A mobile app for self-management of urinary incontinence

Treatment effect and user experience

Ina Asklund

Department of Public Health and Clinical Medicine
Umeå 2020
To all women
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Abstract

Background

Urinary incontinence affects 25-45% of all women. The most common type is stress urinary incontinence, which is the leakage of urine on physical exertion. Pelvic floor muscle training is an effective first-line treatment for this condition but many women do not seek help from their ordinary health care service. There is a need to evaluate new methods to offer effective treatment, and internet-based treatment has previously been found to be effective for women with stress urinary incontinence.

Aim

To evaluate the mobile app Tät® which has a self-management program focused on pelvic floor muscle training for women with stress urinary incontinence, with respect to treatment effect, factors associated with successful treatment, user experience and use by pregnant and postnatal women.

Methods

Papers I, II and III are based on the same study population from a randomized controlled trial (RCT). We recruited adult women who had stress urinary incontinence at least weekly via our website. In total, 123 women were randomized to the app group (n=62) or the control group (n=61). The app included information about incontinence, the pelvic floor and lifestyle factors associated with incontinence, pelvic floor muscle training exercises and functions for reminders and training statistics. Treatment outcome after three months was evaluated using validated questionnaires assessing incontinence symptoms, quality of life, subjective improvement and a leakage diary. Outcomes were compared between the two groups. Factors associated with a successful outcome in the app group were further analysed using logistic regression. We strategically selected 15 women who had used the app and interviewed them about their experiences of using the app. The interviews were analysed according to Grounded Theory. After closing the RCT we made the app freely available and continued to follow its use on a larger scale by incorporating an anonymous questionnaire that appeared within the app upon download and after three months. The data from these questionnaires is used in paper IV.

Results

Participants in the RCT had a mean age of 44.7 years (range 27-72) and 120 of the 123 women had moderate/severe incontinence. The app group reported significant improvements in the primary outcomes, the incontinence symptom score (mean ICIQ-UI SF reduction 3.9, 95% CI 3.0-4.7) and the quality of life
score (mean ICIQ LUTSqol reduction 4.8, 95% CI 3.4-6.2), and the difference between the groups was significant. The app group also reduced their number of leakages and use of incontinence aids compared to the control group. At follow-up 92% of women in the app group experienced subjective improvement and 56% had improved “much” or “very much” and were classified as having a successful treatment outcome.

Factors associated with a successful outcome were higher expectations of treatment effect (OR 11.38, 95% CI 2.02-64.19), weight control (OR 0.44 per kg gained, 95% CI 0.24-0.79), and self-assessed improvement of pelvic floor muscle strength (OR 35.54, 95% CI 4.96-254.61).

The main finding from the interviews was that women experienced that the app “enabled their independence”. They described that the app was “something new” that helped with “keeping motivation up” although they sometimes wondered whether their training efforts were “good enough”.

The freely available app was downloaded by 10,456 pregnant and postnatal women during a period of ten months (41% of all users). At inclusion 51% experienced incontinence and their mean ICIQ-UI SF score was 6.7 (SD 3.45). After three months, 1,805 women answered the follow-up. The majority of women with incontinence at inclusion experienced improvement with greater improvement in the postnatal group than in the pregnant group.

**Conclusion**

The mobile app Tät® offers a new, easily accessible and effective self-management program for women with stress urinary incontinence. Women appreciated that the app enabled them to manage their pelvic floor muscle training independently. Once the app was freely released it reached a large population with many pregnant and postnatal women. We believe that the app could be useful for the prevention of urinary incontinence among pregnant women. We also believe that the app could be used both as a stand-alone treatment and as a complement to other treatments provided by the ordinary health care service.
Original Papers

This thesis is based on the following papers:


Abbreviations

BMI
Body Mass Index

CI
Confidence Interval

CONSORT
Consolidated Standards of Reporting Trials

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

ICS
International Continence Society

IEF
Incontinence Episode Frequency

IQR
Interquartile Range

KHQ
King’s Health Questionnaire

MCID
Minimum Clinically Important Difference

NICE
National Institute of Health and Clinical Excellence

OR
Odds Ratio

PFMT
Pelvic Floor Muscle Training

PGI-I
Patient Global Impression of Improvement

PRO
Patient Reported Outcome

RCT
Randomized Controlled Trial

SD
Standard Deviation

SUI
Stress Urinary Incontinence

UI
Urinary Incontinence
Enkel sammanfattning på svenska

En mobilapp för egenbehandling av urininkontinens. Effekt och upplevelse av behandling.

Bakgrund


Syfte

Att utvärdera appen Tät® som innehåller ett program för egenbehandling av ansträngningsinkontinens med fokus på bäckenbottenträning, med avseende på behandlingseffekt, framgångsfaktorer, upplevelse av behandling och användning bland gravida och nyförlösta kvinnor.

Metod

Resultat

Medelåldern i den randomiserade kontrollerade studien var 44,7 år (27 till 72 år) och 120 av 123 kvinnor hade medelsvår eller svår inkontinens. Appgruppen förbättrades signifikant avseende de primära utfallsmätten inkontinensssymtom (ICIQ-UI SF medelförbättring 3,9 poäng, 95 % KI 3,0 – 4,7) och livskvalitet (ICIQ-LUTSsqol medelförbättring 4,8 poäng, 95 % KI: 3,4 – 6,2) och skillnaden mellan grupperna var signifikant. Appgruppen minskade också antalet episoder av läckage per vecka och användningen av inkontinensskydd jämfört med kontrollgruppen. Vid uppföljningen upplevde 92% i appgruppen att de var bättre och 56% upplevde att de var mycket eller väldigt mycket bättre och bedömdes ha ett lyckat behandlingsresultat. De faktorer som var associerade med ett lyckat behandlingsresultat var högre förväntningar på behandlingsresultatet, viktsstabilitet och självskattad förbättring av bäckenbotten. Det viktigaste fyndet i intervjustudien var att kvinnorna upplevde att appen ”möjliggjorde deras självständighet”. De beskrev att appen var ”något nytt” som hjälpte dem att ”hålla motivationen uppe” trots att de ibland undrade över om bäckenbottenträningen de gjorde var ”tillräckligt bra”.

Den fritt tillgängliga appen laddades hem av 10 456 gravida och nyförlösta kvinnor under 10 månader vilket motsvarade ca 41% av alla användare under den perioden. Vid inklusion hade 51% av kvinnorna inkontinens. Uppföljningsfrågorna efter tre månader besvarades av 1805 kvinnor. Bland kvinnorna som hade inkontinens vid inklusion upplevde en majoritet att de blivit förbättrade.

Slutsats

Introduction

Many women experience urinary incontinence at some time during their life and it can have a negative effect on their quality of life. Pelvic floor muscle training is a well-established first-line treatment that can reduce the symptoms of urinary incontinence. This thesis focuses on a mobile app intervention which contains a pelvic floor muscle training program for self-management of stress urinary incontinence in women.

Definition of urinary incontinence

The symptom definition of urinary incontinence (UI) established by the International Continence Society (a society focusing on research and education about incontinence) is: “the complaint of involuntary loss of urine”.¹ Other definitions also exist based on objective signs and findings of urinary incontinence. I will focus mainly on urinary incontinence based on the above symptom definition since we have chosen to study a self-management intervention without any physical contact with the participants.

There are three main types of urinary incontinence.¹ Stress urinary incontinence (SUI) is the complaint of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing. Urgency urinary incontinence (UUI) is the complaint of involuntary loss of urine associated with urgency. Mixed urinary incontinence (MUI) is a combination of both SUI and UUI.

Epidemiology

Prevalence

The prevalence of urinary incontinence in the adult female population has been investigated in multiple studies. In Europe, a recent study of 4,555 women in Germany and Denmark found a UI prevalence of 48% and 46% respectively.² Another postal survey of 17,080 women from France, Germany, Spain and the United Kingdom found that the UI prevalence was 35%.³ In the large EPINCONT (Epidemiology of Incontinence in the County of Nord-Trøndelag) surveys in Norway conducted in 1995 to 1997 (n=27,992) and again from 2006 to 2008 (n=21,804) 25% and 29% of the women reported that they had UI.⁴ ⁵

In a survey from 2005 which included 19,165 participants from five countries (Canada, Germany, Italy, Sweden and United Kingdom) an overall UI prevalence of 13% was found in women.⁶ Similar surveys have been performed in other countries. In Russia, the Czech Republic and Turkey they found a UI prevalence
of 20% in women. In Korea they found a UI prevalence of 28% and in Egypt they found a UI prevalence of 27%, 8, 9

In Sweden, a population-based study carried out in 2000 found a UI prevalence of 27% (women with UI sometimes) and 11% (women with UI every week). This is similar to earlier studies from 1991 and 1993 where the UI prevalence for “sometimes” was found to be 21% and 28% respectively, and for “weekly” it was 14% and 8% respectively.11, 12

It is difficult to compare the UI prevalence found in different studies since studies may use different definitions of UI, different questionnaires and recruit different study populations. Estimations are that approximately 25-45% of all women are affected by UI at some time and around 10% are affected weekly.13 The most common type of incontinence is stress urinary incontinence, which accounts for approximately half of all incontinence.13, 2, 3, 4, 6 The second most common type seems to be MUI and the third is UUI. In this thesis I will focus on SUI.

Incidence and remission
The natural history of urinary incontinence is not fully understood.14 It does however appear that urinary incontinence is a not a static condition but rather a dynamic one.15-17 A number of longitudinal studies have tried to investigate the incidence and remission rates of UI.

The EPINCONT study followed a cohort of 14,606 Norwegian women from 1995-97 to 2006-08. A total of 18.7% reported UI incidence and 34.1% reported remission of UI. The yearly incidence rate was 1.7% and the yearly remission rate was 3.1%. Parity, increasing BMI and weight gain were found to be associated with increased odds of UI incidence. Incidence and remission were highest in the youngest women (20-39 years). This is similar to the findings in a 16-year follow-up of a Swedish cohort in which the cumulative incidence of UI was 21%, and the yearly incidence was 1.3%. The remission rate was 34%. The increase in UI was largest in the young women (20-34 years).18 Another Swedish study found an annual incidence of 2.9% and annual remission of 5.9% in women aged 20-59 years.19 In middle-aged women (age 47-52) a French study found a yearly incidence of 3.3% and a yearly remission of 6.2%.16

Based on a large cohort of nurses in the United States an annual incidence of 6.9% and remission of 7% was found in middle-aged women (36-55 years).20 Partly based on the same cohort, a follow-up study of 16,867 women (age 39-81) at four time-points during a ten-year period found that although UI severity varied over time, very few (less than 10%) had complete remission of UI symptoms.21 Similar to other studies, less remission was found in older women.
**Risk factors**

The most common risk factors for UI in young and middle-aged women are age, increased BMI, parity and mode of delivery at childbirth. All of these factors are most strongly associated with SUI.\(^\text{13}\)

**Age**

The prevalence of UI in women increases with age. Stress UI is the most common type in young and middle-aged women whereas mixed and urgency UI become relatively more common in older women.\(^\text{4, 5}\)

**Excess weight**

Several systematic reviews have concluded that being overweight, obesity and increased BMI are important risk factors for UI.\(^\text{22, 23}\) A systematic review and meta-analysis from 2018 found that being overweight was associated with a one-third increase in the risk of UI and obesity doubled the risk of UI, compared to the risk with a normal BMI in young to middle-aged women.\(^\text{24}\)

**Pregnancy and childbirth**

Pregnancy and vaginal delivery are important risk factors for developing urinary incontinence and are particularly associated with SUI.\(^\text{13}\) The prevalence of SUI during pregnancy ranges from 18.6% to 75% and increases throughout pregnancy.\(^\text{25, 26}\) Risk factors for UI during pregnancy are parity, maternal age, increased BMI and pre-existing UI.\(^\text{27, 28}\)

A Swedish study compared the prevalence of UI between nulliparous women and women who had experienced vaginal delivery or caesarean section 20 years ago. They found that both pregnancy and vaginal delivery increased the risk of UI.\(^\text{29}\) Vaginal delivery has been associated with an almost twofold increase in the long-term risk for SUI.\(^\text{30}\) Women who delivered exclusively with caesarean section were less likely to have UI than those who had spontaneous vaginal delivery.\(^\text{31-33}\)

During the three months following childbirth the prevalence of UI is approximately 30%.\(^\text{34}\) Risk factors for postpartum UI are parity, maternal age, maternal excess weight and UI during pregnancy.\(^\text{27}\) Wesnes et al found that 21% of women who had been continent during pregnancy were incontinent six months postpartum. Of those who experienced incontinence during pregnancy, 52% were continent six months postpartum.\(^\text{35}\) There seems to be a spontaneous decrease in UI in the postpartum period, stabilizing at around six months postpartum.\(^\text{36}\) Some studies describe a rather stable UI prevalence of around 30% during the first year postpartum.\(^\text{34, 37}\)
**Quality of life**

Urinary incontinence may affect quality of life. Women with UI have been found to report a lower quality of life than women without UI.\(^3\) Several aspects of life may be negatively affected including daily life, work, social and sexual activities.\(^3\) The severity of UI symptoms has been reported as a risk factor for a poorer quality of life.\(^4\)

An interview study in Sweden found that women living with long-term UI experienced feelings of being out of control and powerless.\(^4\) A review of qualitative research also describes how incontinence negatively affects daily activities, social roles, intimacy and sexual satisfaction and provokes a sense of shame.\(^4\)

**Help-seeking**

Although many women experience urinary leakage, few have consulted their health care service regarding their problems. Several studies report help-seeking numbers of 25-30\%.\(^4\) A review from 2006 found that less than 38% of those with symptoms had sought help for their condition.\(^4\) Two population-based surveys in Sweden in 1991 and 2007 reported even lower numbers of only 6% and 7% that had sought help from the health care service.\(^4\)

Factors commonly found to predict help-seeking are the severity and duration of UI and impact on quality of life.\(^3\) In addition, the belief that UI is a natural consequence of childbirth or aging, the feeling that the incontinence is not a big enough problem and embarrassment to talk about UI are all beliefs and perceptions that influence help-seeking.\(^4\)

**Assessment of urinary incontinence**

In primary care the first step in assessing urinary incontinence is the patient history through which the clinician should try to explore the type of incontinence, the severity and inconvenience of the incontinence and the desire for treatment.\(^5\) Several validated questionnaires can be helpful for clinicians in this, such as the International Consultation on Incontinence Modular Questionnaires (ICIQ).\(^5\) The clinician should try to identify reversible factors that could worsen the incontinence like diuretic treatment or excessive fluid intake. In addition, history-taking should include questions to rule out symptoms possibly associated with underlying serious pathology that needs further investigation. These symptoms include recurrent urinary tract infections, dominant symptom of pain, haematuria and symptoms concerning neurological disease. If the type of incontinence is not clear from the history, a bladder diary can be useful to quantify the voiding and leakage episodes.
A review of diagnostic methods for UI concluded that a large proportion of women with SUI can be correctly diagnosed in primary care based on their clinical history and that it is appropriate to initiate low-risk, low-cost conservative treatment at that stage.\textsuperscript{55}

Many guidelines recommend an initial examination including physical examination (general status, abdominal and pelvic examination), urinary tract infection testing, and assessment of post-void residual urine.\textsuperscript{50, 51} However there is a lack of high-quality data regarding the value of this routine examination.\textsuperscript{52, 53} Also, the examination mainly aims at identifying underlying pathology associated with urge incontinence and not with stress incontinence.\textsuperscript{56} Invasive testing should be avoided for patients with uncomplicated SUI.\textsuperscript{52} First-line non-invasive treatments for UI can be initiated without extensive preliminary evaluation.\textsuperscript{50, 57, 53}

If the diagnosis is unclear or the initial conservative treatment has not been successful, the clinician can consult or refer to an incontinence specialist.

In the Methods section of this thesis I describe how we assessed SUI by using comprehensive questionnaires in combination with a leakage diary, but without any physical contact with the participant.

**Treatments for stress urinary incontinence**

Conservative treatments are interventions that do not involve surgery or medication. They are usually low cost and have minimal adverse events and are considered as the initial management for people with UI. A systematic review update carried out in 2018 on non-surgical treatments for any type of UI concludes that behavioural therapy (including pelvic floor muscle training) alone or in combination with other interventions is more effective than other interventions for stress and urgency UI.\textsuperscript{58} Cure rates vary between 15\% and 45\%, improvement is reported as between 30\% and 79\% and treatment satisfaction varies between 51\% and 76\%.

