

Original Research Article

The effects of individual pelvic floor muscle training versus individual treatment with progression to group versus group training for women with stress urinary incontinence: protocol for a randomized controlled trial

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ABSTRACT

Background: Pelvic floor muscle training can be practiced in an individual format or in a group. The research question for this randomised, controlled trial will be: pelvic floor muscle training format including individualized and group training, would be more effective than an individualized training only or groups only? Additionally, it will be evaluated the adherence and follow up (results after 3 and 6 months of the end of training).

Methods: This is a randomized clinical trial. Data collection will be performed at the Women's Health Research Laboratory, allocated in the Department of Physical Therapy of Federal University of São Carlos, from January 2016 to December 2016. It will be included, women with stress urinary incontinence, older than 18 years old. The participants will be allocated into three groups. In Group 1 sessions will be only individualized and Group 2 will perform individualized treatment and then the volunteer will be referred to join the group training sessions. Group 3 only group treatment. Later, all volunteers will be reassessed after 12 sessions, three months and six months from the discharge date. The primary outcome is the severity measures of the King's Health Questionnaire. The secondary outcomes are miccional diary, PERFECT scheme, perineometry, self-efficacy scale for pelvic floor exercises practice, exercise diary and presence of the participants in the supervised sessions. Data normality will be tested by the Shapiro-Wilk test. The comparison between the evaluations will be performed by ANOVA, and the comparison between groups will be performed by Student t-test (independent Measures). In order to measure the practical significance of the date, the size effect and the confidence interval will be calculated. A 5% significance level will be assumed. The data are presented as mean \pm standard deviation.

Conclusions: A combined treatment format including individualized and group training, would be more effective than an individualized training only or groups only.

Trial registration: The study was approved by the Research Ethics Committee of Federal University of São Carlos (UFSCar) (Number 1207393) and Clinical Trials (NCT02664714).

Keywords: Adherence, Pelvic floor muscle, Physiotherapy, Perineometer, Urinary incontinence

INTRODUCTION

The International Continence Society (ICS) considers the pelvic floor muscle training (PFMT), the gold standard for the treatment of stress urinary incontinence (SUI) and its effectiveness in promoting continence has a level 1, grade A evidence in literature.¹⁻⁴

Dumoulin, Hay-Smith and Mark Haber-Séguin (2014) in a systematic review found that women with urinary incontinence (UI) submitted to PFMT were more likely to report improvement or cure when compared with women who did not performed the treatment.⁵

PFMT can be practiced in an individual format or in a group. Robertson and Harding (2014) showed evidence shows that providing rehabilitation in a group format results in equivalent clinical outcomes to offer of similar therapy in an individual format in the treatment of urinary incontinence.⁶

PFMT performed in group is a good alternative to the public health care system, since it has a reduced cost, favors the adherence to the treatment, presents mutual support, information sharing and motivation.⁷ Considering that pelvic floor muscle contraction awareness is primordial to the success of physical therapy treatment, ensure that women are aware of this contraction may favor the results of a treatment.³ Based on this, the objective of this study is to evaluate the effects of an individualized PFMT versus an individualized training with progression to group training versus group training only in women with stress urinary incontinence. Additionally, it will be evaluated the adherence and follow up (results after 3 and 6 months of the end of training). Therefore, the research question for this randomised, controlled trial will be: PFMT format including individualized and group training, would be more effective than an individualized training only or groups only?

METHODS

Study design

This is a randomized clinical trial. Data collection will be performed at the Women's Health Research Laboratory (allocated in the department of physical therapy of Federal University of São Carlos, from January 2016 to December 2016. The project was approved by the Research Ethics Committee of Federal University of São Carlos (UFSCar) (Number 1207393) and Clinical Trials (NCT02664714). Patients will receive information about the research and those who consent to participate, will sign the free informed consent form.

Participants

It will be included, women from the age of 18 years old who report SUI.

Recruitment procedures

The current UI report will be investigated through two modified questions of the questionnaire "King's Health Questionnaire" (KHQ).^{9,10} "Do you feel a strong urge to urinate, with urine loss before reaching the toilet?" and "Do you lose urine during any physical effort such as coughing, sneezing, running, etc.?". Women who answer "yes" to the first question or both questions will be recruited for this study. The exclusion criteria are: urge urinary incontinence report (UII) in an isolated form, neuromuscular diseases, other diseases (asthma, tumors, heart failure, absence of pelvic floor muscle contraction (grade 0) verified by modified Oxford scale, urinary infection, difficulty in understanding the study procedures, uncontrolled hypertension, presence of severe prolapse (visible prolapse in the vaginal opening), women with UI who have done physical therapy in the last 12 months.

