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ORIGINAL ARTICLE

Digital physical therapy intervention to treat female urinary incontinence: a semi-experimental study

Intervenção fisioterapêutica digital para o tratamento da incontinência urinária feminina: um estudo semi-experimental

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Abstract

Background: Urinary incontinence affects 15-40% Brazilian women in rural areas, indicating the necessity of treatment for people in remote regions. Digital technology could be an option, but the evidence-based digital health intervention remains untapped.

Objective: To assess whether a group intervention by synchronous video call reduces the severity of female urinary incontinence symptoms and to assess woman's perception on this modality. **Methods:** Incontinent women who had digital access were invited to this semi-experimental study. An 8-week protocol was conducted through video calls once a week. Lifestyle counseling and exercises were performed. Pre- and post-evaluations were done exclusively by phone call.

Results: 48 women were enrolled in the study and 40 concluded the protocol. They were 56.5 ± 12.0 years old and most of them had mixed urinary incontinence. The impact on quality of life and the severity of urinary incontinence symptoms was significantly improved and most of the participants were completely satisfied with the intervention. A large effect size was observed (Glass's delta = 0.83)

Conclusion: Our findings support a digital group approach for the treatment of female

urinary incontinence as an alternative to be further explored. Combining digital service with group assistance brought satisfaction and clinical results for the participants and it can be promising for public health services.

Keywords: urinary incontinence; pelvic floor muscle training; telemonitoring.

Resumo

Introdução: A incontinência urinária acomete entre 15-40% das mulheres que vivem em áreas rurais no Brasil, evidenciando a necessidade de acesso a tratamentos adequados para indivíduos em regiões remotas. *Objetivo:* Avaliar se uma estratégia fisioterapêutica realizada em grupo e por vídeo-chamada síncrona pode reduzir a gravidade dos sintomas de incontinência urinária feminina, além de analisar a percepção das mulheres sobre essa modalidade. *Métodos:* Mulheres com queixa de incontinência urinária e que tinham acesso a recursos digitais foram convidadas a participar deste estudo semi-experimental. Um protocolo de 8 semanas foi conduzido através de videochamadas realizadas uma vez por semana, que incluíam aconselhamento sobre estilo de vida e treinamento dos músculos do assoalho pélvico. As avaliações pré e pós-tratamento foram realizadas exclusivamente por chamada telefônica. *Resultados:* 48 mulheres foram incluídas no estudo e 40 delas concluíram o protocolo. A idade média das participantes foi de $56,5 \pm 12,0$ anos e a maioria apresentou sintomas de incontinência urinária mista. Observou-se melhora significativa na qualidade de vida e na gravidade dos sintomas, e a maioria das participantes ficou completamente satisfeita com a intervenção. Além disso, um grande tamanho do efeito foi observado (delta de Glass = 0,83). *Conclusão:* Os presentes resultados apoiam a abordagem fisioterapêutica digital para o tratamento da incontinência urinária feminina como uma alternativa promissora a ser explorada. A combinação de serviços digitais com a assistência em grupo proporcionou satisfação e resultados clínicos para as participantes, o que pode ser uma estratégia eficaz para o tratamento dessa condição em serviços públicos de saúde.

Palavras-chave: incontinência urinária; treinamento dos músculos do assoalho pélvico; telemonitoramento.

Introduction

Urinary incontinence (UI) is the most common pelvic floor disorder (PFD) affecting approximately 26% of adult female population in developing countries [1]. In Brazil, the prevalence is also high [2-6], and studies have indicated that 15 to 40% of Brazilians in rural areas suffer from UI [7-9]. This highlights the necessity for establishing

treatment resources targeting populations in remote regions, within which telehealth emerges as a viable consideration.

Digital health practice has emerged as a potential solution to overcome all restrictive measures that were instituted during the Coronavirus Disease 2019 (COVID-19) pandemic [10]. Those technologies were on the sideline of most health care services, but even before the COVID-19 outbreak, the World Health Organization (WHO) had already talked about a Global Strategy on Digital Health to promote wellbeing and health care for everyone and everywhere [11]. Technology evolution has great potential to accelerate human progress and to enhance health outcomes, but the promotion of evidence-based digital health intervention remains largely untapped [11].