Weight reduction can improve the symptoms of UI in overweight and obese women.\textsuperscript{59-61} Reduction in caffeine intake may reduce UI symptoms, but the evidence is low. Evidence is still lacking to support other lifestyle interventions that are often included in treatment guidelines, such as physical activity, smoking cessation, dietary and fluid modifications and avoiding constipation.\textsuperscript{52, 59, 61}

Vaginal pessaries can be helpful to control SUI.\textsuperscript{62} Weighted vaginal cones can be used if women find them acceptable.\textsuperscript{63} There is limited evidence that electrical
stimulation is effective for UI. The usefulness of yoga for treatment of UI is uncertain.

Duloxetine has an effect on SUI in women but it also has common side effects such as nausea, constipation, dry mouth and fatigue. Local oestrogen treatment may improve urinary incontinence. Systemic hormone replacement therapy with oestrogen, on the other hand, may worsen incontinence.

Mid-urethral sling operations are the most studied surgical treatments for SUI. They are minimally invasive, have good treatment effects and a good safety profile.

**Pelvic floor muscle training**

The effect of PFMT
Pelvic floor muscle training (PFMT) is an evidence-based, effective first-line treatment for all types of UI in women. In a recent Cochrane review, PFMT was compared with no treatment or inactive treatment for women with SUI. Women who received PFMT were eight times more likely to report symptomatic cure compared to controls (56% versus 6%; risk ratio (RR) 8.38, 95% CI 3.68-19.07) and six times more likely to report symptomatic cure or improvement compared to controls (74% versus 11%; RR 6.33, 95% CI 3.88-10.33). Women with SUI were also more likely to report significant improvement in incontinence symptoms and quality of life compared to controls. They also reduced their number of leakage episodes in 24 hours (mean reduction 1.23, 95% CI 1.78-0.68) and were more satisfied with their treatment. Adverse events were rare and minor.

PFMT in pregnant and postnatal women
However, the above recommendations are based on studies without pregnant or postnatal participants. For pregnant women who are continent, PFMT reduces the odds and symptom severity of prenatal and postnatal UI but not for women who are already incontinent. A Cochrane review also concludes that PFMT in continent pregnant women can prevent the development of UI. For the mixed approach (where both continent and incontinent women are offered PFMT) PFMT might reduce the risk of UI for pregnant women but is less likely to do so for postnatal women. There is uncertainty about the treatment effect of PFMT for those who are incontinent, both prenatally and postnatally. According to current recommendations PFMT should be offered to pregnant continent women and to women experiencing UI three months postpartum.
The reason why PFMT does not seem to be as effective for treatment of SUI during pregnancy or the postnatal period is not fully understood. It has been suggested that the participants are different in the sense that pregnancy and delivery might have resulted in altered physiological conditions of muscles, nerves and connective tissue in the pelvic floor region, which might influence the effectiveness of PFMT.\(^{71}\) It is also possible that postnatal women have more difficulties in prioritizing PFMT when occupied with caring for a baby. Another possible reason is differences in study design, in that most PFMT interventions for postnatal women were compared with usual care (which could include PFMT), whereas the interventions for non-pregnant/non-postnatal women were often compared with no treatment.\(^{71}\)

**The definition of PFMT**

PFMT is defined as exercises to improve pelvic floor muscle strength, endurance, power, relaxation or a combination of these.\(^{72}\) The effect on stress urinary incontinence is thought to be mediated in two ways.\(^{69}\) By training the pelvic floor muscles they become stronger and stiffer and more resistant to stretching during effort or exertion, which could prevent urine leakage. Also, learning to voluntarily contract the pelvic floor muscles before and during effort or exertion may “clamp” the urethra and thus prevent urine leakage. This kind of contraction prior to a cough is commonly called “the knack”. The idea of contracting the PFM before and during everyday activities that cause effort is often described as “functional” training. Thus, the objective of PFMT is usually to improve the timing of the contraction as well as to increase the strength, endurance and stiffness of the pelvic floor muscles.

Several different PFMT regimens exist that include different types of contractions, different durations, different levels of supervision etc. There is no consensus on the exact best PFMT regimen but the most intensive program available is usually recommended.\(^{69, 73}\) For example, the NICE guidelines recommend supervised PFMT for at least three months, comprising at least eight contractions performed three times a day.\(^{74}\)

PFMT could be classified as an exercise therapy but cognitive and behavioural strategies are often combined with the exercises to achieve effective implementation and effect.\(^{75}\) This interaction can be referred to as the exercise behaviour and includes strategies to establish an exercise routine and promote adherence. Therefore, PFMT could be interpreted as both an exercise therapy and a behavioural therapy. When reporting PFMT interventions, details should be adequately described both in terms of the exercise program and the behavioural change components.\(^{75}\)
Several health behaviour models have been used in PFMT research. The Social Cognitive Theory is the most studied and self-efficacy is considered one of the main determinants of adherence to PFMT. Self-efficacy concerns the belief in one’s ability to successfully perform the behaviour required to produce the outcome, or the belief that one can exercise control over one’s health habits.

The Capability, Opportunity and Motivation behaviour (COM-B) system is a framework of behaviour used to identify targets for improving adherence. The COM-B is at the centre of the behavioural change wheel and the outer circle consists of nine different interventions supporting behavioural change. The interventions found to be important for PFMT were education, training, persuasion and enabling.

**Adherence to PFMT**

Adherence (“the extent to which a patient’s behaviour matches agreed recommendations from the prescriber”) is important for the effectiveness of PFMT and efforts should be made to increase adherence.

Barriers to adherence include forgetting, not prioritizing and not perceiving the training to be of benefit. Other barriers identified are the “obscure nature” of the pelvic floor muscles and the financial cost for individuals who have to pay for many appointments.

Enablers of adherence include finding an exercise routine and perceiving that there is a benefit to PFMT, which could be enhanced by positive feedback. Other factors found to be associated with adherence are positive intention to adhere, positive self-efficacy expectations and severity of incontinence. Strategies found to promote adherence include a structured PFMT protocol with goal-setting combined with enthusiastic clinicians and audio-prompts for home PFMT. The use of apps has also been suggested to be important for short-term and long-term adherence.

**PFMT as a self-management strategy**

Self-management is a subset of the broader concept of self-care that includes the ability to care for oneself and to perform activities to achieve optimal health. Self-management can be described as the ability of a person to manage the symptoms, treatment and consequences of a health condition. Self-management can be supported by self-efficacy, the confidence in one’s ability to perform self-care activities.

Self-management is often used in the context of coping with chronic health conditions such as diabetes or asthma but can also be used to describe the
management of urinary incontinence. Pelvic floor muscle training is an example of a self-management strategy that can be initiated by the women themselves or can be suggested by health care practitioners.

It has been suggested that the treatment of chronic diseases should focus on self-management and that self-efficacy theory can be used in this context to develop cost-effective models.

Evaluation of treatment effect with patient-reported outcomes

When evaluating the effect of the treatment of UI, the objective is to measure something that matters to the women. Currently the recommendation is to evaluate both the symptoms and bother (effect on quality of life) of urinary incontinence. This is done by using patient-reported outcomes. A patient-reported outcome (PRO) is a report of the patient’s health condition that comes directly from the patient. PROs are used to standardize the collection of data or get an objective assessment of a subjective phenomenon from the patient. A validated PRO measurement should show validity (measure what it is intended to measure), reliability (produce similar measurements when repeated), and responsiveness (be able to detect changes in a condition) and be appropriate to use in the selected population. One aspect of responsiveness is whether the detected change in a PRO measurement is meaningful to the patient. To determine the smallest change needed in a PRO measurement to be experienced by the patient, the minimum clinically important difference (MCID) can be estimated for the specific PRO.

An international initiative to standardize and facilitate wide use of the questionnaires for lower pelvic symptoms and their impact on patients’ quality of life resulted in the International Consultation on Incontinence Modular Questionnaires (ICIQ), now commonly used in incontinence research. Use of both a PRO that measures symptoms and one that measures quality of life is recommended when evaluating study effects. Two highly recommended questionnaires for use in both research and clinical practice are the ICIQ Urinary Incontinence Short Form (ICIQ-UI SF) and the ICIQ-Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTS qol). The latter is also known as the King’s Health Questionnaire adapted for use in the ICIQ-structure. The ICIQs have also evaluated electronic versions of their PROs and found them to be as good as the paper versions. This is valuable since electronic PROs can improve data quality and attain more complete data.

There is no consensus on how to define a successful treatment outcome for urinary incontinence. Studies use different measurements to define success. Some report on improvement in symptoms or quality of life, some report on
reduced number of leakages, some report on patient satisfaction and others report on cure.69 “Cure” is further defined in several different ways, including having no leakages according to a urinary diary or reporting no incontinence symptoms.93 “Outcomes” rather than “cure” are suggested to be used when evaluating treatment of urinary incontinence since cure is difficult to evaluate as it implies that the condition is completely treated and will never re-occur.94

The definition of the term “improvement” also varies across studies. Some refer to reductions of 50% to 75% in incontinence episodes and others refer to self-assessed improvement.95 Also, the questions on self-assessed improvement can have more than one level of improvement (such as in the validated question Patient’s Global Impression of Improvement where improvement can be rated as “better”, “much better” or “very much better”). When interpreting reviews of treatment effect of PFMT the definition of improvement used is not always clear, although in the recent Cochrane review, researchers stated that when several levels of improvement were reported in a study they entered data for the greater degree of improvement, with the idea that this would be more likely to represent a clinically important improvement to the participants.69

**mHealth**

mHealth is defined by the World Health Organisation (WHO) as health practice supported by mobile devices and includes functions such as messaging services and mobile apps.96

In 2019, worldwide smartphone use reached 41.5% of the global population.97 In Sweden 92% of the population owned a smartphone in 2019.98 Distribution is not equal between countries or within countries though, and there are therefore concerns about a digital divide. Younger people with higher levels of education and income are more likely to own a smartphone.99 In 2019 more than 85,000 health apps were available on the largest app stores, App Store and Google Play.100, 101

Health apps have the potential to increase accessibility to health care for those with limited access to ordinary health care. They also have the potential to reach people who, for various reasons, do not seek help from their ordinary health care service. It seems like healthcare delivered over the internet lowers the barriers for women to seek help.102 The anonymity when using apps or internet-based interventions has been described as an advantage when dealing with conditions that are sometimes experienced as shameful or stigmatized, like urinary incontinence.103, 104 Apps also have the potential to increase adherence to health interventions by supporting active self-management. An important factor here is
the convenience of using apps since they are close-at-hand and easily accessible, which facilitates integration into daily life.\textsuperscript{105, 106}

Although there is great interest in health apps and a large number of health apps are available, few have been scientifically evaluated. This makes it difficult for both care-givers and patients to have confidence in the effectiveness of health apps.\textsuperscript{107-109} There is evidence that mHealth may increase treatment adherence in the management of chronic diseases such as diabetes mellitus, cardiovascular disease and chronic lung disease.\textsuperscript{110} mHealth interventions have also been found to increase adherence to medication and smoking cessation programs.\textsuperscript{109, 111} Apps for self-management of diabetes, chronic lung disease and cardiovascular disease have the potential to improve symptom management and health outcomes. However, it was not possible to evaluate the specific contribution of these apps since they were not evaluated as stand-alone interventions.\textsuperscript{112}

A review of health apps for behavioural change, such as physical activity, weight and diet control, found that the most common behavioural change theories included in the apps were the theory of planned behaviour and the social cognitive theory. The most common behavioural change techniques were self-monitoring, feedback provided on performance and tailoring messages. The review concluded that most studies were small and that more large-scale trials of app-based interventions were needed.\textsuperscript{113} Also, the studies of user experiences of health apps were often limited to the developmental stages of the apps, and did not investigate the experiences with long-term use.\textsuperscript{114}

There are many apps available for PFMT, but an evaluation in 2017 showed that few of them were developed by professionals or had references to the literature.\textsuperscript{115} Mobile apps for the management of UI have only recently started to be scientifically evaluated. A review from 2019 of mHealth for self-management of UI found 12 relevant articles of which seven came from our Tät project.\textsuperscript{116} Of the remaining five, two were case studies, one was a pilot study,\textsuperscript{117} one described an app for documenting UI symptoms but did not evaluate treatment effect,\textsuperscript{118} and one study evaluated a smartphone-based reminder system to promote PFMT in postnatal women and compared it to a historical control group.\textsuperscript{119} That study found that the smartphone group had better PFMT adherence and a reduced prevalence of UI compared to the control group after eight weeks. Two additional studies from 2019 describe the evaluation of two apps to support pelvic floor muscle training, and focus on the usability and understandability of the apps themselves – they do not evaluate effect.\textsuperscript{120, 121} These studies conclude that the apps seem promising and that their effectiveness will be evaluated at a later time. Another study from 2019 evaluated adherence to home PFMT when using an app and compared it to written instructions. This study found that the app group had higher adherence to PFMT. Both groups had improvements in urinary
incontinence symptoms and quality of life but there was no difference between the two groups. A recent pilot study evaluated a web-based mobile platform for behavioural treatment of urinary incontinence in women veterans. This study found that the reduction of UI symptoms was clinically relevant in the 20 women who completed the program, but they had no control group.

Implementation of mHealth interventions
There is great interest in developing mHealth interventions and multiple pilot studies exist, but there is little experience and evidence about the implementation of these interventions on a larger scale. The research on implementation of eHealth (the use of information and communication technologies for health) has often focused on how to implement new interventions within a health care system rather than implementation at a population level and when a patient is the main user.

A recent article from Sweden suggests that eHealth interventions should be more evidence-based. It proposes six phases for a comprehensive evaluation of an intervention (i.e., design, pre-testing, pilot study, pragmatic trial, evaluation and post-intervention) with the last phase potentially including post-marketing or surveillance studies to follow up the intervention once scaled up and used by a wider audience.

The eContinence project
The eContinence project (Tät.nu) is a research project which aims to develop, evaluate and implement effective treatment for urinary incontinence by using the internet and mobile apps. Eva Samuelsson is the principal investigator. The first intervention developed within the project was an internet program focused on PFMT. This was developed by the researchers and general practitioners Eva Samuelsson and Göran Umefjord in collaboration with two urotherapists (one physiotherapist and one nurse-midwife) and two psychologists. A brochure was also developed and was compared with the internet program in an RCT. Both interventions resulted in improvements in incontinence symptoms and quality of life in women with SUI. Further analysis showed that both interventions had long-term effects after one and two years and that the internet program was a cost-effective alternative.

Since the evolution of health apps was in its infancy, the next step within the project was to use the experience from the internet program to develop a mobile app with a self-management program for stress urinary incontinence.
Summary of Introduction

Stress urinary incontinence is a common and bothersome condition for women. Important risk factors for stress urinary incontinence are pregnancy and childbirth. It is possible to base the symptom diagnosis of SUI on patient history or questionnaires.

Pelvic floor muscle training is an effective, first-line self-management strategy that can improve the symptoms of SUI. Many women do not seek help for their incontinence from their ordinary health care service, and it is therefore important to find new ways to reach these women to be able to offer them effective treatment.

With the widespread use of smartphones and the interest in health apps, new opportunities to deliver self-management programs to the general population exist. Within the research project eContinence, an internet-based program for self-management of stress urinary incontinence has already been evaluated and found to be effective and appreciated. We therefore continued with the development of a mobile app with a self-management program for stress urinary incontinence.
Aims

The aim of this thesis was to evaluate a mobile app with a self-management program focused on pelvic floor muscle training for women with stress urinary incontinence, with respect to treatment effect, factors associated with successful treatment, user experiences and use by pregnant and postnatal women.

The specific aims of the papers included were:

**Paper I:** To compare the mobile app treatment program to no treatment in terms of effects on symptom severity and condition-specific quality of life in women with SUI.

**Paper II:** To find factors associated with a successful outcome in women who used the mobile app for treatment of SUI.

**Paper III:** To explore women’s experiences of using an app-based treatment program for SUI.

**Paper IV:** To investigate the use of the freely available app Tät® during pregnancy and the postnatal period. To describe the characteristics of the users, their use of the app and their frequency of PFMT, and to analyse changes in incontinence symptoms after three months of use.
Materials and methods

The thesis is based on four papers from two different study populations, one RCT-population (Papers I, II and III) and one “real life” population (Paper IV).

Table 1. Overview of the materials and methods used in the thesis.

