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# **INTRODUCTION**

Healthy pregnant women are recommended to be physically active on a moderate intensity level for 30 minutes on most days of the week throughout pregnancy to attain the positive health benefits of physical activity [1-4]. Observational studies have shown that pregnant women have a low physical activity level and only a minority exercise on a regular basis [5-7]. It has been reported that physical fitness is more important than physical activity level to achieve health benefits in the general population [8-10]. Hence, the focus during pregnancy should be to maintain physical fitness.

A meta-analysis performed by Kramer and McDonald [11] concluded that regular exercise during pregnancy seems to improve or maintain cardiorespiratory fitness. However, the authors stated that the studies generally were of low methodological quality. Hand search of the reference list of the Cochrane review and additional search on PubMed until February 2010 identified only two randomized controlled trials (RCT's) with high methodological quality [12;13]. Santos et al.[12] reported a 18% increase in cardiorespiratory fitness in pregnant women after three aerobic dance sessions per week for 12 weeks, while Baciuk et al.[13] reported maintenance, but no improvement of cardiorespiratory fitness in pregnant women after a intervention that consisted of water aerobics three times per week for 16 weeks.

Pregnancy leads to physiological and anatomical changes which may affect women's cardiorespiratory fitness. Firstly, the weight gain leads to a progressive decline in performance in all weight bearing activities [14]. Secondly, there is an increase in blood volume and heart rate [15]. The maximal heart rate is reduced in pregnancy and the blood has decreased haemoglobin concentration [14]. Thirdly, minute ventilation increases by almost 50% [15]. Hence, these changes lead to reduced reserve work capacity in pregnant women [14]. Due to these changes, assessment of physical fitness is challenging during pregnancy. Some studies included in the Cochrane meta-analysis have used submaximal tests based on heart rate to estimate maximal oxygen uptake[13;16], some studies have used simple non validated work load tests [17;18], and two studies have measured maximal oxygen uptake directly [19;20]. Therefore, the outcome measures and parameters used to assess cardiorespiratory fitness may be a limitation in the majority of the previously published studies.

The aim of the present study was to evaluate the effect of a 12 week aerobic dance class twice a week, in addition to 30 minutes of moderate self-imposed physical activity on the remaining week-days, on cardiorespiratory fitness in first time pregnant women.

### **METHODS**

### Design

This is a report on secondary analysis of a RCT comparing the effect of an aerobic fitness class with a non-exercising control group. The study was approved by the Regional Medical Ethics Committee and the Norwegian Social Sciences Data Services. All participants gave written consent to participate. The study is listed in Clinical Trials.gov (NCT00617149).

### **Participants**

The participants were recruited via physicians, midwives and announcements placed in local newspapers and at websites for pregnant women between September 2007 and March 2008. Healthy first time pregnant women who had not participated in a structured exercise program (>60 minutes once a week), including brisk walking (>120 minutes per week) during the past six months were eligible for the trial. Other inclusion criteria were gestational age 12-24 weeks and able to read and understand instructions given in Norwegian language. Exclusion criteria included; severe heart disease, pregnancy induced hypertension, history of two or more miscarriages, bleeding after gestational week 12, uncontrolled thyroid disease, pre-eclampsia or other diseases that could interfere with participation [1]. The present study was carried out in a university setting.

# Intervention

The aerobic classes were held three days a week during the intervention period. Participants randomized to the exercise group were encouraged to participate in at least two one hour aerobic dance classes per week for twelve weeks. The exercise program (table 1) followed the American College of Obstetricians and Gynecologists (ACOG) recommendations [1]. The exercise program was choreographed and led by certified aerobics instructors and each session included a maximum of 25 participants. The intensity was moderate evaluated on the 6-20 Borg's Rating Scale [21]. The participants were made familiar with the Borg scale during the individual fitness testing and posters of the scale were placed on the wall in the exercise room.

In addition to the aerobic dance classes, the women in the exercise group were advised to be physically active for at least 30 minutes on the remaining week days according to the recommendations for physical activity during pregnancy [1].

Adherence to the exercise classes was recorded by the instructors, and the self-imposed daily activity was registered in a personal exercise diary. Participants in the control group were asked to continue their usual physical activity habits and were neither encouraged nor discouraged from exercising. Exercise habits in the control group during the intervention period were determined with a standardized interview at the fitness test after the intervention.

