PROJECT PLAN

TRAINING DURING PREGNANCY

- Effects of regular exercise during pregnancy in prevention of pregnancy-related diseases and complications during labour

A randomised clinical trial

Signe Stafne Western
PhD-student
Dept of Community Medicine and General Practice, Norwegian University of Science and Technology, Trondheim, Norway

Siv Mørkved
PT, MSc, PhD
Senior Researcher Clinical Service, Hospital, Trondheim
Associate professor, Dept of Community Medicine and General Practice, Norwegian University of Science and Technology, Trondheim, Norway

Kjell Åsmund Salvesen
Professor MD, PhD
Department of Obstetrics and Gynecology, Norwegian University of Science and Technology, 7006 Trondheim, Norway.
BACKGROUND

Pregnancy is often regarded as a period of high risk when it comes to development of e.g. excessive weight gain, gestational diabetes and musculo-skeletal problems such as low back and pelvic girdle pain and urinary and fecal incontinence (Romem et al. 1991, Haugen 1998, Warren et al. 1997, Mørkved 2003).

While a pregnancy implies these and other risks, exercise is regarded as advantageous during the period, and is recommended in order to reduce negative symptoms, both physical and psychological (SEF 2000, ACOG 2003). Exercise is defined as regular, leisure-time physical activities, aimed improving physical condition, ability or health. Thus exercise must have a high enough level of intensity and regularity to improve the function of the heart and respiratory systems and muscles (Bouchard et al. 1993). Most published studies indicate that women with normal, uncomplicated pregnancies are fit for exercise with few restrictions, without the risk of hurting either themselves or their child (Sternfeld 1997, Riemann & Hansen 2000). In a review, Clapp (1996) concludes that regular exercise (30 min up to 5 days a week) is not negative for the fetus and has several positive effects on the mother.

Various epidemiological studies have examined the occurrence of different pregnancy-related diseases, and the relationship between such diseases and physical activity among pregnant women. While the pregnancy is a high-risk period for becoming overweight, the condition of being overweight during pregnancy is a risk factor for both the mother and the fetus (Baeten et al. 2001). Overweight in pregnancy is associated with fetal macrosomia, and the combination is associated with prolonged labour, low apgar score, shoulder dystocia, nerve plexus injuries, increased proportion of instrumental deliveries and perineal ruptures Øian (2000). A greater increase in weight than 15 kilos implies a higher risk of developing disease in pregnancy and complications during labour (Haram et al. 1997), as well as problems with weight reduction after the birth (Rooney & Schaubberger 2002). Some studies reveal that women who exercise before and during pregnancy weigh less, and are less likely to gain too much weight than those who do not (Clapp & Little 1995, Clapp 2000), while other studies conclude that exercise does not affect the weight of the mother. (Lokey et al. 1991, Sternfeld et al. 1995, Marquez-Sterling et al. 2000). These conflicting results are probably due to the difficulty of assessing the effect of exercise only, since weight gain is also dependent on food intake and other factors (Rössner 2000).

Gestational diabetes may be related to being overweight, and the prevalence varies between 5% and 12% (Baeten et al. 2001). There has been surprisingly little focus in scientific literature on the effects of physical activity during pregnancy in order to prevent gestational diabetes, despite the fact that the prevalence increases. The training of large muscle groups during pregnancy seems to have a positive effect on pregnancy-related diabetes, due to better insulin sensitivity and utilisation of glucose, and furthermore to a normalised level of blood sugar (Jovanovic-Peterson et al.1989, Garcia-Patterson et al. 2001). Dye et al. (1997) found that the effects of exercise might be positive when it comes to primary prevention of pregnancy-related diabetes. Exercise reduced the women’s risk for developing pregnancy-related diabetes by 47 % among women with BMI>33.

