

Internet-based Treatment of Stress Urinary Incontinence

Treatment Outcome, Patient Satisfaction, and Cost-Effectiveness

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To my family

Table of Contents

Table of Contents	ii
Abstract	iv
Original Papers	vi
Enkel sammanfattning på svenska	vii
Abbreviations	ix
Introduction	1
Background	2
Definition	2
Pathophysiology and Anatomy	2
Prevalence	3
Severity	3
Risk Factors	4
Natural History	4
Quality of Life	5
Help-Seeking Behaviour	5
Access to Care	6
Assessment	6
Treatment	9
Evaluating Treatment	14
Internet-Based Treatment	17
Cost-Effectiveness	18
Aims of the dissertation	20
Materials and methods	21
Enrolment of participants	22
The ICIQ questionnaires	24
Population and Methods - Paper I	24
Population and Methods – Paper II	28
Population and Methods – Paper III	30
Population and Methods – Paper IV	32
Statistics	33
Ethics	34
Tät.nu	35
Results	36
Demographics	36
Incontinence Severity Characteristics	39
Side Effects	39
Loss to Follow-Up	40
Treatment Outcome	41
Reliability of the ICIQ-LUTSqol	44

Patient Satisfaction	44
Cost-Effectiveness	46
Discussion	48
Methodological Considerations	48
<i>Overall strengths</i>	49
<i>Overall limitations</i>	49
<i>Paper I</i>	50
<i>Paper II</i>	50
<i>Paper III</i>	51
<i>Paper IV</i>	51
General Discussion	52
<i>Perspectives Regarding the Study Population</i>	52
<i>Representativeness</i>	52
<i>Access to care</i>	53
<i>Comparisons with other populations seeking care for urinary incontinence</i>	54
<i>Perspectives Regarding Treatment</i>	56
<i>Treatment effects compared with other studies</i>	56
<i>What constitutes clinically relevant improvement?</i>	57
<i>What constitutes a cure?</i>	60
<i>Accomplishment of treatment</i>	61
<i>Cost-effectiveness of the study treatments</i>	64
Future Perspectives	66
General Conclusions	68
Acknowledgements	69
References	71
Appendices	86
Original Papers I-IV	

Abstract

Background

Stress urinary incontinence (SUI) is the leakage of urine when coughing, sneezing, or on exertion. It affects 10-35% of women, and can impair quality of life (QOL). First-line treatment is pelvic floor muscle training (PFMT). However, access barriers and embarrassment may prevent women from seeking care. There is a need for new, easily accessible ways to provide treatment.

Aim

To evaluate the treatment outcome, patient satisfaction, and cost-effectiveness of an Internet-based treatment programme for SUI.

Methods

We recruited 250 community-dwelling women aged 18-70 years, with SUI ≥ 1 /week via our website. Participants were randomised to 3 months of PFMT with either an Internet-based programme (n=124), or a programme sent by post (n=126). We had no-face-to face contact with the participants, but the Internet group received individually tailored e-mail support from an urotherapist. Treatment outcome was evaluated after 4 months with intention-to-treat analysis. After treatment, we telephoned a strategic selection of participants (Internet n=13, postal n=8) to interview them about their experiences, and analysed the results according to grounded theory principles. We also performed a cost-utility analysis with a 1-year societal perspective, comparing the treatment programmes with each other and with a no-treatment alternative. To scrutinize our measure of QOL, we performed a reliability study of the ICIQ-LUTSqol questionnaire.

Results

Participants in both intervention groups achieved highly significant improvements ($p < 0.001$) with large effect sizes (> 0.8) in the primary outcomes symptom score (ICIQ-UI SF: mean change Internet 3.4 [SD 3.4], postal 2.9 [3.1]), and condition-specific QOL (ICIQ-LUTSqol: mean change Internet 4.8 [SD 6.1], postal 4.6 [SD 6.7]); however, the differences between the groups were not significant. Compared with the postal group, more participants in the Internet group perceived they were much or very much improved after treatment (40.9%, vs. 26.5%, $p = 0.01$), reduced their use of incontinence aids (59.5% vs. 41.4%, $p = 0.02$), and indicated satisfaction with the treatment programme (84.8% vs. 62.9%, $p < 0.001$).

Results from the interviews fell into three categories: about life with SUI and barriers to seeking care; about the study treatments and the patient-

provider relationship; and about the sense of empowerment many women experienced. A core category emerged: “Acknowledged but not exposed”.

The extra cost per quality-adjusted life year (QALY) gained through use of the Internet-based programme compared with the postal programme was €200. The extra cost per QALY for the Internet-based programme compared with no treatment was €30,935.

The condition-specific questionnaire ICIQ-LUTSqol is reliable in women with SUI, with high degrees of agreement between overall scores (Intraclass correlation coefficient 0.95, $p < 0.001$).

Conclusion

Internet-based treatment for SUI is a new, effective, and patient-appreciated treatment alternative, which can increase access to care in a sustainable way.

Original Papers

This thesis is based on the following papers:

- I.** Sjöström M, Umejford G, Carlbring P, Andersson G, Samuelsson E. Internet-based treatment of stress urinary incontinence. A randomised controlled study with focus on pelvic floor muscle training. *BJU Int* 2013;112:362-372.
- II.** Sjöström M, Stenlund H, Johansson S, Umejford G, Samuelsson E. Stress-urinary incontinence and quality of life: A reliability study of a condition-specific instrument in paper and web-based formats. *Neurourol Urodyn* 2012;31:1242-1246.
- III.** Björk AB, Sjöström M, Johansson EE, Samuelsson E, Umejford G. Women's experiences of Internet-based or postal treatment for stress urinary incontinence. Accepted for publication in *Qualitative Health Research*, Aug 8, 2013.
- IV.** Sjöström M, Umejford G, Lindholm L, Samuelsson E. Cost-effectiveness of an Internet-based treatment program for stress urinary incontinence. *Neurourol Urodyn* 2013. Dec 17. doi: 10.1002/nau.22540. [Epub ahead of print]

The papers will be referred to in the text by their Roman numerals. All papers are reprinted with permission of the copyright holders.

Enkel sammanfattning på svenska

Bakgrund

Ca 10-35 % av alla kvinnor har ansträngningsinkontinens, dvs läckage av urin i samband med hosta, nysning eller hopp. Besvären kan vara olika svåra, men ibland påverkar de livskvaliteten negativt. Bäckebottenträning ger förbättring eller bot för ca två tredjedelar, men en del drar sig för att söka vård, eller upplever att det är svårt att få vård. Det finns ett behov av nya, enkla och lättillgängliga behandlingsmetoder.

Syfte

Att utvärdera ett internetbaserat behandlingsprogram för ansträngningsinkontinens med avseende på behandlingseffekt, patientupplevelse och kostnadseffektivitet.

Metod

Via vår hemsida rekryterade vi 250 kvinnor, 18-70 år gamla, med ansträngningsinkontinens minst en gång i veckan. De lottades till tre månaders bäckebottenträning antingen via ett internetbaserat behandlingsprogram (n=124), eller via ett program som skickades ut som en broschyr med post (n=126). Under behandlingstiden fick deltagarna i internetgruppen stöd via e-post av en uroterapeut, medan deltagarna i broschyrgruppen genomförde behandlingen på egen hand. Vi träffade aldrig deltagarna, utan både utredning och behandling utfördes på distans. Efter fyra månader utvärderade vi behandlingseffekten. Sedan intervjuade vi ett strategiskt urval av kvinnor från båda grupperna (13 från internetgruppen och 8 från broschyrgruppen) om deras erfarenheter och analyserade resultaten med kvalitativ metodik. Dessutom genomförde vi en hälsoekonomisk analys, där vi jämförde de båda behandlingsprogrammen med varandra, och med ett alternativ där vi antog att deltagarna inte fick någon behandling alls.

Vi undersökte också om det frågeformulär vi använde för att utvärdera deltagarnas livskvalitet är tillförlitligt.

Resultat

Både behandling via Internet och via broschyr gav betydande förbättringar av symptom och livskvalitet, och det var ingen skillnad mellan grupperna i dessa utfallsmått. Däremot var det fler kvinnor i internetgruppen som upplevde en större förbättring, fler som minskade sin användning av inkontinensskydd, och fler som var nöjda med behandlingsprogrammet jämfört med i broschyrgruppen.

I intervjuerna berättade kvinnorna om att leva med inkontinens och att söka vård; om att genomgå behandling och den relation till behandlaren som uppstod; samt om en ökad känsla av egenmakt som upplevdes efteråt. Många av deltagarna, framför allt i internetgruppen, upplevde att de kände sig stöttade och sedda i sin situation, men med bibehållen integritet.

Det internetbaserade behandlingsprogrammet var kostnadseffektivt i jämförelse med broschyren, och även i jämförelse med icke-behandlingsalternativet.

Frågeformuläret ICIQ-LUTSqol är tillförlitligt för att utvärdera livskvalitet hos kvinnor med ansträngningsinkontinens.

Slutsats

Att behandla ansträngningsinkontinens via Internet är ett nytt, effektivt och uppskattat behandlingsalternativ, som skulle kunna öka tillgången till vård för denna patientgrupp på ett ekonomiskt hållbart sätt.

Abbreviations

BMI – Body Mass Index

CBT – Cognitive Behavioural Therapy

CI – Confidence Interval

CONSORT – Consolidated Standards of Reporting Trials

EQ5D-VAS – Euroqol 5 Dimension Visual Analogue Scale

GP – General Practitioner

HTA – Health Technology Assessment

ICC – Intraclass Correlation

ICER – Incremental Cost-Effectiveness Ratio

ICI – International Consultation on Incontinence

ICIQ – International Consultation on Incontinence Modular Questionnaire

ICIQ-LUTSqol – International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract Symptoms Quality of Life

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

ICS – International Continence Society

IEF – Incontinence Episode Frequency

KHQ – King's Health Questionnaire

NICE – National Institute of Health and Clinical Excellence

PFMT – Pelvic Floor Muscle Training

PGI-I - Patient Global Impression of Improvement

QALY – Quality-Adjusted Life Year

QOL – Quality of Life

RCT – Randomised Controlled Trial

SD – Standard Deviation

SUI – Stress Urinary Incontinence

Introduction

Worldwide, hundreds of millions of people are affected by urinary incontinence. It can be a bothersome and burdening condition for the individual, and costs to society are large.^{1, 2} Urinary incontinence occurs in both men and women, although overall it occurs about twice as frequently in women. The condition is more often associated with comorbidity in men than in women.³

Female urinary incontinence can be divided into three main types: stress urinary incontinence (SUI), which is the leakage of urine on sneezing, coughing, or exertion; urgency urinary incontinence, which is the leakage of urine preceded by a strong urge to void; and mixed urinary incontinence, which is a combination of the two.⁴ SUI accounts for approximately 50%, urgency incontinence for 11%, and mixed incontinence for 36% of cases. The remainder of cases (3%)⁵ are referred to as other types, which include for example urinary leakage caused by neurological disease or vesicovaginal fistulas.⁶

The prevalence of female urinary incontinence varies widely, and ranges from 5-69%.^{3, 7} Most studies report prevalence numbers of 25-45%, and approximately 5-15% of adult women suffer from daily leakage episodes.³ Overall, prevalence and severity increase with age. SUI is the predominant type in younger age groups, while urgency and mixed incontinence become more common in older age groups.⁵

I work as a general practitioner (GP) in Östersund, a small town in northern Sweden. My primary care unit employs GPs, nurses, midwives, and physiotherapists, among others. We serve an urban area, and the county hospital, which provides secondary care, is only kilometers away.

In my everyday practice, I meet many women complaining of urinary incontinence. Often, they mention their symptoms *en passant*, and with some embarrassment. Their expectations of treatment are low, and although symptoms might be disturbing, they often accept and adjust. If they do want treatment, I often feel I have little to offer them.

When I came across the research project www.tät.nu, I saw my chance to participate in something that had the potential to help many women. The project is financed with governmental and county council grants, and one of its aims is to develop easily accessible, evidence-based treatments for urinary incontinence. Eva Samuelsson is the principal investigator for the project. The papers included in this thesis are the first to emanate from the project.

From now on, unless otherwise explicitly stated, I will be discussing SUI.

Background

Definition

SUI is defined as the complaint of involuntary leakage of urine on effort or exertion, or on sneezing or coughing.⁴ The inclusion of the word “complaint” is important, because it adds the dimension of impact on quality of life (QOL).

Pathophysiology and Anatomy

An overview of the anatomy of the lower abdomen is presented in Figure 1. Leakage of urine occurs when the pressure in the urine bladder exceeds that exerted by the urethra. The bladder pressure increases when abdominal pressure is augmented, for example when sneezing, or on physical exertion. Consequently, the muscle tension in the pelvic floor (and therefore the pressure exerted by the urethra) is enhanced to inhibit urinary leakage. However, if the pelvic floor muscles are weak or too slow to react, or if the angle of the bladder neck is altered by urethral or bladder neck hypermobility, then the resulting urethral support might be too low, and leakage can result. In addition, the maximum urethral closure pressure (i.e., the strength of the urethral sphincters) is important for continence.⁸

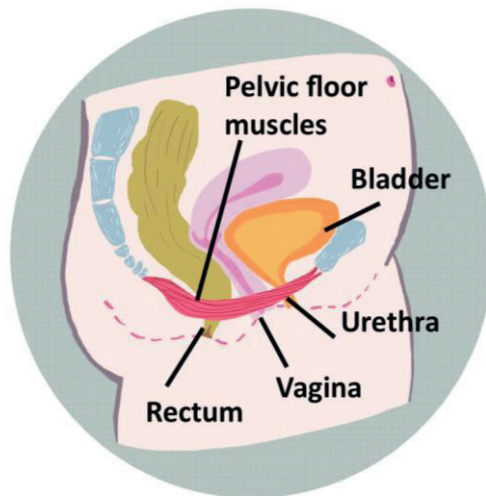


Fig. 1. Anatomy of the female lower abdomen, projection from the side.

Prevalence

The reported prevalence of SUI ranges from $\approx 10\%$ to 35% .³ This range results from heterogeneity in the use of definitions, methods, severity thresholds, and populations investigated. In addition, cultural and language differences may affect these values. The reported prevalence of SUI is at its highest in midlife, and levels off or gradually declines thereafter (Fig. 2).⁵

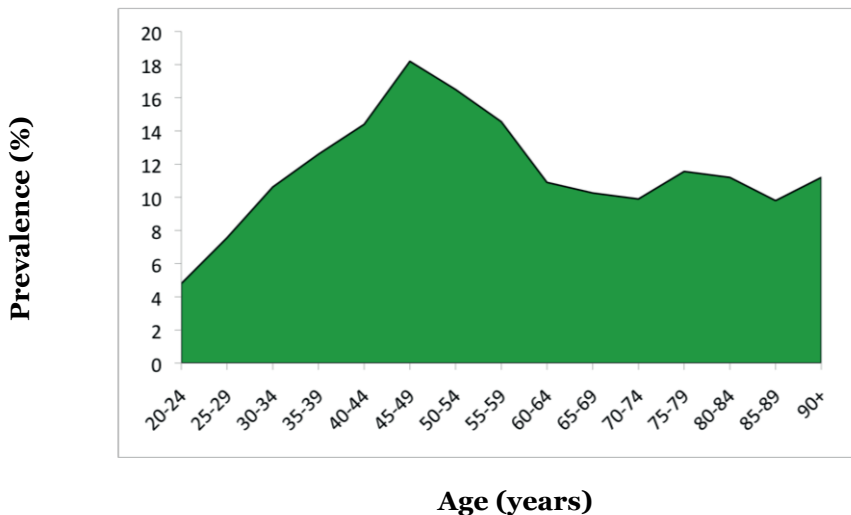


Fig. 2. Prevalence of stress urinary incontinence in community-dwelling women. Data from the Norwegian EPINCONT study (n=27936), Hannestad et al. 2000, compiled with permission from the authors.

Severity

The majority of women with SUI have slight (53%) or moderate (30%) leakage.⁵ As classified with the Incontinence Severity Index,⁹ this typically means leakage of drops from a few times a month (slight), to every day (moderate). Overall, 17% of women with SUI have severe leakage⁵ (i.e., leakage of large amounts at least once weekly⁹).