### Outcomes

Cardiorespiratory fitness was assessed at baseline before randomization between the  $12^{th}$  and  $24^{th}$  week of pregnancy and after at least twelve weeks of enrolment in the study, when subjects were between their  $36^{th}$  and  $40^{th}$  week of pregnancy. All participants underwent sub maximal exercise testing by walking on a treadmill for establishment of the relationship between oxygen uptake (VO<sub>2</sub>), heart rate (HR) and blood lactate concentration ([La<sup>-</sup>]<sub>b</sub>) at 4-6 different sub maximal workloads (lactate profile test). These variables are considered valid predictors of aerobic capacity [22;23]. The sub maximal lactate profile test was chosen because of the limited knowledge concerning safety of strenuous physical activity and maximal exercise testing in pregnancy [1].

The participants were told not to smoke, eat or be physically active two hours before the test. They started with a warm-up walking on the treadmill, with an initial speed of 4.5 km/h and no inclination. Based on the participant's heart rate during the warm up and predicted fitness level, it was decided whether the test should start at 0 or 4% inclination. The speed was kept constant during the test, while the inclination increased 4% every fourth minute. Expired air was collected during the second and third minute of each work load via a mouthpiece for determination of VO<sub>2</sub> (Oxycon Champion Jeager, Germany). The heart rate was recorded at

the end of each work load (Polar sport tester, Finland). In addition, the participants were asked to give a score on the Borgs Ratings scale (6-20) of perceived exertion [21]. During the 30 seconds break between each work load a blood sample was taken with a finger stick to determine blood lactate concentration. The blood sample was immediately analysed (YSI Lactate Analysor 1500 Sport, USA). The test was stopped when the participant's blood lactate concentration was 1.5 mmol·1<sup>-1</sup> above baseline values (defined at anaerobic threshold), or reported RPE between 15-17 on the Borg scale [21].

The change in relative oxygen uptake  $(ml \cdot kg^{-1} \cdot min^{-1})$  at three different levels of blood lactate was used to assess cardiorespiratory fitness and were defined as 0.5 mmol·l<sup>-1</sup> (level 1), 1.0 mmol·l<sup>-1</sup> (level 2) and 1.5 mmol·l<sup>-1</sup> (level 3) above baseline values. Secondary outcome measures were change in absolute oxygen uptake (l/min), work load, heart rate and rating of perceived exertion on the Borg scale at blood lactate level 1, 2 and 3. To calculate oxygen uptake, work load, heart rate and rating of perceived exertion at the three different lactate levels we used llinear 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. All calculations were performed in Microsoft Office Excel 2003.

### Sample size

Since this study was a part of a RCT investigating the effect of exercise on weight gain during pregnancy the a priori power calculation was done according to this outcome measure and not cardiorespiratory fitness.

# Randomization

After baseline assessments, a person, not involved in other aspects of the study, randomly assigned the participants to either the exercise group or the control group following a computerised randomization program. A simple randomization procedure without any stratification was used.

# Blinding

Since the randomization took place after the baseline test, both the assessor and the participants were blinded for group assignment during test one. During the fitness test after the intervention neither the participants nor the assessor were blinded for group assignment.

### Statistical analyses

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 fitness test at baseline and after the intervention period (exercise group, n=34 and control group, n=28). In addition, per protocol analysis based on participants with  $\geq 80$  % adherence to the exercise protocol ( $\geq 19$  exercise session) was done (exercise group, n=18 and control group, n=28). The women in the exercise group were significantly older than the women in the control group, therefore ANCOVA were used to examine the difference in change between the groups in cardiorespiratory fitness. Post test score in cardiorespiratory fitness were set as the dependent variable and baseline score and age were set as covariates. The statistical analyses were conducted in SPSS version 18 and level of statistical significance was set at p<0.05.

# RESULTS

A total of 105 women were randomized to either the exercise group (n=52) or control group (n=53). Of these, 62 women (exercise group n=34, control group n=28) fulfilled the cardiorespiratory fitness test before and after the intervention. Fig. 1 shows the flow chart of participants. Since there was a high drop-out rate on the fitness test, only women who performed both fitness tests were included in the analyses.

The participants' personal characteristics are shown in Table 1. Participants in the exercise group were significantly older (p=0.03) than the participants in the control group, apart from this there were no statistically significant differences in background variables between the groups at baseline. Furthermore, no significant differences in measurement of the outcome variables between the groups were found at baseline (Table 2).