Almost the half of all Norwegian women (42.4%) state that they have been troubled by low back / pelvic girdle pain during pregnancy (Endresen 1995). For many women, the pain
causes difficulties in their everyday work and life; for some of them, the experience from their pregnancy and postpartum period is dominated by pain, disability and reduced quality of life. The extent of these problems makes it a considerable problem not only for the women but also for society. Low back and pelvic girdle pain is the most common reason for sick leave for pregnant Swedish women (Østgaard et al. 1994a), and it has been reported that pregnancy-related pelvic girdle pain is the reason for approximately 300 000 days of sick leave per year in Denmark (Larsen et al. 1999).

Many women have continued pain in the lower back and pelvic girdle during the postpartum period (Mørkved et al. 1998, Larsen et al. 1999), and about 1/5 of the women get chronic pain (Larsen et al. 1999, Østgaard et al. 1997). There are several indications that the normal physiological changes during pregnancy lead to mechanical and structural changes which might cause low back and pelvic girdle pain during pregnancy and after delivery (Vleeming et al. 1997). Most hypotheses about the cause of low back and pelvic girdle pain focus on changes in posture and reduced stability resulting from weight gain and hormonal influences. Several studies show changes in motor control strategies in women with pelvic girdle pain (Avery et al. 2000, O'Sullivan et al. 2002, Hungerford et al. 2003). Results from other studies indicate that exercise does have an effect on low back pain during pregnancy (Norén et al. 1997, Kihlstrand et al. 1999) and on pelvic girdle pain after delivery (Stuge et al. 2004). However, there is still uncertainty on the question of whether or not exercise during pregnancy can prevent pelvic girdle pain.

Pregnancy and childbirth are regarded as important risk periods in the development of incontinence. Prevalence of urinary incontinence varies between studies, with average prevalence estimates of 30-40% during pregnancy and the first months after childbirth (Mørkved & Bø 1999, Hunskaar et al. 2002, Mørkved 2003). Mørkved et al. (2003) found in a randomised clinical study that specific exercise of the pelvic floor muscles during pregnancy had effect on the prevention and treatment of urinary incontinence. A similar effect of pelvic floor muscle exercise has been reported in other studies, both during pregnancy (Reilly et al. 2002) and after childbirth (Mørkved & Bø 1997, Mørkved & Bø 2000). Prevalence of fecal incontinence after delivery is 4-5% (Mørkved & Bø 1999), and no RCT evaluating the effect of pelvic floor muscle exercise to prevent and treat fecal incontinence in a general pregnant and postpartum population has been published.

There is a myth that women who exercise regularly have stronger pelvic floor muscles that may obstruct labour (Riemann et al 2000), but there is no documentation for this claim (Lokey et al. 1991, Sternfeld et al. 1995, Horns et al. 1996). However, results from observational studies indicate that pregnant women who exercise regularly all through their pregnancy have more normal vaginal deliveries (Clapp 1990, Bungum et al. 2000, Clapp 2000), shorter active expulsion time and fewer complications during labour than those who do not exercise (Clapp 1990). In a randomised clinical trial, Salvesen and Mørkved (2004) found that fewer women who followed a scheme for specific strength exercise for the pelvic floor muscles during pregnancy had a prolonged second stage of labour, compared to a control group. Moreover, there was a lower prevalence of episiotomy and fewer cases of breech births in the exercise group (Salvesen & Mørkved 2004). This study is currently the only published randomised clinical trial which has tested such consequences of exercise before labour.

Today’s knowledge about the importance of exercise during pregnancy is mainly based on observational data from epidemiological studies, and the scientific strength of the clinical
recommendations given is open to question. There is a great lack of results from randomised clinical trials with high methodological quality, assessing the effects of exercise during pregnancy. As a result of this, many important questions are still not answered. One of these is the effect exercise during pregnancy has in the prevention and treatment of disease and complications which may arise during pregnancy. Another question is the consequences that exercise during pregnancy has for labour and delivery.

This study is thus designed to find answers to the following:
- Does regular exercise during pregnancy aid in preventing gestational diabetes?
- Does regular exercise during pregnancy prevent low back and/or pelvic girdle pain?
- Does regular exercise during pregnancy prevent urine and/or fecal incontinence?
- Does regular exercise during pregnancy have an effect on labour and delivery?
- Does regular exercise during pregnancy prevent maternal excessive weight gain and fetal macrosomia?

