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ORIGINAL ARTICLE

Effect of a training of pelvic muscles in group for women with urinary incontinence: a randomized clinical test

Efeito de um treinamento de músculos pélvicos em grupo para mulheres com incontinência urinária: um ensaio clínico randomizado

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Abstract

Introduction: Urinary incontinence (UI) is a problem that is often underestimated, not receiving proper attention. Among the possibilities for conservative treatment of UI, supervised pelvic floor muscle training (PFMT) should be recommended as a first line of treatment for women. PFMT can be developed in groups, individually and at home. *Objective*: There are still few studies in the literature involving group PFMT with defined protocols that can be easily understood and reproduced by the patients. The aim of this study is to identify the effect of a group PFMT protocol compared to a PFMT protocol at home for women with UI. *Methods*: This experimental blinded randomized controlled trial

followed CONSORT recommendations. The evaluation instruments were the PERFECT scale, ICIQ-SF and PISQ-12. The main outcome was improvement in pelvic floor muscle (PFM) function, and secondary outcomes were improvement in quality of life (QOL) and sexual function (SF). *Results*: With twelve weeks of treatment, the PFMT group protocol presented as a more effective form of treatment for UI, since it showed improvement in the Power and QV items. When observing the effect of the protocols, after twenty-four weeks, both were effective only when referring to the secondary outcomes, QOL and SF. *Conclusion*: It can be assumed that the group intervention, used in this specific sample, constitutes a feasible and viable physiotherapeutic intervention strategy, able to benefit many women with UI, besides being a tool that is easy for patients to understand and follow.

Keywords: pelvic floor disorders; physical therapy modalities; quality of life; sexual health; urinary incontinence, women.

Resumo

Introdução: A incontinência urinária (IU) é um problema muitas vezes subestimado, não recebendo a devida atenção. Dentre as possibilidades de tratamento conservador da IU, o treinamento dos músculos do assoalho pélvico (TMAP) supervisionado deve ser recomendado como primeira linha de tratamento para as mulheres. O TMAP pode ser desenvolvido em grupos, individualmente e em casa. *Objetivos*: Ainda há poucos estudos na literatura envolvendo TMAP em grupo com protocolos definidos que possam ser facilmente compreendidos e reproduzidos pelos pacientes. O objetivo deste estudo é demonstrar a eficácia de um protocolo de TMAP em grupo comparado a um protocolo de TMAP domiciliar para mulheres com IU. *Métodos*: Este foi um estudo experimental controlado randomizado cego que seguiu as recomendações do CONSORT. Os instrumentos de avaliação foram a escala PERFECT, ICIQ-SF e PISQ-12. O principal resultado foi a melhora da função dos músculos do assoalho pélvico (MAP) e os resultados secundários foram a melhora da qualidade de vida (QV) e da função sexual (FS). *Resultados*: Com doze semanas de tratamento o protocolo do grupo TMAP apresentou-se como uma forma de tratamento mais eficaz para IU, pois apresentou melhora nos itens potência e QV. Ao observar a efetividade dos protocolos, após vinte e quatro semanas, ambos foram efetivos apenas no que se refere aos desfechos secundários, QV e FS. *Conclusão*: Pode-se supor que a intervenção em grupo, utilizada nesta amostra específica, constitui uma estratégia de intervenção fisioterapêutica factível e viável, capaz de beneficiar muitas mulheres com IU, além de ser uma ferramenta de fácil compreensão e acompanhamento pelos pacientes.

Palavras-chave: distúrbios do assoalho pélvico; modalidades de fisioterapia;

qualidade de vida; saúde sexual; incontinência urinária, mulheres.

Introduction

Urinary incontinence (UI) is a problem that is often underestimated, not receiving proper attention, since urinary loss can be considered a normal condition, a result of the aging process [1]. Considering the negative impact of UI on people's lives, and the increase in the prevalence of this condition, it is necessary to implement actions aimed at raising awareness, prevention, diagnosis and management of this situation, since it is a public health problem, often accompanied by a social stigma [2].

Initial treatment for women with SUI (stress urinary incontinence), UUI (urgency urinary incontinence) and MUI (mixed urinary incontinence) should include appropriate lifestyle counseling, physical therapy, a programmed urination regime, behavioral therapy, and medication [3]. Among the possibilities for conservative treatment of UI, supervised pelvic floor muscle training (PFMT) should be recommended as a first line of treatment for women with SUI, UUI and MUI symptoms. However, the effect of this long-term training needs to be researched further [3,4].

FMT can be developed in groups, individually and at home. Group and individual training are commonly supervised by a physiotherapist. Recently Paiva *et al.* [5] have shown in a systematic review that group PFMT is as effective as individual PFMT for UI, but when compared to at-home PFMT, it is more effective [5]. Considering that group PFMT is effective in reducing UI and is a type of intervention that may benefit a greater number of people, it becomes a viable option to be implemented and developed as a first line of treatment for users of the public health system. However, there are still few studies in the literature involving group PFMT which have well-defined protocols and are easily understood and followed by patients. In this sense, the present study aims to identify the effect of a group PFMT protocol compared to an at-home PFMT protocol, for women with UI.