The severity of SUI increases with age. Ten percent of affected women aged 25-44 years experience severe leakage, compared with 15% and 33% of affected women aged 45-59 years and >60 years, respectively.⁵

Risk Factors

Pregnancy, parity, and parturition are probably the most predominant risk factors for SUI. Although ≈ 40 to 60% of pregnant women experience incontinence during pregnancy, it often resolves post-partum.^{10, 11} However, women that are incontinent during pregnancy are more likely to develop future urinary incontinence.^{3, 12, 13} Increasing parity increases the risk for SUI,¹⁴⁻¹⁸ and vaginal deliveries increase the risk compared with cesarian sections,^{19, 20} especially if vacuum extraction or episiotomy are performed.¹²

Overweight increases the risk for SUI.^{17, 18, 21, 22} Each 5-unit increase of the body mass index (BMI) increases the risk for urinary incontinence by 30-60%. This association is stronger for SUI than for other types of incontinence.²³

White women have a higher risk for SUI than black, Hispanic, and Asian women.^{17, 18} The reasons for this are not fully understood.^{3, 24}

Smoking increases the risk of developing SUI.^{17, 18, 21} It may cause coughing, which increases abdominal pressure, and it also affects connective tissue, which might reduce pelvic floor strength.³

The role of menopausal status regarding the risk for SUI is unclear, because it interacts with age, but hormonal factors are probably important.²⁵ Other risk factors are hereditary factors,²⁶ chronic obstructive pulmonary disease, constipation, diabetes mellitus, prolapse, and former gynecological surgery.^{3, 24, 27}

Natural History

SUI is a dynamic condition. Although spontaneous remission is possible, the condition might reoccur over time. In a recent Norwegian study based on a follow-up of the EPINCONT material, the overall incidence rate for SUI was 4.2% and the annual remission rate was 5.3%.²⁸ This data is in accordance with previous research, which reports incidence rates of 4-5%,^{18, 29} and annual remission rates of 4-6.8%.^{29, 30}

Remission is more likely with SUI than with other types of incontinence. It is also more likely in women younger than 55 years of age, and with slight symptoms.²⁸

Quality of Life

SUI affects every individual differently. The consequences of leaking urine may be considerable, and can cause distress, embarrassment, and limitations in everyday life. However, women accept and adjust to symptoms differently, and the condition might be more or less burdensome depending on each patient's life situation.

There are many factors that influence the perception of QOL, and it is difficult to disentangle what is what. In general, QOL in women with urinary leakage deteriorates with increasing age³¹ and with co-morbidity.^{32, 33} Women with urgency or mixed incontinence often experience greater effects on their everyday life than women with SUI.^{31, 34} However, these women are generally older, and experience more severe leakage.^{5, 35} Severe symptoms affect QOL more than slight symptoms,^{31, 32, 35, 36} and severity, rather than type, is the main predictor of QOL in women with urinary incontinence.^{32, 35, 37}

Because severity increases with age,⁵ older women might experience a greater impact on their QOL than younger women. On the other hand, because younger women often lead more active lives, they might be more limited by the leakage. Thus, it has been suggested that SUI affects the QOL of younger women as much as, or even more than, it affects the QOL of older women.^{33, 38, 39}

The leakage itself, or the fear of leaking urine, can affect many aspects of everyday life, such as the ability to travel, work, sleep, participate in physical activity, or interact with family and friends. Negative emotions, such as shame, and loss of dignity may be experienced.³⁶ Also, 11-60% of women with SUI report leakage of urine during sexual activity, which may lead to sexual dysfunction.⁴⁰

Help-Seeking Behaviour

Increasing age,⁴¹⁻⁴³ severity, and impact on QOL are associated with wanting treatment.^{35, 41-43} However, many women never seek care for SUI. Only ~10-20% of women with SUI have consulted a doctor for their symptoms.^{3, 41, 43} Women with SUI seem less prone to seek care than women with mixed or urge incontinence, possibly because women with SUI are generally younger and experience slighter symptoms.⁴¹

Common reasons for not seeking care include that symptoms are slight, and that urinary leakage is not a major problem.⁴⁴⁻⁴⁷ However, women can be ambivalent about how they regard urinary leakage.⁴⁸ These ambiguous

feelings might emanate from a cultural context normalising any leakage from the female body,⁴⁹ although the leakage might affect everyday life. Also, women might believe that urinary leakage is a natural consequence of giving birth,^{47, 50} might be unaware of existing treatment possibilities,^{42, 44, 45, 51} or might consider urinary incontinence a part of growing old.^{42, 44, 46, 52} Moreover, the occurrence of incontinence can be associated with guilt, because women may associate it with bodily neglect or with lack of self-discipline.⁴⁸ Embarrassment, shame, and fear of humiliation can also prevent women from seeking help.^{44, 47, 50, 52}

Access to Care

Access to care varies depending on the location and organisation of the health care system. In addition, urinary incontinence is often considered low-priority during times of financial constraint, with further reductions in access to care.

Once women have sought care, they might perceive that the subject of incontinence embarrasses their doctor or that they are not taken seriously,⁵³ or they might not be provided any treatment.⁴⁴ Furthermore, management of the condition might vary among practices, and among individual health care providers. Often, guidelines are not followed, and only one-third of those seeking care receive optimum treatment.⁴³ In a qualitative study from the Netherlands, the GP's lack of knowledge about treatment options and lack of time are identified as two factors that impede good quality of care.⁵⁴

Assessment

The initial assessment aims to identify symptoms that indicate a need for further physical examination and/or referral, distinguish type of incontinence, and evaluate symptom severity and effect on quality of life.

Symptoms that indicate need of further physical examination can be identified by taking a thorough history.²⁷ Such symptoms include macroscopic haematuria, pain, voiding problems, recurrent infections, symptomatic pelvic organ prolapse, signs of neurological disease, previous pelvic irradiation or malignancy, previous incontinence surgery, and suspected fistulas.⁴ The patient's history should also include information about when leakage occurs, frequency and amount of leakage, previous

treatment, co-existing diseases, obstetric and gynecological history, current medication, and lifestyle factors (e.g., fluid intake, exercise, and smoking).

It is important to distinguish the type of incontinence because treatment might differ with respect to incontinence type. In addition, pure SUI is not associated with any severe conditions, while urgency incontinence is sometimes a symptom of serious conditions, such as bladder or ovarian malignancy.⁶

There is no gold standard regarding how to diagnose SUI. Historically, urodynamics and extensive assessment (including clinical assessment and urodynamic findings) have each been used as reference methods. However, SUI can be diagnosed using simpler methods. For example, in 1991, Lagro-Jansen et al. showed that in primary care, the patient's history of symptoms can diagnose SUI with a sensitivity of 0.78 and a specificity of 0.84.⁵⁵ In 1995, Sandvik et al. demonstrated that the simple question "Do you lose urine during sudden physical exertion, lifting, coughing, or sneezing?" diagnoses SUI with a sensitivity of 0.66 and a specificity of 0.88.⁵⁶ Several other studies confirm these findings, and in 2006, a review of 15 studies presented pooled data establishing that in primary care, thorough history taking alone diagnoses SUI with a sensitivity of 0.92, and a specificity of 0.56.⁵⁷

At present, guidelines confirm SUI can be diagnosed by history alone. There is consensus that urodynamics should be used only when the results might change management (e.g., if treatment has failed, or prior to surgical intervention),^{4, 24, 27, 58} and that pad-testing, cystoscopy, and imaging are not needed initially.^{4, 24, 27, 58} However, guidelines are conflicting regarding exactly what the initial assessment should include (Table I).

Although a physical examination is often recommended,^{3, 27, 58} no studies have determined its necessity. In addition, clinical expertise assumes that a digital assessment of a correct pelvic floor muscle contraction will aid the patient in performing future pelvic floor muscle training (PFMT);²⁷ however, such digital assessment has not been established to enhance the effects of training. Recently, Henderson et al. demonstrated that 83.4% of women with SUI were able to contract their pelvic floor muscles correctly on the first attempt; 88% of those that were unable learned after a simple verbal cue.⁵⁹

In a bladder diary, the woman registers time and volume of micturition, as well as any leakage. Registration during 2-3 non-consecutive days is sufficient.⁶⁰ High frequency of voiding, low average and maximum voided volumes, and nocturia can indicate a type of incontinence other than SUI.

Urine analysis with a dipstick can identify a urinary tract infection, microscopic haematuria, and glucoseuria. However, such symptoms are more often associated with urgency than with stress incontinence

symptoms.⁶ In a stress test, the woman coughs or strains with a filled bladder, either in the supine or erect position. Occurrence of leakage indicates SUI;⁵⁸ however, the test might be difficult to perform in primary care.

In all, there is high level of evidence that SUI can be diagnosed from history alone, and that further investigation can be kept to a minimum.^{4, 24, 27, 57, 58}

Table I. Examples of recommendations regarding what should be included in the initial assessment of women with SUI.

	NICE^a clinical guidelines 2006²⁷	ICS^b Recomm- endations Abrams et al. 2010⁴	AHRQ^c Comparative Effectiveness Review Shamliyan et al. 2012²⁴
SUI distinguishable by history alone	Yes	Yes	Yes
Physical examination	Yes, but low level of evidence	Yes	Unclear
Control of pelvic floor muscle contraction	Yes, based on clinical expertise	Yes	Not mentioned
Bladder diary	Yes	Optional	Yes
Urine analysis	Yes	Yes	Unclear
Stress test	No	Yes	Unclear
Residual urine	Only if symptoms of voiding dysfunction	Only if symptoms of voiding dysfunction	Not mentioned
Low-risk, low-cost treatment can be initiated based on:	1. History 2. Physical examination 3. Bladder diary 4. Urine analysis	1. History 2. Physical examination 3. Urine analysis	1. History (including validated questionnaires) 2. Bladder diary

^a National Institute for Health and Clinical excellence

^b International Continence Society

^c Agency for Healthcare Research and Quality

Treatment

Pelvic floor muscle training

A number of randomised controlled trials (RCTs) have established that PFMT improves SUI.⁶¹⁻⁶⁴ Two-thirds of patients are improved or cured by this treatment, and it has no serious side effects.^{24, 27, 63} Long-term effects are not clear;⁶⁵ however, according to some studies, $\approx 70\%$ remain satisfied after 5 years.^{66, 67} Of women initially treated with PFMT, 4.9% to 58% eventually undergo surgery for their leakage.⁶⁵

Although the exact biological rationale for PFMT is not known, increased muscle volume and stiffness are thought to add support to the bladder.^{68, 69} Continent women have stronger and thicker pelvic floor muscles than incontinent women,⁷⁰ and increased strength of the pelvic floor muscles has been shown in women that were treated successfully with PFMT for SUI.⁶¹

The intensity of training should increase gradually, and should include both maximal and submaximal contractions with adequate resting periods.⁶⁹ In addition to exercises for strength and endurance, “the knack”,⁷¹ a voluntary quick contraction of the pelvic floor before an increase of abdominal pressure (e.g., when lifting, laughing, or sneezing), should be taught for increased coordination and rapidity of the muscles.^{68, 69}

However, it is unclear exactly how PFMT should be performed for the best effect. Comparisons and meta-analyses of existing studies are complicated by the large variety of PFMT regimens. Furthermore, the exact exercise regimens are often poorly reported, and there is broad heterogeneity in training dosage and adherence to training.^{24, 27, 63, 65, 72} No clear dose-response curve has been established, and the ideal number of repetitions, duration, and strength of contractions, as well as in what body position the exercises should be performed, are unknown. In addition, there is uncertainty regarding the best way to deliver PFMT.^{27, 69}

Current guidelines from the National Institute of Health and Clinical Excellence (NICE), dating from 2006, recommend supervised training during at least 3 months, with a minimum of eight contractions three times daily.²⁷ The guidelines state that intense regimens render better outcomes, although why training should be supervised is not explicitly stated. Although several RCTs state that supervised PFMT is more effective than non-supervised,⁷³⁻⁷⁶ the quality of these studies is variable (Table II). Additionally, the International Continence Society (ICS)⁴ and a Cochrane report from 2011 also recommend supervised PFMT.⁷² However, the Cochrane report concludes that there is not enough evidence for any strong recommendations regarding which regimen is the best; nevertheless,

it suggests that supervised training might be the best approach, because women that were offered regular contact with health care personnel were consistently more likely to improve than those that were not offered such contact.⁷² Exactly what supervision should include remains unclear.

On the other hand, although methodological concerns can be raised, several RCTs published within the past 5 years report that self-completed

Table II. Examples of RCTs comparing supervised and unsupervised pelvic

Author & Publication year	Population	Interventions
<i>Pro supervised:</i>		
Bö et al. (1990) ⁷³	57 women with clinical and urodynamic SUI	6 months of PFMT: A. Supervised 1/week B. Unsupervised
Konstantinodou et al. (2007) ⁷⁴	30 women with clinical and urodynamic SUI, ≥ 7 /week	3 months of PFMT: A. Supervised 1/week B. Unsupervised
Zanetti et al. (2007) ⁷⁵	44 women with urodynamic SUI	3 months of PFMT: A. Supervised 2/week B. Unsupervised
Tsai et al. (2009) ⁷⁶	108 women with SUI	3 months of PFMT: A. Supervised B. Unsupervised
<i>Pro unsupervised:</i>		
de Oliveira Camargo et al. (2009) ⁷⁷	61 women with urodynamic SUI	3 months of PFMT: A. Supervised 2/week B. Unsupervised
Felicissimo et al. (2010) ⁷⁸	62 women with urodynamic SUI	8 weeks of PFMT: A. Supervised 2/week B. Unsupervised
Åhlund et al. (2013) ⁷⁹	98 primiparous women with SUI 10-16 weeks after normal-term singleton vaginal delivery	6 months of PFMT: A. Supervised 3 times total B. Unsupervised

PFMT is as effective as supervised training (Table II).⁷⁷⁻⁷⁹

This approach is further supported by a 2012 American review of pooled data, which concludes that there are no significant differences between self-completed and supervised PFMT with regard to the likelihood of improving SUI symptoms, improving QOL, achieving continence, or the rates of treatment failure or discontinuation.²⁴

floor muscle training (PFMT) as treatment for SUI in women.

Mean age, years	Primary Outcome (within-group p-value)	Between-group p-value	Lost to follow-up
45.4	Primary outcome not stated. Proportion reporting continence or almost continence after treatment: A. 60.1% (14/23) B. 17.3% (5/29)	A>B P<0.01	A+B. 8.8% (5/57)
47.8	Subjective Improvement (Yes/No): A. 100% improved B. 20% improved	A>B p<0.001	A. 20% (3/15) B. 33.3% (5/15)
55 (median)	Reduction of 1 h pad test weight (g): A. From 20.1 to 3.2 (p=0.0002) B. From 24.7 to 15 (p=0.045)	0.0018	Not reported
55.4	Reduction of 1 h pad test weight (g): A. From 0.33 to 0.20 (p<0.001) B. From 0.40 to 0.45 (p=0.514)	Not reported	A+B. 8.3% (9/108)
51	Negative 1 h pad test (<2 g): A. 46% (14/30) B. 53% (16/30)	NS	A+B. 1.2% (1/61)
49.7	Reduction of 1h pad test weight (g): A. From 4.5 to 3.2 (p=0.01) B. From 9.3 to 2.8 (p=0.001)	NS	Not reported
33	PFM strength (cmHg): A. From 16.2 to 26.0 (p<0.05) B. From 12.1 to 18.2 (p<0.05)	NS	A. 18.4% (9/49) B. 14.3% (7/49)

Lifestyle changes

Weight loss might be effective in addition to PFMT as SUI treatment in obese (BMI>30) or overweight (BMI>25) women. In women with a mean BMI of 36, an 8% weight reduction reduced the number of weekly leakage episodes by 58% (from 9 to 4).⁸⁰

Other potential lifestyle changes are fluid reduction if high,⁸¹ and decreasing the intake of caffeinated drinks.^{27, 82}

A few studies suggest that cognitive behavioural therapy (CBT) strategies might improve QOL⁸³ and reduce the number of weekly leakage episodes (from 16.8 to 8) in patients with urinary incontinence.⁸⁴ However, these studies included patients with all types of incontinence, and it is not clear whether the results apply to women with pure SUI.