The International Continence Society (ICS) recommends that initial treatment for women with UI should include lifestyle education, bladder training and pelvic floor muscle training (PFMT) for eight to 12 weeks [12]. In addition to being able to be taught one-on-one, PFMT can also be practiced in groups as a lower cost alternative [13-16]. Also, according to recent systematic reviews, it is possible to adapt those intervention from a conventional face-to-face method to a digital basis and also get improvement in urinary symptoms, in pelvic floor muscle (PFM) function and on UI-related QoL [17,18].

Despite the promising results, the strategies are quite heterogeneous ranging from traditional communication methods such as phone calls, to more interactive and innovative approaches as video calls and smartphone applications [17,19]. However, synchronous supervision from the physiotherapist is not part of most of the protocols and usually they are delivered on an individual basis [17,18,20]. Combining supervised group care with digital practice could improve patients' accessibility and optimize service and cost savings in the assistance field.

Therefore, the purpose of this study was to assess whether a digital group physiotherapy intervention by synchronous video call could be developed in a public hospital as a strategy to reduce the severity of UI symptoms in females. Also, we aimed to evaluate the participants' perception on this modality of treatment.

Methods

This was a semi-experimental study following the TREND recommendations [21]. It was developed from December 2020 to April 2022, at Hospital de Clínicas de Porto Alegre (HCPA), a public teaching hospital in southern Brazil. The study was approved by the HCPA Ethics Committee (CAAE: 43638721.5.0000.5327 – registration number 4.977.180) and followed the Circular Letter of the National Commission for Research Ethics of the Ministry of Health about Guidelines for virtual research (Carta Circular

1/2021-CONEP/SECNS/MS). Recommendations for digital physiotherapy practices, provided by the Brazilian Federal Council of Physical Therapy and Occupational Therapy (COFFITO) [22] and by the Brazilian Association of Physical Therapy in Women's Health (ABRAFISM) [23,24], were carefully followed. During the pandemic, digital interventions have been supported by the COFFITO Resolution No 516 from March 2020.

Outcomes

The primary outcomes were the UI symptoms severity and the impact on quality of life (QoL) evaluated by the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) [25] and the secondary outcome was participants' perception on the treatment assessed through a custom survey.

Sample

In the mentioned period, patients who underwent a gynecological appointment complaining of UI and who had indication for conservative treatment were referred to pelvic floor physical therapy by the HCPA Gynecology Outpatient Clinic team. Women were prescreened by telephone to be informed about the intervention and to check for eligibility. Inclusion criteria were females with UI, ≥ 18 years and who had digital access to join a videocall weekly. Exclusion criteria were being in physiotherapeutic treatment or have undergone a rehabilitation program in the past 6 months. Medical records were checked to rule out conditions such as pelvic organ prolapse \geq grade 2, neurological diseases and abdominopelvic surgery/childbirth in the past year.

A pilot study was developed with eleven women to determine a proper sample to detect a four-point reduction in the ICIQ-SF, suggested as a clinically significant improvement for women undergoing non-surgical treatments for UI [26]. Those participants were not included in the main study. Power and Sample Size for Health Researchers (PSS Health) software - online version was used. Considering a power of 95%, a significance level of 5%, and adding 30% for possible losses, the sample size resulted in 20 participants.

Data collection

Participants received the Consent Form on WhatsApp messaging app. They were instructed to read it carefully and write back "I voluntarily agree to participate in this

study", if that was the case, to then be referred for the first evaluation. This method of consent was defined by the HCPA Ethics Committee.

Then, they underwent a prescheduled phone call to check for demographic data, UI symptoms and to answer the ICIQ-SF, which is a three-scored questions questionnaire concerning frequency, amount of leakage, and overall discomfort from 0-10. A fourth unscored question helps in classifying the UI subtype. The score grades from 0 to 21, with higher score indicating greater severity [25].

