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App-based self-management of urgency and mixed urinary incontinence in women: One-year follow-up

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Abstract

Aims: To evaluate the long-term effect of the Tät®II app for treatment of urgency (UUI) and mixed urinary incontinence (MUI).

Methods: Long-term follow-up of a randomized controlled trial, including 123 women ≥18 years old with UUI or MUI, without red-flag symptoms, and ≥2 leakages per week. All participants, regardless of group, had received the intervention, a treatment app, at the long-term follow-up. Long-term data were collected through web-based questionnaires 15 months after participants received the intervention. The app included pelvic floor muscle training, bladder training, psychoeducation, lifestyle advice, an exercise log, reminders, reinforcement messages, and tailored advice. The primary outcome was a change in incontinence symptoms (International Consultation on Incontinence Questionnaire [ICIQ]—Urinary Incontinence Short Form [ICIQ-UI SF]), from baseline to follow-up. Other outcomes were urgency symptoms (ICIQ—Overactive Bladder Module (ICIQ-OAB)), quality of life (ICIQ—Lower Urinary Tract Symptoms Quality of Life Module [ICIQ-LUTSqol]), and improvement (Patient's Global Impression of Improvement [PGI-I]).

Results: Of the 123 women, 102 (83%) completed the long-term follow-up. The ICIQ-UI SF mean score improved from 11.5 to 7.6 (mean difference 4.0, 95% CI 3.2–4.7). The ICIQ-OAB improved from 6.7 to 5.5 (mean difference 1.3, 95% CI 0.9–1.6) and the ICIQ-LUTSqol improved from 38.0 to 30.9 (mean difference 7.1, 95% CI 5.7–8.5). Of the 102 women, 74 (73%) reported improvement.

Conclusions: Self-management with the Tät®II app for UUI and MUI had a significant effect across all outcome measures also long-term and might serve as an alternative first-line treatment for these conditions.

KEYWORDS
eHealth, long-term follow-up, mHealth, mixed urinary incontinence, mobile app, telehealth, treatment, urgency urinary incontinence

1 | BACKGROUND

Urgency (UUI) and mixed (MUI) urinary incontinence are common conditions affecting up to a quarter of all women, often with a significant impact on quality of life.[1–3] UUI is defined as urinary leakage upon a sense of urgency and MUI is defined as a combination of urgency and stress-related urinary leakages.[4]

The recommended first-line treatments for UUI and MUI are pelvic floor muscle training (PFMT) and lifestyle changes.[1,5] Bladder training, or scheduled voiding, is recommended in some cases.[1,5] Regimes vary, but prolonging voiding intervals combined with patient education have been suggested as core components in bladder training.[6] Pharmacological therapy is widely prescribed, but treatment satisfaction is lower than with behavioral interventions, and discontinuation is common —partly due to unwanted side-effects.[5,7,8] Studies of the long-term result of behavioral interventions in urinary incontinence are scarce. A systematic review of the long-term effect of PFMT in stress urinary incontinence (SUI) and MUI described that maintenance training increases the likelihood of a sustained treatment effect, but that adherence is often low.[9]

The use of eHealth interventions is increasing and health apps have been shown to have potential as aids for long-term self-management in various chronic conditions.[10] Recent reviews have examined the effect and implementation of apps and other telehealth interventions in several urological conditions, including urinary incontinence, and found that they are an effective treatment alternative that can be implemented successfully.[11,12] A boost for telehealth has been predicted subsequent to the Covid-19 pandemic.[12] Previous studies on eHealth interventions for SUI have shown a significant and clinically relevant long-term effect.[13–15]

A recent randomized controlled trial (RCT) showed that a new app, Tät®II, was effective for the self-management of UUI and MUI in women. After 15 weeks of treatment, women who received the app had a clinically relevant improvement in all outcomes, including incontinence symptoms and quality of life.[16] A recent Dutch study of a mobile app that included PFMT and bladder training for women with SUI, MUI, or UUI, showed that the long-term effect was noninferior to care-as-usual.[17]

There is a knowledge gap regarding the long-term effect of treatment specifically for UUI and MUI, using app-based interventions and other interventions. The aim of this study was therefore to investigate the long-term results of app-based self-management of UUI and MUI in women.