Surgery

There are several surgical procedures for SUI treatment. Most often, a synthetic mesh or tape is inserted to support the urethra.⁸⁵ There are various techniques that employ different approaches and meshes, all with similar effectiveness.⁸⁶⁻⁸⁸ Most techniques use a transvaginal approach, and can be performed under local anesthesia. Complication rates are 6% to 19%, and include vaginal, bladder, bowel, or vascular injuries; wound infections; tape erosions; voiding difficulties; and new onset of urge incontinence.^{86, 89} Patient-reported cure rates 1 year after surgery are approximately 75%;⁸⁷ after 5 years, 90% remain satisfied with the results of surgery.⁹⁰

Pharmacological treatment

Duloxetine, a selective serotonin and noradrenaline reuptake inhibitor, can be used for SUI treatment. Although it was first registered as an antidepressant, it was found to have beneficial effects on SUI in women.⁹¹ Pooled estimates show that women treated with duloxetine have a greater chance of reducing the number of leakage episodes >50% than those receiving placebo (RR 1.46; 95% CI 1.28 to 1.66).²⁴ In one large RCT, the number of leakage episodes was reduced by 54% with duloxetine (from 14.0 to 6 episodes per week).⁹² However, duloxetine only results in improvement for 75 to 140 women per 1000 women treated, and for many, the risk of side effects is higher than the potential benefits with treatment.²⁴ Between 13% and 20% of women will not tolerate duloxetine owing to side effects including nausea, headaches, insomnia, dizziness, and fatigue.^{24, 82, 92}

Oral estrogen replacement therapy might worsen SUI.²⁵ Two large RCTs (total n=24,821) demonstrate that it increases leakage frequency.^{93, 94}

amount of leakage, limitations on daily activities, and the degree of bother in women with all types of urinary incontinence.⁹³

Conversely, topical estrogens might have beneficial effects on SUI in postmenopausal women.⁹⁵ However, recommendations regarding their use to treat SUI are conflicting. A recent Cochrane report supports their use,²⁵ although other reviews and guidelines do not.^{27, 82}

Recommended treatment pathways

PFMT is the recommended first-line treatment for SUI.^{4, 24, 27, 63, 82} It is safe and effective, with few side effects. Surgical treatment should be considered if the woman is not satisfied with the result of PFMT.^{27, 82} Pharmacological treatment is considered for women who are unsuitable for surgery, or who do not want surgery.²⁷ This treatment pathway is supported by cost-effectiveness analyses.^{27, 82}

A recent RCT compares the effect of PFMT with the effect of sling surgery. After 12 months, 85.2% of participants that underwent surgery reported subjective cure (no leakage symptoms), compared with 53.4% of participants in the PFMT arm (including women that crossed over to surgery). The authors question the position of PFMT as the recommended first-line treatment, and suggest that surgery should be considered earlier and the choice between the two should be based on each patient's preference.⁹⁶

Everyday practice

SUI can be successfully treated in primary care;^{64, 97, 98} however, how first-line treatment is provided varies between countries and between care settings. A GP consultation is often the first level of care,^{43, 82} although in some places women with SUI are referred directly to secondary care for further management.

In Sweden, primary care is expected to provide initial assessment and treatment for SUI, and written instructions for completion of PFMT at home are often employed. Goode et al. have demonstrated that such self-help booklets reduce the number of weekly leakage episodes by 50%, from 14.8 episodes to 7.5.⁹⁹ Conversely, Konstantinoudou et al. reported that handouts with PFMT instructions only reduced the number of weekly leakage episodes from 14.8 to 12.5.⁷⁴

In their review from 2012, Shamliyan et al. addressed the need for more research regarding how to provide new, simple, and accessible ways to deliver non-pharmacological treatment for urinary incontinence.²⁴

Evaluating Treatment

Outcome measures

SUI is not a lethal disease, and there are no hard endpoints to evaluate except for the total absence of leakage. However, reduced symptom severity might greatly improve QOL for many patients and render them satisfied with treatment.¹⁰⁰ Although there is an association between symptom severity and the impact of SUI on QOL, each individual is differently affected. Evaluation of severity alone might not capture outcomes that are of importance for each individual affected woman. Therefore, it is strongly recommended that both symptom severity and impact on QOL be included as outcome measures in clinical practice and research settings. ^{4, 24, 27}

There might be discrepancies in how caregivers and patients regard symptom severity and QOL.¹⁰¹⁻¹⁰³ Therefore, direct reports from the patient have been introduced to achieve more patient-centered care. Typically, patient-reported outcomes are collected in a questionnaire that has been completed by the patient. When correctly developed and thoroughly validated (see below), such a questionnaire is considered a reliable outcome measure. The ICS strongly recommends the use of patient-reported outcomes to evaluate treatment.⁴

Patient-reported outcomes should be combined with other outcomes that quantify the loss of urine.^{4, 103} Examples of such outcomes commonly used in studies of SUI include the number of leakage episodes as registered with a bladder diary [i.e., the incontinence episode frequency (IEF)] and the use of incontinence aids.

Another commonly used, validated, and recommended²⁴ outcome measure is the Patient Global Impression of Improvement (PGI-I).¹⁰⁴ This is a single question posed after treatment, asking the patient to rate her condition now compared with before treatment.

Validating a questionnaire

Several psychometric properties must be established during the development of a questionnaire. The process is often lengthy, and must be repeated in every population in which the questionnaire will be used. A questionnaire is considered validated when the following psychometric properties have been established:^{105, 106}

- *Validity*: The questionnaire measures what it is intended to measure (face validity). It makes sense to patients and clinical experts (content validity). It relates well to other similar measurements (construct validity), and to a gold standard if such a standard exists (criterion validity). Determined by qualitative interviews, comparisons with other measures, and conformity with existing theoretical framework.
- *Internal consistency*: This assesses the extent to which included items are related to each other, and how they contribute to the overall score. Determined by calculation of the Cronbach's alpha coefficient.
- *Stability or test-retest reliability*: The questionnaire measures the same thing in the same person over time, and results can be reproduced with repeated testing. Determined by letting the same person answer the questionnaire twice within a specified amount of time during which symptoms are unlikely to change. Then, intraclass correlation coefficients and kappa values are calculated.
- *Responsiveness*: This assesses how well the questionnaire measures change. Determined by comparing the response of the questionnaire with other measures that are of known clinical relevance.

Although questionnaires are traditionally printed on paper, technological advances provide new possibilities for data collection. Electronic versions of questionnaires can reduce workload and costs because they are easier to administer, response rates might be higher, and transcription errors are minimized.¹⁰⁷⁻¹⁰⁹ However, the mode of administration might alter the psychometric properties of a questionnaire, and it is important to undertake additional testing when converting a questionnaire from paper to a web-based format.¹⁰⁸

Recommended questionnaires

Many highly recommended and validated questionnaires are currently in use. This diversity makes a comparison of outcome measures between settings difficult, and there is a need for more standardisation regarding their use.^{4, 24, 110}

Some examples of grade A recommended²⁷ questionnaires for evaluation of symptom severity and/or QOL in incontinence are: the Incontinence Severity Index (ISI),^{9, 111} the Patient Global Impression of Improvement (PGI-I),¹⁰⁴ the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ),¹¹² the King's Health Questionnaire,¹¹³ the Bristol Female Lower Urinary Tract Symptoms (B-FLUTS),¹¹⁴ the Incontinence Quality of Life (I-QOL),¹¹⁵ the IIQ,¹¹⁶ and the Urinary Incontinence Severity Score (UISS).¹¹⁷

The International Consultation on Incontinence (ICI) was founded in 1998, with support from the ICS and the World Health Organisation (WHO). The organisation has developed a project, known as the International Consultation on Incontinence Modular Questionnaire (ICIQ), that promotes the use of standardised questionnaires in the evaluation of incontinence symptoms. Since its founding, the project has incorporated several questionnaires into its modular structure, an overview of which can be found at the website <http://www.iciq.net>. All ICIQ questionnaires are highly recommended as outcome measures.^{4, 24, 27, 103} This thesis uses two of them:

- 1.** The International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF): a questionnaire for evaluating symptom severity.¹¹⁸ The ICIQ-UI SF is fully validated, brief, and simple to use. It can be used in a wide variety of research and clinical settings ranging from surgery to conservative treatment, and is available in 30 languages.¹¹⁹
- 2.** The International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol): a condition-specific questionnaire for evaluating the impact of incontinence on QOL.¹¹³ The ICIQ derived the questionnaire¹²⁰ from the King's Health Questionnaire (KHQ),¹¹³ a well established questionnaire in terms of validity, internal consistency, and responsiveness in women with SUI.^{105, 113, 121-123} However, when this thesis was being planned, there was no published study on the test-retest reliability of the ICIQ-LUTSqol. It is available in 44 languages.¹¹⁹

Internet-Based Treatment

The expansion of the Internet has brought about new possibilities to provide treatment. In Sweden, 94% of the population had access to a computer with an Internet connection in 2012, and 80% used the Internet on a daily basis.¹²⁴ As of May 2013, 85% of Americans used the Internet regularly, and 76% had Internet access at home.¹²⁵ Those with low income/education and the elderly have lower access to the Internet than the rest of the populace, and do not use it as often.¹²⁴

Among American Internet users 2012, 72% used the Internet to obtain health information.¹²⁶ Women are more likely than men to go online to seek health information,¹²⁶ especially about issues that are perceived as embarrassing.¹²⁷ Younger people, those living in households with annual incomes of >\$75,000 USD, whites, and those with higher education also have a high likelihood of using the Internet to look for health information.¹²⁶

Internet-based treatments have been developed for several conditions, including headache, chronic pain, obesity, and irritable bowel syndrome.¹²⁸ Research in the psychological field has come a long way, and Internet-based CBT for depression, social phobia, and panic disorder is considered well-established.¹²⁹ Internet-based treatments can be used as stand-alone treatment, or as an adjunct to ordinary face-to-face care. Although the literature is not consistent regarding its effectiveness, there are studies that demonstrate effectiveness compared with control groups, care-as-usual, and enhanced face-to-face treatment.¹³⁰

Many patients appreciate Internet-based treatment. It is perceived as convenient, accessible and time-sparing,¹³¹⁻¹³³ and the barrier to seeking care appears to be lower than for ordinary care.¹³²

In addition, the Internet is a useful tool to communicate with patients with stigmatized illnesses.¹³⁴ However, the patient-provider relationship via the Internet is likely to be different than in ordinary care. Communication with the therapist is often text-based, verbal and visual cues are lost, and patients must be able to express themselves in writing. On the other hand, text-based communication might enable the disclosure of sensitive issues because it is perceived as more anonymous.¹³¹

To the best of our knowledge, there are no previous studies on Internet-based treatment for SUI.

Cost-Effectiveness

There is a need for scientific information regarding what treatments to administer within the publically funded health care sector. Health economic evaluations can help guide such decisions by assessing whether or not a specific treatment is cost-effective (i.e., if its costs are reasonable considering the health improvements it renders). The aim of health economic analysis is not to save money, but to direct the use of common resources in a way that provides as much health as possible for the population – known as the principle of health maximisation.¹³⁵ Many analyses include uncertainty, and results should be regarded more as guidance for policymakers, clinicians, and other stakeholders than as a very precise measure of the actual costs and effects of the included alternatives.

There are several different types of health economic analyses. Nowadays the cost-utility analysis is one of the most common. It is comparative and considers the costs and effects of at least two treatment alternatives.¹³⁶ The cost-utility analysis has been recommended by the Swedish Dental and Pharmaceutical Benefits Agency.¹³⁷

Costs

Costs can be considered from one of two perspectives: a health care perspective, which includes only the costs and savings that fall on the health care system; and a societal perspective, which includes all available costs and savings. In Sweden, the Dental and Pharmaceutical Benefits Agency recommends cost-utility analyses that apply societal perspectives.¹³⁷ The same perspective is recommended in the United States,¹³⁸ while NICE in the United Kingdom recommends a narrower perspective that includes only costs that fall on the National Health System.¹³⁹

Effects

In a cost-utility analysis, effects are measured in terms of quality-adjusted life years (QALYs) gained or lost as a result of each treatment alternative. This is a standardised way to evaluate what effect a condition has on the QOL of the patient, and it allows for the comparison of treatments for diverse health conditions. To calculate QALYs, the QOL of the patient is repeatedly evaluated, i.e. before and after treatment. This evaluation can be performed with either a health-specific or a condition-specific QOL questionnaire.

A health-specific questionnaire evaluates QOL using a broad perspective, can be used for different conditions and in different populations, and is the most commonly used measure for QALY calculation. Examples of validated

health-specific questionnaires are the EQ-5D¹⁴⁰ and the SF-36.¹⁴¹ NICE recommends that the EQ-5D be used in health economic evaluations.¹³⁹

However, there is conflicting evidence regarding whether a health-specific questionnaire is sensitive enough to capture the full effect of urinary incontinence on QOL. Some studies demonstrate that increased leakage severity correlates well with a decline of health-specific QOL,^{32, 142} while others suggest that health-specific questionnaires are not sufficiently responsive regarding the symptoms experienced in this population.^{82, 143-146}

A condition-specific QOL questionnaire can be used in lieu of a broader health-specific questionnaire. Such a questionnaire is designed to measure the impact of a particular condition on QOL.¹⁴⁷ Compared with health-specific questionnaires, utility weights derived from condition-specific questionnaires might display a narrower range of values, because the condition-specific questionnaire considers a smaller subset of health problems that affect QOL.¹⁴⁶ A method has been developed that uses the condition-specific QOL instrument KHQ to calculate QALYs for individuals with urinary incontinence.¹⁴⁶

Theoretically, Internet-based treatments are likely to be cost-effective because treatment can be delivered using limited therapist time.^{129, 148} Good or acceptable cost-effectiveness has been established for Internet-based treatment of depression, social phobia, and panic disorders.¹²⁹ However, data on the cost-effectiveness of Internet-based interventions is scarce, owing to the limited number of studies that have been conducted, methodological considerations, and non-conclusive evidence regarding the effects.¹⁴⁹ In many reviews, any specific conclusions have not been able to draw,¹⁴⁹⁻¹⁵¹ and there is a need for more research within this field.^{149, 152}

Aims of the dissertation

The overall aim of this dissertation is to evaluate an Internet-based treatment programme for SUI with respect to treatment outcome, patient satisfaction, and cost-effectiveness.

The specific aims of the included papers are as follows:

- I.** To compare the effects of two treatment programmes for SUI based on pelvic floor muscle training: one Internet-based and one sent by post. (Treatment outcome)
- II.** To examine the reliability of the condition-specific quality of life questionnaire ICIQ-LUTSqol in paper and web-based formats.
- III.** To explore women's experiences of an Internet-based and a postal treatment programme for SUI. (Patient satisfaction)
- IV.** To analyse the cost-effectiveness of an Internet-based and a postal treatment programme for SUI from a 1-year societal perspective, comparing the two treatment programmes with each other and with a no-treatment alternative. (Cost-effectiveness)

Materials and methods

This thesis is based on four papers, an overview of which is presented in Table III.

Table III. Materials and methods used in the papers comprising this thesis.

Paper	I	II	III	IV
Design	RCT	Reliability Study	Qualitative Study	Health Economic Analysis
Study Group	Online recruitment of 250 women, age 18-70 years, with SUI ≥ 1 /week Follow-up 4 months	<i>Paper vs. paper:</i> Cohort of 78 participants from Paper I at baseline <i>Paper vs. web:</i> Cohort of 54 participants from Paper I at follow-up 4 months	Strategic selection of 21 participants from Paper 1 shortly after 4 months of follow-up	All participants in Paper I Follow-up 4 months and 1 year
Data Collection Method	Self-assessed questionnaires 2-day bladder diary	Self-assessed condition-specific quality of life questionnaire in paper or web-based format	Semi-structured telephone interview	Self-assessed questionnaires Continuous registration of costs during treatment delivery
Data Analysis	Comparative	Statistical	Grounded Theory	Deterministic cost-utility analysis; 1 year; societal perspective

Enrolment of participants

The enrolment of participants for *Paper I* is described in Figure 3. *Paper II* is based on a cohort, and *Paper III* on a strategic selection, of these participants. The population in *Paper IV* is the same as in *Paper I*, albeit with a longer follow-up duration.