Methods

This study presents an experimental design of the type randomized blinded trial and follows the recommendations of CONSORT [6]. Women between 30 and 70 years of age with UI who had had intercourse in the last 6 months were eligible for the study. In addition to not having undergone pelvic radiotherapy and/or chemotherapy, not having delivered in the last 12 months, not having participated in group or individual PFMT in the last 6 months, agreeing to participate in the study and signing the Term of Informed

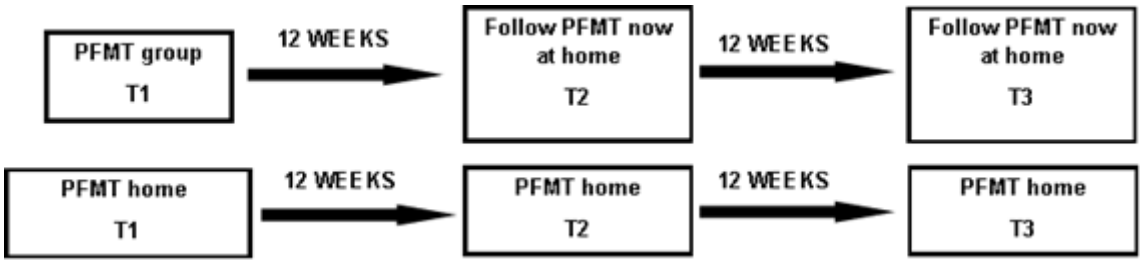
Consent. Patients were excluded if they had latex allergy, did not understand the instruments used in the research and had pelvic floor muscle (PFM) contraction at grade zero (0).

The sample was non-probabilistic by convenience, and patients from the Gynecology and Obstetrics Outpatient Clinic of the Hospital de Clínicas de Porto Alegre (HCPA), where the activities of pelvic physical therapy were performed, in the city of Porto Alegre/RS/Brazil, that met the inclusion criteria of the research were invited to participate.

Initially, the examiner used an anamnesis form to collect personal data. She then applied two self-administered questionnaires: International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) [7,8]. A physical examination was performed to assess the functionality of the pelvic floor muscles (PFM) through pressure biofeedback and vaginal palpation. Also, at this time the participants were advised on the correct voluntary contraction of the PFM.

Participants randomized to the PFMT group protocol performed the exercises with a group of women once a week for one hour under the supervision of a physical therapist for twelve weeks. They were also instructed to perform the exercises at home. After twelve weeks, they followed the same protocol, now at home. At the end of the 12th and 24th weeks, they were re-evaluated. On the other hand, the participants randomized to the home PFMT protocol received the exercise protocol on the day of the initial evaluation and were instructed to perform the exercises daily for a period of twenty-four weeks. After the 12th and 24th weeks, they were re-evaluated as well. Figure 1 demonstrates the sequence of protocols in a 24 weeks follow-up.

In both groups the participants received an exercise protocol with images showing the postures, that could be performed alternately (lying down, sitting and standing), including activation of phasic and tonic fibers. The sustained contractions were 5 seconds of contraction and ten seconds of relaxation, ten repetitions in total. Phasic contractions were one contraction and three relaxation periods, ten repetitions in total. In the home PFMT protocol, participants could lie down, which was not possible in the group PFMT due to the physical space of the outpatient clinic. In the group intervention, a minimum number of eight weeks stay was considered for the study. Figure 2 shows the protocols used in group and at home.



PFMT = Pelvic Floor Muscle Training); T1 (Time 1): Initial assessment; T2 (Time 2) = Evaluation after twelve weeks; T3 (Time 3) = Final evaluation

Figure 1 - *Sequence of protocols in a twenty-four-week follow-up*

Group PFMT

SEATED

Exercise 1:

Sitting on a chair, lean your torso forward and support your elbows on your knees.

Exercise 2:

Sitting in a chair, lean your torso back.

Exercise 3:

Sitting in a chair, keep your hips apart by bringing the soles of your feet together.

Exercise 4:

Sitting in a chair, keeping the spine away from the backrest and arms resting on the legs. Perform contraction of the pelvic floor muscles while performing a long and deep inspiration and raising the arms up.

Exercise 5:

Sitting in a chair, keeping the spine away from the backrest. Starting position of the exercise with the knees together, perform a slow and deep inspiration. As you begin a slow exhalation, pull your knees apart and contract your pelvic floor muscles. Return to the starting position and restart the exercise.

Protocol developed by the Pelvic Physiotherapy team of the HCPA.

STANDING

Exercise 6:

Standing with one leg in front of the other and with your hands on your waist, perform the contraction of the pelvic floor muscles. After completing the number of repetitions with the starting leg, position the leg that was behind in front and repeat.

Exercise 7:

Semi squat position and hands on knee to aid balance. Remain in this position and perform the contraction of the pelvic floor muscles.

Exercise 8:

Standing, facing the back of the chair, place your left hand on the backrest. Raise the right leg while contracting the pelvic floor muscles. Return to the starting position and restart the exercise. After completing the number of repetitions with the starting leg, support the right hand and perform the movement with the left leg.

Exercise 9:

Standing with your arms at your sides. Raise the arms until the palms touch, and at the same time, perform slow and deep inspiration and contract the pelvic floor muscles. Return to starting position and repeat.

Exercise 10:

Start seated, close to the edge of the chair, with your knees apart in line with your hips. Inhale deeply and when performing a long exhalation, contract the pelvic floor muscles and get up from the chair. Return to starting position and repeat.