2 | MATERIALS AND METHODS

This was a study of the long-term results of the app Tät®II (described below), originally evaluated in an RCT.[16] The RCT was performed in Sweden between April 2017 and September 2018 (Clinicaltrials.gov NCT03097549) and included 123 women randomized to either the mobile app Tät®II (intervention group) or brief information (control group). The original RCT study was registered at Clinical Trials and reported according to CONSORT statement guidelines. The present study was a long-term follow-up of the RCT, using the same outcomes as in the RCT. The control group from the RCT received the intervention, a treatment app, after initial follow-up. The original treatment group and the original control group were thus analyzed together, regarding long-term outcomes (Figure 1).

2.1 | Procedure and intervention

The Tät®II app contained a PFMT exercise program, as well as bladder training exercises, incontinence-related psychoeducation, and lifestyle advice. Tailored advice and recurring automated feedback were provided within the app to guide the user to the areas relevant to her condition. Customizable reminders and a statistical overview were also featured in the app. The development and contents of the app and the procedures of the original RCT are further detailed elsewhere.[16]

Figure 1 shows the study flow. The follow-up in the original RCT was performed 15 weeks after randomization. Participants in the control group from the RCT were offered the Tät®II app upon completion of this follow-up ($n = 63$) and asked to complete another follow-up 15 weeks after receiving the app. In the present study, we analyzed the results from the original treatment group at the initial follow-up, together with the results from the former control group at the follow-up after receiving the app (hereinafter referred to as "the short-term follow-up", i.e., 15 weeks after receiving access to Tät®II). The long-term follow-up was performed 12 months after completion of the short-term follow-up (i.e., some 15 months after receiving the app). Both the short-term and the long-term follow-up questionnaires included the symptom scores described below for the primary and secondary outcomes and questions on health, healthcare contacts, and usage of the app. The long-term follow-up questionnaire also included questions on red-flag symptoms.

