Self-Management of Urinary Incontinence using eHealth

Clinically relevant improvement, treatment effect and factors associated with success

Emma Nyström

Department of Public Health and Clinical Medicine
Umeå University
Umeå 2018
To my parents and grandparents,
who worked hard to make sure we received a proper education.
# Table of Contents

Abstract .......................................................................................... iii  
Original Articles ............................................................................... v  
Enkel sammanfattning på svenska .................................................. vi  
Abbreviations ............................................................................... viii  

## Background ................................................................. 2

- Urinary incontinence ........................................................................ 2  
  - Types of urinary incontinence ....................................................... 2  
  - Prevalence ................................................................................... 2  
  - Incidence and remission ................................................................. 3  
  - Burden of disease ......................................................................... 3  
- Risk factors ...................................................................................... 4  
- Help-seeking .................................................................................... 5  
- Assessment ....................................................................................... 6  
- First-line treatment .......................................................................... 7  
  - Pelvic floor muscle training (PFMT) ............................................. 7  
  - Lifestyle advice ............................................................................ 8  
  - Bladder training ............................................................................ 8  
  - Pharmacological treatment .......................................................... 8  
- Specialised treatment ....................................................................... 8  
- Adherence and compliance .............................................................. 9  
- Evaluation of treatment ................................................................... 9  
- Outcomes ......................................................................................... 9  
- Factors associated with treatment success or failure ...................... 11  
  - Adherence .................................................................................... 11  
  - Demographics and medical history ............................................. 11  
- Self-management ............................................................................ 14  
  - Self-management in the care of urinary incontinence ................. 15  
  - Ability to self-manage and barriers ............................................ 15  
- eHealth .......................................................................................... 16  
- Levels of care .................................................................................. 17  
- Scope of this thesis ......................................................................... 18  

## Aim ............................................................... 19  

## Materials and methods .................................................. 20  

- Recruitment ................................................................................... 20  
- Data collection ............................................................................... 21  
- Patient Reported Outcomes (PROs) ............................................. 22  
- Data security .................................................................................. 23  
- Study designs and statistical analysis ......................................... 23  
  - Paper I – Clinically relevant improvement ................................ 23  
  - Additional analyses ..................................................................... 24  

| Paper II – Treatment effect | ................................................................. | 24 |
| Paper III – Factors associated with success | ................................................................. | 27 |
| Paper IV – Factors associated with completion, improvement and success | ................................................................. | 28 |
| Ethics | ................................................................... | 29 |
| The eContinence project and the interventions | ................................................................. | 29 |
| Funding | ................................................................... | 30 |

| Results | ................................................................... | 31 |
| Demographics | ................................................................... | 31 |
| Paper I - Clinically relevant improvement | ................................................................... | 31 |
| Additional analyses | ................................................................... | 32 |
| Paper II - Effect of self-management | ................................................................... | 33 |
| Primary outcomes | ................................................................... | 34 |
| Secondary outcomes | ................................................................... | 34 |
| Paper III - Factors associated with success within the RCT | ................................................................... | 35 |
| Paper IV - Factors associated with completing self-management and achieving improvement and success | ................................................................... | 37 |

| Discussion | ................................................................... | 40 |
| Main findings in relation to aims | ................................................................... | 40 |
| Methodological considerations | ................................................................... | 40 |
| Strengths | ................................................................... | 40 |
| Limitations | ................................................................... | 41 |
| Clinically relevant improvement | ................................................................... | 43 |
| Effect of self-management | ................................................................... | 44 |
| Factors associated with success | ................................................................... | 46 |
| Educational level and socioeconomics | ................................................................... | 47 |
| Adherence and pelvic floor muscle strength | ................................................................... | 48 |
| Freely available self-management | ................................................................... | 48 |
| Implications for clinical practice | ................................................................... | 50 |
| Implications for further research | ................................................................... | 50 |

| Conclusions | ................................................................... | 52 |
| Acknowledgement | ................................................................... | 53 |
| References | ................................................................... | 55 |
| Appendices | ................................................................... | 1 |
Abstract

Background
Urinary incontinence is common among women, with prevalence most often reported to be between 25% and 45%. The most common type is stress urinary incontinence (SUI), defined as leakage upon exertion. First-line treatment includes pelvic floor muscle training (PFMT) and lifestyle advice. eHealth, the use of information and communication technology for health, can lower barriers to seeking help, save time and provide easily accessible care. In other conditions, the use of mobile technology has been argued to improve adherence to, and serve as a support for, self-management leading to improved symptom control.

Aim
To evaluate self-management of urinary incontinence via eHealth with respect to clinically relevant improvement, treatment effect and factors associated with success. This thesis focuses on self-management of SUI via the mobile app Tät®.

Methods
This thesis is based on four papers (I-IV) with data from three different studies (1-3). Studies 1 and 2 were randomised controlled trials, to which adult, community-dwelling women with at least weekly SUI were recruited via the website of the research project. In study 3, we studied the use of the Tät® app once it had been made freely available after study 2. All users with urinary incontinence that were 18 years of age or older were included. All interventions were developed within the research project, focused on PFMT and included lifestyle advice.

In study 1, participants were randomised to either internet-based or brochure-based SUI management. Data from both groups were analysed for correlation with the Patient Global Impression of Improvement (PGI-I) questionnaire and the changes in validated symptom (ICIQ-UI SF) questionnaire and in the quality of life (ICIQ-LUTSqol) questionnaire. We then determined a minimal important difference (MID) for non-face-to-face treatment of SUI. (Paper I)

In study 2, participants were randomised to three months of self-management with the Tät® app or to control group (waiting list). The primary outcomes were ICIQ-UI SF and ICIQ-LUTSqol. These were analysed according to intention to treat using a linear mixed model. (Paper II)

Data from the participants that were randomised to app management were analysed using logistic regression to identify factors associated with success. Success was defined as participants stating that they were much/very much better according to PGI-I. (Paper III)

In study 3, users were asked to participate by completing questionnaires upon download of the app and three months thereafter. Background factors, PFMT
frequency and app usage were analysed using logistic regression to identify factors associated with three outcomes: completion of three months of self-management, improvement (according to PGI-I) and success (defined as described above). (Paper IV)

Results
We found that the symptom and quality of life scores capture a clinically relevant improvement. The MIDs were determined to be a reduction of 2.52 points for ICIQ-UI SF and 3.71 points for ICIQ-LUTSqol. (Paper I)

The Tät® app had a positive effect on symptoms with a mean ICIQ-UI SF reduction of 3.9 points (95% CI 3.0-4.7), and improved quality of life with a mean ICIQ-LUTSqol reduction of 4.8 points (95% CI 3.4-6.2). These scores differed significantly from the control group and were well above the MIDs, and therefore clinically relevant improvements. Women in the intervention groups also had a greater decrease in incontinence episode frequency, and significantly reduced their pad use compared to the control group. In terms of patient satisfaction, 97% found the app to be “good” or “very good”. (Paper II)

After three months of self-management with Tät®, 34 out of 61 participants (56%) stated that they were much or very much better. Three factors were associated with successful management: high expectations on treatment, weight control and self-assessed improvement in pelvic floor muscle strength. (Paper III)

Once the app was freely available, 1 861 of 13 257 users (14%) completed the three-month follow-up. Four factors predicted completion: age, higher educational level, stress-type incontinence episodes and language. Together these factors accounted for 2.7% of the variability (Nagelkerke R²). Among the users that completed self-management, 68% improved and 29% were successful according to the PGI-I. Stress-type leakage and language were also associated with improvement. At least weekly PFMT and app usage predicted both improvement and successful self-management. (Paper IV)

Conclusion
Self-management for urinary incontinence via a mobile app has clinically relevant effects on symptoms and quality of life. This is particularly the case for women with high expectations on app self-management and for those who used the app and exercised their pelvic floor at least weekly. Furthermore, beyond the study setting once the app was freely available, the majority of users’ symptoms improved if users completed three months of training.
Original Articles

This thesis is based on the following articles:


Enkel sammanfattning på svenska

Självbehandling av urininkontinens med hjälp av eHälsa
Kliniskt relevant förbättring, behandlingseffekt och framgångsfaktorer

Bakgrund

Syfte
Att utvärdera självbehandling av urininkontinens via eHälsa med avseende på kliniskt relevant förbättring, effekten av självbehandling och framgångsfaktorer.

Metod
Denna avhandling grundar sig på data från 3 olika studier (1-3). Dessa studier har alla utvärderat behandlingsprogram för ansträngningsinkontinens med fokus på bäckenbottenträning och livsstilsråd som utvecklats inom forskningsprojektet Tät.nu (eContinence). I studie 1 och 2 rekryterades kvinnor med besvär av ansträngningsinkontinens minst en gång i veckan via forskningsprojektets hemsida (www.tät.nu). I den sista studien bjöds alla som laddade ner appen Tät® på svenska eller engelska in att delta.

1. I den första studien fick deltagarna behandling via internet eller som en broschyr. Vi analyserade resultaten för att se om det fanns ett samband mellan symptom- och livskvalitetsskalorna och upplevd förbättring. Utifrån detta bestämde vi också hur många poängs förbättring på dessa skalar som krävdes för att vara en kliniskt relevant förbättring, alltså en märkbar förbättring. (Artikel I)

2. I den andra studien lottades deltagarna istället till självbehandling med mobilappen Tät® eller till väntegrupp (kontrollgrupp som inte fick någon behandling). Vi jämförde de olika gruppernas resultat på symptom- och livskvalitetsskalorna men också avseende upplevd förbättring, läckage/vecka, användning av inkontinensskydd och nöjdhet med behandlingen. (Artikel II)

Sedan analyserade vi resultaten från de kvinnor som använt appen för självbehandling för att se om det fanns olika bakgrunds- eller
behandlingsfaktorer som var förknippade med behandlingsframgång (att man blev mycket eller väldigt mycket bättre).(Artikel III)

3. I den tredje studien analyserade vi data från alla vuxna med urininkontinens som fyllde i frågeformulären vid nedläggning av appen och efter 3 månaders användning. Först analyserades bakgrunds faktorer för att finna om vissa grupper fullföljde behandlingen i högre utsträckning än andra. Sedan analyserades bakgrunds faktorer, hur ofta man bäckenbottentränat och hur ofta man använd appen för att finna om något av detta var förknippat med förbättring eller framgång. (Artikel IV)

Resultat
1. Förändringen på symptom- och livskvalitetskalorna korrelerade till upplevd förbättring och det krävdes förbättringar om 2,5 poäng på symptomskalan ICIQ-UI SF och 3,7 poäng på livskvalitetskalan ICIQ-LUTSɉol för att skillnaden skulle vara kliniskt relevant. (Artikel I)

2. Gruppen som använde appen för självbehandling förbättrades i snitt 3,9 poäng på symptomskalan ICIQ-UI SF och 4,8 poäng på livskvalitetskalan ICIQ-LUTSɉol, alltså kliniskt märkbara effekter. Förbättringarna var statistiskt säkerställda jämfört med kontrollgruppen. De minskade också sin användning av inkontinensskydd och 96% tyckte att appen var bra eller mycket bra. (Artikel II)

Totalt upplevde 34/61 deltagare (56%) också att de blivit mycket eller väldigt mycket bättre. Faktorer som var associerade med framgång var: höga förväntningar på behandlingen, viktkontroll och ökad självskattad bäckenbottentröskraft. (Artikel III)


Slutsatser
Självbehandling med mobilappen Tät® ger kliniskt relevant effekt på symptom och livskvalitet. Särskilt till kvinnor som har ansträngningsinkontinens, höga förväntningar på behandlingen och som tränar och använder mobilappen minst en gång i veckan.
Abbreviations

ANOVA – Analysis of variance
BMI – Body Mass Index
CBT – Cognitive Behavioural Therapy
CI – Confidence Interval
GP – General Practitioner
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
IQR – Interquartile Range
IUGA – International Urogynecological Association
KHQ – King’s Health Questionnaire
MID – Minimal Important Difference
MUI – Mixed Urinary Incontinence
OR – Odds Ratio
OAB – Overactive Bladder
PFMT – Pelvic Floor Muscle Training
POP – Pelvi Organ Prolaps
PRO - Patient Reported Outcome
PGI-I – Patient Global Impression of Improvement
SUI – Stress Urinary Incontinence
UUI – Urgency Urinary Incontinence
Introduction

Urinary incontinence is one of the conditions that has the greatest impact on quality of life at a general population level. First-line treatment includes behavioural therapies, such as pelvic floor muscle training and bladder training, and lifestyle advice, which are rarely or never reported to have side effects. However, only 30% of women with weekly urinary incontinence seek medical care, often due to a lack of knowledge, the perception that urinary incontinence is part of normal aging, or experiencing dismissive behaviour from health care professionals when they have raised the topic.

The eContinence project (Tät.nu) aims to develop and evaluate treatments via the internet or mobile apps for all types of urinary incontinence. The original purpose of the programmes in this thesis was to enable women with stress urinary incontinence (SUI) to self-manage without needing to contact the regular health care system, as most people never seek care. After making the programmes for SUI freely available, it has become clear that usage of these programmes is not limited to the original intent.

