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ORIGINAL ARTICLE

Use of a Mobile Application for Pelvic Floor Muscle Training in Women With Urinary Incontinence: a Randomized Control Trial

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Abstract

Introduction and hypothesis This study was aimed at evaluating the impact of a mobile app-guided pelvic floor muscle training (PFMT) program on urinary symptoms and quality of life in women suffering from urinary incontinence.

Methods The study included women with stress urinary incontinence (SUI), who underwent a structured interview and completed validated questionnaires, including the Questionnaire for Urinary Incontinence Diagnosis (QUID), the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), and the Incontinence Quality of Life Questionnaire (I-QOL). These women were randomly assigned to one of two groups: the app group, which received a visual depiction on the expected contraction pattern through a mobile app to support their PFMT exercises, and the control (paper) group. Both groups were instructed to perform PFMT exercises twice daily for 30 days. Data were collected at baseline and at 30, 60, 90, and 120 days after completing the exercises.

Results A total of 154 women participated, with 76 in the app group and 78 in the paper group. The mean ages were 61 (± 6.1) and 60.6 (± 6.8) in the app and paper groups respectively ($p = 0.644$). Both groups showed significant improvements in QUID SUI scores ($p < 0.001$), overactive bladder (OAB; $p < 0.001$), ICIQ-SF scores ($p < 0.001$), and quality-of-life scores ($p < 0.001$). When comparing the two groups, the app group exhibited a more substantial reduction in OAB ($p = 0.017$) as assessed by QUID and total ($p = 0.042$), psychosocial ($p = 0.032$) and social embarrassment ($p = 0.006$) I-QOL scores.

Conclusions The study findings suggest that PFMT guided by a mobile app with visual guidance leads to greater improvements in storage symptoms and quality of life than the home-based PFMT guidance.

Keywords Urinary incontinence · Pelvic floor muscle training · App · Adherence · Physiotherapy · Treatment

Introduction

According to the International Continence Society, "urinary incontinence" (UI) is defined as the involuntary loss of urine, which not only results in morbidity and mortality but also significantly impairs a patient´s quality of life, affecting physical, psychological, sexual, and social aspects [1].

Conservative treatment involving pelvic floor muscle training (PFMT) is considered the first-line approach for UI and has been shown to yield favorable outcomes. A systematic review demonstrated symptomatic improvement or cure of UI in 74% of cases with PFMT compared with only 11% in untreated women [2]. Some studies have explored the use of electromyographic biofeedback as an adjunct to PFMT. Biofeedback helps to assess muscle integrity and allows patients and physical therapists to observe correct pelvic floor muscle contraction and relaxation, facilitating neuromuscular learning or re-adaptation in the context of pelvic floor dysfunction [3]. Another systematic review has indicated the effectiveness of PFMT with biofeedback in treating UI [4].

Adherence to prescribed exercises is crucial for the success of PFMT [5]. However, several barriers to treatment exist, including the cost associated with frequent visits to physiotherapy services and the requirement for

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specialized physiotherapists to oversee the strengthening process, among others. The possibility of providing home-based treatment through mobile health technologies, which offer a structured sequence and frequency of exercises for PFMT, may benefit women who would otherwise need to travel to a health care facility for treatment. Our research group developed an app called Diário Saúde®, with visual guidance on the expected contraction pattern through a mobile app to support their PFMT exercises. Preliminary results were demonstrated in a randomized study with 21 women, and it showed that adherence was higher in the group that used the app. However, studies with a larger sample size and longer follow-up are needed. The objective of this study was to compare the adherence and effectiveness of visual guidance on the expected contraction pattern through a mobile app for the treatment of UI with exercise instructions provided on paper.

Materials and Methods

Trial Design

This was an open-label, parallel, randomized controlled clinical trial conducted at the Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas, Campinas, SP, Brazil, during the period from December 2018 to September 2020. Ethical approval for the study was obtained from the local institutional ethics committee of the State University of Campinas (CAAE: 578025160.0.0000.5404), and the trial was duly registered in the Brazilian Registry of Clinical Trials (REBEC) under registration number RBR-4HZ5VN. Prior to enrollment, written informed consent was obtained from all participants. The study adhered to the reporting guidelines outlined by Consolidated Standards of Reporting Trials [6].

Participants

We enrolled women aged 18 years and older who exhibited symptoms of stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) with a stress-dominant pattern, following the criteria defined by the International Continence Society [7]. An essential inclusion criterion was that participants owned an Android cell phone. Conversely, we excluded women displaying signs and symptoms of an active urinary tract infection, pelvic inflammatory disease, a total absence of pelvic floor muscle contraction (grade 0 according to the modified Oxford scale), or hypertonia, a history of prior pelvic floor surgery, gynecological cancer, ongoing pregnancy, postpartum status (less than 1 year after childbirth), usage of vaginal hormones, pelvic organ prolapse beyond stage II, and diabetes mellitus.

