50 min. water aerobics classes 3 t/wk	66	Evaluate effect of an exercise program on QoL in pregnant women.	No association between water aerobics and QOL. The participants reported some benefit of the exercise program. High QOL-scores in both the exercise and the control group.
Montoya Arizabaleta et al (36)	RCT. Intervention: 3 months of 60 min supervised aerobic exercise,	64	Asses effect of aerobic exercise during pregnancy on health-related QOL measured by the Colombian version of the Medical Outcome Study Short-Form Health Survey at baseline and immediately after the 3-month intervention.	Supervised aerobic exercise during pregnancy improved health-related quality of life. The exercise group improved significantly more on physical function, bodily pain and, general health, compared to the control group. There were also trends to improvement in most domains of the health-related QOL questionnaire.
Marquez-Sterling et al. (85)	RCT. Variety of aerobic exercise activities, calisthenics and stretching. 1hr, 3 times/wk.15 wks,	15	Examine effect of exercise on physical and psychological variables in sedentary primigravidae.	Significant differences in change scores between EG and CG was found for perceived changes in physical stamina, muscular strength, energy level and body build, pointing to increased body satisfaction and improved sense of well-being.

Appendix 3 – Approval letter from the Regional Committees for Medical Research Ethics

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

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Harald Hårfagres gate 29
N-5007 Bergen
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nsd@nsd.uib.no
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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

Appendix 4 – Approval letter from the Norwegian Social Science Data Services

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

Professor dr. scient Kari Bø
Norges Idrettshøgskole
Pb 4014 Ullevål stadion
0806 Oslo

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

Telefon: 228 44 666
Telefaks: 228 44 661
E-post: rek-2@medisin.uio.no
Nettadresse: www.etikkom.no

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

Appendix 5 - Participant information

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

Appendix 6 – Health survey questionnaire

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

_____

Appendix 7 – Exercise program

5 min.	Warm up:
	Standing on the floor. Flexibility and breathing exercises
35 min.	Aerobic dance, intensity 12-14 (somewhat hard) on the Borg scale:
	Low impact exercises on the floor, or step training. No jumping or running. Focus on safety and mastering (minimizing step length and rotation, avoiding crossing of legs and quick changes of position and direction)
15 min.	Strength training, 12-15 repetitions, maximum three sets:
	Focus on upper/lower extremities, back-, pelvic floor- and deep abdominal stabilization muscles
5 min.	Cool down:
	Stretching, relaxation and body awareness exercises

Appendix 8 – Questionnaire on psychological outcomes

Skjema 3

Test 1☐

Test 2☐

KODE _____

Dette spørreskjema tar utgangspunkt i hvordan du stort sett opplever din livskvalitet, helse og andre sider ved livet ditt. Tenk tilbake hvordan du har hatt det **siste 4 uker**. Hvis du er usikker på hvilket svaralternativ du skal velge, er gjerne din første reaksjon et godt utgangspunkt. Sett kun ett kryss.

1. Hvordan vil du vurdere kvaliteten på livet ditt?

1 2 3 4 5 6

Svært dårlig ☐ ☐ ☐ ☐ ☐ ☐ Svært god

2. Hvor tilfreds er du med helsen din?

1 2 3 4 5 6

Svært utilfreds ☐ ☐ ☐ ☐ ☐ ☐ Svært tilfreds

3. Har du nok energi til dine daglige gjøremål?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ Fullstendig

4. I hvilen grad føler du at livet er meningsfullt?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ I svært høy grad

