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The marathon of labour - does regular exercise training influence course of labour and mode of delivery?

Secondary analysis from a randomized controlled trial

Running head:

Exercise and labour

Lene A. H. Haakstad, Associate professor, exercise scientist, MSc, PhD
Norwegian School of Sports Sciences, Department of Sports Medicine, Oslo, Norway.
(E-mail: lahaakstad@nih.no)

Kari Bø, Professor, exercise scientist, physical therapist, MSc, PhD
Norwegian School of Sports Sciences, Department of Sports Medicine
(E-mail: kari.bo@nih.no)

Corresponding author:
Lene A. H. Haakstad
Norwegian School of Sport Sciences
Department of Sports Medicine
P.O Box 4014, Ullevål Stadion
0806 Oslo, Norway
Ph. +47 23 26 20 00
Fax +47 22 23 42 20, e-mail: lahaakstad@nih.no

ABSTRACT

Objectives: Today all pregnant women are recommended to participate in moderate intensity aerobic and resistance-based physical activity/exercise ≥150 min/week. However, there are still controversies and scant knowledge on the role of regular exercise on delivery outcomes, including mode of delivery and length of active labour. In addition, nutritional counselling have often been examined together with exercise, which may independently effect the outcomes. Hence, the aims of the present study were to investigate the sole effect of supervised group exercise, including pelvic floor muscle training on course of labour and mode of delivery.

Study design: A single blind, randomized controlled trial, performed in the municipality of Oslo, Norway. Out of 105 healthy, inactive nulliparous women, initially enrolled (gestation week 17.7 ±4.2) to study the effect regular aerobic exercise (60 min 2/week) on health benefits for both mother and her baby, 90 (85.7%) completed postpartum follow-up (7.7±1.7) on labour outcomes (exercise: 43 and control: 47). Data were collected via standardized interviews and birth partographs from hospital records, reported on the postpartum visit (weeks after labour 7.6±1.6). The primary investigator was unaware of the original randomization at the time of the interviews. The principal analysis was done on an intention to treat basis (ITT). For the planned subgroup analyses (per protocol), acceptable intervention adherence was defined as attending ≥ 80% of the recommended exercise program (≥ 19 exercise sessions).

Results: There were no differences between the exercise and control groups in induction of labour, use of analgesia, duration of active labour or prolonged labour, according to ITT. Per protocol analyses, showed a shorter duration of total active labour in the exercise group (6.8±5.5 hours) than the control group (9.8±5.4 hours), with a mean between group difference of 3.1 hours (95% CI 0.31 to 5.9, p=0.029). Rate of normal vaginal delivery was 85.7% among adherent participants and 62.3% in the control group (p= 0.051).

Conclusions: Regular exercise during pregnancy decreased duration of total active labour and showed a trend towards more normal vaginal deliveries among participants who adhered to the prescribed program.

Trial registration: ClinicalTrials.gov: NCT00617149

Key word: caesarean section, exercise, labour, pregnancy, RCT

Introduction

If pregnancy is uncomplicated, current guidelines promote continuation of pre-pregnancy exercise activities, and recommend that physically inactive women start exercising during pregnancy [1,2]. According to these recommendations, all pregnant women are encouraged to participate in moderate intensity aerobic and resistance-based PA/exercise ≥2.5 hours/week, in the absence of medical or obstetrical contraindications [1,2]. Still, levels of physical activity (PA) tend to decline during pregnancy [3-5]. A fear of harm to the developing fetus may to some extend explain the low levels of PA/exercise during pregnancy, as well as poor knowledge about prenatal exercise, risks and benefits among health care providers [6,7].

Up to date, several systematic reviews have evaluated the role of regular exercise on delivery outcomes [8-11]. The authors seem to agree that regular moderate intensity exercise may give a higher rate of normal vaginal delivery, however there is no consensus whether regular PA/exercise effects the course and duration of active labour. Current data is hampered by large methodological and clinical heterogeneity. In addition, nutritional counselling have often been included in the interventions together with exercise, which may independently effect the outcomes [9,12]. Hence, it is important to study the sole effect of regular exercise on course of labour and mode of delivery.

Studies have shown that nulliparous women spend six to 12 hour (from the time they are dilated four centimetres), with an average duration of about eight hours in active labour [13,14]. Hence, labour requires both endurance and stamina, and has been compared with a marathon race. It has been hypothesized that physically strong and fit women may be better prepared for labour [10]. In addition, regular pelvic floor muscle training may give toned and well-trained muscles that can facilitate labour and shorten second stage of labour [15].