I work as a resident physician in a primary care centre. Both my colleagues and I found it convenient to recommend the mobile app or the brochure as support for women in performing the recommended pelvic floor muscle training. This was also the case for doctors of the local gynaecology clinic, and my sister-in-law in a completely different part of Sweden reported that she had been recommended to use the app as a preventive measure during and after pregnancy.

Preventive use or use in conjunction with the health care system have not been scientifically evaluated. Although not yet evidence-based, there is nothing to suggest that this usage is harmful. Due to this development, it makes sense to widen the background and the discussion of this thesis. To not only discuss the SUI programmes as a way of making first-line care accessible outside the health care system but also to reflect upon how the self-management programs can support users regardless of level of care.
Background

Urinary incontinence
Urinary incontinence is by definition the complaint of involuntary loss of urine, regardless of amount or type of leakage.\textsuperscript{5}

Urinary incontinence is more common in women than in men. It is a prevalent condition among all adult women whereas in men it is more strongly associated with age.\textsuperscript{6,7} This thesis primarily focuses on urinary incontinence in women and hence only addresses the female condition.

Types of urinary incontinence
The most common types of urinary incontinence in women and their definition: \textsuperscript{2,5}

\textit{Stress Urinary Incontinence (SUI)} – leakage associated with exertion, i.e. upon physical effort, coughing or sneezing.

\textit{Urgency Urinary Incontinence (UUI)} – leakage associated with a sudden, compelling need to void.

\textit{Mixed Urinary Incontinence (MUI)} – leakage both upon exertion and in association with urgency.

Prevalence
Prevalence varies in different populations, based on how surveys are conducted, the definition of incontinence and cultural perceptions of incontinence, and also due to the variations in age and other risk factors.

Among women, most studies report a prevalence of 25% to 45%.\textsuperscript{6} Swedish studies report a prevalence of 15% to 28%,\textsuperscript{7-9} and approximately half a million Swedes are estimated to be affected by urinary incontinence.\textsuperscript{10} There are a few, more recent studies of prevalence from countries where cultural perceptions and distribution of risk factors can be assumed similar to Sweden. A recent Dutch study reported a prevalence rate of 49% among women, but the response rate of 54% of women was a limitation.\textsuperscript{11} The large EPINCONT study reported a prevalence of 29% in a Norwegian community-dwelling population with high rates of response (79% of those who accepted the invitation to the HUNT study).\textsuperscript{12} The results and response rates from the EPINCONT study are similar to the most recent Swedish study reporting a prevalence of 28% in 2007.\textsuperscript{9} These studies are likely to present the
closest estimation of current prevalence in the general population in Sweden, the main setting for this thesis.

SUI is the most common type in women, affecting approximately half of all women with urinary incontinence. It is more common in younger ages and prevalence peaks around menopause.\textsuperscript{12, 13} Approximately 35\% to 40\% of women have MUI, which is more prevalent in older ages.\textsuperscript{12, 13} MUI has components of both stress and urgency symptoms, and as a result MUI with predominant stress symptoms can be similar to SUI in terms of symptoms and first-line treatment approach.\textsuperscript{2}

The prevalence of UUI is often reported to be between 10\% and 15\%, with a somewhat steady distribution over different age categories.\textsuperscript{12, 13} Urgency is also the main symptom of the overactive bladder (OAB), which is characterised by urgency, frequency and nocturia with or without episodes of urgency incontinence.\textsuperscript{2} Other types of incontinence include insensible, postural and continuous urinary incontinence,\textsuperscript{5} but these are far less common.\textsuperscript{13}

According to ICS-IUGA terminology, it is important to distinguish the symptoms of urinary incontinence from the signs of urinary incontinence. Symptoms are the reported abnormalities as experienced by a woman that may indicate a disease or health problem. Signs, on the other hand, are observable upon examination; in the case of urinary incontinence, the observation of leakage upon exertion or associated with urgency.\textsuperscript{5}

**Incidence and remission**
Urinary incontinence is a fluctuating condition. As with prevalence, reported incidence rates vary greatly and research is full of methodological difficulties. For example, some shorter studies have found higher incidence rates, partly due to misclassifications.\textsuperscript{6} In Swedish and Norwegian studies with longer follow-up times (>4 years), annual incidence rates are reported to range from 1.3\% to 4.3\% and remission rates from 2.1\% to 5.9\%.\textsuperscript{8, 9, 13, 14}

Many women (31\% to 61\%) experience incontinence during pregnancy.\textsuperscript{15-18} The largest cohort study reports that 52\% of the women with incontinence in pregnancy were continent six months after delivery, but that incontinence during pregnancy predicted incontinence postpartum.\textsuperscript{16}

**Burden of disease**
Urinary incontinence affects women differently. One study suggests that 15\% to 85\% of women find their urinary incontinence to be bothersome, depending on amount of leakage.\textsuperscript{19} It does, however, often have an impact on quality of life.\textsuperscript{20}
and psychological well-being. In fact, it is one of the conditions that causes the greatest loss of quality of life at a general population level. The impact on quality of life has been argued to be larger for women with episodes of urgency incontinence compared to women with pure SUI. However, quality of life is also related to comorbidities and severity. UUI and MUI are more common among older women and incontinence severity increases with age and when adjusting for age the impact of leakage type has been shown to disappear. Other studies have found that severity rather than type is the factor that most clearly determines the impact on quality of life.

The cost of incontinence is also high, both for the individual and for society, due to related health care and incontinence aids. Incontinence is also associated with admittance into nursing homes, although age, comorbidities, functional status, depression and sensory impairment are confounders.

Further, urinary incontinence is a stigmatised condition, often associated with shame or embarrassment. In addition to feelings of humiliation, urinary incontinence has been associated with a higher degree of musculoskeletal pain, fatigue and sleeping disorders, financial problems and a reluctance to seek medical care. It also may affect sexual function negatively.

**Risk factors**

Large studies report an increase in urinary incontinence with age, although it is difficult to determine precisely the extent to which other risk factors for urinary incontinence also increase with age. For moderate and severe incontinence, prevalence increases steadily with age, whereas slight incontinence peaks around menopause. The prevalence of pure SUI declines after menopause and MUI becomes more prevalent.

Obesity is a well-established risk factor and approximately doubles the risk of urinary incontinence (RR 1.95, 95% Confidence Interval [CI] 1.58 – 2.42). Overweight or obesity increases both occasional and frequent incontinence as well as the prevalence of severe urinary incontinence. Weight loss is in turn associated with improvement or resolution of symptoms.

Parity is also a known risk factor; increasing parity increases the risk of urinary incontinence, up to double the risk for any type of urinary incontinence. Higher odds ratios are reported for the association between parity and SUI. Vaginal deliveries also increase the risk compared to caesarean section. If forceps are used during birth, this further increases the risk for SUI in women younger than 50 years compared to spontaneous vaginal deliveries, but in women older than 50 this difference was no longer present.
Hormonal replacement therapy has been shown to increase the risk of urinary incontinence. Systemic therapy worsens both stress and urgency symptoms. Whereas local oestrogen therapy is still recommended for treating vaginal atrophy and for treating urgency symptoms in peri- and postmenopausal women.

Evidence regarding lifestyle factors is still weak, for example, results from studies investigating smoking and urinary incontinence are contradictory. The current opinion of the International Consultation on Incontinence is that smoking does not increase the risk of incontinence. Caffeine as a risk factor has also been investigated by several studies and there may be an association with urinary incontinence. High impact sports increase the risk of SUI, whereas low-impact sports have a protective effect. This protective effect however seems to be mediated by lower risk of overweight and obesity.

**Help-seeking**

Only the minority of women with urinary incontinence seek help; reported rates of help-seeking often vary between 25% and 40%. A Polish study found that on average, women with SUI waited 13.3 years before seeking care. This is congruent with studies from Norway and Denmark/Germany, which have found that greater severity of incontinence, longer duration of symptoms and higher age are predictors for care-seeking. The Norwegian and a Swedish study also identified that the impact of incontinence was associated with help-seeking, which is in line with a Chinese study that found that the level of bother prompted intention to seek help. Bother was associated with increasing symptom severity, MUI (compared to SUI) and higher income. The Chinese study recruited from health care centres rather than all community-dwelling as in the European studies, and revealed the opposite results; lower age, shorter duration of symptoms and higher educational levels were associated with the intention to seek help. Qualitative research have found that there are important sociocultural differences in help-seeking behaviour, which could explain these contradicting results, but there could also be important differences between the intention to seek care and actually seeking care.

Reasons for not seeking care include not finding the symptoms to be too inconvenient, considering urinary incontinence to be a natural result of aging or child birth and because the health care provider never asked about the condition. However, embarrassment and fear of humiliation also inhibit women from seeking help.
Assessment

Most reviews and guidelines agree that an initial assessment should first aim to determine symptom severity, type of urinary incontinence and desire for treatment. Assessments should also investigate possible reversible causes, including urinary tract infection, excessive fluid intake, medications or conditions that increase the risk for, or worsening of, the incontinence (such as diuretics, constipation, obesity, smoking and depression).

Determining the type of urinary incontinence provides important guidance for recommending different management alternatives. To some extent, it also influences further investigations, as stress urinary incontinence is not associated with any serious underlying conditions.

Most guidelines now suggest that urodynamics is not a necessary part of the primary investigation. However, in a systematic review, the use of clinically reported symptoms has been found to be able to diagnose urodynamic stress urinary incontinence with a 92% sensitivity and 56% specificity. Lukacz et al. state that in most women, an extensive evaluation is not necessary during the first stage as conservative management can be started without any clear distinction between stress and urgency incontinence.

Medical history should preferably focus on onset, duration, severity, frequency and impact on quality of life. A thorough medical history is also important to identify reversible causes and symptoms indicating the need for referral to specialists (e.g. neurological symptoms, pain symptoms, haematuria, post-void residuals). Post-void residuals should be measured in women with symptoms of voiding dysfunction.

Some guidelines recommend a physical examination, mainly to identify any signs of underlying disease and to determine the function of the pelvic floor. However, no studies have shown that such examinations improve urinary incontinence care. Other reviews either do not find examination necessary, or state that a physical examination should be performed when it would alter the planned intervention, such as with a protruding prolapse needing referral or vaginal atrophy indicating the need for treatment with topical oestrogen. Indications of prolapse or atrophy can however also be obtained through a thorough medical history. These variations in recommendations may also depend on the clinical setting. In an American primary care setting, a pelvic examination was performed in 38% of elderly patients, while a hospital-based multi-speciality group examined 98% of patients.
Urine analysis is often recommended to identify urinary tract infections. A bladder diary, recording fluid intake, urine volumes and incontinence episodes with associated activities, is sometimes also recommended.56, 57

First-line treatment

**Pelvic floor muscle training (PFMT)**

Pelvic floor muscle training (PFMT) is recommended as part of the first-line treatment for all types of urinary incontinence.2, 56, 57, 60 Of all types of conservative management, the benefits of PFMT are supported by the strongest evidence.62 Recommendations vary, but often 8 - 10 contractions three times per day is recommended.2, 57 Guidelines that give a time frame agree that three months of PFMT is sufficient to evaluate effect.2, 57

PFMT is particularly effective for women with SUI; a recent Cochrane review concluded cure to be eight times more likely at the end of PFMT treatment compared with controls. According to the pooled data of that review, 74% of women with SUI and 67% of women with any type of urinary incontinence had reported improvement or cure at the end of treatment. In the PFMT groups, leakage decreased and participants were more satisfied with treatment. Adverse events were said to be rare and, when reported, minor.3

PFMT can be provided in many different ways: as supervised training during individual appointments or in groups, as unsupervised training at home, and with or without adjunctive therapy such as biofeedback devices or Kegel spheres. Some guidelines recommends supervised training,2 or that the most intensive treatment available should be offered,63 while others emphasise the need to pursue the treatment that will render the best adherence.56 There is however no solid evidence that any of these options are superior to any other.64-66

Non-face-to-face SUI management via the internet or a postal brochure have also shown proven effects.67, 68 Although it is sometimes argued that physical examination is necessary for correct PFMT, research indicates that 83% of women with SUI contract their pelvic floor muscles correctly following a simple verbal instruction, and of the remaining women, 88% learnt correct contraction techniques once they were further instructed to avoid tightening their buttock muscles.69 Furthermore, preventive PFMT has also proven to be effective without assessment of the ability to contract correctly.70
**Lifestyle advice**
Lifestyle advice consists of low-cost and non-invasive interventions that should be recommended to all women with urinary incontinence, although supporting evidence is generally weak. The most important advice includes smoking cessation, weight loss in the case of overweight or obesity, adjustment to normal fluid intake and reduction of caffeinated beverages. Physical activity is also recommended, even in the case of SUI, although it may be associated with leakage.

**Bladder training**
Bladder training is recommended for MUI and for UUI where there are indications that a small bladder triggers more frequent urgency.

**Pharmacological treatment**
There is no medication for SUI approved by the American Food and Drug Administration. However, Duloxetine is still registered for treatment of moderate to severe SUI in Sweden and may according to international guidelines be considered as part of the conservative management.

Some guidelines recommend medication as part of the first-line treatment for MUI and UUI. Unfortunately, less than 20% achieve continence with anticholinergic medication and discontinuation due to side effects is common.