5. Kan du akseptere utseende ditt?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ Fullstendig

6. Hvor tilfreds er du med hvordan du sover?

1 2 3 4 5 6

Svært utilfreds ☐ ☐ ☐ ☐ ☐ ☐ Svært tilfreds

7. Hvor tilfreds er du din arbeidskapasitet?

1 2 3 4 5 6

Svært utilfreds ☐ ☐ ☐ ☐ ☐ ☐ Svært tilfreds

8. Hvor tilfreds er du med deg selv?

1 2 3 4 5 6

Svært utilfreds ☐ ☐ ☐ ☐ ☐ ☐ Svært tilfreds

9. Hvor tilfreds er du med ditt forhold til andre mennesker?

1 2 3 4 5 6

Svært utilfreds ☐ ☐ ☐ ☐ ☐ ☐ Svært tilfreds

10. Hvor ofte opplever du negative følelser som f. eks at du er trist, fortvilet, engstelig eller deprimert

1 2 3 4 5 6

Alltid ☐ ☐ ☐ ☐ ☐ ☐ Aldri

11. Hvor ofte føler du deg sliten?

1 2 3 4 5 6

Hele tiden ☐ ☐ ☐ ☐ ☐ ☐ Ikke i det hele tatt

12. Får du den type støtte som du trenger fra andre?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ Fullstendig

13. Hvor trygg føler du deg til daglig?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ I svært høy grad

14. Hvor mye gleder du deg over livet?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ I svært høy grad

15. Føler du deg ensom?

1 2 3 4 5 6

Alltid ☐ ☐ ☐ ☐ ☐ ☐ Aldri

16. I hvilken grad har du mulighet for å delta i fritidsaktiviteter?

1 2 3 4 5 6

Ikke i det hele tatt ☐ ☐ ☐ ☐ ☐ ☐ Fullstendig

Appendix 9 – Health and lifestyle questionnaire

Kode _____

2 A

Spørreskjema om graviditet og fysisk aktivitet

BAKGRUNNSOPPLYSNINGER

1. Alder: ☐ år

2. Svangerskapsuke: ☐

3.
☐ Gift ☐ Enslig
☐ Samboer ☐ Annet .....

4. Etnisitet _____

5. Er du født i Norge?
☐ JA ☐ NEI

6. Røyker du daglig?
☐ JA ☐ NEI

7. Er du utsatt for passiv røyking i dagliglivet?
☐ JA ☐ NEI

8. Er barnet unnfanget ved kunstig befruktning/prøverørsmetoden?
☐ JA ☐ NEI

9. Hva er din høyeste fullførte utdannelse?
☐ Grunnskole ☐ Høgskole/universitet inntil 4 år
☐ Videregående yrkesfaglig ☐ Høgskole/universitet mer enn 4 år
☐ Videregående allmennfaglig ☐ Annen utdannelse, hva.....

10. Yrke/stilling
☐ Helse- og omsorg ☐ Industri
☐ Undervisning/forskning ☐ Bygg/anlegg
☐ Kontor ☐ Annet

11. Arbeider du utenom hjemmet?

☐ JA ☐ NEI

☐ Student ☐ Annet _____

12. Dersom Ja, hvor stor stillingsprosent har du på nåværende tidspunkt? _____

12 a) Er du for tiden sykemeldt?

☐ JA ☐ NEI

b) Dersom JA, hvor stor prosentandel er du sykemeldt? _____

TRANSPORTAKTIVITETER

13 a) Bruker du daglig motorisert transportmiddel (bil, buss, tog, trikk, t-bane)?

☐ JA ☐ NEI

b) Dersom JA, hvor lang tid bruker du gjennomsnittlig per dag i transportmiddelet?

☐ Mindre enn 15 min ☐ 1-1.5 time

☐ 15-30 min ☐ Over 1.5 time – 2 timer

☐ Over 30-60 min ☐ Mer enn 2 timer

14 a) Kan du angi hvor mye du totalt **går** (bruker bena) i løpet av en dag (f.eks. til og fra arbeid, hente/bringe barn, til og fra butikken, osv.)?

*(Mosjons- og treningsturer, samt det du går i arbeidstiden skal **ikke** rapporteres her)*

☐ Mindre enn 5 min ☐ Over 30 - 60 min

☐ 5-15 min ☐ Mer enn 60 min

☐ Over 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

15 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.)?

