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# Mobile app for treatment of stress urinary incontinence: A randomized controlled trial

Ina Asklund<sup>1\*</sup> | Emma Nyström<sup>1</sup> | Malin Sjöström<sup>1</sup> | Göran Umefjord<sup>2</sup> | Hans Stenlund<sup>2</sup> | Eva Samuelsson<sup>2</sup>

<sup>1</sup>Department of Public Health and Clinical Medicine, Unit of Research, Education and Development—Östersund, Umeå University, Sweden

<sup>2</sup>Department of Public Health and Clinical Medicine, Umeå University, Sweden

#### \*Correspondence

Ina Asklund, MD, Region Jämtland Härjedalen, Box 654, SE-831 27 Östersund, Sweden.  
Email: ina.asklund@regionjh.se

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**Aims:** To evaluate the effect of a mobile app treatment for stress urinary incontinence (SUI) in women.

**Methods:** Randomized controlled trial, conducted 2013-2014 in Sweden. Community-dwelling adult women with  $\geq 1$  SUI episode/week recruited through our website and randomized to app treatment ( $n = 62$ ) or control group (postponed treatment,  $n = 61$ ). One participant from each group was lost to follow-up. Intervention was the mobile app Tåt<sup>®</sup> with a treatment program focused on pelvic floor muscle training (PFMT), and information about SUI and lifestyle factors. Primary outcomes, 3 months after randomization: symptom severity (International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form [ICIQ-UI SF]); and condition-specific quality of life (ICIQ Lower Urinary Tract Symptoms Quality of Life [ICIQ-LUTSqol]).

**Results:** One hundred and twenty-three women were included (mean age 44.7), with moderate/severe SUI (97.5%, 120/123), mean ICIQ-UI SF score 11.1 (SD 2.8) and mean ICIQ-LUTSqol score 34.4 (SD 6.1) at baseline. At follow-up, the app group reported improvements in symptom severity (mean ICIQ-UI SF score reduction: 3.9, 95% confidence interval 3.0-4.7) and condition-specific quality of life (mean ICIQ-LUTSqol score reduction: 4.8, 3.4-6.2) and the groups were significantly different (mean ICIQ-UI SF score difference:  $-3.2$ ,  $-4.3$  to  $-2.1$ ; mean ICIQ-LUTSqol score difference:  $-4.6$ ,  $-7.8$  to  $-1.4$ ). In the app group, 98.4% (60/61) performed PFMT at follow-up, and 41.0% (25/61) performed it daily.

**Conclusions:** The mobile app treatment was effective for women with SUI and yielded clinically relevant improvements. This app may increase access to first-line treatment and adherence to PFMT.

#### KEYWORDS

mobile applications, pelvic floor muscle training, randomized controlled trial, self-management, stress urinary incontinence

[This article was corrected in September 2016 after initial online publication because the copyright line needed to be modified.]

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## 1 | INTRODUCTION

Urinary incontinence affects 25–45% of adult women.<sup>1,2</sup> The most common type is stress urinary incontinence (SUI),<sup>1,2</sup> defined as urine leakage upon exercise, coughing, or sneezing.<sup>3</sup> SUI may affect quality of life, but many women do not seek care.<sup>1</sup> Potential reasons for avoiding care may be that incontinence is believed to be “normal,” discussing incontinence is embarrassing, the symptoms are not taken seriously by health care personnel, or the available treatment options are unsatisfactory.<sup>4</sup>

Before treatment, urinary incontinence can be diagnosed in ambulatory care, based on patient-reported measures, including questionnaires, rating scales, and voiding diaries.<sup>5</sup> The first-line treatment for SUI is pelvic floor muscle training (PFMT), but there is no clear consensus on whether the training must be supervised.<sup>5,6</sup> Adherence to PFMT is a key factor in its effectiveness, but many barriers to exercise exist, including forgetting, not prioritising, and not perceiving the benefits of training.<sup>7,8</sup>

With increasing smartphone availability, mobile health apps are a growing field that offers new possibilities for delivering health services.<sup>9</sup> Health apps may increase access to care for people who are unwilling to seek out or have limited access to ordinary health care. It has been suggested that health apps can increase adherence to disease management.<sup>10</sup> Few apps are evaluated in high-quality trials, thus, it is difficult for both patients and caregivers to have confidence in the effectiveness of health apps,<sup>11,12</sup> and there is a need for more studies that evaluate them.<sup>13</sup>

Based on our previous experience with internet-based SUI treatment,<sup>14</sup> our research group developed a mobile app with a treatment program for SUI, with a focus on PFMT. The aim of this study was to compare the mobile app treatment program to no treatment for effects on symptom severity and condition-specific quality of life in women with SUI.

