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# Effect of regular exercise on blood pressure in normotensive pregnant women. A randomized controlled trial

***Running head:***

*Exercise and maternal arterial blood pressure*

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## ABSTRACT

**Objective:** To evaluate the effect of regular exercise on maternal arterial blood pressure (BP) at rest and during uphill walking, in healthy former inactive pregnant women.

**Methods:** A single blind, single center, randomized controlled trial including 61 out of 105 healthy, inactive nulliparous pregnant women, initially enrolled in a controlled trial studying the effect of 12 weeks of aerobic exercise (60 min 2/week) on maternal weight gain. Primary outcome was the mean adjusted difference in change in resting systolic and diastolic BP from baseline to after intervention. Secondary outcome was the mean adjusted difference in change in systolic BP during uphill treadmill walking at critical power. Measurements were performed prior to the intervention (gestation week 17.6±4.2) and after the intervention (gestation week 36.5±0.9).

**Results:** At baseline, resting systolic and diastolic BP was 115/66±12/7 and 115/67±10/9 mmHg in the exercise (n=35) and control group (n=26), respectively. After the intervention, resting systolic BP was 112±8 mmHg in the exercise group and 119±14 mmHg in the control group, giving a between group difference of 7.1 mmHg (95% CI 1.5 to 12.6, p=0.013). Diastolic BP was 71±9 and 76±8 mmHg, with a between group difference of 3.9 mmHg (95% CI -0.07 to 7.8, p=0.054). During uphill treadmill walking at critical power, the between group difference in systolic and diastolic BP was 5.9 mmHg (95% CI -4.4 to 16.1, p=0.254) and 5.5 mmHg (95% CI –0.2 to 11.1, p=0.059), respectively.

**Conclusions:** Aerobic exercise reduced resting systolic BP in healthy former inactive pregnant women.

**Key word**: Aerobic dance, blood pressure, exercise, pregnancy

## INTRODUCTION

Hypertensive disorders of pregnancy (HDP) represent a group of medical conditions including high blood pressure (BP), proteinuria and in some cases convulsions [1]. HDP are among the leading causes of maternal morbidity and mortality, affecting six to eight percent of all pregnancies [2], and being responsible for 13 percent of all maternal deaths [1]. Treatments of HDP with antihypertensive drugs are usually given to prevent stroke and hypertrophy of the myocardium and to reduce the incidence of preterm births [3]. However, drug therapy such as β-blockers, is controversial in treatment of pregnant women due to reduced heart rate (HR) and fall in mean arterial BP, which may cause adverse effects on fetal growth and health [4].

Little attention has been given to the other end of the spectrum, hypotension, affecting about 10% of pregnant women [5]. It usually occurs during the second trimester because of hormonal shifts, as well as a rapid change in the maternal circulatory system [6]. Hypotension may cause dizziness or faintness which may inhibit participation in physical activity [7].

In the general adult population, regular exercise reduces the incidence of hypertension and ensures adequate venous blood flow to the heart to avoid fall in BP [8-10]. On the other hand, pregnant hypertensive women have been discouraged from participating in exercise, due to fear of impacting the underlying disorder and fetal outcomes [7, 11, 12]. To date, there is limited data on effect of regular exercise on resting BP in pregnant women [13-15]. In addition, the knowledge about BP during maternal exercise is scarce. Hence, the aims of the present study were to evaluate the effect of regular exercise on arterial systolic and diastolic BP at rest and during uphill treadmill walking, in healthy former inactive pregnant women. Our primary hypothesis was that pregnant women who performed aerobic exercise would show less increase in resting BT after the intervention period compared with controls. Change in BP during up-hill walking at critical power was also studied.

## MATERIALS AND METHODS

*Design*

This study was part of a single-blind, single-center, randomized controlled trial comparing pregnant women undertaking aerobic exercise with standard prenatal care, conducted at the Norwegian School of Sport Sciences in Oslo in 2008. The present paper reports on blood pressure measurements at rest and during a treadmill exercise test before and after the intervention period. The Regional Committee for Medical Research Ethics, Southern Norway, Oslo, Norway (reference number S-05208) approved the study, and written informed consents were obtained by all participants. The study was conducted in agreement with the CONSORT statement [16] and prospectively registered in the ClinicalTrials.gov (NCT00617149).

*Participants and randomization*

The study was performed in a university setting (Oslo, Norway) and included 61 out of 105 healthy, former inactive nulliparous pregnant women that completed the exercise test and measurements of BP before and after the intervention[17]. A healthy pregnancy was defined as no diseases or pathology (severe heart or lung disease, history of more than two miscarriages, persistent bleeding after week 12 of gestation, poorly controlled thyroid disease and pre-eclampsia) in the mother or fetus by inclusion. Former inactive was defined as not performing regular structured exercise ≥ once a week.