The women in the exercise group (n=34) participated in mean 20.0 (SD 11.8) out of 24 aerobic dance sessions. Eighteen of 34 women (53%) attended the prescribed exercise protocol (80%) with  $\geq$ 19 aerobic dance sessions. Thirty-two of 34 women (94%) in the exercise group returned their exercise diaries. In addition to the aerobic dance sessions, women in the exercise group reported a mean weekly exercise time of 90 minutes (SD 73) in their exercise diaries. Walking was the most frequently reported exercise mode followed by cross country skiing, biking, muscular strength training and swimming.

No exercise related injuries or other adverse events were reported by the participants in the exercise group.

Two of 28 women in the control group reported that they had exercised at least twice a week for a minimum of 60 minutes of moderate intensity during the intervention period.

### **Change in cardiorespiratory fitness**

Because not all subjects continued the test until they reach lactate level 2 and 3 and because of error during tests, the number of participants are varying in the different variables.

### Oxygen uptake

The differences in change in relative  $VO_2$  (ml·kg<sup>-1·</sup>min<sup>-1</sup>) between the groups were not significant at level 1, 2 or 3 (table 2). Nine of 34 (26%) women in the exercise group had an increase in  $VO_2$  (ml·kg<sup>-1·</sup>min<sup>-1</sup>) during the intervention period, compared to five of 25 (20%) women in the control group (p=0.56). Furthermore, there were no significant differences in change in absolute  $VO_2$  (L·min<sup>-1</sup>) at level 1, 2 or 3 between the groups.

#### Work load

There were no statistically significant differences between the groups in change in work load at level 1, 2 or 3 (Table 2). Four of 33 (33%) women in the exercise group walked at a higher inclination before onset of blood lactate accumulation after the intervention period, compared to only one of 28 (4%) women in the control group (p=0.36).

# Heart rate

There were no statistically significant differences between the groups in change in heart rate at level 1, 2 or 3 (table 2). Both groups had a lower heart rate at onset of blood lactate accumulation after the intervention period, indicating a lower intensity at the same blood lactate level. There were no differences in the proportion of women that had a higher heart rate before onset of blood lactate accumulation after the intervention after the intervention between the groups (p=0.88).

# Rating of perceived exertion

The differences between the groups in change in rating of perceived exertion on the Borg scale were not significant at level 1, 2 or 3. Nineteen of 34 (56%) women in the exercise group and 10 of 28 (36%) women in the control group reported a lower rating of perceived exertion during the fitness test after the intervention (p=0.13).

Per protocol analyses (data not shown) based on participants with  $\geq 80$  % adherence to the exercise protocol (exercise group: n=18, control group: n=28) did not change any of the above presented results.

# DISCUSSION

The present study showed that a 12 week aerobic dance program had no effect on cardiorespiratory fitness in pregnant women.

It has been reported that even small improvements in cardiorespiratory fitness may cause an overall lower mortality in adults.[24;25]. Myers et al.[24] reported that each 3.5 ml·kg<sup>-1</sup>·min<sup>-1</sup> increase in peak VO<sub>2</sub> were associated with a 12% improvement in overall survival, and Keteyian et al.[25] reported that every 1 ml·kg<sup>-1</sup>·min<sup>-1</sup> increase in peak VO<sub>2</sub> were associated with a 15% decrease in risk of death. Hence, the significant decrease of 1.3 ml·kg<sup>-1</sup>·min<sup>-1</sup> VO<sub>2</sub> we observed from baseline to after the intervention in both groups might be of clinical importance. Since this was similar in both groups, this indicates that a higher exercise dose than observed in the exercise group is needed to maintain cardiorespiratory fitness during pregnancy.

The strengths of the present study was a randomized controlled design, use of an exercise program following ACOG recommendations [1], and assessment of cardiorespiratory fitness by a valid, reliable and responsive method [22;23;26]. Furthermore, we registered the participant's adherence to the exercise protocol. Limitations are that the sample size was not based on an a priori power calculation of cardiorespiratory fitness and a high loss to follow up on the fitness test. In addition, participants in the exercise group showed low adherence to the exercise protocol and level of physical activity in the control group was only recorded after the intervention period. The participants in this study were first time pregnant, had a normal body mass index and a high educational level, hence, the result of this study may only be generalized to this group.

Our results are in contrast to the conclusion of the Cochrane review [11]. However, Kramer & McDonald[11] included studies without randomization. Hence, we have identified only two RCT of high methodological quality [12;13], that have assessed the effect of exercise on cardiorespiratory fitness in pregnant women. However, comparisons of results between studies are difficult due to the use of different measurement methods to assess

cardiorespiratory fitness, and the fact that cardiorespiratory fitness can be influenced by anatomical and physiological changes that occurs during pregnancy [15].

