ORIGINAL ARTICLE

Effects of pelvic floor muscle training on quality of life of a group of women with urinary incontinence: Randomized controlled trial

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KEYWORDS
Urinary incontinence; Quality of life; Pelvic floor; Physical therapy

Abstract
Objective: To evaluate the effects of kinesiotherapy on function and level of pressure of pelvic floor muscle (PFM) and quality of life (QOL) of a group of women with urinary incontinence (UI).

Materials and methods: This is a randomized controlled pilot trial. Thirty women (age 60.87 ± 9.05 years) were evaluated, before and after 12 weeks of treatment, for urinary loss, PFM function and pressure, and QOL. Volunteers were randomly allocated into two groups: Kinesiotherapy Group (KG) and Control Group (CG). The KG protocol consisted of 12 1-h sessions with exercises to strengthen PFM and information for UI. The CG did not receive any treatment during the corresponding time. The data were analyzed by non-parametric Wilcoxon and Mann–Whitney test. The significance level was 5%.

Results: The KG presented a significant improvement in urinary loss (p = 0.053), PFM function (p < 0.006) and pressure (p = 0.0014) and in some domains of King’s Health Questionnaire (KHQ) for QOL assessment: incontinence impact (p = 0.034), limitations of daily activities (p = 0.025), sleep and disposition (p = 0.018) and gravity domains (p = 0.004). No differences were found in the CG for any variables.

Conclusion: The protocol to strengthen the PFM used by the KG was effective to improve the UI, QOL, function and pressure of PFM contraction.

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PALABRAS CLAVE
Incontinencia urinaria; Calidad de vida; Suelo pélvico; Terapia física

Efectos del fortalecimiento del suelo pélvico en la calidad de vida de un grupo de mujeres con incontinencia urinaria: Estudio aleatorizado controlado

Resumen
Objetivos: Evaluar los efectos de la kinesioterapia en un grupo de mujeres con incontinencia urinaria (IU) sobre la calidad de vida (CV), el nivel de presión y función de los músculos del suelo pélvico en mujeres con IU.


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Effects of pelvic floor muscle training on quality of life of a group of women with urinary incontinence

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**Introduction**

UI is defined as any involuntary loss of urine and it affects about 21.4% of women over 40 years old. Kinesiotherapy to strengthen the PFMs was developed in 1948 by Arnold Kegel, and is one great physical therapy option for stress urinary incontinence (SUI), vesical hyperactivity (VH), and mixed urinary incontinence (MUI) treatment.

The available literature demonstrates positive effects of kinesiotherapy performed in individual sessions; however, in the last few years, publications started showing the effects of kinesiotherapy performed in group sessions. As such, a trial that analyzes the effects of kinesiotherapy to strengthen the PFM in group is necessary, as this is a low-cost treatment for UI, which would increase the number of women who have access to this treatment.

In this context, the purpose of this randomized trial was to evaluate the effects of a kinesiotherapy protocol to strengthen the PFM on urinary symptoms, function, and level of pressure of PFM and QOL on a group of women with UI.

**Materials and methods**

This was a randomized controlled pilot trial performed from August/2008 to June/2009. The Ethics Committee for Human Research of the Federal University of São Carlos – Brazil approved the study (report # 180/2008), which is in agreement with the Declaration of Helsinki and the resolution 196/96 from the National Health Council. Study procedures were explained to all volunteers and an informed consent term was obtained before any procedure.

Thirty-five women aged 45 years old and over, who presented some complaint of urinary loss and had never undergone physical therapy for UI treatment were included in the study. Women presenting latex allergy, urinary and vaginal infection, inadequate vagina size to introduce perineometer probe, pelvic organ prolapse greater than levels 3 or 4, neurologic or cognitive impairment, uncontrolled systemic arterial hypertension, and some disability that could impair evaluation or treatment were excluded from the study.

The 35 volunteers who met the inclusion criteria were randomized in two groups: KG (n = 20) and CG (n = 15). For randomization purposes, the participants blindly removed one of 35 preprinted cards in opaque sealed envelopes from a box (twenty labeled ‘group session’ and fifteen labeled ‘control group’) and were arranged in the groups according to the removed card.