A secretary, not involved in the assessment or the aerobic exercise classes, assigned the participants to either an exercise group (n=35) or a control group (n=26). Allocations were sealed in opaque numbered envelopes following a simple computer-based randomisation program. As randomization took place after the baseline assessment, both the assessor and

the participants were blinded for group assignment during the first measurement. During the post-intervention measurements, neither the participants nor the assessor were blinded for group assignment. The primary investigator (LAHH) was blinded to the participants' allocation throughout the entire project, including plotting and analysing the data.
A-priori power calculation was done for the primary outcome of the trial. Detailed description of inclusion and exclusion criteria's are presented in Haakstad and Bø [17].

*Measurements*

Measurements were performed in the 2nd trimester between 12 and 24 weeks of gestation (baseline visit) and at gestation week 36-38 (after the intervention). The participants were told not to smoke, eat or be physically active for two hours prior to the measurements. Resting systolic and diastolic BP was measured three times by auscultatory techniques with a mercury sphygmomanometer (Big Ben, Riester, Junginen, Germany) and performed in the sitting position after a minimum of five minutes of rest. The lowest systolic and diastolic value was recorded. The participants then performed a step test by walking on a treadmill for calculation of critical power.

Prior to the treadmill walking, the participants warmed up at an initial speed of 4.5 km/h with no inclination. Based on the participant's predicted fitness level HR during the warm up, the exercise test started at 0 or 4 % inclination. The treadmill inclination then increased by four percent every forth minute, followed by a 30 sec break, while the speed was kept constant. The oxygen uptake ($VO_2$) and HR was measured during the last minute of each work load after reaching steady state (Jaeger gas analyser, Wurzburg, Germany and Polar Sports Watch,Kempele, Finland). Results from these measurements are published separately[18]. Before the end of each workload, the systolic and diastolic BP were manually recorded (Big Ben, Riester, Junginen, Germany). The rating of perceived exertion (RPE) was obtained by the Borg scale 6-20[19]. During the 30 seconds break between each workload, a capillary blood sample was taken for measurement of blood lactate concentration (YSI 1500 Sport, Incorporated Lactate Analyser, YellowSprings, USA). The test was stopped when the blood lactate concentration increased by 1.5 mmol·L$^{-1}$ above the baseline values, or rating of perceived exertion >17 on the Borg scale [19], or if the participant had a HR above 85 % of age predicted maximal HR.

*Data processing*

Critical power was defined by an increase in blood lactate of 1.5 mmol·L$^{-1}$ above the lowest value [20]. To calculate the systolic and diastolic BP at critical power, we used linear regression based on the formula y=ax+b, where “a” is the gradient of the curve and “b” is where the curve intersects the y-axis.

*Exercise intervention*

The aerobic exercise program was designed to follow the ACOG recommendations [11] and consisted of aerobic dance sessions. Each session lasted 60 min, of which 35-40 minutes of aerobic exercise, and was performed at least two times per week for a minimum of 12 weeks (Table 1). Highly qualified aerobics instructors led the aerobic dance sessions which were performed at moderate intensity, measured by ratings of perceived exertion at 12-14 (somewhat hard) on the 6-20 Borg’s rating scale [19] . The participants were familiarized with the Borg scale during the exercise testing. In addition to the aerobic dance classes, the participants were advised to undertake at least 30 minutes of moderate physical activity on the remaining week days (such as walking, bicycling, water-gymnastics), in accordance with recommendations for physical activity during pregnancy [11].

Adherence to the exercise classes was recorded by the instructors, and the self-imposed daily activity was registered in a personal exercise diary. High adherence was defined as participating in at least 80% of all supervised exercise sessions. Participants in the control group were asked to continue their usual physical activity habits and were neither encouraged nor discouraged from exercising.

*Outcomes*

The primary outcome was the mean adjusted difference in change in resting systolic and diastolic BP from 2$^{nd}$ trimester (baseline) to after intervention. Secondary outcome was the mean adjusted difference in change in systolic BP during uphill treadmill walking at critical power.

*Statistical analysis*

Background variables are presented as mean with standard deviations (SD) and frequencies (%). Differences between the groups at baseline were examined using a two-sided independent sample t-test for continuous variables and chi-square for categorical variables. The principal analysis was based on participants who completed the standardized treadmill test at baseline and after the intervention period (exercise group, n=35 and control group, n=26). In addition, we compared women with ≥80 % exercise adherence (per protocol), defined as ≥19 exercise sessions (n=16) with the control group (n=26). Analyses of covariance were used to examine the difference in change in systolic and diastolic BP between the groups. The post-intervention value for BP was set as the dependant variable, and baseline value was set as covariate. Due to that women in the exercise group were significantly older then the controls, age was also set as a covariate in the linear regression model. Statistical analyses were performed using SPSS software V.21, and level of statistical significance was set at $p \leq 0.05$.