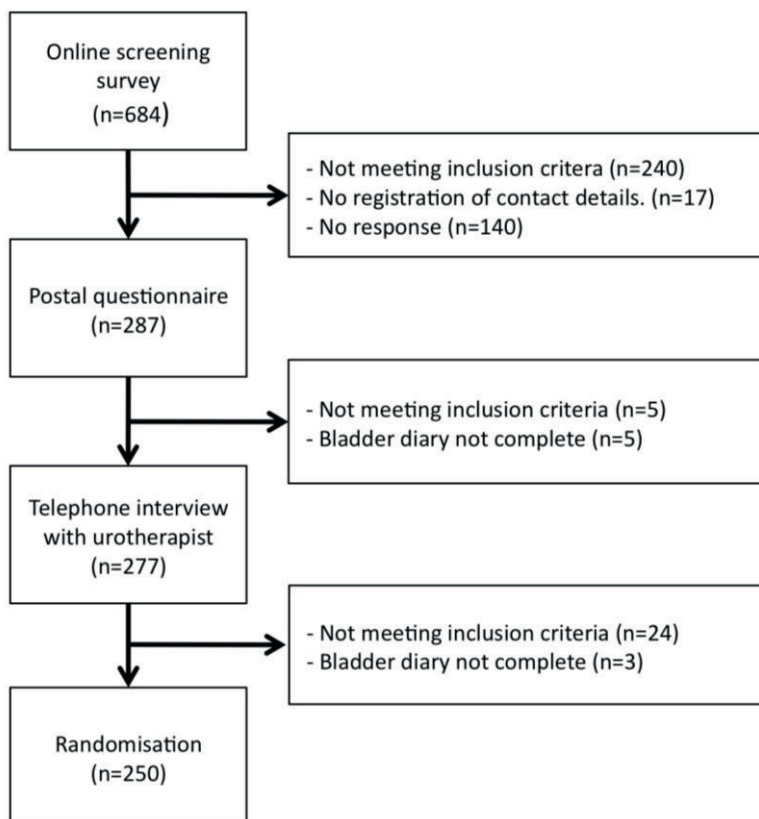


Fig. 3. Enrolment of participants for *Paper I*.

We included 250 community-dwelling women, aged 18-70 years, with SUI ≥ 1 incident per week. Participants had to have access to a computer with an Internet connection and had to be able to communicate in Swedish. Exclusion criteria were: pregnancy, previous incontinence surgery, known malignancy in lower abdomen, difficulties passing urine, macroscopic

haematuria, intermenstrual bleeding, severe psychiatric disorder, and neurological disease affecting sensibility in the legs or lower abdomen.

The study was launched with a press release, and was mentioned by several media (e.g. radio, newspapers, websites, etc.). In addition, we advertised the study in waiting rooms at primary care units, national newspapers, gym chains, and websites on health-related topics, as well as in social media.

Women interested in participating were referred to the project's open access web site, <http://www.tät.nu>. Here, they answered a 17-item online survey with immediate automated response for initial screening of inclusion and exclusion criteria. Those considered eligible registered their contact details. For further evaluation, we sent them a postal questionnaire including a detailed medical history, socio-economic data, lifestyle, Internet usage, symptoms of anxiety or depression [the Hospital Anxiety and Depression Scale (HADS)],¹⁵³ validated questionnaires, and a two-day bladder diary.

On return, all questionnaires and bladder diaries were assessed by one of the GPs in the research team. Finally, the clinical diagnosis of SUI was confirmed by a urotherapist via telephone.

We considered bladder diaries normal when the maximum bladder volume was >250 ml, and the mean micturition volume was ≥ 150 ml.

If participants stated any medication that could affect incontinence, such as diuretics, antimuscarinics, or duloxetine, the urotherapists investigated for how long the medication had been used. If it had been used for more than 6 months, the woman was included in the study.

A GP contacted all women with HADS score ≥ 11 for depression or anxiety by telephone. If the HADS score was ≥ 15 for either scale, the woman was given medical advice and excluded. If the HADS score was 11-14 on either scale, an individual assessment was performed.

GPs and urotherapists conducted weekly telephone conferences in which any medical uncertainty was discussed. In each case, we made an individual assessment about inclusion or exclusion. If it was considered necessary, a GP contacted the woman via telephone to provide medical advice and/or referral. We had no face-to-face contact with the study participants during the enrolment process.

The ICIQ questionnaires

ICIQ-UI SF

This validated questionnaire¹¹⁸ measures symptom severity, and is used in *Paper I* and *Paper IV*. It contains three scored items that respectively assess frequency, amount of leakage, and overall impact on QOL. Overall score is additive (0-21), and higher scores indicate increased severity. The questionnaire also contains a fourth item, not included in the total score, which can be used to assess type of incontinence (Appendix A).

Using the overall score, symptoms can be categorised into severity categories¹⁵⁴ (overall score 1-5=slight, 6-12=moderate, 13-18=severe, 19-21=very severe).

ICIQ-LUTSqol

This questionnaire¹¹³ measures condition-specific QOL, and is used in *Papers I, II*, and *IV*. It contains 19 items that assess role, physical and social limitations, personal relationships, emotions, and sleep. All items are scored 1-4 (not at all/slightly/moderately/a lot, or never/sometimes/often/all the time). Three items on personal relationships have an additional answer: not applicable. The overall score is additive (19-76), and higher values indicate an increased impact on QOL. In addition, each item is followed by a scale of bother (1-10). Although the bother scale is not included in the overall score, it can be used to analyse the impact of individual symptoms (Appendix B).

We used these questionnaires with permission from the ICIQ project office.

Population and Methods - Paper I

This is an RCT comparing the effects of two treatment programmes for SUI: one Internet-based and one sent by post.

Population

We conducted this study from Dec 2009 to April 2011. Study participants were recruited as described previously in this chapter. A flow chart of the study population after randomisation is presented in Figure 4.

Randomisation

We randomised eligible participants consecutively, using a pre-specified computer-generated list in blocks of eight. An independent administrator

kept the list and allocated participants to one of the two intervention groups. There was no blinding of group allocation to study participants, caregivers, or researchers.

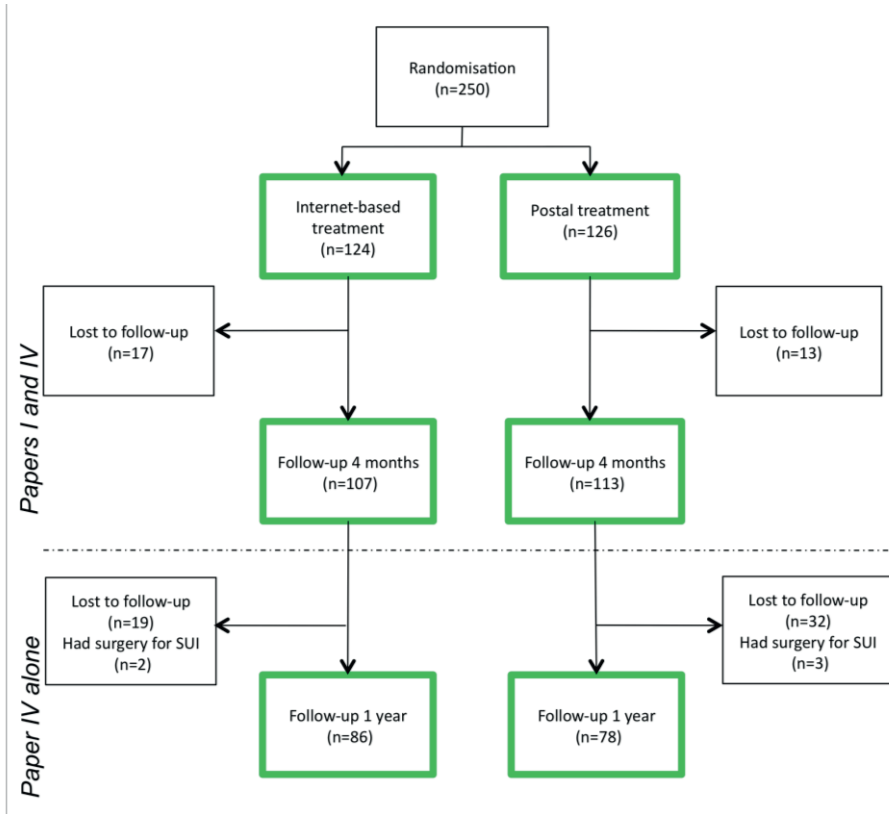


Fig. 4. Subjects included in *Paper I* and *Paper IV*.

Interventions

Both intervention groups received 3 months of treatment based mainly on PFMT. The minimum intensity was at least 8 contractions 3 times daily, and contractions for increased strength, endurance, and quickness were included. In addition, the programmes included information on SUI and associated lifestyle factors, as well as training reports (frequency and time spent). There was no face-to-face contact with the participants at any time. The PFMT regimens are described in detail in Appendix C. Each intervention is briefly described below.

Internet-based treatment programme

The Internet-based programme contained eight escalating levels that featured gradual increase of PFMT intensity and complexity (Fig. 5).

1	2	3	4	5	6	7	8
2 minutes 3 times per day	2 minutes 3 times per day	3-4 minutes 3 times per day	3-4 minutes 3 times per day	4 minutes 3 times per day	7-8 minutes 2 times per day	7-8 minutes 2 times per day	12 minutes 3 times per week

Fig. 5. Illustration of the gradual increase of PFMT intensity in the eight escalating levels of the Internet-based treatment programme.

Participants received individually tailored support from an urotherapist during the treatment period. The urotherapist gave the participants login codes for two levels at a time, and recommended that they maintain training at each level for at least 1 week.

The programme was reached via <http://www.ekontinens.se>. A screenshot is depicted in Figure 6. Progress was self-monitored, and every level contained a self-evaluated test on PFMT performance. Participants were required to report the result of every other test to the urotherapist in order to receive login codes for the following levels. In addition, participants provided weekly training reports. The programme also included CBT assignments for lifestyle change (if applicable), as well as for the identification and change of behaviours of redundant security measures and avoidance (if applicable).

All contact with the urotherapist was via encrypted e-mail, which required separate logins from participants and urotherapists. The urotherapists actively contacted participants that did not report according to plan. Participants were able to contact the urotherapist at any time for questions or support. All contact was asynchronous, and response from the urotherapist was promised within three working days. Technical support was available separately via encrypted e-mail contact with the website manager.

Treatment programme sent via post

This treatment programme was presented in an illustrated 8-page booklet (Fig. 7). The first pages contained information, and the following pages contained instructions for PFMT categorised in five levels. Participants had access to all exercises from start, but were encouraged to increase their training gradually. Together with the booklet, we sent the participants a training report for continuous registration during the training period. It was returned to the research group together with the first follow-up questionnaire. Participants in this group had no contact with the urotherapists during the training period.



Fig. 6. Screenshot of the Internet-based treatment programme, level 2.

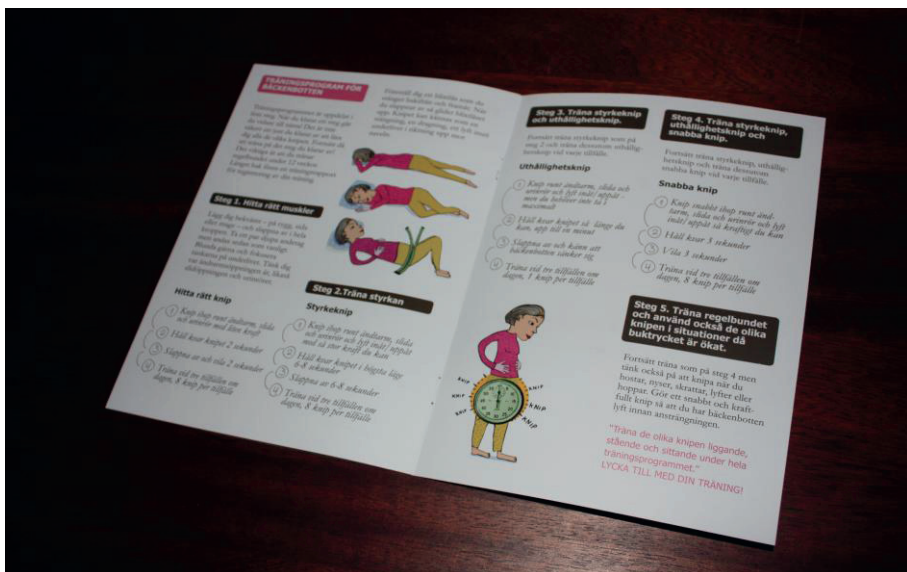


Fig. 7. Picture of the treatment programme sent by post, pages 6 and 7.

Outcome measures

Primary outcome measures were:

- Symptom severity, measured with the ICIQ-UI SF.¹¹⁸
- Condition-specific QOL, measured with the ICIQ-LUTSqol.¹¹³

Secondary outcomes were:

- Incontinence episode frequency (IEF), calculated from the 2-day bladder diaries (number of leakage episodes \times 3.5).
- Health-specific QOL, measured with the EQ5D-VAS.¹⁴⁰ This is a vertical analogue scale ranging from 0 (worst imaginable health state) to 100 (best imaginable health state).
- The Patients Global Impression of Improvement (PGI-I) (Yalcin),¹⁰⁴ in which the participant rated her symptoms after treatment as compared with before treatment. There are seven answer alternatives, ranging from very much worse to very much better.
- Usage of incontinence aids. Participants rated their usage after treatment compared with before treatment. Only participants that were using incontinence aids at baseline were included in this analysis.
- Satisfaction with the treatment programme. The participants rated their experience of the treatment programme. There were five response options, ranging from very bad to very good.

We performed follow-up 4 months after treatment initiation, using postal sendings with validated questionnaires in paper versions.

Population and Methods – Paper II

This is a reliability study of the paper- and web-based versions of the condition-specific ICIQ-LUTSqol questionnaire.

Population

We conducted this study in 2010-2011. The disposition of the included subjects is presented in Figure 8. The internal consistency of the paper version was examined using baseline data from all participants (n=250); internal consistency of the web-based version was examined using data from setting 2 (see below). To examine the test-retest reliability, participants answered the questionnaire twice with an interval of 6-42 days, in two different settings:

1. Paper versus paper versions. We sent participants the paper version of the questionnaire twice at baseline. Calculations are based on 78 participants.
2. Paper versus web-based versions. We sent participants e-mail with a link to the web-based version, either shortly before (n=18) or after (n=36) the 4-month follow-up point. Calculations are based on 54 participants.

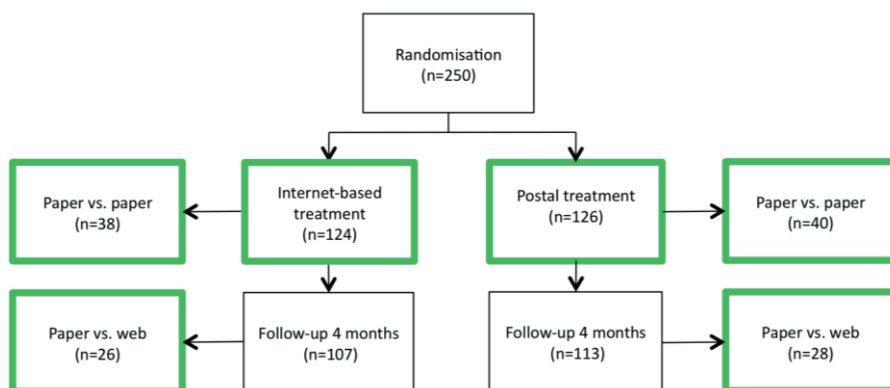


Fig. 8. Subjects included in Paper II.

Methods

The *internal consistency* of the paper- and web-based versions was evaluated by calculating Cronbach's alpha coefficient. The value should be >0.7 .¹⁰⁴

The *test-retest reliability* was assessed by calculating the intraclass correlation coefficients of overall scores. Coefficients ≥ 0.7 demonstrate good test-retest reliability.¹⁰⁴ We also calculated weighted kappa values to examine the stability of each individual item. We considered values <0.4 poor, $0.4-0.6$ fair, $0.61-0.8$ good, and >0.8 excellent.¹⁵⁵

Population and Methods – Paper III

This is a qualitative study of 21 semi-structured individual telephone interviews. We analyzed data according to grounded theory principles.¹⁵⁶

Population

We conducted this study in 2011. The recruitment of study subjects is described in Figure 9. We e-mailed participants shortly after the 4-month follow-up point and asked them to elaborate on their experiences in a telephone interview. We aimed for a strategic selection with diversity of age, location, group allocation, and treatment satisfaction. We interviewed 13 participants from the Internet group and 8 from the postal group.

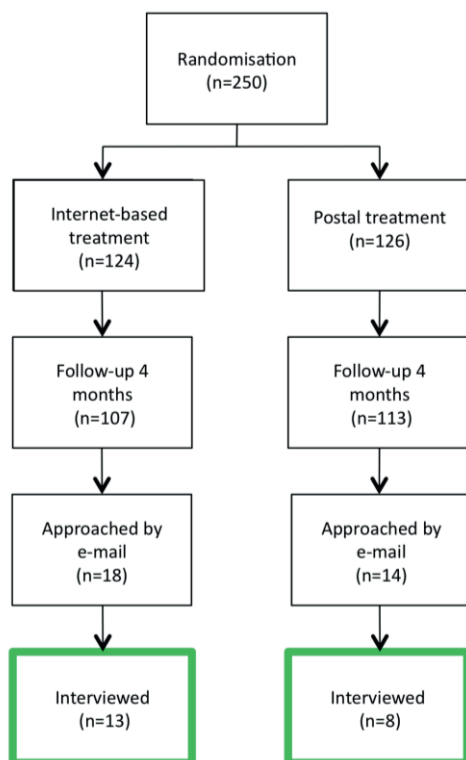


Fig. 9. Subjects included in Paper III.