<table>
<thead>
<tr>
<th>Paper</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>RCT</td>
<td>Secondary analysis from RCT</td>
<td>Qualitative study</td>
<td>Prospective cohort study</td>
</tr>
<tr>
<td>Participants</td>
<td>123 women with stress urinary incontinence randomized to the app group (n=62) and the control group (n=61)</td>
<td>61 women from the RCT app group</td>
<td>15 women from the RCT app group</td>
<td>10,456 pregnant and postnatal women who downloaded the app</td>
</tr>
<tr>
<td>Intervention</td>
<td>The Tät® app for 3 months</td>
<td>The Tät® app for 3 months</td>
<td>The Tät® app for 3 months</td>
<td>The freely available Tät® app for 3 months</td>
</tr>
<tr>
<td>Data collection</td>
<td>Self-reported online questionnaires and leakage diaries</td>
<td>Self-reported online questionnaires and leakage diaries</td>
<td>Semi-structured telephone interviews</td>
<td>Self-reported questionnaires within the app</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Difference in treatment outcomes between the app group and the control group</td>
<td>Factors associated with successful treatment outcome</td>
<td>Experience of using the app</td>
<td>Change in incontinence symptoms after 3 months’ use of the app</td>
</tr>
</tbody>
</table>
Recruitment of participants
For the randomized controlled trial, we recruited community-residing women via our homepage www.tät.nu (www.econtinence.se). To reach potential participants we placed advertisements in daily newspapers and on the web, and distributed posters to training centres and primary health care centres. We also posted information on social media. The app was visible on App Store and Google Play with information that it was only possible for study participants to activate the app. All women who were interested in participating in the study answered a web-based screening questionnaire which contained questions about inclusion and exclusion criteria.

Inclusion criteria: Women ≥18 years who could read and write Swedish. Symptoms of stress urinary incontinence and no symptoms of urgency incontinence during the last six months. Leakage episodes at least once per week. Access to a smartphone and e-mail.

Exclusion criteria: Pregnancy. Previous incontinence surgery. Present or previous malignancy in the lower abdomen. Impaired mobility or reduced feeling in the legs or lower abdomen. Severe psychiatric disorders. Macroscopic haematuria. Irregular bleeding. Difficulty passing urine. Maximum urine volume <300 ml.

Those who reported macroscopic haematuria, irregular bleeding or difficulty passing urine received an automatic reply that they were advised to contact their ordinary health care service. Those who fulfilled the inclusion criteria and did not have any exclusion criteria were sent an e-mail with an informed consent form and a leakage diary. They were asked to fill in both forms and send them back by regular mail to our research coordinator. If a woman reported a maximum urine volume of less than 300 ml she was excluded. After receiving both the informed consent and the leakage diary we sent another e-mail with a link to a more extensive online questionnaire. This questionnaire included questions related to background characteristics, lifestyle factors, previous medical history, and the validated questionnaires about incontinence symptoms (ICIQ-UI SF) and quality of life (ICIQ-LUTSqol). Women who answered these questionnaires were contacted by telephone by me or one of the other general practitioners involved in the study (E.S. or M.S.). The purpose of this was to make sure they had understood the study procedure before they were randomized to either the app group or the control group (waiting list group).

For the interview study, 15 strategically selected women were approached by e-mail within three months after completing the RCT follow-up and were asked to participate in a telephone interview at a convenient time.
For the study regarding the freely available Tät app, we included women who downloaded the app from App Store and Google Play and answered the inclusion questionnaire. When the app was opened, information appeared about the study, data collection and data security. A short questionnaire appeared which was optional to answer, and those who answered the questionnaire were included in the study. Those who chose not to answer could still use the app. In Paper IV we included women of 18-50 years old who were pregnant or had given birth during the last three months.

**The Tät® app**

The app was developed based on experience from the previously evaluated internet program for treatment of stress urinary incontinence. The original app was developed by Eva Samuelsson, Göran Umefjord and Malin Sjöström in collaboration with software engineers at ICT Services and System Development, Umeå University. The app is CE marked in accordance with regulations for medical devices class I (LVFS 2003:11).

The app can be considered a complex intervention since it includes both information about lifestyle factors associated with incontinence, instructions for pelvic floor muscle exercises and methods for behavioural change to increase adherence to the exercises.

<table>
<thead>
<tr>
<th>The Tät® app</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information</strong></td>
</tr>
<tr>
<td>• about incontinence</td>
</tr>
<tr>
<td>• about the pelvic floor</td>
</tr>
<tr>
<td>• lifestyle factors associated with incontinence</td>
</tr>
</tbody>
</table>

*Figure 1. Content of the Tät® app.*

The app included information about stress urinary incontinence, the pelvic floor, and lifestyle factors associated with incontinence such as being overweight and excessive fluid intake.
The pelvic floor muscle training exercises consisted of 12 different exercises with increasing difficulty, six basic and six advanced levels (table 2). The exercises included several types of contractions such as a basic contraction to identify the correct muscles, strength contractions, endurance contractions, quick contractions and contractions prior to coughing. Participants were advised to perform training three times per day during the three-month treatment program.

Table 2. Pelvic floor muscle training exercises in the Tät® app.

<table>
<thead>
<tr>
<th>Exercises</th>
<th>Type of contraction</th>
<th>Duration of contraction (s)</th>
<th>Constructions per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic 1</td>
<td>basic contraction</td>
<td>2</td>
<td>8 x 3</td>
</tr>
<tr>
<td>Basic 2</td>
<td>basic contraction</td>
<td>2</td>
<td>6 x 3</td>
</tr>
<tr>
<td></td>
<td>strength</td>
<td>5</td>
<td>2 x 3</td>
</tr>
<tr>
<td>Basic 3</td>
<td>basic contraction</td>
<td>2</td>
<td>5 x 3</td>
</tr>
<tr>
<td></td>
<td>strength</td>
<td>5</td>
<td>5 x 3</td>
</tr>
<tr>
<td>Basic 4</td>
<td>strength</td>
<td>5</td>
<td>8 x 3</td>
</tr>
<tr>
<td>1–2 weeks</td>
<td>endurance</td>
<td>14</td>
<td>1 x 3</td>
</tr>
<tr>
<td>Basic 5</td>
<td>strength</td>
<td>5</td>
<td>10 x 3</td>
</tr>
<tr>
<td>1–2 weeks, standing</td>
<td>endurance</td>
<td>24</td>
<td>1 x 3</td>
</tr>
<tr>
<td>Basic 6</td>
<td>strength</td>
<td>5</td>
<td>10 x 3</td>
</tr>
<tr>
<td>1–2 weeks, lifting, coughing, walking</td>
<td>endurance</td>
<td>34</td>
<td>1 x 3</td>
</tr>
<tr>
<td></td>
<td>quick</td>
<td>3</td>
<td>5 x 3</td>
</tr>
<tr>
<td>Advanced 1</td>
<td>strength</td>
<td>7</td>
<td>20 x 3</td>
</tr>
<tr>
<td>1–2 weeks, standing</td>
<td>endurance</td>
<td>34</td>
<td>1 x 2–3</td>
</tr>
<tr>
<td></td>
<td>quick</td>
<td>3</td>
<td>5 x 3</td>
</tr>
<tr>
<td>Advanced 2</td>
<td>strength</td>
<td>7</td>
<td>20 x 2–3</td>
</tr>
<tr>
<td>1–2 weeks, standing</td>
<td>endurance</td>
<td>34</td>
<td>1 x 2–3</td>
</tr>
<tr>
<td></td>
<td>quick</td>
<td>3</td>
<td>10 x 2–3</td>
</tr>
<tr>
<td>Advanced 3</td>
<td>strength</td>
<td>7</td>
<td>10 x 3</td>
</tr>
<tr>
<td>1–2 weeks, lifting</td>
<td>endurance</td>
<td>44</td>
<td>1 x 3</td>
</tr>
<tr>
<td>Advanced 4</td>
<td>strength</td>
<td>7</td>
<td>10 x 3</td>
</tr>
<tr>
<td>1–2 weeks, walking</td>
<td>endurance</td>
<td>44</td>
<td>1 x 3</td>
</tr>
<tr>
<td>Advanced 5</td>
<td>strength</td>
<td>7</td>
<td>20 x 2</td>
</tr>
<tr>
<td>1–2 weeks, lifting, coughing, walking</td>
<td>endurance</td>
<td>59</td>
<td>1 x 2</td>
</tr>
<tr>
<td></td>
<td>quick</td>
<td>3</td>
<td>10 x 2</td>
</tr>
<tr>
<td>Advanced 6</td>
<td>strength</td>
<td>7</td>
<td>40 x 2</td>
</tr>
<tr>
<td>1–2 weeks, lifting, coughing, walking</td>
<td>endurance</td>
<td>59</td>
<td>2 x 2</td>
</tr>
<tr>
<td></td>
<td>quick</td>
<td>3</td>
<td>20 x 2</td>
</tr>
</tbody>
</table>

The app included strategies to support behavioural change such as a visual aid to retain focus when performing the exercises, possibility to set personal reminders, self-monitoring by recording the exercises in a statistics overview, and automatic positive feedback when reaching a certain level.
After completing the randomized controlled trial, we made several updates to the app based on user experiences. This eventually led to the freely available version of the app studied in Paper IV (figure 2b). The biggest changes from the original app were updates to the design, additions to the information section about sexuality, the addition of sound to the exercises, improvement of the statistics function and the incorporation of an anonymous questionnaire that appeared within the app upon downloading and then again after three months. The app was also translated from Swedish to five more languages. Only minor adjustments were made in the PFMT exercises.

**Patient-reported outcomes**

The International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF) is a validated questionnaire that evaluates incontinence symptom severity. This questionnaire was used both in the RCT and in the study of the freely available app. The ICIQ-UI SF contains three questions about the frequency and amount of urinary leakage and its overall impact on everyday life. The responses add up to a score of between 0 and 21 where 21 is the most severe. The overall scores can be categorized by severity; slight (1-5), moderate (6-12), severe (13-18) and very severe (19-21).
The ICIQ Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol) is a validated questionnaire that evaluates condition-specific quality of life. This questionnaire contains 19 questions that add up to an overall score of between 19 and 76 where 76 corresponds to the greatest impact on quality of life. Three questions ask about personal relationships and have the potential response “not applicable”. When calculating the overall score this response was set to one, i.e., no impact.

The Patient’s Global Impression of Improvement (PGI-I) is a validated question that asks about the change experienced by the participant after treatment. It has seven response options, ranging from “very much better” to “very much worse”.

The incontinence episode frequency (IEF) was based on the self-reported number of leakages in a two-day diary. It was multiplied by 3.5 to give the number of leakages per week.

**Population and methods**

**Paper I**

This was a randomized controlled trial conducted in Sweden between March 2013 and October 2014. The study was registered at Clinical Trials.gov, ID: NCT01848938. We reported the study according to the CONSORT guidelines and the CONSORT EHEALTH Checklist.

Women were recruited as described above and those who met the inclusion criteria, had no exclusion criteria, provided informed consent and a leakage diary, answered the inclusion questionnaire and accepted the study procedure described during the telephone call, were included in the study.

Randomization was performed by concealing the allocations in sequentially numbered, sealed envelopes. The envelopes had been prepared by an independent administrator who generated the allocation sequence and prepared 130 envelopes (equally distributed between the two study groups). The study coordinator opened a sequentially numbered envelop for each participant and sent an e-mail to the participant that indicated the assigned study group. The app group also received details on how to download the app from the App Store or Google Play and a code to open the app.

Three months after randomization we sent both groups a new e-mail with a leakage diary and a link to a follow-up questionnaire. The questionnaire included the validated questionnaires ICIQ-UI SF and ICIQ-LUTSqol as well as questions
about subjective improvement (PGI-I), use of the app and frequency of pelvic floor muscle training. After completing the leakage diary and the questionnaire the control group were given access to the app. They were not further followed up.

Outcomes
The primary outcomes were symptom severity (ICIQ-UI SF) and condition-specific quality of life (ICIQ-LUTSqol). Secondary outcomes were subjective improvement measured with the PGI-I, incontinence episode frequency (IEF), use of incontinence aids, satisfaction with the app and the treatment effect, and intention to seek further treatment.

Paper II
This was a secondary analysis from the RCT. We analysed only the answers from the women in the app group.

We defined treatment success as answering “much” or “very much better” on the PGI-I question at the three-month follow-up. This definition has been used in other studies.138, 139

From the baseline questionnaires we recorded the following factors possibly associated with successful treatment:

The symptom severity (ICIQ-UI SF), impact on quality of life (ICIQ-LUTSqol) and number of leakages (IEF) were analysed as continuous variables. The incontinence severity categories based on the ICIQ-UI SF score were analysed as categorical variables. Background variables such as level of educational, use of internet and smartphone, and previous medical history were analysed as categorical variables. Lifestyle factors such as smoking, physical activity, and intake of coffee and tea were also analysed as categorical variables. Calculated body mass index (BMI), weight and age were analysed as continuous variables. The participants’ expectations of the treatment effect were analysed as a categorical variable.

From the three-month follow-up questionnaire, we also recorded factors possibly associated with successful treatment:

The same lifestyle factors as at baseline were analysed and changes compared to baseline were calculated (such as the difference in weight) and analysed as a continuous variable. The frequency of pelvic floor muscle training during the last four weeks was analysed as a categorical variable and the total number of exercises registered in the app was analysed as a continuous variable. The number
of contractions per day was calculated and categorized into four different categories (<15, 15-29, 30-44, ≥45) as in a study by Borello-France et al, and then analysed as categorical variables. The participants’ self-assessed improvement of pelvic floor muscle strength was analysed as a categorical variable.

In this paper, I was the second author and Emma Nyström was the first author. We independently performed all the analyses and discussed our results. Emma was responsible for the manuscript which I read and provided comments on.

**Paper III**

This was a qualitative study based on telephone interviews. The participants were selected from the app group in the RCT, based on a strategic selection representing a large variety of ages, places of residence, smartphone types and effect on incontinence symptoms at the three-month follow-up in the RCT. The interviews were conducted between January and November 2014, within four months after completion of the follow-up in the RCT.

I performed all the interviews using a semi-structured interview guide with open-ended questions. The main topics in the interview guide were the participants’ expectations about using an app, their experiences using the app, their interaction with the app, and their experiences performing pelvic floor muscle training. Interviews were audio-recorded and transcribed verbatim by me or a medical secretary.

We started the preliminary analysis in the research group directly after the first interview to be able to adapt the interview guide if interesting unforeseen topics emerged. The transcripts were analysed according to the principles of Grounded Theory with the aim of developing a rich description rather than a whole new theory. All five authors read and coded the initial transcripts and then had meetings to discuss the codes and sort them into different categories. After the first ten interviews we did not find any new categories and we therefore decided that 15 participants was a sufficient amount.

**Paper IV**

This was a cohort study of the pregnant and postnatal users of the freely available Tät app. During the study period the app was updated with Finnish, Spanish, German and Arabic languages. We included participants who downloaded the app and answered the inclusion questionnaire between January 16 2018 and November 15 2018.

When opening the app, a questionnaire appeared with questions about age, gender, country, place of residence, education, reason for downloading the app,
pregnancy, childbirth during the last three months, and incontinence symptoms according to the ICIQ-UI SF questionnaire. After three months a follow-up questionnaire automatically appeared in the app with questions about pregnancy, childbirth during the last three months, incontinence symptoms according to the ICIQ-UI SF, improvement based on the PGI-I question, use of the app and frequency of PFMT.

Answering the questionnaires was optional, and the answers were anonymously transferred to a secure research database at Umeå University via SSL encryption. The follow-up questionnaire was linked to the inclusion questionnaire through a unique app identification and the answers could not be traced to a specific user or telephone number. We analysed follow-up questionnaires that were completed within 135 days after inclusion. We defined participants as having urinary incontinence if they answered both that they had urinary leakage and that they had at least a small amount of leakage (the first two questions on the ICIQ-UI SF questionnaire).

**Statistics**

We used SPSS version 22.0, 23.0 or 26.0 for all analyses. P-values of <0.05 were considered statistically significant.

**Sample size**

The sample size in Paper I was calculated based on results from the previous internet study.\(^{129}\) We estimated ICIQ-UI SF score reductions in the app group of 2.9 (SD 3.1) and in the control group of 1.0 (SD 2.0). We estimated ICIQ-LUTSqol reductions in the app group of 4.6 (SD 6.7) and in the control group of 2.0 (SD 3.0). We estimated large improvements in the PGI-I in 26.5% of the app group and 4% of the control group. The sample size was calculated to detect an effect difference between the 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 different outcomes. We anticipated a drop-out rate of one third, and therefore aimed at a sample size of 60 in each group.