**Specialised treatment**
If first-line treatment is not sufficient, patients who so wish should be referred for specialised management. For women with predominantly stress-type leakage episodes, surgery is effective. In a systematic review, the pooled median cure rates were reported to be 82.3% (Interquartile Range, IQR: 72% - 89.5%) for surgical interventions, not including open colposuspension. Cure, as discussed below, might seem intuitively comprehensible but may vary greatly in definition.

The most researched type of surgery is the mid-urethral sling, for which short-term cure rates vary between 62% and 98%, and long-term rates between 43% and 92%. Adverse events include bladder perforation during surgery, voiding dysfunction after surgery, groin pain and suprapubic pain. These vary based on how the sling is inserted but rates of adverse events are considered low. Erosion of the sling occurs in approximately 2% of cases.

Percutaneous tibial nerve stimulation, urethral injection and sacral modulation are treatment options for women who are primarily bothered by urgency-type leakage. Reported improvement rates vary between 60% and 90%.
Adherence and compliance

The success of most treatment options is highly dependent on the extent to which the regime is followed. Two different terms are used to describe this:

Compliance – “the extent to which the patient’s behaviour matches the prescriber’s recommendation”.\(^{76}\)

Adherence – “the extent to which a person’s behaviour corresponds with agreed recommendations from a health care provider”.\(^{77}\)

The difference lies in whether the health care provider and patient have arrived at the recommendation as part of a dialogue or not. Regarding PFMT, it is more often a matter of adherence, and that term is most often used in urinary incontinence research, although there are many similarities between the concepts.

As this thesis is based on data from participants, who signed up voluntarily to different self-management programmes fully aware of their content and without any persuasion from caregivers, it will only discuss adherence.

Evaluation of treatment

When treating a condition, the aim is often complete symptom relief or “cure”. Within urinary incontinence research, there have been many definitions of “cure” as there are many ways to measure symptoms: negative pad tests, negative cystometry, no leakage according to symptom scores or urodynamics. A patient may thus be free of symptoms according to one definition but not according to another. Also, as described above, short and long-term cure rates vary. This way of reporting treatment effects has also made comparison between different studies difficult. Therefore, it is currently recommended to report outcomes instead of cure rates.\(^{74}\)

Recommendations now include assessing different aspects when evaluating treatment, including symptoms, health-related quality of life, patient satisfaction and health economics.\(^{74,78}\) There has also been changes regarding the most highly valued outcome, but consensus is now to aim for patient-defined goals both in clinical work and in research.\(^{74}\)

Outcomes

Patient reported outcomes (PROs) are a way to objectify reports directly from the patient, to make them measureable and comparable, sometimes between patients
and sometimes before and after treatment. The outcomes can be generic or condition-specific.\textsuperscript{78}

If correctly validated PROs perform as well as objective signs, and offer other advantages such as preserved integrity and an opportunity for non-face-to-face evaluation.

The validation process is essential to ensure that the PRO captures the intended aspect. A PRO should be validated linguistically and culturally, that is validated in the setting where it is intended to be used. The following three aspects are important:\textsuperscript{78}

\textbf{Reliability} – the ability of a PRO to produce the same results if the test is repeated (test-retest-reliability). This also includes internal consistency, i.e. how well the items within a sub-scale correlate.

\textbf{Validity} – the ability of a PRO to measure what it is intended to measure. This includes content validity (whether it catches the full range of the condition), convergent validity (whether it correlates to the theoretical framework), discriminant validity (whether it is able to discriminate between different levels of severity), and criterion validity (whether it correlates to a previous Gold standard).

\textbf{Responsiveness} – the ability of a PRO to detect differences in a condition. PROs that have good discriminant validity often have high responsiveness. This is often measured as a Minimal Important Difference (MID) or Minimal Clinically Important Differences, which is the smallest difference that resembles a change that is clinically detectable by the patient.

A MID can be defined as “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient’s management”.\textsuperscript{79} A MID can be established using anchor-based or distribution-based methods.\textsuperscript{80} Some researchers also differentiate between within-treatment MIDs, the smallest important difference when evaluating the effect of a treatment, and between-treatment MIDs, the smallest important difference when comparing treatment to placebo or another treatment.\textsuperscript{81}

The ICIQ questionnaires are a set of validated\textsuperscript{82, 83} and recommended questionnaires.\textsuperscript{57} They have also been translated into several languages and been validated for electronic use.\textsuperscript{84} However, their responsiveness and MIDs have not been evaluated for non-face-to-face management.
Factors associated with treatment success or failure

**Adherence**
Adherence is considered crucial for achieving desired treatment effects.\(^8^5\) Leading researchers agree that there are several theories on motivation that have been shown to be useful in obtaining patient commitment to PFMT, and that other theories have yet to be explored.\(^8^6\) However, they draw no conclusions stating that one theory is more beneficial than any other. Their review of quantitative research found intention to adhere, self-efficacy expectations, attitudes to exercise and social pressure to be determinants of adherence.\(^8^7\) A review of qualitative research found that similar factors impacted adherence: knowledge, physical skills, feelings about PFMT, cognitive analysis (including planning and attention), prioritisation and service provision.\(^8^8\) Self-efficacy has also been shown to predict adherence to treatment.\(^8^9\)–\(^9^1\) Generally, health care professionals perceived low motivation to be the most important barrier to PFMT adherence, whereas responses from the general public indicated that perceiving little benefit from PFMT was a more important barrier.\(^9^2\)

**Demographics and medical history**
Several studies have looked at factors that are associated with a successful outcome from conservative management including PFMT; most of them are secondary analyses of RCT data (Table 1 and 2).

Two studies have found older age to be a predictor of better results,\(^9^3\)–\(^9^4\) while others have not.\(^9^5\)–\(^9^6\) Others have found educational level to influence the outcome but with contradictory results.\(^9^7\)–\(^9^8\) Less severe incontinence at baseline has been associated with better PFMT results.\(^9^6\)–\(^9^8\)

Coexisting Pelvic Organ Prolapse (POP) has, when evaluated, been found to be associated with failure.\(^9^5\)–\(^9^7\) Higher parity has shown positive influence on the outcome on sexual function,\(^9^1\) but negative on global perceived effectiveness.\(^9^5\) Previous pelvic surgery also influences results differently depending on type of incontinence and surgery performed. Other comorbidity appear to have negative impact, both in terms of physical\(^9^7\) and psychological conditions.\(^9^5\)–\(^9^6\)
<table>
<thead>
<tr>
<th>Definition of Outcome</th>
<th>Definition of Intervention</th>
<th>Definition of Population</th>
<th>Definition of Risk Factors</th>
<th>Definition of other factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower PFR</td>
<td>Reduction education</td>
<td>Higher function PFR, PFR estimated PFR</td>
<td>Age, lower BP, lower T1D, lower BMI</td>
<td>Age, lower BP, lower T1D, lower BMI</td>
</tr>
<tr>
<td>Lower PFR, reduction education</td>
<td>Reduction T1D, reduction education</td>
<td>Higher function PFR, PFR estimated PFR</td>
<td>Age, lower BP, lower T1D, lower BMI</td>
<td>Age, lower BP, lower T1D, lower BMI</td>
</tr>
<tr>
<td>Lower T1D, reduction education</td>
<td>Lower PFR, reduction education</td>
<td>Higher function PFR, PFR estimated PFR</td>
<td>Age, lower BP, lower T1D, lower BMI</td>
<td>Age, lower BP, lower T1D, lower BMI</td>
</tr>
</tbody>
</table>

Table 1: Factors associated with success in studies of conservative management including pelvic floor muscle training.
Table 2. Factors associated with failure or cross-over to surgery in studies of conservative management including pelvic floor muscle training

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population</th>
<th>Ages</th>
<th>Intervention</th>
<th>N</th>
<th>Follow-up</th>
<th>Outcome</th>
<th>Definition of success</th>
<th>Factors associated with poor outcomea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannu et al. (2004)46</td>
<td>Women with</td>
<td>26-80</td>
<td>PFMT with visual electromyography feedback</td>
<td>447</td>
<td>10 weeks</td>
<td>Five point scale</td>
<td>Cured/ significantly improved</td>
<td>Higher IEF, psychotropic medication, positive stress test on first cough</td>
</tr>
<tr>
<td>Hendriks et al. (2010)24</td>
<td>SUI or MUI</td>
<td>≥18</td>
<td>Physiotherapy including PFMT</td>
<td>267</td>
<td>12 weeks</td>
<td>LS-scale ≤ 4 points</td>
<td>Moderately to very much better</td>
<td>Severe UI, MUI, poor outcome of previous physiotherapy, prolonged 2nd stage of labour, BMI ≥30, psychological distress, poor physical health status</td>
</tr>
<tr>
<td>Labrie et al. (2015)30</td>
<td>Women with SUI</td>
<td>35-80</td>
<td>PFMT with electrical stimulation and biofeedback</td>
<td>198</td>
<td>12 months</td>
<td>Cross over to surgery</td>
<td>-</td>
<td>Age ≥55 years, higher Sandvik index score, higher UDI-score, combined variable of age ≥55 and higher education</td>
</tr>
<tr>
<td>Truijen et al. (2001)25</td>
<td>Women with SUI</td>
<td>28-79</td>
<td>PFMT with electrical stimulation and biofeedback</td>
<td>87</td>
<td>1-3 months</td>
<td>Cessation of leakage or only a few drops on heavy strain</td>
<td>High BMI, previous pelvic surgery, strong levator muscles</td>
<td></td>
</tr>
</tbody>
</table>

a”Results from multivariate models if available. Factors significant at 0.05-level.

Self-management

Self-management is a health education concept, conceptualised as a subset of self-care, including self-monitoring and to some degree, symptom management. All of these concepts are widely used and their meanings have changed over time. The definitions applied in this thesis are summarised in Table 3.

Table 3. Key concepts and definitions

<table>
<thead>
<tr>
<th>Concept</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-care</td>
<td>“activities performed by individuals or communities to achieve, maintain or promote maximum health”</td>
</tr>
<tr>
<td>Self-management</td>
<td>“a subset of self-care focused on managing the actual or potential impact of disease”</td>
</tr>
<tr>
<td>Self-monitoring</td>
<td>&quot;awareness of symptoms or bodily sensations, that is enhanced through periodic measurements, recordings and observations to provide information for improved self-management&quot;</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>&quot;the belief in one's capabilities to organise and execute the course of action required to produce given attainments&quot;</td>
</tr>
</tbody>
</table>

Benefits from self-management programmes are often measured in terms of behavioural changes, use of medications, improved symptoms, psychological and social health. These factors are also important in continence care. Beyond symptom management, self-management also extends to the management of emotional, psychosocial, functional and physical impacts of the disease, and self-efficacy has been identified as an important mediator.

Self-efficacy is also a measure of patient empowerment, which is an important aspect of patient-centred care. Self-efficacy improves the patient’s executional function and diminishes the impact of a lower education level, which may otherwise impair the patient’s ability to take measures for their own health. This important loop of action and mental response, has also been emphasised as an aspect that may improve adherence to PFMT. Several studies have evaluated patient empowerment or enhanced self-efficacy in urinary incontinence and other conditions, however more research is needed on how to best empower patients in order to achieve clinical results.
The researchers Lorig and Holman argue that a variety of programmes are needed to make management acceptable to patients. They also recommend that approval of new programmes should only take place after they have been tested in small-scale trials and after generalisability studies.

**Self-management in the care of urinary incontinence**

Research into self-management is most often applied to chronic conditions. The issue of whether urinary incontinence can be viewed as a chronic condition is a matter that can be discussed. Nonetheless, the EPINCONT study reported an 11-year remission rate amongst 34%, and cure rates are not 100% from either conservative management or surgery. So for many women it is a chronic condition. Regardless of the chronicity most women manage their urinary incontinence for a long time without seeking health care, and upon contact the recommended first-line treatment includes PFMT, bladder training and medications that can clearly be defined as self-management tasks. In a qualitative study by Milne et al., participants reported performing these tasks for a long time after consulting professional care; although none managed to adhere to the bladder training schedule for more than a few days, the majority performed PFMT once a day.

In a review of self-management for incontinence, Wilde et al. summarise self-management as being accepted for coping with chronic diseases but that the benefit for those suffering from urinary and faecal incontinence may not be fully realised by health care providers. They also stress the importance of evaluation; any lack of success might be due to a lack of adherence to the plan or, in the case of PFMT, that the exercises are not performed correctly. Realistic goals and reasonable time frames also promote successful self-management.

In congruence with other types of self-management, self-efficacy has also been identified as an important mediator of adherence to PFMT for management of urinary incontinence.

**Ability to self-manage and barriers**

According to Wilkinson and Whitehead, the ability to self-manage should be defined as “the individual’s ability in conjunction with family, community and the appropriate health care professionals, to successfully manage the symptoms, treatment, physical, psychosocial, cultural and spiritual consequences and inherent lifestyle changes required for living with a long-term chronic disease.”