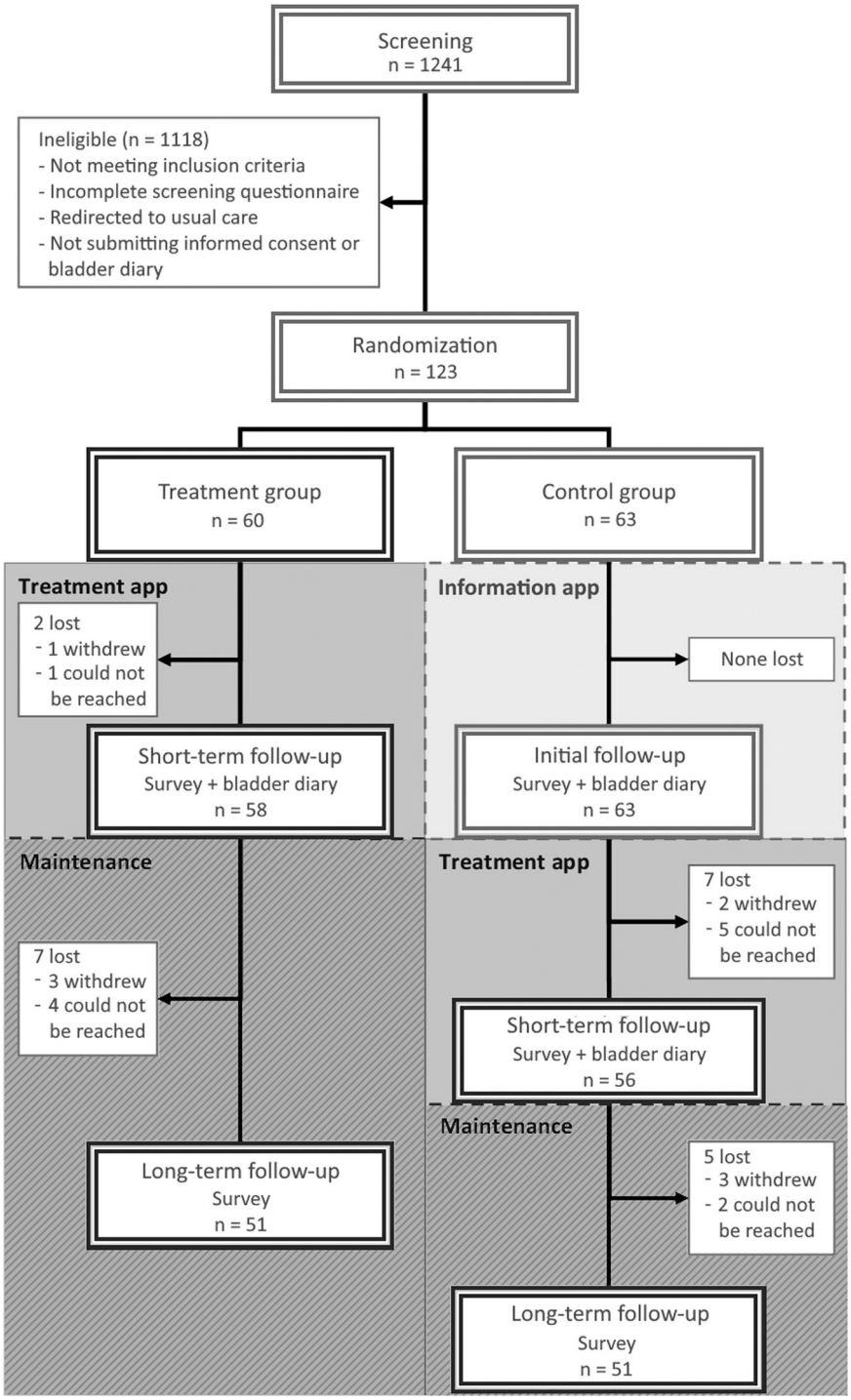

FIGURE 1 Flow chart: Please note that the short-term follow-up as defined in this study, was in fact the second follow-up for the original control group; the first follow-up being before receiving access to the treatment app. For both groups, the treatment duration was 15 weeks—after this, maintenance pelvic floor muscle training was recommended. The long-term follow-up took place 12 months after the end of the 15-week treatment

2.2 | Outcome measures

2.2.1 | Primary outcome

The primary outcome was the change in urinary incontinence symptoms from baseline to the long-term treatment follow-up. This was measured using the validated International Consultation on Incontinence Questionnaire (ICIQ)—Urinary Incontinence Short Form (ICIQ-UI SF) score (0–21 points) assessing the amount, frequency, and everyday effects of urinary leakage (Swedish version).[18] Additionally, the scores were used to categorize the participants' incontinence symptoms as slight (1–5 points), moderate (6–12 points), severe (13–18 points), or very severe (19–21 points).[19]

2.2.2 | Secondary outcomes

The validated ICIQ—Overactive Bladder Module (ICIQ-OAB) score (0–16 points) was used for measuring

urgency symptoms.[18] The validated ICIQ—Lower Urinary Tract Symptoms Quality of Life Module (ICIQ-LUTSqol) score (19–76 points) measured incontinence-related quality of life.[18] The Incontinence Catastrophizing (IC) Scale (0–21 points) was used to assess the participant's tendency to catastrophize over their incontinence. It was adapted from the validated Pain Catastrophizing Scale (short version) and contains 7 items covering fear of leakage and urgency.[20]

A higher score indicates a more severe condition in all the above scores.

The Patient's Global Impression of Improvement (PGI-I) assessed self-perceived improvement of incontinence symptoms. Participants compare their follow-up condition to their pretreatment condition on a seven-item scale, ranging from "Very much better" to "Very much worse".[21] Improvement was defined as any improvement on the PGI-I scale.

Usage of incontinence protection products was measured via a six-item scale where participants estimated their consumption over the preceding 4 weeks with response options ranging from "No, never" to "Yes, more than one pad per day".

Patient satisfaction was assessed at the short-term and long-term follow-up, by asking whether the participant was satisfied with the treatment results, with three response options considering satisfaction and intention to seek further care.

2.2.3 | App usage and treatment adherence

Participants were asked to estimate how frequently they had used the app, performed PFMT, and used the bladder training exercises during the preceding 4 weeks (for each item, the response options ranged from "Never" to "Daily: three times a day, or more often"). Adherence to PFMT maintenance treatment was defined as performing pelvic floor exercises at least once a week.

2.3 | Statistical analyses

Participants with valid data for at least the first question in the questionnaires, the PGI-I, were defined as having completed the long-term follow-up. For each analysis, participants with missing or invalid data were excluded. Baseline data for the completing participants were compared with data for those lost to follow-up to discern any significant differences.

In the analyses of baseline data, the Student's t test was used to compare mean scores for the continuous variables ICIQ-UI SF, ICIQ-OAB, ICIQ-LUTSqol, and the IC Score, and Pearson's χ^2 test was used to compare the categorical variables.