## 2 | MATERIALS AND METHODS

From March 2013 to October 2014, we conducted a randomized (1:1) controlled trial (RCT) with two parallel groups (treatment vs. no treatment, no blinding) in Sweden. The study was approved by the Regional Ethics Review Board, Umeå University, and was registered at ClinicalTrials.gov, ID: NCT01848938. We followed the CONSORT guidelines and the CONSORT EHEALTH Checklist.<sup>15</sup>

We recruited community-dwelling women through our website, [www.econtinence.se](http://www.econtinence.se), where they filled out a questionnaire to determine whether they met the study criteria. Criteria for inclusion were age  $\geq 18$  years, SUI  $\geq 1$  episode/week for the last 6 months (SUI defined as urine leakage upon coughing, sneezing, or physical activity, and no

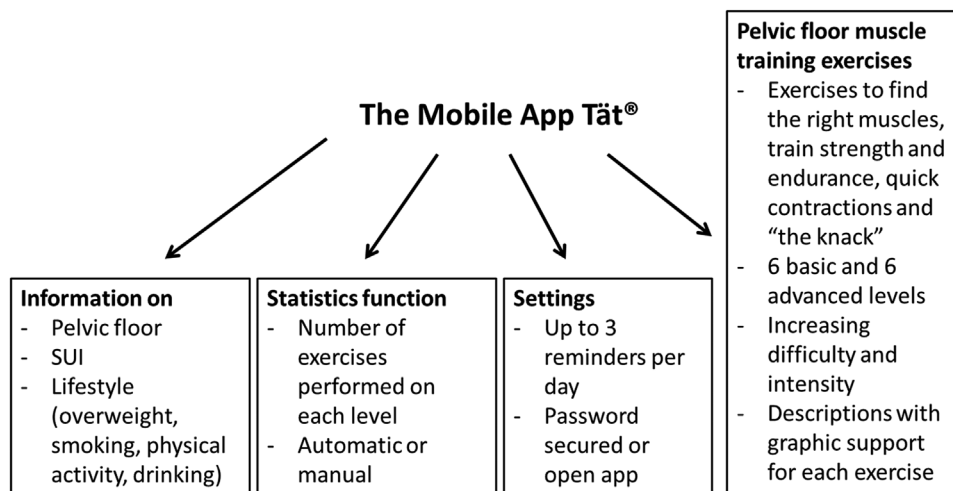
leakage associated with urgency), access to a smartphone and e-mail, and Swedish literacy. Exclusion criteria were pregnancy; previous UI surgery; present or previous malignancy in the lower abdomen; impaired mobility or sensibility in the legs or lower abdomen; severe psychiatric disorders; or macroscopic haematuria, irregular bleeding, or difficulty passing urine (these women were advised to contact a health care professional). Women who met the inclusion criteria received a letter with informed consent and a 2-day leakage diary including a maximum voiding volume. Women with maximum voided volumes  $\geq 0.3$  L were included, as this was considered to indicate a normal bladder capacity. After returning the informed consent and leakage diary, participants answered a web-based questionnaire that recorded background characteristics and lifestyle. They also completed two validated questionnaires: the International Consultation on Incontinence Modular Questionnaire (ICIQ) Urinary Incontinence Short Form (ICIQ-UI SF) to evaluate symptom severity,<sup>16</sup> and the ICIQ Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol) to evaluate condition-specific quality of life.<sup>17</sup> Participants were contacted by telephone before randomization to ensure that they had understood the study procedure. There was no face-to-face contact with the women at any time before, during, or after the study.

We randomized eligible women to the intervention group or to the control group. Randomization was performed by concealing the allocations in sequentially numbered, opaque, sealed envelopes. An independent administrator generated the allocation sequence and prepared 130 envelopes (with assignments equally distributed between the two study groups). The study coordinator opened one envelope for each participant and assigned an e-mail to the participant, with materials for the corresponding study group.

