Haakstad, L. A. H., Torset, B. S., Bø, K. (2015). What is the effect of regular group exercise on maternal psychological outcomes and common pregnancy complaints? An assessor blinded RCT. *Midwifery, 32*, 81-86

Abstract

Objective: To examine the effects of supervised group exercise on maternal psychological outcomes and commonly reported pregnancy complaints.

Design: An observer-blinded randomized controlled trial

Setting: Norwegian School of Sport Sciences, Oslo, Norway

Participants: 105 sedentary, nulliparous pregnant women, mean age 30.7(± 4.0) years, pre-pregnancy BMI 23.8 (± 4.3), were assigned to either exercise (n=52) or control group (n= 53) at mean gestation week 17.7 (±4.2).

Intervention: The exercise intervention followed ACOG guidelines and included a 60 min general fitness class, with 40 min of endurance training/aerobic and 20 min of strength training and stretching/relaxation, performed at least twice per week for a minimum of 12 weeks.

Measurements: Outcome measures were assessed through standardized interviews pre- and post-intervention (gestation week 36.6, ± 0.9), and included psychological variables related to quality of life, well-being, body image and pregnancy depression, as well as assessment of 13 commonly reported pregnancy complaints.

Findings: Post-intervention, using intention to treat (ITT) analysis, women randomized to exercise rated their health significantly better compared to women in the control group ($p=0.02$) and reported less fatigue related to everyday activities ($p=0.04$). Women with complete exercise adherence (≥24 sessions) had significantly better scores on measurements of feelings related to sadness, hopelessness and anxiety ($p<0.01$), compared to the control group. Contradictory, the control group reported higher life enjoyment ($p<0.01$). There were no significant group differences in body-image or pregnancy depression. With respect to analyzing pregnancy complaints according to ITT, no differences between the groups were found. A comparison of the women who attended ≥19 (80%, n=21) or ≥24 (100%, n=14) exercise sessions with the control-participants, showed that fewer women in the exercise group reported nausea/vomiting and numbness/poor circulation in legs.

Key conclusion and implication for practise: Participation in regular group exercise during pregnancy contributed to improvements in some variables related to maternal well-being and quality of life. Women with high exercise adherence had significantly better results on several health variables reaping the highest benefits. A qualitative study exploring the barriers of women in achieving recommended amount of activity may be necessary to understand this population and developing better clinical practice educational tools.

Key words:

exercise, maternal well-being, pregnancy complaint, pregnancy depression, quality of life

Introduction

Being pregnant is accompanied by several physiological and biomechanical changes and with possible subsequent pregnancy complaints (Symonds & Symonds, 2004). The changes may also affect psychological health, including quality of life and well-being (Foxcroft et al., 2011). To date, pregnant women constitute one third of all sick-leave for women between 20-39 years, and by 32 weeks of gestation, 63% of Norwegian women receive sick-leave , with fatigue/sleep problems (34.7%), pelvic girdle pain (31.8%) and nausea/vomiting (23.1%) being the most common reported contributors (Dorheim et al., 2013). In addition, pregnancy may be a vulnerable time period for women's psychosocial condition, with negative mood symptoms/depression frequently reported (Marcus et al., 2009) and causing the longest duration of sick-leave (Dorheim et al., 2013).

In the general adult population, regular exercise and physical activity may improve mild and moderate depression symptoms (Rimer et al., 2012), as well as positively enhance well-being and quality of life (Penedo & Dahn, 2005). Current recommendations for exercise during pregnancy suggest that, in the absence of medical and obstetric complications, pregnant women should aim to perform 30 minutes or more of moderate intensity daily physical activity, and/or exercise 3-5 times weekly for a minimum of 15-30 minutes (ACOG, 2002; Artal & O'Toole, 2003). However, studies show that most women appear to reduce their leisure time physical activity and are resistant to exercise regularly with a recommended dosage when they become pregnant (Haakstad et al., 2007; Hegaard et al., 2011; Owe et al., 2009). Mottola (2009) has suggested that interventions for pregnant women need to be behaviour-based because education programs increase knowledge, but do not change behaviour. This is consistent with Hui (Hui et al., 2014), showing that participating in a lifestyle intervention can increase physical activity level.

Search on PubMed throughout October 2014 revealed few studies investigating the effect of regular exercise on psychological variables in a pregnant population and no high quality RCTs were found. In addition, no RCTs evaluating the effect of exercise on a wide range of commonly reported pregnancy complaints were published.

