



Assessment of the pelvic floor exercises with iPelvis[®] app. for treatment of women with urinary incontinence: a randomized controlled trial

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ABSTRACT

Objective: To analyze the effectiveness of an application iPelvis[®] “app” for pelvic floor exercises, alone and associated with physiotherapy, in reducing urinary symptoms and improving the quality of life of incontinent women.

Materials and Methods: This is a longitudinal randomized controlled clinical trial study. The Kings Health Questionnaire (KHQ) and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) were used as outcome measurements. The participants were divided into four groups: application + physiotherapy (AP + PHYSIO); home exercise sheet + physiotherapy (P + PHYSIO); only application (AP); only home exercise sheet (P).

Results: From the 138 women who were evaluated, 77 (who presented a mean age of 48.31 years) completed the proposed treatments. In the KHQ domains and overall scores, the only ones who presented significant difference between groups were: the General Health Perception (P + PHYSIO higher than P, $p=0.008$), Social Limitations (P + PHYSIO higher than AP, $p=0.04$; P higher than AP, $p=0.05$) and Part I Score (P + PHYSIO higher than P, $p=0.04$). The analysis of the ICIQ-SF showed P + PHYSIO higher than P ($p=0.01$). Between the other groups there were no significant differences. The other nine variables analysed no significant differences in all groups.

Conclusion: The use of the application alone and associated with physiotherapy, produces better resulted in reducing urinary symptoms and improving the quality of life of incontinent women, in most variables, but it is not significantly superior in related to the other groups.

Keywords: Applications; iPelvis[®] app. exercise; pelvic floor; quality of life; urinary incontinence

INTRODUCTION

Pelvic floor dysfunctions are health problems that negatively impact the quality of life of hundreds of thousands of women worldwide.¹ Urinary incontinence (UI), in particular, has a variable prevalence of 13.1% to 70.9% in different populations.²

Currently, the first-line therapy for UI is pelvic floor muscle training (PFMT), which is level one evidence and grade A recommendation,³ indicated by the International Consultation on Incontinence (ICI).^{2,4} A recent review by Cochrane confirms that PFMT is effective in curing or improving symptoms of stress urinary incontinence (SUI) and improving quality of life.⁵ Despite

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this, there is no consensus on the literature on the administration of this therapy, i.e., if it should be performed by a professional or self-administered.⁶

It is known that the success of PFMT depends on the understanding of the commands given by the therapist and their incorporation into the patient's daily activities.⁷ Because of this, one important aspect that should be taken into account when dealing with unsupervised PFMT is adherence, that is defined as "the degree to which a person correctly follows the medical or health professional advice".⁸

With the increased availability of smartphones, the number of applications is growing widely, offering new possibilities for health care provision. Although these applications "apps" are considered capable of increasing adherence to medical treatments, only few have proven their effectiveness in scientific studies.⁹

The PFMT available by the chosen application, follow the protocol developed by Bo et al.¹⁰ and is represented in five stages, respecting the chronological order of motor learning.¹¹⁻¹³ Its differential is the creation of a playful, friendly and encouraging character, who acts as the facilitator in the learning process.¹¹

The objectives of this study are: to analyze the effectiveness, of an application for pelvic floor exercises, alone and associated with physiotherapy, in reducing urinary symptoms and improving the quality of life of incontinent women.

MATERIALS AND METHODS

This is a longitudinal, randomized, controlled clinical trial with four parallel groups (1:2) developed in the facilities of Faculdade Inspirar, in Curitiba, Paraná, south of Brazil. We recruited women with stress (SUI), urgency urinary incontinence (UUI), and mixed urinary incontinence (MUI), aged between 18 and 59 years, and with objective demonstration of urinary loss.

We searched for female volunteers in two environments. First, participants were recruited from lists of patients waiting for surgery at the Hospital de Clínicas of the Federal University of Paraná (HC-UFPR). Also, urologists and gynecologists, who work both at HC-UFPR and in their private practices, indicated patients followed in private outpatient clinics who would fit the study. This criterion was important so that there would be no difference in the medical conduct.

Excluded were: pregnant women, women up to six months postpartum, women with prolapse equal or greater than Stage III according to the Pelvic Organ Prolapse - Quantification (POP-Q),¹⁴ with urinary infection, with intrapelvic tumors, with pelvic pain that prevented the performance of the available therapies or who had undergone pelvic surgery in a period shorter than six

months, and carriers of pacemakers or intrauterine devices. In addition, participants who missed physical therapy twice in a row were also excluded.

Before performing the evaluation and treatment procedures, each volunteer was informed about the objectives of the study and signed the Informed Consent Form. The research project was approved by the Research Ethics Committee of Faculdade Inspirar, AX – Centro de Estudos da Saúde LTDA. – EPP (opinion number 1,833,987); as well as by the Co-participant Institution, HC-UFPR – Hospital de Clínicas of Federal University of Paraná (opinion number 2,520,073). The study was registered at ClinicalTrials.gov ID: NCT04484753.

The initial evaluation was performed as described in the Clinical Practice Guide of the Brazilian Association of Pelvic Physiotherapy (ABFP), translated from the guide updated and recently published guide of the Royal Dutch Society for Physical Therapy.^{15,16} In addition to this evaluation we also applied and analyzed the results from the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF),^{17,18} and Kings Health Questionnaire (KHQ).¹⁹

Other ramifications of our research have the functions of pelvic floor muscles as object. Therefore, all participants underwent a physical examination, among other assessment instruments. Due to the fact that about 30% of women are unable to perform contraction only through verbal commands, and that the performance of the inverted maneuver or simultaneous contraction of muscles such as the gluteus, hip adductors and abdominal muscles are very common,²⁰ all women who presented any difficulty received instruction along with vaginal pelvic floor examination.

After the initial evaluations, each participant went through a drawing to define their participation groups. The groups received the following interventions, without modifications during the research period: application + physiotherapy group (AP + PHYSIO): performed 12 pelvic physiotherapy sessions, in group, once a week and received the iPelvis® Application with PFMT guidelines to be performed at home; home exercise sheet + physiotherapy group (P + PHYSIO): they did 12 Pelvic Physiotherapy sessions, in group, once a week and received a sheet with PFMT guidelines to be performed at home; application "app" only group (AP): received the iPelvis® Application with PFMT guidelines to be performed at home; home exercise sheet only/control group (P): received a sheet with PFMT guidelines to be performed at home. After 3 months all participants were re-evaluated. Many of the women waiting for surgery at HC-UFPR had low financial conditions, hence we offered to cover their transportation costs in order to enable their access to the appointments. The division of the groups is shown in Figure 1.

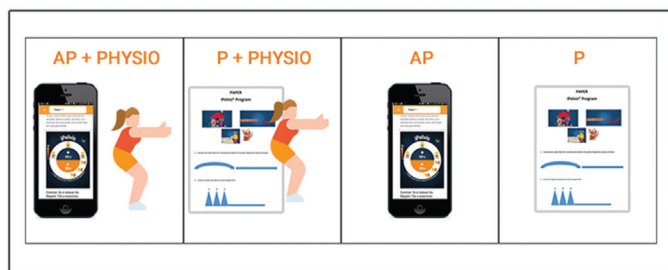


Figure 1. Division of the groups

Source: The Author (2020). AP + PHYSIO: application + physiotherapy; P + PHYSIO: home exercise sheet + physiotherapy; AP: only application; P: only home exercise sheet

The randomization scheme was carried out by a member of the research team, who placed balls with different colors in a box, each one representing one of the intervention groups. Each volunteer took a ball out of the box and from there she was directed to the corresponding group. Initially, groups with physiotherapy (AP + PHYSIO and P + PHYSIO) were allocated, and, after completing these groups, a sequence was given to randomize the groups AP and P. In order to reduce the number of losses of volunteers in the AP and P groups, the answers of the questionnaires from those who could not attend the face-to-face re-evaluation were collected through telephone.

The volunteers drawn for the groups with applications “apps” (AP + PHYSIO and AP), but who did not have a compatible cell phone for their installation, were redirected to the groups with a sheet: from the AP + PHYSIO group they went to the P + PHYSIO group and, from the AP group went to the P group. This was done so that we would not be left with a very small sample and so that the volunteers would have the opportunity to receive intervention.

The team of researchers presented the iPelvis® application to the AP + PHYSIO and AP groups, as well as instructed its installation on the cell phone of each participant, who then received a password. A blocking system was created in order to disable the use of the application in other devices, thus individualizing the system. During the development of the study, the available version of the iPelvis® Application was 1.0, which included 6 phases that lasted 15 days each, totaling 3 months. The P + PHYSIO and P groups received an exercise sheet that contained exactly the same training instructions and life hygiene tips offered by the iPelvis® application.

In the application there are dynamic exercises with sound and image that show how many times each exercise should be performed, the level of strength, and how many seconds to contract and relax the pelvic floor, as shown in Figure 2. The exercises performed in Physiotherapy sessions were the same as those offered within the application and on the exercise sheet.



Figure 2. Example of PFMT in the iPelvis® application

Source: iPelvis® application

PFMT pelvic floor muscle training

Primary outcomes

The primary outcome measures were defined through the ICIQ-SF (a validated Portuguese translation), a tool that assesses the impact of UI on the quality of life and severity of urinary symptoms. The questionnaire is composed of four questions related to frequency, severity of urinary loss and its impact on quality of life.^{17,18} The ICIQ score is the sum of the scores from questions three, four and five and ranges from 0 to 21. The impact on quality of life was defined according to the score of question 5: (0) none; (1-3) mild; (4-6) moderate; (7-9) severe; (10) very severe.²¹

Secondary outcomes

The secondary outcomes measure is KHQ, a questionnaire that analyzes the presence of UI symptoms and their impact on various aspects of individuality in quality of life. The questionnaire is composed of 30 questions subdivided into nine domains and a Symptom Severity scale.¹⁹ According to Hebbbar et al.²², KHQ has three Parts Overall Scores: Part 1 Score contains general health perception and incontinence impact domains; Part 2 Score contains role limitations, physical limitations, social limitations, personal relationships, emotions, sleep and energy and severity measures domains; Part 3 Score is considered as a single item where in there are 10 different bladder symptoms. The domains scored between 0 (best) and 100 (worst). The Symptom Severity scale is scored from 0 (best) to 30 (worst).²²

Sample size

The required sample size of 139 women was calculated taking into consideration the world’s female population (3,704,194,620, coutrymeter.com) when the study was conducted, a sampling error of 5% at a 95% confidence level, and a minimum prevalence

of 10% of both urinary and sexual dysfunction. The calculation performed was for prevalence analysis, disregarding the size of the clinically significant effect for the two instruments used.

Statistical analysis

The chi-square test of independence was used to analyze the homogeneity of the groups regarding anthropometric and sociodemographic factors. For age and body mass index, the Snedecor test was used.

The Wilcoxon test for paired data was used to verify whether there were differences between the pre- and post-intervention moments in the ICIQ-SF, KHQ domains and Overall Scores of Parts I, II and III. Analysis of Variance (ANOVA) was used to identify possible effects of the groups under the difference of the means of pre- and post-intervention across ICIQ-SF, all the KHQ domains and Overall Scores of Parts I, II and III. For those

variables where there was a significant difference, the Tukey test was applied to identify which groups were significantly different from each other. Statistical analyses were performed using the R software. A significance level of 95% was used ($p < 0.05$).

RESULTS

A total of 685 phone calls were made to invite women to participate in this study, from which 177 appointments were scheduled, but only 138 women attended the evaluations that occurred between January 2017 and April 2018. The volunteers evaluated were randomized among the four treatment groups, as shown in Figure 3.

Of the 138 randomized volunteers, 77 completed the treatment and entered the statistical analysis. According to the ICIQ score, 27.3% had mild UI (21/77), 25.9% moderate UI (20/77), 18.2% severe UI (14/77), and 28.6% very severe UI (22/77).

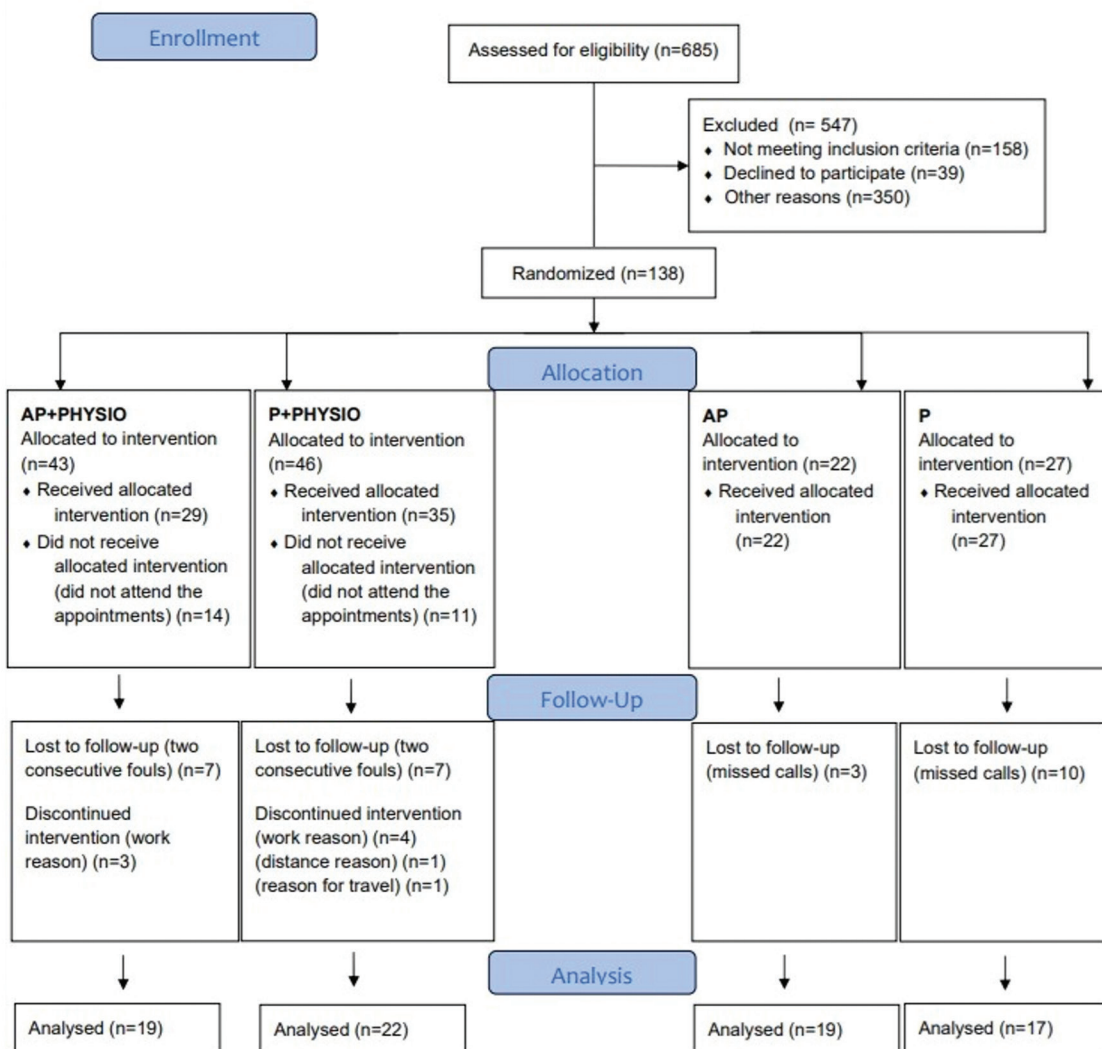


Figure 3. Flow diagram of the study

AP + PHYSIO: application + physiotherapy; P + PHYSIO: home exercise sheet + physiotherapy; AP: only application; P: only home exercise sheet; n: Number

The anthropometric and sociodemographic characteristics of the 77 participants who completed the treatments are shown in Table 1.

Primary outcomes

In the follow-up, AP + PHYSIO, P + PHYSIO and AP groups reported statistically significant reduction in urinary symptoms: (mean reduction in ICIQ-SF score: -4.42 (± 4.4); -5.5 (± 3.96) and -3.63 (± 3.95), respectively), while group P did not present a statistically significant reduction (mean reduction in the ICIQ-SF score): -0.64 (± 5.79). The Analysis of Variance showed significant differences between the mean differences of at least two groups, with $p=0.01$. Tukey's test was performed to identify the

significantly different groups. A significant difference was found between the mean differences of the groups P + PHYSIO and P, with $p=0.01$. The other differences were not significant (Table 2).

Secondary outcomes

The Analysis of Variance demonstrated significant differences between the mean differences of at least two groups in the following KHQ domains and Overall Scores: General Health Perception (P + PHYSIO higher than P, $p=0.008$), Social Limitations (P + PHYSIO higher than AP, $p=0.04$; P higher than AP, $p=0.05$) and Part I Score (P + PHYSIO higher than P, $p=0.04$). The other differences were not significant. The other domains and Parts did not present significant differences between the groups (Table 3).

Table 1 – Baseline demographic and clinical characteristics.

		AP + PHYSIO (19)	P + PHYSIO (22)	AP (19)	P (17)	p-value
Age	Average	46.73	51.4	45.84	48.82	0.11
	Standard deviation	9.01	6.62	6.26	9.4	
BMI	Average	26.63	28.47	27.51	28.14	0.57
	Standard deviation	3.75	5.12	4.77	3.55	
Type of incontinence	SUI	12 (63%)	6 (27%)	10 (52%)	5 (29%)	0.07
	UUI	0	0	1 (5%)	2 (11%)	
	MUI	7 (36%)	16 (72%)	8 (42%)	10 (58%)	
Marital status	Married	13 (68%)	15 (68%)	11 (57%)	9 (52%)	0.70
	Separated	3 (15%)	4 (18%)	6 (31%)	3 (17%)	
	Single	1 (5%)	2 (9%)	2 (10%)	4 (23%)	
	Widowed	2 (10%)	1 (4%)	0	1 (5%)	
Ethnicity	Caucasoid	19 (100%)	21 (95%)	18 (94%)	15 (88%)	0.31
	Mongoloid	0	0	1 (5%)	2 (11%)	
	Negroids	0	1 (4%)	0	0	
Schooling	1 to 5 years	1 (5%)	5 (27%)	0	0	0.003*
	6 to 10 years	10 (52%)	12 (54%)	4 (21%)	7 (41%)	
	>10 years	8 (42%)	5 (22%)	15 (78%)	10 (58%)	
Income	<2	7 (36%)	13 (59%)	3 (15%)	5 (29%)	0.08
	3 to 4	4 (21%)	3 (13%)	4 (21%)	7 (41%)	
	5 to 6	6 (31%)	6 (27%)	8 (42%)	5 (29%)	
	>6	2 (10%)	0	4 (21%)	0	
Urinary infection (last year)	Yes	9 (47%)	4 (18%)	7 (36%)	7 (41%)	0.22
Smoking	Yes	0	1 (4%)	4 (41%)	1 (5%)	**
Alcoholism	Yes	10 (52%)	3 (13%)	11 (57%)	4 (23%)	0.04*
Sedentarism	Yes	12 (63%)	14 (63%)	9 (47%)	13 (76%)	0.35

*p-value <0.05, rejecting the hypothesis of independence between the groups and the variables schooling and ethylism; ** The low frequency of smokers volunteers made it impossible to perform the test of homogeneity; BMI: body mass index; SUI: stress urinary incontinence; MUI: mixed urinary incontinence; urgency urinary incontinence

Table 2. Primary outcomes measures baseline and at the 3-month follow-up.