Among people with chronic illnesses, barriers to self-management have been found to be depression, weight problems, difficulty exercising due to other physical symptoms, poor doctor communication, fatigue, low family support,
pain and financial support. Jerant et al. also found that participants expressed a desire for more self-management resources and they concluded that there would be an interest in home-delivered self-management resources.\textsuperscript{115}

In the case of urinary incontinence, realistic goal setting, positive affirmation, incorporating PFMT into daily routines and follow-up have also been found to facilitate self-management with PFMT. Financial cost, on the other hand, has been found to be a barrier to self-care PFMT, along with insufficient information, characteristics of the exercises, competing interests and minor psychological impact from urinary incontinence.\textsuperscript{113}

There are also several methods of delivering supportive interventions, and according to theoretical frameworks and some evidence from incontinence research, interactive methods can be more successful than passive methods, such as standard written information.\textsuperscript{109, 113, 116}

\textbf{eHealth}

eHealth is the use of information and communication technologies for health.\textsuperscript{117} This includes clinical, educational, research and administrative use, both locally and at a distance.\textsuperscript{118} The latter is referred to as telehealth and has been identified as a way to reduce costs and physical visits to outpatient clinics and emergency rooms, as well as increasing health-related quality of life.\textsuperscript{119} Internet-delivered interventions are low-cost easily-accessible treatment options.\textsuperscript{120} mHealth is a subdivision of eHealth and refers to health practice with support of mobile devices.\textsuperscript{121} mHealth both includes the use of mobile phones for messaging services and more complex applications.\textsuperscript{121} Mobile applications, that is computer programs designed for mobile devices, are often just referred to as “apps”.

eHealth and mHealth are often used to support self-management, for example through increasing adherence or compliance.\textsuperscript{122, 123} They can be integrated into the medical treatment or a stand-alone management option.\textsuperscript{124} Internet and mobile-based interventions can be used to influence lifestyle factors (smoking, physical activity, weight), and as an integral part of the self-management of diabetes, asthma and congestive heart failure.\textsuperscript{124} They have therefore been applied in different aspects of health care; prevention, treatment and follow-up.\textsuperscript{124} In a systematic review, Whitehead and Seaton find that mHealth self-management could improve outcomes and symptom management.\textsuperscript{122}

Other advantages of eHealth include privacy. An analysis of internet users in the USA revealed that people with stigmatised conditions, such as psychiatric disorders and urinary incontinence, were more likely to use the internet for seeking health information. They were almost twice as likely to use the internet
to communicate with a physician compared to people reporting non-stigmatised conditions.\textsuperscript{125} This has also been supported by patient reports in qualitative research.\textsuperscript{126, 127}

Among women with urinary incontinence eHealth was also found to lower the barriers to seeking care.\textsuperscript{128} Internet-management was appreciated as a way to acknowledge the condition, which might be considered embarrassing, without the participants feeling exposed.\textsuperscript{128} Furthermore, first-line treatment to women with stress urinary incontinence was successfully and cost-effectively provided over the internet.\textsuperscript{67, 68, 129}

There is a vast quantity of mobile apps and few have been evaluated scientifically,\textsuperscript{122} and there is no general control of the content’s medical accuracy. A summary of apps for urogynecological providers identified 368 apps using urogyn as the search word. After excluding patient-centred, student-centred, advertisements for commercial products or health care suppliers, provider locators, gaming apps and apps with inaccurate information, the summary found eight information or decision-making apps intended for urogyn providers.\textsuperscript{130}

In terms of patient-centred apps for urinary incontinence, there are many apps but few with scientific documentation. There is one scientifically validated app for recording symptoms, evaluating progress and reporting back to health care providers (iDry). It does not include any active management.\textsuperscript{131}

As for other apps providing active management, one Dutch app is currently being evaluated in comparison to care as usual.\textsuperscript{132} Results are yet to be published. An American app for PFMT has been found to be user-friendly in terms of understandability and actionability.\textsuperscript{133} Similarly, through collaboration between Dutch and Brazilian teams, an app called iPelvis has been constructed, based on the creators’ opinions of the best mechanisms for promoting adherence.\textsuperscript{134} These latter apps have also yet to be tested in studies.

**Levels of care**

Depending on the organisation of the health care system (Figure 1), it is often suggested that primary health care providers should offer this first-line treatment for urinary incontinence, and some literature suggests that, if possible, care should be nurse-based to make care more accessible to all who need it.\textsuperscript{135} One review also emphasises that unsupervised PFMT should be introduced directly,\textsuperscript{56} while another calls for new accessible methods for providing first-line treatment\textsuperscript{60} as ways to increase access to care.
Self-management and eHealth are supportive concepts that can be applied at all levels of care. Both are already used to support management strategies in specialised care, either separately or together. Some researchers argue that self-management education may be an integral part to ensuring high quality primary care. However, if the patient does not wish to consult with regular health care professionals, self-management also constitutes a level of care in and of itself.

**Scope of this thesis**

A summary of previous research indicates that there is a need for new ways to provide first-line treatment for urinary incontinence. Self-management research also suggests that there is a need for different treatment options, since needs differ between users. eHealth may be a new way to provide care that could lower barriers to seeking care, and help provide evidence-based support for self-management, even without the user contacting the regular health care system.

This thesis evaluates if eHealth can effectively support self-management for urinary incontinence. The objective was primarily to reach women from the base of the pyramid above (Figure 1) who were interested in self-management via eHealth. That is women who would otherwise seek primary care, but have refrained from doing so due to the barriers listed above, or who would self-manage, with or without evidence-based support.
**Aim**

The aim of this thesis was to study the self-management of urinary incontinence via eHealth with respect to:

a. What constitutes a clinically relevant effect after non-face-to-face management of stress urinary incontinence in women, in terms of symptom reduction and improved quality of life?

b. What effect does a mobile app have for self-management of stress urinary incontinence in women?

c. Are there any background or treatment factors associated with completing the programme and achieving successful results from self-management of urinary incontinence via a mobile app?
Materials and methods

This thesis is based on four papers with data from three different studies (Table 4). Paper I addresses clinically relevant improvement, the first aim. Paper II evaluates treatment effect, the second aim. Papers III and IV analyse factors associated with success, the third aim.

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>I</td>
<td>II</td>
</tr>
<tr>
<td>Aim</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>Study design</td>
<td>Secondary analysis of data from RCT</td>
<td>Randomised Controlled Trial (RCT)</td>
</tr>
<tr>
<td>Participants</td>
<td>Women with SUI</td>
<td>Women with SUI</td>
</tr>
<tr>
<td>Data collection</td>
<td>Self-reported via postal questionnaires</td>
<td>Self-reported via online questionnaires</td>
</tr>
<tr>
<td>Intervention</td>
<td>Pelvic floor muscle training and lifestyle advice</td>
<td>The mobile app Tät®</td>
</tr>
</tbody>
</table>

RCT: Randomised Controlled Trial, SUI: Stress Urinary Incontinence

**Recruitment**

In all of the studies, community-dwelling participants volunteered to take part after finding information on the research project’s website or in the Tät® app. Information about the studies was posted in waiting rooms in primary care centres. Midwives and general practitioners received information about the studies and might have suggested to their patients that they participate. However, all of the participants were enrolled via the website, without help from health care personnel. For the RCTs providing the data for papers I - III, press releases were issued, and advertising was placed in different newspapers and in fitness centres to raise awareness among potential participants all over Sweden. For studies 2 and 3, we also posted information on social media. There was no advertising targeted to specific groups, but during the inclusion of participants for paper IV,
targeted ads were placed on social media about another study within the research project. That study aimed to recruit women with MUI and UUI and the ads were targeted at adult women.

For studies 1 and 2 (papers I - III), women with at least weekly SUI were recruited via the website of the research project. Participants answered screening questionnaires and completed telephone interviews. For study 3 (paper IV), recruitment took place directly within the app after a pop-up message informed users about the study. Table 5 summarises inclusion and exclusion criteria.

### Table 5. Inclusion and exclusion criteria in the different studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>Female</td>
<td>Pregnancy</td>
</tr>
<tr>
<td></td>
<td>SUI ≥1/week</td>
<td>Previous incontinence surgery</td>
</tr>
<tr>
<td></td>
<td>Age 18 - 70 years</td>
<td>Known malignancy in the lower abdomen</td>
</tr>
<tr>
<td></td>
<td>Access to the Internet</td>
<td>Neurologic disease in lower abdomen or legs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe psychiatric disorder, or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HADS score &gt;15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Macroscopic haematuria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Irregular bleeding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difficulties passing urine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bladder capacity &lt;3 dL</td>
</tr>
<tr>
<td>Study 2</td>
<td>Female</td>
<td>Pregnancy</td>
</tr>
<tr>
<td></td>
<td>SUI ≥1/week, (during the previous 6 months)</td>
<td>Previous incontinence surgery</td>
</tr>
<tr>
<td></td>
<td>Age ≥18 years</td>
<td>Malignancy in the lower abdomen (present or previous)</td>
</tr>
<tr>
<td></td>
<td>Access to smartphone and email</td>
<td>Impaired mobility or sensibility in lower abdomen or legs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe psychiatric disorders</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Macroscopic haematuria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Irregular bleeding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difficulties passing urine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bladder capacity &lt;3 dL</td>
</tr>
<tr>
<td>Study 3</td>
<td>Urinary incontinence according to ICIQ-UI SF Age ≥18 years</td>
<td>Invalid postal code</td>
</tr>
</tbody>
</table>

SUI: Stress Urinary incontinence, HADS: Hospital Anxiety and Depression Scale, ICIQ-UI SF: International Consultation on Incontinence Modular Questionnaire - Urinary Incontinence Short Form, IEF: Incontinence Episode Frequency

**Data collection**

All interventions in this thesis were non-face-to-face programmes for self-management. Hence, data collection occurred without physical contact with
participants. They filled out inclusion and follow-up questionnaires and sent them to us via mail (study 1), via a survey webpage (study 2) or through the app (study 3).

**Patient Reported Outcomes (PROs)**

We used the following validated outcome measures to evaluate symptoms and quality of life:

**ICIQ-UI SF** (International Consultation of Incontinence Modular Questionnaire – Urinary Incontinence Short Form) is a validated questionnaire for the comprehensive evaluation of urinary incontinence symptoms. It consists of three items: how often urine leaks, the amount of leakage and how much this interferes with life. These add up to a total score ranging from 0 - 21 points (Appendix A), a higher score indicates more symptoms. Additionally, a fourth diagnostic item can be used for categorising the type of urinary incontinence. The validated incontinence severity index has also been correlated with the ICIQ-UI SF and from this work the questionnaire can be divided into these severity categories: 1 - 5 points = slight incontinence, 6 - 12 points = moderate incontinence, 13 - 18 points = severe incontinence, 19 – 21 points = very severe incontinence.

**ICIQ-LUTSqol** (International Consultation of Incontinence Modular Questionnaire – Lower Urinary Tract Symptoms Quality of Life) is derived from the King’s Health Questionnaire (KHQ) and has been incorporated as the ICIQ tool for quality of life assessment. It consists of 19 items covering different aspects of life that may be affected by urinary incontinence. Each item contributes 1 - 4 points adding up to a total score ranging from 19 - 76 points. A lower number indicates that urinary incontinence has no or little impact on the different aspects of life, and a higher score means that more of the different aspects are impacted “a lot” or “all the time” (Appendix B). Paired with each item there is also a bother scale to rate how bothersome a particular symptom is. However, the bother scale is not included in the total score and has not been used in the papers of this thesis.

**PGI-I** (Patient Global Impression of Improvement) is a validated single item questionnaire that asks the participant to rate their condition now compared to prior to treatment. The seven answers form a Likert scale ranging from “Very much worse” to “Very much better”.

**IEF** (Incontinence Episode Frequency) is calculated from a patient-recorded bladder diary as the number of leakages per week. We used a two-day diary and multiplied the amount of leakage by 3.5.
Data security
In study 1, the participants did not submit any study information online but had contact with the urotherapists via an email service that was secured with SSL-encryption. In study 2, the participants answered screening, inclusion and follow-up questionnaires via a secure and encrypted webpage. No data was submitted via the app. In both of these studies, an informed consent was provided from all participants via mail.

In study 3, the participants answered inclusion and follow-up questionnaires via the app, the data was anonymised and the questionnaires were linked together by a unique code created through the app, not by any information that could be traced back to the user. Data was then stored in a secure database.

Study designs and statistical analysis

Paper I – Clinically relevant improvement
This was a secondary analysis of data collected during a randomised controlled trial, conducted from December 2009 to April 2011. Women with at least weekly SUI were recruited via the website of the research project. Exclusion criteria were pregnancy, previous incontinence surgery and symptoms indicating a need for further examination. Table 5 describes the inclusion and exclusion criteria in detail.

The participants filled out a screening questionnaire, a two-day bladder diary and completed a telephone interview to confirm the diagnosis of SUI, but there was no face-to-face contact with the researchers. Participants were then randomised to 12 weeks of Pelvic Floor Muscle Training and lifestyle advice, provided via either the internet or a brochure. The internet programme entailed eight levels of PFMT with increasing intensity and support via email contact with an urotherapist. It also included a component of cognitive behavioural training to deal with the impact of fear of leakage on quality of life. The brochure included information about SUI and PFMT at five levels. The women were able to start at any level they preferred but were recommended to increase the intensity as they progressed. The RCT and the interventions are described in detail elsewhere.67

In the analysis of treatment effect on symptoms and quality of life, there were no differences between the groups.67 Hence, we considered both groups equal for the purposes of the analysis of MIDs and analysed them as one group.
**Statistical analysis**

Correlation was analysed using the Spearman correlation co-efficient. The participants were then divided into groups depending on their answer to the PGI-I question and the differences between these groups were analysed using a one-way-ANOVA. Post-hoc analyses were performed according to Tukey.