Methods

The first author, Dr. Björk, conducted all 21 interviews via telephone. During the interviews, she used a semi-structured interview guide that included open-ended questions. Examples of questions are provided below:

- Why did you join the study?
- Please describe your symptoms before joining the study?
- How did you experience the treatment?
- In what way has the treatment altered your incontinence symptoms?
- How was your contact with the urotherapist? (if applicable)

Nineteen interviews were recorded and transcribed verbatim by Dr. Björk. Two interviews were not recorded, one owing to technical problems, and the other because of non-acceptance by the participant. Notes were taken during the two unrecorded interviews.

Data collection and analysis were conducted simultaneously, which made it possible to identify new topics for elaboration in forthcoming interviews. The emerging codes were incorporated into categories, and eventually a core category emerged.

All authors contributed to the analytical process, and we used a constant comparative method. After 21 interviews, no new categories were revealed, and we considered saturation obtained. Memos were kept throughout the process. To check the trustworthiness of the results, an external group of researchers coded parts of an interview. They recognised and thereby confirmed our results.

My contribution

I am the second author of this paper. I participated in the planning and design of the study, and actively contributed to the analytical process and to the critical revision of the first version of the manuscript. Later, during Dr. Björk's maternity leave, I was responsible for the major revision and resubmission of the manuscript.

Population and Methods – Paper IV

This is a cost-utility analysis with a 1-year societal perspective. This study compared the Internet-based and the postal treatments with each other, and with a no-treatment alternative.

Population

The study was conducted in 2009-2012. The population is the same as in *Paper I*, albeit with a 1-year follow-up period (Fig. 4).

Costs

We considered costs from a societal perspective.

The cost of assessment and treatment delivery included the actual costs for postal sendings, domains, servers, service of the Internet-based programme, and registered time spent on the participants by the urotherapists and by the research team. We did not include developmental costs.¹⁵²

Data regarding participants' costs were collected from training reports, as well as postal questionnaires at baseline, the 4-month follow-up, and the 1-year follow-up. This included time spent on PFMT, use of incontinence aids, additional laundry, and any other regular expenditure due to the leakage that the participants could identify.

If prices per unit were not known, we derived them from the literature. All costs are provided in Euros at the 2010 mid-year level.

QALYs

We measured QOL with the condition-specific ICIQ-LUTSqol questionnaire. Using a validated preference-based index,¹⁴⁶ we incorporated nine of the items in the questionnaire to create a health state classification. Using the algorithm of the index, we then translated these classifications to utility weights, with values ranging from 0 (worst imaginable health state) to 1 (best imaginable health state).

Outcome measure

The treatment alternatives were compared with each other by calculating the incremental cost effectiveness ratio (ICER) for each comparison.

An ICER is calculated with the following formula:

$$ICER = \frac{COST_{treatmentA} - COST_{treatmentB}}{QALY_{treatmentA} - QALY_{treatmentB}}$$

We calculated three different ICERs: Postal treatment vs. no treatment; Internet-based treatment vs. postal treatment; and Internet-based treatment vs. no treatment.

The no-treatment alternative was based on the assumption that participants would not have sought other treatment if they had not been offered the study treatments. In this alternative, we assumed costs and utility weights to be the same as for the study population at baseline, and to remain unchanged over the year.

Statistics

We used IBM-SPSS for Mac, version 18.0 or 19.0 (IBM, Armonk, NY, USA) for most calculations. In *Paper II*, calculation of weighted kappa values was performed in R, version 2.12.1. In *Paper IV*, parts of the calculations were conducted using Excel for Mac, version 12.3.6 (Microsoft Corporation, Redmond, WA, USA).

P-values <0.05 were considered statistically significant.

Sample size

The power calculation in *Paper I* aimed to show a between-group difference of 20% with a power of 80% and a two-sided significance level of 0.05, allowing a dropout rate of 20%. We based this calculation on the primary outcome ICIQ-UI SF,¹⁵⁷ and the secondary outcomes PGI-I¹⁵⁸ and IEF.⁹⁸ The resulting sample sizes were 203 (PGI-I), 210 (IEF), and 281 (ICIQ-UI SF) participants. For the ICIQ-UI SF, we anticipated the effect would be better in our study than in the study protocol used for the calculations, because our participants would be younger and would have pure SUI. Thus, we decided to aim for a total of 250 participants.

Statistical analysis

In *Paper I*, we performed an intention-to-treat analysis based on all available data.¹⁵⁹ In order to compare the intervention groups at baseline, we used Student's *t*-test for continuous variables and the chi-squared test for categorical variables. We used paired *t*-tests for analysis of treatment effects within groups. For comparison of the treatment effects between groups, we used a mixed model analysis for the primary outcomes and for health-specific QOL. In the IEF measure, we used a negative binomial regression. The remaining secondary outcomes were analysed using the

Wilcoxon/Mann-Whitney rank sum test for differences between treatment groups.

In *Paper II*, we based the calculation of intraclass correlation coefficients on a two-way mixed ANOVA model. For comparison of groups, we used the Mann-Whitney rank sum test or the Kruskal-Wallis H test.

In *Paper IV*, we assumed that costs would change linearly, while QALYs were calculated using the “area under the curve” method. We used the same methods as are detailed in *Paper I* for baseline comparison of intervention groups, as well as treatment effects within and between groups. To evaluate the stability of our results, we performed a one-way sensitivity analysis in which we varied the input data regarding participants’ time for PFMT, time for laundry, and costs for laundry, one at a time. We also performed a multi-way analysis in which we incorporated all three of these variables at their lowest level.

Ethics

The Regional Ethical Review Board of Umeå University gave ethical approval for the studies (number 08-124M). All participants were thoroughly informed, and provided their consent. We informed participants that they could end their participation at any time, and that the results would be presented only at group level, without the possibility to identify any individual information. We gave no reimbursements. Results have continuously been presented at the project’s website (<http://www.tät.nu>).

We registered the RCT at <http://www.clinicaltrials.gov> (ID: NCT01032265), and reported it in accordance with the CONSORT guidelines for RCTs.^{160, 161} To provide secure communication over the Internet, the Internet-based treatment programme was built on a secure platform, using a two-factor authentication and Secure Sockets Layer (SSL).

Tät.nu

Eva Samuelsson (GP) conceived the idea of the research project tät.nu and applied for funding with Göran Umeåfjord (GP), Per Carlbring (Psychologist), and Gerhard Andersson (Psychologist) as co-applicants. I joined the project when funding had been granted, and from then on took part in the detailed design and performance of the studies included in this thesis.

Eva Samuelsson and Göran Umeåfjord developed the Internet-based treatment programme in collaboration with the urotherapists Eva Källström (nurse midwife) and Annika Andreasson (physiotherapist). Per Carlbring and Gerhard Andersson gave advice about the included CBT assignments.

Eva Samuelsson developed the postal treatment programme with assistance from the urotherapists.

Eva Samuelsson and Göran Umeåfjord supervise the research project. Eva Samuelsson is the guarantor.

The project has received funding from the Swedish Council for Working Life and Science; the Swedish Society of Medicine; the Jämtland County Council; the Västerbotten County Council (ALF); and Visare Norr, Northern County Councils, Sweden.

I have received financial support from the Jämtland County Council; the Swedish Society of Medicine; and the Swedish Council for Working Life and Science.

Results

In this chapter, the results of *Papers I-IV* are summarised and presented together with additional data.

Demographics

Baseline demographic data of all 250 participants are presented in Table IV. There were no significant differences between the treatment groups.

The participating women were located throughout Sweden. Their distribution corresponds to that of the average population in Sweden in 2010 (Fig. 10).^{162, 163}

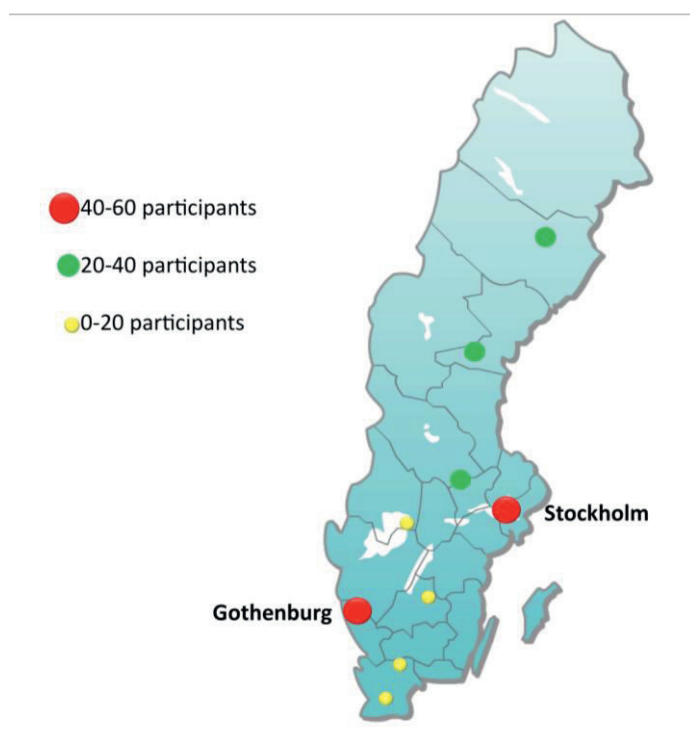


Fig. 10. Map of Sweden with the location of the 250 participants in *Papers I and IV*. Graphics by Anneli Göransson, modified.

Table IV. Baseline demographics of study participants by treatment group.

		Internet-based treatment n=124	Postal treatment n=126	P- value^a
<i>Continuous variables, mean (SD):</i>				
Age, years		47.9 (10.6)	49.4 (9.8)	NS
BMI, kg/m ²		24.7 (4.2)	24.5 (3.6)	NS
Parity		2.2 (0.9)	2.3 (0.8)	NS
EQ5D-VAS score		79.1 (13.6)	79.2 (14.0)	NS
HADS score				
	Depression	2.2 (2.2)	2.3 (2.3)	NS
	Anxiety	3.4 (2.6)	3.8 (3.2)	NS
Internet use, hours per week		13.5 (11.0)	15.8 (13.1)	NS
<i>Categorical variables, n (%):</i>				
Postmenopausal		43 (35.8)	48 (39.7)	NS
Any medication		54 (43.5)	53 (42.1)	NS
Estrogen use				
	Systemic	7 (5.6)	6 (4.8)	NS
	Topical	15 (12.1)	13 (10.7)	NS
SUI duration >5 years		59 (47.6)	71 (56.3)	NS
Previously sought care for SUI		75 (61.0)	89 (70.6)	NS
BMI groups, kg/m ²				NS
	Overweight (25-29.9)	23 (18.5)	36 (28.8)	
	Obese (≥ 30)	15 (12.1)	10 (8.0)	
Any comorbidity ^b		49 (39.8)	44 (35.2)	NS
Daily smoker		4 (3.2)	5 (4.0)	NS
Sedentary lifestyle ^c		5 (4.1)	5 (4.0)	NS

^a Based on Student's t-test (continuous variables), or on the chi-squared or Fisher's exact test (categorical variables).

^b For example, hypertension, diabetes, asthma, hypothyreosis, and anxiety or depression disorders.

^c Less than 2 hours of walking, cycling, or other physical activity per week during the last 12 months. Definition from The Swedish National Institute of Public Health.

In all, 75.2% of the participants had post-secondary education. The level of education was similar in both intervention groups. The educational attainment of the participants in comparison with the Swedish female population aged 25-74 in 2010¹⁶⁴ is depicted in Figure 11.

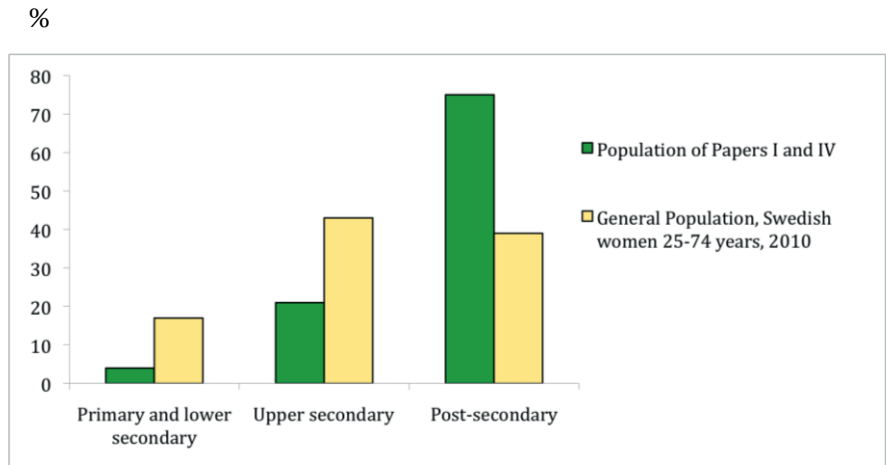


Fig. 11. Educational attainment of the population compared with the general population of Swedish women aged 25-74 in 2010.¹⁶⁴

Incontinence Severity Characteristics

Baseline incontinence severity measures are demonstrated in Table V. Participants in the Internet-based group experienced significantly more incontinence episodes at baseline. There were no other differences between the groups.

Table V. Baseline incontinence severity characteristics by treatment group.

	Internet-based treatment n=124	Postal treatment n=126	p-value ^a
<i>Continuous variables, mean (SD):</i>			
ICIQ-UI SF score	10.4 (3.1)	10.3 (3.5)	NS
ICIQ-LUTSqol score	33.6 (6.8)	33.6 (8.2)	NS
Incontinence episode frequency (IEF), per week	12.7 (12.0)	9.4 (8.6)	0.013
Use of incontinence aids, per week	6.8 (7.4)	7.7 (8.2)	NS
<i>Categorical variables, n (%):</i>			
Participants with daily leakage episodes	53 (42.8)	49 (38.8)	NS
Severity ^b			NS
Slight	8 (6.5)	6 (4.8)	
Moderate	81 (65.3)	89 (70.6)	
Severe	34 (27.4)	30 (23.8)	
Very severe	1 (0.8)	1 (0.8)	

^a Based on Student's *t*-test (continuous variables), or on the chi-squared test or Fisher's exact test (categorical variables).

^b Based on overall ICIQ-UI SF score at baseline. Classified according to Klovning et al. 2009.

Side Effects

One participant in the Internet-based group experienced lower abdominal pain when conducting PFMT and discontinued treatment. No other side effects were registered.

Loss to Follow-Up

After 4 months, we had lost 12% (30/250) of participants to follow-up [Internet 13.7% (17/124), Postal 10.3% (13/126); $p = 0.44$]. At 1 year, we had lost 32.4% (81/250) of participants. [Internet 29.0% (36/124), Postal 35.7% (45/126); $p = 0.28$].

Compared with completers, participants lost to follow-up were younger and reported a greater effect of SUI on condition-specific QOL at baseline (Table VI). Participants lost to follow-up at 4 months experienced more severe leakage at baseline than completers; however, this difference was not observed after 1 year. There were no differences regarding Internet usage or education.

Table VI. Baseline data from participants lost to follow-up compared with completers at 4 months and 1 year.

Baseline data	Completed follow-up 4 months n=220	Lost to follow-up 4 months n=30	p- value ^a	Completed follow-up 1 year n=169	Lost to follow- up 1 year n=81	p- value ^a
<i>Continuous variables, mean (SD):</i>						
Age, years	49.2 (10.2)	44.2 (9.2)	0.01	50.3 (10.1)	45.1 (9.5)	<0.001
ICIQ-UI SF, overall score	10.2 (3.2)	11.9 (3.9)	0.01	10.1 (3.2)	10.9 (3.5)	NS
ICIQ-LUTSqol, overall score	33.1 (7.3)	37.2 (8.5)	0.01	32.7 (6.8)	35.5 (8.6)	<0.001
Internet use, h/week	14.4 (12.1)	16.9 (11.7)	NS	14.3 (12.2)	15.4(12.0)	NS
<i>Categorical variable, n (%):</i>						
Education			NS			NS
Primary and lower secondary	5 (2.3)	0 (0)		3 (0.75)	2 (2.4)	
Upper secondary	50 (22.7)	7 (23.3)		38 (22.5)	19 (23.4)	
Post-secondary	165 (75.0)	23 (76.6)		128 (75.7)	60 (74.1)	

^a Based on Student's *t*-test (continuous variables), or on Fisher's exact test (categorical variable).