Protocol developed by the Pelvic Physiotherapy team of the HCPA.

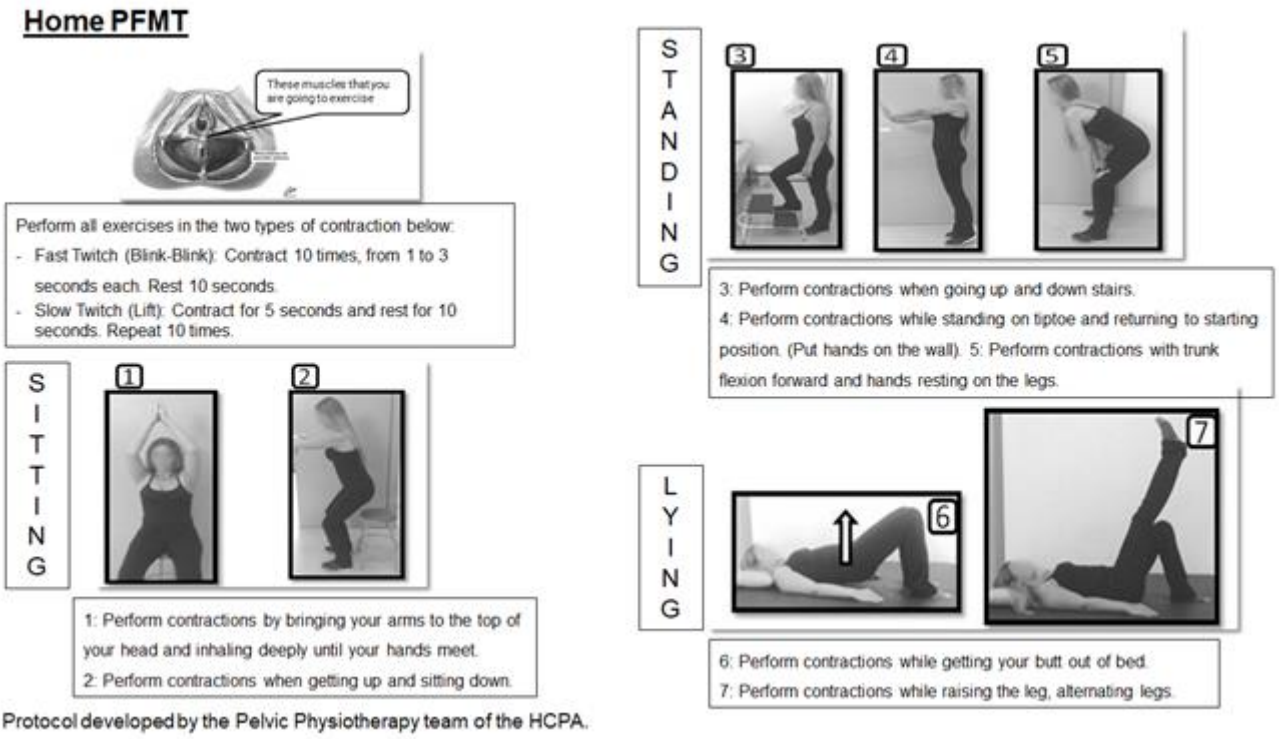


Figure 2 - *Protocols*

The primary outcome was improvement of PFM functionality. In this study, it was evaluated by measuring the pressure through pressure biofeedback and by vaginal palpation. Pressure biofeedback is a device with a vaginal catheter containing a pressure gauge, which measures the PFM pressure by assessing the maximum peak muscle contraction of the pelvic floor in cm H2O. This study used the device "Vaginal probe transducer" (VPT) developed at HCPA. The transducer consists of a silicone probe attached to a pressure sensor and to the computer which, upon being inflated, measures the PFM pressure according to its dynamic response as soon as the patient performs a MVC (maximum voluntary contraction) [9]. The PERFECT Scale was used during vaginal palpation. It is an acronym, composed of seven items, that was developed and validated by Laycock and Jerwood [10], to evaluate the contractility of the PFM and to enable professionals to plan patients' treatments. The PERFECT Scale used in the present study was the updated version described by Laycock, Whelan & Dumoulin [11].

For the secondary outcomes, the two self-administered questionnaires, ICIQ-SF and PISQ-12, were used to assess the impact of UI on quality of life (QOL) and sexual function (SF), respectively. The ICIQ-SF is a questionnaire validated for the Portuguese language, which proposes to assess the impact of UI on the QOL of women/men. It consists of four items that check the frequency of urinary loss, the amount of urinary loss, how much this loss interferes with daily life and the situations in which urinary losses occur. The results are based on the sum of the answers given to each item, with points

varying of 0 to six. The maximum score to be reached is 21, with higher scores indicating a worse QOL [7]. PISQ-12 was used to assess sexual function, a questionnaire validated for the Portuguese language, which assesses sexual function in women with UI and pelvic organ prolapse (POP). It has four items: emotional concerns, physical aspects, and relationship with the partner. The results are based on the sum of the individual questions, consisting of answers like "never" to "always", with points of 0 to four. The maximum score of 48, where higher scores indicate better SF [8].