At the end of treatment, another phone call was scheduled to reassess UI symptoms and to reapply the ICIQ-SF questionnaire. Participants' perception on the treatment was assessed through a 7-question' custom satisfaction survey, adapted from Hui *et al.* [27], with answers on a scale from 0 to 10. The answers were categorized into groups, as it is shown in Table I.

Table I – Patients' perception of improvement (ver PDF)

Phone calls were performed by a student who was not involved in the videocalls so participants would feel comfortable giving their opinion. All data collection was carried out exclusively digitally due to the pandemic restrictions adopted at the time of data collection.

Intervention

WhatsApp groups with no more than 5 participants (plus one physiotherapist) were organized. Groups were created to enable a good communication between the participants and the researcher. Women received a reminder 30 minutes before every meeting to encourage adherence to treatment.

An 8-week digital group physical therapy intervention was done once a week, in a 30-minute synchronous video call, supervised by a physiotherapist with expertise in PFDs. All sessions started with a conversation about lifestyle habits (around 20 minutes), followed by exercises (around 10 minutes). A chatting space was stimulated, and women were encouraged to share their experiences and ask questions. For reference at home, all provided information was forwarded in digital files in the end of each meeting, according to what was discussed. The intervention' protocol is shown in Figure 1.

Figura 1 – Intervention protocol (ver PDF)

The exercise protocol was created based on Ferreira *et al.* [28] recommendations, having breathing and pelvic mobility exercises, PFMT and stretching exercises. Breathing exercises were based on inhaling through the nose and exhaling through the mouth, with awareness and concentration, in the lying, sitting, and standing posture. Pelvic mobility had lateral legs' movement in a lying position, pelvic ante/retroversion in a sitting position and pelvic circumduction and lateral mobility in a standing position. PFMT series consisted of slow and fast PFM contractions in lying, sitting, and standing, and executing a bridge, a sitting/standing exercise, and walking steps. Stretching of the spine and lower limbs were also performed. As well as lifestyle orientations, the exercise protocol was sent to the participants digitally.

To provide even better support, YouTube videos were uploaded in the WhatsApp groups after the first, second and last meeting. The first was about the PFM and its relationship to women's health, the second one was about basic PFMT exercises and the last one about advanced PFMT. These videos were created by our research group, in a previous study.

Analysis

Data were tabulated by the double-key entry method and analyzed in IBM® SPSS® Statistics. Normality of the data was defined by the Shapiro–Wilk test. Parametric quantitative data were expressed as mean and standard deviation and nonparametric as median and minimum and maximum. Comparisons was done through paired t tests and Wilcoxon tests, according to the normality of the data. Categorical variables were expressed as absolute and relative frequencies. The significance level was set at 5% for all analyses. The effect size for the ICIQ final score was calculated using Glass's delta:

$$\frac{\text{mean pre}-\text{mean post}}{\text{SDpre}}$$

and common language effect size [29]. To evaluate the participants' perception about the treatment, a frequency analysis was performed.

Results

One hundred and eleven women were referred to the Pelvic Floor Physiotherapy service in the meantime. Of these, 23 did not answer our phone calls and two were not

contacted because they had only pelvic organ prolapse and no urine leakage. From the 86 participants who were invited to participate in the study, 19 were excluded due to multiple reasons and after undergoing the first assessment, only 48 were enrolled in the intervention. Some women did not attend any session or withdrew along the protocol, being 40 included in the final analysis. The CONSORT flow diagram is shown in Figure 2.