Treatment Outcome (Paper I)

Adherence to treatment

More participants in the Internet group than in the postal group discontinued treatment [28% (35/124) vs. 10% (12/126); $p < 0.001$]. Most participants did not state any reasons for discontinuing treatment [Internet 77% (27/35), Postal 100% (12/12)]. Some participants in the Internet group stated technical problems (8.6%, 3/35), diseases or trauma (11.4%, 4/35), or painful PFMT (2.9%, 1/35) as their reasons for not completing treatment. The highest level of the programme achieved by completers of the Internet-based treatment is demonstrated in Table VII.

Table VII. Highest level of the programme achieved by the 89 participants in the Internet group that completed treatment.

Level	1	2	3	4	5	6	7	8
Participants, n (%)	-	1 (1.1)	1 (1.1)	9 (10.1)	16 (18.0)	7 (7.9)	17 (19.1)	38 (42.7)

Primary outcomes

Within both treatment groups there were highly significant ($p < 0.001$) improvements of the overall symptom (ICIQ-UI SF) and QOL scores (ICIQ-LUTSqol). However, the differences between the groups were not significant. The overall scores and the mean differences for each measure are reported in Table VIII.

Table VIII. Continuous outcome measures by treatment group. Values are mean (SD).

Outcome Variable	Treatment group	Baseline n=250	4-month follow-up n=220	Difference ^a	Between-group p-value ^b
ICIQ-UI SF	Internet	10.4 (3.1)	6.9 (3.1)	3.4 (3.4)	0.27
	Postal	10.3 (3.5)	7.3 (3.9)	2.9 (3.1)	
ICIQ-LUTSqol	Internet	33.6 (6.8)	27.8 (6.0)	4.8 (6.1)	0.52
	Postal	33.6 (8.2)	28.8 (7.3)	4.6 (6.7)	

^a Based on participants with complete data on both occasions.

^b Based on a mixed model analysis.

The effect sizes in the ICIQ-UI SF were 0.99 (95% CI 0.76 to 1.22) in the Internet group, and 0.95 (95% CI 0.72 to 1.17) in the postal group. For the ICIQ-LUTSqol, the effect sizes were 0.79 (95% CI 0.57 to 1.01) in the Internet group, and 0.68 (95% CI 0.47 to 0.89) in the postal group.

Participants with severe leakage at baseline achieved a significantly lower mean score on the ICIQ-UI SF (mean score at follow-up 8.1 (SD 3.4) vs. 11.0 (SD 3.5), $p=0.006$) when treated with the Internet-based programme compared with the postal programme.

Secondary Outcomes

All secondary outcomes are reported in Table IX.

The IEF was significantly ($p<0.001$) reduced within both groups, although the difference between the groups was not significant. Overall (both intervention groups incorporated), 69.8% of the participants reported that urinary leakage had stopped completely or the number of leakage episodes experienced had been reduced by >50% after treatment.

Health-specific QOL improved in the Internet group ($p=0.001$), but not in the postal group ($p=0.13$).

Significantly more participants in the Internet group than in the postal group rated their leakage as much or very much better [40.9% (43/105) vs. 26.5% (30/113); $p=0.01$]; reported that they had stopped or reduced their use of incontinence aids [59.5% (47/79) vs. 41.4% (34/82)]; and were satisfied with the treatment programme [84.8% (89/105) vs. 62.9% (71/113); $p<0.001$].

After treatment, 14.1% (15/106) of the participants in the Internet group and 20.6% (22/112) of the participants in the postal group experienced daily leakage episodes. Complete absence of leakage was reported by 3.8% (4/106) in the Internet group, and 5.4% (6/112) in the postal group.

Table IX. Secondary outcome measures by treatment group.

	Internet-based treatment	Postal treatment	Between-group p-value ^a
<i>Continuous variables, mean (SD):</i>			
Incontinence episode frequency (IEF), per week	N=89	N=82	0.23
4-month follow-up	4.8 (7.7)	4.4 (6.7)	
Difference from baseline ^b	7.6 (9.1)	4.5 (7.1)	
EQ5D-VAS	N=103	N=110	0.30
4-month follow-up	83.3 (10.3)	81.8 (13.9)	
Difference from baseline ^b	3.7 (10.9)	1.9 (13.0)	
<i>Categorical variables, n (%):</i>			
Patient Global Impression of Improvement (PGI-I)	N=105	N=113	0.01
Very much better	12 (11.4)	4 (3.5)	
Much better	31 (29.5)	26 (23.0)	
A little better	48 (45.7)	60 (53.1)	
No change or worse	13 (12.4)	19 (16.8)	
Worse	1 (1.0)	3 (2.7)	
Much worse	0	1 (0.9)	
Very much worse	0	0	
Use of incontinence aids	N=79	N=82	0.02
No use	17 (21.5)	11 (13.4)	
Less than before	30 (38.0)	23 (28.1)	
Same as before	32 (40.5)	46 (56.1)	
More than before	0	2 (2.4)	
Treatment programme experience	N=105	N=113	<0.001
Very good	46 (43.8)	15 (13.3)	
Good	43 (40.9)	56 (49.5)	
Neither good or bad	13 (12.4)	31 (27.4)	
Bad	3 (2.9)	8 (7.1)	
Very bad	0	3 (2.7)	

^a Based on a negative binomial regression (IEF), mixed model analysis (EQ5D-VAS), and Mann-Whitney's U-test (categorical variables).

^b Based on participants with complete data at baseline and at the 4-month follow-up.

Reliability of the ICIQ-LUTSqol (Paper II)

Internal consistency

In both versions of the questionnaire, the included items correlated well and contributed to the overall score (Cronbach's alpha coefficient: Paper version 0.87; Web-based version 0.86)

Test-retest reliability

In the paper versus paper setting, mean overall scores did not differ significantly when compared with each other [mean overall score; Paper 1: 32.9 (SD 8.1); Paper 2: 33.1 (SD 8.9)]. The intraclass correlation coefficient demonstrated a high degree of agreement (0.95, $p < 0.001$), and weighted kappa values ranged from 0.46 to 0.84 (mean 0.61, SD 0.10).

The same conformity was observed in the paper versus web-based setting. The mean overall score was 28.4 (SD 6.8) in the paper version, and 29.7 (7.0) in the web-based version. The intraclass correlation coefficient was 0.92 ($p < 0.001$), and weighted kappa values ranged from 0.34 to 0.84 (mean 0.61, SD 0.13). The order in which the paper and the web-based versions were answered did not affect the results.

Patient Satisfaction (Paper III)

The mean age of the interviewed participants was 47.6 years (range 30-69 years), and the mean interview time was 23 min (range 11-45 min). We grouped the results into three categories:

1. "Hidden but present" concerning experiences of living with incontinence and what led to participation in the study.

"I am relatively young, still just 31 at the moment, but I thought, am I supposed to live with an invisible but very real problem for the rest of my life, then, if I don't do anything about it." (Participant in the Internet group)

Many women did not define urinary leakage as a major health problem, although it might affect their everyday life. Often they perceived it as embarrassing and shameful. The greater its effect on everyday life, the more motivated participants were to seek help. Some women mentioned they had not been taken seriously when they sought care on previous occasions. The barrier to applying for the non-face-to-face study treatments seemed to be lower than the barrier to seeking ordinary health care. Seeking this kind of

treatment was perceived as a possibility to do something about the leakage by themselves. Some women also regarded the treatments as potentially time sparing and easily accessible, and considered this appealing.

2. “At a distance but close” concerning experiences of the treatment programmes and of the patient-provider relationship.

“One could say, had she been sitting in front of me like anybody else, then I would not have asked in the same way... Yes, I thought so. It felt natural in a way, I did not feel as exposed and vulnerable.” (Participant in the Internet group)

Many women in the Internet group established a relationship with their urotherapist. The patient/urotherapist relationship was described as both personal and distant, leading to a sense of being acknowledged and supported without exposure. The lack of face-to-face contact allowed some women to feel freer to communicate about sensitive issues, while others felt that the lack of visual cues contributed to make the relationship superficial. The support from the urotherapist was experienced as motivating, although at times it induced feelings of guilt and negative pressure.

Women in the postal group expressed feeling a lack of support and sometimes found it difficult to maintain motivation to perform PFMT over a longer time period. However, they also expressed a sense of loyalty towards the research team, and often described their contribution with positive words.

3. “By myself but not alone” regarding the sense of empowerment that many women experience during and after treatment.

“And when you know how, then it is easier to do it.” (Participant in the Internet group)

The Internet-based treatment, and to some extent the postal treatment as well, increased many women’s awareness of and knowledge about how to handle the incontinence. Some women described how they had been able to incorporate the pelvic floor exercises into their daily routines. The majority of the women felt empowered by the treatments, even those that did not improve their symptoms. The treatments also helped to break down some of the shame barriers.

Core category

A core category emerged, “Acknowledged but not exposed”, that summarises and describes the three categories.

Cost-Effectiveness (Paper IV)

Costs

The total cost for assessment and delivery of treatment was €53.1 for the Internet-based programme, and €21.5 for the postal programme. During treatment, the urotherapists spent a mean total of 1 h and 21 min (6 min and 45 s per week) on each participant in the Internet group. Participants in the Internet group achieved larger savings regarding time for PFMT, laundry, incontinence aids, and other costs than participants in the postal group. Thus, the total 1-year societal cost was similar for both programmes (Table X).

Table X. Cost per participant for Internet-based treatment, postal-based treatment, and no treatment for women with stress urinary incontinence.

	Cost Internet-based treatment (€)	Cost Postal treatment (€)	Cost No treatment (€)
<i>Assessment</i>			
Printing and sending of questionnaires ^a	4.0	4.0	.
Urotherapist's time for interview ^b	1.7	1.7	.
General practitioner's time	9.2	9.2	.
<i>Treatment delivery</i>			
Urotherapist's time,	36.8	.	.
Domains, servers, administration	1.4	.	.
Printing and sending of treatment programme ^a	.	6.6	.
<i>Participant's costs</i>			
Participant's time for PFMT	435.7	451.0	.
Participant's time for laundry	41.8	43.5	125.0
Incontinence aids	33.5	41.7	47.1
Extra laundry loads	31.3	32.9	93.9
Other costs ^c	1.1	5.6	8.0
Total cost	596.5	596.2	274.0

All prices are in Euros (€) at the 2010 mid-year level. Exchange rate 1 SEK=9.62 €.

^a Including 5 min of research assistant's time (€24.95 per hour).

^b Mean interview time 7.5 min. 50% accounted for as treatment-specific. Cost for urotherapist's time: €27.2 per hour.

^c Any leakage-associated cost identified by the participant herself (e.g., extra clothing, tampons for leakage protection).

QALYs

QOL improved significantly ($p < 0.001$) with both treatments at 4 months (see *Paper I*), and at 1 year [mean change ICIQ-LUTSqol compared with baseline; Internet 5.3 (SD 6.4), Postal 4.5 (SD 6.4)]. The differences between the groups were not statistically significant ($p = 0.52$ at 4 months, $p = 0.79$ at 1 year). The corresponding utility weights and total QALY changes are presented in Figure 12.

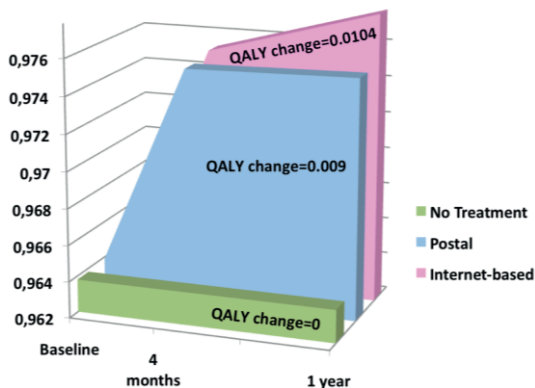


Fig. 12. Utility weights at baseline, 4 months, and 1 year of follow-up, with corresponding changes in quality-adjusted life years (QALYs).

Outcome measure - ICERs

The ICERs for the base case are presented in Table XI.

Table XI. Incremental cost effectiveness ratios (ICERs) for the Internet-based, postal, and no treatment options.

Base case ^a	Total cost (€ ^b)	QALY-gain	Δ Cost (€)	Δ QALY-gain	ICER ^c
No treatment	274	0	274	0	.
Postal vs. No treatment	596.2	0.0090	322	0.0090	35,905
Internet-based vs. Postal	596.5	0.0104	0.3	0.0014	200
No treatment	274	0	274	0	.
Internet-based vs. No treatment	596.5	0.0104	322	0.0104	30,935

^a Each alternative is compared with the previous. ^b €= Euros at 2010 mid-year level. ^c ICER=Δ Cost/Δ QALY-gain.

In the sensitivity analyses, the extra cost per QALY for the Internet-based programme ranged from €688 to €7253 compared with the postal programme. Compared with no treatment, the extra cost per QALY for the Internet-based programme ranged from €10,022 to €38,921.

Discussion

This thesis contributes new knowledge about how to provide women with SUI with accessible, evidence-based, and affordable first-line treatment.

In *Paper I*, we demonstrated that participants in two programmes based mainly on PFMT, an Internet-based programme and a postal treatment programme, achieved highly significant improvements in the primary outcomes symptom score and QOL. Between-group differences in these measures were not statistically significant. However, the Internet programme was more effective regarding most secondary outcomes. More women in the Internet group than in the postal group perceived the leakage was much improved or very much improved after treatment, reported reduced usage of incontinence aids, and indicated satisfaction with the treatment programme.

In *Paper II*, we determined the reliability of the paper and web-based versions of the condition-specific QOL questionnaire (ICIQ-LUTsqol) in women with SUI. Both versions featured excellent internal consistency. High intraclass correlation coefficients of overall scores and good weighted kappa values for each individual item indicate that both versions can be used for repeated measurements.

In *Paper III*, we concluded that both treatment programmes are well accepted by women, and that both programmes might lower the barrier for seeking care. Many women in the Internet-based group felt supported and acknowledged without exposure, and a patient-provider relationship developed despite the lack of face-to-face contact. The treatments enabled the women to self-manage their condition, and empowered them.

In *Paper IV*, we demonstrated that the Internet-based programme is a cost-effective treatment alternative when assessed from a 1-year societal perspective, compared with the postal programme and with a no-treatment alternative. The results were consistent in all included scenarios.

Methodological Considerations

As for all research, several methodological concerns must be considered. I begin this chapter by addressing some of the overall strengths and limitations of this thesis, and continue by discussing some of the limitations specific to each of the included papers.

Overall strengths

The studies included in this thesis were conducted by a research group with broad knowledge about both urinary incontinence and Internet-mediated care. The group includes experienced GPs, urotherapists, psychologists, a statistician, a health economist, and an administrator.

We registered the study in *Paper I* at <http://www.clinicaltrials.gov> and reported it according to the CONSORT guidelines for RCTs.^{160, 161} We used validated outcome measures, some of which are widely used. The study in *Paper II* was conducted according to the ICIQ validation protocol.¹¹⁹ The interval between answering occasions was well within the stipulated time limit of 2-6 weeks, and both paper- and web-based versions of the questionnaire were easy to use. In *Paper III*, the research group analysed the results in close collaboration according to grounded theory principles, a method that is suitable for the qualitative analysis of new topics and approaches. The health economic analysis in *Paper IV* is based on continuously registered data and measurements obtained directly from the participants during one year, and not on assumptions and modelling, which is otherwise common in health economic analyses.

Overall limitations

The design of the RCT reported in *Paper I*, and that was the basis for *Papers III* and *IV*, deserves discussion. We took a pragmatic approach when designing the RCT, and chose postal treatment as a comparison because we wanted both interventions to be easily accessible and to allow women from all over the country to participate. We also wanted both interventions to lack face-to-face contact, so women that for some reason do not seek ordinary care would feel free to participate.

The design is head-to-head (i.e., we compare two active treatments). It would have been interesting to compare the Internet-based treatment with a standardised care-as-usual alternative; however, no such alternative exists for SUI. Also, it could be argued that handouts for the self-completion of PFMT are a sham treatment, although these handouts are used as active treatment in our everyday praxis.

Furthermore, if we had included a control group that received no active treatment as a third intervention arm in the study design, we would have been able to evaluate the effect of participating in a study.