**Statistical analysis**

In Paper I we performed intention-to-treat analysis on all outcomes. We used a linear mixed model analysis to compare treatment effects between groups for the primary outcomes ICIQ-UI SF and ICIQ-LUTSqol. To compare effects between groups for the secondary outcomes PGI-I, IEF and use of incontinence aids, we used the Mann-Whitney U test. Missing values for the secondary outcomes at follow-up were replaced with the corresponding values at baseline, and a missing PGI-I answer was replaced with “unchanged”. We analysed treatment effects
within groups with a paired t-test for the primary outcomes and a Wilcoxon signed-rank test for the secondary outcomes – IEF and incontinence aids. At baseline we compared the groups using the Student’s t-test for continuous variables, the chi-square test for categorical variables and the Mann-Whitney U test for ordinal variables.

In Paper II, all factors potentially associated with a successful treatment outcome were first analysed with univariate logistic regression to find any significant association. If the association was significant or almost significant (p<0.20), the variable was entered into the multivariate model. We adjusted for age in all analyses. In the multivariate model we removed variables one at a time according to significance level until only age and variables significantly associated (p<0.05) with success remained.

In paper IV we performed descriptive statistics of the baseline and follow-up characteristics and presented them as means (standard deviation) and numbers (percent). Changes in the mean ICIQ-UI SF score between baseline and follow-up were analysed using the paired t-test.

**Ethics**

All studies included received ethical approval by the Regional Ethics Review Board, Umeå University. Papers I and III (the RCT study and the qualitative study) were included in the same original approval (Dnr 2012–325-31M). Paper II (the factors associated with success) was approved as an amendment (Dnr 2015-375-32M). For paper IV (the cohort study) there were three additional amendments (Dnr 2014-389-32M, Dnr 2016-80-32M and Dnr 2017-405-32M).

The name Tät (mobile app) and the logo Tät.nu are registered as trademarks by the Swedish Patent and Registration Office for Eva Samuelsson at Umeå University. Copyright for Tät.nu (eContinence.se) at Umeå university. The Tät® app is registered as a medical device class I at the Swedish Medical Products Agency according to LVFS 2003:11. None of the researchers have any financial interest in the products.
Results

Papers I-III are based on the same study population of 123 women who were randomized to the app group (n=62) or the control group (n=61) (figure 3).

Figure 3. Flow diagram of participants included in Papers I-III.
Paper I – Treatment effect

The mean age of the 123 participants was 44.7 years (range 27–72 years) (table 3). Concerning their smartphone use, 34% used their smartphone to look up health information every week and 71% did so every month. They had apps for health (23%), for exercise (60%), for diet (29%), for social media (84%) and for games/music (78%).

Table 3. Baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>App group n=62</th>
<th>Control group n=61</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years, mean (SD)</td>
<td>44.8 (9.7)</td>
<td>44.7 (9.1)</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>24.0 (4.1)</td>
<td>24.5 (4.4)</td>
</tr>
<tr>
<td>University education ≥3 years, n (%)</td>
<td>52 (83.9)</td>
<td>46 (75.4)</td>
</tr>
<tr>
<td>Daily smokers, n (%)</td>
<td>2 (3.2)</td>
<td>3 (4.9)</td>
</tr>
<tr>
<td>Nullipara, n (%)</td>
<td>5 (8.1)</td>
<td>4 (6.6)</td>
</tr>
<tr>
<td>Unipara, n (%)</td>
<td>11 (17.7)</td>
<td>9 (14.8)</td>
</tr>
<tr>
<td>Multipara, n (%)</td>
<td>46 (74.2)</td>
<td>48 (78.7)</td>
</tr>
<tr>
<td>On regular medication, n (%)</td>
<td>28 (45.2)</td>
<td>24 (39.3)</td>
</tr>
<tr>
<td>Medication for incontinence, n (%)</td>
<td>0 (0)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>Medication with oral oestrogen, n (%)</td>
<td>0 (0)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>Medication with local oestrogen, n (%)</td>
<td>3 (4.8)</td>
<td>2 (3.3)</td>
</tr>
<tr>
<td>Medication with diuretics, n (%)</td>
<td>1 (1.6)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>Medication with anti-depressants, n (%)</td>
<td>9 (14.5)</td>
<td>5 (8.2)</td>
</tr>
<tr>
<td>Medication for hypertension/heart, n (%)</td>
<td>4 (6.5)</td>
<td>6 (9.8)</td>
</tr>
<tr>
<td>Previous help-seeking for incontinence, n (%)</td>
<td>26 (41.9)</td>
<td>19 (31.1)</td>
</tr>
<tr>
<td>Feeling confident of correct contraction, n (%)</td>
<td>21 (33.9)</td>
<td>21 (34.4)</td>
</tr>
<tr>
<td><strong>Incontinence severity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICIQ-UI SF score, mean (SD)</td>
<td>11.1 (3.0)</td>
<td>11.0 (2.6)</td>
</tr>
<tr>
<td>Severity category slight, n (%)</td>
<td>3 (4.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Severity category moderate, n (%)</td>
<td>36 (58.1)</td>
<td>42 (68.9)</td>
</tr>
<tr>
<td>Severity category severe, n (%)</td>
<td>23 (37.1)</td>
<td>19 (31.1)</td>
</tr>
<tr>
<td>ICIQ-LUTSqol score, mean (SD)</td>
<td>34.1 (6.1)</td>
<td>34.8 (6.1)</td>
</tr>
<tr>
<td>IEF per week, median (IQR)</td>
<td>21.0 (10.5–28.0)</td>
<td>17.5 (10.5–24.5)</td>
</tr>
<tr>
<td>Any use of UI aids in prior 4 weeks, n (%)</td>
<td>56 (90.3)</td>
<td>51 (83.6)</td>
</tr>
<tr>
<td>Daily use of UI aids, n (%)</td>
<td>13 (21)</td>
<td>14 (23)</td>
</tr>
</tbody>
</table>

SD = standard deviation; 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; UI = urinary incontinence
Primary outcomes
At the three-month follow-up there were significant differences between the groups regarding both symptom severity (ICIQ-UI SF mean score difference -3.2, 95% CI -4.3 to -2.1) and condition specific quality of life (ICIQ-LUTSqol mean score difference -4.6, 95% CI -7.8 to -1.4) with larger improvements in the app group (table 4).

The app group had an ICIQ-UI SF mean score reduction of 3.9 (95% CI: 3.0-4.7) and an ICIQ-LUTSqol reduction of 4.8 (95% CI 3.4-6.2).

The control group had an ICIQ-UI SF mean score reduction of 0.9 (95% CI: 0.1-1.6) and an ICIQ-LUTSqol reduction of 0.7 (95% CI -0.5 to 1.8).

Table 4. Primary outcomes

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Treatment group</th>
<th>Baseline (n=123)</th>
<th>Follow-up (n=121)</th>
<th>Within group difference (95% CI)a</th>
<th>Between group difference (95% CI)b</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICIQ-UI SF mean score (SD)</td>
<td>App group</td>
<td>11.1 (3.0)</td>
<td>7.0 (3.5)</td>
<td>3.9 (3.0-4.7)</td>
<td>3.2 (4.3-2.1)</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>11.0 (2.6)</td>
<td>10.2 (3.2)</td>
<td>0.9 (0.1-1.6)</td>
<td></td>
</tr>
<tr>
<td>ICIQ-LUTSqol mean score (SD)</td>
<td>App group</td>
<td>34.1 (6.1)</td>
<td>28.8 (6.4)</td>
<td>4.8 (3.4-6.2)</td>
<td>4.6 (7.8-1.4)</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>34.8 (6.1)</td>
<td>34.1 (6.7)</td>
<td>0.7 (-0.5-1.8)</td>
<td></td>
</tr>
</tbody>
</table>

ICIQ-UI SF = International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form. ICIQ-LUTSqol = ICIQ Lower Urinary Tract Symptoms Quality of Life. a Within group differences are based on paired samples t-test. b Between group differences are based on linear mixed models.

Secondary outcomes
The incontinence episode frequency (IEF) decreased in both groups but significantly more so in the app group compared to the control group at follow-up. The median number of leakages per week decreased from 21.0 (IQR 10.5-28.0) to 7 (IQR 0-17.5) in the app group and from 17.5 (IQR 10.5-24.5) to 14 (IQR 7-26) in the control group. In the app group, 56.5% (35 out of 62) reported no leakage or ≥50% reduction of leakage episodes compared to baseline, and in the control group the corresponding proportion was 29.5% (18 out of 61) (between group p=0.005).

The use of incontinence aids had reduced significantly in the app group at follow-up (p<0.001) but not in the control group (p=0.602), and use was significantly lower in the app group compared to the control group at follow-up (p=0.023). At follow-up 62% of the app group and 77% of the control group used incontinence aids.
The results of the PGI-I question showed that the app group had improved significantly more than the control group at follow-up (p<0.001). At follow-up, 92% of the app group experienced their leakage to be better compared to 20% of the control group, and 56% of the app group experienced their leakage to be much or very much better compared to 5% of the waiting group (figure 4).

In the app group, 66.7% (40 out of 60) were satisfied with the treatment outcome and of those, five people reported that they were completely free of leakage. At follow-up, 13 out of 60 (21.7%) were planning to seek additional treatment and one out of 61 (1.6%) had already looked for additional help. The app was experienced as “good” or “very good” by 96.7% of the participants and 100% would recommend it to others.

In the app group 48 out of 61 (78.7%) felt confident that they could contract their pelvic floor muscles correctly at follow-up. The vast majority, 58 out of 61 (95.1%) rated their pelvic floor muscle strength as better at follow-up compared to baseline and 29 out of 61 (47.5%) rated it as much better.

In the control group seven out of 60 (11.7%) had looked for additional help at follow-up. At follow-up, 25 out of 60 (41.7%) felt confident of correct contraction, five out of 60 (8.3%) rated their pelvic floor muscle strength as better and one out of 60 (1.7%) as much better.
Adherence to the PFMT program
At follow-up, 41.0% (25 out of 61) of the app group reported that they had performed PFMT daily during the last four weeks, and another 42.6% (26 out of 61) had performed PFMT weekly but not daily.

In the control group 3.3% (2 out of 60) had performed PFMT daily and 13.3% (8 out of 60) had performed it weekly but not daily.

The statistics function was used by 53 of the 61 (86.9%) women and 37 (60.7%) reported performing exercises at least up to level six of basic exercises. The highest level was reported by one woman at level five of the advanced level. The reminder function was used by 51 of the 61 women (83.6%).

Paper II – Factors associated with successful treatment
The participants in Paper II were the 61 women from the app group who answered the three-month follow-up questions.

The 56% of women who answered that they were “much” or “very much better” on the PGI-I scale at follow-up were considered to have had a successful treatment outcome.

In the univariate analyses, four factors from the baseline questionnaire were significantly or borderline significantly (p<0.20) associated with success; expectations of the treatment, daily tea consumption, use of incontinence aids and level of physical activity. From the follow-up questionnaire three additional factors were identified: weight change, self-assessed improvement of the pelvic floor muscle strength and categorized number of PFMT contractions per day.

All seven factors were included in the multivariate analysis and were then removed step-by-step until only three significantly associated (p<0.05) factors remained (table 5). These factors were expectations of the treatment effect (OR 11.38, 95% CI 2.02-64.19), weight control (OR 0.44 per kg gained, 95% CI 0.24-0.79), and self-assessed improvement of pelvic floor muscle strength (OR 35.54, 95% CI 4.96-254.61). These factors explained 61.4% (Nagelkerke R square) of the variability in success.
### Table 5. Adjusted OR for factors associated with success

<table>
<thead>
<tr>
<th>Factors in the multivariate model (reference category)</th>
<th>P*</th>
<th>Adjusted OR (CI)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (continuous)</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tea consumption (≥3 cups/day)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;3 cups/day</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity (regular exercise ≥3 times/week)</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>sedentary lifestyle or modest exercise &lt;3 times/week</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pad use (daily)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>weekly</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>more seldom</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise amount, contractions/day (&lt;15)</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15–29</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30–44</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥45</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expectations of the treatment (to be much improved)</td>
<td>0.006</td>
<td>11.38 (2.02–64.19)</td>
<td></td>
</tr>
<tr>
<td>to be very much improved/completely free of leakage</td>
<td>0.006</td>
<td>0.44 (0.25–0.79)</td>
<td></td>
</tr>
<tr>
<td>Weight change (per kg gained)</td>
<td>0.006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-assessed pelvic floor strength (unchanged/a little better)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>much better</td>
<td>&lt;0.001</td>
<td>35.54 (4.96–254.61)</td>
<td></td>
</tr>
</tbody>
</table>

The variable age was entered into the model to adjust for possible confounding. OR = odds ratio, CI = confidence interval, NS = not significant

*The final p-value in the multivariate logistic regression model. P<0.05 was considered significant.

### Paper III – User experiences

Fifteen women (ages 27 to 72 years) from different parts of Sweden were interviewed and the interview time ranged from 22 to 55 minutes (mean 34 minutes).

In the analysis we found several sub-categories which were able to be grouped into three categories labelled: “Something new” “Keeping motivation up” and “Good enough” We also found a core category that related to all other categories and this was called “Enabling my independence” (figure 5).
Figure 5. The core category and the underlying categories and sub-categories.

**Something new**

*New technology, something new and modern*

This sub-category describes how the women appreciated the use of new technology to deliver a PFMT program. Many of them had actively searched for such an app and had expectations that it could be a useful tool. Apart from it being useful, women also seemed to find the app more “fun” and appealing than other PFMT programs they had previously received from the health care service, often in the form of black-and-white photocopies. Many women experienced that incontinence was not taken seriously within health care and they felt that the development of an app for this condition made it feel more prioritized.

“Yes, great, solve it in a good, I mean use technology in a good way to solve a typically feminine problem, which otherwise is just a scrappy piece of paper from the health care centre, you know.”

*Low threshold, easily accessible*

The app-based treatment had the advantage of being easily accessible from home without the women having to book appointments through their ordinary health care service. This seemed to lower the threshold for help-seeking since most women stated that they would not have turned to the ordinary health care service for their incontinence at present. The app was also easily available since most women described frequent use of their smartphones.
“That was what was so good about this, I can do this at home myself, no need to book an appointment, find the time and suit others, and you know, that process of booking a time.”

“I think it has a lot to do with the fact that it is easily available, that you bring it with you, that you are reminded all the time.”

**Keeping motivation up**

**Motivational support**
Most women thought that the main advantage of using an app for PFMT was the possibility of getting reminders to do the exercises, since forgetting or not prioritizing the exercises was a common problem.

“Of course, I’ve read all the brochures and I’ve searched on the internet for pelvic floor exercises, but you just forget all about it, so what I wanted help with was exactly this, to remember it more.”

“It works pretty much like when somebody tells you, you know, that you have to exercise.”

Despite the reminders some women described having difficulty in keeping their motivation up during the three-month treatment. One reason given was that the training became boring when the novelty of the app had worn off.

**Visualizing treatment**
Many women emphasised that the animated graphics for each contraction helped them to see how to perform the contractions. This visual aid also helped them to stay focused during the exercise.

"And that I also think it’s a bit interesting to notice that if I visualise it, it actually becomes so much easier.”

**Good enough**

**Unsure expectations of the result**
Some women described that they were uncertain about what expectations to have on the app treatment but regardless of the possible effect, they felt satisfied that they had “given it a chance” and done what they could for themselves.
Some women found it difficult to evaluate whether the treatment result after three months was good enough. They wondered if they could get even better if they exercised more.

“It has become much better. And that makes me wonder about something, how good can it actually get? Can I actually become like really, really good?”

Insecurity about training correctly
Most women felt more confident that they could contract their pelvic floor muscles and felt that they had improved their muscle strength after the treatment period. Nonetheless, some wondered whether they could have been even stronger if they had contracted “better” or more “correctly”. Some women would have liked someone to examine them and confirm that they were contracting correctly but most women felt that their own experience and the instructions in the app were sufficient.

“Well, I seem to remember that there was some text that said that in the beginning you could feel for yourself to see if you were contracting in the right way, and I think that was good enough.”