## RESULTS

*Study population and characteristics*

In total, 105 women were randomized to either the exercise group (n=52) or control group (n=53). Of these, 61 women (exercise group n=35, control group n=26) completed the exercise test and measurements of BP before and after the intervention. Two of the participants in the control group dropped out of the study due to pre-eclampsia (Figure 1).

Based on measurements of BP and antenatal health records, none of the women completing the present study was classified with pre-eclampsia defined as hypertension combined with proteinuria (1+ on a dipstick). The participants' characteristics are shown in Table 2. Apart from age, there were no statistically significant differences in background or outcome variables between the groups at baseline, including gestational weight gain (exercise: 12.9±4.8 vs. controls: 14.5±3.9 kg, p=0.15) (Table 2 and 3), or significant differences between those completing the intervention from those that did not.

*Adherence*

Mean adherence to the aerobic exercise classes was 20±11.8 out of 24 recommended sessions. Fifty-three % attended the prescribed exercise dosage of at least 80% of the training sessions. Thirty-two of 35 women (91%) returned their exercise diaries. Walking was the most frequently reported exercise mode followed by cross country skiing, biking, muscular strength training and swimming. Two women in the control group informed that they had worked-out regularly during the intervention period. No adverse effects or other exercise-related injuries were reported by the participants in the exercise group.

*Blood pressure at rest*

Prior to the intervention (gestation week 17.6±4.2), resting systolic and diastolic BP were 115±12 mmHg and 66±7 mmHg in the exercise group and 115±10 mmHg and 67±9 mmHg in the control group, respectively. After the intervention (gestation week 36.5±0.9), resting systolic BP was 112±8 mmHg in the exercise group and 119±14 mmHg in the control group, giving a between group difference of 7.1 (95% CI 1.5 to 12.6, p=0.013). Diastolic BP was 71±9 and 76±8 mmHg, giving a between group difference of 3.9 (95% CI -0.07 to 7.8, p=0.054) (Table 3).

*Blood pressure during uphill walking*

As shown in Table 3, both groups were within normal rates for systolic BP during treadmill walking at critical power exercise (range 160- 220 mmHg) [21]. The between group difference in systolic and diastolic BP was 5.9 mmHg (95% CI -4.4 to 16.1, p=0.254) and 5.5 mmHg (95% CI –0.2 to 11.1, p=0.059), respectively.

*Hypertension and hypotension*

Four women (11.4%) in the exercise group and one woman (3.8%) in the control group had borderline hypertension (systolic BP >140 and/or diastolic BP >90 mmHg) at the time of randomization. After the intervention, none in the exercise group were hypertensive vs. two women (3.8%) in the control group. Hypotension (systolic BP ≤ 90 and/or diastolic BP ≤ 60 mmHg) was measured in one woman (3.8%) at rest in the control group at baseline.

## DISCUSSION

The aim of the present study was to evaluate the effect of following the current exercise guidelines, including supervised aerobic exercise performed twice a week from the start of the 2nd trimester and throughout pregnancy, on BP at rest and during uphill treadmill walking in previously inactive pregnant women. After the intervention, we found significantly and clinically lower resting systolic BP in the exercise group compared to the control group. In comparison with reported results in other meta-analysis investigating the effect of exercise on BP in non-pregnant subjects with normal values [22, 23], an overall reduction in resting systolic (7.1 mmHg) BP is substantial. Thus, our results are within the range of findings among hypertensive groups, which is more or the same as medications [22]. In addition, we found a borderline non-significant increase in diastolic BP in the control group at critical power during uphill walking. Hence, the data of this study shows that regular exercise may be useful in preventing pregnancy induced hypertension. It is also notable is that two women in the control group were not included in final results because of preeclampsia, lending further credence to possible benefit of exercise.

In general, the evidence between an increase in regular physical activity and a reduction in the risk of hypertension is well documented [8-10]. On the other hand pregnant women with hypertension are advised to rest [11], and there has been relatively little research about the possible effect of maternal exercise on BP, hypertension, or pre-eclampsia. Case-control and cohort studies have suggested a reduced risk of gestational hypertension and pre-eclampsia with more vigorous intensity exercise [24, 25]. These studies have largely evaluated the effect of exercising before conception and during the first half of pregnancy.

RCTs evaluating the effect of exercise on BP, hypertension and pre-eclampsia are sparse and most of low methodological quality including small sample sizes [13-15, 26-28]. Comparison of findings is difficult due to huge differences in interventions and exercise dosage (mode, intensity and duration), time point in pregnancy the women were recruited, the length of the intervention, as well as different study populations. Avery et al [14] and Yeo et al [15] compared moderate intensity aerobic training in women who had moderate to high risk of pre-eclampsia, and concluded with conflicting results. Avery et al [14] found no effect of exercise with respect to prevention of gestational hypertension, pre-eclampsia, or its complications, whereas Yeo et al [15] reported that 10 week of moderate exercise lowered diastolic BP, concurrent with the present study.