Procedures

Women from the surgical gynecology outpatient clinic of the Department of Gynecology and Obstetrics at the State University of Campinas, who had been diagnosed with UI and were recommended PFMT by a gynecologist, were invited to participate in the study. The women were evaluated by a physiotherapist who conducted the PERFECT examination (digital palpation) to assess pelvic floor muscle contraction capability. PERFECT, developed by Laycock and Jerwood [8], is an acronym outlining key components for assessing pelvic floor muscles. PERFECT stands for Power (or pressure, indicating strength measured with a manometric perineometer), Endurance, Repetitions, Fast contractions, and Every Contraction Timed. This scheme was designed to streamline and clarify the assessment of PFM. Power, representing the force of contraction, was validated through the examination of perineal lift and perineometric pressure during a maximum voluntary contraction.

After providing information about the study's objectives and obtaining signed consent forms from the participants, the women completed a questionnaire concerning socio-demographic, obstetric, and gynecological characteristics. Additionally, they responded to four questionnaires that had been validated in Portuguese: the Questionnaire for Urinary Incontinence Diagnosis (QUID), the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), the Incontinence Quality of Life Questionnaire (I-QOL), and the Female Sexual Function Index (FSFI) [9–12]. In the questionnaires used in this study, higher scores indicate more severe symptoms or impact, except in the FSFI questionnaire, where higher scores indicate better sexual health. The satisfaction was evaluated using a visual analog scale in which 0 signified completely unsatisfied and 10 signified completely satisfied. In addition, the patients responded to a Likert scale regarding their subjective impression of UI symptoms categorized as much worse, worse, the same, almost cured, and fully cured. SUI was defined by the sum of the scores from the first three questions of the QUID questionnaire. Each question was worth 5 points, resulting in a total score of 15 points. Similarly, overactive bladder (OAB) was defined by the sum of the remaining three questions of the QUID questionnaire, with a maximum score of 15.

Randomization

The sequence for randomization was generated using a computer program (the Uniform probability distribution function from SAS software version 9.4), employing a permuted block size of 10. Information regarding the

assigned treatment was enclosed within sealed opaque envelopes, each identified by a number. The random allocation sequence was managed by a single researcher who was responsible for concealing the allocation and was not involved in patient recruitment. This researcher assigned participants to either the PFMT-guided app mobile group (app) or the paper guide group (control). Data analysts were blinded to group allocation.

Intervention

App group

The app group utilized a dedicated app (Diário Saúde®), which was developed for this study and has been previously described by our research team [13]. In summary, the Diário Saúde® app was designed for conducting home-based exercises and included visual electromyography components to guide PFMT. The app was developed using the visual component of surface electromyography as a guiding tool for PFMT. It does not require the use of a vaginal probe and offers improved screen resolution. The app includes an alarm feature that reminds users to perform the exercises twice a day.

Women in this group were instructed to perform the exercises following the sequence displayed on their mobile phone screens. The app provided graphical representations of the intensity and duration of contractions required, accompanied by synchronized rhythmic music. Specifically, women were instructed to perform eight repetitions, with each contraction lasting 8 s, followed by 8 s of relaxation, and ending with three phasic contractions at the conclusion of each set [14]. This exercise protocol was based on the study conducted by Bo and colleagues [14].

Control (Paper) Group

The control group received written instructions detailing the same PFMT protocol as the app group, but without the dynamic sequence of PFMT images. The written instructions included images guiding the execution of the exercises, but it was not a dynamic video with music created exclusively for the app, guiding the rhythm of the exercises.

Follow-Up

Both groups were instructed to perform PFMT exercises twice daily for a duration of 30 days. Women in both groups were scheduled for follow-up appointments at 30, 60, 90, and 120 days after commencing PFMT. During these appointments, the participants completed the same initial assessment questionnaires and responded to the following question: "How do you feel about your symptoms today? Would you say you are cured, almost cured, better, the same, or worse?" [13].

Outcomes

The primary objective of this study was to compare the scores of urinary symptoms assessed by QUID and ICIQ-SF questionnaires for UI before and after a physiotherapy program using a mobile app and paper. As secondary outcomes, we compared the scores of the quality-of-life (I-QOL) and sexual-function questionnaire (FSFI), as well as the assessment of pelvic floor muscle function through a physical examination.

Statistical Analysis

For this study, we opted for a convenience sample. To describe the sample profile according to the variables under study, we generated frequency tables for categorical variables (race, hypertension, etc.) with absolute frequency (n) and percentages (%). For numerical variables, we provided descriptive statistics, including mean, standard deviation, minimum and maximum values, median, and quartiles. To compare categorical variables, we employed the Chi-squared test or Fisher's exact test (for expected values less than 5). o compare numerical variables, the Mann–Whitney test was utilized owing to the absence of a normal distribution. Variables without a normal distribution were transformed into ranks.

For the comparison of numerical variables between the two groups and the five assessments simultaneously, repeated measures analysis of variance (ANOVA) was employed, followed by Tukey tests (intergroup comparisons) and profile contrast tests (intragroup comparisons). Variables without a normal distribution were transformed into ranks.