The sample calculation considered, following a study by Felicíssimo *et al.* [12], a minimum difference of 2.9 points to be detected in the QOL (ICIQ-SF) in addition to a standard deviation of 4.35. The level of significance and statistical power were set at 5% and 80%, respectively, and thus the sample size was at least 28 individuals for each group. The sample calculation was performed on the software G*Power, version 3.0.10.

Participants were randomly assigned to the group PFMT protocol or the home PFMT protocol according to a random list generated by the software WinPepi, version 4.0. Participants were allocated in eight blocks of eight, as suggested in the literature [13]. The allocation sequence was concealed using numerically sequenced, opaque sealed envelopes opened after inclusion of patients in the study. One researcher, blind to treatment, was responsible for assigning, registering, evaluating and monitoring individuals.

Initially the Shapiro-Wilk test was performed to verify the distribution of the data. Symmetric variables were expressed as mean and standard deviation, or by median and 95% Confidence Interval [95% CI]. Categorical variables were described as absolute (n) and relative (n%) frequencies. To compare means between intergroups, Student’s t test for independent samples was applied. In asymmetry cases, the Mann-Whitney test was used to perform comparisons. The Chi-Square test with standardized residuals was applied for determining the association between two nominal variables. To compare means between intragroups, t-test of Paired Samples was applied. In asymmetry cases, the Wilcoxon test was used to perform comparisons. The Chi-Square test with standardized residuals was applied for determining the association between two nominal variables.

For assessing intervention type (PFMT group or PFMT home) and the outcomes involving the primary and secondary outcomes between and within groups, simultaneously, the model of Generalized Estimating Equations (GEE) adjusted by Bonferroni was applied. All data were evaluated using the SPSS, version 18.0. (SPSS Inc., Released in 2009, PASW Statistics for Windows, Version 18.0. Chicago). The significance level adopted for all analyses was set at 5%. This study was approved by

the Ethics Committee of the Hospital de Clínicas de Porto Alegre (no. 150316) and was registered at Clinical Trials (no. NCT03500185).

Results

One hundred and ninety women diagnosed with UI were selected to participate in the study. Of these, one hundred and twenty-six were excluded because they did not meet the inclusion criteria. Sixty-four were randomized to one of the two treatment groups. Thirty-two women were treated according to the group they were allocated. Fourteen and twelve women were removed from the analysis, missing their follow-up, after twelve weeks of treatment, respectively in the group PFMT and the home PFMT. The results according to protocol were analyzed in 17 participants in each group at the end of the 24 weeks of treatment (Figure 3). The baseline data of the studied sample are described in Table I and Table II, with categorical and numerical variables, respectively.

Table I - *Characterization of the sample - categorical variables*

Variables	Protocols Group PFMT (*n* = 32)	Home PFMT (*n* = 32)	*p* value*
MC *n*(*n*%)			
SUI	13(40.6)	13(40.6)	
UUI	2(6.3)	0(0.00)	0.481
MUI pred. SUI	10(31.3)	13(40.6)	
MUI pred. UUI	7(21.9)	6(18.8)	
Linings *n*(*n*%)			
Yes	21(65.6)	20(62.5)	1.000
No	11(34.4)	12(37.5)	
Dyspareunia			
Yes	16(50.0)	15(46.9)	1.000
No	16(50.0)	17(53.1)	
Menopause *n*(*n*%)			
Yes	17(53.2)	20(62.5)	0.435
No	15(46.9)	12(37.5)	
Smoking *n*(*n*%)			
Yes	3(9.4)	6(18.8)	0.132
No	29(90.7)	26(81.3)	
Medicines *n*(*n*%)			
Yes	25(78.1)	30(93.8)	0.150
No	7(21.9)	2(6.3)	
Previous surgeries *n*(*n*%)			
Yes	15(46.9)	14(43.8)	1.000
No	17(53.1)	18(56.3)	
Intestinal function *n*(*n*%)			
Normal	22(68.8)	18(56.3)	
Constipated	9(28.1)	12(37.5)	0.609
Fecal incontinence	1(3.1)	1(3.1)	
Anal incontinence	0(0.00)	1(3.1)	
Bulging evaluation *n*(*n*%)			
Yes	16(50.0)	19(59.4)	0.616
No	16(50.0)	13(40.6)	

N = absolute frequency; n% = relative frequency; MC = main complaint; SUI = Stress urinary incontinence; UUI = Urgency urinary incontinence; MUI = Mixed urinary incontinence; MUI pred. SUI = MUI predominance SUI; MUI pred. UUI = MUI predominance UUI; p = statistical significance. *Statistical representation of the initial assessment categorized distribution, as measured by the Chi-Square test. Statistical significance was set at $p \leq 0.05$ for all analyses. * Shapiro-Wilk normality test

