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# Self-management of stress urinary incontinence via a mobile app: two-year follow-up of a randomized controlled trial

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**Key words**
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**Conflict of interest**
The authors have stated explicitly that there are no conflicts of interest in connection with this article. The application Tät® was developed by Eva Samuelsson, Malin Sjöström, and Göran Umefjord in cooperation with ICT Services and System Development (ITS), Umeå University, Sweden. Copyright 2010–2017 for Tät.nu (eContinence.se) at Umeå University. The name Tät® (mobile application) and the logo Tät.nu are registered as Trademarks by The Swedish Patent and Registration office for E. Samuelsson at Umeå University. None of the researchers have any financial interest in the product. It is CE marked as a Class 1 medical device in accordance with Swedish regulation LVFS 2003:11. The app is available in Swedish and English at no cost from the App Store and Google Play.

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## Abstract

*Introduction.* We investigated the long-term effects of using a mobile app to treat stress urinary incontinence with a focus on pelvic floor muscle training. *Material and methods.* A previous randomized controlled trial of 123 women aged 27–72 years found that three months of self-managing stress urinary incontinence with support from the Tät® app was effective. We followed up the women in the app group ($n$ = 62) two years after the initial trial with the same primary outcomes for symptom severity (International Consultation on Incontinence Questionnaire Short Form) and condition-specific quality of life (ICIQ-Lower Urinary Tract Symptom Quality of Life) and compared the scores with those at baseline. *Results.* Of the 62 women, 61 and 46 (75.4%), respectively, participated in three-month and two-year follow-ups. Baseline data did not differ between responders and non-responders at follow-up. The mean decreases in International Consultation on Incontinence Questionnaire Short Form and ICIQ-Lower Urinary Tract Symptom Quality of Life scores after two years were 3.1 (95% confidence interval 2.0–4.2) and 4.0 (95% confidence interval 2.1–5.9), respectively. Of the 46 women, four (8.7%) rated themselves as very much better, nine (19.6%) as much better, and 16 (34.8%) as a little better. The use of incontinence protection products decreased significantly ($p$ = 0.04), and the proportion of women who felt they could contract their pelvic muscles correctly increased from 14/46 (30.4%) at baseline to 31/46 (67.4%) at follow-up ($p$ < 0.001). *Conclusions.* Self-management of stress urinary incontinence with support from the Tät® app had significant and clinically relevant long-term effects and may serve as first-line treatment.

**Abbreviations:** BMI, body mass index; ICIQ-LUTSqol, International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract Symptoms Quality of Life; ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; MIDs, minimum important differences; PFMT, pelvic floor muscle training; PGI-I, Patient Global Impression of Improvement; SUI, stress urinary incontinence.



 

## Introduction

Urinary incontinence can affect quality of life significantly and generate large costs for society. Approximately 10–25% of women experience urinary incontinence (1,2). Stress urinary incontinence (SUI), defined as leakage of urine concurrent with coughing, sneezing, or physical exertion (3), occurs predominantly in women. Only 15% of people with SUI seek care (4). Some regard their leakage as a small problem that does not require healthcare, and others avoid seeking care because they are embarrassed or feel ashamed. Moreover, the availability of healthcare varies, and women who seek care do not always receive the optimal treatment because addressing SUI is not prioritized or there is a lack of knowledge regarding the condition among healthcare personnel (5,6).

Pelvic floor muscle training (PFMT) is recommended as the first-line treatment for SUI (7). In a previous study, 56% of women with SUI reported successful control of symptoms after following a personalized PFMT plan (8). Three of 10 women treated with PFMT achieve continence (9,10). Some women prefer supervised training, whereas others prefer to manage the training on their own (6). It is difficult to compare different approaches to PFMT, because there is no gold standard for PFMT and the methods and outcomes used by studies vary (7).

Women can perform PFMT without face-to-face contact, and eHealth offers new ways to provide care. SUI treatment with a focus on PFMT provided via the internet is associated with marked improvements in symptoms and quality of life, in both the short and the long term (11,12). It also seems to be a cost-effective first-line treatment alternative (13).

Mobile apps for smartphones offer new options for diagnosis and treatment, and can increase access to first-line treatment. Indeed, they have been used as part of the treatment of chronic conditions such as diabetes, cardiovascular disease, and chronic lung disease, sometimes with positive results (14,15). However, few mobile health apps have been developed with the input of a university or professional organization (16), and it can be difficult for individuals seeking treatment to identify high-quality apps.

A previous randomized controlled trial evaluated the efficacy of mobile app treatment for SUI in 123 women. Compared with the control group, after three months, women in the app group had significant and clinically relevant improvements in symptoms and quality of life (17).

Few long-term studies of SUI have evaluated the results after treatment with PFMT. Two follow-up investigations after 10 and 15 years found that 15–28% of women still trained regularly and 47–50% had undergone incontinence surgery (18,19). A systematic review concluded that the long-term success (defined as one year or more after treatment) of PFMT, was between 41 and 85%, with a surgery rate of 4.9–58% (20). However, the methods and outcomes of the individual studies differed, making comparisons difficult (20). The aim of the present study was to investigate the long-term results of treating SUI with PFMT supported by the mobile app Tät®.

## Material and methods

The present study is a follow-up investigation of women who took part in a randomized controlled trial (17) that was conducted from March 2013 to October 2014 in Sweden (registered at ClinicalTrials.gov: NCT01848938). The Tät® mobile app contains information about SUI, lifestyle, and the pelvic floor, and it allows users to set reminders and save statistics. The mobile app presents PFMT exercises with increasing levels of difficulty (six basic and six advanced). The exercises include four different types of contractions in different combinations, and they are meant to be performed three times a day. A total of 123 women with SUI, aged 27–72 years, were randomized either to receive the mobile app at the beginning of the study period (app group, $n = 62$), or to wait three months to receive it (control group, $n = 61$) (Figure 1). Of the study participants, 121 were followed up at three months (app group, $n = 61$; control group, $n = 60$) (Figure 1). At three months, the reduction in symptoms [the International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF)] and quality of life scores [International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol)] were 3.9 and 4.8, respectively. These reductions were significantly greater than those achieved for the control group (17).

All 121 participants of the three-month follow-up for the previously published randomized controlled trial received an email with a link to a web survey. E-mails were sent approximately 18–32 months after inclusion in the initial study (average 24 months) (17). In the present study, we analyzed all of the women who had received the mobile app following randomization in the previous

### Key Message

Two years after an app-based treatment for stress urinary incontinence, improvements in symptoms and quality of life were still highly significant. These promising long-term effects further support use of the app for first-line treatment of stress urinary incontinence.

 

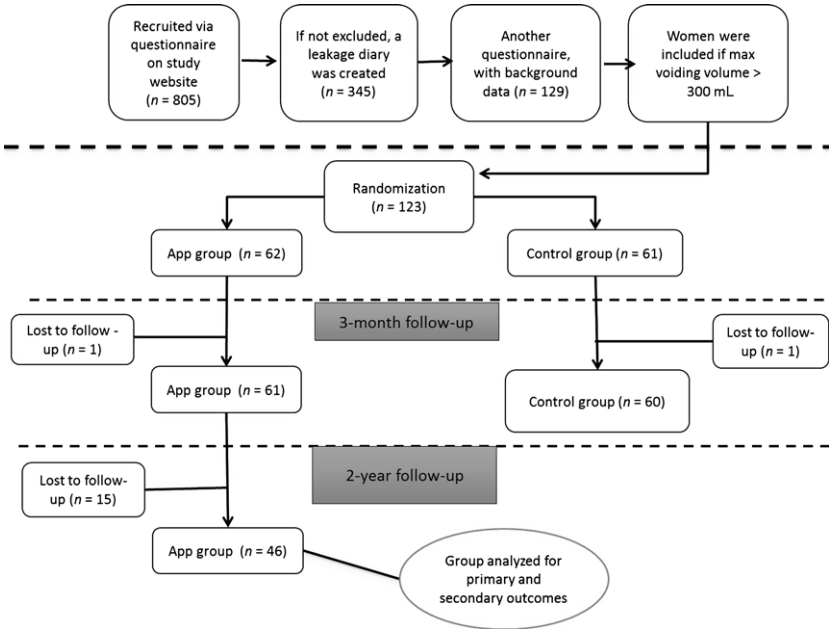


**Figure 1.** Flowchart of participants during the study.

study (intervention group = app group, $n = 61$). Further, we knew that these women had used the app during their treatment period. The women that were randomized to the control group (postponed treatment group) received the app after the three-month follow-up (17) but were not followed for the next three months. Consequently, we have no data for their post-treatment outcomes or app usage over this time frame.

The survey included the following validated questionnaires: ICIQ-UI SF (21) to measure symptom severity, ICIQ-LUTSqol (22) to gauge quality of life, and the Patient Global Impression of Improvement (PGI-I) (23). The survey also included questions about medication and the use of local estrogen therapy, further treatments, and incontinence protection products. Moreover, the survey queried the women regarding their subjective experience of satisfaction with the treatment and the need for further treatment. We sent two e-mail reminders and one postal reminder to women who did not answer the survey after the first email.

## Outcome measures

*Primary outcome.* The ICIQ-UI SF measured symptom severity with a score of 0–21, with higher values indicating increasing severity. The ICIQ-LUTSqol measured condition-specific quality of life with a score of 19–76, with higher values indicating more affected quality of life. The difference in score from baseline to the two-year follow-up was the primary outcome.

*Secondary outcomes.* Secondary outcomes included changes in answers to the PGI-I, the proportion of women who had sought further treatment for SUI since joining the study, changes in the use of incontinence protection products since the women joined the study, and changes in the proportion of women who felt they could contract their pelvic floor muscles correctly since joining the study.

The PGI-I asked the question: "How is your urinary leakage now compared with before you joined the study two years ago?" This validated question had seven possible answers, from "very much improved" to "very much deteriorated." The purpose of this question was to evaluate the women's urinary leakage at follow-up compared with baseline.

At the two-year follow-up, we compared the use of incontinence protection products in the previous four weeks with that at baseline. There were six possible answers regarding protection use, ranging from "No, never" to "Yes, more than one per day."

The proportion of women who felt that they could contract their pelvic muscles correctly was compared with that at baseline. We also determined the proportion of women who had sought other treatments for their SUI, including surgery.

## Statistical analyses

We used the Student's *t*-test to analyze differences in baseline data between responders and non-responders at


 

the two-year follow-up with respect to symptom and quality of life scores, age, and body mass index (BMI). We used Fisher's exact test to analyze the proportion of smokers, those with more than three years of university education, and parity. For median differences in the number of leakages per week and the incontinence episode frequency, we used the Mann–Whitney *U*-test.

We used the Student's *t*-test to analyze differences in symptom and quality of life scores at the two-year follow-up compared with baseline, and the Wilcoxon signed-rank test to compare the use of incontinence protection products before and after treatment. McNemar's test evaluated whether the proportion of women who felt they could contract their pelvic muscle correctly had changed at two years compared with baseline. Once the total score for ICIQ-LUTSqol was determined, the answer "not applicable" for the question regarding personal relationships was changed to one, meaning no impact, as described by Sjöström et al. (12). As we were evaluating the impact of leakage on quality of life, if they had no personal relationships that could be affected by leakage, we counted this as "no impact". A $p$-value of $<0.05$ was considered to be significant. If one part of the three answers in the ICIQ-UI SF score was missing, we substituted that missing value with the baseline response ("carry forward") or, vice versa ("carry backward"). We also performed five multiple imputations for missing symptom score values using the MCMC method. Finally, we performed the analyses for all outcomes, excluding the two women who had undergone surgery. IBM SPSS Statistics 23 (IBM Corp., Armonk, NY) was used for all statistical analyses.

### *Ethical approval*

The study followed STROBE guidelines for reporting results (24). The Regional Ethical Review Board, Umeå, approved the ethics application for the study (2015-389-32M, added to 2012-325-31M). All participants provided written informed consent for participation. No reimbursement was given.

## Results

Of the 61 women who participated in the three-month follow-up of the original study, 46 responded at two years (Figure 1); thus, loss to follow-up was 24.6% (15/61). Of these 46 women, one had a missing ICIQ-UI SF value at baseline and for another, both ICIQ-UI SF and ICIQ-LUTSqol values were missing at follow-up. Four women had incomplete ICIQ-UI SF scores at follow-up, with one of the three values missing. With substitutions for the missing values, we could collate an additional five complete scores for ICIQ-UI SF and none for ICIQ-LUTSqol. There were no significant differences between responders and non-responders with respect to age, BMI, smoking, education, and the severity of incontinence at baseline (Table 1).

All 46 women reported that they had downloaded the mobile app and used it; eight women (17.4%) were still using it at the two-year follow-up. Of the 46 women, 12 (26%) had not performed PFMT, 21 (46%) had performed it sporadically, and 13 (28%) had performed it regularly in the previous four weeks.

### *Primary outcomes*

The symptom severity score (ICIQ-UI SF) decreased significantly from baseline to the two-year follow-up, mean decrease 3.1 (95% CI 2.0–4.2). For condition-specific quality of life (ICIQ-LUTSqol), the mean decrease was 4.0 (95% CI 2.1–5.9) (Table 2). Significance was retained following use of an imputation approach for missing values in the ICIQ-UI SF dataset.

**Table 1.** Baseline demographics and incontinence severity in responders and non-responders at the two-year follow-up (App group, $n = 61$).

| Variable (Mean (SD)) | Responders at 2 years ($n = 46$) | Non-responders at 2 years ($n = 15$) | Difference |
|---|---|---|---|
| Age, years | 44.2 (10.3) | 46.4 (7.8) | NS |
| BMI, kg/m$^2$ | 23.7 (3.7) | 25.0 (5.2) | NS |
| University education three years or more, *n* (%) | 37 (80.4) | 14 (93.3) | NS |
| Daily smokers, *n* (%) | 1 (2.2) | 1 (6.7) | NS |
| Incontinence severity | | | |
| ICIQ-UI SF score[a] | 11.3 (3.2) | 10.6 (2.6) | NS |
| ICIQ-LUTSqol score | 34.2 (6.4) | 33.6 (5.3) | NS |
| IEF, Median (IQR) | 21.0 (10.5, 28.0) | 17.5 (10.5, 28.0) | NS |
| Parity *n* (%) | | | |
| 0 | 4 (8.7) | 1 (6.7) | NS |
| 1 | 8 (17.4) | 2 (20.0) | NS |
| ≥2 | 34 (73.9) | 11 (73.3) | NS |

App, application for smartphone; 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; NS, nonsignificant; SD, standard deviation.
[a]Saved score.

 

**Table 2.** Primary outcome measures at two-year follow-up for responders.

| | ICIQ-UI SF | ICIQ-LUTSqol |
|---|---|---|
| Responders at two years ($n$ = 46) | | |
| Baseline, mean (SD) | 11.2 (3.2)[a] | 34.2 (6.5)[b] |
| Follow up, mean (SD) | 8.1 (3.9)[a] | 30.2 (7.8)[b] |
| Difference (95% CI) | 3.1 (2.0–4.2) | 4.0 (2.1–5.9) |
| $p$-value | <0.001 | <0.001 |

App, application for smartphone; CI, confidence interval; 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.
[a]45/46 complete answers for analysis.
[b]45/46 complete answers for analysis.

### *Secondary outcomes*

At the two-year follow-up, 66.7% of the women (29/46) reported that their leakage had improved compared with baseline (Figure 2). The proportion of women who felt they could contract their pelvic muscles correctly at two years was significantly greater than at baseline (67.4% vs. 30.4%, $p < 0.001$). The use of incontinence protection products decreased significantly compared to baseline ($p = 0.04$) (Figure 3). Of the 46 women, 21.7% (10/46) had sought other treatment for their SUI since the beginning of the study, and 4.3% (2/46) had undergone surgery (Table 3).

When we excluded the two women who had undergone surgery, the results were not affected except for the outcome use of incontinence protection products. The change in use of incontinence protection products was no longer significant when we excluded the two women who underwent surgery.

## Discussion

We noted significant and clinically relevant improvements in symptom severity and quality of life two years after treatment with a mobile app for SUI. Of the participating women, 66.7% felt that their leakage had improved. At the two-year follow-up, two women had undergone surgery for their incontinence, two-thirds of the women felt that they could contract their pelvic muscles correctly, and the use of incontinence protection products had decreased. Loss to follow-up in our study was 24.6%, which is in line with the 0–39% loss that other studies have reported after 1–15 years of follow-up (11,20).

The most common reported outcome in studies of the long-term effects of PFMT for SUI is subjective improvement, and a systematic review reported that the long-term success in original responders was 41–85% (20). In our study, two-thirds of the women reported improvement compared with baseline, as measured by the PGI-I.

The surgery rate for incontinence at long-term follow-up varies from 4.9 to 58% (20). It is usually higher if patients are recruited from waiting lists for incontinence, as in Aukee et al.'s study (25), which reported a surgery rate of 47% after 1 year. A higher surgery rate is expected with recruitment of women who are positively predisposed to and expecting surgery. However, in a small study by Bö et al. (26), 23 women were recruited from a waiting list for incontinence surgery. They received intensive training in a group led by a physiotherapist, and the surgery rate after five years was only 13%. Our group

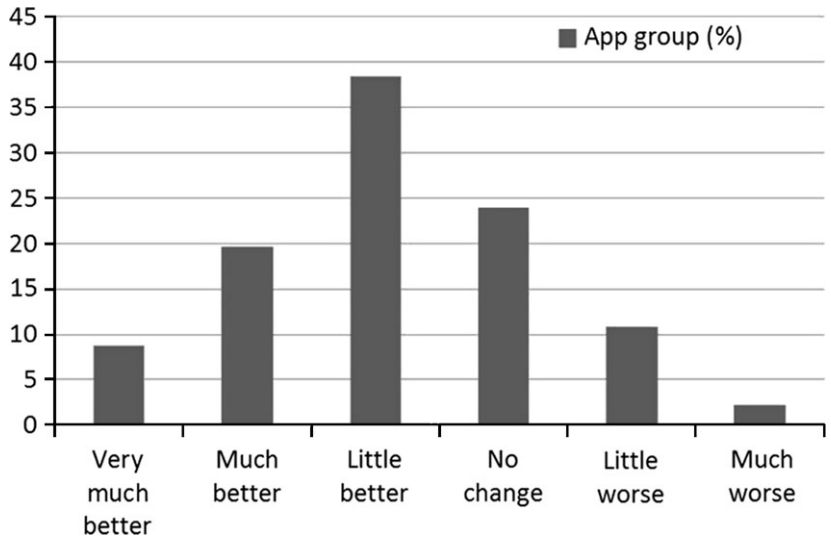


**Figure 2.** Patient global impression of improvement at two-year follow-up.


 

**Table 3.** Number and percentage of women who sought other treatment during follow-up.

| Variable *n* (%) | App group (*n* = 46) |
|---|---|
| Prescription of incontinence aids/protection | 2 (4.3) |
| Advice on pelvic floor muscle training | 4 (8.7) |
| Local estrogen treatment | 1 (2.2) |
| Medication | – |
| Electrostimulation | – |
| Operated | 2 (4.3) |
| Referral/waiting on answer after referral | 3 (6.5) |
| Total number seeking other care | 10 (21.7) |

previously conducted a study (11) that compared internet treatment with written instructions for SUI. In this study, in which women were recruited through a website, there was an overall surgery rate of 5.2% after two years (11), similar to our findings in the present study. Both studies used the same validated outcome measures: the ICIQ-UI SF and ICIQ-LUTSqol. After two years, the mean decrease in the ICIQ-UI SF was 3.6 and 3.4 in the internet and postal groups, respectively, and the mean decrease in the ICIQ-LUTSqol was 6.4 and 4.8 in the internet and postal groups (11). The decreases in these two scores in the previous study (17) are in the same range as in the present study. The mean decrease in the app group was 3.1 for the ICIQ-UI SF and 4.0 for the ICIQ-LUTSqol, from baseline to two years. This effect appears to be maintained from three months post-treatment (17) as similar reductions were found at that time (3.9 and 4.8, respectively). However, the studied group is small and lacks sufficient statistical power with which to detect any deterioration or improvement in the scores post-treatment to two years. More long-term follow-up studies that use validated scores are required to facilitate comparisons of incontinence studies.

Our study yielded promising long-term results in terms of a condition that can severely affect quality of life. The app is noninvasive and can be used without seeking medical care, and may serve as a first-line treatment for women who feel confident in managing their condition independently. The long-term effects are at the same level as in studies of supervised PFMT. In cases where self-management is not successful, the next step may be to seek healthcare. The app may also be used as a complement to other healthcare treatments for those who want it. Tät® is CE marked as a Class 1 medical device, according to Swedish regulations (LVFS 2003:11). It is now available free of charge in Swedish and English for Android and iOS platforms.

The strengths of the present study include the length of follow-up, the response rate of 75.4%, and the lack of differences in sociodemographic and incontinence variables at baseline between responders and non-responders. The women had moderate or severe incontinence with a median leakage value of three times a day at study commencement, with improvements that were clinically relevant. The minimum important differences (MIDs) established for ICIQ-UI SF and ICIQ-LUTSqol after PFMT for SUI are 2.52 and 3.71, respectively (27); the reductions in symptom and qol scores reported here (at two years) are greater. Further, 29 of the 46 women (63%) felt (subjectively) that their condition had

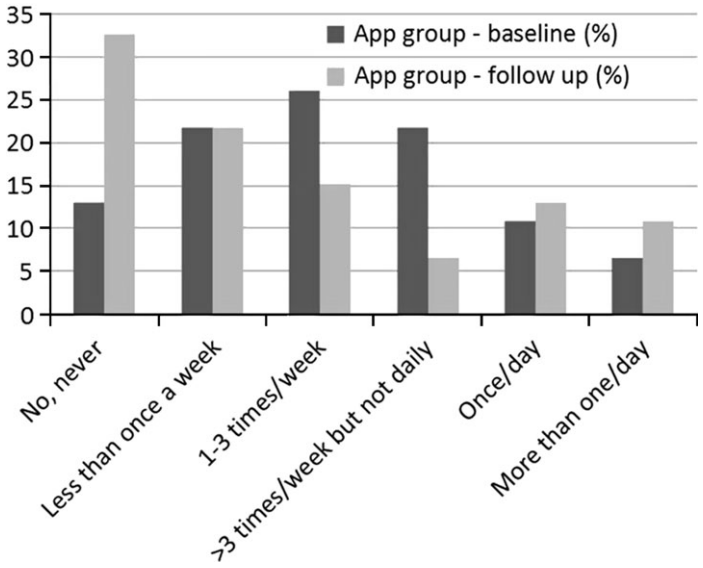


**Figure 3.** Use of incontinence aids during previous four weeks at study baseline and at two-year follow-up.

 

improved at the two-year follow-up vs. baseline. We therefore regard these changes as clinically relevant.

We used validated and recommended patient-reported outcome measures, and the study management adhered to clinical guidelines (21–23). The same primary outcomes as in the original randomized clinical trial were used (17). The original study (17) was registered at ClinicalTrials.gov, and we reported its results upon completion. When we analyzed the change in scores for the primary outcomes both with and without saved scores for missing values, there was no effect on the significance of the change from baseline. We had data about women who had sought other treatments during the follow-up, and we also performed analyses that excluded the two women who had undergone surgery for incontinence. Again, there was no effect on the significance of changes from baseline for the primary and secondary outcomes, except for the variable "use of incontinence aids." The two women who underwent surgery both reported that their incontinence was very much improved.

A limitation of our study is the absence of a control group given that the original control group could access the mobile treatment app after their first follow-up at three months. Another limitation is that the studied group was too small to permit robust statistical comparisons to be made between the three-month (17) and two-year follow-ups, post-treatment. However, we believe that the most important clinical data are the improvements achieved from baseline to two years. Finally, the participants may not be representative of the general population. Approximately 80% had studied at university level; in the general Swedish population, approximately 25% of women aged 25 years and older have some university education (28). New technology generally attracts highly educated individuals. However, the educational level does not appear to be associated with the ability to understand instructions and perform PFMT (29).

## Conclusion

The promising long-term effects seen in this two-year follow-up study further support the use of the Tät® app as a first-line treatment for SUI.

## Acknowledgments

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