Considering that the loss to follow-up may have occurred because the treatment was not beneficial, the statistical analysis was carried out using the baseline carried forward (BCF) method. All dropouts were treated as failures, and their values were imputed with baseline values for analysis. In the ANOVA analysis, p value 1 is designated as a measure of the time effect, gauging the impact of time on the dependent variable. A p value of 2 is dedicated to assessing the group effect, delving into the influence of group membership on the dependent variable and a p value of 3 scrutinizes the interaction effect

(time × group), signifying a comprehensive examination of how time and group collectively influence the dependent variable. The interaction effect observed implies a noteworthy divergence in the relationship between time and the dependent variable across different groups. The significance level for all statistical tests was set at 5%, i.e., $p < 0.05$.

Results

A total of 154 women participated in the study, with 76 in the app group and 78 in the paper group. The participant flowchart is presented in Fig. 1. Sociodemographic characteristics of the participants are detailed in Table 1. The average age of participants was 61 ± 6.1 years in the app group and 60.6 ± 6.8 years in the paper group. No significant differences were observed in body mass index ($p = 0.650$), ethnicity ($p = 0.078$), parity ($p = 0.614$), smoking status ($p = 0.854$), baseline SUI scores assessed by QUID ($p = 0.062$), or by ICIQ-SF ($p = 0.807$) between the two groups. However, the baseline OAB scores were higher in the app group (9.9 ± 3.2) than in the paper group (5.2 ± 3.1, $p < 0.001$). Quality-of-life scores were higher in the paper group (48.1 ± 21.5) than in the app group (53.3 ± 21, $p = 0.005$; Table 1).

Significant differences were observed between baseline and final assessments, with improvements in SUI scores ($p < 0.001$) and OAB ($p < 0.001$) assessed by QUID total, ICIQ-SF score ($p < 0.001$), and quality-of-life score ($p < 0.001$) in both the app and the paper groups (Fig. 2). When comparing the two groups, there was a greater reduction in OAB ($p = 0.005$) assessed by QUID in the app group and no significant difference in the SUI scores assessed by the QUID and ICIQ-SF questionnaire. There was improvement in all domains of PERFECT, which includes power, endurance, repetition, and fast, in both study groups, but with no difference between them (Table 2).

Additionally, there was an improvement in the quality of life in both groups ($p < 0.001$), with superior improvement in the app group in the psychosocial ($p = 0.032$), social embarrassment ($p = 0.006$), and total score ($p = 0.042$) of the I-QOL questionnaire (Table 2). Regarding treatment