As described in ClinicalTrials.gov (NCT00617149), the Pregnancy Exercise Intervention was designed to evaluate whether supervised group exercise, at least twice weekly for a minimum of 12 weeks, gave measurable health benefits for the mother and child. We have previously reported on gestational weight gain [16] and neonatal well-being and birth weight [17]. In this pre-specified secondary analyses, we aimed to investigate the effect of the Pregnancy Exercise Intervention on 1) course of labour (induction, use of analgesia, duration of labour), and 2) mode of delivery (normal vaginal, instrumental assisted delivery, Caesarean sections).

Materials and Methods

The Pregnancy Exercise Intervention was performed in the municipality of Oslo, Norway, and was a single-blind, single-center RCT, comparing pregnant women undertaking cardiovascular and strength training with standard prenatal care. The complete study was conducted in agreement with the CONSORT statement (http://www.consort-statement.org) and was registered in the ClinicalTrials.org Protocol Registration System (NCT00617149). The Regional Committee for Medical Research Ethics, Southern Norway, Oslo, Norway (reference number S-05208) approved the study. The Norwegian Social Sciences Data Services (NNT) provided licence to store and register individual health information (reference number 17804/2/KH).

Participants and randomization

Eligible participants were healthy, inactive nulliparous women with a singleton pregnancy. Healthy was defined as having no diseases or pathology by inclusion (severe heart or lung disease, history of more than two miscarriages, persistent bleeding after week 12 of gestation, poorly controlled thyroid disease, pregnancy-induced hypertension or pre-eclampsia, diabetes or gestational diabetes) [18]. Being former physical inactive was defined as not having performed regular structured exercise > once week the past six months. Exclusion criteria were disabilities that could preclude participation in the intervention, inability to understand, speak and read Norwegian, as well as planned relocation outside the county of Oslo the next year.

Participants were recruited via websites for pregnant women, health practitioners (physicians, midwives), articles and posters. A priori sample size calculation was only done for the primary outcome of the trial (gestational weight gain), and are presented in detail elsewhere [16].

Out of 211 women who agreed to participate, 54 were lost or withdrew before study enrolment. Hence, 157 women were assessed for eligibility February - April 2008. Of these, 105 women signed an informed consent form and completed the initial interview/ assessments, before a secretary, not involved in the assessment or the supervised 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 randomisation program. The primary investigator (LAHH) was blinded to the participants' allocation throughout the entire project, including plotting and analysing the data.

As illustrated in the flow chart (Figure 1), some participants who were lost to post-intervention interview, re-entered the study at the postpartum assessment and follow-up after labour. There was no financial compensation to the participants.

Exercise intervention

From time of randomization (gestation week 17.3 ±4.1) until delivery (gestation week 39.9±1.4), the intervention participants were encouraged to participate in at least two out of three weekly supervised group sessions, offered at the University fitness club, for a minimum of 12 weeks. Thus, at least 24 exercise sessions were prescribed for each participant.

The exercise program was tailored for pregnancy and followed contemporary guidelines [18]. Each session lasted 60 minutes and included five minutes of warm-up, 35-40 minutes of cardiovascular exercise and 10-15 minutes of strength training, with emphasis on exercises for the core and pelvic floor muscles [19]. All sessions had a maximum of 15 participants and was accompanied by music. Due to variations in maternal heart-rate responses to exercise (ACOG 2002), self-perceived exertion was set to 12–14 on the 6–20 Borg's rating scale [20].

Although practical and economic considerations limited classes to maximum three per week, all women in the intervention group were encouraged to be physically active at moderate intensity on three additional days per week, lasting at least 30 minutes, in accordance with recommendations for physical activity during pregnancy [18].

The instructors recorded adherence to the exercise classes and sent this to the project leader weekly. Good adherence to the exercise intervention was defined as participating 19/24 supervised sessions over a period of 12 weeks (≥80% of the recommended exercise program) [16].

Control group

It was not considered unethical to have a control group not receiving treatment in the present trial. However, as we considered asking the control group not to exercise to be against current guidelines, participants in the control group were asked to continue their usual physical activity habits and were neither encouraged nor discouraged from exercising. To treat the two groups identically apart from for the experimental intervention, the control group underwent all tests and completed the same interview as the exercise group, including assessment of physical activity/exercise. This was also done to ensure that the primary investigator was “blind” to the treatment received. The control group did not complete a training diary.

Measurements and outcomes

The baseline interview at trial inclusion covered sociodemographic information (e.g. age, gestational week, college/university education, occupation, sick-leave, pregnancy complaints, pre-pregnancy weight, smoking habits). In addition, we assessed height, current weight, physical activity and sedentary behaviour (at work, transportation and household). The PA questions have been validated with a portable activity monitor [21].