Only one experienced physical therapist performed evaluations of the two groups. Initially, all women went through a complete physical examination and an interview regarding their thorough medical history. The women were evaluated before and after treatment for urinary loss with the one-hour pad test and for QOL with KHQ (primary outcomes); and PFM pressure and PFM strength (secondary outcomes).

The one-hour pad test was carried out to evaluate urinary loss according to the protocol proposed by Abrams et al. The volunteers were instructed to place a pad previously weighed on a precision balance Denver APX200 (precision of 0.0001 g, Denver instruments, Denver, USA) and then drink 500 ml of water. After 30 min, they started performing a series of provocative exercises and after 1 h, the pad was removed, reweighed, and the urinary loss was calculated and classified in mild (2–10 g), moderate (10–50 g), and severe (more of 50 g) UI.

For the assessment of QOL, the KHQ was used, as it is one reliable instrument, specific to assess the QOL of women with UI and validated in Brazilian Portuguese. This questionnaire consists of 30 questions, divided into nine individually scored domains. These domains are: general health, incontinence impact, limitations of daily activities, physical limitations, social limitations, personal relationships, emotions, sleep and disposition, and gravity. The total score ranges from 0 to 100; a score of 100 represents the worst possible QOL, and 0 represents the best possible QOL.

PFM functional evaluation was carried out using the PERFECT method. The volunteers were positioned in supine
with hip and knee flexion. In this position, the evaluator introduced two fingers up to one third of the vagina. The volunteers were then instructed to lift and contract the PFM as hard as possible. The strength was measured on a 6-graded Modified Oxford Scale.\textsuperscript{16}

The perineometer Perina (Quark Medical Products, Piracicaba, Brazil), graded from 0 to 60 cmH\textsubscript{2}O, was used to evaluate PFM pressure. The participants were placed at lithotomy position and the vaginal probe, previously covered by a condom (Microt"{e}x\textsuperscript{®}) and lubricated (K-med\textsuperscript{®} gel), was introduced 3.5 cm into the vagina. The equipment was then calibrated. Initially, the participants performed two PFM contractions for familiarization with the procedures. After that, they performed a third contraction, which was the one considered for data analysis. PFM contractions were performed for 3 s. They were instructed to avoid performing abdominal, gluteus, and hip adductor muscle contractions during maximum PFM evaluation.\textsuperscript{9}

The KG protocol consisted of 12 1-h sessions performed once a week in groups of 8–10 people. Exercises to strengthen the PFM, information, and guidance for UI were part of the treatment sessions. Initially, the exercises were performed at supine and sitting positions. The exercises evolved gradually, either by increasing the number of repetitions and/or the contraction time. The exercises then evolved to orthostatic position, squat, and main situations that could induce urine loss. Moreover, the volunteers received basic information about UI, urinary system anatomy, self-care, and food habits that could contribute to the treatment.

The CG did not receive any treatment during the corresponding time. After this time, the subjects were evaluated and referred to physical therapy treatment.

The statistical analyses were performed using nonparametric tests as the variables did not present a normal distribution, tested by the Shapiro–Wilks test. The comparison between the baseline and outcome measurements was made using the Wilcoxon test. For the intergroup analysis before and after treatment, the Mann–Whitney test was used. Differences were considered significant when the \( p \) value was <0.05. To measure the clinical significance of the data, the confidence interval was calculated. The data were expressed as means ± standard deviations. Data analysis was performed by Statistica 7.0 (Copyright © Statsoft Inc. 1984–2004).

Results

Out of the 35 women who took part in the study, 5 women of the KG did not complete the treatment or did not perform the final evaluation due to health problems in their family (three volunteers), loss of telephone contact (one volunteer), and moving from the city (one volunteer). Therefore, they were excluded from the sample (Fig. 1). Among the 30 volunteers (age: 60.87 ± 9.05 years; Body Mass Index: 26.02 ± 2.81 kg/m\textsuperscript{2}) analyzed in this study, 14/15 (93.33\%) of the CG women, and 15/15 (100\%) of the KG women presented mild UI in the one-hour pad test. Moreover, there were no significant differences between the groups in terms of demographical and clinical characteristics (Table 1).