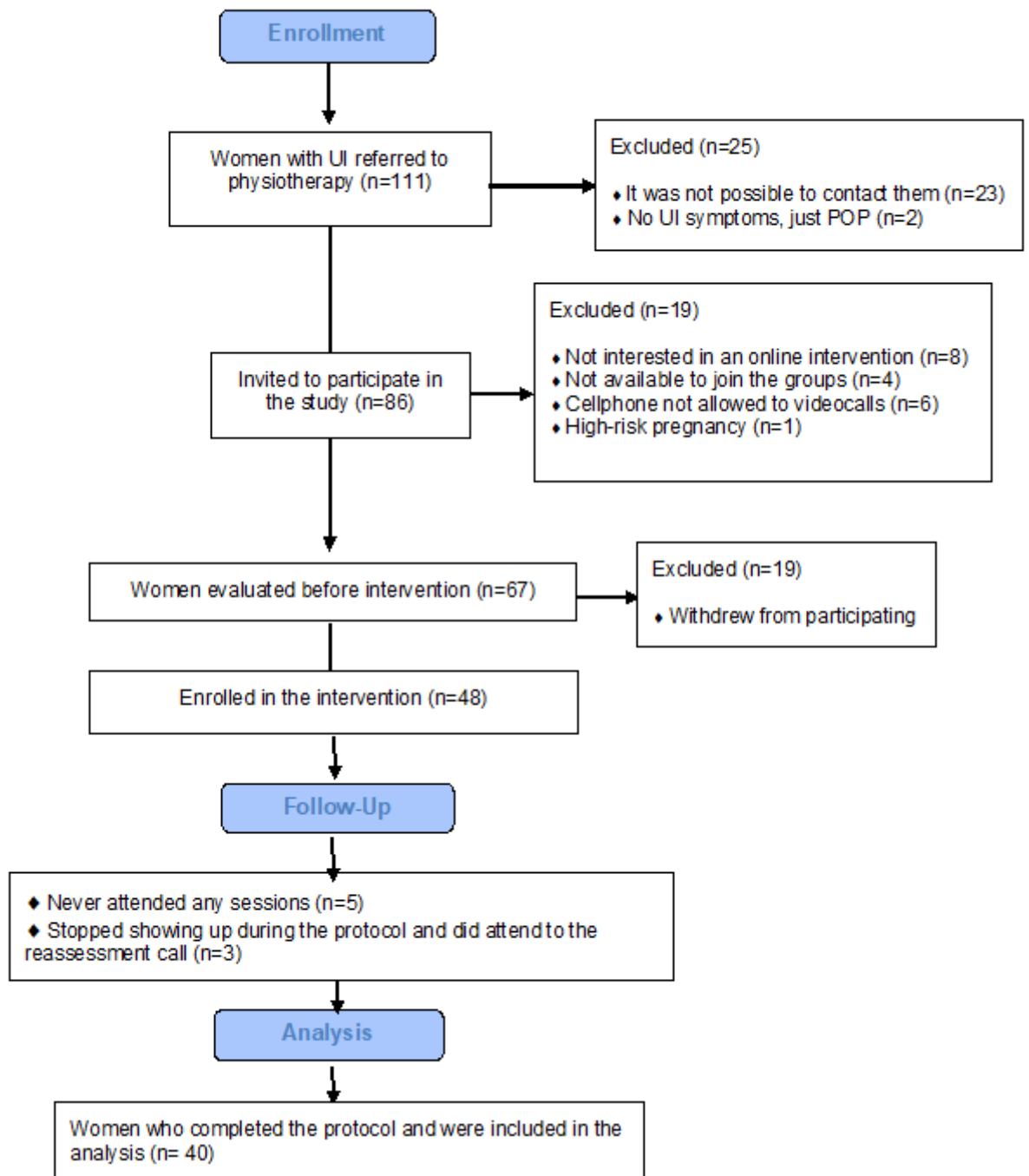


Figura 2 – Flowchart

The mean age was 56.5 years (± 12.0), the most prevalent subtype of UI was mixed UI (MUI) (57.5%) and there was a wide range on the duration of symptoms (from 3 months to 30 years). More than half of the sample did not live where the reference hospital of the study was located (57.5%). The characterization of the sample is demonstrated on Table II.