Enabling my independence
This core category reflects that the women wished to take responsibility for and handle their pelvic floor muscle training independently and that they experienced that the app and its different features supported them to realize this goal.

“So then I felt that I kind of know how to contract these muscles, I'll do it on my own ... and that’s why I started to look for information.”

"And several times I have found out the type of exercises that are needed, but I just never get going. You need someone to tell you this is how you do it, and this is how many times, and this little reminder that now it’s time to train.”

Paper IV– Pregnant and postnatal users
In this study we included women who were pregnant (n=4,607) or had given birth during the last three months (n=5,849), in total 10,456 women. This was 41% of the total amount of people (n = 25,276) who answered the inclusion questionnaire during that time. The mean age of the pregnant and postnatal women was 31 years and 51.2% experienced incontinence. At follow-up, 1,811 (17%) of the 10,456 women who answered the inclusion questionnaire also completed the three-month follow-up within 135 days. Baseline characteristics for all included participants and for certain sub-groups of interest are described in table 6.
Table 6. Baseline characteristics of participants in Paper IV.

<table>
<thead>
<tr>
<th>Variable</th>
<th>All (n=10,456)</th>
<th>Pregnant (n=4,607)</th>
<th>Postnatal (n=5,849)</th>
<th>Completed follow-up (n=1,811)</th>
<th>Did not complete follow-up (n=8,645)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>30.9 (4.47)</td>
<td>30.6 (4.47)</td>
<td>31.16 (4.42)</td>
<td>31.6 (4.06)</td>
<td>30.8 (4.52)</td>
</tr>
<tr>
<td>University education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden, n (%)</td>
<td>9,933 (95.0)</td>
<td>4,364 (94.7)</td>
<td>5,569 (95.2)</td>
<td>1,738 (96.0)</td>
<td>8,195 (94.8)</td>
</tr>
<tr>
<td>Denmark, Finland, Iceland, Norway</td>
<td>231 (2.2)</td>
<td>115 (2.5)</td>
<td>116 (2.0)</td>
<td>38 (2.1)</td>
<td>193 (2.2)</td>
</tr>
<tr>
<td>Other</td>
<td>292 (2.8)</td>
<td>128 (2.8)</td>
<td>164 (2.8)</td>
<td>35 (1.9)</td>
<td>257 (3.0)</td>
</tr>
<tr>
<td>App language</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swedish, n (%)</td>
<td>10,026 (95.9)</td>
<td>4,410 (95.7)</td>
<td>5,616 (96.0)</td>
<td>1,757 (97.0)</td>
<td>8,269 (95.7)</td>
</tr>
<tr>
<td>English, n (%)</td>
<td>374 (3.6)</td>
<td>179 (3.9)</td>
<td>195 (3.3)</td>
<td>46 (2.5)</td>
<td>328 (3.8)</td>
</tr>
<tr>
<td>Other, n (%)</td>
<td>56 (0.5)</td>
<td>18 (0.4)</td>
<td>38 (0.7)</td>
<td>8 (0.4)</td>
<td>48 (0.6)</td>
</tr>
<tr>
<td>Place of residence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural area</td>
<td>1,333 (12.7)</td>
<td>542 (11.8)</td>
<td>791 (13.5)</td>
<td>188 (10.4)</td>
<td>1,145 (13.2)</td>
</tr>
<tr>
<td>Town with &lt;50,000 inhabitants, n (%)</td>
<td>2,220 (21.2)</td>
<td>948 (20.6)</td>
<td>1,272 (21.7)</td>
<td>311 (17.2)</td>
<td>1,909 (22.1)</td>
</tr>
<tr>
<td>Town with 50,000 to 1 million inhabitants, n (%)</td>
<td>3,999 (38.2)</td>
<td>1,816 (39.4)</td>
<td>2,183 (37.3)</td>
<td>765 (42.2)</td>
<td>3,234 (37.4)</td>
</tr>
<tr>
<td>City with &gt;1 million inhabitants, n (%)</td>
<td>2,903 (27.8)</td>
<td>1,301 (28.2)</td>
<td>1,602 (27.4)</td>
<td>546 (30.1)</td>
<td>2,357 (27.3)</td>
</tr>
<tr>
<td>Reason for downloading</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment, n (%)</td>
<td>3,228 (30.9)</td>
<td>937 (20.3)</td>
<td>2,291 (39.2)</td>
<td>566 (31.3)</td>
<td>2,662 (30.8)</td>
</tr>
<tr>
<td>Prevention, n (%)</td>
<td>6,948 (66.4)</td>
<td>3,584 (77.8)</td>
<td>3,364 (57.5)</td>
<td>1,212 (66.9)</td>
<td>5,736 (66.4)</td>
</tr>
<tr>
<td>Other, n (%)</td>
<td>280 (2.7)</td>
<td>86 (1.9)</td>
<td>194 (3.3)</td>
<td>33 (1.8)</td>
<td>247 (2.9)</td>
</tr>
<tr>
<td>Pregnant, n (%)</td>
<td>4,607 (44.1)</td>
<td>4,607 (100)</td>
<td>0 (0)</td>
<td>918 (50.7)</td>
<td>3,689 (42.7)</td>
</tr>
<tr>
<td>Postnatal, n (%)</td>
<td>5,849 (55.9)</td>
<td>0 (0)</td>
<td>5,849 (100)</td>
<td>893 (49.3)</td>
<td>4,956 (57.3)</td>
</tr>
<tr>
<td>Incontinence, n (%)</td>
<td>5,349 (51.2)</td>
<td>2,149 (46.6)</td>
<td>3,200 (54.7)</td>
<td>958 (52.9)</td>
<td>4,391 (50.8)</td>
</tr>
<tr>
<td>Leakage upon physical activity/ coughing/ sneezing*, n (%)</td>
<td>4,300 (80.4)</td>
<td>1,883 (87.6)</td>
<td>2,417 (75.5)</td>
<td>788 (82.3)</td>
<td>3,512 (80.0)</td>
</tr>
<tr>
<td>ICIQ-UI SF*, mean (SD)</td>
<td>6.67 (3.445)</td>
<td>6.29 (3.165)</td>
<td>6.92 (3.598)</td>
<td>6.70 (3.388)</td>
<td>6.66 (3.457)</td>
</tr>
</tbody>
</table>

*In those with incontinence. ICIQ-UI SF = International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form
Of the 1,811 women who answered the follow-up we excluded six women who had answered that they were both pregnant and postnatal, leaving 1,805 participants for the follow-up analysis. Of these women 74% had used the app and performed PFMT at least weekly during the last month. 46% had used the app daily and 29% had performed PFMT daily.

In the women with incontinence at inclusion the result of the PGI-I question showed that 55% of the pregnant group improved and 23% answered that they were much or very much better at follow-up. According to our definition, 25% no longer experienced incontinence. Of the postnatal women, 76% improved, 41% were much or very much better and 30% no longer experienced incontinence. The incidence of new incontinence during the follow-up time was 25% in the pregnant group and 19% in the postnatal group.

The mean ICIQ-UI SF score at inclusion in those with incontinence was 6.7 (SD 3.445). The analysis of changes in the ICIQ-UI SF mean score in women with incontinence showed significant improvements at follow-up except in the group of women who were pregnant both at inclusion and follow-up. The improvements were larger in the postnatal group than in the pregnant group and the largest improvements were in women who were in the first three months postpartum both at inclusion and follow-up (table 7).

Table 7. Changes in the ICIQ-UI SF mean score between baseline and follow-up in different sub-groups of incontinent women.

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline ICIQ-UI SF mean (SD)</th>
<th>Follow-up ICIQ-UI SF mean (SD)</th>
<th>Mean diff, mean (SD)</th>
<th>95% CI interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant at inclusion and follow-up (n=179)</td>
<td>5.8 (2.5)</td>
<td>5.6 (3.3)</td>
<td>0.2 (3.0)</td>
<td>-0.2-0.7</td>
</tr>
<tr>
<td>Pregnant at inclusion and postnatal at follow-up (n=230)</td>
<td>6.2 (3.1)</td>
<td>4.6 (4.1)</td>
<td>1.6 (3.8)</td>
<td>1.1-2.1</td>
</tr>
<tr>
<td>Pregnant at inclusion and neither pregnant/postnatal at follow-up (n=19)</td>
<td>7.1 (2.9)</td>
<td>5.1 (3.8)</td>
<td>2.0 (3.6)</td>
<td>0.3-3.7</td>
</tr>
<tr>
<td>Postnatal at inclusion and at follow-up (n=111)</td>
<td>8.1 (3.7)</td>
<td>5.3 (4.0)</td>
<td>2.8 (3.6)</td>
<td>2.1-3.5</td>
</tr>
<tr>
<td>Postnatal at inclusion but not at follow-up (n=415)</td>
<td>7.0 (3.7)</td>
<td>4.7 (3.9)</td>
<td>2.3 (3.9)</td>
<td>1.9-2.7</td>
</tr>
</tbody>
</table>

ICIQ-UI SF = International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form
Discussion

Main findings
The main finding in this thesis is that a mobile app is an appreciated and effective tool for self-management of stress urinary incontinence in women. After free release it reached a large, new population that also seem to have benefitted from using the app.

In Paper I we found that women randomized to the app group had significantly larger improvements in all treatment outcomes compared to the control group. The app group reported clinically relevant improvements in incontinence symptoms, and condition-specific quality of life. They also reduced their number of leakages per week, and their use of incontinence aids.

In Paper II we found that the factors associated with a more successful treatment outcome were higher expectations on the treatment effect before treatment, weight stability, and improved self-assessed pelvic floor muscle strength after treatment.

In Paper III we found that women appreciated using an app for self-management of urinary incontinence because the app “enabled their independence”. They found this new technology a suitable support for increasing their motivation and adherence to the pelvic floor muscle training program.

In Paper IV we found that after free release of the app it reached a new population of pregnant and postnatal women. They had improvements in incontinence symptoms after three months, but the reason for this was difficult to interpret since we had no control group.

Methodological considerations

Strengths
Due to our clinical knowledge and experience of treating women with urinary incontinence in primary care we were able to identify the need for more treatment options for this group. Within our research group we had previous experience from an internet-based treatment program for stress urinary incontinence and the app could therefore be developed based upon extensive experience from both the researchers and users of that internet program. After the evaluation of the first app we continued to update the freely available app based on input from the users.
We had no face-to-face contact with the women in the studies and this approach made the study setting more similar to the “real world” setting where we intend the app to be used in the future. This study design also made it possible for women from all over Sweden to participate.

We used electronic questionnaires wherein the participants could not continue to the next question until they had answered the present one. For this reason, we had very few missing answers. The ‘lost to follow-up’ number was very low in the RCT with only one person from each group. We had no major technical problems during the studies.

We used several validated and highly recommended patient-reported outcome measures such as the ICIQ-UI SF, ICIQ-LUTS-qol and PGI-I. This is in line with recommendations for research on urinary incontinence and it makes it possible to compare our results with results from other studies.

We were the first research group to perform and publish the results from a randomized controlled trial of an app for self-management of urinary incontinence. We registered the trial on ClinicalTrials.gov and we reported the results according to the CONSORT guidelines and the CONSORT EHALTH checklist.

In the study of the freely available app, the incorporation of the questionnaire within the app made it easy for people to answer it and made it possible for us to receive data from a large number of users. In this way we were able to follow up our intervention and see if the characteristics of the users and the effect of the intervention would be different after free release, which is an important step in the evaluation process.

In the interview study we used the well-established Grounded Theory method, which was a suitable method for analysis since there was little previous knowledge in the literature about what findings to expect. All my co-authors had previous experience of this method. By using telephone interviews, we were able to reach women from all over Sweden. I performed all the interviews, wrote most of the transcripts and coded all interviews which gave me a thorough understanding of the interview data. During the study I continuously wrote memos and reflected over my own role in the study process.

We followed the criteria suggested for good quality in qualitative research by addressing the quality indicators of credibility, dependability, conformability and transferability.141
Credibility refers to how the data collection and analysis is performed in order to get results that can be trusted and truthful. As I am a general practitioner, I have experience in talking to women about sensitive topics like incontinence and I am also used to using open questions which helped to get informative data. The use of a well-established method like Grounded Theory was also important for the credibility of the analysis.

Dependability is about how well a study can adapt to changes or new input during the study. By using the Grounded Theory method, we were able to perform data collection and analysis in parallel and we developed the interview guide as we proceeded with the interviews and new topics arose. This also guided our inclusion of participants in that we stopped inclusion when we felt that no new major topics emerged in the analysis.

Confirmability refers to the neutrality of the study, that the results should depend on the analysis of the data and not on the subjective views of the researcher. The method of Grounded Theory is suitable for this since it starts by coding the data to see what the data reveals. To increase confirmability, two researchers coded most of the transcripts individually and a larger group of five researchers coded two of the transcripts individually before we discussed our findings together. All five researchers read all transcripts and we had several meetings during the study where we analysed the data and came to common conclusions.

Transferability relates to generalizability, whether our findings could be relevant in other settings. To make this comparison possible for others we have described our study population and our selection criteria.

Limitations

Limitations of the non-face-to-face design
We could only base the symptom diagnosis of SUI on the participants’ self-reported symptoms and a leakage diary with a maximum voiding volume. It is a limitation that the type of incontinence could have been misclassified, meaning that some participants might not have “pure” SUI. However, there are current recommendations to support that non-invasive conservative treatments can be initiated based on a symptom diagnosis.\textsuperscript{50, 55, 57} Also, we had tried this diagnostic procedure before in the internet study and found it to be feasible.

Another limitation is that we were not able to examine the participants’ ability to perform correct pelvic floor muscle contractions. This might have resulted in some women not being able to perform effective PFMT and thus not improving. The interviews also revealed that some women missed this personal feedback and
would have liked a health professional to examine them. We did however include information in the app stating that those who did not get better after three months’ training could contact their ordinary health care service for further advice. Also, it seems that most women can learn to correctly perform pelvic floor muscle contractions after a simple verbal instruction.\textsuperscript{142}

The non-face-to-face design may also have limitations for the interview study since it may be difficult to feel confident and have a personal discussion on the telephone with a researcher you have never met. This might be a reason for the relatively short interview times (mean time 34 minutes). Also, body language could not be detected. It is possible that with face-to-face interviews or repeated interviews we could have received even more detailed information from the participants.

\textit{Limitations of Paper I}

The two groups in our RCT were not blinded to group allocation since this is difficult to achieve in an app study. The control group was a waiting list group, meaning that they were informed at randomization that after the three-month follow-up they would be given access to the app. This approach may have some limitations, for example it may cause women in the control group to feel deprived of treatment and possibly even increase their experience of bother from their incontinence. On the other hand, it might also inspire them to initiate some kind of treatment or information-seeking about incontinence while waiting.

We compared the app to an inactive control and not to another active treatment or care-as-usual. A limitation of this is of course that we cannot know if self-management with an app is as good as or better than another treatment. However, we had several reasons for selecting this study design. Firstly, since app-based treatment for urinary incontinence had not previously been evaluated, and the literature about app-based treatments overall was limited when we designed the study, we wanted to investigate if an app treatment was possible. The aim was not to study if it was better than other treatments for urinary incontinence but to evaluate if an app per se could be an effective treatment option. Secondly, there was no established “care-as-usual” for women with stress urinary incontinence in Sweden and no national guidelines to refer to. Therefore care-as-usual could differ in different regions of Sweden and we wanted to reach women from all over Sweden. Also, our aim was to reach women who did not seek help through the ordinary health care service, and for whom care-as-usual was not an option.

\textit{Limitations of Paper II}

The small sample size in this study is a limitation since some factors that might have been associated with success could have been missed. The small sample size
also leads to the wide confidence intervals for the factors that we did find associated with success. This was a secondary analysis from the RCT and therefore some of the variables were not primarily selected or designed for the purpose of being included in a logistic regression analysis.

**Limitations of Paper III**
My own preconceptions may of course have limited the possibility for me to be open to new findings in the analysis, although it is difficult to judge in what way. My previous knowledge of the subject came mostly from my experience of meeting women with stress urinary incontinence in my daily work as a general practitioner, which could also be an advantage when performing an interview study about incontinence. Also, I had heard about the experiences from the previous internet-based program for incontinence although I had not taken part in that research.

**Limitations of Paper IV**
In the study of the freely available app the major limitation is that we had no control group. Therefore, we cannot say if the improvements in incontinence symptoms are related to the use of the app and performing PFMT or the natural history of urinary incontinence during pregnancy/the postpartum period. It is however difficult to achieve a control group in this kind of follow-up study of an intervention that is freely released.