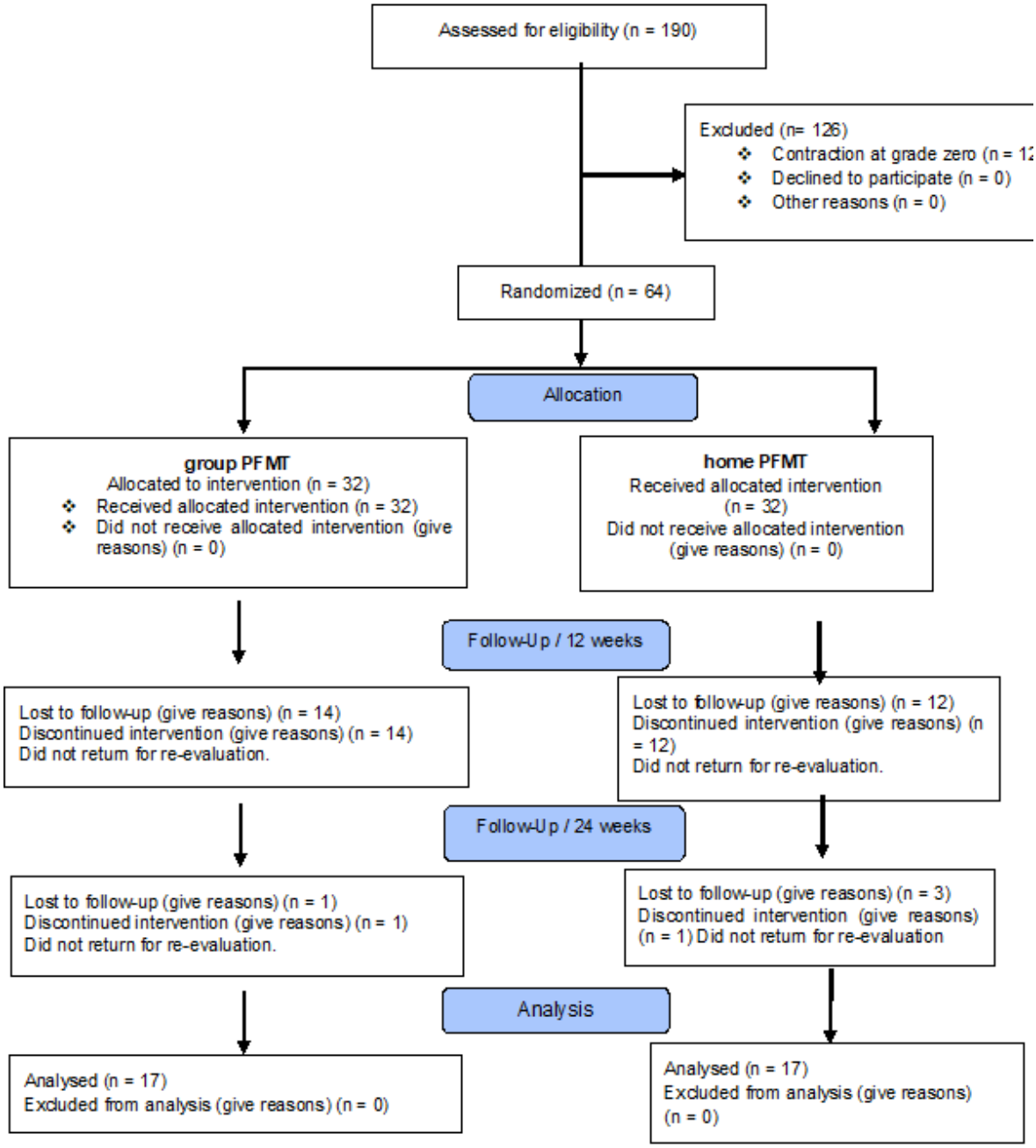


Figure 3 - *Flowchart of the study population randomized to two treatment groups*

Table II - *Characterization of the sample - numerical variables*

Variables	Absolute(*N*=64)	groupPFMT(*n*=32)	homePFMT(*n*=32)	*p* value
Age (years) mean ± sd	50.39±8.69	50.06±9.52	50.72±7.92	0.765
IMC (kg/cm²) mean ± sd	28.75±4.37	28.38±3.88	29.12±4.85	0.499
Sexarch (years) md[CI95%]	17.00[16.45–17.58]	18.00 [16.40–18.10]	16.50 [15.99–17.54]	0.269
Gestations (number) md[CI95%]	2.00[2.39–3.01]	2.00[2.23–3.15]	3.00[2.28–3.16]	0.626
Parturition (number) md[CI95%]	2.00[1.74–2.42]	2.00[1.60–2.59]	2.00[1.57–2.56]	0.666
Cesarean (number) md[CI95%]	0.00[0.35–0.87]	0.00[0.29–0.84]	0.00[0.19–1.12]	0.524
Number of exchanges (day) md[CI95%]	2.00[1.63–2.71]	3.00[1.52–3.04]	2.00[1.24–2.88]	0.611
ICIQ-SF (score) mean ± sd	14.91±3.87	14.97±3.98	14.84±3.81	0.898
MVC mean (cmH_2O) md[CI95%]	20.13[19.31–25.60]	19.48 [15.77–24.66]	22.41[20.15–29.26]	0.089
Power (PFM strength by Modified Oxford Scale) *n*(*n*%)				0.477
0	0(0.00)	0(0.00)	0(0.00)	
1	8(12.5)	4(12.5)	4(12.5)	
2	18(28.1)	7(21.9)	11(34.4)	
3	28(43.8)	14(43.8)	14(43.8)	
4	10(15.6)	7(21.9)	3(9.4)	
5	0(0.00)	0(0.00)	0(0.00)	
Endurance md[CI95%]	5.00[4.97–6.25]	5.00[4.81–6.38]	4.50[4.57–6.68]	0.510
Repetitions md[CI95%]	3.45[3.12–3.79]	3.00[2.78–3.84]	4.00[3.16–4.03]	0.181
Fast contractions md[CI95%]	6.00[6.04–7.27]	6.00[5.42–7.39]	6.00[6.11–7.71]	0.204
PISQ-12 (score) mean±sd	29.94±9.68	32.06±8.20	27.88±10.65	0.086

