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Stafne S N<sup>1</sup>, Salvesen K Å<sup>1</sup>, Volløyhaug l<sup>2</sup>, Mørkved S<sup>1</sup> **1.** Norwegian University of Science and Technology, **2.** St.Olavs Hospital Trondheim University Hospital

# DOES A REGULAR EXERCISE PROGRAM INCLUDING PELVIC FLOOR MUSCLE EXERCISES PREVENT URINARY INCONTINENCE IN PREGNANCY?

### Hypothesis / aims of study

Our main objective was to evaluate short and long term effects of regular exercise during pregnancy in the prevention of pregnancy related diseases and complications during labor. Aim of this substudy was to assess if pregnant women following a general exercise course including pelvic floor muscle exercises (intervention group), were less likely to report urinary incontinence in late pregnancy than a group receiving standard care (control group).

## Study design, materials and methods

#### Design

We conducted a randomised controlled trial, between 2007 and 2009 at two centres. The women were randomly allocated (following a computerized randomization procedure) to intervention and control groups. Measurements were performed with validated instruments before (18-22 weeks) and after (32-36 weeks) the 12 week intervention period during pregnancy.

#### Materials and methods

Pregnant women from an unselected population attending the routine ultrasound examination at 18 weeks of pregnancy were invited to participate. Women were eligible if they were 18 years or older, with a singleton live foetus at the routine ultrasound scan. Exclusion criteria were pregnancy complications, high risk for preterm labour or diseases that could interfere with participation siv(1).

Outcome measure in this substudy was self reported urinary incontinence. Women reporting urinary incontinence once per week or more were categorised as incontinent.

Women in the intervention group were invited to attend a 12 week exercise program, following general recommendations for physical exercise in pregnancy. The program included weekly group training (60 minutes; aerobic activity, pelvic floor muscle and additional exercises) led by a physiotherapist, and additional home exercises 45 minutes at least twice per week. Women in the control group received the customary information given by their midwife or general practitioner. In addition, they were given a detailed information brochure including evidence based pelvic floor muscle exercises program.

The power calculation was based on two of the less prevalent pregnancy related diseases (gestational diabetes and faecal incontinence). A two sample comparison of proportions with a 5% level of significance and test strength of 0.80 gave a study population of approximately 400 patients in each group. A 10% estimated drop-out required a total of 880 included pregnant women. The procedures followed were in accordance with the Helsinki declaration. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK 4·2007·81) and registered with Clinical trial gov (NCT 00476567).

The principal analysis was done on an intention-to-treat basis. The missing last values were carried forward by their baseline values. Groups were compared with exact computation of Pearson  $\chi^2$  - test. Relative risks and their 95% confidence intervals were calculated for comparisons of proportions.

#### **Results**

In all, 875 women consented to participate in the trial. Twenty women were excluded or withdrew before the first examination: five miscarried, two had twin pregnancies and 13 did not meet the inclusion criteria. A total of 855 women were randomly allocated to an intervention group or a control group. However, 33 women in the intervention- and 61 in the control group were lost to follow-up. The groups were similar regarding the baseline characteristics.

We found significant differences in the number of women reporting urinary incontinence in late pregnancy between women in the intervention and control groups: 54/429 (13%) versus 79/426 (19%), respectively (p=0.016).

# Interpretation of results

In this trial, there was evidence that including pelvic floor muscle exercises in a 12-week standard exercise program during the second half of pregnancy prevented urinary incontinence more than only written information to train on their own. Further results from our trial will show if this general exercise program for pregnant women may prevent more of the known pregnancy related diseases.

#### Concluding message

We found that women following our 12 week exercise program during pregnancy were less likely to report urinary incontinence than women given standard care.

#### **References**

1. ACOG (American College of Obstetricians and Gynecologists). Exercise during pregnancy and the postpartum period. Clinical Obstetrics and Gynecology 2003;46:496-99

Specify source of funding or grant	The RCT has been funded by The Norwegian Fund for Postgraduate Training in Physiotherapy and The Liaison Committee for Central Norway Regional Health Authority (RHA) and NTNU.
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	ClinicalTrials.gov number, NCT 00476567

Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Regional Committee for Medical and Health Research Ethics (REK 4•2007•81)
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes