

Conservative Management Award (Joint)

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TREATMENT OF STRESS URINARY INCONTINENCE VIA A SMARTPHONE APPLICATION: A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

Female urinary incontinence is common and affects approximately one-fourth of adult women. The most common type of this condition is stress urinary incontinence (SUI) and the recommended first line treatment is pelvic floor muscle training (PFMT) [1]. Internet-based treatment is a cost-effective and patient-appreciated alternative [2]. Mobile health applications are a growing field and provide new possibilities for delivering health care. Based on our experiences in Internet-based treatment, we have developed a treatment programme delivered as a Smartphone application. The aim of this study was to evaluate if treatment of SUI via a Smartphone application is effective.

Study design, materials and methods

This study was a randomised controlled trial conducted between March 2013 and October 2014 in Sweden. Women with at least weekly SUI and age ≥ 18 years were consecutively recruited through our open website. The symptom diagnosis of SUI was based on validated questionnaires. In addition, the women completed a two-day leakage diary including a maximum voided volume and were included in the study if the volume was ≥ 0.3 litres.

Eligible women were randomised to either the app group, receiving the smartphone application (Android or iOS) immediately, or to the postponed treatment group receiving the application after a 3 month follow-up. Randomisation was performed with allocation concealment using sequentially numbered, opaque, sealed envelopes without blinding. The study is registered under Clinical Trials id. Nr. NCT01848938.

The application contained information about SUI, PFMT exercises at different levels (6 basic and 6 advanced) with graphic support, and functions for statistics and reminders. Follow-up after 3 months included a web-based questionnaire and a leakage diary. There was no face-to-face contact with the participants during the study.

Primary outcome measures were symptom severity measured by the International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF) and condition-specific quality of life measured by the ICIQ Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol). Secondary outcomes were Patient Global Impression of Improvement (PGI-I), change in incontinence episode frequency (IEF), change in usage of incontinence aids, and patient satisfaction.

Results

The study included 123 women (mean age 44.7 (9.4) years and median IEF 17.5/week) randomised to either the app group (n=62) or the postponed treatment group (n=61). Baseline demographics and mean score on ICIQ-UI SF and ICIQ-LUTSqol at inclusion did not significantly differ between the groups. One participant from each group was lost to follow-up. We performed intention-to-treat-analysis on all available data.

We found highly significant improvements in the primary outcomes within the app group at follow-up compared to baseline ($p < 0.001$). The improvements were significantly larger in the app group than in the postponed treatment group at follow-up (Table 1).

We also found significant improvements in the secondary outcomes in the app group compared to the postponed treatment group. The PGI-I answers at follow-up showed that significantly more participants (55.7%) in the app group perceived their leakage as much or very much better than in the postponed treatment group (5%; $p < 0.001$). There was a significant reduction of IEF per week in both groups, but it was significantly larger in the app group than in the postponed treatment group ($p < 0.001$, Table 1). The use of UI aids at follow-up was significantly reduced in the app group ($p < 0.001$) but not in the postponed treatment group ($p = 0.602$). We also found a significant difference in the use of UI aids between the groups at follow-up ($p = 0.032$). Concerning patient satisfaction, 66.7% (40/60) in the app group thought that the treatment was satisfactory at the moment, 96.7% experienced the application as "good" or "very good", and 100% would recommend the treatment programme to a friend.

Interpretation of results

The improvements in the app group were highly significant and clinically relevant. In an earlier study, overall score reductions of 2.5 and 3.7 on the ICIQ-UI SF and ICIQ-LUTSqol, respectively, were considered clinically relevant [3]. Non-face-to-face treatment based on PFMT is possible and effective for women with SUI, and our Smartphone application adds a new treatment option. Delivering treatment programmes via mobile health applications may be a way to increase access to care.

Concluding message

Treatment via a Smartphone application is an easily accessible and effective treatment option for women with stress urinary incontinence.

Table 1. Treatment outcomes

Outcome variable	Treatment group	Baseline n=123	3-month follow-up n=121	Difference	Within group p-value	Between group p-value	Effect size /Partial Squared Eta
Primary outcomes							
ICIQ-UI SF Mean (SD)	App group	11.1 (3.0) n=62	7.0 (3.5) n=59	4.0 (3.3) n=59	<0.001 ^a	<0.001 ^c	0.233
	Postponed treatment group	11.0 (2.6) n=61	10.2 (3.1) n=60	0.9 (2.8) n=60	0.02 ^a		
ICIQ-LUTSqol Mean (SD)	App group	34.1 (6.1) n=62	28.8 (6.4) n=58	5.1 (5.5) n=58	<0.001 ^a	<0.001 ^c	0.198
	Postponed treatment group	34.8 (6.1) n=61	34.1 (6.7) n=60	0.7 (4.5) n=60	0.25 ^a		
Secondary outcome							
Incontinence episode frequency Median	App group	21 n=62	7 n=58	14 n=58	<0.001 ^b	<0.001 ^d	0.359
	Postponed treatment group	17.5 n=61	14 n=60	3.5 n=60	0.004 ^b		

^a Paired-samples t-test, ^b Wilcoxon signed rank test, ^c One-way ANCOVA, ^d Mann-Whitney U test SD=standard deviation

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Disclosures

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