Missing data due to participant's refusal to complete the assessments may have reduced the statistical power of the study. Hence, lack of statistical significant differences may be due to type II error [27]. The only study of high methodological quality that found positive results after regular aerobic dance exercise in pregnancy included 92 women, and 72 of these completed the study and were analyzed [12]. Hence, our study had similar power. Santos et al.[12] reported a significant increase inVO<sub>2</sub> per kilogram of body weight and heart rate at the anaerobic threshold in the exercise group compared to the control group. Difference in result from our study may be explained by a higher adherence to the exercise protocol and lower loss to follow up. Furthermore, it may also be explained by a larger exercise dose (three aerobic dance sessions per week) and that Santos et al.[12] included overweight participants only.

Our result are in accordance with Baciuk et al. who reported no differences between the exercise group and the control group [13]. The study of Baciuk et al. was a RCT with high methodological quality due to concealed randomization, adequate follow-up and ITT-analysis. However, lactate testing as used in our study is considered to be more responsive to change in cardiorespiratory fitness than the submaximal exercise test for estimation of maximal VO<sub>2</sub> used by Baciuk et al.[13].

In general, studies reporting a positive effect on cardiorespiratory fitness during pregnancy had a higher exercise dosage than the present study, with three or more exercise sessions per week with a duration between 25-60 minutes [11]. According to the current exercise guidelines the recommended exercise dose to maintain cardiorespiratory fitness in the general population is  $\geq 5$  times per week of moderate intensity [28]. We assumed that it was easier to recruit and achieve high adherence in a population of previous sedentary pregnant women with an exercise protocol of two aerobic dance sessions per week, and rather encourage to 30 minutes of self-imposed physical activity the remaining week days to meet the exercise recommendations. Still, only 18 of 34 women (53%) attended the recommended exercise sessions. Kardel et al.[20] reported that top-level athletes participating in an exercise regime consisting of four cardiorespiratory exercise sessions per week had an increase in VO<sub>2max</sub> per kilogram of body weight from baseline at week 17-19 of pregnancy to 12 weeks postpartum. However, the study was not randomized and the participants could choose the mode and intensity of exercise individually. They reported no improvement in cardiorespiratory fitness from week 17 to week 36 of pregnancy, despite a high cardiorespiratory exercise dose. Most likely, the reported increase in VO<sub>2max</sub> per kilogram of body weight 12 weeks postpartum was caused by the rapid weight loss after giving birth, which leads to an increase in relative oxygen uptake. This emphasises the challenges when assessing cardiorespiratory fitness in pregnant women.

#### CONCLUSION

A 12 week aerobic dance program had no effect on cardiorespiratory fitness in pregnant women. Further randomized controlled trials of high methodological and interventional quality on the effect of regular exercise on cardiorespiratory fitness in sedentary pregnant women are warranted. Ethical approval: National Committee for Medical Research Ethics, Sourthern Norway (S-05208). The Norwegian Social Sciences Data Services provided licence to store the data (17804/2/KH). The study is listed in Clinical Trials.gov (NCT00617149). Conflict of interest: None declared.

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Time	Part	Content	Intensity
5 min	Warm-up	<ul><li>Standing on the floor</li><li>Flexibility exercises</li><li>Breathing exercises</li></ul>	
35 min	Aerobic Dance	<ul> <li>Low impact aerobic on the floor or</li> <li>Step aerobic</li> <li>No running or jumping</li> </ul>	12-14 (somewhat hard) on the Borg Scale
15 min	Muscular strength exercises	<ul> <li>Upper/lower extremities</li> <li>Back</li> <li>Pelvic floor</li> <li>Deep abdominals</li> </ul>	12-15 repetitions maximum, 3 sets
5 min	Cool down	<ul><li>Stretching</li><li>Relaxation</li><li>Body awareness</li></ul>	

## Table 2

Personal characteristics at baseline in the Exercise (n=34) and the control group (n=28)

Detail	Exercise	Control	
	n= 34	n= 28	
Mean (SD)			
Age	31.5 (3.2)	29.5 (4.0)	
Gestational wk	17.1 (3.9)	18.5 (4.4)	
Height (m)	1.68 (0.1)	1.70 (0.1)	
Pre-pregnancy weight (kg)	64.9 (9.5)	66.4 (8.4)	
Weight (kg)*	68.9 (9.9)	71.3 (8.2)	
BMI before pregnancy (kg/m <sup>2</sup> )	22.9 (3.2)	23.0 (2.9)	
n (%)			
Married/living together	33 (97.1)	28 (100)	
College/university education	28 (82.3)	23 (82.1)	
Sicklisted	5 (14.7)	3 (10.7)	
Daily smoker	1 (2.9)	0 (0)	
* Measured at baseline			

# Table 3

Oxygen uptake, work load, heart rate and rating of perceived exertion (RPE) at level 1, 2 and 3 in the exercise (EG) and the control (CG) group at baseline, after the intervention and mean adjusted difference of change between the groups. Values are number of participants (n), mean with (SD), mean difference of change ( $\beta$ ) with 95% CI and p-value of the difference in change from baseline to after the intervention.