MATERIAL AND METHODS

Subjects
Pregnant women who attend the routine ultrasound control at the three hospitals at 18 weeks of pregnancy are invited to participate in the study. Women are eligible for the trial if they are 18 years or more, with a singleton live foetus at the routine ultrasound scan. Exclusion criteria are pregnancy complications, high risk for preterm labour, pain during pelvic floor muscle contractions, ongoing urinary tract infection, or diseases that could interfere with participation (following recommendations from SEF 2000, ACOG 2003). In addition, women who live too far from the hospitals to be able to attend weekly exercise groups will be excluded. A total of 800 women will be included. A 12 months inclusion period is planned, in accordance with experiences from previous studies where 20% of eligible pregnant women agreed to participate in the trial (Mørkved & Bø 1997, Mørkved et al 2003). The procedures to be followed will be in accordance with the ethical standards of the responsible regional committee on human experimentation and with the Helsinki declaration.

Design
We are planning a randomised clinical trial (RCT) with two arms; one group will attend a standardised regular exercise course for 12 weeks during pregnancy (Mørkved et al. 2003) (exercise group); another group will follow the standard procedure (control group). The trial is a multi-center study with blocked design, involving three hospitals in Trøndelag and More and Romsdal where a total of approximately 5000 women give birth annually (St.Olavs Hospital, Levanger Hospital and Álesund Hospital). Participants at each hospital will be randomised to an exercise group or a control group. All participants will receive information concerning nutrition. Measurements will be taken of all participants before and after the intervention period during pregnancy, and 8 weeks and 1 year after delivery.

Randomisation procedure
A computerised randomisation procedure will be used.

**Power calculation**
The power calculations will be made taking into account the diseases we want to treat/prevent with the lowest prevalence (faecal incontinence and gestational diabetes (Mørkved & Bø 1999, Baeten et al 2001). We aim at reducing the prevalence from 5% to 1% in the exercise group. Based on these assumptions a two way t-test with a 5% level of significance and test strength of 0.90 give a study population of approximately 400 patients in each group (Altman 1991).

**Evaluation methods**
According to the aims of study, we have several primary outcome measures.

Several variables are routinely registered during pregnancy and labour:

*During pregnancy*
- Weight, height (BMI)

*Labour and delivery*
- Mode of delivery
- Epidural analgesia or oxytoxin augmentation during labour
- Episiotomy
- Perineal tears
- Neonatal outcomes
- Duration of 1. and 2. stages of labour

Other variables are registered by validated clinical measurement tools and/or questionnaires for registration of the women’s own experiences:

- **Gestational diabetes:**
  - Oral glucose tolerance test at around 26 weeks

- **Low back and pelvic girdle pain**
  - Pain intensity 100mm Visual Analogue Scale
  - Disability Rating Index (Salèn et al. 1994)
  - Registration of sick leaves
  - Clinical tests
    - Active straight leg raise (ASLR) (Mens et al. 2000)
    - Posterior pain provocation test (P4) (Kristiansson et al. 1996, Østgaard et al. 1994b)
    - Balance (variations)

- **Incontinence (urinary/faecal)**
  - Self-reports of urinary/faecal incontinence. (Women reporting urinary/faecal incontinence once per week or more during the previous month are categorised as incontinent)
  - Change in continence status (better, unchanged, worse)

**Strength and function of the pelvic floor muscles**
Vaginal palpation and observation during contraction used to assess the women's ability to perform pelvic floor muscle contraction. Pelvic floor muscle strength (vaginal squeeze pressure, cm H₂O) measured by a vaginal balloon catheter (balloon size 6.7 x 1.7 cm) connected to a pressure transducer (Camtech Ltd. 1300 Sandvika,
Norway). The method was found to be reliable and valid in a previous study (Bø et al 1990a).