<u>Course of labour and mode of delivery</u>

The course of labour and mode of delivery (induction, duration, prolonged labour, use of analgesia, normal vaginal, instrumental assisted delivery, Caesarean section, episiotomy, and postpartum haemorrhage $\geq$500mL) were based on data from the birth partographs of hospital records, which the women brought to the personal interview at the post-test.

According to WHO, we defined the first stage of active labour as the time from regular contractions and cervix dilation of 4 cm to complete dilation at 10 cm. Second stage of labour is from the cervix is fully dilated until the delivery of the baby [22]. To calculate the total time of active labour, the duration of first and second stage was added.

Prolonged active labour was categorized as >12 hours and >20 hours [22,23], and prolonged active second stage as >180 minutes (with epidural) or >120 minutes (without epidural) [24].

Caesarean section was categorized as elective or acute. Instrumental vaginal deliveries included both vacuum and forceps deliveries. A normal vaginal delivery was defined as labour without any operative involvement.

Statistical analysis

The principal analysis were done on an intention to treat basis (ITT). Losses to follow-up were less than 20%, hence missing values were replaced with the mean or proportion value in the exercise and control group, respectively [25]. In addition, we did a priory planned subgroup analysis (per protocol), comparing participants with good adherence to the exercise program (≥19 supervised session, n=21) with the control group (n = 53). Because of low numbers of women adhering to the recommended exercise sessions (a minimum of 24 sessions), the sample size in the present study is not large enough to compare less frequent and severe obstetric outcomes. Hence, we chose not to use a higher cut-off to define good adherence, compared with some previous papers published by the same research group [16, 17]. Descriptive statistics are presented as mean with standard deviation or proportions with n (%), as appropriate. For group comparisons, categorical variables were analysed using Pearson's Chi-squared test (or Fisher's exact test for small numbers), and continuous variables were analysed using the independent sample t-test. No multivariable analysis was conducted. All statistical analyses were conducted with SPSS Software V. 24 for Windows.

Results

At trial inclusion (gestation week 17.7±4.2), there were no differences between the exercise and control groups in background or health variables (Table 1).

Out of 105 participants initially randomized, 90 (85.7%) women (exercise group n=43, control group n=47) completed the postpartum interview (7.7±1.7). Participants lost to follow-up in the intervention group (9/52, 17.3%) and control group (6/53, 11.3%) were not different in baseline characteristics from those who participated.

Mean adherence to the exercise classes was 17.0 (± 12.5) out of 24 prescribed exercise sessions, with 21 women (40.4%) attending ≥80% of the program (≥19 supervised sessions). Fourteen women completed two exercise sessions per week with a total of 24 exercise sessions. Adherence to exercise classes was not associated with socioeconomic characteristics, nor pre- pregnancy BMI or commonly reported pregnancy complaints such as nausea, fatigue, urinary incontinence, pelvic-girdle pain or low-back pain. No adverse effects or other exercise-related injuries were reported.

Adherence rates are based on registrations taken by the aerobic instructors, and the total number of women randomized to the exercise group. However, four women never attended, and one woman was excluded because of twins. The mean adherence to the exercise classes was 17.0 (± 12.5) out of 24 recommended exercise sessions, with 21 women (40.4%) attending ≥ 80% of the prescribed exercise sessions (≥ 19 supervised exercise sessions).

Course of labour

There were no differences between the exercise and control group in induction of labour, use of analgesia, duration of labour, or participants with prolonged active labour, according to ITT-analysis (Table 2).

Per protocol analysis showed that mean duration of active labour was shorter in the exercise group (Table 2), with a mean between group difference of 3.1 hours (95% CI 0.31 to 5.9, p=0.029). When participants with caesarean sections were excluded from the per protocol analyses, the duration of labour was 6.8±5.5 hours and 8.7±5.9 hours in the exercise and control group, respectively.

Mode of delivery

In the exercise group 9.6% had caesarean sections compared with 22.6% in the control group ($p = 0.072$). In addition, per protocol analyses showed a higher rate of normal vaginal delivery among participants with good adherence to the exercise program compared with the control group (85.7% versus 62.3%, $p = 0.051$). Otherwise, no other differences in obstetrical outcomes were observed between the exercise and the control group (Table 2).

Comment

A between group difference of 13% in caesarean sections, favouring regular exercise, are in line with what others have reported [23,26]. No group differences were found in duration of labour, or proportion of women with prolonged active labour. In planned subgroup analysis of participants with good exercise adherence, total active labour was three hours shorter and only one had instrumental assisted delivery. Also, there was a positive trend in difference in the rate of normal vaginal delivery compared with the control group.