The socio-demographic information as well as clinical data will be collected in the first assessment using a evaluation form. The following information will be collected: gynecological and obstetric history, incontinence historic and urinary symptoms, associated diseases, surgeries performed; sexual history and participants will answer the KHQ and self-efficacy scale for pelvic floor exercises practice.^{10,11}

Randomisation procedures and masking/blinding

After the evaluation, the randomization of the participants will be performed using <http://www.randomization.com> website by a blinded researcher who will not have knowledge of the assessment and treatment procedures. This randomization list will be kept in a brown paper envelope and the physiotherapist responsible for implementing the PFMT protocol will only be informed in the first day of intervention.

Details of the intervention and control

After the first evaluation the participants will be randomized into three groups: Group 1: Individualized training, Group 2: Individualized training with progression to group training, Group 3: Group training only. All participants will receive guidance about the anatomy and function of the pelvic floor muscles (PFM) and how to perform a properly contraction. For all groups it will be used the same protocol which was developed for this study, with progression parameters of the sustained contractions based on the recommendations for the strength training of the American College of Sports Medicine and fast contractions based on the Ferreira et al., 2011.^{12,13} The parameters are summarized in Table 1. In each group, the volunteers will participate of 12 sessions, once a week with 30 minutes of duration which will be supervised by a single physiotherapist. In Group 1 the first four sessions will be individualized (with vaginal palpation of the first to the fourth day of training) and

then the volunteer will be referred to join the group training sessions. Group 2 will perform only individualized treatment (with vaginal palpation of the first to the fourth day of training) and Group 3 only group

treatment. The volunteers will be oriented to follow the exercise protocol, daily, at home in order to increase the treatment efficacy.

Table 1: PFMT progression parameters.

Sustained contractions												
Week	Number of series			Repetitions			Sustained contraction time			Resting time		
1	2			6			2s			4s		
2	2			8			3s			6s		
3	3			10			4s			8s		
4	3			10			5s			10s		
5	3			10			5s			5s		
6	3			10			5s			5s		
7	4			10			6s			6s		
8	4			10			6s			6s		
9	4			10			8s			8s		
10	4			10			8s			8s		
11	4			10			10s			10s		
12	4			10			10s			10s		
Fast contractions												
Weeks	1	2	3	4	5	6	7	8	9	10	11	12
N of repetitions	5x	10x	15x	20x	30x	40x	50x	50x	50x	50x	50x	50x

Primary and secondary outcome measures and assessment points

Primary outcome

The primary outcome is the severity measures of the King's Health Questionnaire.^{10,11}

Secondary outcomes

The secondary outcomes are the miccional diary, PERFECT scheme, perineometry and self-efficacy scale for pelvic floor exercises practice, exercise diary and presence of the participants in the supervised sessions.

Assessment points

After evaluating UI reports (KHQ) it will be performed the pelvic floor muscles function evaluation, by a researcher with two years of experience in this assessment. For this evaluation, the volunteer will be placed in the supine position with flexed hip and knees. Then, it will be performed the muscle function evaluation through the PERFECT scheme which was developed by Laycock and Jerwood (2001), the researcher will introduce the index finger about 4 cm into the participant vaginal canal and will guide her to contract the PFM.¹⁴ On initial evaluation, the research records whether women could correctly contract the PFM after hearing a brief verbal prompt, "Now please squeeze the muscles in the vagina and hold like you are holding urine". A contraction will consider correct if the researcher felt inward pressure or upward traction on the examining

finger in the vagina, without accompanying significant valsalva or gluteal squeeze.¹⁵

After, it will be evaluated the pelvic floor muscles contraction pressure using the Peritron manometer (Cardio Design Pty Ltd, Oakleigh, Victoria, Australia) which has a graduation scale from 0-300 cmH₂O and is equipped with a vaginal probe (28×55 mm). The perineometer probe will be coated with a male non-lubricated condom and will be introduced with KY® lubricant gel into the participant's vagina. The center of the probe will be positioned approximately 3.5 cm of distance from the introitus as the study BØ (1992).¹⁶ Then, the participant will be instructed to keep the PFM relaxed and the vaginal resting pressure value will be registered. Soon after, the device will be calibrated and the volunteer will receive a verbal instruction to perform a maximal PFM voluntary contraction with five seconds of duration. The specific instruction will be to contract the PFM as strong as possible performing an inward movement. Three contractions will be performed, with two-minute interval between them.

For data analysis, it will be used the average of the three contractions. The researcher will examine visually if the pelvic floor muscle contractions were performed correctly, by observing the inward movement of the vaginal probe, the absence of Valsalva maneuver minimum contraction of the accessory muscles.¹⁷ The participants will receive a miccional diary and will be orientated to fill it for three consecutive days, and return it in the next treatment session.