Tabela II – Characterization of the sample

Variables	Sample (n = 40)
Age (years) – mean(\pm SD)	56.5 (\pm 12.0)
Living location - n(%)	17 (42.5)
Same city where the reference hospital of the study was located	23 (57.5)
Other cities	
BMI (kg/m ²)* - mean(\pm SD)	29.5(\pm 6.5)
Parity - n(%)	
Nulliparous	1 (2.5)
Primiparous	3 (7.5)
Multiparous (2-3)	27 (57.5)
Multiparous (>3)	9 (32.5)
UI subtypes -n(%)	
SUI	11 (27.5)
UUI	5 (12.5)
MUI	23 (57.5)
Continuous urinary leakage	1 (2.5)
How long since the symptoms have started? (years) – median (min-max)	5.5 (0.25-30)

n = absolute frequency; SD = standard deviation; BMI = body mass index; UI = urinary incontinence; SUI = stress urinary incontinence; UUI = urgency urinary incontinence; MUI = mixed urinary incontinence. Parametric and nonparametric quantitative variables are presented as mean and standard deviation and median and minimum (min) and maximum (max) values respectively. Categorical variables are presented as total number and percentage. *Data available from 36 participants

The impact on QoL and the severity of the UI were significantly improved after the intervention (Table III). These two outcomes were evaluated by the ICIQ-SF third question and by the final score, respectively. The ICIQ-SF final score dropped from 14.5 ± 3.0 (a severe UI) [30] to 12.0 ± 5.0 (a moderate UI) [30]. Also, the effect size calculated by the Glass's delta formula was large for this variable (0.83) [31] and the common language resulted in 72.2% probability of superiority with the treatment [29], considering the ICIQ-SF final score.

Tabela III – Comparison between pre and post intervention regarding the impact on quality of life and the severity of UI symptoms

Variables	Pre-treatment (n=40)	Post-treatment (n=40)	p-value	Effect size
Impact on quality of life – median (min-max)	8.0 (4-10)	7.0 (0-10)	0.002 ^a	n/a
ICIQ-SF overall score - mean(\pm SD)	14.5 (\pm 3.0)	12.0 (\pm 5.0)	0.004 ^b	0.83 ^c

n = absolute frequency; ICIQ-SF = International Consultation on Incontinence Questionnaire = Short Form. Nonparametric quantitative variables are presented as median and minimum and maximum values and the parametric quantitative variables in mean and standard deviation. ^aWilcoxon test for quantitative non-parametric variables. ^bPaired-t test for quantitative parametric variables. ^cMeasure of effect size calculated by Glass's delta. Statistical significance was $p < 0.05$ for the analyses. The overall score ranges from 0 to 21, with greater values indicating increased severity of UI symptoms.

The impact on quality of life is assessed through question 5 of the questionnaire, with a score from 0 to 10 (greater values indicating worst impact)

About participants' perception on the treatment, 65% were completely satisfied, 25% were satisfied and 80% would strongly recommend the digital group for other people. The support materials were considered very useful and most of them (62.5%) followed all behavioral instructions exactly as recommended. The participants' perception questionnaire and the complete data are presented in Table I.

Discussion

Our findings support a digital group physical therapy intervention as an alternative to reduce UI severity and to improve QoL in women from a public health service. Self-reported satisfaction on this modality was also high, suggesting an alternative to enhance patients' access and content to UI health care, corroborating previous studies [20,27].

Digital strategies used on the management of UI are diverse [17,18,32] but, to our knowledge, this is the second study to propose a group video call intervention for UI and the first one to propose it for women in a public hospital. A randomized clinical trial comparing an 8-week intervention protocol through videoconferencing with face-to-face sessions was published in 2006 [27], showing a reduction in the number of daily incontinence episodes and improvement in PFM strength in both groups. A face-to-face first assessment was done, affording necessary guidance for the participants on PFM awareness. However, it was a completely different global health context, and the protocols were conducted by nurses and not by physiotherapists.