Another topic that needs discussion is the use of the condition-specific QOL questionnaire ICIQ-LUTSqol as an outcome measure in *Paper I* and *Paper IV*. We chose to use this questionnaire because it is highly recommended,^{4, 24, 27, 103} clinically relevant, and includes items regarding

aspects of QOL that are of importance to women with SUI. In addition, it is easy to use and comprehensible to both study participants and clinical staff.

The questionnaire, which was derived from the KHQ, was fully incorporated into the ICIQ structure in 2006.¹²⁰ The two questionnaires are similar, but not identical. Items included in the ICIQ-LUTSqol are exactly the same as in the KHQ; however, for refinement towards QOL, some items from the original questionnaire have been removed. Although the ICIQ-LUTSqol is considered validated for internal consistency, responsiveness, and construct validity, the references mainly go back to the KHQ.^{105, 113, 121-123} Furthermore, when the questionnaire was adopted into the ICIQ structure, its scoring system was simplified to facilitate interpretation of the results. While the KHQ is widely used, we have found no other published treatment studies that employ the ICIQ-LUTSqol; thus, comparisons with other settings cannot be performed.

In *Paper II*, we determined the test-retest reliability of the questionnaire in our population. This research was performed because we discovered that it was lacking. However, if the questionnaire had not been reliable, the methodology in *Paper I* and *Paper IV* would have been weakened.

Paper I

It is possible that the RCT is underpowered. We based the power calculation for the ICIQ-UI SF on a published study protocol¹⁵⁷ because at that time there were few published studies using this outcome measure. The protocol describes a pragmatic study involving a nurse practitioner for the treatment of all types of urinary incontinence in primary care. We anticipated that the effect of treatment would be better in our population; however, this might have been an overestimation.

Although low (Internet 13.7%, Postal 10.3%), the loss to follow-up might have affected our results. Participants lost to follow-up were generally younger, reported more severe leakage, and reported a greater impact on QOL than completers. There might have been a larger difference between the interventions if these participants had not been lost, because those with severe leakage were seen to benefit more from the Internet-based treatment.

Paper II

We consecutively recruited participants for the two settings in *Paper II* from the cohort of participants that were last to be randomised in *Paper I*. As a consequence, several women participated in both settings, and answered the questionnaire a total of four times. Theoretically, these women might have accomplished better skills regarding how to use the questionnaire, and might have remembered their former answers to individual items. However, we

believe that the risk for this potential bias is low because there were 4 months between the settings, during which the women had 3 months of treatment.

Paper III

The same person conducted all interviews (Dr. Björk), and her preconceptions might have affected the topics discussed. However, using only one interviewer might also confer some advantages. For example, it might be easier to quickly adjust to new topics and explore new themes. To ensure confirmability,¹⁶⁵ we analysed the collected data continuously and discussed the emerging results in the research group in order to identify new subjects to elaborate on in forthcoming interviews.

One might question whether sufficient depth was obtained during the interviews. The mean interview time (23 min) was relatively short for an in-depth interview, and it is possible that the depth of interviews was affected because interviews were conducted by telephone and visual cues were lost. On the other hand, not sitting face-to-face with the interviewer might facilitate the disclosure and discussion of sensitive topics.^{131, 166}

Paper IV

The QALY calculations might have been affected by the rates of loss to follow-up after 1 year (Internet 29.0%, Postal 35.7%). Compared with completers, lost participants were younger and reported a greater impact of urinary incontinence on their QOL at baseline. However, the rates of loss to follow-up were similar in both intervention groups ($p=0.28$); therefore, it is unlikely that they affected the orders of magnitude of the ICERs.

We based costs on the continuous registration of time consumption reported by the urotherapist, known bills, actual wages, and reports directly from participants. The use of this information reduces some of the uncertainty that is often observed in health economic analyses. Nevertheless, several entries are based on subjective measures; in addition, some of the data was obtained only from a minority of the participants. Thus, there is a risk that small defaults might be scaled up in the calculations. However, this risk is the same for all three treatment alternatives, and should have been offset in the ICER calculations because the analysis is comparative.

General Discussion

Before drawing any conclusions, our research must be contextualised. I will now focus on different aspects of the study population and the study treatments, and compare them with the published literature.

Perspectives Regarding the Study Population

Representativeness

The participants in our studies actively wanted treatment, and therefore represent a clinically relevant sample. In addition, the diagnosis of SUI is well substantiated. However, the participants are probably not representative for the general population of women with SUI. Although their mean age (48.6 years) coincides with the mid-life peak in prevalence,⁵ their educational level (75.2% had post-secondary education) is much higher than that of the general population in Sweden, where 39% of women aged 25-64 years had the same level of education in 2010.¹⁶⁴

The high educational level might have increased our participants' ability to absorb the written instructions for PFMT and to put them into practice, and thereby enhanced their results. Also, our participants' ability to express themselves in writing is likely to be higher than the mean, which could have affected the extent and quality of communication and the relationship with the urotherapist in the Internet group, and perhaps also their ability to interpret and complete questionnaires.

Education is regarded as an indirect measure of socioeconomic group, and higher education might improve health through several mechanisms, including lower prevalence of overweight and obesity, less smoking, reduced economic vulnerability, fewer workplace accidents, and reduced stress.¹⁶⁷ As expected, our participants appear to represent women with a healthy and active lifestyle, and with little psychological distress. Compared with a Swedish general population of women aged 30-64 years,¹⁶⁸ a smaller proportion of our population was overweight or obese (33.8% vs. 44%), fewer were smokers (3.6% vs. 14%), and fewer had a sedentary lifestyle (4.1% vs. 13%). In addition, compared with reports from a general population sample, our participants reported lower mean scores on the HADS for both depression (mean score HAD-D 2.3 vs. 3.8) and anxiety (mean score HAD-A 3.6 vs. 4.8).¹⁶⁹

The online recruitment procedure and the offer of an Internet-based treatment probably contributed greatly to the high educational level of our study population. Women with higher education are known to have greater

Internet access, to more often use the Internet on a daily basis,¹²⁴ and to more often use it to search for health information, versus women with lower education.¹²⁶

Another explanation for the large proportion of highly educated participants in our sample might be differences in prevalence and help-seeking behaviours in diverse socioeconomic cohorts. There are studies that indicate that SUI might be more prevalent in populations with higher educational status.^{18, 170} However, women with more education might have lower thresholds for reporting symptoms, be more active, and be more aware of their health status than women with less education.¹⁷⁰ On the other hand, these numbers should be offset by the fact that several risk factors, such as smoking, obesity, and diabetes, are more prevalent in lower socioeconomic cohorts.¹⁶⁷

Questioning of the representativeness of the study sample is a well-known problem in Internet-mediated research, and our study results might not be generalisable.¹⁰⁶ Of course, although it would have been interesting to evaluate the treatment effects reported in *Paper I* according to educational level, the RCT was not designed for subgroup analyses. However, the high educational level of our participants might not contradict the applicability of the treatment programmes in a more general population. Henderson et al. conclude that educational level does not affect the ability to perform (or the ability to learn to perform) correct pelvic floor muscle contractions.⁵⁹ Other studies suggest that socioeconomic status¹⁰⁰ and educational level,¹⁷¹ do not interfere with adherence to treatment or with the ability to fulfil web-based questionnaires.¹⁷²

Access to care

In *Paper III*, some participants describe the barrier to seeking care for SUI as quite high. Nevertheless, a large proportion of our participants (65.8%) had sought care for their leakage on a previous occasion. Their reasons for seeking care again are not revealed by this research, although in *Paper III* some women mention discontent with previous health care providers. In addition, based on both user and provider causes, primary care is not always readily accessible.

As our participants are likely to represent a well-informed and active sector of the female population with SUI, they would likely have had the capacity to seek, reach, and use the ordinary health care system if they had wanted to. However, some women described the barrier to applying for the study treatments was lower than the barrier to seeking ordinary health care. Presumably, the offer of Internet-based treatment helped them overcome some of the access barriers by providing them the opportunity to seek care

with greater anonymity and less embarrassment; in addition, it was perceived as flexible and time saving, which was appealing.

There is a risk that the offer of Internet-based treatment for SUI contributes to inequality in access to care because it assumes health literacy, computer literacy, and Internet access, and is therefore not available for all. However, Internet coverage is increasingly complete,¹²⁴ and in the future not using the Internet is likely to be based more on individuals' active decisions than on lack of access.

Comparisons with other populations seeking care for urinary incontinence

Table XII presents the baseline characteristics of our population in comparison with other populations seeking care for urinary incontinence. Two studies report data from primary care: Lagro-Janssen et al. is a study of Dutch women presenting with complaints of SUI,⁶⁴ and Seim et al. is a study of Norwegian women with complaints of any urinary incontinence.⁹⁸ Sykes et al.¹⁷³ and Monz et al.^{31,32} report data from the PURE study, which investigates women seeking primary and secondary care for all types of urinary incontinence in 14 European countries.

The comparison is not complete, owing to differences in the reported data; however, it does provide context for our study population.

Table XII. Comparison of baseline characteristics of the population in Paper I versus other populations seeking care for SUI.

	Sjöström et al. 2013 n=250	Lagro-Janssen et al. 1991⁶⁴ n=66	Scim et al. 1996⁹⁸ n=105	Sykes et al. 2005¹⁷³ Monz et al. 2005³¹ and 2007^{32 a} n=9434
Proportion with SUI, %	100	100	50	29
Mean age in years	48.6	45.4	57	60.7
Mean BMI, kg/m ²	24.6	-		27.3
Mean EQ-5D VAS	79.2	-	-	78.0 ^b
Mean parity	2.3	2.3	2.9	2.2
Mean incontinence episode frequency (IEF) per week	11.1	20.2		<7/week 40.8% 7-13/week 22% ≥14/week 37.1%
Daily leakage episodes, %	40.8	-	45	-
Duration >5 years, %	52	44	49	≈25
Any comorbidity, %	37.5	48.5	74.2	58.5
Any medication, %	42.8	24		-
Any estrogen use, %	16.4	-	-	-
Daily smokers, %	3.6	-	-	16.5

^a All three articles report data from the PURE study.

^b Data based on Swedish women with SUI only.

Perspectives Regarding Treatment

Treatment effects compared with other studies

In *Paper I*, symptom severity, as measured with the ICIQ-UI SF, improved significantly with both Internet-based and postal treatment. Table XIII, presents a comparison with improvements observed in other RCTs using the same outcome measure for the evaluation of treatment for SUI using PFMT, surgery, or duloxetine.

We cannot fully rule out the possibility that our observed improvements are merely an effect of participating in a study. In *Paper III*, participants expressed a sense of loyalty towards the research team; it is possible that the attention given to study subjects (e.g., the reporting of symptoms, and the completion of a bladder diary¹⁷⁴) might make women feel more cared for, which in turn might increase their comfort level, and therefore their reporting of symptoms.

However, there are several indications that the demonstrated improvements are real. First, although our management lacked face-to-face contact and treatment was unsupervised, the improvements are of the same order of magnitude as improvements observed in studies of supervised PFMT for SUI.^{78, 175-177} Second, the extent of improvement in both intervention groups in our study was larger than the improvement observed in the placebo arm of a pharmacological study.¹⁷⁸ Third, the extent of improvement in both treatment groups was larger than observed in the care-as-usual arm in a Dutch primary care study.¹⁷⁷

Furthermore, all results in *Paper I* are consistently in favour of the Internet-based treatment, although statistical significance for differences between the groups was only obtained for the secondary outcomes, and not for the primary outcomes. We anticipated that the post-treatment differences between the groups would be larger; however, participants in the postal group improved more than expected. Interestingly, none of the RCTs on PFMT presented in Table XIII reported any significant differences between their interventions regarding the same outcome. This finding is in line with previous research, which has not been able to show any clear evidence for how PFMT should be delivered for best effect.^{69,72}

What constitutes clinically relevant improvement?

When a questionnaire is employed to evaluate treatment outcome, we must know the minimum difference in overall score that is detectable for the individual in order to ascertain what constitutes a clinically relevant improvement. This minimum difference must be established in every new population.

For the ICIQ-UI SF, the minimum detectable difference for women undergoing surgery for SUI has recently been established as -5 after 12 months and -4 after 24 months.¹⁷⁹ However, these numbers might be overestimations in a population of patients receiving PFMT because the surgical population examined in that study had uniformly high pre-operative scores with little variance, and also obtained greater improvements than might be expected with conservative treatment.

For the ICIQ-LUTSqol, I have found no studies that report data about the minimum detectable differences. Such data is available for the KHQ after surgical intervention for SUI in women;¹⁸⁰ however, as previously mentioned, direct comparisons are not possible between the two questionnaires. Thus, we must relate the improvements observed in *Paper I* to other measures for which the minimum detectable differences are known.

After treatment, approximately 70% of our participants reported a complete lack of leakage or an improvement of the number of weekly leakage episodes by >50% in the 2-day bladder diary. Previous research shows that women experience clinically relevant improvement when the number of leakage episodes is reduced by >40-50%,¹⁸¹ and often indicate complete satisfaction with treatment when the number of leakage episodes is reduced by >70%.¹⁸¹

The PGI-I ("How is your leakage now, compared with before treatment?")¹⁰⁴ is easy to comprehend, and it provides an instantaneous understanding of any detectable improvement for the individual. In the Internet group, 11.4% reported that their leakage was very much better, 29.5% reported that it was much better, and 45.7% reported that it was a little better after treatment. In the postal group, the corresponding proportions were 3.5%, 23.0%, and 53.1%. In a pharmacological study, Yalcin et al. determined that this corresponds to reductions in leakage episode frequency of -93%, -63%, and -46% respectively.¹⁰⁴ In addition, they validated the response categories against changes in the pad test, and their data further strengthens the clinical relevance of our outcome regarding the PGI-I.

Table XIII. Comparison of achieved improvements in the primary outcome ICIQ-UI SF in Paper I versus other randomised controlled trials using the

Author and year of publication	Population	Intervention	Mean age
<i>PFMT:</i>			
Sjöström et al. (2013)	250 community-dwelling women, 18-70 years, SUI ≥ 1 /week	3 months of: A. Internet-based PFMT B. Postal PFMT	48.6
Hirakawa et al. (2013) ¹⁷⁵	46 female outpatients from urological clinic, SUI ≥ 1 /week	3 months of: A. PFMT with biofeedback B. PFMT without biofeedback	56.8
Sherburn et al. (2011) ¹⁷⁶	83 community-dwelling women with troublesome SUI	3 months of: A. Supervised PFMT B. Supervised bladder training	71.8
Albers-Heitner et al. (2011) ¹⁷³	384 (355 female) patients in primary care setting, all UI	3 months of: A. PFMT supervised by nurse B. Care-as-usual	64.7
Felicissimo et al. (2010) ⁷⁸	62 women with predominantly SUI ≥ 3 /week	8 weeks of: A. Supervised PFMT B. Unsupervised PFMT	49.7
<i>Pharmacological Treatment:</i>			
Castro-Diaz et al. (2007) ^{c 174}	516 women ≥ 18 years old, predominantly SUI ≥ 7 /week	8 weeks of: A. Duloxetine 80 mg/day B. Placebo	53.0
<i>Surgery:</i>			
Meschia et al. (2007) ¹⁸²	231 women with SUI and urethral hypermobility	6 months postoperatively from: A. Tension-free vaginal tape B. Transobturator tape	57

UI= Urinary Incontinence

^a Values are means (SD).

^b Based on participants with complete data on both occasions.

^c Additional data provided by Dr. Richard C. Bump. Reprinted with permission from Eli Lilly and Company.

same outcome measure. Presented values are after 3 months of treatment; when available.

Baseline ICIQ-UI SF score ^a	Post-treatment ICIQ-UI SF score ^a	Improvement of ICIQ-UI SF score ^a	Difference between groups	Lost to follow- up
A. 10.4 (3.1) B. 10.3 (3.5)	A. 6.9 (3.1) B. 7.3 (3.9)	A. 3.4 (3.4) ^b B. 2.9 (3.1) ^b	NS	A. 13.7% (17/124) B. 10.3% (13/126)
A. 11.2 (3.9) B. 12.0 (3.5)	A. 7.8 (3.3) B. 8.3 (3.5)	A. 3.4 B. 3.7	NS	A. 17.4% (4/23) B. 13.0% (3/23)
A. 10.4 (5.0) B. 10.4 (4.2)	A. 7.4 (4.1) B. 9.1 (4.4)	A. 3.0 B. 1.3	NS	A. 4.7% (2/43) B. 12.5% (5/40)
A. 11.1 (4.3) B. 11.3 (3.7)	A. 9.1 (2.9) B. 9.7 (2.9)	A. 2.0 B. 1.6	NS	A. 7.5% (14/186) B. 7.1% (14/198)
A. 14 (9-16) B. 14 (10-16)	A. 8 (6-12) B. 8 (5-13)	A. 6 B. 6	NS	Not reported
A. 13.2 (3.8) B. 13.3 (3.4)	A. 10.5 (4.5) B. 11.6 (4.1)	A. 2.8 B. 1.7	A>B p=0.004	A. 18.7% (74/396) B. 12.5% (15/120)
A. 15 ±3.6 B. 16 ±3.6	A. 2.5 ±4.3 B. 2.8 ±4.8	A. 12.5 B. 13.2	NS	A. 5.2% (6/114) B. 6.0% (7/117)

What constitutes a cure?