A paired t test was used to estimate the change in mean score for continuous variables. Comparisons were made between baseline and long-term follow-up and between short-term and long-term follow-up. A Wilcoxon's signed-rank test was used to estimate the change in incontinence aid usage from baseline to long-term follow-up.

The software IBM SPSS version 25 was used for all analyses.

2.4 | Safety measures

Red-flag symptoms, including painful urgency, dysuria, metrorrhagia, visible hematuria, previous pyelonephritis, ≥3 urinary tract infections in the preceding 12 months, and noninvestigated bladder-emptying difficulties, were assessed in the screening questionnaire and led to exclusion and advice to consult a healthcare professional. Additionally, those with cancer in the pelvic area, bladder, or bowels; diabetes; neurological disease; decreased mobility or sensitivity in the legs or pelvic area; or history of stroke, were excluded. Upon inclusion, the participants were specifically advised to consult a healthcare professional should any red-flag symptoms occur during the study. Throughout the study, participants were able to email nonurgent questions to the study team.

2.5 | Ethical approval

The study was approved by the regional ethical review board of Umeå, Sweden (registry number 2016/523-31). All participants provided written informed consent.

3 | RESULTS

Of the 123 women included in the original RCT,[16] 102 (83%) responded to the long-term follow-up. Two women did not respond to the short-term follow-up and a further 19 women were lost to follow-up between the short-term and the long-term follow-up (Figure 1). The baseline characteristics did not differ between the participants who completed follow-up ($n = 102$) and the participants who were lost to follow-up ($n = 21$), apart from the body mass index (BMI), with those lost to follow-up having a slightly lower mean BMI (Table 1).

TABLE 1 Baseline characteristics

	Completed follow-up ($n = 102$)	Lost to follow-up ($n = 21$)	p value
General information			
Age (years), mean (SD)	58.6 (9.1)	56.9 (11.8)	0.464
BMI (kg/m^2), mean (SD)	26.7 (4.6)	23.6 (2.4)	<0.001
University education ≥3 years, *n* (%)	63 (61.8)	16 (76.2)	0.621
Smoker, *n* (%)[a]	2 (2.0)	1 (4.8)	0.433
Coffee consumption ≥5 cups/day, *n* (%)	13 (12.7)	4 (19.0)	0.678
Tea consumption ≥5 cups/day, *n* (%)	4 (3.9)	2 (9.5)	0.597
Treatment for chronic disease, *n* (%)[b]	42 (41.2)	6 (28.6)	0.281
Gynecology			
Parity, *n* (%)			
0	11 (10.8)	4 (19.0)	0.559
1	9 (8.8)	2 (9.5)	
≥2	82 (80.4)	15 (71.4)	
Postmenopausal >1 year, *n* (%)	72 (70.6)	17 (81.0)	0.680
Urinary incontinence			
Symptom diagnosis, *n* (%)			
Mixed urinary incontinence	75 (73.5)	13 (61.9)	0.297
Urgency urinary incontinence	27 (26.5)	8 (38.1)	
ICIQ-UI SF score, mean (SD)	11.6 (3.3)	11.3 (3.3)	0.714
ICIQ-OAB score, mean (SD)	6.7 (1.8)	6.6 (1.4)	0.700
ICIQ-LUTSqol score, mean (SD)	38.2 (8.0)	35.9 (8.9)	0.242
Incontinence severity, *n* (%)			
Slight	3 (2.9)	0 (0.0)	0.839
Moderate	60 (59.0)	13 (61.9)	
Severe	36 (35.3)	7 (33.3)	
Very severe	3 (2.9)	1 (4.8)	
IEF per week, mean (SD)[c]	21.7 (15.6)	20.2 (13.8)	0.778

Abbreviations: BMI, body mass index; ICIQ-UI SF, International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form; ICIQ-LUTSqol, International Consultation on Incontinence Questionnaire–Lower Urinary Tract Symptoms Quality of Life Module; ICIQ-OAB, International Consultation on Incontinence Questionnaire–Overactive Bladder Module; IEF, incontinence episode frequency; SD, standard deviation.

[a]There were no daily smokers, only weekly, in the study.

[b]The conditions assessed were hypertonia, heart disease, asthma, depression/anxiety, renal disease, cancer, and others (unspecified).

[c]Mean (SD) values are presented for comparability with other populations.

