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Is a 6-week supervised pelvic floor muscle exercise program effective in preventing stress urinary incontinence in late pregnancy in primigravid women?: a randomized controlled trial

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ABSTRACT

Objective: The study investigated the effect of a 6-week supervised pelvic floor muscle exercise (PFME) program to prevent stress urinary incontinence (SUI) at 38 weeks' gestation.
Study design: We conducted a randomized controlled trial into two arms design: one intervention group and one control group, using the randomly computer-generated numbers. A research assistant, who was not involved with care of the participants, randomly drawn up and opened the envelope for each participant to allocate into the intervention group and the control group. The investigators could not be blinded to allocation. Seventy primigravid women who had continent with gestational ages of 20–30 weeks were randomly assigned to participate in the intervention ($n = 35$) and control groups ($n = 35$). The intervention was a supervised 6-week PFME program with verbal instruction and a handbook, three training sessions of 45 min with the main researcher (at 1st, 3rd and 5th week of the program) and self-daily training at home for an overall period of 6 weeks. The control condition was the PFME and the stop test had been trained by the main researcher to all of the participants in the intervention group.
Outcomes: The primary outcome was self-reported of SUI, and the secondary outcome was the severity of SUI in pregnant women which comprises of frequency, volume of urine leakage and score of perceived severity of SUI in late pregnancy at 38th weeks of pregnancy. Statistical analysis was performed using Chi-square test, Independent-sample *t*-test, and Mann–Whitney *U*-test. Significance *P*-value was <0.05.
Results: At the end of the intervention, 2 of 35 women in the intervention group and 5 of 35 women in the control group dropped out of the study. Therefore, the total of the study participants consisted of 63 pregnant women (33 in the intervention group and 30 in the control group). Fewer women in the intervention group reported SUI than the control group: 9 of 33 (27.3%) versus 16 of 30 (53.3%) at 38 weeks' gestational age (OR 3.05, 95% CI 1.07–8.70, $P = 0.018$).
Conclusions: The 6-week supervised PFME program was effective in preventing SUI and decreasing the SUI severity in pregnant women who reported SUI at late pregnancy. The women who performed PFME program under the training sessions once every two weeks found that the program demands less time, incurs lower costs and possibly offers more motivation to exercise. This 6-week supervised PFME program may be suitable in real clinical situation.

Introduction

Pelvic floor muscle exercise (PFME), the repetitively selective voluntary contraction and relaxation of specific pelvic floor muscles (PFM) [1], is used to increase the strength of the PFM and periurethral muscles which these are leading to improve the efficiency of the supportive function by immobilized the urethra, and improve the sphincteric function by increases intraurethral closure pressure during physical activities [2,3]. Therefore, PFME is considered the first-line intervention of prevention and treatment for stress urinary incontinence (SUI) during pregnancy before consideration of other treatments [4]. The National Institute of Clinical Excellence (NICE) also suggests PFME for all women in their first pregnancy for the prevention of SUI [5].

According to the Cochrane review, PFME should be recommended as the first-line management for the prevention and

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treatment SUI during pregnancy and postpartum period. In addition, it has been concluded that pregnant women without prior UI who practice intensive supervised antenatal PFME are 56% less likely to report UI in late pregnancy than women who do not practice PFME [6]. These are evidences of the effectiveness of intensive supervised PFME in preventing the antenatal UI.

The intensive supervised PFME training is a weekly exercise interventions provided under either individually supervised or group training session by a physiotherapist over a period of 8–12 weeks [7].

Although, the intensive supervised PFME is effective to prevent and treat SUI, some physicians disagree. They suggest that the weekly follow-up by the therapist cannot be implemented into real clinical practice, because some women may not want to take much effort or time in PFME training classes [8]. It is likely that the success of the randomized controlled trials reported in the literature would not be repeated in the 'real situations' [9]. Freeman [10] suggested that this exercise is impractical for all pregnant women to receive intensive supervised PFME from a physiotherapist or continence expertise during pregnancy. Nevertheless, there was a previously published study showed the 6-week antenatal PFME combined with group supervised training by midwife once every two weeks has been demonstrated as significantly effective in treating SUI during pregnancy by decreased severity of SUI symptoms in pregnant women [11]. As well, they also emphasized the possibility of the implementation of 6-week supervised PFME by midwife into real clinical practices.