The intervention was a mobile app (designed for iOS or Android devices) with a treatment program for SUI, focused on PFMT. Our research group developed this app, called Tåt<sup>®</sup>, in collaboration with software engineers at ICT Services and System Development, Umeå University. The treatment program was based on experiences reported by researchers, clinicians, and users with our previous internet program.<sup>14</sup> During the development process, the app was reviewed by the researchers and a test group, until a final version was accepted. The app was not modified during the study period. No data were transmitted from the app to our research database.

Women assigned to the app group received an e-mail with instructions for downloading and installing the app from the App Store or Google Play and a code to open the app. After 4 weeks, they received an e-mail that reminded them to use the app and asked them whether they had experienced any technical problems.

The app focused on PFMT exercises but also contained information that described SUI, the pelvic floor, and lifestyle



**FIGURE 1** The mobile app Tät®

factors related to incontinence (Fig. 1). The PFMT exercises were ordered by increasing difficulty (six basic and six advanced levels; see Table S1). The exercises included different combinations and repetitions of commonly used contractions: a basic contraction to identify the correct muscles, contractions to improve strength and endurance, quick contractions, and contractions prior to coughing. The treatment program prescribed exercises three times daily, and the app provided the ability to set three reminders/day. Each exercise description included graphics showing the duration and intensity of each contraction with concomitant relaxation. After completing an exercise, women could save it in a statistics table. The goal was to exercise regularly for 3 months, not to reach a particular exercise level.

The control group was a postponed treatment group and did not receive the app or any material included in the app during the study period. After completing the 3-month follow-up, they received access to the app.

Three months after randomization, we sent both groups a web-based questionnaire with follow-up questions on lifestyle, PFMT, symptom severity, and condition-specific quality of life. They also completed a 2-day leakage diary. We reminded non-respondents twice by e-mail, after 2 and 4 weeks, and once by telephone after 6 weeks.

## 2.1 | Primary outcomes

The primary outcome measures were symptom severity (ICIQ-UI SF) and condition-specific quality of life (ICIQ-LUTSqol). The ICIQ-UI SF contained three questions about the frequency and amount of urinary leakage and its overall impact on everyday life. The responses summed to an overall score of 0-21, where 21 was most severe. In addition, a fourth, unscored question asked when leakage occurred. The overall scores can be divided into severity categories (1-5 = slight, 6-12 = moderate, 13-18 = severe, 19-21 = very severe).<sup>18</sup> To

save one overall score at baseline, we replaced a missing answer from one woman in the app group with her corresponding answer at follow-up, which would correspond to no change.

The ICIQ-LUTSqol contained 19 questions that summed to an overall score of 19-76, where 76 corresponded to the highest impact on quality of life. Three questions that asked about personal relationships included the potential response “not applicable.” When calculating the overall ICIQ-LUTSqol score, a “not applicable” response was set to 1, that is, no impact.

## 2.2 | Secondary outcomes

The Patient's Global Impression of Improvement (PGI-I) is a self-rated, validated question that asks about the change experienced after treatment.<sup>19</sup> It has seven response options, ranging from “very much better” to “very much worse.”

The incontinence episode frequency (IEF) was calculated at baseline and follow-up. The number of leakages self-reported in 2-day diaries was multiplied by 3.5 to give the number of leakages per week.

All participants estimated their usage of incontinence aids over the last 4 weeks, before baseline and before follow-up.

App group participants rated their satisfaction with the app over five response options, from “very bad” to “very good.” They also indicated whether they were satisfied with the treatment effect (yes/no) and whether they were planning to seek additional treatment.

## 2.3 | Sample size

We calculated the sample size based on results from our previous internet study.<sup>14</sup> We expected ICIQ-UI SF score reductions of 2.9 (SD 3.1) in the app group and 1.0 (SD 2.0) in the control group; we expected ICIQ-LUTSqol score reductions of 4.6 (SD 6.7) and 2.0 (SD 3.0) in the app and

control groups, respectively. We estimated large improvements on the PGI-I in 26.5% of the app group and 4% of the control group. The sample size for each outcome was calculated to enable detection of an effect difference between groups with a power of 80% and a two-sided significance level of 0.05. The sample sizes were calculated to be 30, 35, and 39, respectively, for the outcomes. Anticipating a dropout rate of 33%, we thus aimed for a sample size of 60 in each group.