The MID was set at the mean value of the group that stated to be “a little better”, and a between-treatment MID was set at the difference between “a little better” and “no change”. This was carried out in accordance with anchor-based determination of MIDs\(^{141, 142}\) and previous research\(^{81, 143}\). All statistical analyses were performed using the IBM-SPSS software version 21.

**Additional analyses**

For this thesis, data from the participants who completed app-based treatment in study 2 were also analysed as described above to compare whether MIDs differed between different non-face-to-face treatment options.

**Paper II – Treatment effect**

Again, study participants were recruited via the project’s website after advertising placed in regular media. Inclusion and exclusion criteria were similar to study 1, but the upper age limit was abandoned (Table 5). The study was conducted from April 2013 to October 2014.

The participants completed an inclusion questionnaire online. In this, they answered questions related to background factors such as: demographics, lifestyle, medical history including gynaecological history and current medications. They also filled in the validated ICIQ-UI SF and ICIQ-LUTSqol questionnaires and then completed a two-day bladder diary and submitted it by post.

They were then randomised (1:1) to either three months of app management or to the control group (waiting list) (Figure 2). An independent administrator performed the randomisation using concealed envelopes.
**The Tät® app**

Based on the experiences from the internet and brochure treatment programmes, the Tät® app was developed within the eContinence project. The app focused on PFMT and included information about the pelvic floor, stress urinary incontinence and lifestyle. It featured a reminder function, in which the user could set up to three reminders a day to remember to do the exercises. It also included a statistics function and a security function in case the user wanted to lock the app so that it was not readable by others (Figure 3).

![Figure 2. Simplified flow chart of study 2 showing the data used for papers II and III.](image)

**Figure 2.** Simplified flow chart of study 2 showing the data used for papers II and III.

**The pelvic floor**

The pelvic floor is a cup-shaped muscle group at the bottom of the pelvic cavity. It runs from the coccyx and the rectum at the rear, loops around either side of the vagina and urethra, and attaches to the pubic bone and outward towards the inner sides of the pelvis.

The muscles’ task is to keep the pelvic organs in place and at the same time be able to close the rectal, vaginal and urethral openings. The pelvic floor, known as the levator muscles, is also important for your sex life.

Pregnancy, childbirth and age-related changes affect the muscles and connective tissue. If you are overweight, suffer from intense coughing or do heavy physical work, the pelvic floor muscles have to work harder and must ‘hold back’ more.

When the pelvic floor is affected there is less support for the bladder and urethra. It is more difficult to contract the muscles. During physical

![Figure 3. Images from the English version of the app Tät® showing from left to right: an information section, the overview of exercises, one of the exercises and the different settings.](image)

**Figure 3.** Images from the English version of the app Tät® showing from left to right: an information section, the overview of exercises, one of the exercises and the different settings.

This app included PFMT exercises featuring contractions for finding the right muscles, for strength, for endurance and “the knack”, a quick contraction performed to stop an expected urine loss upon coughing. The programme
consisted of six different basic level exercises and six advanced level exercises (Appendix C, supporting material to paper II).

The lifestyle advice contained information about the impact of weight, smoking and fluid intake on incontinence.

Follow-up was conducted after three months as this is the recommended duration of PFMT. Follow-up again included an online questionnaire and a two-day bladder diary submitted by post. The follow-up questionnaire included lifestyle questions, questions regarding the pelvic floor muscle training and app use, feedback about the app as well as the validated patient reported outcomes described as the outcome measures above. If either the electronic questionnaire or the bladder diary was not submitted as planned, the participant was reminded by email after two and four weeks and via phone after six weeks.

**Primary and secondary outcome measures**
The primary outcomes were validated questionnaires for symptoms (ICIQ-UI SF) and quality of life (ICIQ-LUTSqol). To obtain a comprehensive evaluation, secondary outcome measures included the validated PGI-I, IEF, Patient Satisfaction and pad use.

**Sample size**
We based the sample size calculations on the effects of the internet-based management, described above and in paper I. We therefore expected the reductions in the ICIQ-UI SF score to be 2.9 (SD 3.1) after self-management with the app, and in the ICIQ-LUTSqol score to be 4.6 (SD 6.7). For the control group, we expected there to be a smaller improvement in the ICIQ-UI SF of 1.0 (SD 2.0) and in the ICIQ-LUTSqol of 2.0 (SD 3.0). We made sample size calculations for the secondary outcome the PGI-I, estimating large improvements in 26.5% of the app group and in 4% of the control group. Based on a 0.05 significance level, two-sided, and an 80% power, these calculations resulted an estimated need for 30, 35 and 39 participants in each study arm, for the outcomes described above. We expected a 33% dropout rate and therefore aimed to recruit 60 participants into each arm.

**Statistical analysis**
Baseline data were compared between the groups using the Student t-test for continuous variables, the Mann-Whitney U-test for ordinal variables and the Chi² test for categorical variables.

At follow-up, intention to treat analysis was performed. The primary outcomes ICIQ-UI SF and ICIQ-LUTSqol were analysed using a linear mixed model and no values were imputed. For the secondary outcomes, IEF and pad use, if values at
follow-up were missing they were replaced with the corresponding value from baseline, and missing PGI-I values were replaced with the answer “unchanged”. These were analysed using Mann-Whitney’s U-test. For the secondary outcome, Patient Satisfaction, descriptive statistics were calculated. All statistical analyses were performed using the IBM-SPSS software version 22.

**Paper III – Factors associated with success**

Only the participants in the app group were included in the analysis (n=62). If they reported to be “much better” or ”very much better” in their answer to the question about their impression of improvement (PGI-I), they were categorised as having self-managed successfully (Figure 2). Participants who reported to be a little better, unchanged or worse were classified as not having self-managed successfully.

At baseline, the participants answered questions about educational level, lifestyle (physical activity, smoking, coffee and tea consumption) and medical history (incontinence history, gynaecological and other conditions). These were all analysed for their association with success as categorical variables.

Furthermore, participants stated their age, weight and height, and the two latter were used to calculate the Body Mass Index (BMI) (kg/m²). Age, weight and BMI were analysed for their association with success as continuous variables.

The ICIQ-UI SF and LUTSqol questionnaires and the reports from the bladder-diaries (IEF) were also analysed as continuous variables. ICIQ-UI SF was also categorised into severity categories according to Klovning, and also analysed as a categorical variable.

Among the variables collected at follow-up, the following were considered to possibly be associated with success: difference in weight from baseline, app use (including use of the statistics and other functions of the app), frequency of PFMT (self-estimations and report from the statistics function), and self-rated improvement in pelvic floor muscle strength. These were all analysed as categorical variables, with the exception of weight change, which was analysed as a continuous variable. The frequency of PFMT from the statistics function was categorised as in a previous study by Borello-France at al., but also analysed as a continuous variable.

**Statistical analysis**

First, all baseline and follow-up factors that could influence a successful outcome were analysed using univariate logistic regression. Continuous variables were analysed without further alteration, whereas categorical variables were
sometimes collapsed as appropriate to form groups that were more equal in size, or when the confidence intervals indicated that there were no differences between categories.

All factors with significant or borderline significant correlation (p<0.20) were then entered into the multivariate model and finally stepwise removed until only factors with significant correlation (p<0.05) remained. Age was adjusted for throughout the model. All statistical analyses were performed using the IBM-SPSS software version 22.

**Paper IV – Factors associated with completion, improvement and success**

Once the efficacy of the Tät® app had been demonstrated in the RCT (study 2), the app was made freely available for everyone. It was also translated to English by a certified translator and proofread by the research team. The translated app was then released for free use without any cultural adaptations. Data from users willing to participate are collected continuously, but the data for this study were collected from the Swedish app from May 26, 2015 to April 29, 2017, and from the English app from April 26, 2016 to April 29, 2017.

To further study the use of the app and its effectiveness as a self-management programme, we included a short questionnaire about age, educational level, current residency and the ICIQ-UI SF for symptom evaluation. After three months, a follow-up questionnaire appeared if the app was still in use. This again included the ICIQ-UI SF and also the PGI-I questionnaire, questions about PFMT frequency and app use. If the participants did not answer the questionnaire, they were reminded to do so upon reopening the app, but no reminders were sent in any other way.

The data in this study were analysed for three different outcomes: completion of self-management, defined as submitting the follow-up questionnaire within 135 days; improvement, defined as improvement according to the PGI-I questionnaire; and treatment success, defined as providing an answer to the PGI-I questionnaire with the response “much better” or “very much better”. All outcomes were measured at the three-month follow-up. Figure 6 provides an overview of the study including the different outcomes.

**Statistical analysis**

First, the background variables and app language were analysed using the Pearson Chi² or Fischer’s exact test, and univariate regression to determine any association with completion of three months of self-management. Then all variables were analysed, regardless of significance level in the univariate
analyses, in the multivariate regression model and stepwise removed according to significance level, until only significant factors remained.

The analyses were then repeated for the improvement and success outcomes, first using a descriptive analysis and then a multivariate model. All statistical analyses were performed using the IBM-SPSS software version 24.

**Ethics**

The ethical review board of Umeå University approved all the studies in this thesis. The analyses in paper I were approved on March 10, 2014 (number 2014-87-32M) as an amendment to the previously approved RCT (number 2008-124M). The RCT in paper II was approved on October 2, 2012 (number 2012-325-31M), and the analyses in paper III were approved as an amendment (number 2015-375-32M). The collection of data in study 3 was approved on December 16, 2014 (number 2014-389-32M) and the analysis for paper IV was approved as an additional amendment (number 2017-405-32).

The RCTs were registered at Clinical trials http://clinicaltrials.gov (Study 1: Identifier NCT01032265, Study 2: Identifier NCT01848938) and reported according to CONSORT guidelines.

In studies 1 and 2, all participants signed a written informed consent form. In study 3, the inclusion questionnaire included information about the study and that participating by answering the questionnaire was voluntary. Therefore, we considered it informed consent if participants submitted the questionnaires. No reimbursements were given during any of the studies.

**The eContinence project and the interventions**

The internet-based programme was developed by Eva Samuelsson (general practitioner) and Göran Umefjord (general practitioner), in collaboration with urotherapists Eva Källström (nurse midwife) and Annika Andreasson (physiotherapist). Psychologists Per Carlbring and Gerhard Andersson advised on the CBT exercises within the programme. The brochure programme was developed by Eva Samuelsson in collaboration with Eva Källström and Annika Andreasson.

The application Tät® was developed by Eva Samuelsson, Göran Umefjord, and Malin Sjöström (general practitioner) in collaboration with ICT Service and System development at Umeå University. Copyright 2010–2018 Tät.nu, at Umeå University. All rights reserved. The name Tät (mobile application) and the logo Tät.nu are registered as trademarks by the Swedish Patent and Registration
Office for E. Samuelsson at Umeå University. The application is CE-marked as a medical device Class I, according to Swedish regulation LVFS 2003:11. It is available for free in Swedish, English, Finnish, German, Spanish and Arabic through the Apple App Store and Google Play. None of the researchers has any financial interests in the product.

**Funding**

This research was funded with grants from the Swedish Research Council for Health, Working life and Welfare (FORTE), the Västerbotten County Council (ALF); the Visare Norr, Northern County Councils; Region Jämtland Härjedalen (former Jämtland County Council), and the Kamprad Family Foundation for Entrepreneurship, Research, and Charity.
Results

Demographics

All of the studies included participants from all over Sweden, from sparsely populated areas and from urban areas, and in study 3 from over 30 different countries. Participants were generally well educated and the studies of the app attracted younger women, in particular when freely available. Based on the mean ICIQ-UI SF score, they had urinary incontinence of moderate severity and users of the freely available app had slightly less symptoms (Table 6).

<table>
<thead>
<tr>
<th>Table 6. Baseline characteristics of participants in the different studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
</tr>
<tr>
<td>Internet and brochure groups (n=218)</td>
</tr>
<tr>
<td>Mean age, years (range)</td>
</tr>
<tr>
<td>Educational level, n (%)</td>
</tr>
<tr>
<td>Primary and lower secondary school</td>
</tr>
<tr>
<td>Upper secondary school</td>
</tr>
<tr>
<td>University level</td>
</tr>
<tr>
<td>BMI (range)</td>
</tr>
<tr>
<td>Dwelling, n (%)</td>
</tr>
<tr>
<td>Metropolitan area</td>
</tr>
<tr>
<td>Urban, rural or sparsely populated area</td>
</tr>
<tr>
<td>Parity, n (%)</td>
</tr>
<tr>
<td>Nullipara</td>
</tr>
<tr>
<td>Unipara</td>
</tr>
<tr>
<td>Multipara</td>
</tr>
<tr>
<td>Type of urinary incontinence, n (%)</td>
</tr>
<tr>
<td>Leakage upon exertion</td>
</tr>
<tr>
<td>Leakage associated with urgency</td>
</tr>
<tr>
<td>Mean ICIQ–UI SF score (range)</td>
</tr>
<tr>
<td>Median IEF (IQR)</td>
</tr>
<tr>
<td>Previously sought care for incontinence, n (%)</td>
</tr>
</tbody>
</table>

SD: Standard Deviation, ICIQ - UI SF: International Consultation on Incontinence Modular Questionnaire - Urinary Incontinence Short Form, IEF: Incontinence Episode Frequency, IQR: Interquartile Range

*Completed follow-up within 135 days.