3.1 | Outcomes

3.1.1 | Primary and secondary outcomes

The primary outcome, the ICIQ-UI SF mean score, improved from 11.5 (SD 3.3) at baseline to 7.6 (SD 4.0) at the long-term follow-up. Similarly, the ICIQ-OAB improved from 6.7 (SD 1.8) at baseline to 5.5 (SD 2.1) at the long-term follow-up, the ICIQ-LUTSqol improved from 38.0 (SD 7.9) to 30.9 (SD 8.8), and the IC score improved from 4.8 (SD 2.7) to 2.5 (SD 2.5). The difference between baseline and the long-term follow-up score was statistically significant for all outcomes (Table 2). There were no significant differences in any of the scores between the short-term and long-term follow-up (Figure 2).

According to the PGI-I, improvement in incontinence symptoms from baseline to the long-term follow-up was reported by 73% (74/102) of the women.

Use of incontinence aids decreased from baseline to the long-term follow-up. At baseline, 84% used incontinence protection products compared with 66% at the long-term follow-up (Figure 3). There was no significant difference between the use of incontinence aids at the short-term and the long-term follow-up ($p = 0.295$)

Regarding the ability to contract the pelvic floor, 78/100 women reported an improvement at the long-term follow-up compared with before treatment. For the ability to resist the urge to void, the corresponding number was 67/100 women.

A total of 57/98 (58%) women reported being satisfied with the treatment at the long-term follow-up. Of the remaining 41 women, 12 intended to seek further care. Six women in the study had sought further care for their incontinence symptoms at the long-term follow-up. Five of them had received a pharmacological prescription and one had been referred for incontinence surgery. Four received instructions on PFMT in addition to medication or surgery referral.

3.1.2 | App usage and treatment adherence

The number of women who reported at the long-term follow-up that they had performed PFMT and/or bladder training regularly (once a week or more) in the preceding 4 weeks was 58/100, and 13/99 women still used the app regularly.

3.1.3 | Safety

A total of 17 women had experienced one or more red-flag symptoms after enrollment and nine of them contacted healthcare. Of those, two were diagnosed with urinary tract infection; and two women—both with metrorrhagia—were referred to a gynecologist. One was later diagnosed with gynecological cancer, leading to hystero-oophorectomy; the other had a nonmalignant ovarian cyst.

4 | DISCUSSION

The results from this follow-up study show that treatment with the app Tät®II resulted in significant and clinically relevant long-term improvement of UUI and MUI regarding all parameters measured: incontinence symptoms (ICIQ-UI SF), urgency (ICIQ-OAB), quality of life (ICIQ-LUTSqol), incontinence aid usage, and catastrophizing (IC-Scale).[15] Furthermore, the improvement at the short-term follow-up was sustained at the long-term follow-up for all outcomes.

Our study participants had a mean ICIQ-UI SF score improvement of −4.0 points at the long-term follow-up. This improvement is of similar, or slightly larger, magnitude compared with other long-term studies. A recent study by Loohuis et al.[17] found a mean improvement in the ICIQ-UI SF score of −2.17 for app-based treatment and of −3.43 for care-as-usual, whereas a study by

TABLE 2 Continuous outcomes at baseline and at the long-term follow-up

		Mean value		Mean change	
Outcome	***n***	**Baseline**	**Long-term follow-up**	**Mean (95% CI)**	***p* value**[a]
Incontinence symptoms (ICIQ-UI SF)	101	11.5	7.6	4.0 (3.2–4.7)	<0.001
Urgency symptoms (ICIQ-OAB)	100	6.7	5.5	1.3 (0.9–1.6)	<0.001
Quality of life (ICIQ-LUTSqol)	100	38.0	30.9	7.1 (5.7–8.5)	<0.001
Incontinence Catastrophizing (IC) Scale	99	4.8	2.5	2.2 (1.6–2.8)	<0.001

Abbreviations: CI, confidence interval; ICIQ-LUTSqol, International Consultation on Incontinence Questionnaire–Lower Urinary Tract Symptoms Quality of Life Module; ICIQ-OAB, International Consultation on Incontinence Questionnaire–Overactive Bladder Module; ICIQ-UI SF, International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form.

[a]Analyzed using a paired *t* test.