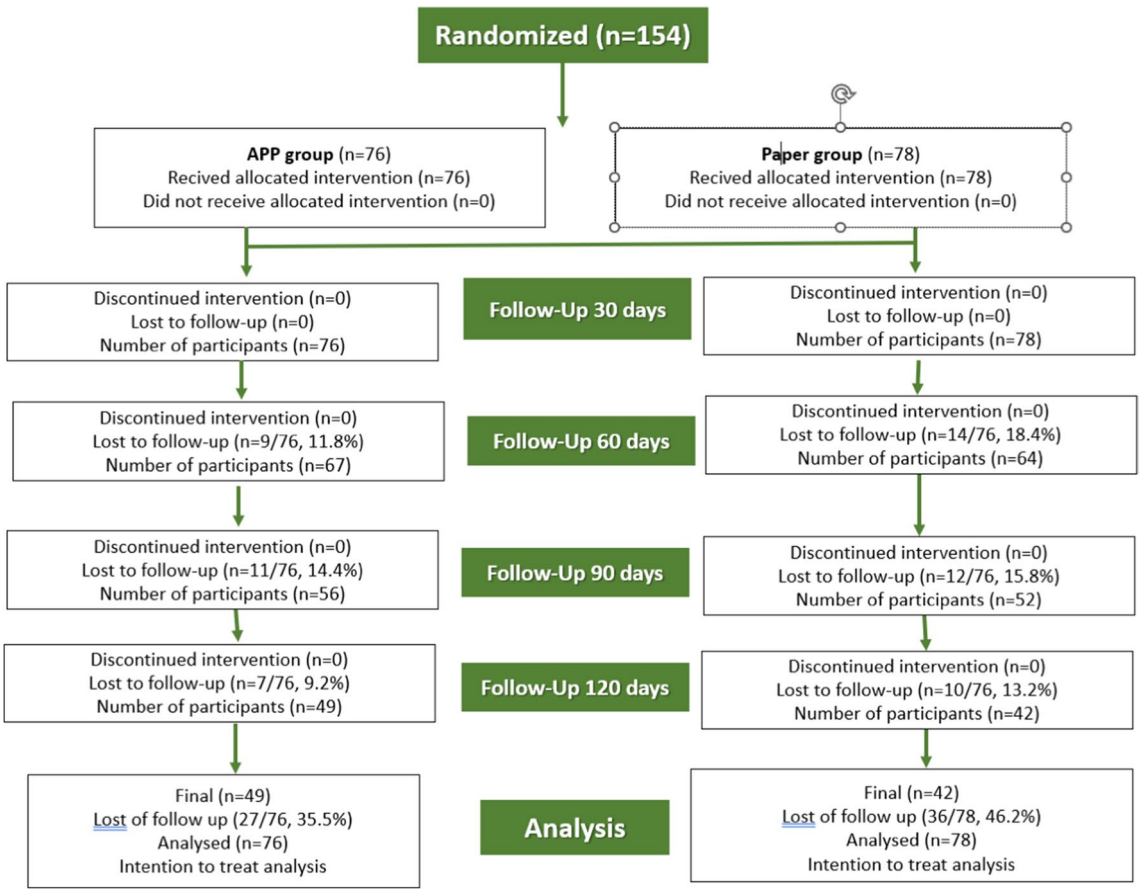

Fig. 1 Flow chart of the participants with stress urinary incontinence

Table 1 Baseline sociodemographic, obstetric, and clinical characteristics of the 156 women with stress urinary incontinence included in the study

Characteristics	App group ($n=76$)	Paper group ($n=78$)	p value
Age, years (±SD)	61 (6.1)	60.6 (6.8)	0.644*
Ethnicity, *n* (%)			
White	52 (68.4)	63 (80.8)	0.078**
Black or mixed race	24 (31.6)	15 (19.2)	
BMI, mean (±SD)	28.2 (4.7)	27.4 (4.9)	0.65*
Smoking, *n* (%)	9 (11.8)	10 (12.8)	0.854*
Parity, mean (±SD)	1.5 (1.6)	2.3 (1.3)	0.614*
Marital status			
With partner	30 (39.5)	39 (30)	0.189**
QUID basal mean (±DP)			
Total			
SUI	9.7 (±3)	8.9 (±3.6)	0.06*
OAB	6.3 (±3.1)	5.2 (±3.1)	0.003*
ICIQ-SF	3.2 (±1.1)	3.3 (±1)	0.807*
FSFI			
Desire	2.5 (±1.3)	2.7 (±1.4)	0.369*
Arousal	2.2 (±1.7)	2.4 (±1.8)	0.467*
Lubrification	2.6 (±2)	2.5 (±2)	0.903*
Orgasm	2.4 (±1.9)	2.5 (±2)	0.772*
Satisfaction	2.7 (±1.6)	3.1 (±1.8)	0.150*
Pain	2.8 (±2.3)	2.9 (±2.4)	0.800*
Total	15.4 (±9)	16.2 (±10.5)	0.493*
I-QOL	43 (21.5)	53.3 (±21)	0.005*

SD standard deviation, *BMI* body mass index, *QUID* Questionnaire for Urinary Incontinence Diagnosis, *SUI* stress urinary incontinence, *OAB* overactive bladder, *ICIQ-SF* International Consultation on Incontinence Questionnaire — Short Form, *FSFI* Female Sexual Function Index, *I-QOL* Incontinence Quality of Life Questionnaire

*Mann–Whitney *U* test

**Chi-squared test

satisfaction, as assessed by the visual analog scale (VAS) (0–10), the app group reported a satisfaction score of 6.9 (±2.5), whereas the paper group reported a score of 7.7 (±2.5) ($p=0.109$). After treatment, approximately half of the women reported feeling almost cured of UI symptoms, with 25 (51%) in the app group and 20 (47%) in the paper group, and no difference between the groups ($p=0.961$). There was also no difference in the results for "worse," "the same," and "cured" (Table 3).

Discussion

Our study demonstrated a significant improvement in urinary, sexual, and quality-of-life symptoms among women with symptoms of SUI following a 30-day treatment period using either a mobile app-based physiotherapy program or paper-based instructions. Notably, the improvement in urinary symptoms, as assessed by the QUID questionnaire, was significantly greater in the app-based group.

Stress urinary incontinence is a prevalent condition that substantially impacts the quality of life of affected women. Although physiotherapy represents the primary treatment modality, long-term adherence remains challenging [2, 5]. Adherence is the logistical challenge faced by many women in attending frequent physiotherapy sessions. The adoption of a mobile app could serve as a convenient alternative to traditional care approaches. A similar study to ours, focused on the treatment of UI symptoms and quality of life, demonstrated that app-based treatment for women with stress, urgency, and mixed UI could serve as an effective alternative to conventional care in general practice. After 12 months, both treatments resulted in clinically significant improvements in primary outcome measures [15], similar to our 4-month follow-up results.