Another limitation is that we only included a short questionnaire and therefore there is a lack information about factors that could influence the result, for example stage of pregnancy, mode of delivery at childbirth and parity. Also, the data from the questionnaires is anonymous and we cannot contact any participant to check for accuracy.

**Perspectives on our study populations**
The participants in our RCT were on average middle-aged women (mean age 44.7 years) and the majority had had several children. This seems representative of the population since there is a peak in UI prevalence in middle-aged women and parity has been found to be a risk factor for SUI in this group. Almost all participants had moderate or severe stress urinary incontinence which means that they were probably bothered by their incontinence. Also, their odds for remission would be lower than for younger women with slight severity. Therefore, this seems like a relevant group for a treatment intervention.

Only 37% of participants had looked for help previously, which is similar to findings in other studies on help-seeking of women with urinary incontinence. This means that we reached many women who had not previously sought care
and who might not have been willing to seek help from their ordinary health care service. In the interviews, some women also expressed that they would not consult ordinary health care at present. The fact that it was possible to reach these women is an important finding, and one reason could be our study design with online recruitment and no face-to-face contact. In the interviews, women expressed that this design was convenient since everything was accessible from home and they did not have to spend any time on booking appointments.

Women in our RCT had a high level of education (79.7% had ≥3 years of university education compared to 30% of the general female population aged 25 to 64 years). It has previously been found that the use of health apps is more common among people with a higher level of education. It is possible that our online recruitment resulted in a selection of participants who were more used to searching for health information on the internet and with a higher level of education. Although the high educational level in our RCT might not be surprising, it is still a limitation when considering the generalizability of our findings to other settings with women with other educational backgrounds. However the ability to perform correct pelvic floor muscle training does not seem to depend on educational level.

When the app was released for free, the university educational level of the pregnant and postnatal users was 72.9% compared to the expected 53% of women aged 25 to 34 years in Sweden 2018. Of those who actually completed the follow-up after three months, 85.5% had a university education. Of the pregnant and postnatal users, 27.8% reported living in a city with > 1 million inhabitants, which in Sweden equates to Stockholm. It also reflects the fact that 24.8% (28,706 of 115,832) of all births in Sweden in 2018 took place in Stockholm. The Swedish participants correspond to approximately one tenth of all pregnant/postnatal women in Sweden.

**Perspectives on the treatment effect**

We found that self-management with the support of the app Tät® gave statistically significant improvements on all outcomes in the RCT study. The outcomes were also significantly different from the control group at follow-up. Statistically significant improvements are not necessarily clinically relevant since they might be so small that they are not noticeable for the individual. Therefore, it is important to consider whether the improvements are large enough to be of clinical interest. One way to do this is to compare the results on an outcome to the minimum clinically important difference (MCID) estimated for that specific outcome.
The MCID for ICIQ-UI SF and ICIQ-LUTS-qol have been estimated by my colleague Emma Nyström using data from the RCT comparing two self-management programs for SUI, one internet-based and one in a booklet. She calculated the MCID for ICIQ-UI SF to be 2.5 and the MCID for ICIQ-LUTS-qol to be 3.7.\textsuperscript{148} Compared to these estimates the improvements in the app group in our RCT (mean ICIQ-UI SF reduction of 3.9 and ICIQ-LUTS-qol reduction of 4.8) were well above these numbers and we therefore consider them to be clinically relevant at the group level.

A recent article by Lim et al also estimated the MCID for the same outcomes but from another RCT population evaluating a non-surgical intervention for SUI.\textsuperscript{149} They estimated a MCID of four for ICIQ-UI SF and of six for ICIQ-LUTS-qol. A large methodological difference in the estimates that could explain the lower MCID in the study by Nyström was that she used the mean ICIQ-UI SF score for participants who answered that they were “a little better” in response to the PGI-I question. However, in the study by Lim et al they calculated the difference in the mean ICIQ-UI SF score between participants who answered that they were “much” or “very much better” versus all other participants.

\textbf{Comparing with other app interventions}\n
This was the first app for self-management of stress urinary incontinence to be studied in a randomized controlled trial. Although there has been a recent increase in the publication of studies evaluating apps to support pelvic floor muscle training, there are still few apps that have been evaluated for efficacy.\textsuperscript{116} Therefore, it is difficult to make direct comparisons with other app interventions. Another factor that makes comparison difficult between incontinence studies is the use of different outcome measurements for incontinence improvement. With these limitations in mind I will try to compare our results to relevant findings in the literature.

During 2019 two studies were published on mHealth (one with an app and one with a web-based mobile platform) to support PFMT, that evaluated the effects by using the outcome measurement ICIQ-UI SF. Araujo et al performed an RCT comparing an app with written instructions to support adherence to PFMT.\textsuperscript{122} The app group achieved higher adherence. Both groups improved their mean ICIQ-UI SF score, the app group from 16.3 (4.0) to 9.1 (6.6) at three-month follow-up and the control group from 15.9 (4.7) to 9.7 (6.6). There was no difference between the groups. This reduction in ICIQ-UI SF was larger than the 3.9 found in our RCT study. However, we only had one person lost to follow-up in each group while the study by Araujo had a bigger loss to follow-up, and only analysed the outcome for those who completed the follow-up (12 out of 17 in the app group and nine out of 16 in the control group) which could lead to a selection of those
with the best effects. Another difference was the selection of participants where Arajo et al excluded women who could not perform a pelvic floor contraction at the initial assessment. Further, their participants were referred from a gynaecologist and had more severe urinary incontinence with higher baseline scores of ICIQ-UI SF than the participants in our RCT (11.1 (3.0) in the app group). In total, 91% of the women in both groups reported improvement after PFMT, which is similar to the 92% that experienced improvement in our app group.

The pilot study by Goode et al evaluated a web-based mobile platform for behavioural treatment of urinary incontinence (SUI, UI and MUI) in women veterans. There was no control group in this study but a pre-test/post-test design was followed. For 20 of the 29 women who completed the program, the mean ICIQ-UI SF score decreased from 12.6 (3.9) at baseline to 8.7 (4.0) at the eight-week follow-up. This mean score reduction of 3.9 is the exact same magnitude of reduction as we found in our RCT study. However, this study only analysed the outcomes for the 69% who completed the program. 65% of the completers reported improvement after eight weeks.

**Comparing with other PFMT interventions**

There is a variety of other PFMT interventions for treatment of SUI with which to compare our app intervention. Several randomized controlled trials that have used ICIQ-UI SF as an outcome measurement have found reductions in the mean ICIQ-UI SF score of between 3.0 and 4.5 which is similar to our findings.

Porta-Roda et al evaluated the addition of vaginal spheres to PFMT and compared this with PFMT only. They performed pelvic examination and instruction at inclusion, but the intervention was unsupervised. They found that the ICIQ-UI SF score improved in both groups with no significant difference between the groups at the six-month follow-up. The ICIQ-UI SF mean score in the intervention group decreased from 8.63 (2.65) at baseline to 4.77 (3.52) after six months.

Sherburn et al compared PFMT to bladder training for treatment of SUI in older women. Both groups had weekly supervised sessions for 20 weeks and the participants in the PFMT group underwent pelvic examination. The results showed that PFMT was more effective than bladder training for reducing incontinence symptoms. The mean ICIQ-UI SF score in the PFMT group decreased from 10.4 (5.0) at baseline to 5.9 (3.3) after five months.

Hirakawa et al evaluated the addition of biofeedback to PFMT. Both groups exercised at home, unsupervised but with regular follow-ups during the 12-week
treatment period. Both groups underwent an initial pelvic examination with instructions on correct contraction. The results showed that both groups improved with no difference between the groups. The mean ICIQ-UI SF score in the PFMT group decreased from 12.0 (3.5) at baseline to 8.3 (3.5) at follow-up.\textsuperscript{151}

In a non-randomized, pragmatic study, women with UI could choose to perform a 12-week PFMT program unsupervised at home or be supervised weekly at the health centre. The study found that the mean ICIQ-UI SF score improved for both groups with no difference between the groups.\textsuperscript{154} As part of their pragmatic approach researchers performed an initial examination of the pelvic floor muscle contractions by inspecting the exercises over the participants’ underwear and not by palpation. The mean ICIQ-UI SF score was 12.2 at baseline for both groups and 5.6 at follow-up one month after the intervention period.

An RCT evaluating a one-time group intervention using behavioural treatment (including instructions for PFMT) for urinary incontinence in older women showed that the ICIQ-UI SF score of the intervention group improved significantly more than the control group at both the three-month and 12-month follow-up.\textsuperscript{153} The baseline ICIQ-UI SF in the intervention group was 8.78 (3.74) which decreased to 6.87 (3.66) after three months and 5.75 (3.52) after 12 months.

In the study on internet-based PFMT, Sjöström et al found that women in the internet group had a mean ICIQ-UI SF score reduction of 3.4 (3.4), from 10.4 (3.1) at baseline to 6.9 (3.1) at the three-month follow-up.\textsuperscript{129} Women in the brochure group had a mean score reduction of 2.9 (3.1), from 10.3 (3.5) at baseline to 7.3 (3.9) at follow-up. There was no difference between the groups. The mean score reductions in the ICIQ-LUTSqol were 4.8 (6.1) in the app group and 4.6 (6.7) in the brochure group with no difference between the groups. These reductions are similar to the 4.8 (95% CI 3.4-6.2) found in the app group in our RCT study.

Another way to measure effect is by reported subjective improvement. In the app group in our RCT 56\% of the women reported that their incontinence was much or very much improved at follow-up. In the internet-based study 40.9\% of the women in the internet group reported to be much or very much improved. These results are in line with findings from the recent review on conservative treatments for UI which concluded that improvement was reported by 30\% to 79\% of participants.\textsuperscript{58} According to the same review, treatment satisfaction usually varies between 51\% and 76\%. In our RCT 66.7\% (40 out of 60 participants) were satisfied with their treatment outcome. Although the cure rate might not be the most appropriate measurement for evaluating treatment, as mentioned earlier, 8.3\% of our app group reported that they were completely free of leakage. The
corresponding number in the internet group was 3.8%. This is lower than the 15% to 45% cure rates described in the review of conservative treatments.

The finding that 56.5% of our app group reported either no leakage or ≥50% reduction in leakage episodes at follow-up is also clinically relevant since patients seem to experience clinically important improvements when incontinence episodes decreased by >50%.155

**Treatment effect in pregnant and postnatal women**

In our study on the use of the freely available app by pregnant and postnatal women, the improvements found are difficult to interpret. We had no control group and the prevalence of incontinence is known to change during the pregnancy and postnatal period.13 Thus, we cannot say whether the improvements experienced by the participants were due to the intervention or the natural improvement over time. It is also difficult to find treatment studies of pregnant and postnatal women with which we could compare our results, and the evidence base for treatment effect of PFMT in these groups is still limited.

When analysing the changes in the ICIQ-UI SF score we divided the results into different groups depending on the participants’ pregnancy or postnatal status. In this way, we found that women who used the app during pregnancy had the smallest reduction in the ICIQ-UI SF score of only 0.2, which was statistically significant but hardly clinically relevant. This was expected since the prevalence of UI is known to increase during pregnancy.25, 26 The largest improvements in the ICIQ-UI SF were found in the two groups that used the app postpartum (mean score reductions of 2.3 and 2.8). This may have been due to the natural course of incontinence, since it has been described that the prevalence of UI decreases during the first six months postpartum and then stabilizes.26 Other studies, however, have found a rather stable prevalence of UI during the first year postpartum.34, 37 We believe that although we cannot know the reason for the improvement in the postnatal group, it is clinically relevant. This is both because it is close to the previously described minimum clinically important difference for ICIQ-UI SF of 2.5, and because as many as 76% of the postnatal women experienced improvement at the three-month follow-up.

I have not found any treatment studies of pregnant and postnatal women that have used the ICIQ-UI SF as an outcome measure. Two intervention studies of pregnant women reported that the prevalence of UI changed after the intervention. Fritel et al reported an increased UI prevalence from 37.6% to 44.2% during pregnancy with no difference between the intervention group (supervised PFMT) and the control group (written instructions).156 In contrast, Miqueletti et al found a reduction in UI prevalence from 53.6% to 41.2% during
pregnancy in the intervention group (PFMT instructions) compared to the control group (standard care), where the prevalence increased from 53.0% to 68.4%. In our study the prevalence of UI in the pregnant group was 46.6% at inclusion and increased to 48.1% at follow-up.

The prevalence of UI in the postnatal women in our study was 54.7% at inclusion and 49.3% at follow-up. An intervention study on postpartum women by Hilde et al found that the UI prevalence changed from 44.6% to 36.6% at six months postpartum, but with no effect from the PFMT program. Kinouchi et al found that the prevalence of UI in postnatal women was lower in the intervention group (smartphone-based reminder system to promote PFMT) after eight weeks compared to a historical control group.

**What made the app intervention effective?**

How can we explain the positive effects found in the RCT? The qualitative study gave us valuable insights into why and how the app intervention could be effective. Also, the user data from the RCT and the analysis of factors associated with success gave us clues as to what affected the positive outcome.

Overall the interviews revealed that the app intervention was very much appreciated by the participants. This was regardless of the effects the women experienced on their incontinence symptoms. One reason for this positive attitude was probably that they had chosen to enter this study because they were interested in trying an app and had high expectations that an app was a suitable tool for increasing their adherence to PFMT. The women also expressed high expectations on their own ability to perform independent PFMT. However, they did not express the same high expectations on the result to expect, but had more vague goals of “getting better”. In our analysis of factors associated with a successful treatment, we found that higher expectations on the treatment effect was associated with a better treatment outcome. Since goal-setting has been described as a facilitator of adherence to PFMT our findings could indicate that women who had a clearer or higher expectation on the result also succeeded better. It is also possible that the finding indicates that those who succeeded had a higher level of self-efficacy.

It is not certain that a different population of women would have the same positive attitude. For example an interview study of expectations regarding eHealth interventions in women with SUI in the Netherlands found that those women were not comfortable with using a non-face-to-face internet-based intervention and instead preferred to combine it with visits to a health care professional. However, these women were recruited from primary care centres and had all had previously unsuccessful treatment for SUI.
As previously mentioned, apps have the obvious benefit of being close-at-hand and convenient to use which was also emphasized by the women in our study. The app included strategies known to reduce barriers and facilitate adherence to PFMT such as offering a structured PFMT protocol, helping the participants to remember to do the exercises, visualizing the obscure contractions and delivering a cheap and convenient treatment option.

As described earlier, reminders are one way to increase adherence to PFMT. We think that the adherence rate in our RCT study was good with 41.0% of the app group reporting daily PFMT at follow-up and 83.6% reporting weekly PFMT. However, there is no consensus about how to measure adherence to PFMT or what constitutes a critical level of adherence to achieve effect. As a comparison to our study, a study on adherence to PFMT reported that after a visit to a care practitioner and receiving instructions, 31.5% of the participants performed daily PFMT after three months. In our study of the freely available app, the adherence rate was lower. Nonetheless, of those who completed the follow-up, 29% reported daily PFMT and 74% reported weekly PFMT.

The visualization of the exercises and the contractions was described as very helpful and seemed to add something new to the PFMT program. It has previously been described that an app intervention provided a new visual understanding of diabetes self-management. The ability to visualize the pelvic floor muscle exercises in some way and the progress achieved by the training has also been found to motivate women to continue with PFMT. This could be of extra importance in the context of PFMT since many women in our interviews described that it was challenging to exercise muscles that they could not see.

In our secondary analysis of the RCT we found that improved self-assessed pelvic floor muscle strength at follow-up was associated with successful treatment. This may indicate that women who succeeded better had trained their PFM more, although we did not find any association between adherence to PFMT and treatment success. This is contrary to the results found in the one-year follow-up of the participants included in the internet versus brochure study. Here it was shown that performing regular PFMT (at least weekly) doubled the OR of having a successful outcome after one year. Adherence to PFMT was suggested as being important for long-term success.

The app probably increased the participants’ adherence to the PFMT which contributed to the favourable effect on incontinence symptoms. It is also possible that the information and visualization given in the app provided women a new understanding of both incontinence and PFMT, which in turn increased the effectiveness of their self-management and improved their incontinence symptoms.
In relation to the Social Cognitive Theory, the participants in our RCT seem to have had a high level of self-efficacy from the beginning which would positively affect their adherence to the PFMT program. They also experienced that the app enabled their self-management, implying that the use of the app also increased their feeling of self-efficacy and thus their adherence to the PFMT.