Paper I - Clinically relevant improvement

At follow-up after 3 months of self-management via internet or brochure, 218 women completed the follow-up questionnaire and were included in the analysis.

Greater impressions of improvement were associated with larger reductions on the symptom score (ICIQ-UI SF) and the quality of life score (ICIQ-LUTSqol). The correlation was moderate and significant for both ICIQ-UI SF (Spearman rho=0.547, p<0.001) and ICIQ –LUTSqol (Spearman rho=0.520, p<0.001).
The ANOVA confirmed that there was a difference in mean reductions between the different PGI-I categories. Post-hoc analyses showed significant differences in reductions in the ICIQ-UI SF and ICIQ-LUTSqol between all response categories indicating improvement and no change. Only a few participants stated that their condition was worse, these categories were collapsed to be enable post-hoc analyses. The differences between “no change” and “a little/much worse” were not statistically significant (Table 7).

The MID was set at 2.5 points for ICIQ-UI SF and at 3.7 points for ICIQ-LUTSqol. The between-treatment MID was determined to be 1.6 points for ICIQ-UI SF and 3.0 points for ICIQ-LUTSqol.

**Table 7. Mean reduction in symptom and quality of life scores for each category of Patient Global Impression of Improvement at follow-up after 3 months of self-management.**

<table>
<thead>
<tr>
<th>PGI-I</th>
<th>ICIQ-UI SF</th>
<th></th>
<th>ICIQ-LUTSqol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean reduction (95%)</td>
<td>N</td>
<td>Mean reduction (95%)</td>
</tr>
<tr>
<td>Very much better</td>
<td>16</td>
<td>7.59 (7.07 - 7.93)</td>
<td>16</td>
<td>14.50 (13.65 - 15.35)</td>
</tr>
<tr>
<td>Much better</td>
<td>54</td>
<td>4.61 (4.18 - 5.04)</td>
<td>56</td>
<td>6.63 (5.78 - 7.47)</td>
</tr>
<tr>
<td>A little better</td>
<td>108</td>
<td>2.52 (2.09 - 2.95)</td>
<td>107</td>
<td>3.71 (2.86 - 4.56)</td>
</tr>
<tr>
<td>No change</td>
<td>31</td>
<td>0.94 (0.51 - 1.36)</td>
<td>31</td>
<td>0.71 (-0.14 - 1.56)</td>
</tr>
<tr>
<td>Worse</td>
<td>5</td>
<td>-1.40 (-1.83 - -0.97)</td>
<td>4</td>
<td>-6.50 (-7.35 - -5.65)</td>
</tr>
<tr>
<td>Total</td>
<td>214</td>
<td></td>
<td>214</td>
<td></td>
</tr>
</tbody>
</table>

p <0.05 between groups. N = participants that answered both PGI-I and ICIQ-UI SF or ICIQ-LUTSqol at follow-up and hence were included in the analyses. ICIQ-UI SF: International Consultation on Incontinence Modular Questionnaire - Urinary Incontinence Short Form, ICIQ-LUTSqol: International Consultation on Incontinence Modular Questionnaire - Lower Urinary Tract Symptoms Quality of Life

*No significant difference between the categories "No change" and "Worse"

**Additional analyses**

For app self-management there were also significant correlations between PGI-I and changes in both ICIQ-UI SF score (Spearman rho =0.451, p <0.001) and ICIQ-LUTSqol score (Spearman rho =0.404, p=0.002). The ANOVAs confirmed that there were differences between the groups based on the PGI-I categories (ICIQ UI SF p=0.001 and ICIQ-LUTSqol p=0.015). The mean for the group that felt “a little better” was 2.6 points (95% CI 1.2 - 4.0) for ICIQ-UI SF, and 3.5 points (95% CI 1.5 - 5.4) for ICIQ-LUTSqol. However, the differences between the groups expressing “no change”, “a little better” and “much better” were not significant.
Paper II - Effect of self-management

A total of 123 women were randomised to either the app group (n=62) or the control group (n=61). Of these women, 121 completed the 3-month follow-up questionnaire, one from each group was lost to follow-up (Figure 4).

Figure 4. Flow chart of study 2.
**Primary outcomes**
Both groups reported significantly less symptoms at follow-up compared to baseline. The app group had a mean decrease of 3.9 points (95% CI 3.0 - 4.7) in the ICIQ-UI SF score and the control group had a mean decrease of 0.9 points (95% CI 0.1 - 1.6). However, the decrease was larger in the app group and the difference between the groups was significant (p<0.001).

The app group also reported significantly less impact on quality of life after self-management, a mean ICIQ-LUTSqol reduction of 4.8 points (95% CI 3.4 – 6.2). The reduction in the control group’s mean ICIQ-LUTSqol score 0.7 points (95% CI -0.5 – 1.8) was not significant. There was a significant difference between the groups (p=0.005).

**Secondary outcomes**
For the PGI-I the vast majority of the app group reported improvements (56/61, 92%), while only a smaller portion of the control group reported improvements (12/60, 20%) (Figure 5). The app group reported greater improvements than the control group (p<0.001).

---

**How is your urinary leakage now compared to before treatment?**

![Graph showing responses to PGI-I question](image-url)

Figure 5. Answers to the Patient Global Impression of Improvement (PGI-I) question at 3-month follow-up in the RCT comparing management of SUI via the Tät® app (n=61) with a control group (waiting list) (n=60).
The median IEF decreased in both groups, from 21.0 leakage episodes per week (IQR 10.5 – 28.0) to 7.0 (IQR 0.0-17.5) in the app group, and 17.5 (IQR 10.5 – 24.5) to 14.0 (IQR 7.0 -26.5) in the control group. The decreases were larger in the app group (p<0.001).

The app group had a significant decrease in pad use (p<0.001). At follow-up, 23 women (38%) reported no use at all and 13 women (21%) used incontinence aids less often than once a week. In the control group there was no significant decrease (p=0.602) and the corresponding numbers were 14 (23%) and 11 (18%). The differences in pad use were significantly different between groups (p=0.023).

In the app group, two-thirds (40/60) reported to be satisfied with the outcome, while 22% (13/60) planned to seek additional care. Only the app group answered this question and therefore comparison between groups was not possible.

**Paper III - Factors associated with success within the RCT**

In total 61 women completed the follow-up after three months of self-management. Of these, 56% (34/61) rated their condition as much or very much better after training with the app (Figure 5) and were considered to have successfully self-managed.

The univariate analysis revealed six factors having significant or borderline significant association with success (Table 8), and these along with age were included in the multivariate model. The final model found three variables having significant association with success: expectations for treatment, weight change and self-assessed improvement in pelvic floor muscle strength (Table 8). These variables accounted for 61.4% (Nagelkerke R²) of the variability in success.
<table>
<thead>
<tr>
<th>Variable</th>
<th>% (95% CI)</th>
<th>p-value</th>
<th>% (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighth and Height</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>11.3%</td>
<td>0.06</td>
<td>11.3%</td>
</tr>
<tr>
<td>Baseline Level</td>
<td>11.3%</td>
<td>0.06</td>
<td>11.3%</td>
</tr>
<tr>
<td>Self-assessed Physical Health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>31.4%</td>
<td>0.02</td>
<td>31.4%</td>
</tr>
<tr>
<td>Baseline Level</td>
<td>31.4%</td>
<td>0.02</td>
<td>31.4%</td>
</tr>
<tr>
<td>Pod Use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>35.2%</td>
<td>0.006</td>
<td>35.2%</td>
</tr>
<tr>
<td>Baseline Level</td>
<td>35.2%</td>
<td>0.006</td>
<td>35.2%</td>
</tr>
<tr>
<td>Receptor (Yes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>25.0%</td>
<td>0.006</td>
<td>25.0%</td>
</tr>
<tr>
<td>Baseline Level</td>
<td>25.0%</td>
<td>0.006</td>
<td>25.0%</td>
</tr>
</tbody>
</table>

Table 8. Results from univariate and multivariate logistic regression of possible factors associated with a successful outcome.
Paper IV - Factors associated with completing self-management and achieving improvement and success

Of the users that submitted the baseline questionnaire, 13,257 had urinary incontinence and were included in these analyses (Figure 6).

At follow-up, 1,861 participants (14%) submitted the questionnaire within 135 days and were considered to have completed the self-management. The

Figure 6. Flow chart of study 3.

At follow-up, 1,861 participants (14%) submitted the questionnaire within 135 days and were considered to have completed the self-management. The
multivariate model revealed four factors associated with completion: age, episodes of stress urinary incontinence, higher educational level, and Swedish app language (Table 9). These four factors accounted for 2.7% (Nagelkerke $R^2$) of variability.

<table>
<thead>
<tr>
<th>Factors</th>
<th>Completion N=13 256</th>
<th>Improvement N=1610</th>
<th>Success N=1 610</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted OR (CI)*</td>
<td>Adjusted OR (CI)*</td>
<td>Adjusted OR (CI)*</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30 years</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>30-39 years</td>
<td>1.67 (1.43 - 1.95)</td>
<td>1.19 (0.84 - 1.71)</td>
<td>0.84 (0.60 - 1.18)</td>
</tr>
<tr>
<td>40-49 years</td>
<td>1.28 (1.07 - 1.52)</td>
<td>0.90 (0.59 - 1.35)</td>
<td>0.73 (0.49 - 1.09)</td>
</tr>
<tr>
<td>≥50 years</td>
<td>1.24 (1.04 - 1.48)</td>
<td>0.95 (0.63 - 1.43)</td>
<td>0.86 (0.58 - 1.28)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No higher education</td>
<td>1.0</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>University</td>
<td>1.78 (1.57 - 2.01)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td><strong>Type of incontinence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No leakage upon exertion</td>
<td>1.0</td>
<td>1.0</td>
<td>NS</td>
</tr>
<tr>
<td>Leakage upon exertion</td>
<td>1.16 (1.01 - 1.34)</td>
<td>1.50 (1.09 - 2.07)</td>
<td></td>
</tr>
<tr>
<td><strong>Language</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swedish</td>
<td>1.0</td>
<td>1.0</td>
<td>NS</td>
</tr>
<tr>
<td>English</td>
<td>0.57 (0.44 - 0.74)</td>
<td>4.16 (1.88 - 9.18)</td>
<td></td>
</tr>
<tr>
<td><strong>Pelvic floor muscle training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1/week</td>
<td>1.0</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>1-6 times/week</td>
<td>NA</td>
<td>1.91 (1.44 - 2.55)</td>
<td>1.39 (1.01 - 1.91)</td>
</tr>
<tr>
<td>Daily</td>
<td>1.75 (1.24 -2.47)</td>
<td>1.66 (1.17 - 2.35)</td>
<td></td>
</tr>
<tr>
<td><strong>Usage of app</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>About once per month or less often</td>
<td>1.0</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>About once per week</td>
<td>NA</td>
<td>3.41 (2.43 - 4.78)</td>
<td>1.91 (1.24 - 2.94)</td>
</tr>
<tr>
<td>Daily</td>
<td>7.55 (5.38 - 10.60)</td>
<td>3.44 (2.29 -5.18)</td>
<td></td>
</tr>
</tbody>
</table>

*Results from the multivariate logistic regression model adjusted for age. P<0.05 was considered significant. OR: odds ratio, CI: confidence interval, NA: not applicable, NS: not significant

Among those who completed, 251 participants had downloaded an older version of the app, which did not include the PGI-I question. Hence, 1 610 participants were included in the second and third multivariate models. Of these, 1 094 (68%) stated that their condition had improved (Figure 7).

Episodes of stress urinary incontinence and app language were also associated with outcome improvement. However, in this model a larger portion of the
English app users improved. Those who performed pelvic floor muscle training and those who used the app at least weekly had also higher odds of improvement (Table 9). Together, these factors accounted for 23.2% (Nagelkerke R²) of the variability.

Figure 7. Answers to the Patient Global Impression of Improvement (PGI-I) question at follow-up after 3 months of self-management with the freely available Tät® App (n=1 610).

Of the participants completing self-management programme, 474 (29%) stated that they were much or very much better and were considered to have successfully self-managed. The model for this outcome showed that only frequency of pelvic floor muscle training and app usage predicted success. These factors explained 8.4% (Nagelkerke R²) of the variability.

The variables frequency of training and app use correlated moderately usage (Spearman r=0.534, P<.001). Frequency of app use predicted improvement and success to a greater extent, but not as well as the two variables combined. Therefore, both were included in the final models.
Discussion

Main findings in relation to aims
This thesis evaluates a new way of managing urinary incontinence via eHealth. The main finding is that providing first-line management with pelvic floor muscle training and lifestyle advice via a mobile app is feasible and effective for women with stress urinary incontinence.

Clinically relevant improvement
In paper I, we found that the symptom score ICIQ-Ul SF and the quality of life score ICIQ-LUTSqol measure clinically relevant improvement. We established MIDs of 2.5 and 3.7 points respectively.

Treatment effect
In paper II, we found that self-management via a mobile app significantly improved symptoms and quality of life. These improvements were significantly larger than in the control group (waiting list) and should be considered clinically relevant, as they were greater than the previously established MIDs.