### Table 1. Demographic and clinical characteristics of the study participants \( n=30 \).

<table>
<thead>
<tr>
<th></th>
<th>KG ( n=15 )</th>
<th>CG ( n=15 )</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>60.20 (8.16)</td>
<td>61.53 (10.12)</td>
<td>0.80</td>
</tr>
<tr>
<td>BMI (kg/m\textsuperscript{2})</td>
<td>26.03 (3.60)</td>
<td>26.00 (1.85)</td>
<td>0.63</td>
</tr>
<tr>
<td>Number of deliveries</td>
<td>2.00 (1.56)</td>
<td>2.80 (1.32)</td>
<td>0.15</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>1.47 (1.51)</td>
<td>2.13 (1.46)</td>
<td>0.19</td>
</tr>
</tbody>
</table>

BMI: Body Mass Index; KG: Kinesiotherapy Group; CG: Control Group; SD: standard deviations.

After the treatment, 9/15 (60\%) of the women became urinary continent and there was a significant reduction in urinary loss measured by the one-hour pad test \( p=0.053 \) for the KG; the CG did not present significant differences in this variable. In the intergroup analysis, there was a significant difference after the treatment between the KG and the CG \( p<0.001; 95\% \) confidence interval from 0.57 to 5.81 (Table 2) in favor of the KG.

The pressure perineometry of the PFM significantly increased for the KG \( p=0.0014 \) but not for the CG. The intergroup analysis showed statistical differences between the KG and the CG \( p<0.001; 95\% \) confidence interval from \(-39.68 \) to \(-19.12 \) after treatment, again in favor of the KG. There was significant improvement in muscle function as measured by the PERFECT method in the KG \( p<0.006 \) after treatment and the intergroup analysis verified statistical differences between the KG and the CG \( p<0.001 \) (Table 2).

In evaluation of QOL, a significant reduction of scores in the incontinence impact \( p=0.034 \), limitations of daily activities \( p=0.025 \), sleep and disposition \( p=0.018 \), and gravity domains \( p=0.004 \) was observed in the KG after the treatment. In the intergroup analysis, significant differences were observed in the incontinence impact \( p=0.0034; 95\% \) confidence interval from 6.55 to 51.45), physical limitations \( p=0.03; 95\% \) confidence interval from 2.25 to 42.23), and gravity domains \( p=0.03; 95\% \) confidence interval from 2.17 to 35.55) when comparing the KG and the CG after the treatment (Table 3).
Effects of pelvic floor muscle training on quality of life of a group of women with urinary incontinence

Table 2  Outcomes of one-hour pad test, pelvic floor muscle pressure and digital (PERFECT).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Pre means (SD)</th>
<th>Post means (SD)</th>
<th>Intragroup p-value</th>
<th>Intergroup p-value</th>
<th>CI</th>
<th>ES</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-hour pad test</td>
<td>KG</td>
<td>1.88 (2.85)</td>
<td>0.46 (0.45)</td>
<td>0.053</td>
<td>&lt;0.001</td>
<td>0.57−5.81</td>
<td>−0.91</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>3.87 (5.57)</td>
<td>3.65 (4.94)</td>
<td>0.46</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure (cm H2O)</td>
<td>KG</td>
<td>22.67 (21.52)</td>
<td>41.33 (18.65)</td>
<td>0.0014</td>
<td>&lt;0.001</td>
<td>−39.68 −19.12</td>
<td>2.14</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>11.53 (5.29)</td>
<td>11.93 (5.48)</td>
<td>0.37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERFECT: Power</td>
<td>KG</td>
<td>1.93 (1.33)</td>
<td>3.07 (0.70)</td>
<td>0.006</td>
<td>&lt;0.001</td>
<td>−2.06 −1.14</td>
<td>2.59</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>1.40 (0.51)</td>
<td>1.47 (0.52)</td>
<td>0.96</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERFECT: Endurance</td>
<td>KG</td>
<td>4.53 (3.89)</td>
<td>8.87 (1.85)</td>
<td>0.003</td>
<td>&lt;0.001</td>
<td>−5.53 −2.61</td>
<td>2.09</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>4.73 (1.98)</td>
<td>4.80 (2.04)</td>
<td>0.81</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERFECT: Repeat</td>
<td>KG</td>
<td>3.07 (3.28)</td>
<td>8.27 (2.31)</td>
<td>0.003</td>
<td>&lt;0.001</td>
<td>−6.79 −4.01</td>
<td>2.91</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>2.87 (1.51)</td>
<td>2.87 (1.25)</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERFECT: Speed</td>
<td>KG</td>
<td>5.27 (4.01)</td>
<td>9.20 (1.70)</td>
<td>0.005</td>
<td>&lt;0.001</td>
<td>−5.61 −2.53</td>
<td>1.98</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>5.27 (2.63)</td>
<td>5.13 (2.36)</td>
<td>0.73</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

KG: Kinesiotherapy Group; CG: Control Group; SD: standard deviations; CI: confidence interval; ES: effect size.