## 2.4 | Statistical analysis

We compared the two groups at baseline with the Student's *t*-test for continuous variables, the chi-square test for categorical variables, and the Mann-Whitney *U*-test for ordinal variables. We analyzed treatment effects within each group with a paired *t*-test for the primary outcomes and with a Wilcoxon signed-rank test for the secondary outcomes (IEF and use of incontinence aids). To compare treatment effects between groups for the primary outcomes, we used a linear mixed model analysis, which incorporated all available data for each participant. For the secondary outcomes (IEF, PGI-I, and use of incontinence aids), we used the Mann-Whitney *U*-test. *P* values <0.05 were considered statistically significant.

We performed intention-to-treat analysis on all outcome measures by using the mixed model analysis for the effect between the groups for the primary outcomes and by imputing values for the secondary outcomes. Missing values at follow-up were replaced with the corresponding values at baseline (ie, no change). A missing answer on the improvement question PGI-I was replaced with "unchanged." For all analyses, we used SPSS version 22.0.

## 3 | RESULTS

The study included 123 women, aged 27-72 years (mean age 44.7 years), with slight (2.4%, 3/123), moderate (63.4%, 78/123), or severe (34.1%, 42/123) SUI. Women were randomized to either the app group (*n* = 62) or control group (*n* = 61). One participant from each group was lost to follow-up. In addition, the app group was missing outcome data on the ICIQ-UI SF (*n* = 2), ICIQ-LUTSqol (*n* = 3), and IEF (*n* = 3). Figure 2 shows the flow diagram for study participants. The groups were similar in age, education, BMI, and incontinence severity (Table 1). The median time from randomization to completion of the follow-up questionnaire was 101 days (IQR 95-109.5).

### 3.1 | Primary outcomes

At follow-up, the app group reported improvements in symptom severity (mean ICIQ-UI SF score reduction: 3.9, 95% confidence interval [CI]: 3.0-4.7) and in the condition-

specific quality of life (mean ICIQ-LUTSqol score reduction: 4.8, 95%CI: 3.4-6.2). The control group reported a statistically significant reduction in symptom severity (mean ICIQ-UI SF score reduction: 0.9, 95%CI: 0.1-1.6), but not in condition-specific quality of life (mean ICIQ-LUTSqol score reduction: 0.7, 95%CI: -0.5-1.8). The groups were significantly different for both outcome measures at follow-up (Table 2).

### 3.2 | Secondary outcomes

The follow-up PGI-I results showed that app group participants reported much improved or very much improved urinary incontinence more often than control group participants (*P* < 0.001; Table 3).

Concerning weekly leakage episodes, the app group improved more than the control group (*P* < 0.001; Table 3), although the episodes also decreased in the latter. At follow-up, 56.5% (35/62) of the app group and 29.5% (18/61) of the control group reported either no leakage or ≥50% fewer leakage episodes than at baseline (between-group *P* = 0.005).

The app group significantly reduced the use of incontinence aids (*P* < 0.001), but the control group did not (*P* = 0.602). At follow-up, the groups were significantly different in the use of incontinence aids (*P* = 0.023; Table 3).