Search on PubMed, revealed six RCTs evaluating the effect of supervised exercise on duration of labour [23,27-31]. Two studies found no difference between the exercise and control groups in second stage of labour or proportion of women with prolonged active labour [23,27], whereas two reported a shorter first stage of labour in the exercise group [28,30] . Contrary, two studies also found that second stage of labour was shorter in the control group compared with the exercise group [29,31]. Hence, the studies report inconsistent results. Varying exercise programs, interventional length and what gestation week the intervention started, also challenge a comparison, as well as inclusion of different parity groups and classifications of labour duration.

Explanatory research asks whether an intervention works under ideal or selected conditions [32]. Hence, we also performed planned per protocol analysis, including those who adhered to the clinical trial instructions as stipulated (≥80% of the recommended exercise program). Total active labour was three hours shorter among adherent participants compared with the control group, consistent with two previously published studies [28,30]. This type of analysis may provide an answer to the efficacy of the treatment, but can the other hand also overestimate the effect size, because those exercising as prescribed may differ from those who did not. Conclusions from per protocol analysis should therefore be viewed with caution.

In accordance with the present study, four systematic reviews have found that regular exercise during pregnancy may benefit vaginal deliveries [8-11]. However, current evidence does not suggest a clear dose–response relation, and is somewhat confounded by the large variety of exercise interventions, many also including nutritional counselling [9,12]. In addition, the quality of the original studies included in systematic reviews, ranged from low to high, reflecting methodological and clinical heterogeneity.

Pelvic floor muscle training was a part of the 10-15 minutes strength training program, supervised and performed at least twice weekly at the end of each one hour session. In contrast to myths claiming that regular exercise and strong pelvic floor muscles may obstruct labour, our data suggest that such training does not seem to affect labour and birth negatively. This is in line with Du et al. [15] and two more recent RCTs, reporting that pelvic floor muscle training seems to facilitate labour and reduce labour duration [28,30]. In our study we cannot separate the effect of pelvic floor muscle training from the other aspects of the standardized exercise program.

In previous studies investigating the effect of exercise on delivery outcomes, the sample sizes have varied greatly (n= 62 to 855), as well as ambiguity in inclusion criteria, increasing study heterogeneity [23,27-31]. We aimed for high internal validity, using selective inclusion and exclusion criteria to have a more homogeneous sample, allowing for unbiased group comparisons. Still, a limitation was the sample size, which may have not been large enough for subgroup comparisons. Nonetheless, we found some important results, and observed less caesarean sections in the exercise group compared with the control group. The reductions were probably due to the effect of exercise, and not to weight, as both groups had similar gestational weight gain [16]. Also, birthweight and head circumference of the new-borns were similar in the two groups [17]. In addition, post sample sized calculations revealed that, if the samples were larger (just 10 participants in each group) with the same proportions and mean group difference, the p-value and confidence intervals would be much smaller.

Studies have generally shown that few women meet recommended levels of physical activity and that there is a decline in exercise frequency from pre-pregnancy levels and throughout pregnancy [3-5]. Therefore, more research and interventions aimed at maintaining or increasing pregnant women's physical activity level are warranted, including studies on adherence strategies. To date, very little documentation exists in this field and only a small number of feasibility studies have been carried out in a non-English-speaking population [33]. Why the women in the present study did not adhere is difficult to understand, and information on the reason for the low participation rate is not available. A fitness class of 60 minutes prescribed twice a week, including endurance training of 40 minutes may be considered demanding. Thus, former physically inactive women who were the target group for this study may have been less motivated to adhere to this program.

Besides, 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, the participants may have had problems getting into a weekly exercise routine, as well as possibly lacking the necessary social support from spouse, family, and friends [16,17].

The strengths of the present study was a RCT design with blinded assessors and blinded analyses of outcomes, as well as a supervised group exercise program following ACOG recommendations [18]. The same primary investigator examined all the participants, we had few losses to follow-up (≥85%) and data was analysed by ITT. In addition, we used definitions of start and duration of labour in accordance with WHO, and registered the participant's adherence to the exercise protocol. Limitations are the small number of women being adherent with the exercise intervention and that the sample size was not based on an a priori power calculation for labour outcomes. Nevertheless, we were able to show important group differences in the per protocol analysis, emphasizing the importance of understanding and encouraging adherence in this type of intervention.

Conclusion

Our results add to the literature that moderate intensity endurance and strength training twice weekly or more, including pelvic floor muscle training, does not seem to give higher risk of negative delivery outcomes among healthy, former inactive, nulliparous women.

Declaration of interest

The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

Stringh

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