In paper IV, we showed that two thirds of the users who completed app management improved and 29% were much or very much improved.

Factors associated with success
In paper III, we found that high expectations at baseline, weight stability during self-management and self-assessed increase in pelvic floor muscle strength were associated with success. Success was defined as feeling much or very much better after self-management with the app.

In paper IV, we found that age, educational level, app language and stress type leakage had a small predictive value of who would complete three months of self-management. Among those who completed self-management, app language and stress type leakage predicted improvement but not success. Higher frequency of both PFMT and app usage was associated with both improvement and success.

Methodological considerations

Strengths
This thesis evaluated a completely new way of providing PFMT and managing urinary incontinence. The self-management programme in the app was based on the effective and appreciated internet-based programme, which was
developed by general practitioners with extensive experience and urotherapists
with both nursing and physiotherapy backgrounds. The research group therefore
had both clinical and scientific experience.

Other strengths included the prospective study designs and the clinically relevant
setting. The participants in all studies actively sought care, but only about 35%
had sought care for their urinary incontinence previously. This suggests that we
reached a new section of the population: women that might not seek regular
primary care but are nonetheless interested in treatment. In paper IV, we also
studied the app in the environment in which it was intended to be used.

Another general strength was the high follow-up rates. In paper I, the vast
majority (87%) of participants in the RCT could be included in the analysis and
of those included, only a few answers were missing (4 out of 218). In papers II
and III, only one participant from each group was lost to follow-up. Reasons for
this could be the reminders per email or phone and that the electronic
questionnaires made it easier for the participants to submit their answers. Paper
IV studied the use of the app for complete self-management where there was no
contact with researchers. This is likely to have affected the motivation to keep
training and, as discussed under limitations below, only 14% of participants
completed the 3-month follow-up. However, among those who completed the
questionnaires there were no missing answers, once again due to the electronic
questionnaire format.

In all studies, we used validated and recommended patient-reported outcome
measures. The ICIQ questionnaires have also been validated for
electronic use. ICIQ-LUTSqol has also been validated for electronic use in the
population of study 1, which was similar to the population of study 2 in terms
of incontinence severity and attitudes towards eHealth.

Other strengths included the use of the frequently used ICIQ-UI SF, the
registration at Clinical trials and reporting of results according to CONSORT and
eCONSORT guidelines. All these factors increase the possibility for comparison
with other studies.

Limitations

EHealth interventions have several general limitations. Firstly, although the lack
of face-to-face contact is advantageous in that the anonymity may encourage the
participants to seek care, it does not resemble the ordinary clinical situation,
and results may therefore not be generalizable to those clinical settings.
Another aspect that may limit the generalisability of these results is the large proportion of well-educated women in our studies (70 - 90%). In Sweden, 41% of all women aged between 16 to 74 years have a college or university education (2017).148 The large proportion of highly educated women in our studies may reflect a generally high use of health apps in this population.149 It may also be an expression of a higher tendency to seek help for urinary incontinence.6 How and why this may have influenced our results is further discussed in relation to success factors.

Furthermore, data collection was all self-reported and the research team never controlled any of the reported data. On the other hand, compared to conventional research there would be less reason for participants to alter their answers to please the researcher or be influenced by the researcher during the completion of the questionnaires.

In paper II, a control group that received no active treatment (waiting list) was used for comparison. This was done in order to control for the study effects and spontaneous improvements as part of the natural course of SUI. This may be considered as a weakness because app management was not compared with care as usual. Unfortunately, there is no generally accepted Gold standard for how to provide first-line treatment and care as usual varies greatly. Furthermore, the majority of these women had refrained from seeking ordinary care. In a qualitative study of the participants, they stated that app management supported their independence, which they appreciated.150 Hence, care as usual might not have been an acceptable treatment option for this population.

In paper III, the greatest limitation was the small sample size. Furthermore since this was a secondary analysis of data from the RCT, the coding of factors had not explicitly been intended for analysis of possible predictors of successful management. Factors with a minor impact on success could have been missed due to the small sample or pre-determined categorisation.

In paper IV, we gathered less information about the participants, partly because we considered that participants would only respond to a shorter questionnaire. Additionally, no personal data was collected to ensure data security. For example, the questionnaire did not include any question about whether participants were women or men. However the app clearly addressed women and when the question of gender was added after study 3, less than 0.5% of app users were male. Also, we had no means of controlling for pregnancy or whether participants received additional treatment elsewhere.

The large dropout rates could be viewed as a limitation of paper IV, but in my opinion this should instead be viewed from the perspective current app use and
not compared with completion rates of other first-line treatments for urinary incontinence. As an example, 3.3% of users are long-term users (>30 days) of the app iDry.\textsuperscript{131} It is likely that many users were just curious or searching for information rather than seeking apps for active self-monitoring or self-management.

**Clinically relevant improvement**

A MID is perhaps best considered as a guide, for how to interpret a change in a score, for example a quality of life score, and interpretation may depend on the perspective.\textsuperscript{141}

The determination of a MID is dependent on the population studied, the intervention and the follow-up time. It also depends on the method of establishing the MID (anchor or distribution-based) and the definitions chosen. The populations in study 1 and 2 were similar in terms of type of incontinence and severity, and both interventions were non-face-to-face self-management focused on PFMT, although effects were larger in study 2 (Table 10). The additional analyses in this thesis were insufficiently powered to render a reliable estimation of MID for app management. The mean reductions of the group expressing to be a little better in study 2 were comparable to the means found in paper I, ICIQ-UI SF score reductions of 2.6 vs 2.5 points and ICIQ-LUTSqol score reductions of 3.5 vs. 3.7 points. However not statistically significant, these similarities indicate that the results of paper I can be generalised to other settings of non-face-to-face conservative management of female SUI.

As an example of how MIDs can vary, Sirls et al. determined a MID at 12 months after surgery using several different anchors, and within the same population the MID varied from ICIQ-UI SF decreases of 4.5 to 5.7 points. At 24 months' follow-up, the values ranged from 3.1 to 4.3 points reductions. They also determined a distribution-based MID and found a lower value.\textsuperscript{151}

The advantage of the anchor-based method is linking the outcome measure, that otherwise may be difficult to interpret, to a meaningful anchor. Using a global rating scale as an anchor has been argued to be the best measure from the individual’s perspective but it has also been noted that over extended time, recall bias may be a significant limitation.\textsuperscript{142} This would explain some of the variance in Sirls’ results and contribute to them not being comparable to ours. Our use of PGI-I as an anchor for results at three months reduces the risk for recall bias compared to the results of Sirls et al. It also corresponds to the time frame for which the PGI-I is validated.\textsuperscript{140}
Sirls et al. also used PGI-I as an anchor and established the MID to be 4.8 points at 12 months. However, they used a different definition of the smallest important difference; the difference in means between the group finding themselves to be “very much better” and the group giving all other responses. This may be a meaningful anchor when evaluating surgical interventions, but the interpretation and intended use is still not intuitively clear. This is why we found it more useful to determine a mean for the group that actually could detect a small improvement, an anchor-based approach that has also been used by others.81

**Effect of self-management**

The app management evaluated in paper II showed significant effects on symptoms and quality of life. These improvements should be considered clinically relevant based on the previously established MIDs (paper I). The reduction in IEF should also be considered clinically relevant as it exceeded the 50% reduction that Yalcin et al. found to be clinically relevant.152

Furthermore, these effects are comparable with effects found in other studies (Table 10). The 3.9 points reduction in ICIQ-UI SF scores in the self-management group of study 2 is exactly the same reduction as in a study of PFMT with vaginal cones after six months of training. However, the women in that study had less severe UI symptoms at the first visit, with a mean ICIQ-UISF score of 8.6 (SD 2.6), which tends to give smaller reductions. In that study, symptoms improved significantly in both groups. The reduction was gradual, with symptoms improving with every visit, but at six months there was no difference between groups.153

Looking at more intense programmes, others have reported larger effects of physiotherapy. In a clinical trial of an intensive physiotherapy programme, 72 women with SUI (92%) and MUI (8%) improved their ICIQ-UI SF scores from 14.6 (SD 4.2) to 7.2 (SD 4.5). The programme studied took place over one month and included eight individual, clinical, 60-minute visits with information, PFMT, pelvic floor electro-stimulation, and strategies for reducing leakage including urination schedules. The participants were somewhat older (mean age 53.1 SD 2.2) and 50% were housewives or retired.156 Similar effects were reported in another study evaluating supervised PFMT twice a week, unfortunately exact reductions in symptom scores were not reported.157

When freely available, the app also led to improvement in 68% of those who completed three months of self-management. This is comparable to the two thirds of women with any type of urinary incontinence who reported improvement from other types of PFMT in the pooled data of the latest Cochrane review.3
### Table 10. Effects in randomised controlled trials evaluating different types of Pelvic Floor Muscle Training

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population</th>
<th>Ages</th>
<th>Intervention(s)/Control</th>
<th>Duration</th>
<th>N</th>
<th>Baseline ICIQ-UI SF (SD)</th>
<th>Follow-up (SD)</th>
<th>Difference (SD)</th>
<th>Loss to follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albers-Heitmer et al (2011)</td>
<td>Women with SUI, MUI or UUI</td>
<td>≥18 months</td>
<td>Conservative management via a nurse-specialist, Care as usual via GP</td>
<td>3 months</td>
<td>186</td>
<td>11.1 (4.3)</td>
<td>9.1 (2.9)</td>
<td>2.0</td>
<td>14 (7.5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>198</td>
<td>11.3 (3.7)</td>
<td>9.7 (2.9)</td>
<td>1.4</td>
<td>14 (7.1%)</td>
</tr>
<tr>
<td>Asklund et al (2016)</td>
<td>Women with SUI</td>
<td>27-72 years</td>
<td>Non-face-to-face PFMT, Waiting-list</td>
<td>3 months</td>
<td>62</td>
<td>11.1 (3.0)</td>
<td>7.0 (3.5)</td>
<td>3.9</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>61</td>
<td>11.0 (2.6)</td>
<td>10.2 (3.2)</td>
<td>0.9</td>
<td>1 (1.6%)</td>
</tr>
<tr>
<td>Porta-Roda et al. (2015)</td>
<td>Women with SUI or MUI</td>
<td>35-60 years</td>
<td>PFMT with vaginal spheres, PFMT alone</td>
<td>6 months</td>
<td>37</td>
<td>8.6 (2.6)</td>
<td>4.7 (3.5)</td>
<td>3.9</td>
<td>2 (5.4%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33</td>
<td>8.9 (2.3)</td>
<td>5.7 (3.5)</td>
<td>3.2</td>
<td>4 (9.1%)</td>
</tr>
<tr>
<td>Sherburn et al. (2011)</td>
<td>Women with SUI</td>
<td>≥65 years</td>
<td>PFMT, Bladder training</td>
<td>5 months</td>
<td>43</td>
<td>10.4 (5.0)</td>
<td>5.9 (3.3)</td>
<td>4.5</td>
<td>2 (4.7%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40</td>
<td>10.4 (4.2)</td>
<td>8.5 (4.4)</td>
<td>1.9</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Sjöström et al. (2013)</td>
<td>Women with SUI</td>
<td>18-70 years</td>
<td>Internet-based PFMT, PFMT via a brochure</td>
<td>3 months</td>
<td>124</td>
<td>10.4 (3.1)</td>
<td>6.9 (3.1)</td>
<td>3.4 (3.4)</td>
<td>17 (13.7%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>126</td>
<td>10.3 (3.5)</td>
<td>7.3 (3.9)</td>
<td>2.9 (3.1)</td>
<td>13 (10.3 %)</td>
</tr>
</tbody>
</table>

Factors associated with success

In our studies, we found expectation for treatment to be associated with success. This may be an expression of self-efficacy, that is the participants’ perception of their ability to perform PFMT, which was found to be predictive of success in a study by Lindh et al. Self-efficacy, is regarded as one of the most important factors for adherence, which has also been shown in research. Richard and Shea conclude that “Self-efficacy and outcome expectations mediate the relationship between personal factors and behaviour”. High expectations on treatment may also indicate that participants had no previous experience of poor outcomes from PFMT, which has been found to predict treatment failure.

The fact that weight stability turned out to be associated with success is completely in line with research indicating that overweight and obesity increase the risk of urinary incontinence. However, the increase in risk is larger for women with MUI and UUI and becomes steeper as weight approaches obesity. Prior research has shown that incontinence symptoms are improved by weight reduction, but it is new knowledge that it would also be important in normal-weight women during SUI management. Weight change may however also be a surrogate measure for a general commitment to a healthier life.

The influence of demographic factors such as age, educational level and app language was minor and should be interpreted with care. Younger age and higher education have also been associated with higher eHealth literacy, leading to a better ability to use health information from electronic resources. However, as previous reviews have concluded, age is often confounded or is itself a confounder. In this case, the age group that was the most successful (30 - 39 years), is also an age when women suffer primarily from slight SUI symptoms. SUI is known to have a better effect from PFMT and less symptoms have been associated with better outcomes on global rating scales. Less symptoms are also associated with higher odds for cessation of leakage, no cross-over to surgery and improvement of sexual function. Whereas, as mentioned earlier, higher baseline symptom scores are more likely to have larger symptom reductions. Less severe symptoms and treatment nativity has also been found to induce a larger placebo response in a drug trial. If there is a similar response when performing PFMT, the younger age group would be more likely to not have any previous treatment experiences.