However, despite the app used in this study enhancing motivation through reminders and participants showing increased engagement, adherence remained a significant challenge. The pandemic exerted a notable influence on

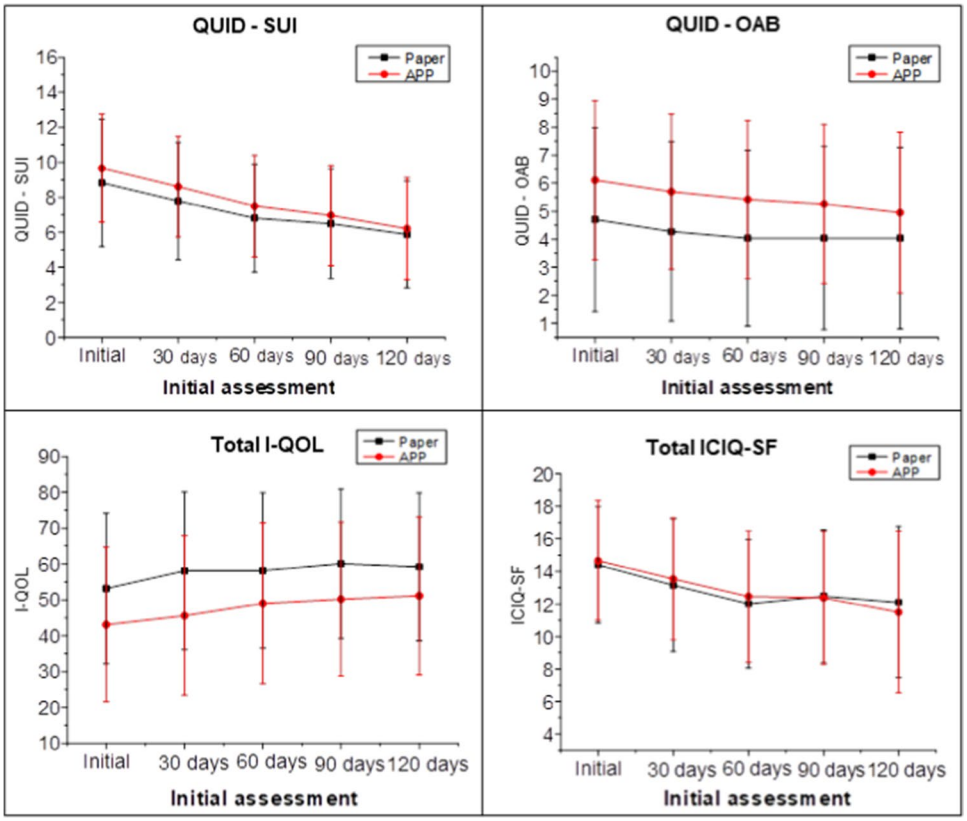

Fig. 2 Scores of urinary symptoms and quality-of-life questionnaires in the two groups and at four follow-up times. *QUID* Questionnaire for Urinary Incontinence Diagnosis, *SUI* stress urinary incontinence, *I-QOL* Incontinence Quality of Life Questionnaire, *ICIQ-SF* International Consultation on Incontinence Questionnaire—Short Form

the study, yet it cannot entirely account for the 46% attrition in the paper group and 35% in the app group before reaching the study endpoint. These findings underscore the difficulty women face in adhering to a pelvic floor exercise program and sustaining it over the long term. This raises questions about the true impact of first-line treatment for women with SUI.

Our results align with those of a previously published randomized non-inferiority trial, specifically regarding lower urinary tract symptom and OAB outcomes. In both groups, there was a noteworthy enhancement in scores based on the International Consultation on Incontinence Lower Urinary Tract Symptoms questionnaire. Notably, no statistically significant differences were observed between the "usual care" approach, which encompassed various interventions, and the UI app group. In the app group, participants demonstrated a mean improvement of −2.16 points (SD 2.56) in the ICIQ-SF questionnaire [16]. Another study also demonstrated improvements in SUI symptoms (11.5 to 7.6, mean difference 4.0, 95% CI 3.2–4.7) [17]. Our study failed to demonstrate improvement in ICIQ-SF symptoms over the 4-month follow-up period.

Furthermore, the growing interest in health apps is underscored by the widespread use of smartphones worldwide. Additionally, conservative treatment involving PFMT requires time, adherence, motivation, and often incurs high costs. Multiple studies have highlighted the cost-effectiveness of health apps [18–20]. This heightened interest further emphasizes the potential value of health apps.

Our results also demonstrated a significant impact on OAB symptoms. Few studies have evaluated the use of apps in women with OAB symptoms. One study included 102 women with OAB or MUI symptoms and showed an improvement in OAB scores (ICIQ-OAB improved from 6.7 to 5.5, mean difference 1.3, 95% CI 0.9–1.6). Although our study did not employ the ICIQ-OAB questionnaire, we observed an improvement in QUID OAB scores, from 6.1 (±2.8) to 4.9 (±2.9) points, indicating that app-based training also has an impact on OAB symptoms [16].

Despite the benefits demonstrated, it is important to note that many PFMT apps available in app stores exhibit credential issues. Specifically, a significant portion (70%, $n = 14$ out of 20) of these apps were developed by unknown sources, raising concerns about their safety, particularly when prescribed for pregnant women. Safety considerations are increasingly emphasized in the quality standards of mHealth apps [21]. In contrast, the Diário Saúde® app, utilized in this study, was developed by a multidisciplinary team comprising gynecologists, urogynecologists, and women's health specialists. Notably, the innovative visual feature of the app enhances exercise comprehension and adherence.