Primary outcome	Treatment group	Baseline (SD)	3-month follow-up (SD)	Difference (SD)	Within group p-value (Wilcoxon)	Between groups p-value (ANOVA)	Different groups (Tukey)
ICIQ-SF score	AP + PHYSIO	10.68 (5.37)	6.26 (3.75)	-4.42 (4.14)	0.0009*	0.01*	P and P + PHYSIO (p=0.01)
	P + PHYSIO	13.09 (4.81)	7.59 (4.43)	-5.5 (3.96)	0.00006*		
	AP	9.89 (5.01)	6.26 (6.14)	-3.63 (3.95)	0.001*		
	P	11.82 (5.41)	11.17 (6.18)	-0.64 (5.79)	0.71		

*p-value <0,05; ICIQ-SF: International Consultation on Incontinence Questionnaire - Short Form; SD: standard deviation; ANOVA: Analysis of Variance;

DISCUSSION

Since the first contact with the volunteers, we noticed their anguish and their desire for a fast and resolute treatment due to the fact that many of the women invited to participate in this study were waiting for a surgical procedure and were not considering PFMT as a treatment option. We observed this situation in the analysis of the number of volunteers who attended the initial assessment, but did not initiate the appointments and follow-up with the physiotherapy groups, claiming that they preferred to wait for surgery (32% in the AP + PHYSIO group, 14/43; and 23% in the P + PHYSIO group, 11/46).

Those who participated in the research had the opportunity not only to learn about a new form of treatment, but also to improve their quality of life. However, some of them reported difficulty to be absent from work, which was the main reason for quitting the attendance in physiotherapy groups (7% in the AP + PHYSIO group, 3/43; and 8.7% in the P + PHYSIO group, 04/46).

Sjöström et al.²³ reported a loss of 12% in 4 months and 38% after two years of follow-up,²⁴ while in our study we observed a loss, including withdrawals and exclusions, of 44%. We believe that the difference is due to the presence of two face-to-face groups in our study, while the Sjöström study did not have any.

Regarding anthropometric and sociodemographic characteristics, we obtained homogeneity in the great majority of variables between groups, except for schooling. P and AP groups had a higher number of participants with more than 10 schooling years, while AP + PHYSIO and P + PHYSIO groups had more participants with low schooling. Despite these differences, the literature describes that the educational level does not seem to affect the ability to learn or perform correct pelvic floor muscle contractions,²⁵ and does not have association with success in treatment with PFMT.²⁶ However, the groups can be considered homogeneous regarding income (p=0.08), assuming that not necessarily a higher income indicates a higher education.

The KHQ analysis was performed individually for each of the nine domains and three Parts Overall Scores. The first domain with differences between groups was General Health Perception.

All groups showed significant improvement before and after treatment, except the P group. The only significant difference was between the groups P and P + PHYSIO (p=0.008), that is, there is no significant difference between the P + PHYSIO and AP + PHYSIO or AP groups, all of which improve General Health Perception. These data lead us to consider that the use of the application alone or as an aid to Pelvic Physiotherapist promotes improvement of General Health Perception, while only the home exercise sheet with instructions without the physiotherapist's intervention does not produce significant differences.

Social limitations decreased significantly in the AP + PHYSIO, P + PHYSIO and P groups. The AP group was the only one without significant difference. The groups that were significantly superior were P + PHYSIO and P in relation to the AP (p=0.04 and p=0.05, respectively). In this domain, women were asked about their social limitations or meetings with friends resulting from to their bladder problem. It was noticed that the AP group had the lowest initial average in relation to the other groups. Possibly a more careful strategy regarding randomization could present different results.

In the Part I Overall Score all groups showed significant improvement before and after treatment, except the P group. The only significant difference was between the groups P and P + PHYSIO (p=0.04); that is, there is no significant difference between the P + PHYSIO and AP + PHYSIO or AP groups, all of which improve. The other seven domains (incontinence impact, role limitations, physical limitations, personal relationships, emotions, sleep/energy and severity), Parts II and III did not present significant differences between the groups. In general, except group P in Part I, all groups showed improved quality of life, demonstrating that the application is a good option for treating female UI.