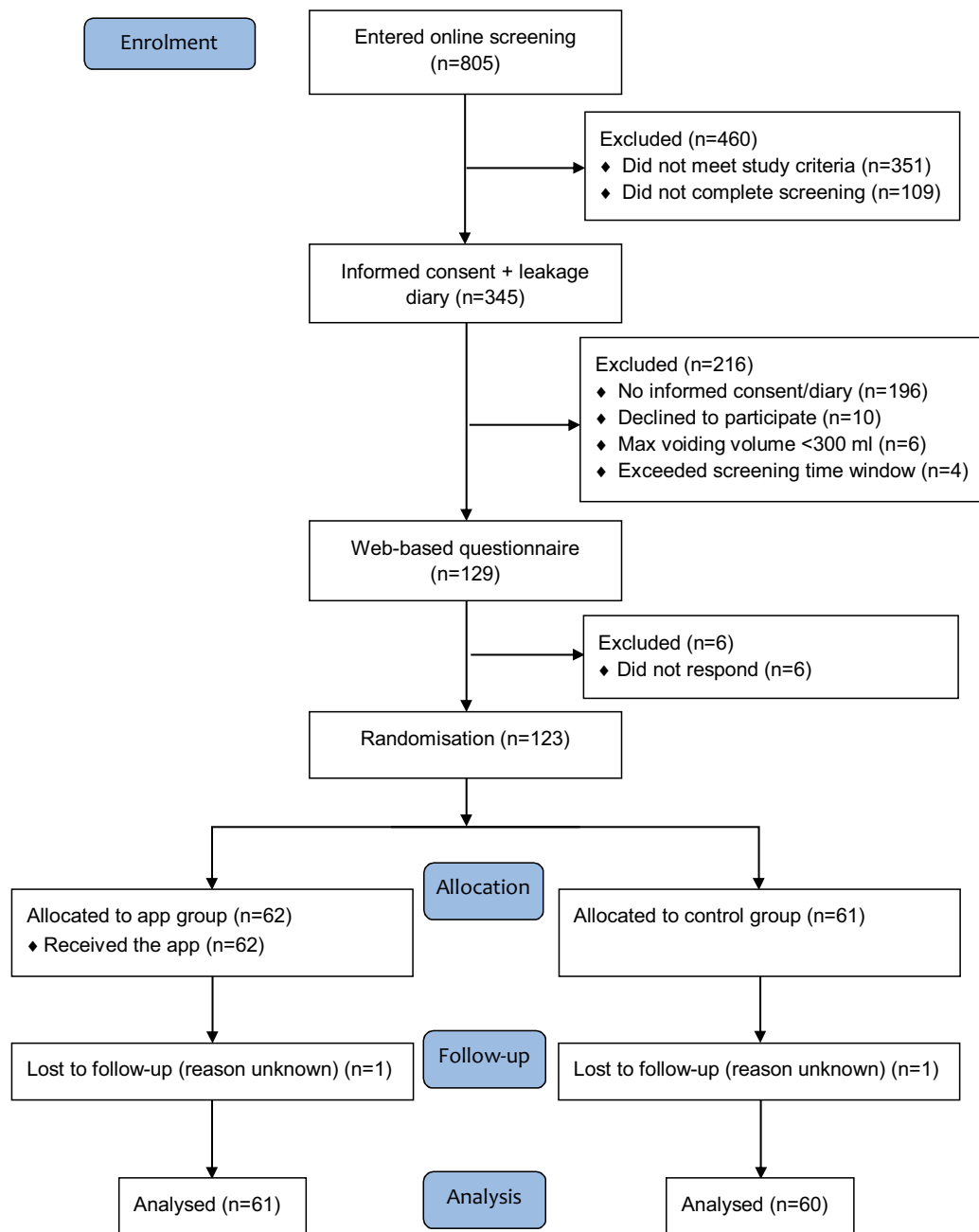
Patient satisfaction with the app was "good" or "very good" in 96.7% (59/61) of the app group. Two thirds of the app group (66.7%; 40/60) reported satisfaction with the treatment outcome, and 21.7% (13/60) planned to seek additional treatment for incontinence.

### 3.3 | App usage and adherence to PFMT

All women assigned to the app group who completed follow-up (*n* = 61) had used the app. The reminder setting was used by 83.6% (51/61), and 86.9% (53/61) used the statistics function. Women who used the statistics function (*n* = 52) registered a mean of 141 exercises/person during the study, which would correspond to a mean of 1.6 exercises/day during a 90-day period. At follow-up, all but one woman in the app group reported having performed PFMT during the last 4 weeks; 41.0% (25/61) had performed PFMT daily; 42.6% (26/61) had performed PFMT weekly but not daily; and 14.8% (9/61) had performed PFMT more sporadically. In the control group, 26.7% (16/60) reported that they had not performed any PFMT; 56.7% (34/60) had performed PFMT sporadically; 13.3% (8/60) had performed PFMT weekly but not daily; and 3.3% (2/60) had performed PFMT daily.

## 4 | DISCUSSION

In this RCT, we demonstrated that the mobile app Tät<sup>®</sup> with a treatment program focused on PFMT was effective in



**FIGURE 2** Flow diagram of the study

comparison with no treatment for women with SUI. The differences between groups were highly significant in both primary and secondary outcome measures. After treatment, participants in the app group experienced fewer symptoms, better quality of life, greater subjective improvement, fewer leakage episodes per week, and lower pad usage compared to participants in the control group.