Table 2 Urinary symptoms, sexual symptoms, quality of life, and evaluation of the perineal musculature before and after treatment with app-guided or paper-based instructions

	App group					Paper group							
	Basal	Follow-up				Basal	Follow-up						
Variable (mean ± SD)		1 month	2 months	3 months	Final (4 months)		1 month	2 months	3 months	Final (4 months)	p1	p2	p3
QUID													
SUI	9.7 (3.1)	8.6 (2.9)	7.8 (2.9)	7.6 (3)	7.2 (3.3)	8.8 (3.6)	7.8 (3.4)	7.1 (3)	7.2 (3.3)	7 (3.2)	0.188	< 0.001[a]	0.043[a]
OAB	6.1 (2.8)	5.7 (2.8)	5.6 (2.8)	5.5 (2.8)	5.2 (2.9)	4.7 (3.3)	4.3 (3.2)	4.1 (3.1)	4.3 (3.4)	4.4 (3.4)	0.003[b]	< 0.001[b]	0.005[b]
ICIQ-SF													
Question 1	3.2 (1.2)	3.1 (1.2)	2.8 (1.1)	2.7 (1.2)	2.6 (1.3)	3.3 (1)	3.2 (1)	2.9 (0.9)	2.8 (0.9)	2.7 (1.3)	0.464	< 0.001[c]	0.586
Question 2	3.2 (1)	2.9 (0.9)	2.8 (0.9)	2.7 (0.8)	2.6 (1.0)	3 (1)	2.7 (0.9)	2.5 (0.7)	2.6 (0.8)	2.5 (1)	0.121	< 0.001[d]	0.503
Question 3	8.3 (2.3)	7.5 (2.5)	6.9(265)	7 (2.6)	6.3 (3.1)	8.1 (2.4)	7.3 (2.8)	6.6 (3)	7.1 (2.8)	6.9(2.9)	0.913	< 0.001[e]	0.293
Total	14.7 (3.7)	13.5 (3.8)	12.5 (4)	12.4 (4.1)	11.5 (5)	14.4 (3.6)	13.2 (4.1)	12 (4)	12.5 (4.1)	12.1 (4.7)	0.873	< 0.001[f]	0.147
I-QOL													
Total	43.1 (21.5)	45.6 (22.2)	49 (22.4)	50.1 (21.5)	51.2 (22)	53.1 (21)	58.1 (21)	58.2 (21.7)	60 (20.9)	59.2 (20.7)	0.005[g]	< 0.001[g]	0.042[g]
Urinary incontinence	43.9 (22.9)	46.9 (24.1)	50.3 (21.5)	51.4 (22)	52.5(22.6)	49.7 (23)	54.4 (24.5)	54.2 (23.9)	57.1 (21.1)	56.1 (21.5)	0.172	< 0.001[h]	0.121
Psychosocial	51.7 (25.5)	54.6 (23.3)	51.4 (22.3)	58.1 (25.7)	59 (26)	64.1 (23.2)	69.9 (24.1)	69.8 (24.1)	70.7 (22.5)	69.1 (21.6)	0.001[i]	< 0.001[i]	0.032[i]
Social embarrassment	26.2 (20.4)	27.6 (20.4)	33.3 (21.3)	33.8 (21.3)	34.8 (22.8)	38.8 (24.1)	43.4 (24.2)	43.4 (24.3)	45.6 (26.4)	46.3 (26.2)	0.001[j]	< 0.001[j]	0.006
FSFI													
Desire	2.5 (1.3)	2.7 (1.3)	2.8 (1.4)	2.7 (1.4)	3.1 (1.1.5)	2.7 (1.4)	2.7 (1.4)	2.8 (1.4)	2.8 (1.5)	3.1 (1.5)	0.819	< 0.001[k]	0.117
Arousal	2.2 (1.7)	2.4 (1.8)	2.3 (1.8)	2.4 (1.8)	2.5 (1.9)	2.4 (1.8)	2.6 (1.9)	2.7 (2)	2.7 (2)	2.8 (2)	0.355	< 0.001[l]	0.317
Lubrification	2.6 (2)	2.6 (2)	2.6 (2)	2.7 (2)	2.7 (2.1)	2.5 (2)	2.6 (2)	2.7 (2.1)	2.6 (2.1)	2.7 (2.2)	0.967	< 0.001[m]	0.614
Orgasm	2.4 (1.9)	2.5 (2)	2.5 (2)	2.4 (2)	2.6 (2.1)	2.5 (2)	2.6 (2)	2.7 (2.1)	2.6 (2.1)	2.8 (2.1)	0.571	< 0.001[n]	0.213
Satisfaction	2.7 (1.6)	2.8 (1.6)	2.8 (1.6)	2.8 (1.6)	3 (1.7)	3.1 (1.8)	3.2 (1.8)	3.3 (1.9)	3.3 (1.9)	3.4 (1.8)	0.139	< 0.001[o]	0.513
Pain	2.8 (2.3)	2.8 (2.3)	2.8 (2.4)	2.8 (2.3)	2.9 (2.4)	2.9 (2.4)	3 (2.4)	3 (2.5)	3 (2.5)	3.2 (2.4)	0.588	0.151	0.181
Total	15.4 (9)	15.8 (9.4)	15.4 (9)	15.8 (9.3)	16.8 (10)	16.2 (10.5)	16.6 (10.6)	17.1 (11.3)	16.9 (11.1)	17.9 (11.1)	0.468	< 0.001[p]	0.509
PERFECT													
Power	2.2 (0.3)	2.1 (0.3)	2.2 (0.4)	2.5 (0.5)	2.3 (0.6)	2.1 (0.4)	2.1 (0.3)	2.2 (0.4)	2.4 (0.6)	2.3 (0.6)	0.309	< 0.001[q]	0.544
Endurance	2.3 (0.7)	2.7 (0.8)	2.9 (0.9)	2.9 (0.8)	3.1 (1.4)	2.1 (0.8)	2.6 (0.8)	2.7 (0.9)	2.6 (0.9)	3.1 (1.4)	0.139	< 0.001[r]	0.346
Repetition	1.9 (0.6)	2.6 (0.8)	3 (1)	2.7 (1)	2.4 (1.0)	1.8 (0.7)	2.5 (0.8)	2.8 (1.1)	2.7 (1.1)	2.4 (01)	0.364	< 0.001[s]	0.671
Fast	1.8 (0.8)	3.4 (1)	3.6 (1.3)	3.1 (1.3)	2.8 (1.3)	1.8 (0.8)	3.2 (1.1)	3.4 (1.4)	3.1 (1.4)	2.8 (1.3)	0.530	< 0.001[t]	0.580