*(Mosjons- og treningsturer skal **ikke** rapporteres her)*

☐ Mindre enn 5 min ☐ Over 30 - 60 min

☐ 5-15 min ☐ Mer enn 60 min

☐ Over 15 - 30 min ☐ Går sjelden eller aldri

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

☐ JA ☐ NEI

JOBBAKTIVITETER

16. Hvordan utfører du ditt arbeid hovedsakelig?

- ☐ Stillesittende
- ☐ Stående
- ☐ I bevegelse

17. Hvor lang tid bruker du på disse aktivitetene i løpet av en normal arbeidsdag?

a) Meget anstrengende aktivitet (tunge løft, tungt byggearbeid, gravearbeid ol)?

- ☐ 0 timer
- ☐ Mindre enn 30 min
- ☐ 30 min - 1 time
- ☐ 2-3 timer
- ☐ 4-5 timer
- ☐ 6-7 timer
- ☐ 8 timer eller mer

b) Middels anstrengende fysisk aktivitet (rydde, vaske, pleie/stell, bære lette ting ol)?

- ☐ 0 timer
- ☐ Mindre enn 30 min
- ☐ 30 min - 1 time
- ☐ 2-3 timer
- ☐ 4-5 timer
- ☐ 6-7 timer
- ☐ 8 timer eller mer

c) Gå/bevegelse?

- ☐ 0 timer
- ☐ Mindre enn 30 min
- ☐ 30 min - 1 time
- ☐ 2-3 timer
- ☐ 4-5 timer
- ☐ 6-7 timer
- ☐ 8 timer eller mer

d) Stillesittende aktiviteter?

- ☐ 0 timer
- ☐ Mindre enn 30 min
- ☐ 30 min - 1 time
- ☐ 2-3 timer
- ☐ 4-5 timer
- ☐ 6-7 timer
- ☐ 8 timer eller mer

18. Vil du karakterisere jobben din som fysisk krevende?

- ☐ JA, spesifiser.....
- ☐ Av og til, spesifiser .....
- ☐ NEI, spesifiser .....

AKTIVITET I HJEM OG NÆRMILJØ

19. Hvor lang tid bruker du på **lett til middels anstrengende** arbeid i hjemmet daglig?
(F.eks. støvsuge, vaske gulv, trappevask, innkjøp av mat, pleie og omsorgsoppgaver)

- ☐ 0 timer
- ☐ Mindre enn 30 min
- ☐ 30 min - 1 time
- ☐ 2-3 timer
- ☐ 4-5 timer
- ☐ 6-7 timer
- ☐ 8 timer eller mer

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

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

ROLIGE AKTIVITETER

21 a) Hvor mange timer bruker du totalt til stillesittende aktiviteter daglig (både i arbeid og fritid)?
(se TV, slappe av, lese, Internet, PC, høre på musikk, kontorarbeid m.m.)?

	Hverdag	Helg/fridag
Mindre enn 6 timer		
7-8 timer		
9-10 timer		
11-12 timer		
13-14 timer		
Mer enn 14 timer		

b) Er dette mer tid enn du normalt ville brukt på stillesittende aktiviteter dersom du ikke var gravid?

- ☐ Mer tid på stillesittende aktiviteter
- ☐ Like mye tid på stillesittende aktiviteter
- ☐ Mindre tid på stillesittende aktiviteter

22 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?

☐ Sover mer som gravid
☐ Sover like mye nå
☐ Sover mindre nå

SVANGERSKAPSKOMPLIKASJONER

23. Har du tidligere og/eller i din nåværende svangerskapsuke noen svangerskapskomplikasjoner?

☐ JA ☐ NEI

24. Har du tidligere og/eller i din nåværende svangerskapsuke søvnproblemer?

☐ JA ☐ NEI

25. Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med uvanlig tretthet?

☐ JA ☐ NEI

26. Har du tidligere og/eller i din nåværende svangerskapsuke problemer med nummenhet/dårlig sirkulasjon? (for eksempel i fingre og/eller tær)

☐ JA ☐ NEI

27. Har du tidligere og/eller i din nåværende svangerskapsuke problemer med leggkramper?

☐ JA ☐ NEI

28. Har du tidligere og/eller i din nåværende svangerskapsuke problemer med halsbrann/sure oppstøt?

☐ JA ☐ NEI

29. Har du tidligere og/eller i din nåværende svangerskapsuke problemer med kvalme/oppkast?

☐ JA ☐ NEI

30. Har du tidligere og/eller i din nåværende svangerskapsuke koordinasjons- og/eller balanseproblemer?

☐ JA ☐ NEI

31 a) Har du tidligere og/eller i din nåværende svangerskapsuke problemer med mage/tarmfunksjonen?