App language shows incongruent associations. Swedish app language was associated with higher odds of completing three months of self-management but lower odds of improving. This may have been due to the introduction of the English app. Users may either have been early responders with a high self-efficacy
level or just curious. The English users were also rather few in numbers, and some of them may have been researchers attending conferences where results from the original study were presented.

**Educational level and socioeconomics**

Higher education has previously been associated with greater improvements on the stress subscales of the Urogenital Distress Inventory (UDI), but not with any other positive outcomes of conservative management in women with SUI (Table 1 and 2). Qualitative research, however, has found that women with a higher socioeconomic status, based on education and income, were less likely to be satisfied with treatment results. A higher demand for treatment results is confirmed by quantitative research, finding cross-over to surgical treatment more likely among women with higher education level. Burgio et al. also found that patients with UUI and lower educational levels had better odds of treatment success.

Higher education is associated with higher self-efficacy and higher eHealth literacy. Factors that would influence the women’s ability to comprehend the information, use the app and perform PFMT. This may offer one explanation for the high completion rates in study 2 and the positive association between high education and completion found in paper IV.

Furthermore, education level is used as a measurement of socioeconomic position and is associated with income level. Lower socioeconomic status and income are associated with poorer health in general and higher rates of economic stress, which in turn has been found to be associated with failure of physiotherapy treatment.

In an American study of reasons for urinary incontinence remaining undiagnosed and untreated, lower income was associated with a lower rate of patient-provider discussions about incontinence. Whether this was due to lack of interest from the patient or reluctance on the part of the provider was not investigated.

At this point, it is impossible to answer the question of whether the large proportion of highly educated participants in our studies was due to the eHealth intervention, to a generally high participation of highly educated people in studies, or simply due to the implication that highly educated women prioritise treatment to a greater extent than women with lower education do. High educational level had a small impact on completion rates, but the diverging results from previous studies of success factors, and the lack of association with the global impression of improvement in papers III and IV, suggest that it would not have influenced the improvements from the app found in paper II and IV.
In conclusion, previous research provides several possible reasons for the high proportion of highly educated. However, neither previous research nor our results provide convincing evidence that women with lower educational level would benefit less if completing self-management.

**Adherence and pelvic floor muscle strength**

Adherence and increased pelvic floor muscle strength were clearly associated with higher odds of success. This is in line with many other studies finding that adherence\(^{93,101}\) and increased muscle strength\(^{101,163}\) both improve incontinence and sexual symptoms.

An increase in pelvic floor muscle strength improves symptoms even if there is no perfect correlation. This is partly probably explained by the increased sense of control due to the stronger voluntary contraction in the pelvic floor. It has also been argued that the physical skill of learning the contractions is linked with an emotional response and thereby empowers the patient.\(^{88}\) This would also increase self-efficacy, which in turn improves self-management.

When discussing self-management of urinary incontinence, Wilde et al. stress the importance of evaluation; lack of success might be due to lack of adherence to the plan or, in the case of PFMT, because the exercises have not been performed correctly.\(^{114}\) It is important to be aware that some women need further instructions to perform PFMT correctly, although instructions in the app offered similar advice as the verbal cues in the study by Henderson et al.\(^{69}\) Furthermore, there is some evidence that vaginal palpation and biofeedback may increase the effect of PFMT.\(^{164,165}\) Hence, women who self-managed with the app but did not perceive improvement in symptoms or pelvic floor muscle strength, may benefit from further assessment including a physical examination and feedback on pelvic floor muscle contractions. This should then not be seen as a failure of the patient or the app, but rather as functional stepped care.

Current recommendations are to perform PFMT with at least eight contractions three times a day, but scientific evidence for that recommendation is weak. Our results may suggest that performing PFMT regularly every week is sufficient. Furthermore, the additive effect of frequent app use could indicate that it is important to focus properly on the exercises. Perhaps, in light of discussed behavioural research, it is more important to enhance self-efficacy by reassuring women that they are doing enough by exercising focused a few times a week.

**Freely available self-management**

There are no previously published studies that assess complete self-management of urinary incontinence, without any contact with researchers or health care
personnel. Since only about 30% of women seek medical care for their urinary incontinence, it is reasonable to assume that they do indeed self-manage to a certain extent. However, Wilde et al. found that it cannot be expected of patients to self-manage completely on their own as their management strategies might not be evidence-based. If patients have no assistance in identifying helpful strategies, they may instead try harmful management strategies, such as severe fluid restriction, which may increase the risk of urinary tract infections without improving incontinence symptoms. A mobile app providing evidence-based information and support for PFMT may be a good way to increase access to evidence-based self-management.

Cost has been listed as a barrier to seeking help and to accessing self-management programmes. Research has also found that there is a demand for home-delivered self-management. That the Tät® app was free of charge and easily accessible could provide explanations for so many people using the app. Aside from cost, the barriers reported by Milne et al. may all have contributed to low completion rates. The app was developed for SUI management and participants with such symptom improved to a greater extent (Paper IV), participants with other types of incontinence may have found the information to be insufficient. Furthermore, some participants may have felt uncertain about performing the exercises correctly and others may simply have dropped out due to competing interests, or the perception of low psychosocial impact of urinary incontinence. However, the study also reported that most of the participants that performed PFMT on a regular basis had an established exercise routine. This was also a recommendation in the app, to incorporate the exercises into daily routines to be able to keep up the exercises long-term without thinking about having to do them. If successful, this would also cause the app to be redundant.

Another aspect that needs to be addressed is the demand for treatment. Non-face-to-face management of urinary incontinence increases access and lowers the barriers to seeking care. However, performing daily or weekly exercises requires commitment. If the woman does not find her symptoms bothersome, then she is less likely to seek care. She is probably also less likely to invest the time and effort required to complete the training and achieve improvements. Hence, the lack of effort required upon download may also be a reason explaining why a large portion of the users did not commit to the full three months of training.

As self-management research argues: the health care professionals can be of guidance but in the end it is the patient who decides to implement one intervention over another. Embarrassment or privacy concerns, as well as personal preferences and priorities, can influence this decision, which makes self-management an attractive, low-cost and time-efficient treatment option. Overall,
this thesis has shown both the efficacy and the effectiveness of self-management for urinary incontinence with the mobile app Tät®. Evaluation of the freely available app found it to be very effective for some, but not all, users. Perhaps this is also why systematic reviews of other mobile-based interventions for self-management have shown diverging results. Consequently, this thesis argues that the app should be offered as one of a range of treatment options.

**Implications for clinical practice**

Enhancing self-management is seen as an important part of high quality primary care. A stepped approach to assessment and management of urinary incontinence is one way of tackling the challenge of providing care for urinary incontinence. In the case of other somatic conditions the incorporation of internet and mobile-based solutions into routine care is already increasing. It is my opinion that primary care and the health care system in general, at least in Sweden, would benefit from working more actively with self-management and improving self-efficacy. A stepped care approach is suitable for many conditions including urinary incontinence. However, this also requires a variety of management options to meet the individual needs of each patient and achieve truly patient-centred care. Mobile-based self-management for urinary incontinence is an evidence-based way of providing a first step in high quality stepped care and of supporting self-management within primary care.

The Tät® app has the potential to reach many people and to help meet a great need for evidence-based care. Current statistics report that more than 55 000 users from countries all over the world have downloaded the app and submitted the baseline questionnaire. Further research has shown that it is a cost-effective way of providing first-line care and effective also at 2-year follow-up. However, Lorig and Holman highlight some problems with incorporating self-management into the health care provision; that there is a lack of structure and documentation, and that the health care system itself does not support self-management. This is also a problem of evidence-based eHealth interventions, and it most likely holds true for self-management of urinary incontinence via mobile apps. If we are to reap the full benefits of incorporating such methods into general health care, more research is needed, but also changes to the health care systems. Those changes include incitements for empowering patients to self-manage and offering a variety of evidence-based cost-effective management options.

**Implications for further research**

Only 14% of participants completed the three months of self-management, and even if there are some uncertainties about this data, many women did not
complete the self-management on their own when the app was freely available. There is also consensus that different behavioural changes could be used to improve PFMT adherence. Further, there are likely to be unexplored areas where self-management with the app could be even more effective in combination with regular primary health care system, using motivational interviewing, goal setting and other techniques to support the self-management.

Other advantages of the mobile app are that it can be translated into other languages and have a wide reach. When the last study of this thesis was conducted, the app was only available in Swedish and English. Since then it has been translated and released in Finnish, Spanish, German and Arabic, and work on an app in Sorani is in progress. The brochure described in study 1 has also been translated into those languages as well as Bosnian/Serbo Croatian. These are estimated to be the most common languages among minority populations in Sweden. Other Sweden-based minority groups have expressed language to be a barrier for seeking care for their urinary incontinence. This could be a way to increase the provision of evidence-based care to new populations within and outside of Sweden. However, inconsistency in our results concerning the use of the app in different languages indicates that more research is needed. Such research should aim to identify whether differences, attributable to language or culture, significantly influence the use of the app and the results from the self-management.

The Tät® app was developed to treat women with SUI, and when it was made freely available users with stress episodes also completed the programme and experienced improvements to a greater extent. Further research should evaluate the effects self-management via a mobile app for other types of urinary incontinence. This research is ongoing within the project eContinence.

Furthermore, the app has been reported to be used for preventive PFMT among pregnant and post-partum women. Determining whether training with the support of the app can be an effective preventive measure requires further evaluation.
Conclusions

- The symptom score ICIQ-UI SF and quality of life score ICIQ-LUTSqol are responsive enough to evaluate non-face-to-face conservative management in women with stress urinary incontinence. At a group level, reductions of 2.5 and 3.7 points respectively, or more should be considered clinically relevant improvement.

- Three months of self-management with the mobile app Tät® resulted in a clinically relevant reduction in symptoms and increased quality of life. The effects were comparable to other means of providing first-line treatment.

- Two thirds of users in an unselected population who completed three months of self-management without any support from the research team also experienced improvement and 29% stated that they were much or very much better.

- High expectations, weight stability and self-assessed improvement in pelvic floor muscle strength increase the odds of successful management.

- Background factors (age, educational level, type of incontinence and app language) only explain 2.7% of completion of self-management. Hence, there are no grounds for recommending self-management to certain groups based on such factors. Self-management with the Tät® app should instead be targeted at women who are interested in self-management and have high expectations for such management, and to women with stress incontinence symptoms.

- The frequency of pelvic floor muscle training and app use were the only factors that predicted both small and large improvements in the context of complete self-management when the app was freely available.

- Self-management of stress urinary incontinence via a mobile app is a new, effective way to provide first-line treatment.
Acknowledgement

As with self-management, the writing of a thesis is the result of the individual's ability in conjunction with surrounding support. I am very grateful to everyone who helped me through my work on this thesis. I would however, like to especially express my gratitude to the following:

_Eva Samuelsson_, my main supervisor, for your high scientific standards, concerning everything from writing accurately to data security. I might not have liked it at every step of the way but I am very thankful now. Thanks for setting deadlines and always finding time for feedback and support.

_Malin Sjöström_, my second supervisor, for always providing scientific and practical advice when needed, and for leading by example how to be a good researcher and physician without this having significant impact on quality of life.

_Ina Asklund_ for all your work with our joint articles and for your general support. It has been a pleasure sharing this time as a PhD student with you.

My _eContinence colleagues_ for making this research project such a structured, helpful and caring place to start a research career. A special thanks to _Susanne_ for the fantastic study coordination and being so supportive about everything.

_Hans Stenlund_ and _Lars Söderström_ for statistical support.

The _Unit of Education, Research and Development_ in Östersund for financial support and an encouraging atmosphere. Thank you all for making me feel included from the very beginning.

The _Family Medicine Unit, Umeå University_, for providing a supportive environment both in Östersund and in Umeå. In particular, _Maria Boström_ and _Marie Hammarstedt_, thanks for all your helpfulness.

The participants in the studies that made this thesis possible, for participating and for sharing your thoughts, and reminding us why this research is important.

My friends and colleagues at _Brunflo Primary Care Centre_ for making it so easy to combine research and clinical work. All of your support has meant a lot to me.

_Lena Lilja_, for your enthusiasm and caring supervision in my clinical work and for helping me balance work and life. Future research should take you as an example of how to improve self-efficacy.
The National Research School in General Practice for a great platform for finding inspiration, discussing science and learning from the best. A special thanks to Lars-Hjalmar Lindholm for your enthusiasm for internationalisation.

The National Institute for Health Innovation, Auckland University, for hosting me during my work on paper IV and Bruce Arroll, Auckland University, for teaching me the value of brief interventions in primary care.

My family, extended family and relatives, for the decades of support and encouragement that have led me here. A special thanks to Kathi for helping me through the writing process.

My friends for all your support and interest in this project for sharing your good advice in general and as fellow PhD students. I could never have managed without you.

Finally, my husband Kristoffer, for setting your priorities aside to support me and for helping me to cherish the challenge.
References


70. Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R. Pelvic floor muscle training included in a pregnancy exercise program is effective in primary