Discussion

After the KG treatment, 60% of the KG women were urinary continent. Laycock16 showed that kinesiotherapy to strengthen the PFM is indicated for UI treatment. Moreover, kinesiotherapy to strengthen the PFM presented better results than other physical therapy modalities for UI.5,6 Some remaining complaints about urinary loss after the treatment could be due to insufficient treatment time. More kinesiotherapy sessions might be necessary to induce muscle hypertrophy and improve UI in those women.

Improvement of UI symptoms in the KG could be verified by positive results in the one-hour pad test, digital and perineometer evaluation for PFM function, and QOL. These results demonstrated that kinesiotherapy to strengthen the PFM represents one good option for UI treatment, with better results than other physical therapy modalities for UI treatment.9

There was a significant decrease of urinary loss after the treatment, as shown by the one-hour pad test. Zanetti et al.17 found significant urinary loss decrease in the supervised and non-supervised KG by one-hour pad test assessment. Balmforth et al.4 also found significant decrease in urinary loss measured by the 30-minute pad test. The one-hour pad test is effective, presents strong correlation with UI self-evaluation and severity, and it is not painful or invasive,18 which justifies its use in clinical practice. However, this test may not be so sensitive to detect mild urinary loss. The study by Tsai and Liu9 observed women with urinary loss that presented one-hour pad test values between 0.05 and 3.10 g, which indicates that this test may not be sensitive enough to classify women as urinary incontinent.

Table 3  Means, standard deviations, and level of significance of KHQ domains.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Groups</th>
<th>Pre means (SD)</th>
<th>Post means (SD)</th>
<th>Intragroup p-value</th>
<th>Intergroup p-value</th>
<th>CI</th>
<th>ES</th>
</tr>
</thead>
<tbody>
<tr>
<td>General health</td>
<td>KG</td>
<td>31.67 (17.89)</td>
<td>30.00 (14.02)</td>
<td>0.68</td>
<td>0.71</td>
<td>−8.77 −15.43</td>
<td>−0.35</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>40.00 (17.59)</td>
<td>33.33 (18.09)</td>
<td>0.14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incontinence impact</td>
<td>KG</td>
<td>53.33 (27.60)</td>
<td>28.84 (30.54)</td>
<td>0.034</td>
<td>&lt;0.001</td>
<td>6.55 −51.45</td>
<td>−0.27</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>60.00 (33.81)</td>
<td>57.84 (29.48)</td>
<td>0.59</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limitations of daily activities</td>
<td>KG</td>
<td>21.11 (25.56)</td>
<td>11.09 (16.21)</td>
<td>0.025</td>
<td>0.17</td>
<td>−2.42 −40.16</td>
<td>−0.97</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>30.00 (37.37)</td>
<td>29.96 (36.84)</td>
<td>0.97</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>KG</td>
<td>18.89 (16.51)</td>
<td>13.31 (15.63)</td>
<td>0.097</td>
<td>0.03</td>
<td>2.25 −42.25</td>
<td>−0.83</td>
</tr>
<tr>
<td>Limitations</td>
<td>CG</td>
<td>33.36 (30.89)</td>
<td>35.56 (34.43)</td>
<td>0.33</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social limitations</td>
<td>KG</td>
<td>7.38 (18.76)</td>
<td>5.97 (9.08)</td>
<td>0.75</td>
<td>0.39</td>
<td>−6.40 −28.18</td>
<td>−0.82</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>16.30 (29.95)</td>
<td>17.76 (29.63)</td>
<td>0.96</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal</td>
<td>KG</td>
<td>7.78 (18.76)</td>
<td>11.02 (16.13)</td>
<td>0.68</td>
<td>0.47</td>
<td>−17.13 −3.97</td>
<td>−0.18</td>
</tr>
<tr>
<td>relationship</td>
<td>CG</td>
<td>4.44 (11.73)</td>
<td>4.44 (11.73)</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotions</td>
<td>KG</td>
<td>18.52 (23.63)</td>
<td>11.79 (14.77)</td>
<td>0.059</td>
<td>0.12</td>
<td>−4.35 −29.65</td>
<td>−0.23</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>24.41 (28.24)</td>
<td>24.44 (28.54)</td>
<td>0.98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep and disposition</td>
<td>KG</td>
<td>21.11 (23.96)</td>
<td>5.55 (10.25)</td>
<td>0.018</td>
<td>0.95</td>
<td>−9.31 −22.73</td>
<td>−0.41</td>
</tr>
<tr>
<td>Gravity measures</td>
<td>CG</td>
<td>38.24 (25.86)</td>
<td>26.64 (21.50)</td>
<td>0.004</td>
<td>0.03</td>
<td>2.17 −35.55</td>
<td>−0.86</td>
</tr>
</tbody>
</table>