In reference to the COM-B framework for improving adherence, the app has addressed several of the interventions supporting PFMT behavioural change. These include education, a training regimen, persuasion through reminders and the fact that the app was described as an “enabler” by the users.

Although we have tried to understand which parts of the app intervention were important for the positive effect, we cannot analyse them separately. The intervention must be considered as a whole as it is a complex intervention. We think that to be effective all parts are important; relevant, evidenced-based information, a solid PFMT program and behavioural strategies to support good PFMT adherence.

**Perspectives on self-management**

Self-management of urinary incontinence is probably the most common way women deal with incontinence, both those who never ask for help from their health care service and try to manage by themselves, and those who receive advice from the health care service about conservative treatment. The important role and positive effects of self-management of urinary incontinence are well-documented. However, there are different ways for health care to deliver or support this self-management.

In the context of pelvic floor muscle training there is sometimes a distinction made between supervised and unsupervised PFMT. The difference is that in supervised PFMT the participant usually has an initial appointment with a health care professional who examines the pelvic floor and instructs the participant about correct pelvic floor muscle training. Supervised training programs typically include follow-up visits with additional training or examinations and a final follow-up visit. The training can be individual or group-based. In unsupervised PFMT the participant is often given verbal or written instructions about how to perform PFMT and is then left to perform the training at home. It is worth mentioning that in both supervised and unsupervised PFMT the participant is expected to perform pelvic floor muscle training frequently, on their own, at home. Therefore, a common challenge for both approaches is to achieve good adherence to the home PFMT program.
The participants’ view on self-management
It was the preference of the participants in our interview study to independently self-manage their incontinence. The main reason for this was not shame or embarrassment to talk about incontinence with healthcare professionals, but because they believed that they were capable of handling it themselves. They described a high level of self-efficacy. In their opinion they were the only ones who could perform the PFMT and they felt responsible for their own health. They viewed the app as an “enabler” that could help them achieve their goal of adhering to a PFMT program.

Previous research has described that people who want to have more control over their health are more likely to use digital health. Similar to our findings, qualitative studies of apps for physical activity and chronic illnesses have found that the users appreciated that they could use the app independently, that it was an important aid that empowered them to manage their health condition and it made them feel more in control.

Qualitative studies of women with urinary incontinence describe that the women try to manage their incontinence in different ways to gain control and to continue living as normal. Also the goal of women in engaging with self-management strategies such as PFMT is to maintain or achieve a normal daily life. They therefore choose strategies that they can fit in to their daily lives and that do not disrupt life too much.

Gaining control appears to be an important aspect affecting several areas of the self-management of urinary incontinence. Control may be the reason why women engage in self-management, the feeling of control can be enhanced through the support of an app, and this in turn can lead to increased adherence to a PFMT program.

Performing pelvic floor muscle contractions
There are some concerns about unsupervised PFMT - performing self-management without face-to-face contact with a health care professional. The concerns centre around whether women can learn how to perform correct pelvic floor muscle contractions by themselves, or whether they need a pelvic examination (digital palpation) from a health care professional to be sure about correct contraction.

One study that evaluated this performed vaginal examination after the group was given initial information about PFMT. It found that 68% of participants were able to correctly perform the contraction, 32% required further instructions, 89% were ultimately successful and 11% were not successful. Another study in
primary care also found that of women with SUI, 83.4% were able to perform correct pelvic floor muscle contractions on the first attempt. Of the remaining women, 78% were able to perform a correct contraction after a brief verbal instruction. In a study of an mHealth intervention for UI, the participants had the possibility to send an alert to a nurse if they had problems with the pelvic floor muscle training program. It turned out that only one of the 29 women asked for help because of difficulties in contracting her pelvic floor muscles. Intervention studies that have not included pelvic examination have found improvements in incontinence symptoms in the intervention groups, indicating that it is possible for women to learn the skill of PFMT and to achieve a positive effect on their incontinence symptoms without a physical examination.

In our RCT 34% of the app group felt confident that they could contract their pelvic floor muscles correctly at inclusion and 79% felt confident at follow-up. 95% rated their pelvic floor muscle strength as better at follow-up. It would appear that, although only 34% were confident of their ability to perform PFMT before the intervention, something happened during the intervention that increased their confidence. In the interviews, women described that reading the information and instructions about PFMT, trying out the exercises, feeling progress in terms of their muscle strength and improvement in incontinence symptoms assured them that they were doing it right. It would appear that a non-face-to-face intervention can facilitate the learning of correct pelvic floor muscle contractions and that this is significant for its effect. Further, this is mirrored in our finding that increased self-assessed pelvic floor muscle strength at follow-up was associated with a better treatment outcome. Among those who did not have a successful outcome in our RCT there may be some women who had difficulties training their PFM and who need additional support from a health care professional.

In our interview study it was an interesting finding that although many women expressed some uncertainty about whether they were doing the pelvic floor muscle contractions correctly, they accepted this uncertainty for the sake of being able to perform the self-management program independently and hoped that it would be “good enough”.

**Implementing the app in the “real world”**

The intention of the eContinence project is to develop, evaluate and implement new interventions for urinary incontinence. In this thesis I have described several stages of the evaluation of the app including the RCT, the analysis of factors associated with success and the qualitative study of the users’ experiences. To further supplement the evaluation of the app other members of the research group have also performed a long-term follow-up and a cost-effectiveness
analysis. The long-term follow up included 46 of the 61 women from the RCT app group. It showed that after two years the effects seemed to persist with a mean ICIQ-UI SF score reduction of 3.1 and an ICIQ-LUTS-qol score reduction of 4.0 compared to baseline. At follow-up, 66.7% of the women reported that their incontinence had improved compared to baseline. The cost-effectiveness analysis showed that the app treatment was cost-effective from a one-year societal perspective, compared to no treatment.

After these evaluations of the app we released the app for free in order to enable widespread use. To achieve this, several updates of the app were made based upon user experiences reported in the app studies and from correspondence with users via e-mail, telephone and stores (App Store and Google Play) after the free release. Our primary goal has not been to implement the app within ordinary health care, although we have shared information about the app within our clinical and research networks.

It is important to follow up on an intervention once it has been implemented after a controlled trial since the effects might be different when the intervention reaches a new more diverse population. We find this particularly important since app interventions are a new area of research. A review on the usability and effectiveness of apps supporting health care during pregnancy concluded that while most apps seemed feasible and acceptable, the evidence on effectiveness was modest due to small study groups.

We found that once the app was released freely it did indeed reach a new population and 41% of the users were pregnant and postnatal women. This is natural since these women have an increased risk of UI and are often recommended to perform PFMT by health care professionals. It was this finding that inspired us to include a picture of a pregnant woman as an option for a background image in an update to the app. We also found that many women used the app to train their pelvic floor muscles preventively and did not have UI. This corresponds well with recommendations given to pregnant women aimed at preventing the onset of incontinence. Although our app was developed for treatment of incontinence in non-pregnant women it also seems to be appreciated by pregnant women for preventive training.

The symptom severity of the incontinent users was milder (mean ICIQ-UI SF score 6.7) than in the RCT study (mean ICIQ-UI SF score 11.1) at inclusion. This is similar to the severity (mean ICIQ-UI SF 6.2) described in another cohort study of incontinent pregnant women. Even milder incontinence was found in a study of incontinent pregnant women (mean ICIQ-UI SF 3.7) and incontinent women one year postpartum (mean ICIQ-UI SF score 5.1). Lower ICIQ-UI SF scores at baseline might have an impact on the size of the reduction that is possible upon
completion of an intervention. In an unpublished manuscript in which we analyse users of the freely available app who were not pregnant or postnatal, we found that the reductions in the ICIQ-UI SF score at follow-up differed depending on the incontinence severity at baseline, in that those with milder incontinence had smaller reductions.\textsuperscript{166}

Only 17\% of the women who answered the inclusion questionnaire completed the three-month follow-up. It is natural that the follow-up rate is lower than in our RCT. This is comparable to a study of a web-based cognitive behavioural therapy for anxiety and depression symptoms. That study compared completion rates between participants in a controlled trial and spontaneous users of the program and found that 66\% of the trial participants completed more than two modules in the program while the corresponding number for the spontaneous users was only 15.6\%.\textsuperscript{167}

**Clinical implications**

The Tät® app already has clinical implications since it is freely available all over the world in six different languages. Currently, over 100,000 people in 117 different countries have used the app. As such, the app offers an easily accessible and effective self-management intervention for women with stress urinary incontinence.

Given that worldwide smartphone distribution is still on the rise, and that there is great interest in health apps for self-management of different conditions, we believe that the use of the Tät® app will also increase. Even though the health benefits of an app intervention are small they might have a valuable impact on public health if the population reach is high.\textsuperscript{113}

In our controlled studies the participants have predominantly been Swedish, highly educated women. However, we hope that through the freely available app we will also reach those with less education and from other countries. In the future the distribution of smartphones may also become more even which would reduce the current digital divide.

We have evaluated the app as a stand-alone, self-management intervention for women with SUI. This kind of self-management might not be suitable for everyone, but it gives women one more option when considering how to deal with their incontinence. Our interviews revealed that the app provided valuable support to women who preferred to independently self-manage their incontinence. In clinical practice the app could easily be used as a complement to other treatments for SUI. Mobile apps have been suggested as effective tools for
improving adherence to home PFMT for patients who have regular appointments with a health care professional for supervised PFMT.\textsuperscript{168}

Cost-effectiveness is an important consideration when evaluating the treatment options to offer within health care. The app would be a suitable first-line option for those who are interested, and the resources for individualized, supervised treatment can be redirected to those who do not improve after app-based self-management, or to those who prefer a personal contact.

Performing PFMT during pregnancy to prevent urinary incontinence is evidence-based and the app could also be recommended for this purpose within maternal health care.

Since ours was the first group to perform an RCT and publish results on an app-based intervention for stress urinary incontinence, the study has gained interest from researchers in the field of incontinence. The results of our research have already been incorporated into several reviews and have had an impact on guidelines and recommendations for conservative management of stress urinary incontinence.\textsuperscript{116, 69, 93} The app is also recommended in the guidelines of our regional health authority for initial treatment of stress urinary incontinence.

**Future research**

With the widespread use of the app and the incorporation of a questionnaire within the app we have the potential to gather information from a large number of participants and understand even more about the app users. We might be able to find out more about the factors that are associated with successful treatment. We also want to understand more about how to reach certain groups of women, such as those with less education and a lower income. Are there barriers or factors within the app that we can adjust to enable us to reach more hard-to-reach groups?

Building on our experience of creating an app for SUI, more apps have been developed for other conditions within the eContinence project. These include the Tät II\textregistered app for women with urgency and mixed urinary incontinence and the Tät III\textregistered app for men who are due to undergo or have undergone a prostatectomy. These apps could potentially be implemented within health care and we need to study how this could be done. Thus far, we have focused on interventions targeted directly at the users and not at the health care service. We also need to investigate the care-givers’ views on the use of apps for their patients.
Conclusions

- Tät® is the first app for the self-management of stress urinary incontinence focused on pelvic floor muscle training to be evaluated in a randomized controlled trial. Women using the app for three months achieved clinically relevant reductions in incontinence symptoms and increased their quality of life. The improvements were significantly larger than in the control group.

- Improvement was reported by 92% of the app group and 56% of participants reported that they were much or very much better at follow-up, which was considered a successful treatment outcome. Factors associated with success were high expectations on treatment effect, weight stability, and improved self-assessed pelvic floor muscle strength.

- App-related factors that were appreciated by and important for the users were the easy access, the convenience of fitting the training into daily life, the well-structured PFMT program, the visualization of the PFM contractions and the reminders.

- Women preferred to manage their PFMT independently and they described that the app supported and enabled them to achieve this.

- When freely released, the app quickly reached a large, more diverse population with many pregnant and postnatal women. It appears that these groups could also benefit from using the app-based program since 55% of the pregnant women with incontinence improved after three months’ use and 23% were much or very much better. In terms of postnatal women with incontinence, 76% improved and 41% were much or very much better.

- Only 17% of those who answered the baseline questionnaire in the freely available app also completed the follow-up questionnaire after three months. In this group, adherence to the PFMT program was good with 29% performing PFMT daily and 74% performing the program weekly.

- The Tät® app is a new, easily available, effective and popular self-management aid for women with stress urinary incontinence.
Acknowledgements

I would like to express my gratitude to the following:

The women who participated in our studies and made this research possible.

Eva Samuelsson, my main supervisor, for inviting me to join your research and for making this whole research project possible.

Malin Sjöström, my co-supervisor, for guiding and supporting me with clear and friendly advice.

Katarina Hamberg, my co-supervisor, for inspiration and valuable expertise in the area of qualitative research.

Göran Umefford, my co-author, for patiently providing wise suggestions on our articles.

Emma Nyström, my co-author and former fellow PhD-student, for showing me the way by finalizing your thesis before me. Also, many thanks for the statistical help, the general support and for making the PhD studies much more fun.

Susanne Johansson, our study coordinator, for making sure everything is in order and for always having your door open for questions.

Hans Stenlund, for statistical support.

Tina (Kristina) Johansson, for helping with transcribing the interviews.

The Unit of Education, Research and Development in Östersund for funding and for providing a stimulating work place. Special thanks to Cecilia Högberg and Gunnar Nilsson for sharing room and experiences.

The Unit of Family Medicine at Umeå University, for providing a supportive environment which inspires to further research and teaching.

The National Research School in General Practice for inspiring scientific meetings and discussions.

My co-workers at the health centre in Krokom for making me feel included even when I have been absent.
My family for always being there for me.

My husband Ragnar and my children Rut, Nils and Tage for all your love.
References


Appendices
För att mera exakt kunna värdera dina besvär med urinläckage ber vi dig att så noggrant som möjligt fylla i en läckagelista under två dygn där du anger klockslag för urinläckaget och uppskattar hur mycket du läcker. 1 = läcker några droppar, 2 = blir fuktig, 3 = blir våt. Listan behöver inte fyllas i två dygn i rad utan du kan välja två dygn som passar dig.


Du ska alltså på denna lista:
- fylla i listan under två hela dygn, både dag och natt
- ange klockslag för eventuella läckage, eller när du upptäckte läckaget
- ange hur mycket du läckte: 1 (droppar), 2 (fuktig) eller 3 (våt)
- fylla i klockslag för när du kissat som mest (maxvolym) och ange mängden urin (mätt i deciliter)

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Exempel på hur en ifylld urinläckagelista kan se ut:

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<th>MAXVOLYM</th>
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</table>

Praktiska tips inför urinmätningen:

Lämpliga kärl att kissa i kan vara ett decilitergraderat litermått, en avklippt sirapsflaska, eller något annat graderat mått. En potta eller ett avklippt mjölkpaket går också bra. Mängden urin kan du ju kontrollera efteråt genom att hålla över urinen i ett mätkärl.

Skicka in den ifyllda urinläckagelistan till följande adress:

Studiekoordinator Susanne Johansson
Jämtlands läns landsting
FoU-enheten
Box 654
831 27 Östersund

OBS! För att vara med i studien vill vi att du skickar in den ifyllda urinläckagelistan inom 3 veckor efter det att du fått e-postmeddelandet med länken till dokumentet.
Välkommen till studien om behandling av urinläckage vid ansträngning!


Webbenkäten består av tre delar. Den första och andra delen handlar om ditt urinläckage, din allmänna hälsa, din bakgrund och din smartphoneanvändning. Den tredje och sista delen handlar om livskvalitet.

När du besvarat webbenkäten hör vi av oss till dig för ett kort telefonsamtal och sedan lottas du till antingen en grupp som får appen direkt eller till en grupp som får vänta i tre månader.

För mer information om studien kan du gå in på vår hemsida tät.nu.

Vid frågor om studien eller enkäten kan du kontakta oss via e-post: tat@fammed.umu.se

Ansvariga för studien är:
Susanne Johansson (koordinator för studien, handläggare FoU-enheten, Jämtlands läns landsting)
Eva Samuelsson (huvudansvarig för studien, docent, distriktsläkare)

Nu kommer den första delen av enkäten som handlar om ditt urinläckage, din allmänna hälsa, din bakgrund och din smartphoneanvändning. Fråga 1 - 42.