Md = median; CI = Confidence Interval; sd = standard deviation of the mean; PFMT = Pelvic Floor Muscles Training. MVC = Maximum Voluntary Contraction; PFM = Pelvic Floor Muscles. *Statistical representation of the categorized comparison pre-intervention intergroups, measured by the Independent Samples t-test or Mann-Whitney and Chi-square, when applicable. Statistical significance was set at $p \leq 0.05$ for all analyses. *Shapiro-Wilk normality test

Observing the intragroup variables after twelve weeks of treatment, both protocols were not effective in improving PFM functionality, measured by pressure biofeedback. When the PERFECT Scale was considered, the group PFMT protocol was effective in improving the Power item (Chi-square, $p = 0.042$). The remainder of the items in the PERFECT Scale did not change. These results are described in Table III.

Table III - *Intergroup / intragroup comparison after 12 weeks*

Absolute	group PFMT	home PFMT		*p* value
PISQ-12 (score) – [CI95%]				0.175
T1 *N* = 64[a]	31.00[27.50–32.37]	32.00[29.06–35.07]	31.00[24.03–31.72]	0.091
T2 *N* = 38[b]	31[25.46–32.27]	34.00[27.96–36.63]	24.50[20.87–31.03]	
p value*		0.232	0.737	
ICIQ-SF (score) – [CI95%]				0.914
T1 *N*=64[a]	15.50[13.94–15.87]	15.50[13.53–16.40]	15.50[13.47–16.22]	0.051
T2 *N*=38[b]	11.00[10.12–13.25]	9.50[8.40–12.04]	15.00[10.52–15.28]	
p value*		0.002*	0.068	
MVC mean (cmH_2O) – [CI95%]	20.13[19.31–25.60]			
T1 *N*=64[a]	15.27[15.62–24.69]	19.48[15.77–24.66]	22.41[20.15–29.26]	0.089
T2 *N*=38[b]		15.52[13.72–26.97]	11.93[13.12–26.83]	0.851
p value*		0.647	0.420	
Power (PFM strength by Modified Oxford Scale) – *n*(*n*%)				
T1 *N*=64[a]				0.510
0	0(0,00)	0(0.00)	0(0.00)	
1	8(12.5)	4(12.5)	4(12.5)	
2	18(28.1)	7(21.9)	11(34.4)	
3	28(43.8)	14(43.8)	14(43.8)	
4	10(15.6)	7(21.9)	3(9.4)	
5	0(0.00)	0(0.00)	0(0.00)	
T1 *N*=38[b]				0.106
0	0(0.00)	0(0.00)	0(0.00)	
1	2(3.1)	0(0.00)	2(6.3)	
2	4(6.30)	4(12.5)	0(0.00)	
3	14(21.9)	5(15.6)	9(28.1)	
4	15(23.4)	7(21.9)	8,(25.0)	
5	3(4.7)	2(6.3)	1(3.1)	
p value*		0.042*	0.408	
Endurance – md[CI95%]				
T1 *N*=64[a]	5.00[4.97–6.25]	5.00[4.81–6.38]	4.50[4.57–6.68]	0.510
T2 *N*=38[b]	6.00[5.73–7.21]	6.00[5.36–7.41]	6.50[5.40–7.70]	0.919
p value*		0.067	0.073	
Repetitions – md[CI95%]	3.45[3.12–3.79]			0.181
T1 *N*=64[a]	4.00[3.62–4.54]	3.00[2.78–3.84]	4.00[3.16–4.03]	0.515
T2 *N*=38[b]		4.00[3.56–5.00]	4.00[3.26–4.54]	
p value*		0.074	0.456	
Fast contractions – md[CI95%]				
T1 *N*=64[a]	6.00[6.04–7.27]	6.00[5.42–7.39]	6.00[6.11–7.71]	0.204
T2 *N*=38[b]	6.50[6.23–8.14]	6.00[5.17–7.83]	7.00[6.39–9.21]	0.141
p value*		0.420	0.123	

Md = median. CI = Confidence Interval; sd = standard deviation of the mean; T1 = Initial evaluation; T2 = Evaluation after 12 weeks; PFMT= Pelvic Floor Muscles Training; MVC = Maximum Voluntary Contraction; PFM = Pelvic Floor Muscles. [a]PFMT group N=32 / PFMT home N=32. [b]PFMT group N=18 / PFMT home N=20. *Statistical representation of the intergroup categorized comparison after 12 weeks, as measured by the Independent Samples t test or Mann-Whitney and Chi-Square, where applicable. Statistical significance was set at p ≤ 0.05 for all analyzes. * Shapiro-Wilk normality test. *Statistical representation of the intragroup categorized comparison after 12 weeks, as measured by the t-test of Paired Samples or Wilcoxon and Chi-Square, where applicable. Statistical significance was set at p ≤ 0.05 for all analyses. *Shapiro-Wilk normality test