To our knowledge, this is the first app for SUI treatment to be evaluated in a RCT. Study strengths included our previous experiences with non-face-to-face SUI treatments. During the study, there were no major technical problems, and we made no changes to the app. We based the SUI diagnosis on patient-reported symptoms, according to previous recom-

mendations.<sup>5</sup> The vast majority of our study population had moderate to severe SUI (97.5%) and actively sought treatment, thus representing a clinically relevant group of women with incontinence. Most outcome measures were validated and highly recommended, which enabled comparisons with other studies. Our loss to follow-up was very low, and we had few missing outcome values, reducing the risk of bias that may be introduced when imputing values. To facilitate future implementation of the app, we simulated a routine setting, with minimal contact between the participants and the research group.

One limitation of this study was that we did not compare the app with another active treatment or care-as-usual. However,

**TABLE 1** Baseline demographics and characteristics of incontinence severity

Variable	App group	Control group
Demographics		
Age, years, mean (SD)	44.8 (9.7)	44.7 (9.1)
BMI, kg/m <sup>2</sup> , mean (SD)	24.0 (4.1)	24.5 (4.4)
University education $\geq 3$ years, no. (%)	52 (83.9)	46 (75.4)
Daily smokers, no. (%)	2 (3.2)	3 (4.9)
Nulliparous, no. (%)	5 (8.1)	4 (6.6)
On regular medication, no. (%)	28 (45.2)	24 (39.3)
Incontinence severity		
ICIQ-UI SF score, mean (SD)	11.1 (3.0)	11.0 (2.6)
ICIQ-LUTSqol score, mean (SD)	34.1 (6.1)	34.8 (6.1)
IEF per week, median (IQR)	21.0 (10.5-28.0)	17.5 (10.5-24.5)
Any use of UI aids in prior 4 weeks, no. (%)	56 (90.3)	51 (83.6)
Daily use of UI aids, no. (%)	13 (21)	14 (23)

APP, application for mobile phone; BMI, body mass index; ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ-LUTSqol, ICIQ lower urinary tract symptoms quality of life; IEF, incontinence episode frequency; IQR, interquartile range; SD, standard deviation; UI, urinary incontinence.

there is no gold standard for PFMT, and care-as-usual varies in different settings. Also, we wanted to provide country-wide treatment accessibility to women, including women who choose, for whatever reason, not to seek ordinary health care. Moreover, the control group allowed an evaluation of intervention efficacy and helped with ruling out effects achieved by merely participating in a study.

Although the mean age of our participants (44.7 years) reflects the fact that SUI is most common among middle-aged women,<sup>1</sup> their education level was higher than that of the general population; 80% had  $\geq 3$  years of university education, compared to the 30% expected in a study group representative of the general population of Swedish women aged 20-74 years.<sup>20</sup> Theoretically, this factor might have increased their ability to understand the written instructions

**TABLE 2** Primary outcome measures at the 3-month follow-up

Outcome variables	App group	Control group	Difference (95%CI) <sup>a</sup>	P-value <sup>a</sup>
ICIQ-UI SF score	7.0 (3.5)	10.2 (3.2)	-3.2 (-4.3 to -2.1)	<0.001
ICIQ-LUTSqol score	28.8 (6.4)	34.1 (6.7)	-4.6 (-7.8 to -1.4)	0.005

Values represent the mean (SD). APP, application for mobile phone; ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ-LUTSqol, ICIQ lower urinary tract symptoms quality of life; SD, standard deviation.

<sup>a</sup>Between-group differences are based on linear mixed models.