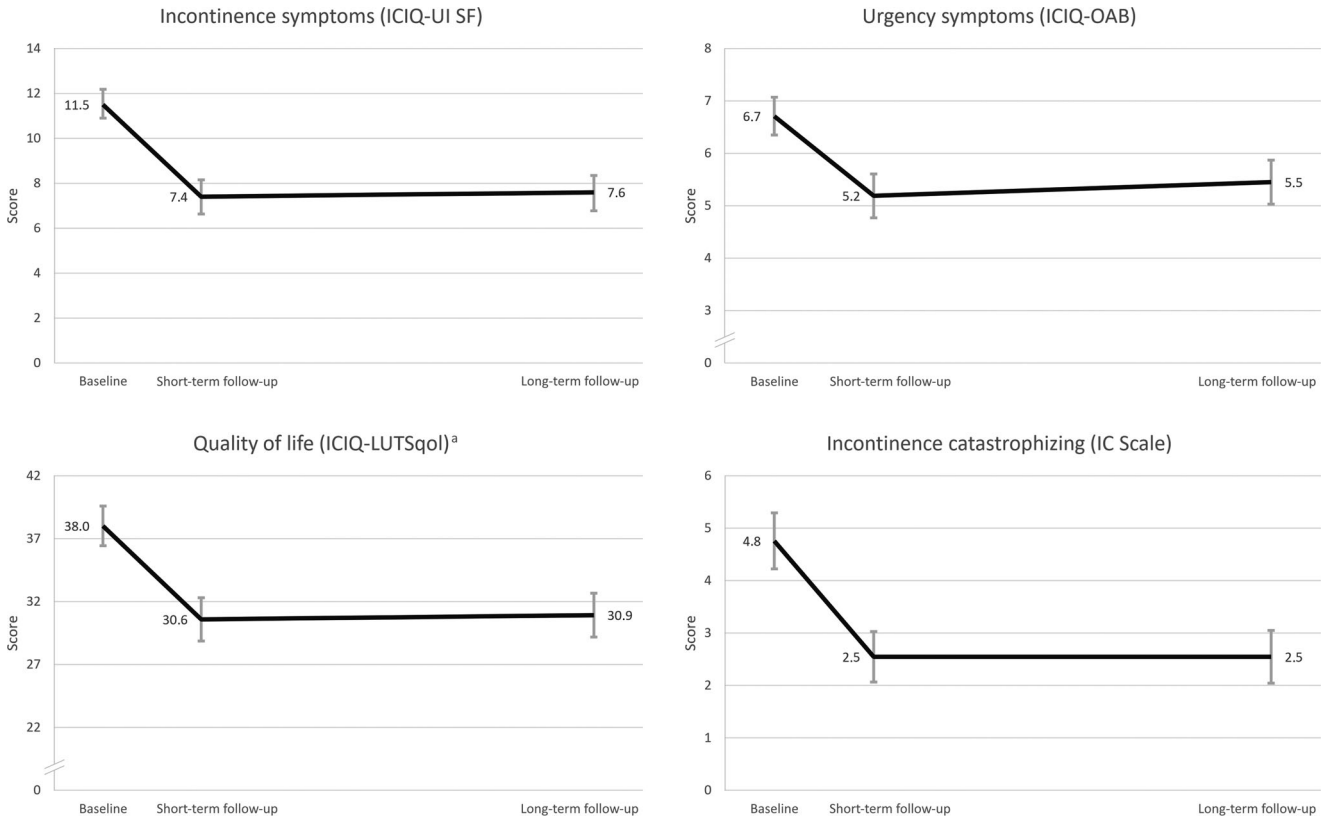

FIGURE 2 Overview of the change over time for the symptom mean scores. The error bars represent 95% CI. [a]Please note that the lowest possible score for the ICIQ-LUTSqol is 19. CI, confidence interval; ICIQ-UI SF, International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form; ICIQ-OAB, International Consultation on Incontinence Questionnaire–Overactive Bladder Module; ICIQ-LUTSqol, International Consultation on Incontinence Questionnaire–Lower Urinary Tract Symptoms Quality of Life Module