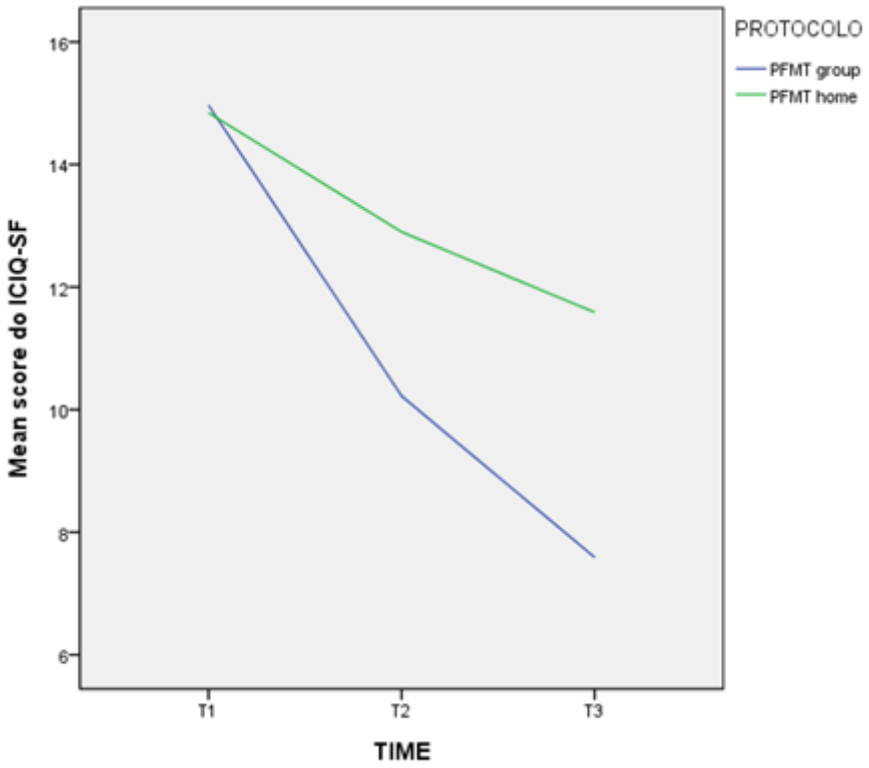
After the twenty-four weeks, the average MVC, Endurance and Fast contractions variables remained unchanged in both protocols. The Power and Repetition items, however, were affected by time, but one should be careful when analyzing these items. Despite this, the test was not able to demonstrate the interaction, probably due to the large loss of follow-up throughout the study and the proximity of the averages found in both groups. The same occurs with the Power item, but in this case an additional test

was performed (Chi-square, p = 0.139), which confirmed that none of the protocols were effective at the end of twenty-four weeks. These results are described in Table IV.

Table IV - *Group, time and interaction pairwise comparisons using generalized estimating equations (see PDF annexed)*

Observing the intra-group variables after twelve weeks of treatment, only the group PFMT protocol was effective in improving the QOL variable (Wilcoxon, p = 0.002), while none of the protocols presented difference in the SF variable. These results are described in Table III.

Time and protocol interactions were observed for the ICIQ-SF and PISQ-12 variables. In the group PFMT, the PISQ-12 variable already showed improvement from T2 until T3. In the home PFMT protocol, the PISQ-12 variable worsens in T2 and from it until T3 presents an evolution. Analyzing the variable in pairs, the group PFMT protocol was the most effective (T2 and T3). The ICIQ-SF item in both protocols presents evolution in T2. However, the home PFMT protocol in T3 is not shown to be more effective. Analyzing the variable in pairs, the group PFMT protocol was the most effective (T2 and T3). Figure 4 shows the evolution of the protocols. These results are described in Table IV.



ICIQ-SF = Consultation on Incontinence Questionnaire-Short Form); PFMT = Pelvic Floor Muscle Training
Figure 4 - *ICIQ-SF Consultation on Incontinence Questionnaire-Short Form)*

Discussion

The objective of this study was to identify the effect of a group PFMT protocol compared to a home PFMT protocol for women with UI, with the main outcome being improvement of PFM functionality. With twelve weeks of treatment, in a general context, it was observed that only the PFMT group protocol was presented as a more effective form of treatment for UI because it demonstrated improvement in the Power and QOL aspects. When we observed the effect of the protocols after twenty-four weeks, both were effective only when referring to the secondary outcomes, that is, quality of life and sexual function.

According to Bo *et al.* [14], PFMs present a constant level of rest tonus (except before and during urination and defecation), symmetry and the ability to contract and relax voluntarily. The normal contractile function of the PFM is verified by a movement of internal constriction of the pelvic openings in the ventrocephalic direction. The "Power" muscle variable is one of the characteristics of muscle action, defined as the explosive aspect of force, the product of force and moving speed (force × distance/time).

PFMT is a type of exercise whose goal is to improve the strength, endurance, potency and relaxation of these muscles [14]. In addition, it can alter the morphology of the muscles by increasing its thickness and strength in the first six to eight weeks, being predominantly neural. Hypertrophy occurs after six to eight weeks and can be prolonged for years. The latter is general for all muscle fibers; however, the potential of hypertrophy is greater in phasic fibers than in tonic ones. The success of this training also depends on the ability to identify the PFM, awareness of correct contraction, compliance, and motivation to perform the exercise protocol [15]. In the present study, the Power variable showed improvement only at twelve weeks of the group PFMT intervention, which is consistent with what is advocated by ICS (International Continence Society), that PFMT involves the voluntary and repeated contraction of this striated muscle, and that this training should be maintained for eight to 12 weeks [3].