1. Hur besvärande är ditt urinläckage? Markera en av siffrorna 1 till 7, där 1 betyder inte alls besvärande och 7 betyder mycket besvärande.

   1  2  3  4  5  6  7

2. Vad har du för förväntningar på resultatet av 12 veckors träningsprogram för ditt urinläckage?

   □ att bli helt fri från läckage
   □ att bli väldigt mycket bättre
   □ att bli mycket bättre
   □ att bli lite bättre
   □ att det blir oförändrat

3. När du valde att anmäla dig till en studie om behandling via smartphone, hur pass viktiga var följande faktorer?

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<tr>
<th>Faktor</th>
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<td>- att du hade dålig tillgång till annan behandling</td>
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<td>- att tidigare erfarenhet av vård påverkade</td>
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4. Om du inte hade anmält dig till studien, hade du I NULÄGET sökt annan vård för ditt urinläckage?

☐ ja, absolut
☐ ja, kanske
☐ troligen inte
☐ nej
☐ vet ej

5. Hur uppfattar du tillgängligheten till vård för urinläckage?

☐ mycket bra
☐ ganska bra
☐ inte så bra
☐ inte alls bra
☐ vet ej

Nu kommer några frågor om vilken hjälp du tidigare fått för ditt urinläckage.


☐ nej
☐ ja, hos distriktssköterska/barnmorska/uroterapeut
☐ ja, hos distriktsläkare/gynekolog/urolog
☐ ja, hos sjukgymnast
☐ ja, hos annan


☐ ingen
☐ förskrivning av hjälpmedel/skydd
☐ råd om bäckenbottenträning (knipövningar)
☐ lokal östrogenbehandling (slidpiller, kräm)
☐ medicinering
☐ elektrostimulering
☐ remiss
☐ annan

9. Har du använt någon typ av absorberande skydd (t.ex. trosskydd, binda) för ditt urinläckage under de senaste fyra veckorna?

□ nej, aldrig  
□ ja, mer sällan än 1 gång per vecka  
□ ja, 1-3 gånger per vecka  
□ ja, mer än 3 gånger per vecka, men inte dagligen  
□ ja, 1 skydd per dag  
□ ja, mer än 1 skydd per dag  


□ inte någon extra tvätt  
□ 1-2 extra tvättar  
□ 3 extra tvättar eller fler  

Nu kommer några frågor kring barnafödande och din kroppsliga hälsa.

11. Har du fött barn?

□ nej  
□ ja, ett barn  
□ ja, två barn eller fler  


□ nej, jag har inte bortopererat livmodern, äggstock/äggstockar eller opererats pga framfall  
□ ja, bortoperation av livmodern  
□ ja, bortoperation av äggstock/äggstockar  
□ ja, operation pga framfall  

13. En kvinnas menstruationer upphör vanligen någon gång mellan 45-55 års ålder. Har dina menstruationer upphört?

□ nej  
□ ja  
□ vet ej  

14. Har du besvär av förstoppning?

□ nej  
□ ja
15. Har du ofrivilligt läckage av avföring?
 □ nej
 □ ja

16. Har du besvär av tyngd- och/eller skavningskänsla i underlivet?
 □ nej
 □ ja

17. Har du behandling med ring mot framfall?
 □ nej
 □ ja

Här kommer några frågor om din "knipförmanda" i bäckenbotten.

 □ nej, aldrig
 □ ja, sporadiskt, mer sällan än 1 gång per vecka
 □ ja, regelbundet, 1-3 gånger per vecka
 □ ja, regelbundet, mer än 3 gånger per vecka, men inte dagligen
 □ ja, regelbundet, dagligen

19. Kan du knipa så att det känns att det drar ihop sig runt ändtarmsöppningen?
 □ nej
 □ ja

20. Kan du knipa så att det känns att det drar ihop sig runt slidmynningen?
 □ nej
 □ ja

21. Kan du knipa så att det känns att bäckenbotten lyfts (slida, ändtarm lyfts inåt och uppåt)?
 □ nej
 □ ja

22. När du kissar, kan du få strålen att minska om du kniper?
 □ nej
 □ ja
23. När du kissar, kan du avbryta strålen helt om du vill?
□ nej
□ ja

24. Känner du dig säker på att du kniper "rätt"?
□ nej
□ ja

□ ingen gång
□ 1 gång
□ 2 gånger
□ 3 eller fler gånger

26. Använder du regelbundet (varje vecka) något eller några receptbelagda läkemedel (även plåster, salva, inhalator etc)? Markera ett eller flera alternativ.
□ nej
□ ja, mot inkontinens
□ ja, östrogen i tabletform
□ ja, lokalt östrogen (salva, slidpiller, ring)
□ ja, vätskedrivande
□ ja, antidepressiva
□ ja, för blodtrycket eller hjärtat
□ ja, annat läkemedel

27. Använder du lokalt i underlivet något receptfritt östrogenpreparat (t.ex. salva, slidpiller eller ring)?
□ nej
□ ja

Nu behöver vi veta lite mer om din bakgrund och levnadsvanor.


□ grundskola eller folkskola
□ realskola eller flickskola
□ 2-årigt gymnasium eller yrkesskola
□ 3-4 årigt gymnasium
□ universitet eller högskola, 2,5 år eller kortare
□ universitet eller högskola, 3 år eller längre


□ stillasittande fritid - Du ägnar dig mest åt läsning, TV, bio eller annan stillastittande sysselsättning på fritiden. Du promenerar, cyklar eller rör dig på annat sätt mindre än 2 timmar i veckan.
□ måttlig motion på fritiden - Du promenerar, cyklar eller rör dig på annat sätt under minst 2 timmar i veckan oftast utan att svettas. I detta räknas också promenad eller cykling till och från arbetet, övriga promenader, ordinärt trädgårdsarbete, fiske, bordtennis, bowling.
□ måttlig regelbunden motion på fritiden - Du motionerar regelbundet 1-2 gånger per vecka minst 30 minuter per gång med löpning, simning, tennis, badminton eller annan aktivitet som gör att du svettas.
□ regelbunden motion och träning - Du ägnar dig åt t.ex. löpning, simning, tennis, badminton, motionsgymnastik eller liknande vid i genomsnitt minst 3 tillfällen per vecka. Vardera tillfället varar minst 30 minuter per gång.


□ 5 timmar i veckan eller mer
□ mer än 3 timmar i veckan, men mindre än 5 timmar i veckan
□ mellan 1-3 timmar per vecka
□ högst 1 timme per vecka
□ inte alls

33. Röker du dagligen?

□ nej
□ ja


□ inga
□ 1-2 koppar
□ 3-5 koppar
□ mer än 5 koppar

□ inga
□ 1-2 koppar
□ 3-5 koppar
□ mer än 5 koppar

Vi vill också veta hur mycket du använder appar, smartphone och internet.

36. Använder du din smartphone för att skicka eller ta emot e-post?

□ nej
□ ja

37. Använder du din smartphone för att komma åt internet?

□ nej
□ ja

38. Använde du din smartphone under gårdagen för att komma åt internet?

□ nej
□ ja

39. När det gäller att komma åt internet använder du oftast din smartphone eller använder du något annat alternativ som t.ex. stationär dator, laptop eller surfplatta?

□ oftast smartphone
□ oftast annat (stationär dator, laptop eller surfplatta)
□ ungefär lika ofta smartphone som annat
□ vet inte


□ ja, flera gånger om dagen
□ ja, en gång om dagen
□ ja, några gånger per vecka
□ ja, en gång per vecka
□ ja, några gånger per månad
□ ja, några gånger per år
□ ja, mer sällan än en gång per år
□ nej

☐ jag har inga appar
☐ app/appar för hälsovård
☐ app/appar för träning och motion
☐ app/appar för kost och diet
☐ app/appar för sociala nätverk
☐ app/appar för spel, musik, film
☐ app/appar för annat

42. Vilket fabrikat har du på din smartphone?

☐ Apple iPhone
☐ Samsung
☐ Sony
☐ Nokia
☐ HTC
☐ LG
☐ Annat märke

Kommande sidor utgörs av färdiga enkäter som är vetenskapligt utvärderade i tidigare studier. Frågorna handlar om urinläckage, hälsa och livskvalitet.
Många människor drabbas periodvis av urinläckage. Vi försöker ta reda på hur många som har besvär och hur stort problemet är för dem. Vi vore tacksamma om du ville svara på följande frågor om hur du i genomsnitt har haft det, under de SENASTE FYRA VECKORNA.

1. Fyll vänligen i ditt födelsedatum:
   DAG          MÅNAD            ÅR

2. Är du:
   Kvinna  Man

3. Hur ofta drabbas du av urinläckage?
   aldrig
   ungefär en gång i veckan eller mer sällan
   två eller tre gånger i veckan
   ungefär en gång per dygn
   flera gånger per dygn
   alltid

4. Vi skulle vilja veta hur mycket urin som du tror läcker ut.
   ingen
   liten mängd
   måttlig mängd
   stor mängd

5. På det hela taget, i hur hög grad inverkar urinläckage på ditt normala, dagliga liv?
   inte alls  väldigt mycket

   ICIQ poäng: summa poäng 3+4+5

6. När läcker urin ut?
   aldrig – inget urinläckage
   läcker innan du hinner till toaletten
   läcker när du hostar eller nyser
   läcker när du sover
   läcker när du är fysiskt aktiv/tränar
   läcker när du har slutat kissa och tagit på dig kläderna
   läcker utan synbar anledning
   läcker hela tiden

Ett stort tack för att du besvarade dessa frågor.

Vi är tacksamma om du vill besvara följande frågor och tänka på hur du i genomsnitt har haft det under de senaste fyra veckorna.

1. Fyll i ditt födelsedatum:

2a. I vilken utsträckning påverkar dina problem med blåsan dina sysslor kring hemmet (t.ex. städning, inköp, etc.)?

2b. Hur mycket besvärar du av detta?

3a. Påverkar dina problem med blåsan ditt arbete eller dina normala dagliga aktiviteter utanför hemmet?

3b. Hur mycket besvärar du av detta?

Copyright © "ICIQ Group". ICIQ-LUTSqol baseras på King’s Health Questionnaire.
Copyright © "ICIQ Group". the ICIQ-LUTSqol is based on the King’s Health Questionnaire.
ICIQ-FLUTS (Quality of Life Module) - Sweden/Swedish - Final version - 31 Jan 07 - Mapi Research Institute.
f:\institut\cladap\project3298\study3298\final_versions\iciq-fluts\iciq-flutsqol_sweq.doc-31/01/2007
4a. Påverkar Dina problem med blåsan Dina fysiska aktiviteter (t.ex. att promenera, springa, sporta, gymnastisera, etc.)?

- inte alls □ 1
- lite □ 2
- en del □ 3
- mycket □ 4

4b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10

inte alls mycket

5a. Påverkar Dina problem med blåsan Din förmåga att åka med buss, bil, tåg, flyg, etc.?

- inte alls □ 1
- lite □ 2
- en del □ 3
- mycket □ 4

5b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10

inte alls mycket

6a. Begränsar Dina problem med blåsan Ditt sociala liv?

- inte alls □ 1
- lite □ 2
- en del □ 3
- mycket □ 4

6b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10

inte alls mycket

7a. Begränsar Dina problem med blåsan Din förmåga att träffa/besöka vänner?

- inte alls □ 1
- lite □ 2
- en del □ 3
- mycket □ 4

7b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10

inte alls mycket
8a. Påverkar Dina problem med blåsan Ditt förhållande med Din partner?

- ej tillämpligt
- inte alls
- lite
- en del
- mycket

8b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

- 0
- 1      2      3      4      5      6      7      8      9    
- 10

9a. Påverkar Dina problem med blåsan Ditt sexliv?

- ej tillämpligt
- inte alls
- lite
- en del
- mycket

9b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

- 0
- 1      2      3      4      5      6      7      8      9    
- 10

10a. Påverkar Dina problem med blåsan Ditt familjeliv?

- ej tillämpligt
- inte alls
- lite
- en del
- mycket

10b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

- 0
- 1      2      3      4      5      6      7      8      9    
- 10

11a. Känner Du Dig nedstämd på grund av Dina problem med blåsan?

- inte alls
- lite
- en del
- mycket

11b. Hur mycket besväras Du av detta?

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

- 0
- 1      2      3      4      5      6      7      8      9    
- 10
<table>
<thead>
<tr>
<th>Nr</th>
<th>Fråga</th>
<th>Svaralternativ</th>
<th>Skala</th>
<th>Beskrivning</th>
</tr>
</thead>
<tbody>
<tr>
<td>12a</td>
<td>Känner Du Dig orolig eller nervös på grund av Dina problem med blåsan?</td>
<td>[ ] inte alls</td>
<td>[ ] lite</td>
<td>[ ] en del</td>
</tr>
<tr>
<td>12b</td>
<td>Hur mycket besväras Du av detta?</td>
<td>Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13a</td>
<td>Har Du dålig självkänsla på grund av Dina problem med blåsan?</td>
<td>[ ] inte alls</td>
<td>[ ] lite</td>
<td>[ ] en del</td>
</tr>
<tr>
<td>13b</td>
<td>Hur mycket besväras Du av detta?</td>
<td>Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14a</td>
<td>Påverkar Dina problem med blåsan Din sömn?</td>
<td>[ ] aldrig</td>
<td>[ ] ibland</td>
<td>[ ] ofta</td>
</tr>
<tr>
<td>14b</td>
<td>Hur mycket besväras Du av detta?</td>
<td>Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15a</td>
<td>Känner Du Dig sliten/trött på grund av Dina problem med blåsan?</td>
<td>[ ] aldrig</td>
<td>[ ] ibland</td>
<td>[ ] ofta</td>
</tr>
<tr>
<td>15b</td>
<td>Hur mycket besväras Du av detta?</td>
<td>Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Hur ofta gör eller känner Du något av följande?

16a. Använder skydd för att hålla Dig torr?
- **aldrig** □ 1
- **ibland** □ 2
- **ofta** □ 3
- **alltid** □ 4

16b. Hur mycket besväras Du av detta?
- Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)
  - 0
  - 1 2 3 4 5 6 7 8 9 10
  - inte alls  mycket

17a. Är försiktig med hur mycket vätska Du dricker?
- **aldrig** □ 1
- **ibland** □ 2
- **ofta** □ 3
- **alltid** □ 4

17b. Hur mycket besväras Du av detta?
- Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)
  - 0
  - 1 2 3 4 5 6 7 8 9 10
  - inte alls  mycket

18a. Behöver byta underkläder därför att de blivit våta?
- **aldrig** □ 1
- **ibland** □ 2
- **ofta** □ 3
- **alltid** □ 4

18b. Hur mycket besväras Du av detta?
- Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)
  - 0
  - 1 2 3 4 5 6 7 8 9 10
  - inte alls  mycket

19a. Oroar Dig för att Du kanske luktar?
- **aldrig** □ 1
- **ibland** □ 2
- **ofta** □ 3
- **alltid** □ 4

19b. Hur mycket besväras Du av detta?
- Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)
  - 0
  - 1 2 3 4 5 6 7 8 9 10
  - inte alls  mycket
**20a. Blir generad över Dina problem med blåsan?**

- aldrig □ 1
- ibland □ 2
- ofta □ 3
- alltid □ 4

**20b. Hur mycket besvärar Du av detta?**

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

<table>
<thead>
<tr>
<th>Siffra</th>
<th>inte alls</th>
<th>mycket</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>

**21. Totalt sett, hur mycket påverkas Ditt dagliga liv av Dina problem med blåsan?**

Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

<table>
<thead>
<tr>
<th>Siffra</th>
<th>inte alls</th>
<th>mycket</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>

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APPENDIX C

Intervjumall Appstudien

Informera kort om syftet med intervjun

Några korta enkätfrågor:
Ålder:
Yrke:
Familjeförhållanden:
Bostadsförhållanden:

Beskrivning av inkontinensbesvären före behandlingen

Vad hade kvinnorna för förväntningar på behandling via en app?

Hur uppfattas behandling via en app?

Hur uppfattas behandlingseffekten?

Hur ser kvinnorna på bäckenbottenträning?

Vad tycker kvinnorna om att bedöma sin egen knipförmåga?

Hur upplever kvinnor att svara på frågor om inkontinens via formulär och självskattning utan direkt vårdkontakt?

Ambivalensen mellan morot och piska i ett behandlingsprogram?

Vad har kvinnorna för relation till sin smartphone?

Tidigare erfarenheter av appar

Övrigt

Be att få återkomma