KG: Kinesiotherapy Group; CG: Control Group; SD: standard deviations; CI: confidence interval; ES: effect size.
Bø and Sherburn\footnote{Bø and Sherburn\cite{Bø2010} and Sung et al.\cite{Sung2009} showed some improvement in vaginal pressure after kinesiotherapy treatment, confirming the results of the present study. Bø and Sherburn\cite{Bø2010} compared kinesiotherapy for the PFM, electrostimulation, vaginal cone training, and CG and found that kinesiotherapy was the only treatment that presented significant improvement in vaginal pressure after treatment. On the contrary, Sung et al.\cite{Sung2009} compared kinesiotherapy and functional electric stimulation (FES), and they found improvements in vaginal pressure for both groups. Nonetheless, the FES group presented better results for this variable.}

Digital PFM functional evaluation showed significant improvement for every PERFECT step in the KG. Castro et al.\cite{Castro2007} evaluated PFM strength with the Modified Oxford Scale, in women submitted to kinesiotherapy performed in group. After treating four groups with different interventions (kinesiotherapy, electrostimulation, vaginal cone, and CG), the only group that presented significant improvement for the PFM functional status was the one that underwent the kinesiotherapy intervention.\footnote{Castro et al.\cite{Castro2007} showed that UI affects the QOL of women\cite{Bø2010} and the increase of PFM strength is associated with improvement of UI and QOL.\cite{Carneiro2008, Arruda2011, Girão2011} In the present study, women in the KG showed improvement in QOL verified by the following KHQ domains: incontinence impact, limitations of daily activities, sleep and disposition, and gravity. Balfour et al.\cite{Balfour2011} evaluated the QOL with KHQ, and also found significant improvement due to UI treatment for the domains of incontinence impact, limitations of daily activities, physical limitations, social limitations, emotions, sleep, and disposition. In the study by Carneiro et al.,\cite{Carneiro2008} they found significant improvement of PFM strength evaluated by the functional digital palpations and in limitation of daily activities and incontinence impact domains of KHQ.}

Initially, the volunteers presented high values of UI impact in the incontinence impact domain of the KHQ and the QOL impairment varied among the volunteers, which can be verified by high standard deviation in all domains of KHQ. This heterogeneous impairment level of QOL can be the result of social, cultural, religious, and hygienic diversity of the study sample.\footnote{This study presented some limitations, as it was not possible to carry out urodynamic exams, and it cannot be ignored either that a larger sample size could have altered some of the results of the study. However, despite the small sample size, the calculation of effect size showed that the treatment had a large effect on clinical variables.}

This study presented some limitations, as it was not possible to carry out urodynamic exams, and it cannot be ignored either that a larger sample size could have altered some of the results of the study. However, despite the small sample size, the calculation of effect size showed that the treatment had a large effect on clinical variables.

Future studies might evaluate the adherence of patients to treatment and the long-term effects of kinesiotherapy to strengthen the PFM with a larger sample size than in the present study. Another interesting point to be evaluated is the sensitivity of the one-hour pad test to assess women with mild, moderate, and severe urinary loss.

In conclusion, the kinesiotherapy protocol to strengthen the PFM was effective to decrease complaints about urinary loss and to improve the QOL, function, and pressure of PFM contraction of women suffering from UI.

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## Conflict of interest

The authors declare that they have no conflict of interest.

## References


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