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Mobile App-treatment of Mixed and Urgency Urinary Incontinence in Women

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Tät II clinical trial: Study Protocol

Summary

The purpose of this study is to determine the short-term effect of self-management of mixed urinary incontinence (MUI) and urgency urinary incontinence (UUI) via a mobile app.

Description

Female urinary incontinence (UI) is common and affects up to one fourth of adult women (1). It may reduce quality of life for those affected and costs for society are high. The most common type of urinary incontinence is stress urinary incontinence (SUI), i.e. leakage when coughing, sneezing or jumping. UUI, i.e. a strong urge to urinate combined with leakage and MUI, i.e. a combination of both types, together adds up to nearly half of the cases of UI in women (1). Many women do not seek care, sometimes due to embarrassment (2). The recommended first line treatment for all types of UI is pelvic floor muscle training (PFMT) in combination with lifestyle changes. This treatment leads to improvement or cure in two-thirds of patients. In addition, bladder training might be effective in treatment of UUI and MUI, leading to improvement or cure in one-sixth of treated women with MUI (3,4). Research also suggests that psychological treatment might be valuable for some women with UUI or MUI (5).

The use of smartphones is increasing rapidly. About 81% of all cell phones in Sweden today (in 2017) are smartphones. The majority of adults in Sweden own a smartphone. Many smartphone owners have at least one health app on their phone. Exercise, diet, and weight apps are the most popular types.

There is a need for new, flexible and easily accessible treatment programmes for female urinary incontinence. The investigators have previously demonstrated the efficacy of the mobile app Tät® for treatment of SUI (6). Apps have the potential to improve symptoms in many chronic conditions through self-management interventions (7).

From our previous experience of a smartphone app treatment for SUI, we have developed a new app combining some of the features from the previous app with new features more specifically aimed towards treatment of UUI and MUI. The effect of the treatment programme will be evaluated after three months by comparing the effect in a group which receives the full contents of the new app (the “treatment app group”) with a group which initially receives a limited version of the app containing only brief information and no actual exercises (the “information app group”).

Intervention and control

Intervention: Tät II treatment app

Smartphone treatment with various exercises: A smartphone application with information on UUI/MUI, lifestyle information, psychological education and exercises, different programmes of PFMT and Bladder Training with increasing challenges, statistics on training. Possibility to set reminders. The treatment period is 15 weeks, and after that, maintenance training is recommended.

Control: Information app

Limited version of app, containing brief information, for three months. They receive the activation code for the treatment app after follow-up.

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Interventional Study Model: Parallel Assignment, 2 arms
Masking: No masking
Allocation: Randomized
Time to follow-up: 15 weeks

Procedure

Participants are consecutively recruited through our website tät.nu. They answer an online screening survey with automated immediate response for initial screening of eligibility criteria. Informed consent and leakage diary (number of episodes of urinary leakage during 48 hours) are sent by post. After that, they answer a web questionnaire and finally they are interviewed by a researcher to confirm the diagnosis UUI or MUI, to discover any alarm symptoms motivating directing the participant to other care, and to ascertain that the patient is well informed of the study procedure. Women are then randomized to either of the two groups. Women in both groups get a smartphone application for iPhone or Android. The treatment app group receives a unique code for activation of the complete app. Follow-up after three months with a web questionnaire and a leakage diary. After that the information app group get their unique activation code.

Monitoring

The study will be monitored according to GCP principles by study research nurse Agneta Lindberg at the local clinical research centre of the Region of Jämtland Härjedalen to ascertain a proper procedure of conduction, recording and reporting data. The monitor will review study records, observe protocol procedures and the randomization process, ensure that written informed consent has been correctly obtained and verify patient safety by monitoring the correct reporting of any adverse events.

Sample size

Based on previous results from our study and the findings of Albers-Heitner et al (6, 8), we assume an improvement in the ICIQ UI SF of 2.5 p in the treatment app group and 0.9 p in the information app group. To detect this difference with 80% power, 2-side test and significance 0.05, we need a sample size of 49 in each group. With an expected drop-out rate of 20%, we need approximately 60 participants in each group. We therefore aim to recruit 120 women aged 18 and older via our website www.tät.nu.