Sjöström et al.^{23,24} in 2013 and 2015 conducted a study on women with SUI based on PFMT. Two hundred and fifty volunteers were treated, 124 in the internet group and 126 in the postal group. They also studied quality of life with ICIQ-LUTSqOL. In their study they found short- and long-term significant life quality

Table 3. Secondary outcomes measures baseline and at the 3-month follow-up

Secondary outcomes (KHQ domains)	Treatment group	Baseline (SD)	3-month follow-up (SD)	Difference (SD)	Within group p-value (Wilcoxon)	Between groups p-value (ANOVA)	Different groups (Tukey)
General health perception	AP + PHYSIO	18.42 (16.3)	10.52 (15.2)	-7.89 (11.9)	0.01*	0.01*	P and P + PHYSIO (p=0.008)
	P + PHYSIO	36.27 (22.8)	21.59 (20.8)	-14.77 (16.7)	0.002*		
	AP	27.63 (14.2)	21.05 (17.2)	-6.57 (11.3)	0.03*		
	P	26.47 (28.6)	29.41 (28.3)	2.94 (24.8)	0.66		
Incontinence impact	AP + PHYSIO	47.36 (35.7)	14.03 (25.6)	-33.3 (33.3)	0.002*	0.2	No significant differences
	P + PHYSIO	68.18 (33.3)	39.39 (31.9)	-28.3 (31.4)	0.001*		
	AP	56.13 (33.4)	31.57 (34.2)	-24.6 (21.8)	0.001*		
	P	56.86 (25.7)	43.13 (25.7)	-13.7 (23.7)	0.08		
Role limitations	AP + PHYSIO	30.7 (32.5)	11.4 (17.6)	-19.29 (22.4)	0.005*	0.16	No significant differences
	P + PHYSIO	49.24 (35.4)	25 (30.3)	-24.24 (21.7)	0.0004*		
	AP	32.45 (34)	25.43 (33)	-7.01 (14)	0.09		
	P	54.9 (37.6)	35.29 (31.1)	-19.6 (37.8)	0.05*		
Physical limitations	AP + PHYSIO	36.84 (29.7)	15.79 (14.1)	-21.05 (25.4)	0.004*	0.13	No significant differences
	P + PHYSIO	52.27 (26.9)	27.27 (26)	-25 (23.4)	0.0004*		
	AP	36.84 (32.7)	27.19 (34.3)	-9.64 (19.5)	0.06		
	P	60.78 (38.2)	33.33 (25.7)	-27.44 (30.6)	0.005*		
Social limitations	AP + PHYSIO	22.81 (31.3)	3.22 (8.5)	-19.59 (28.7)	0.014*	0.026*	AP and P + PHYSIO (p=0.04); AP and P (p=0.05)
	P + PHYSIO	39.65 (32.7)	18.18 (25.1)	-21.46 (26.6)	0.003*		
	AP	12.57 (14.7)	11.4 (13.8)	-1.17 (3.5)	0.371		
	P	40.85 (38.4)	18.63 (18.1)	-22.22 (28.4)	0.008*		
Personal relationships	AP + PHYSIO	27.27 (33.6)	6.67 (14.0)	-12.28 (30.3)	0.223	0.071	No significant differences
	P + PHYSIO	56.25 (27.8)	28.12 (36.4)	-20.45 (30.8)	0.014*		
	AP	35.19 (41.2)	27.78 (33.3)	-3.51 (11.9)	0.371		
	P	42.86 (36.2)	23.8 (33.1)	-25.49 (27.7)	0.097		
Emotions	AP + PHYSIO	36.84 (29.4)	24.56 (25.5)	-12.28 (32.1)	0.22	0.13	No significant differences
	P + PHYSIO	60.6 (30.8)	32.32 (29.3)	-28.28 (21.6)	0.00005*		
	AP	27.48 (22.9)	16.37 (21.7)	-11.11 (12.8)	0.007*		
	P	49.01 (40.6)	36.6 (31.4)	-12.41 (37.9)	0.13		
Sleep/Energy	AP + PHYSIO	42.1 (25.7)	18.42 (19.2)	-23.68 (22.4)	0.001*	0.57	No significant differences
	P + PHYSIO	46.21 (26.7)	28.03 (23.8)	-18.18 (17.7)	0.0009*		
	AP	31.57 (24.1)	19.29 (25)	-12.28 (20.7)	0.02*		
	P	49.99 (36.8)	31.37 (25.6)	-18.62 (36.7)	0.09		
Severity	AP + PHYSIO	56.14 (26.1)	25.96 (17.2)	-30.17 (20)	0.0003*	0.48	No significant differences
	P + PHYSIO	66.66 (21.8)	42.72 (30.1)	-23.94 (19.6)	0.0002*		
	AP	45.96 (22.3)	24.56 (26.1)	-21.4 (19.4)	0.001*		
	P	62.35 (29)	42.35 (24)	-19.99 (26.6)	0.011*		
Part I	AP + PHYSIO	32.9 (21.4)	12.3 (14.6)	-20.6 (18.9)	0.001*	0.04*	P and P + PHYSIO (p=0.040)
	P + PHYSIO	52.3 (22.7)	30.5 (22.2)	-21.8 (20.2)	<0.001*		
	AP	41.9 (20.3)	26.3 (22.9)	-15.6 (12.6)	0.001*		
	P	41.7 (24.2)	36.3 (26.1)	-5.4 (21.7)	0.247		