After the twelve weeks, no change was observed for the Power variable in the group treatment, probably because the participants were unsupervised from this moment, and training adherence was not controlled [3]. This does not refer to the intervention itself, but the patients' commitment to change their behavior and adhere to the intervention [14].

In their systematic review, Dumoulin et al demonstrated that individual PFMT protocols are better than no treatment, placebo or inactive control for women with UI. However, follow-up (usually twelve weeks) after the end of treatment is limited in most

studies, thus meaning that the long-term results of individual PFMT protocols remain unclear [4].

Paiva *et al.* [5] opted to perform a systematic review of the behavior of the group PFMT protocol. These authors demonstrated that the group PFMT protocol is as effective as the individual PFMT for UI, but when compared to the home PFMT it is more effective. However, the effect of individual and group PFMT protocols is observed for up to twelve weeks. Thus, the present study corroborates with Paiva *et al.* [5], since it demonstrates that the group PFMT, considering twelve weeks, is more effective than the home PFMT in relation to the Power aspect of PFM functionality and QOL improvement, in the conservative treatment of UI.

On the other hand, observing the 24 weeks of treatment, both protocols are effective regarding QOL and SF, but with specific behaviors. Regarding QOL, it was observed that in 12 weeks both protocols were already effective. QOL depends on the subjective perception of UI and on treatments that target the social, physical and mental levels [16]. Thus, the group PFMT protocol (in twelve weeks) relied on the interaction between the participants and the physiotherapeutic supervision, which may benefit the three levels mentioned. However, even without supervision, the home PFMT protocol was also effective for QOL in this period. The fact that they received orientation and education during the evaluation proved to be an important strategy capable of initially modifying these women's QOL. A good level of education and health has an intrinsic value for people: education helps to improve health and good health contributes to better education [17].

After 12 weeks, only the group PFMT protocol remained effective regarding QOL. Participants in the group PFMT are likely to remain more engaged in treatment because of prior interaction with other women and supervision, which has not occurred with the participants who performed home PFMT. The sample of this study had a predominance of MUI and when comparing the different types of UI, some studies indicate that MUI has a greater impact on women's QOL [18,19]. Thus, probably the questionnaires were able to identify the effect of both protocols in these outcomes due to the predominance of MUI in this sample.

Regarding sexual function, the group and home interventions showed different effects. While the group PFMT protocol was effective for SF, as early as the 12th week, improving the PISQ-12 score, home protocol behaved inversely, probably because the participants did not have supervision. The presence of UI in women's lives causes feelings of low self-esteem, restricting social contact and interferes with sexual life [1]. As well as the impact that the different types of UI have on QOL, they also have an impact on SF. Women with overactive bladder would be more prone to sexual problems

than women with SUI and MUI. Lower urinary tract symptoms, urgency and urinary incontinence, are associated with sexual dysfunction in women [20]. After 12 weeks, both protocols presented an evolution in the PISQ-12 score, probably because at this moment the home PFMT participants were re-evaluated and received a new incentive to perform the exercises, a fact that may explain the behavior change of the PISQ-12 variable.

Thus, group PFMT was an effective strategy in the conservative treatment of female UI when compared to home treatment. And as stated by Dumoulin *et al.* [21], if we consider demographic projections, human resources, and health system limitations, there is an urgent need to expand the evidence on the long-term benefits of low-cost interventions for UI treatment in women, a condition that is often underestimated, as is the case of group interventions.

We can cite as limitations of this study the great loss of follow-up in both treatment groups, with 46.87% of loss in each group after 24 weeks. This fact can be justified by the large number of patients from outside the city who seek treatment at the HCPA. In addition, it was not possible to control adherence to the exercises in any of the protocols, especially in the home PFMT.

Conclusion

The group PFMT protocol used in the present study was effective in improving the functionality of the PFM and QOL in women with UI when applied under supervision for twelve weeks. After 24 weeks of intervention, in this studied sample, the group and home protocols were effective in the secondary outcomes, QOL and SF. It can be assumed that the group intervention constitutes a feasible and viable physiotherapeutic intervention strategy, able to benefit many women with UI, besides being a tool that is easy for patients to understand and follow.

It is important to remember that group PFMT is a strategy that has been used in the Outpatient Clinic of Pelvic Physiotherapy developed in partnership with the Outpatient Clinic of Gynecology and Obstetrics of the Hospital de Clínicas de Porto Alegre for six years, and it is clinically possible to verify the improvement of the patients in care. However, there was a need for scientific evidence on the effect of group interventions. Thus, in addition to answering the question of the effect, this study was able to identify that group PFMT protocol, supervised by a physiotherapist, can be an easy and practical tool to be applied as a basis for the treatment of female UI in the public health system.

Conflict of interest
There is no conflict of interest.

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Authors' contributions
Research conception and design: Ferla L; Data collection: Ferla L, Darski C; Data analysis and interpretation: Ferla L, Statistical analysis: Ferla L, Writing of the manuscript: Ferla L; Critical review of the manuscript for important intellectual content: Ferla L, Darski C, Paiva LL, Ramos JGL

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