**TABLE 3** Secondary outcome measures at the 3-month follow-up

	App group	Control group	P-value <sup>a</sup>
IEF, median leakage/week (IQR)	7 (0-14)	14 (7-26)	0.001
PGI-I: How is your urinary leakage now compared to before you entered the study? No. (%)			<0.001
Very much better; No. (%)	6 (9.8)	0 (0)	
Much better	28 (45.9)	3 (5.0)	
A little better	22 (36.1)	9 (15.0)	
No change	5 (8.2)	42 (70.0)	
A little worse	0 (0)	6 (10.0)	
Much worse	0 (0)	0 (0)	
Very much worse	0 (0)	0 (0)	
Incontinence aids: Have you used any incontinence aids for your urinary leakage during the last 4 weeks?			0.023
No	23 (37.7)	14 (23.3)	
Less than once a week	13 (21.3)	11 (18.3)	
One to three times/week	10 (16.4)	13 (21.7)	
>3 times/week but not daily	5 (8.2)	4 (6.7)	
One aid a day	8 (13.1)	12 (20.0)	
More than 1 aid a day	2 (3.3)	6 (10.0)	
Satisfaction: Do you currently feel that the treatment you have undergone is sufficient?			
Yes, I am completely free of leakage.	5 (8.3)	NA	
Yes, sufficient, although I am not completely free of leakage	35 (58.3)	NA	
No	20 (33.3)	NA	

IEF, incontinence episode frequency; IQR, interquartile range; NA, not applicable; SUI, stress urinary incontinence.

<sup>a</sup>P values are based on the Mann-Whitney U-test.

for PFMT and put them into practice, thereby enhancing their results. On the other hand, Henderson et al concluded that education level does not seem to affect the ability to learn or perform correct pelvic floor muscle contractions.<sup>21</sup>

Before treatment, participants in the app group had a mean ICIQ-UI SF score of 11.1 (SD 3.0); after treatment, the mean score was reduced by 3.9. This reduction was of the same magnitude as reductions previously reported in other RCTs with different types of PFMT programs, thus indicating that the improvement in our study was not a mere placebo effect. For example, 3 RCTs<sup>22-24</sup> that tested PFMT programs (1 supervised and two unsupervised) included participants with mean baseline ICIQ-UI SF scores ranging from 8.6-12.0. After treatment, mean scores were reduced by 3.0 to 4.5. In two of those studies,<sup>23,24</sup> participant ages (32-72 years and 35-60 years) were similar to those in our study; the third study<sup>22</sup>

included older women. Also, in our previous RCT with 250 participants (mean age 48.6 years, baseline ICIQ-UI SF score 10.4), we reported mean score reductions of 3.4 and 2.9, respectively, in groups randomized to either an internet-based or a postal program that focused on PFMT.<sup>14</sup> Previously, the minimum important differences for conservative treatments were established for the ICIQ-UI SF (2.5) and the ICIQ-LUTSqol (3.7)<sup>25</sup>; thus, improvements above those levels are likely to be clinically relevant at the group level.

The Tåt<sup>®</sup> app was evaluated as a first-line treatment for SUI, suitable for women who wanted to try an easily accessible, self-management treatment. One advantage of app treatment is the reminder function, which may increase adherence to PFMT. On the other hand, the lack of face-to-face contact may decrease adherence. In a study on adherence to PFMT,<sup>8</sup> the most common barrier was difficulty in remembering to perform the exercises. After instructions at clinical visits, 31.5% of participants continued daily exercises after 3 months, which was lower than the 41.0% observed in our study. Thus, in our study, the lack of face-to-face contact was not a disadvantage in terms of adherence.

With the present study, we have shown that app treatment is effective in the short term. Evaluations of the long-term adherence and effects are ongoing, as are studies on the cost-effectiveness of app treatment. After the study closed, the Tåt<sup>®</sup> app was released for free in Swedish (iOS and Android) and English (Android), and we continue to assess its use and effectiveness after implementation.

## 5 | CONCLUSIONS

The mobile app treatment program was effective for women with SUI, yielding clinically relevant improvements. This new tool can increase access to and serve as first-line treatment. The app also can potentially increase adherence to PFMT and may possibly be used as a complement to other treatments.

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## POTENTIAL CONFLICTS OF INTEREST

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All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: Hans Stenlund has nothing to disclose. Ina Asklund, Emma Nyström, Malin Sjöström, Göran Umeffjord, and Eva Samuelsson had financial support from the Swedish Research Council for Health, Working Life and Welfare, Visare Norr, Northern County Councils, The Västerbotten County Council (ALF), the Jämtland County Council for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

The application Tåt<sup>®</sup> was developed at Umeå University (contact E. Samuelsson). None of the researchers have any financial interests in the product. The application is CE-marked as a medical device Class 1, according to Swedish regulation LVFS 2003:11. Available for free at the Apple App Store and Google Play.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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