☐ JA ☐ NEI

b) Hvis JA, på hvilken måte?

☐ Forstoppelse ☐ Løs mage
☐ Treg mage ☐ Diare
☐ Annet .....

32. Har du tidligere og/eller i din nåværende svangerskapsuke problemer med hovne ben/ødem?

☐ JA ☐ NEI

33. Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med hodepine/migrene?

☐JA ☐NEI

34. Har du tidligere og/eller i din nåværende svangerskapsuke problemer med åreknuter, hemmorider og/eller brokk?

☐JA ☐NEI

35 a) Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med smerter i bekkenområdet?

☐JA ☐NEI

b) Hvis JA, hvor er smertene lokalisert?

☐Foran (symfysen)
☐Bak, en side
☐Bak, to sider
☐Både foran og bak (en side)
☐Både foran og bak (to sider)

c) Hvis JA, har du hatt så store vansker at det har hemmet deg i utføring av daglige gjøremål?

☐JA ☐NEI

d) Hvis JA, har du hatt så store vansker at det har hemmet deg i utføring av fysisk aktivitet?

☐JA ☐NEI

e) Hvis JA, har du hatt så store vansker med å gå at du må bruke stokk eller krykker?

☐Ikke i det hele tatt
☐Ikke så ofte
☐I perioder
☐Mesteparten av tiden
☐Nei

36 a) Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med smerter i ryggen?

☐JA ☐NEI

b) Hvis JA, hvor er smertene lokalisert?

☐Øvre del av ryggen
☐I korsrygg uten utstråling til ben (a)
☐I korsrygg med utstråling til ben (a)

b) Hvis JA, har du hatt så store vansker at det har hemmet deg i utføring av daglige gjøremål?

☐JA ☐NEI

c) Hvis JA, har du hatt så store vansker at det har hemmet deg i utføring av fysisk aktivitet?

☐JA ☐NEI

37 a) Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med urinlekkasje?

☐JA ☐NEI

b) Hvis JA, hvor ofte lekker du urin?

☐Omtrent en gang i uken eller sjeldnere
☐2-3 ganger i uken
☐Ca 1 gang per dag
☐Flere ganger per dag
☐Hele tiden

c) Hvis JA, hvor mye urin tror du at du lekker?

☐Dråper (en liten mengde)
☐Små skvetter (en moderat mengde)
☐Større mengder (en stor mengde)

d) Hvis JA, når lekker du urin?

☐Lekker før jeg når toalettet (ved sterk vannlatingstrang)
☐Lekker når jeg hoster/nyser eller ler
☐Lekker når jeg sover
☐Lekker når jeg er fysisk aktiv /trener
☐Lekker når jeg har tisset og har tatt på meg klærne
☐Lekker uten noen opplagt grunn

e) Hvis JA, har du hatt så store vansker at det har hemmet deg i utføring av daglige gjøremål?

☐JA ☐NEI

f) Hvis JA, har du hatt så store vansker at det har hemmet deg i utføring av fysisk aktivitet?

☐JA ☐NEI

38. Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med lekkasje av luft?

☐JA ☐NEI

39. Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med lekkasje av avføring?

☐JA ☐NEI

40. Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med depresjon eller andre psykiske plager?

☐ JA ☐ NEI

41. Har du tidligere og/eller i din nåværende svangerskapsuke vært plaget med høyt blodtrykk?

☐ JA ☐ NEI ☐ Vet ikke

42. Har du tidligere og/eller i din nåværende svangerskapsuke hatt sukker i urinen?

☐ JA ☐ NEI ☐ Vet ikke

43. Har du tidligere og/eller i din nåværende svangerskapsuke hatt eggehvite (protein) i urinen?

☐ JA ☐ NEI ☐ Vet ikke