Our study was conducted in a period when vaccination wasn't fully widespread and the recommendations for social distancing were strong [33]. Proposing a remote service was an alternative to meet the waiting lists but performing it in a group was also a way to encourage socialization. Besides the social isolation context, a group intervention collaborates with the environment for learning by allowing real time interaction between patients and health-care professionals [27] and it has a significant difference in mean cost comparing to an individual treatment [14].

Paiva *et al.* [13] demonstrated in their metanalysis no difference when comparing PFMT in groups vs individual PFMT intervention. When comparing PFMT in groups vs PFMT at home, the group intervention was more efficient, probably due to physiotherapeutic supervision [15,34]. Poor patient compliance has been investigated in PFDs and assumptions converge with our thoughts regarding the lack of ongoing support [35]. Poor motivation, forgetting to perform the exercises, disinformation on PFM and UI were identified as impact factors [35,36]. Supervised and shared treatment with other

people can be a motivating factor and we do consider that the practices chosen in our protocol comprise a good part of these points.

PFMT has grade A recommendation by ICS, but beyond it, lifestyle interventions and bladder training are also highly recommended [12]. We made a strong use of these approaches proposing an even more complete assistance. Given the time that physiotherapists spend weekly with the patients, they contribute to patient's comprehension on behavioral practices. The same strategy was adopted by Santiago *et al.* [20] and a good adherence to behavioral measures and changes in the participants' lifestyle was seen.

As access to pelvic floor physiotherapists is not a reality everywhere, a digital program can be an alternative to manage UI in remote areas. In our study, more than half of the sample (57.5%) did not live in the same city where the reference hospital was located. The literature also provides data on high prevalence of UI in rural areas of Brazil [7-9]. To attend face-to-face appointments, these patients would have costs regarding transport and other expenses related to the time away from home, such as food. This approach may contribute to the choice of a low-cost intervention, especially in referral hospitals where patients from other locations are admitted.

Another interesting way of using digital health strategies in this context is the hybrid-telerehabilitation intervention proposed by Santiago *et al.* [20]. A randomized controlled trial was performed comparing a 12-week hybrid program versus a conventional face-to-face one. UI-related quality of life and UI severity significantly improved in both groups, highlighting the potential and diverse use of digital intervention in health care. A hybrid service can improve accessibility, without giving up on face-to-face appointments when necessary.

Some limitations in our study warrant mention. The design did not present a control group and a randomized sample. This small sample reflects the pandemic period when few elective appointments were being performed. Since face-to-face appointments were not allowed, a proper physical evaluation to check for pelvic floor awareness, and objective methods to quantify the severity of urine leakage, like a pad test, were missed.

However, despite the limitations, a digital physical therapy intervention to treat UI has been developed and we aim to keep studying it to ensure a more affordable form of treatment for women in the Unified Health System in Brazil. In 2020, 52.000 teleconsultations in different areas were performed at our hospital, increasing almost 30% in 2021 [37]. An important health strategy has emerged and can no longer be left behind, though further investigation is still required.

Conclusion

Our findings support a digital group physical therapy intervention for the treatment of female UI as an alternative to be further explored. UI affects thousands of women around the world and PFMT has strong evidence for UI treatment, so distance should not be a limiting factor.

Combining digital service accessibility with group assistance brought satisfaction and good clinical results for the participants, but it can also be promising for public health services as it does not require much physical space and absorbs greater demand in a shorter time. The COVID-19 pandemic has given a significant boost to the use of digital health, and more robust data through rigorous methods are necessary to consolidate these practices beyond the pandemic.

Conflicts of interest

The authors report no competing interests to declare.

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Authors' contribution

Research conception and design: Rodrigues MP, Paiva LL, Ramos JGL; Data collection: Rodrigues MP, Peterson BS; Data analysis and interpretation: Rodrigues MP, Mallmann S; Statistical analysis: Rodrigues MP, Mallmann S; Writing of the manuscript: Rodrigues MP, Mallmann S; Critical review of the manuscript for important intellectual content: Paiva LL, Ramos JGL.

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