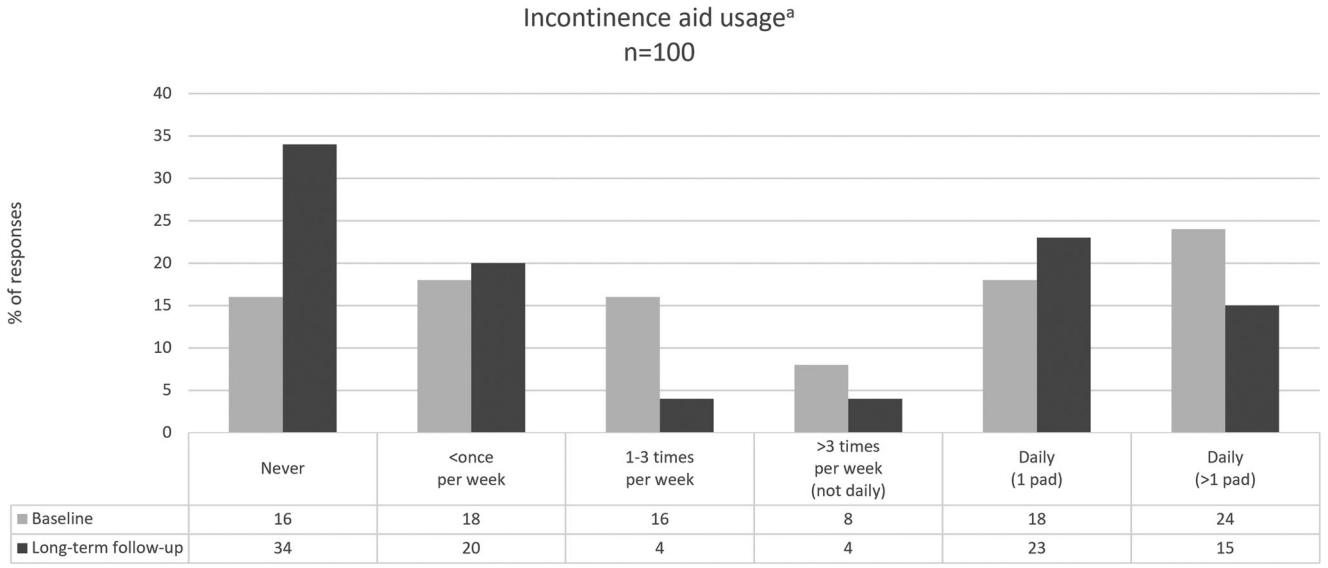

FIGURE 3 Incontinence aid usage at baseline and at the long-term follow-up. [a]$p < 0.001$ (Wilcoxon's signed-rank test)

Albers-Heitner et al.[22] found a mean improvement in ICIQ-UI SF score of −1.5 points for nurse specialist intervention and of −1.0 points for care-as-usual. Moreover, a study by Hagen et al found a mean improvement in ICIQ-UI SF score of −3.4 points for PFMT with biofeedback and of −3.6 for PFMT alone; although that study only included participants with SUI or MUI with higher baseline scores.[23] As noted above, studies on the

long-term effect of complex treatments specifically for UUI and MUI, similar to the program in the Tät®II app, remain scarce.

The PGI-I score measured at the short-term follow-up indicated that the majority of Tät®II users reported improvement.[16] At the long-term follow-up, the majority of users still reported improvement, but the number had decreased, even though the results for the other outcomes indicated a sustained treatment effect. The PGI-I score has not been validated for use in long-term follow-up studies and might be affected by recall bias.

Pharmacological treatment is frequently used in urgency-predominant urinary incontinence. In studies of anticholinergics or Mirabegron, 43.5%–49% reported symptom control with the prescribed medication.[5] However, studies on persistence rates have shown that less than 36% continued the treatment after 1 year—side effects being a common reason for discontinuation.[5]

Low adherence and persistence rates have also been described with behavioral interventions such as PFMT or bladder training. In a 2010 study of women with urgency-related incontinence treated with PFMT and bladder techniques combined with pharmacological treatment, only 32% of the participants adhered to the recommended training frequency at 12 months. The most important barriers to adherence were difficulties remembering to do the exercises and difficulties finding time for the training.[24]

In the current study, the general frequency with which the participants used the app was lower over the long term than the short term. Some explanations could be a change of device, developing conflicting interests, or losing interest over time. Additional explanations could be proceeding to maintenance training, or practicing the exercises without using the app. The results from the current study show that the treatment effect was largely sustained at 12 months even with less frequent app usage.

Six of the participants had sought further care for their incontinence sometime during the study period and the majority of them received pharmacological treatment. Four received PFMT instructions, which might have served as a reinforcement of the instructions in the app.