Variable	Group	n	Baseline	After intervention	Mean adjusted difference in change $\beta^*$ (95%CI)	p-value
$VO_2$ (ml·kg <sup>-1</sup> ·min <sup>-1</sup> ) level 1	EG	34	22.0 (2.9)	20.7 (3.9)	· · · · · · · · · · · · · · · · · · ·	
2 0 /	CG	25	21.6 (3.2)	20.0 (2.9)	-0.6 (1.0, 2.1)	0.48
$VO_2$ (ml·kg <sup>-1</sup> ·min <sup>-1</sup> ) level 2	EG	31	24.8 (3.3)	23.1 (4.2)		
	CG	24	24.3 (3.3)	22.7 (2.8)	-0.02 (-1.6, 1.6)	0.98
$VO_2$ (ml·kg <sup>-1</sup> ·min <sup>-1</sup> ) level 3	EG	24	25.8 (3.3)	24.5 (3.8)		
	CG	19	25.8 (3.3)	24.5 (2.5)	0.1 (1.4, 1.7)	0.89
$VO_2$ (l/min) level 1	EG	33	1.5 (0.2)	1.6 (0.2)		
	CG	25	1.5 (0.2)	1.6 (0.3)	0.001 (-0.1, 0.1)	0.99
VO <sub>2</sub> (l/min) level 2	EG	31	1.7 (0.2)	1.8 (0.3)		
- ` ` `	CG	24	1.7 (0.2)	1.8 (0.3)	-0.04 (-0.2, 0.1)	0.52
$VO_2$ (l/min) level 3	EG	24	1.8 (0.2)	1.9 (0.2)		
	CG	19	1.9 (0.2)	2.0 (0.2)	-0.1 (-0.2, 0.03)	0.15
Work load (inclination %) level 1	EG	33	9.6 (2.4)	8.2 (2.9)		
	CG	28	9.5 (2.8)	7.4 (2.3)	0.8 (-0.3, 1.9)	0.14
Work load (inclination %) level 2	EG	32	12.0 (2.8)	10.1 (3.1)		
	CG	27	11.7 (2.8)	9.7 (2.3)	0.2 (-0.8, 1.3)	0.67
Work load (inclination %) level 3	EG	26	12.8 (2.7)	11.2 (3.0)		
	CG	21	12.9 (2.8)	11.0 (2.2)	0.6 (0.4, 1.7)	0.22
Heart rate (beat·min <sup>-1</sup> ) level 1	EG	34	146 (13)	142 (12)		
× · · ·	CG	28	149 (11)	144 (11)	1 (-4, 5)	0.85
Heart rate (beat·min <sup>-1</sup> ) level 2	EG	32	155 (11)	150 (12)		
	CG	27	158 (10)	153 (11)	-2 (-6, 3)	0.52
Heart rate (beat·min <sup>-1</sup> ) level 3	EG	26	160 (11)	156 (12)		
× · · ·	CG	21	162 (11)	160 (12)	-3 (-7, 2)	0.23
RPE level 1 (The Borg scale)	EG	34	13.1 (1.5)	13.1 (1.5)		
	CG	28	12.8 (1.6)	13.9 (1.5)	0.1 (-0.6, 0.9)	0.73
RPE level 2 (The Borg scale)	EG	32	14.3 (1.3)	13.9 (1.6)		
	CG	27	13.8 (1.3)	14.1 (1.3)	-0.3 (-1.0, 0.5)	0.45
RPE level 3 (The Borg scale)	EG	26	14.7 (1.2)	14.4 (1.5)		
	CG	21	14.3 (1.2)	15.0 (0.9)	-0.5 (-1.2, 0.3)	0.23

RPE; rating of perceived exertion (the Borgs Scale).  $\beta$ ; regression coefficients with adjustments for age and baseline score, CI; confidence interval Numbers of participants are varying since not all participants continued the test until they reach level 2 and 3.