SD standard deviation, *SUI* stress urinary incontinence, *OAB* overactive bladder, *QUID* Questionnaire for Urinary Incontinence Diagnosis, *ICIQ–SF* International Consultation on Incontinence Questionnaire—Short Form, *FSFI* Female Sexual Function Index, *I-QOL* Incontinence Quality of Life Questionnaire, *ANOVA p1* comparison between groups, *p2* comparison between assessments, *p3* group and time interaction

[a]Significant interaction effect of groups versus times: significant differences between groups (Tukey test): t0: $p = 0.041$ (app ≠ paper); t30: $p = 0.070$; t60: $p = 0.175$; t90: $p = 0.480$; t120: $p = 0.763$; significant differences between times (profile contrast test): t0 ≠ (t30, t60, t90, t120), t30 ≠ (t60, t90, t120), t60 ≠ t120, t90 ≠ t120 in the app group; t0 ≠ (t30, t60, t90, t120), t30 ≠ (t60, t90, t120) in the paper group

[b]Significant interaction effect of groups versus times: significant differences between groups (Tukey test): t0: $p = 0.002$ (app ≠ paper); t30: $p < 0.001$ (app ≠ paper); t60: $p < 0.001$ (app ≠ paper);

Table 2 (continued)

t90: $p=0.008$ (app≠paper); t120: $p=0.041$ (app≠paper); significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠t120, t60≠t120, t90≠t120 in the app group; t0≠(t30, t60, t90, t120) in the paper group

[c]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120), t60≠t90 in the app group; t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120) in the paper group

[d]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120) in the app group; t0≠(t30, t60, t90, t120), t30≠t60, t60≠t90 in the paper group

[e]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120), t90≠t120 in the app group; t0≠(t30, t60, t90, t120), t30≠t60 in the paper group

[f]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120), t90≠t120 in the app group; t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120) in the paper group

[g]Significant interaction effect of groups versus times: significant differences between groups (Tukey test): t0: $p=0.008$ (app≠paper); t30: $p<0.001$ (app≠paper); t60: $p=0.013$ (app≠paper); t90: $p=0.006$ (app≠paper); t120: $p=0.026$ (app≠paper); significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120) in the app group; t0≠(t30, t60, t90, t120), t30≠t90, t60≠t90 in the paper group

[h]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120) in the app group; t0≠(t30, t60, t90, t120), t60≠t90 in the paper group

[i]Significant interaction effect of groups versus times: significant differences between groups (Tukey test): t0: $p=0.002$ (app≠paper); t30: $p<0.001$ (app≠paper); t60: $p=0.001$ (app≠paper); t90: $p=0.002$ (app≠paper); t120: $p=0.019$ (app≠paper); significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t90, t120), t60≠t120 in the app group; t0≠(t30, t60, t90, t120) in the paper group

[j]Significant differences between groups (Tukey test): t0: $p<0.001$ (app≠paper); t30: $p<0.001$ (app≠paper); t60: $p=0.009$ (app≠paper); t90: $p=0.006$ (app≠paper); t120: $p=0.004$ (app≠paper); significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t60, t90, t120) in the app group; t0≠(t30, t60, t90, t120), t30≠(t90, t120) in the paper group