We found no differences in baseline data when we compared those who completed follow-up and those who were drop-outs, apart from the BMI. Other research has indicated that there is a relation between a higher BMI and more severe incontinence symptoms, thus the participants who were lost to follow-up could be more likely to have lower symptom scores than those who completed follow-up.[1]

4.1 | Strengths

This is the first study of the long-term results of using a complex app for self-management of UUI and MUI specifically. The original RCT was well powered and registered on ClinicalTrials.org and monitored on-site by an independent monitor.[16] The app Tät®II was developed based on scientific evidence and clinical experience. In addition to PFMT, the app featured different levels of bladder exercises, patient education, reminders, and reinforcement messages—features that have been proposed as important in bladder training interventions.[6]

The loss to follow-up in this study was small: one-fifth of the participants did not respond to the follow-up questionnaire. In long-term follow-up studies of eHealth interventions for UI, one-third of the participants were lost, and other studies report a loss of between 0% and 39%.[9,13,14,17]

All but one of the outcome measures used in this study were validated and recommended and they were chosen to represent the variety of aspects of UUI and MUI.

4.2 | Limitations

One limitation of this long-term follow-up study is the lack of a control group. The original control group from the RCT received the intervention after the initial follow-up and was analyzed together with the original intervention group. We cannot know whether the long-term effect was the result of a maintained regimen or sustainment of the short-term effect. Furthermore, the app Tät®II contains several treatment components and while this makes the app more flexible for the user, it also means that we cannot differentiate between any effect of individual treatment components and the treatment effect of the app as a whole.

Another potential limitation is that the effect of postponed treatment might differ from that of the immediate treatment and analyzing all participants as one group could affect the results. However, control analysis showed no significant differences between postponed and immediate treatment for all of the outcomes.

Due to data safety and privacy concerns, there was no automatic collection of usage data from the app. Instead, adherence was self-reported by the user and recall bias might influence the data.

Participants for this study were recruited through advertising in newspapers, magazines, television, and social media, to reach a broader target population. However, the extensive enrollment procedure following the initial web-based screening might have contributed to selecting the

most motivated participants. Analysis showed that the average level of education was higher among the participants than in the general population in Sweden. This is a common concern in studies of eHealth interventions and it may affect the generalizability of the results.

4.3 | Future research

The results of this study indicate that many participants retained improvement 1 year after treatment, even though the general usage frequency of the app was low at the long-term follow-up. Future research might investigate possible explanations for this.

More research is also needed into how the Tät®II app can be made available outside a study setting. Investigations should include for whom app treatment is suitable and how to reach those users. Another research direction would be to explore the importance of different features of the app to the user experience and the treatment effect, and whether specific factors influence the probability of treatment success.

It is important to pay attention to the digital divide when studying eHealth interventions to avoid increasing health disparities. Future studies should seek to evaluate app-based interventions in populations with other socioeconomic conditions or educational levels.

5 | CONCLUSIONS

This study showed that self-management with the app Tät®II was effective for long-term reduction of urinary leakage and urgency symptoms and improved incontinence-related quality of life, for women with UUI and MUI. An app providing an extensive intervention for these conditions might be a valuable addition to other first-line treatments, both over the short and long term.

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CONFLICT OF INTERESTS

The logos Tät and Tät.nu are registered as trademarks by The Swedish Patent and Registration office for eContinence AB, a Swedish e-health company founded in July 2021, with the aim to maintain, spread, commercialize, and further develop the apps created within the research project Tät.nu (eContinence.se). Eva Samuelsson, Emma Nyström and Malin Sjöström are cofounders and shareholders of eContinence AB. Eva Samuelsson is also the Chairman and Managing Director of the company.

AUTHOR CONTRIBUTIONS

Eva Samuelsson conceptualized the study, was the principal investigator and led the study at all stages. Eva Samuelsson, Emma Nyström, and Towe Wadensten designed the study with input from Anna Lindam. Towe Wadensten, Emma Nyström, and Anneli Nord performed the statistical analyses of the trial data, and Eva Samuelsson, Anna Lindam, and Malin Sjöström participated in the analyses. All authors had full access to all study data and participated in the interpretation of the data and statistical analyses. Towe Wadensten wrote the manuscript draft, with substantial input from Eva Samuelsson, Emma Nyström, and Malin Sjöström, and all authors critically reviewed successive drafts of the report and approved the final version of the manuscript before publication.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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