To date, although, the studies on the efficacy of the supervised antenatal PFME to prevent SUI during late pregnancy are rather limited. Therefore, this study has aimed to determine the effectiveness of the 6-week antenatal PFME program with supervised training by midwife in preventing the development of SUI during late pregnancy in continent primigravidae women.

Materials and methods

Study design and participants

A randomized controlled trial (RCT) with two arms study design: one intervention group and one control group, using the randomly computer-generated numbers was conducted. This study was approved by the Research Ethics Committee (RAJ-IRB 080/2555). Informed consent was obtained from all participants.

Between July 2012 and October 2012 with follow-up until March of 2013, primigravida women who attended in the antenatal care unit and met the inclusion criteria were recruited to participate in this study. The inclusion criteria were as follows: pregnant women who were age 18 years and older, gestational ages of 20–30 weeks, singleton fetus and pre-pregnancy body mass index (BMI) of <30 kg/m^2. Pregnant women with SUI symptoms during pregnancy, the pregnancy complications such as preterm labor, pregnancy induced hypertension (PIH), gestational diabetes mellitus (GDM), antenatal hemorrhage, etc., pain during pelvic floor muscle contraction, or diseases that could interfere with the participant were excluded. The women who withdrawn from the study before the end of the study by various reasons such as lack of time, changing hospital, or move to other provinces were included in drop out criteria. In addition, the women who failed to perform PFME for a period of 6 weeks or <28 days, or those who came to follow-up appointments less than twice were excluded to analyze data.

Sample size calculation and randomization

The sample size was predetermined by using power calculation with the G*power program version 3.1.3. Power analysis involved a one-tailed *t*-test for two groups independent mean with a power of 0.80, a significance level of 0.05, and an effect size of 0.70. The minimum number per group was calculated to be 26 participants. We added 35% of the 26 participants to prevent loss of the sample, finally, a total of 35 participants who were recruited for each group.

The 70 participants who met the inclusion criteria were randomly allocated by computer-generated numbers into two groups: the intervention group and the control group. Written informed consent was obtained from all patients before randomization.

Before the study had begun, the principle investigator used the www.randomizer.org/form.htm (2012) to prepare the sealed opaque envelopes was used to perform a simple randomization (not block) to allocate women into each group. The sealed opaque envelopes contained the randomly computer-generated numbers to generate 35 sets of numbers: each set containing two numbers ranging from 1 to 2 with random order. A total of 70 unique codes were generated based on the 35 sets of randomly ordered {1, 2} (e.g. Set 1 Group 1, Set 1 Group 2).

A random number table found in a statistics book or computer-generated random numbers can also be used for simple randomization of subjects.

After written informed consent forms were obtained, a research assistant, who was not involved with care of the participants, randomly drawn up and opened the envelope for each participant to ensure the 70 participant were equally allocated into two groups based on the group number of each code: group 1 (the intervention group), and group 2 (the control group).

Once randomization occurred it was not possible to blind participants or health providers (who were also the research investigators) to treatment group. Outcome assessment was not blind because all the outcomes were patient-reported.

The CONSORT diagram of the participants' flow of this study is shown in Fig. 1.

Treatment protocol

The intervention group followed a specially designed, 6-week supervised PFME program as previously published by Sangsawang and Serisathien [11]. All women in the intervention group were trained by one midwife (main researcher) in small groups of 4–5 participants for 45 min per session once every 2 weeks for a period of 6 weeks (at the 1st, 3rd and 5th week of the program). Therefore, the program consisted of three sessions at the first, third and fifth week of the program. A day before each session (at the 3rd and 5th week) of program, the researcher made an appointment via telephone to remind time and date of the class for the women to return to hospital and meet the researcher.

At the beginning of the program, the women who participated in the PFME instruction session were led to a health education room. They were instructed about the introduction of SUI and PFME during pregnancy, in the following topics: (1) risk factors of SUI, (2) how pregnancy can cause SUI, (3) the functions of the PFM, (4) how the PFME can prevent SUI, (5) the benefits of PFME and (6) performance of PFME. Before pregnant women begin PFME, they must be ascertained to exercise the correct muscles, by using "stop test". The stop test is ability of controlling the PFM to stop or slow urinary flow over a toilet for a one or 2 s, then relax and finish emptying without straining. Pregnant women who performed correct PFM contractions would able to stop urine flow for a brief moment [12]. In cases of incorrect perform of PFME, they were instructed until they were able to make an accurate contraction. In this study, therefore, the correct contraction of PFM was affirmed by only after the instruction of stop test.