This study was part of a single-blind, single-center RCT comparing pregnant women with healthy pre-pregnancy weight undertaking aerobic exercise with standard prenatal care ("usual care") on maternal weight gain (Haakstad & Bo, 2011). The present paper reports on maternal psychological outcomes (self-reported well-being, quality of life, body-image, pregnancy depression) and common pregnancy complaints before and after the intervention period.

Methods

Design

This was the secondary analysis of an assessor blinded RCT. The complete study was conducted in agreement with the CONSORT statement (http://www.consort-statement.org) and was registered in the ClinicalTrials.gov Protocol Registration System (NCT00617149).

Participants

Participants were recruited via health practitioners (physicians, midwives), articles and advertisement in newspapers, websites for pregnant women, flyers and word of mouth. Interested women telephoned or mailed the principal investigator (LAHH). At the first phone contact, the aims and implications of the study were explained and the eligibility criteria checked. Nulliparous women whose pre-pregnancy exercise levels did not include participation in a structured exercise program (> 60 minutes once per week), including brisk walking (>120 minutes per week) for the past six months, were eligible for the trial. Other inclusion criteria were ability to read, understand and speak Norwegian language, and to be within their first 24 weeks of pregnancy. Exclusion criteria were a history of more than two miscarriages, severe heart disease (including symptoms of angina, myocardial infarction or arrhythmias), persistent bleeding after 12 weeks of gestation, multiple pregnancy, poorly controlled thyroid disease, pregnancy-induced hypertension or pre-eclampsia, diabetes or gestational diabetes, and other diseases that could interfere with participation (Artal & O'Toole, 2003).

In total, 105 women with healthy pre-pregnancy weight were recruited to the trial. The majority of the participants came from the city of Oslo, Norway. A-priori power calculation

was done for the primary outcome of the trial, which was gestational weight gain (Haakstad & Bo, 2011).

The participants were examined between 12 and 24 weeks of gestation (baseline visit) and at gestation week 36-38 (after the intervention). Each visit lasted approximately 60-75 minutes. There was no financial compensation to the participants. All participants gave written consent to participate and the procedures followed the World Medical Association Declaration of Helsinki. The project was approved by The National Committee for Medical Research Ethics, Southern Norway, Oslo, Norway (reference number S-05208). The Norwegian Social Sciences Data Services (NNT) provided licence to store and register individual health information (reference number 17804/2/KH).

Randomization

A secretary, not involved in the assessment or exercise classes, assigned the participants to either an exercise group (n=52) or a control group (n=53). Allocations were sealed in opaque numbered envelopes following a simple computer-based randomization program.

Intervention

Participants randomized to exercise were prescribed to participate in at least two out of three possible one hour aerobic dance classes per week, for a minimum of 12 weeks. Each session started with 5 minutes warm up, followed by 35 minutes of endurance training and aerobic dance, including cool down. This was followed by 15 minutes of strength training with a special focus on the deep abdominal stabilization muscles (internal oblique and the transverse abdominal muscle), pelvic floor and back muscles. The last 5 minutes included stretching, relaxation and body awareness exercises. The aerobic dance routine included low impact

exercises (no jumping or running) and step training. The exercise-program followed the current ACOG exercise prescription (ACOG, 2002; Royal College of Obstetricians and Gynaecologists, 2006), and all aerobic activities were performed at moderate intensity measured by ratings of perceived exertion at 12-14 (somewhat hard) on the 6-20 Borg's rating scale (Borg, 1970). Highly qualified aerobics instructors educated with respect to guidelines for exercise during pregnancy led the group sessions, gave instructions on intensity and emphasized the importance of adherence to the exercise protocol. Each session was accompanied by music and a maximum of 25 participants attended in an airy, modern exercise room.

In addition to joining the scheduled aerobic classes, all women in the exercise group were asked to include 30 minutes of moderate self-imposed physical activity on the remaining week-days. Adherence to the exercise classes was reported by the aerobic-instructors, and the self-imposed daily activity was registered in a personal training diary. High adherence was defined as participating in at least 80% of all supervised exercise sessions. The participants in the control group were asked to continue their usual physical activity habits and were neither encouraged nor discouraged from exercising.

In order to treat the two groups identically apart from for the experimental intervention, the controls underwent all tests and completed the same interview as the exercise group, also with respect to assessment of total physical activity level and exercise habits.

Outcome measures

The primary outcomes were four psychological variables (well-being, quality of life, body-image and negative mood symptoms/maternal depression) measured by 16 questions adapted

from two well-known questionnaires (WHOQOL-bref and SF-36) for the general adult population (Goldberg & Hillier, 1979; Slade et al., 2009), as no instrument measuring these outcomes in a pregnant population were found. According to these instruments, the participants rated their "feelings" regarding different statements (for the last 4 weeks) on a 6 item scale (from 1 to 6), where 1 was negative and 6 was positive.

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 safe do you feel in your daily life? 1 (not at all) – 6 (very much*

Negative mood symptoms/maternal depression:

4. *How often do you have negative feelings such as sadness, despair, anxiety or depression? 1 (always) – 6 (never)*
5. *How much do you enjoy life?1 (not at all) – 6 (very much)*

Body-image:

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

Quality of life:

7. *How would you rate the quality of your life?1 (very bad) –6 (very good)*
8. *How satisfied are you with your health?1 (not satisfied) – 6 (very satisfied)*
9. *Do you have enough energy for your everyday life activities?1 (not at all) – 6 (completely)*
10. *How satisfied are you with your sleep? 1 (not satisfied) – 6 (very satisfied)*
11. *How satisfied are you with your capacity for work? 1 (not satisfied) – 6 (very satisfied)*
12. *How satisfied are you with your personal relationships? 1 (not satisfied) – 6 (very satisfied)*

13. *How often do you feel worn out?1 (all the time) – 6 (not at all)*
14. *How satisfied are you with the support you get from others? 1 (not at all) – 6 (completely)*
15. *Do you feel lonely? 1 (always) – 6 (never)*
16. *To what degree are you able to participate in leisure-time activities? 1 (not at all) – 6 (completely)*

Well-being and Quality of life were analyzed separately and as a mean sum-score for each sub-group. In addition, a mean sum-score for all the psychological variables was calculated by combining the scores from all the statements and dividing the sum by the number of questions (total 16).

Besides answering questions 3-5, pregnancy depression was also assessed by a yes or no response in the health and lifestyle-section of the interview guide: *"Have you experienced this week or in previous gestation weeks negative mood symptoms and/or pregnancy depression?"*

Secondary outcomes were reported pregnancy complaints, and included a yes or no response to one separate question for 13 different conditions, asked on two occasions: ***"Have you experienced*** *(… poor sleep, unusual tiredness, numbness/poor circulation in legs, leg cramps, heartburn/acid reflux, nausea/vomiting, coordination- and/or balance problems, problems with intestinal function, swollen legs/oedemas, pregnancy-related headache/migraine and/or hemorrhoids/varicosities/hernia)* ***this week or in previous gestation weeks?"*** (Zib et al., 1999). Assessments of pelvic girdle pain and low back pain were obtained as part of the questions concerning pregnancy complaints and included pain localization, as well as disability or severity of the two conditions. Results from these measurements are published separately (Haakstad & Bo, 2014).

Data analysis

All statistical analyses were conducted with SPSS Statistical Software version 19.0 for Windows. Data are presented as means with standard deviation (SD) or numbers with percentages. The principal analysis was done on an intention to treat basis (ITT). Missing values were replaced with values based on existing data (Last-Observation-Carried-Forward). Mean scores for psychological variables and group differences in number of women with common pregnancy complaints were analysed by independent sample t-test or *X2*-test, respectively. Per protocol analysis was based on adherence to ≥ 80% of the recommended exercise sessions (≥19 exercise sessions). In addition, we compared women with 100% exercise adherence (≥24 exercise sessions) with the control group. Level of statistical significance was set at $p < .05$.

Findings

Demographic variables of the 105 nulliparous women randomized to exercise (n=52) or control (n= 53) are shown in Table 1. As shown both groups started with a healthy bodyweight (normal pre-pregnancy BMI). There were no statistically significant difference between the groups in background variables at baseline (week 17.7 ± 4.2), or study outcomes variables except from the question *"How often do you feel worn out?"*, where the exercise group reported less fatigue than the controls (3.52±1.1 vs. 3.08±1.0, p=0.04). Post-intervention results were 3.44±1.0 in the exercise group and 3.04±0.9 in the control group, giving a between group difference of 0.49 (95% CI 0.33 to 0.66, p<0.001).