Part II	AP + PHYSIO	36.31 (21.2)	15.77 (10.8)	-14.76 (18.4)	0.0003*	0.108	No significant differences
	P + PHYSIO	51.97 (23.8)	28.51 (23.5)	-22.06 (13.5)	0.0000005*		
	AP	30.84 (19.1)	20.21 (20.8)	-7.62 (9.3)	0.0007*		
	P	50.8 (31.69)	31.63 (21.9)	-17.3 (24.3)	0.003*		
Part III	AP + PHYSIO	9.21 (5.1)	4.26 (4.2)	-4.95 (4.7)	0.001*	0.241	No significant differences
	P + PHYSIO	12.82 (5.5)	7 (6.3)	-5.82 (5.4)	0.0004*		
	AP	8.58 (6.5)	5.63 (5.3)	-2.95 (3.4)	0.002*		
	P	12.94 (7.0)	7.88 (6.0)	-5.06 (4.1)	0.0006*		

*p-value <0,05; KHQ: Kings Health Questionnaire; SD: standard deviation; ANOVA: Analysis of Variance; AP + PHYSIO: application + physiotherapy; P + PHYSIO: home exercise sheet + physiotherapy; AP: only application; P: only home exercise sheet

improvements in both groups, but no differences between them. In our study, we also did not find significant differences between the application and home exercise sheet groups, but we noticed some superiority of the groups with pelvic physiotherapy. In congruence with the literature, we highlight the possibility of using the application as another work tool option with good results, even better when associated with the work of an expert.

Also, in the study of Sjöström et al.^{23,24} in 2013 and 2015, the participants were questioned about the use of incontinence absorption materials. They observed a significant reduction in both groups, internet and postal, but with superiority of the Internet group ($p=0.02$). In this study, the use of cloths was questioned in the “Severity Measures” domain of KHQ and all groups showed significant improvement between the pre- and post-intervention periods, without significant differences between the groups.

Asklund et al.²⁷ performed in 2016 an PFMT-based study of 123 women with SUI, in which 62 received an application and 61 had their treatment postponed. They also studied quality of life with ICIQ-LUTSQoL. As a result, they found a mean score reduction of 4.8 points in the application group and 0.7 in the control group, with the application group being significantly better than the control group. The groups were also significantly different regarding the use of strategies for coping with incontinence ($p=0.023$).²⁷ Despite significant differences, the main limitation of the aforementioned study was to not compare the results with other active or proven treatment. In our study, expectations regarding treatment, weight change and self-rated improvement of pelvic floor muscle strength were significantly associated with a successful outcome of SUI treatment with the application aid.²⁶

Also, the analysis of ICIQ-SF in our study was performed by questioning the participants on how often and how much they lose urine, as well as how this loss interferes with their daily lives. The groups that showed statistically significant difference were AP + PHYSIO, P + PHYSIO and AP. The only group without significant difference was P. A significant difference was observed

between the groups P + PHYSIO and P ($p=0.01$), that is, there is no significant difference between the P + PHYSIO and AP + PHYSIO or AP groups, all of which improve urinary symptoms. We noticed that the application alone or as an aid to the pelvic Physiotherapist is capable of improving women’s bladder weakness symptoms, and that only a home exercise sheet with instructions does not promote such improvement.

Sjöström et al.²³ in 2013 obtained as primary results in ICIQ-SF, pre- and post-intervention, mean differences in the internet group of -3.4, and in the postal group of -2.9. After two years of follow-up, Sjöström et al.²⁴ in 2015 published mean differences in the internet group of -3.5 and the postal group of -3.4, demonstrating that the two programs produce significant improvement in urinary symptoms, but present no significant differences between themselves in the short or long term. In the study by Asklund et al.²⁷ in 2016, a mean score reduction of -3.9 points was found in the application group and -0.9 in the control group. Bokne et al.²⁸ in 2019 described mean differences in the internet group of -3.4 and the postal group of -2.6. In our study, similar results were found for the AP group (-3.63).

The ICI recommends supervised training.⁴ The positive results obtained in groups with Pelvic Physiotherapy in our study corroborate the evidences, suggesting that the application is a good tool option for incontinent women when guided by a specialist, proving to be as effective as current treatments. In addition, according with the studies published so far, applications are instruments of easy access to the patient and that present a positive cost-benefit ratio.^{29,30}

In our study, when used alone, analyzing the differences between groups, the application was significantly inferior to the exercise sheet in just one domain of the KHQ (social limitations).

Moreover, exercise sheet alone showed significantly inferior in the primary outcome the ICIQ-SF, General Health Perception and Part I Score of the KHQ, while the application alone was statistically significant. An adequately powered randomized controlled study comparing the application only with the home

exercise sheet only may shed some more light on any superiority in results between stand-alone intervention. This is important because, so far, about ninety percent of women with UI do not have any supervised treatment. Next to this, the comparison between the application as a stand-alone intervention and the application additional to supervised physiotherapy, again adequately powered, is of great interest related to home maintenance programs and adherence. Finally, we suggest future research with a larger sample in each group and greater segmentation of age of women to investigate whether or not younger populations have better acceptance of using the application.