[k]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠t120, t60≠t120, t90≠t120 in the app group; t0≠t120, t30≠t120, t60≠t120, t90≠t120 in the paper group

[l]Significant differences between times (profile contrast test): t0≠(t30, t90, t120) in the app group; t0≠(t30, t60, t90, t120), t30≠(t60, t120), t60≠t90 in the paper group

[m]Significant differences between times (profile contrast test): no difference in the app group; t0≠(t30, t60, t90, t120), t30≠t120 in the paper group

[n]Significant differences between times (profile contrast test): no difference in the app group; t0≠(t30, t60, t90, t120), t30≠(t60, t120) in the paper group

[o]Significant differences between times (profile contrast test): t0≠(t30, t120), t30≠t60, t60≠t120 in the app group; t0≠(t60, t120), t30≠t120 in the paper group

[p]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠t120, t60≠t120, t90≠t120 in the app group; t0≠(t30, t60, t90, t120), t30≠(t60, t120), t90≠t120 in the paper group

[q]Significant differences between times (profile contrast test): t0≠(t60, t90, t120), t30≠(t60, t90, t120), t60≠(t90, t120) in the app group; t0≠(t90, t120), t30≠(t90, t120), t60≠(t90, t120), t90≠t120 in the paper group

[r]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t90, t120), t60≠t120, t90≠t120 in the app group; t0≠(t30, t60, t90, t120), t30≠t120, t90≠t120 in the paper group

[s]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠t60, t60≠(t90, t120) in the app group; t0≠(t30, t60, t90, t120), t30≠t60, t60≠t120, t90≠t120 in the paper group

[t]Significant differences between times (profile contrast test): t0≠(t30, t60, t90, t120), t30≠(t90, t120), t60≠(t90, t120), t90≠t120 in the app group; t0≠(t30, t60, t90, t120), t30≠t120, t60≠(t90, t120), t90≠t120 in the paper group

Table 3 Subjective impression of women with urinary incontinence after home treatment with pelvic floor muscle training guided by an app or paper instructions

Subjective impression)	App group, *n* (%)	Paper group, *n* (%)	*p**
Worse	5 (10.2)	4 (9.52)	0.961
The same	15 (30.6)	13 (31)	
Almost cured	25 (51)	20 (47)	
Cured	4 (8.1)	5 (11.9)	

*Fisher's exact test

The Diário Saúde® app possesses unique features that distinguish it from other apps adhering to mHealth quality standards. The Diário Saúde® app stands out because of its innovative use of visual electromyography, lack of a vaginal probe requirement, enhanced screen resolution, alarm feature, dynamic exercise sequences, and adherence to a scientifically supported exercise protocol. These features collectively contribute to its uniqueness in comparison with other apps following mHealth quality standards.

As strengths of our study, it is noteworthy that our research design incorporated an RCT framework with an adequately calculated sample size, following consort reporting guidelines, and an appropriately registered trial. To enable meaningful comparisons and draw conclusions related to the app, all participants received instructions for the same exercise protocol. Furthermore, the Diário Saúde® app was developed based on scientific evidence and clinical experience.

A limitation of the study was the relatively brief follow-up period, spanning only 120 days for participant monitoring. In addition, there was a significant drop in patient follow-up. Given the possibility that follow-up losses could stem from a lack of treatment efficacy, the statistical analysis employed the Baseline Carried Forward method. In this approach, all dropouts were treated as failures, and their values were imputed with baseline values for the purpose of analysis. However, it is important to note that we employed a convenience sample size, and the 120-day follow-up period could be perceived as relatively brief, largely influenced by the constraints imposed by the COVID-19 pandemic. Additionally, the app was designed exclusively for Android smartphones.

To validate and build upon these promising findings, future randomized clinical trials with longer follow-up periods are warranted. These trials will help to consolidate the role of mobile app-based interventions as an effective and accessible approach to managing SUI and related conditions, potentially transforming the landscape of women's health care.

In conclusion, our study has provided valuable insights into the management of SUI among women, highlighting the potential of mobile app-based interventions as a promising avenue for treatment. We observed significant improvements in urinary, sexual, and overall quality-of-life symptoms in women with SUI following a 4-month treatment period, whether through a mobile app-based physiotherapy program or paper-based instructions. Importantly, the app-based group exhibited a notably greater improvement in urinary symptoms, as indicated by the QUID questionnaire. Additionally, our findings extend to OAB symptoms, demonstrating a significant impact of app-based training on OAB symptom scores. Although few studies have explored app-based interventions for women with OAB symptoms, our results indicate their potential in improving this aspect of women's health.

Authors' Contributions C.C. de Araujo: project development, data collection, manuscript writing; L.G.O. Brito: data analysis, manuscript writing; A.A. Marques: project development, manuscript writing; C.R.T. Juliato: project development, data analysis, manuscript writing.

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Data Availability The data from this study are available in the data repository of the Universidade Estadual de Campinas.

Declarations

Conflicts of Interest None.

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