At mean gestation week 36.6 (SD 1.0), a total of 80% (42 women in each groups) completed posttests and assessment of primary and secondary outcomes (Haakstad & Bo, 2014).

In total, mean adherence to the exercise classes was 17.2 (SD 12.5) out of 19 recommended training sessions (80% exercise adherence), followed by 21 women (40.4%). Fourteen women completed a total of ≥24 exercise sessions (100% exercise adherence) (Haakstad & Bø 2011).

Table 2 summarises the results of assessment of well-being, quality of life, body-image and negative mood symptoms/maternal depression, examined as ITT, per protocol and analyses of women attending 24 exercise sessions. Women randomized to exercise rated their health significantly higher compared to women in the control group (p=0.02), as well as reported less fatigue related to everyday activities (p=0.04). In addition, women with high exercise adherence (≥24 sessions) had significantly better scores on feelings related to sadness, hopelessness or anxiety (p<0.01), compared to the control group. There was a trend towards women attending ≥24 exercise sessions reporting increased overall energy levels (p=0.06). Contrary, the control group reported higher life enjoyment (p<0.01). Analyzing the data

adjusting for individual consideration and baseline values (analyses of covariance) did not change the overall results related to psychological variables.

Fewer women in the exercise group (n=3) reported to have experienced pregnancy depression compared to women being controls (n=9), but the difference did not reach statistical significance (p=0.07) (Table 3).

No differences between the groups were found in either specific or total number of pregnancy complaints, according to IIT analysis (Table 3). A comparison of the women who attended ≥19 (80%) or ≥24 (100%) exercise sessions with the control-participants showed a borderline lower prevalence of total number of physical symptoms (p=0.07). No one in the exercise group reported nausea/vomiting vs. 12 in the control group (p= 0.02) or numbness/ poor circulation in legs vs. 16 among controls (p=0.02).

No harmful effects of the 12 week exercise intervention were noted in the mother or the fetus

Discussion

The results showed that in a group of previously sedentary, healthy weight women, regular maternal group exercise contributed to improvements in some variables related to maternal well-being and quality of life, as well as gave reduction in two common pregnancy complaints (nausea/vomiting and numbness/ poor circulation in legs). Women exercising ≥24 sessions reported less enjoyment with life compared to the controls receiving standard prenatal care. No harmful effects of the 12 week exercise intervention were noted in the mother or the fetus.

The strengths of the present study included the use of an assessor blinded RCT design, an exercise program following ACOG recommendations (ACOG, 2002), plus integration of exercise into daily life activities. Others have reported that a lifestyle intervention, including advice to accumulate at least 30 minutes of moderate intensity physical activity on most days of the week, gave significant improvements in physical activity level from baseline to after the intervention, comparable to structured activity groups (Dunn et al., 1999; Opdenacker et al., 2011). Hence, it might be that the additional activity had an impact also in the current study. Unfortunately, we have no data on whether or not they fulfilled the criteria of 30 min of PA a day, as few reported adherence in their exercise diary.

The same primary investigator examined all the participants and we had relatively few losses to follow-up. Personal, but standardized interviews, in contrast to questionnaires based on self-report, may have contributed to more reliable responses. In addition, the presence of qualified instructors for guidance and supervision, as well as registration of exercise adherence both by the fitness instructors and via recordings in a training diary, may be considered strengths of the study.

A limitation of the study was the low adherence to the exercise program and use of instruments with questions adapted from questionnaires designed and developed for other populations (Goldberg & Hillier, 1979; Slade et al., 2009). Hence, these questions may not account for psychological variables specific for pregnant women. Likewise, we might not have covered all pregnancy-specific symptoms. The present study measured 13 pregnancy complaints, plus pelvic girdle pain, low back pain and urinary incontinence, in contrast to the 41-item Pregnancy Symptoms Inventory (Foxcroft et al., 2011). However, in 2008, at the time of planning and developing the original RCT, this questionnaire was unfortunately not yet published. If we should have done the study protocol once more, we would have included a wider range of physical symptoms, as well as measuring pain intensity (e.g.VAS Pain), determining the discomfort from "no pain" (score of 0) to "pain as bad as it could be" or "worst imaginable pain" (score of 10).

The present study included secondary analysis of data from a RCT on maternal weight gain (Haakstad, 2010) and a priori power calculations was done for this outcome only. Results from a previous study on psychological variables 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 for quality of life measurements using the12-item Medical Outcome Study Short-Form Health Survey (SF12 version 2) (Montoya Arizabaleta et al., 2010).