Eligibility

Inclusion Criteria

- age 18 years or older
- female
- urge urinary incontinence or mixed urinary incontinence
- leakage twice a week or more often
- duration of symptoms for at least 12 months
- motivation and time to perform a 12-week treatment with pelvic floor muscle training
- ability to read and write Swedish
- access to smartphone/tablet
- possibility to send and receive email and asset to printer
- accept to be randomized to one of two groups; a treatment app group or an information app group

Exclusion Criteria

- participation in our previous internet study or smartphone study
- pregnancy
- former incontinence surgery
- known malignancy in lower abdomen
- unassessed difficulties in emptying bladder
- visual blood in urine
- three or more urinary tract infections within the last year or pyelonephritis in the last three years
- painful urgency
- intermenstrual bleeding
- neurological disease with affection on sensibility in legs or lower abdomen
- Usage of the previous app Tät® during the last month
- Usage of anticholinergic drugs during the last month
- Maximum urinary volume of less than 100 ml
- Need for further assessment of symtoms, based on a telephone interview performed by an experienced urotherapist

Tät II clinical trial: Statistical analysis plan

Intention-to-treat analysis will be performed on all outcome measures.

Baseline comparison

The two groups will be compared at baseline regarding demographic factors and incontinence-related parameters:
For continuous variables, Student´s t-test will be used.
For categorical variables, Pearson´s chi-square test will be used.
For ordinal variables, and continuous variables with a non-normal distribution, the Mann-Whitney U-test will be used.

Primary outcome

Comparison between groups:
The primary outcome is the difference between the groups in mean ICIQ-UI SF score change from baseline to 15-weeks follow-up. This will be compared using a linear mixed models analysis.

Comparison within groups:
For comparison within the groups regarding the change in ICIQ-UI SF score from baseline to 15-weeks follow-up, a paired t-test will be used.

Secondary outcomes

Comparison between groups:
For the secondary outcomes the difference between the groups in mean ICIQ-LUTSqol, ICIQ-OAB and Incontinence Catastrophizing Scale (ICS) score changes from baseline to follow-up, a linear mixed models analysis will be used.
For the secondary outcome the difference between the groups in the median value of Patient's Global Impression of Improvement (PGI-I), a question on improvement only used at follow-up, the Mann-Whitney U-test will be used.
For the secondary outcome the difference between the groups in the median Incontinence Episode Frequency (IEF) from baseline to follow-up, the Mann-Whitney U-test will be used.
For the secondary outcome the changes in usage of incontinence aids from baseline to follow-up, we will use a six-item question about the frequency of usage in the last four weeks. We will compare the groups using the Mann-Whitney U-test.

Comparison within groups:
For comparison within the groups regarding the change in ICIQ-LUTSqol, ICIQ-OAB and ICS scores from baseline to 15-weeks follow-up, a paired t-test will be used.
For comparison within the groups regarding the change in IEF and incontinence aid usage from baseline to 15-weeks follow-up, a Wilcoxon signed-rank test will be used.

Missing data

The questionnaires will be web-based and every question will, if technically possible, be mandatory. However, should there for some reason be missing values, they will be replaced with the value corresponding to "no change", i.e. a missing value at follow-up will be replaced with the participant´s baseline value and a missing value at baseline will be replaced with the follow-up value. A missing answer in the PGI-I at follow-up will be assumed as "unchanged".

Outcome Measures

1. Primary Outcome Measure

Measure Title	International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF)
Measure Description	Three items on frequency, amount of leakage and overall impact. Scoring 0-21, higher values indicating increasing severity

2. Secondary Outcome Measure:

Measure Title	International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol)
Measure Description	The instrument includes 19 items on the impact of the leakage. All items are scored 1-4 (not at all/never, slightly/sometimes, moderately/often, a lot/all the time). The overall score is 19-76, with higher values indicating increased impact on QOL.

3. Secondary Outcome Measure:

Measure Title	International Consultation on Incontinence Modular Questionnaire Overactive Bladder (ICIQ OAB)
Measure Description	Four items on frequency of micturition during day and during night, frequency of urgency and urgency leakage, each item scored 0-4, total score 0-16, higher values indicating increased severity.

4. Secondary Outcome Measure:

Measure Title	Incontinence catastrophizing scale (ICS)
Measure Description	Seven items on fear of leakage and urgency. Alternatives on each item; Never (=0), sometimes (=1), often (=2), Always (=3). Score 0-21.

5. Secondary Outcome Measure:

Measure Title	Incontinence Episode Frequency (IEF)
Measure Description	number of incontinence episodes per week

6. Secondary Outcome Measure:

Measure Title	Change from baseline Usage of incontinence aids at 15 weeks
Measure Description	Use of incontinence aids during the last four weeks, six response options from "Never" to "more than one incontinence aid per day"

7. Secondary Outcome Measure:

Measure Title	Patient global impression of improvement (PGI-I)
Measure Description	Validated 7-item scale on improvement from very much improved to very much worse.

8. Secondary Outcome Measure (only for the Tät® II treatment app group)**:**

Measure Title	Patient Satisfaction
Measure Description	A self-rated question about if the current treatment was sufficient, with three response options (satisfied without any leakages remaining; satisfied with leakages remaining; not satisfied)

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