- **Registration of nutrition**

**Statistical analysis**

The principal analysis will be done on an intention-to-treat basis. The missing last values are carried forward by their baseline values. Groups are compared with exact computation of Pearson $\chi^2$ - test if data are categorical. Relative risks and their 95% confidence intervals are calculated for comparisons of proportions [observed ratio of proportions (StatXact -5)]. Normality will be evaluated by using the Shapiro-Wilk W test for normality, and the Mann-Whitney U test will be used to compare distributions between groups when variables are not normally distributed (SPSS-10). The influence of covariates on the primary outcome variables will be explored using logistic regression for odds ratio (SPSS-10). Additional subgroup analyses will be carried out. Results will be given as mean values with 95% confidence intervals (CI). P-values < 0.05 will be considered significant.

**Interventions**

Before randomisation, a physiotherapist will provide all women with information related to food intake and with individual instruction in pelvic floor anatomy and how to contract the pelvic floor muscles correctly (Bø et al 1990a).

The exercises group will follow a specially designed exercise course including specific exercises for stabilisation of the lower back and pelvis, the pelvic floor muscles, and general exercises including balance exercises. They will exercise with a physiotherapist for 60 minutes once a week for a period of 12 weeks (between 20 and 36 pregnancy weeks). In addition, the women will be encouraged to follow a home exercise program including 45 minutes of exercise twice a week (30 minutes endurance exercise and 15 minutes strength/balance exercise) and daily pelvic floor muscle contractions. Motivation will be strongly emphasised by the physiotherapists. Adherence to the training protocol will be based on registrations in the women's personal training diary and the reports from the physiotherapists who lead the group exercises. The training protocol follows recommendations from SEF (2000) and ACOG (2003).

Women in the control group will receive the customary information provided by their midwife or general practitioner. They will not be discouraged from exercising on their own.

**Research group**

*Project manager and adviser for PhD students:*
- Associate professor/Senior researcher, PhD Siv Mørkved, Dep. of Community Medicine and General Practice, NTNU, Trondheim / Clinical Services, St. Olavs Hospital, Trondheim

*Medical responsible and adviser for PhD students:*
- Professor Kjell Åsmund Salvesen, Dep Obstetrics and Gynecology, St. Olavs Hospital, Trondheim

*Statistical analysis:*
Feasibility
In both national and international literature the importance of physical activity are highlighted. WHO has recently presented a global strategy for nutrition, physical activity and health (Sosial- og helsedepartementet, 2004). In Norway physical activity and exercise have been strongly addressed, and is an issue of high priority also in pregnant and postpartum women (St.meld.nr.16, Handlingsplan for fysisk aktivitet). Nevertheless, few trials evaluating the effects of regular exercise have been published. The present trial aims at answering some questions related to the effects of regular exercise in a very important group, that is pregnant women.

Intervention trials including exercise programs are complicated, and needs close follow up of the participants. However, this research group has previously carried through several similar RCT’s in women during pregnancy and after delivery (see publication lists).

REFERENCES


Clapp JF III. Morphometric and neurodevelopmental outcome at age five years of the offspring of women who continued to exercise regulary throughout pregnancy. The Journal of Pediatrics 1996; 129(6): 856-863


Haugen IE. Svangerskap, fødsel og barseltid, 6. utg. 1998 Oslo: Ad Notam Gyldendal.


Mørkved, S. Prevalence of pelvic girdle pain during pregnancy and postpartum. 3rd interdisciplinary world congress on low back and pelvic pain. The most effective role for exercise therapy, manual techniques, surgery and injection techniques. 1998 edn, European Conference Organizers, Rotterdam 427-428


Mørkved S. Urinary incontinence during pregnancy and after delivery. - Effect of pelvic floor muscle training in prevention and treatment. Dr.philos. thesis 2003. Department of Community Medicine & General practice, National Center for Fetal Medicine, Department of Laboratory Medicine and Children`s and Women`s Health, Faculty of Medicine, Norwegian University of Science and Technology.


Sosial- og helsedepartementet, Strategi for kosthold, fysisk aktivitet og helse, 2004


St.meld. nr.16 (2002-2003) Resept for et sunnere Norge – Folkehelsepolitikken (Folkehelsemeldingen)


Øian P. Tidskr. Nor Lægeforen. 2000;120:1847