Explanatory research asks whether an intervention works under ideal or selected conditions. Hence, to adjust for the low adherence in the present study, per protocol analysis (≥80% of the exercise sessions) and analysis of 100% exercise adherence were done. These methods may be helpful to assess the "true" effect of the exercise intervention, but may also

overestimate the effect due to selection bias (type I error), meaning that participants following the prescribed exercise may differ from those who do not. Hence, conclusions from the "per protocol" analysis cannot be generalized to other pregnant women or settings.

Also previous trials in sedentary pregnant women have reported low adherence to the exercise program, and why the women in the present study did not adhere is difficult to understand. A fitness class of 60 minutes prescribed twice a week, including endurance training of 35-40 minutes may be considered demanding. Thus, the sedentary women who were the target group for this study may have been less motivated to adhere to this specific program. In addition, finding time to exercise is vital if an exercise program is to be adhered to. Even though the exercise groups were arranged in the evenings, previously sedentary women may have had problems getting into a weekly exercise routine, as well as possibly lacking the necessary social support from family and friends.

Results from the few RCTs evaluating the relationship between exercise during pregnancy and psychological variables show inconsistent results (Barakat et al., 2011; Marquez-Sterling et al., 2000; Montoya Arizabaleta et al., 2010; Nascimento et al., 2011; Robledo-Colonia et al., 2012). Comparison of findings is also 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 relatively high perception of overall psychological health (quality of life, well-being and body-image) at admission to this study. Hence, the likelihood to find improved scores after the intervention period is reduced.

As for the secondary outcomes, significant group differences in favor of the exercise group were found for two common pregnancy complaints: nausea/vomiting and numbness/poor circulation in legs. It should be noted that the total number of women reporting nausea/vomiting at post-test was low (19% vs. 60% at baseline). This could be explained by a general decrease in these symptoms throughout pregnancy (LaCasse et al., 2009). Less numbness and poor circulation in legs in the exercise group are likely due to the fact that regular physical activity increases blood flow of the extremities, especially when involving large muscle groups (Powers, 2014).

Conclusion

A comprehensive group fitness class for healthy weight pregnant women two times a week had positive effects on well-being and quality of life, reduced fatigue and negative feelings, as well as increased health satisfaction. Our results showed a huge variation in exercise attendance, but women who were able to attend more of the group sessions reaping the highest benefits. Qualitative data exploring pregnant women's barriers to exercise in more depth are warranted.

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Table 1

Background variables in the exercise and control groups (n=105). Means with standard deviation (SD) and numbers (n) with percentage (%).

Details	**Exercise (n= 52)**		**Control (n= 53)**	
Age	31.2	(3.7)	30.3	(4.4)
Gestational wk	17.3	(4.1)	18.0	(4.3)
Married/living together	51	(98.1)	52	(98.1)
College/university education	44	(84.6)	45	(84.9)
Sedentary occupations *(>50% of the working day)*	37	(71.2)	36	(67.9)
Daily smokers	2	(3.8)	1	(1.9)
Height (m)	1.69	(0.1)	1.69	(0.1)
Pre-preg weight (kg)	67.9	(11.4)	68.4	(14.6)
Weight (kg)*	71.8	(11.4)	72.7	(14.3)
Pre-preg BMI (kg/m^2)	23.8	(3.8)	23.9	(4.7)
Pre-preg BMI≥25	13	(25.0)	14	(26.4)
Sick-leave	10	(19.2)	13	(24.5)

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

Table 2

Primary outcome measures at posttest (week 36.6 ± 1.0) including psychological variables related to well-being, quality of life, body-image and mood symptoms, 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.

Primary outcome variables	ITT					Per protocol					100% exercise adherence				
	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
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
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
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 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

** Pooled mean score for all measured psychological variables*

Table 3

Secondary outcomes measures at posttest (week 36.6 ± 1.0), including 13 different pregnancy complaints, as well as a yes or no response to negative mood symptoms/maternal depression. Total number of reported pregnancy complaints is presented as a mean value with standard deviation (SD), otherwise the results are presented as numbers (n) with percentage (%). All variables are analyzed by intention to treat (ITT), per protocol (≥80% exercise adherence) and 100% exercise 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	-
Pregnancy depression	3 (5.8%)	9 (17%)	0.07	3 (14.3%)	9 (17%)	0.8	1 (7.1%)	9 (17%)	0.4