CONCLUSION

New versions of the iPelvis® Application have been launched and other studies are in progress, with the main objective of improving the applicability and adherence of patients to PFMT.

The application, alone or associated with pelvic physiotherapy, improves urinary symptoms and quality of life for incontinent women, in most variables, but it is not significantly superior in related to the other groups. The groups that underwent physiotherapy presented better results to the groups that underwent only application or only home exercise sheet.

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The creators of the iPelvis® Application were Maura Regina Seleme and Claudia Veloso Mueller. Currently the developers of the new versions are Maura Regina Seleme and Bary Berghmans.

Contributions

Concept: C.E.F.B., R.D.F., M.R.S., Data Collection or Processing: C.E.F.B., R.D.F., M.R.S., Analysis or Interpretation: C.E.F.B., R.D.F., M.R.S., B.B., Literature Search: C.E.F.B., R.D.F., M.R.S., B.B., Writing: C.E.F.B., R.D.F., M.R.S., B.B.

Ethics

Ethics Committee Approval: The research project was approved by the Research Ethics Committee of Faculdade Inspirar, AX – Centro de Estudos da Saúde LTDA. – EPP (opinion number 1,833,987); as well as by the Co-participant Institution, HC-UFPR – Hospital de Clínicas of Federal University of Paraná (opinion number 2,520,073). The study was registered at ClinicalTrials.gov ID: NCT04484753.

Informed Consent: Before performing the evaluation and treatment procedures, each volunteer was informed about the objectives of the study and signed the Informed Consent Form.

Peer-review: Internally peer-reviewed.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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Editor's comment

Applications are now introduced to help with the management of health issues. They have a special role, mainly in these times of periodic lock-downs, making the regular appointments with health care providers difficult to resume. The significance of the treatment of urinary incontinence is known to the readers of this Journal. Still, we asked Dr. Andrea Ambrosetti of the Centro Italiano Studio e Sviluppo Psicoterapia a Breve Termine (CISSPAT) Associazione Italiana Sessuologia e Psicologia Applicata (AISPA), to write a discussion elaborating on that issue.

Professor Jacob Bornstein, Editor in Chief, Pelviperineology

Invited Discussion

Given the continuous development of the interaction between human relations and the smartphone, the aim of this study is to verify how an app could become a valid tool for the treatment of the urinary incontinence.

The pelvic floor is a body district composed of muscles and ligaments. It is located at the base of the abdominopelvic cavity and it performs different functions such as urination, defecation, reproduction, and sexual satisfaction. The malfunction of this area may lead to a condition that can affect everyday life and sexuality.

The pelvic floor is not just a muscle. On the contrary, it is an active part of the human body for the whole life of every human being. The proposed article underlines an important problem: the urinary

incontinence in a relevant sample of women between 18 and 59 years old. The purposes of this study were to analyze the efficacy of an application of exercises of the pelvic floor, both alone and associated with physiotherapy, in reducing the urinary symptoms in order to improve the life quality of incontinent women.

The results of this study show that the intervention of a professional of the pelvic floor combined with the use of the app improve the lifestyle and quality of life patients. The pelvic floor is not only an organ or a function but it should be considered also from a psychological and sexological point of view.

The pelvic floor is an intimate part of the body, usually protected, often “forgotten” and untreated, sometimes even unknown. An intimate part of the body invested with symbolical meanings according to the relationship with ourselves, the self-perception, the attributed meanings, the beliefs, the relationship with the other, the culture, the religion, the experiences that may modify the psychological convictions and the events, for example, what happened, the personal life, or the symptom.

Avoiding the problem from the beginning may worsen the physical condition with an aggravation of the psychological state. The urinary incontinence influences in a decisive way all aspects of a woman's life and for this reason, her self-esteem may be affected over time, by activating feelings of inadequacy.

The concern with one's own incontinence may impact different day-to-day moments of everyday life. Even at work, a woman may be constantly worried about frequently going to the toilet or checking her clothes in case of leakages. Moreover, the quality of sleep and night rest may be compromised by the need of getting up frequently to urinate, affecting the wakefulness in the daytime.

Urinary incontinence and sexuality may be closely related: those who suffer from leakage during sexual intercourses may experience shame, enough in some cases to renounce this important part of the couple's relationship. It may happen that leakages may occur during sexual intercourses due to pressure on the bladder, with fear of judgment. Places without a restroom, the idea of not being able to get changed and the fear of external judgment may create strategies of avoidance in the social environment, preventing people from going out and from spending time with other people, out of shame of letting the others know their difficulty.

The lack of a correct diagnosis made by specialized doctors, the tendency to underestimate the pathological status, for example, believing that the situation will heal on its own, like with a regular delivery, the coexistence with the pathology and the delay of its treatment due to a lack of resources may worsen the disfunction or make it chronic.

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