Monitoring and follow up

The volunteers will be assessed after 12 sessions and will receive the self-efficacy for the practice of pelvic floor exercises (SEPPFE), exercise diary and will be oriented to fill and deliver it in the reassessments, after three months (the end of the physicaltherapy treatment) and six months (from the discharge date). The SEPPFE was elaborated and validated by Sacomori et al (2013) and developed based on the instructions provided by Bandura(2008), it is a scale that aims to predict adherence

to PFMT in which 13 items of the scale measure the self-efficacy in the areas expected performance, considering the action and the preparation for action, plus four items assessing the expectation results.^{11,18} The data collected in these reassessments will include the urinary symptoms, miccional diary, KHQ, pelvic floor muscles functional assessment, perineometry, SESPPFE, exercise diary and presence of the participants in the supervised sessions. The study design, including the monitoring and follow up are described in the timeline below as shown in Figure 1.

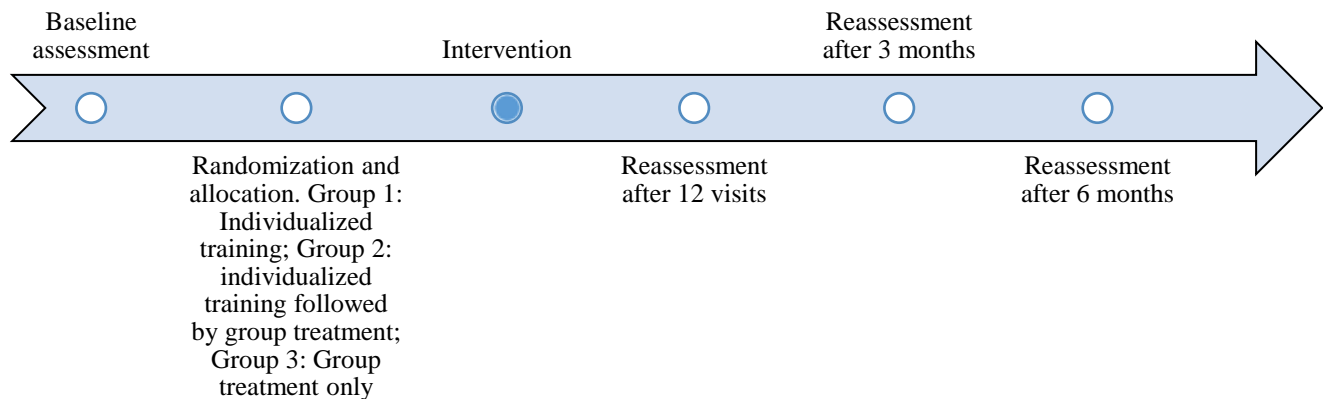


Figure 1: Study design, including the monitoring and follow up.

Statistical analysis and sample size calculation

The sample size calculation was performed using the GPower Software (3.1.5, Germany) based on the study of Pereira et al (2011) considering the intergroup comparison of data post treatment of the severity measurement of the KHQ.⁸ It was used the ANOVA (repeated measures), 80% power, effect size of 0.40 and 5% of significance level, being estimated a sample size of 30 subjects in each group.

The data collected will be tabulated in excel and statistical analysis will be conducted through the software "Statistical Package for Social Sciences" - SPSS version 19.0 for Windows. Data normality will be tested by the Shapiro-Wilk test. The comparison between the Evaluations Will Be Performed by ANOVA, and the comparison between groups will be Performed by Student t-test (independent Measures). In order to measure the practical significance of the date, the size effect and the confidence interval (CI) will be calculated. A 5% significance level will be assumed. The data are presented as mean \pm standard deviation.

DISCUSSION

Pelvic floor muscles training (PFMT) can be recommended as the first conservative treatment option for urinary incontinence in women.^{19,20} Some studies concluded that providing physical therapy for urinary

incontinence in a group format results in clinical results equivalent to the same treatment in the individual

format.^{6,7,21,22} Also, evidence shows that PFMT in a group format has clinical outcomes equivalent to an individual format in the treatment of stress urinary incontinence.^{8,23,24} A systematic review comparing the effectiveness of PFMT in group versus individual PFMT versus PFMT performed at home for the conservative treatment of female urinary incontinence, found through meta-analysis that there was no difference when comparing PFMT in group versus individual PFMT. However, the authors suggested that PFMT performed in group may be a viable option for the public health system, since it is possible to treat more women during a shorter period of time with low cost.²⁵

The present study was initiated in January 2016 and is currently active. The results of this study can guide physical therapists in choosing the treatment format of stress urinary incontinence, indicating whether the training of the pelvic floor muscles, which starts individualized and progresses to group treatment, would be more effective than only individual or only group treatment.

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Conflict of interest: None declared

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