Petrov et al [13] included 92 women to assess the effect and safety of moderate-to vigorous resistance training on several outcomes, including resting BP. No difference in maternal BP between intervention and control group were reported, and the authors conclude that resistance training does not adversely impact maternal BP. Our results support this conclusion, and showed, in addition, that regular aerobic exercise with focus on cardiovascular training reduced resting systolic BP in healthy inactive pregnant women. The reductions were probably due to the effect of exercise itself, not to weight, as both groups had similar gestational weight gain [17].

Little is known about the mechanism by which exercise may reduce the risk of high BP and the development of pre-eclampsia. Exercise has been proposed to reduce oxidative stress, improve endothelial function, as well as immune and inflammatory responses [29, 30]. In addition, exercise is associated with an increase in cardiac output, so that the heart can pump more blood with less effort [30].

During exercise at critical power, the between group-difference in diastolic BP was 5.5 mmHg, but did not reach statistical significance, probably due to low statistical power (p=0.059). From a clinical point of view, however, this trend show that regular aerobic training in the 2nd and 3rd trimester not only have an effect on resting BP, but could also benefit BP during exercise and physical exertion. We believe that these results warrant further investigation, given that current literature suggests that women with gestational hypertension need to limit physical activity [11, 31].

Even though the numbers were too small for meaningful statistical analysis, it is of interest that four women in the exercise group and one woman in the control group had borderline hypertension (≥140/90 mmHg) at baseline measurement. At post-test, none in the exercise group was hypertensive vs. two women in the control group. This finding is consistent with Yeo et al [28] showing that pregnant women who participated in a walking-program, 3-4 times weekly, duration of 30-35 minutes, had lower incidence of gestational hypertension (22%) compared to the control group (home-exercise stretching) (40%). However, Yeo et al's study recruited only women with previous pre-eclampsia and therefore was at increased risk of developing the illness in current pregnancy. The opposite effect was found with respect to incidence of pre-eclampsia [28]. Hence, it is possible that exercising during pregnancy could reduce the risk of hypertension, although this may not necessarily influence the risk of pre-eclampsia.

We included 105 healthy nulliparous former inactive women, however, only 61 (exercise, n=35 and control, n=26) completed the exercise test and measurement of BP before and after the intervention. Hence, missing data due to participant's refusal to complete the assessments may have reduced the statistical power of the study. We were not able to find

RCTs that were based on a priory sample size calculations according to BP in a normotensive pregnant population, therefore, there were no comparable sample size calculations for this outcome. Avery et al [14] and Yeo et al [15] investigated the effect of regular exercise on a high risk population of pregnant women, with a population size of 16 and 29, respectively. Hence, our study had higher participation rate and sample size.

During pregnancy unforeseen obstacles may occur, and as shown in Consort diagram (Figure 1), many of the drop-out reasons in the present study were pregnancy-related (premature birth, pelvic girdle pain, uterine contractions, pre-eclampsia). However, no matter reason, it is unfortunate to have high drop-outs rate. Hence, it could be questioned if the results are overestimated, meaning that participants completing the study differ from those who did not (61 of 105 women). On the other hand, a possible bias associated with the drop-outs was probably minor, as there was only a small difference in reasons for drop-out between the exercise and control group. In addition, apart from the age, there were no statistically significant differences in background or outcome variables between the two groups prior to the intervention

Explanatory research asks whether an intervention works under ideal or selected conditions [32]. Hence, we also performed per protocol analysis, defined as those who adhered perfectly to the clinical trial instructions as stipulated in the protocol (≥80% exercise adherence to exercise sessions). In the present study, these analyses (exercise group: n=16, control group: n=26) did not show a larger treatment effect compared with completers analyses (exercise group: n=35, control group: n=26).

The strengths of the present study was a randomized controlled design, use of an aerobic exercise program following ACOG recommendations [11], and use of a valid and reliable submaximal treadmill step-test to measure BP during exercise [33-35]. Furthermore, we registered the participant's adherence to the exercise protocol, showing a relatively high mean exercise dosage (20 out of 24 recommended sessions). Limitations are that the sample size was not based on an a priori power calculation for BP. The participants in this study were first time pregnant and had a normal body mass index, hence, the result of this study may only be generalized to this group.

**Conclusions:**

Aerobic exercise reduced resting systolic BP in healthy former inactive pregnant women. Future RCTs of high methodological and interventional quality on a risk population including women with previously pre-eclampsia are warranted.

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