In *Paper I*, although many participants achieved clinically relevant improvements, only a few reported complete cure (no remaining leakage) after treatment (Internet 3.8%, Postal 5.4%). Studies of surgical interventions for SUI often report high cure rates, and our results appear modest when compared with such studies. Indeed, surgery for SUI is an effective treatment; nevertheless, comparison of cure rates should be performed with caution.

The concept of “cure” is absolute, and describes a permanent and complete end to a medical condition.¹⁸³ However, definitions vary in studies reporting cure rates. For example, cure might be defined as any improvement of symptoms, patient satisfaction with treatment, patient-reported complete absence of leakage, negative pad tests, negative urodynamics, etc.¹⁰³ Hilton et al.¹⁸⁴ applied different definitions of cure to data from a study comparing the outcomes of two surgical procedures for SUI (tension-free vaginal tape and colposuspension).¹⁸⁵ Depending on the definition applied, resulting cure rates varied between 9% and 85% for the former procedure, and between 6% and 82% for the latter.¹⁸⁴

In a benign condition like SUI, in which the perception of symptoms is highly subjective, it might be better to use the concept of “outcome” instead of “cure”.¹⁰³ “Outcome” refers to the consequence, result, or effect of an experiment, test, or treatment.¹⁸⁶

However, it is not obvious which is the most appropriate way to define the outcome of SUI treatment. Although patients and caregivers agree that subjective measures of symptoms and QOL are the most relevant outcomes, patients often rate objective outcomes, cost reductions, and avoidance of surgery higher than health care personnel do.¹⁰¹ Patients and clinicians also disagree in their views of what are unacceptable remaining symptoms after treatment.¹⁰²

Hilton et al. suggest that the following be included as outcome measures: patient’s observations of symptoms, quantification of symptoms, physician’s observations or objective measurements, QOL measurements, and socioeconomic evaluations. It is not clear whether any measurement is more relevant than any other, or whether they should be used as individual measures or incorporated to a single composite outcome. If “cure” is used as an outcome, it must be transparently defined to enable comparisons. Furthermore, the authors advocate we should move away from defining cure as the absolute absence of leakage. Instead, we should define it in accordance with what patients perceive as a good enough improvement.¹⁰³

Accomplishment of treatment

Both of our treatment programmes were newly developed within the project tät.nu, and the training regimens were not exactly the same (Appendix C). The Internet-based programme was a complex intervention, and it included more information and more advanced pelvic floor exercises than the postal programme. We informed participants in the Internet-based treatment group that progress to the next level would be paced according to individual achievements, and that not everyone would complete all levels. Participants in the Internet-based group interacted with the urotherapist on a weekly basis via e-mail and received individually tailored support, while the postal group completed training on their own.

In *Paper III*, many participants stated that they appreciated the treatments. Participants in the Internet-based group expressed that they developed a relationship with the urotherapist, and previous research confirms that strong therapeutic relationships can develop despite the absence of face-to-face contact.^{131, 187, 188} Non-face-to-face treatment might have an advantage over ordinary care, in that the perceived anonymity reduces embarrassment, makes participants feel more relaxed, and enables disclosures.¹³¹

The therapeutic relationship developed despite a low consumption of urotherapists' time. In *Paper IV*, we reported that urotherapists spent an average of 1 h and 21 min (6 min and 45 s per week) on each participant in the Internet-based group during the treatment period. This is comparable to the use of therapist time reported in other studies of Internet-based interventions. For example, in a study of 12 weeks of Internet-based CBT for severe health anxiety, therapists spent a total of 1h and 48 min on each participant,¹⁸⁹ and in a study of social anxiety disorders, therapists spent an average of 5.5 min per week on each participant.¹⁴⁸

If participants failed to report according to plan, the urotherapist would contact them via e-mail and provide additional support. In *Paper III*, many participants expressed how these extra contacts motivated them to continue training, while others described how they might be perceived as demanding, which induced feelings of guilt and insufficiency. It has been known that computerized therapy might be experienced as too demanding, fast-paced, and patronising.¹⁹⁰ Conversely, participants in the postal group expressed a lack of support, and at times had difficulties motivating themselves to adhere to treatment, although many were driven by a sense of loyalty towards the research team.

Despite more support, the treatment discontinuation rates reported in *Paper I* were higher in the Internet-based group than in the postal group [Internet 28% (35/124), postal 12% (12/126)]. The reasons for this difference

are unclear, because most participants did not provide us with a cause for not completing treatment. One plausible explanation might be that rates in the Internet-based group are predicated on urotherapists' reports, while rates in the postal group are based on active reports from individual participants. Also, it is a known phenomenon that adherence to treatment is lower and dropout rates are higher for Internet-based interventions than for face-to-face treatments.¹⁹⁰ Our discontinuation rate is similar to that reported by Donkin et al. In a review of 69 studies on self-help user-directed online interventions, they report a mean discontinuation rate of approximately 23%.¹⁹¹

Nevertheless, the discontinuation rate in the Internet-based group might have negatively affected the outcomes of treatment. Success with a self-care treatment programme based on PFMT is known to depend on each participant's motivation, as well as the ability of the individual to maintain training.⁶⁴ However, for Internet-based interventions, it is unclear whether adherence rates and other metric measures of usage, such as number of log-ins, actually affect treatment outcomes.¹⁹²

Factors known to enhance adherence to PFMT, include help identifying training goals, positive feedback, and advice about how to integrate exercises into daily routines,^{69, 193} all of which were provided to participants in the Internet-based group. Commonly mentioned reasons for not adhering to PFMT are difficulty remembering to complete the regimen and difficulty finding time.^{171, 193}

For Internet-based interventions, individually tailored support is one factor that has been shown to add beneficial effects,¹⁹⁴⁻¹⁹⁷ while lack of time and technical problems are factors that might have a negative influence.^{190, 194} Also, older participants are known to express more confusion around technology, yet they often have higher adherence, mainly because they have fewer issues with time demands and competing interests than younger users.¹⁹⁴

Based on our findings in *Paper IV*, it is possible that participants in the Internet-based treatment group performed less PFMT than the postal group. We observed that the participants' cost for PFMT was lower in the Internet-based treatment group than in the postal treatment group (€435.7 vs. €451.0). The Internet-based group was given the login codes for the next level successively every other week, depending on the result of the weekly self-monitored test; participants in the postal group had access to all exercises from the start. Consequently, participants in the postal group might have had a longer and more intense training period than participants in the Internet group, thus increasing the costs, and probably also enhancing the effects of training.

However, another explanation for this difference in costs could be that participants in the Internet-based group learned to perform PFMT in a more time-effective way in the long run, because of the more extensive information provided, as well as the urotherapists' support.

After treatment, participants from both treatment groups, and particularly from the Internet-based group, stated that they had gained increased knowledge about SUI, had become more aware of how to handle their symptoms, and felt less ashamed and alone (*Paper III*). Some participants that did not achieve any clinically relevant improvement of their symptoms shared the same experience, and it is possible that the CBT assignments included in the Internet-based programme contributed to this. CBT works by helping people change their habitual reactions and learn new patterns of thought,¹⁹⁸ and it has been demonstrated that cognitive strategies might enhance comfort and QOL for patients with urinary incontinence.^{83, 198}

In addition, many participants stated that they were able to handle their situation better after treatment and were enabled to self-manage (i.e., they were empowered).

The concept of patient empowerment refers to patients taking an active part in the management of their own health,¹⁹⁹ and it focuses on the capabilities of the individual. Empowerment is an important component of self-management and of patient-centered care because empowered patients are well informed, take responsibility for their own health as much as possible, and are capable of participating in shared decision-making. Furthermore, it has been pointed out that both patient empowerment²⁰⁰⁻²⁰² and shared decision-making²⁰³ render better health outcomes.

Highly educated women from Northern Europe with SUI have been shown to be especially prone to participate in shared decision-making and play an active role in their treatment, versus women with all types of urinary incontinence from 15 European countries.²⁰⁴

Cost-effectiveness of the study treatments

In *Paper IV*, we reported overall assessment and delivery costs of €53.1 for the Internet-based programme and €21.5 for the postal programme. If the treatment programmes were implemented, then the health care system would bear these costs; however, it should be remembered that the assessed costs are based on standardised procedures. Nevertheless, the study treatments are likely to be cheaper than providing face-to-face treatment. In comparison, the cost of a GP consultation has been estimated at €173 in Sweden;²⁰⁵ in the United Kingdom, the cost for the National Health Service to deliver 3 months of PFMT supervised by a trained nurse has been estimated at €158 to €293.⁸²

Although the delivery costs were higher for the Internet-based programme than for the postal programme, the total societal costs for the two programmes were almost the same (Internet €596.5 and Postal €596.2), owing to larger savings on participants' costs in the Internet-based group. This similarity means that it is mainly the number of QALYs gained with each treatment that will determine the outcome of the cost-utility analysis of this comparison.

We decided to measure QOL with the condition-specific ICIQ-LUTSqol questionnaire because theoretically it would be more sensitive to change in this population than a health-specific measure.^{82, 143-145, 147} Using a validated algorithm,¹⁴⁶ we then translated the responses to utility weights mapped on EQ5D values. Therefore, one might question whether our QALY estimates are comparable to those derived directly from health-specific measures. However, this methodology should have no effect on the differences across the intervention arms, which is the primary aim of the cost-utility analysis.

The number of QALYs gained with each of our interventions might seem small (Internet 0.0104, Postal 0.0090); the difference between the groups is even smaller (Δ QALY 0.0014) and not statistically significant. This result is often observed in health economic analyses that are performed alongside RCTs, because the trials are seldom sufficiently powered to detect these differences.²⁰⁶ However, the reported QALY gains must be put in perspective.

For SUI, several studies report cost-utility data collected alongside RCTs of surgical interventions,²⁰⁷⁻²⁰⁹ while few report data collected alongside RCTs of PFMT.^{210, 211} Instead, many published health economic evaluations are based on modelling (i.e., using assumptions to estimate costs and/or effects). In addition, comparisons are complicated by a large degree of variety in the methods used, as well as in how results are reported.

For primary care settings, I have found only one cost-utility analysis of conservative non-pharmacological treatment for SUI based on data collected

alongside an RCT. Here, incremental QALY gains of 0.01 to 0.02 are observed when a nurse specialist is involved for intense incontinence care based on PFMT, compared with a GP care-as-usual alternative.²¹⁰ In addition, Labrie et al. have promised a cost-utility analysis²¹² of their RCT comparing supervised PFMT with sling surgery for SUI;⁹⁵ however, that analysis has not yet been published.

NICE has performed a cost-utility analysis of PFMT based on modelling.²⁷ They used data from a published cost-effectiveness analysis on duloxetine,²¹³ and estimated expected gains of QALY to be 0.035 with PFMT treatment, 0.063 with sling surgery, and 0.027 with duloxetine.²⁷ However, some of these gains in QALY appear to be overestimations when compared with studies based on real data. For example, in addition to the gains of QALY with PFMT (0.01 to 0.02) provided in the previous paragraph, Montecino-Semper et al. report QALY gains of 0.0504 in 45 women who underwent sling surgery for SUI,²¹⁴ while Mihaylova et al. report QALY gains of 0.026 with duloxetine.²¹¹

For additional comparison, Arlandis-Guzman et al. use the KHQ for their calculations, and report QALY gains with the antimuscarinic drugs fesoterodine, tolterodine, and solifenacin of 0.01014, 0.00846, and 0.00957, respectively.²¹⁵

The extra cost per QALY (i.e., the ICERs) for the Internet-based versus postal treatment ranged from €200 to €7253, and for the Internet-based versus non-treatment alternative from €10,022 to €38,921. Although this variety is due to uncertainty in the data, our results are strengthened by their consistency in the base case and the sensitivity analyses.

Whether or not these extra costs are considered affordable depends on how much society is willing to pay for a QALY. There are no explicit limits for this; in addition, willingness to pay might vary with the severity of the underlying condition.²¹⁶ In Sweden, the Dental and Pharmaceutical Benefits Agency normally considers treatments with an incremental cost <500,000 SEK (≈€52,000) per QALY gained as cost-effective.²¹⁷ This approach is comparable that of other countries. For example, a threshold of \$50,000 USD (≈€40,500) is often used in the United States.^{218, 219} The NICE guidelines employed in the United Kingdom apply a health care perspective, and usually recommend implementation of treatments with ICERs of <£20,000 to £30,000 (≈€17,000-25,000).¹³⁹

Hence, if these limits can be employed for SUI, the Internet-based programme appears to be a cost-effective treatment option in all of the scenarios included in our analyses.

Future Perspectives

This thesis establishes Internet-based treatment based on PFMT as a new, acceptable, and affordable first-line treatment for SUI. However, although it seems more effective and more cost-effective, than the postal treatment, this kind of treatment is not likely to suit all women. Postal treatment also rendered clinically relevant improvements, and for some women it might be the more appealing alternative.

While our ambition is to implement the study treatments in everyday practice, exactly how this should be achieved is unclear, and more research is needed before the programmes can be made fully accessible. One possibility would be an open-access website where women could self-diagnose SUI and choose from different kinds of treatment. Another possibility is that women diagnosed with SUI within the ordinary health care system could be referred to the Internet-based programme for PFMT.

However, a substantial amount of the treatment effect reported by an RCT might be lost in a clinical setting, where circumstances are less controlled and the population is more diverse. Therefore, it is essential to carefully assess the effect of treatment when it is implemented in clinical practice. Additionally, the long-term effects of the treatment programmes must be determined, and for more widespread use and increased accessibility, they must be translated into other languages.

Furthermore, to enable individualised recommendations to women with SUI, it would be valuable to determine who benefits the most from each treatment (i.e., predictors of successful outcomes). More knowledge is also needed regarding why women choose this kind of treatment.

The Internet-based treatment is a complex intervention, and we do not know if any part of the programme is particularly important. A simpler design that lacks urotherapist support might be equally effective. Moreover, it could be further developed to treat other kinds of urinary incontinence.

Many women of today have high demands, expect to live an active life until high age, and will probably not accept being limited by leakage symptoms. In addition, patients are increasingly undertaking the role of consumers and demanding prompt access to care. Furthermore, the Internet contributes to changing the role of the patient by providing access to more information than before.

Most GPs want to provide good quality, patient-centered care, with patients participating in shared decision-making and taking as active a role in their treatment as possible. In our everyday practice, the study treatments would increase the number of treatment options for women with SUI. A

reliable questionnaire to evaluate QOL in these women would also be helpful.

If the Internet-based programme can be implemented as the first part of stepwise care, then GPs will not be directly included in first-line treatment, but are likely to meet women that treatment has failed. This might contribute to optimise the use of GPs' time. Furthermore, at that point of time, we could expect women to have gained greater knowledge on the subject of SUI, and our communication could start at a higher level, which would facilitate our job. However, it is important that the ordinary health care system continues to offer first-line care to women that prefer face-to-face treatment, as well as to vulnerable patient groups.

In my point of view, one important aspect of the Internet-based treatment programme is its ability to provide access to good quality care in a sustainable way. Health care systems face great challenges, and clinicians must deliver treatment in cost-effective and affordable ways.

Increasing self-management and patient empowerment might be one way to meet future demands.²⁰¹ Technology provides us with new ways of supporting patients, and Internet-based interventions are increasingly used to enhance patient empowerment in individuals with various chronic conditions.^{220, 221} In addition to adding value for the individual patient, it has the potential to reduce the need for support from the health care system, thereby helping to save its resources for those with implicit needs.

If the Internet-based treatment can be implemented, then the workload in the health care system might initially increase because the problem of SUI is put on the map. However, in the long run, it could off-load primary care while increasing both access to care and the quality of care given to this group of patients.

General Conclusions

- Management of SUI is possible without face-to-face contact.
- Women with SUI can achieve clinically relevant improvements with 3 months of unsupervised PFMT, whether it is provided as an Internet-based or a postal treatment programme. Improvements are comparable to those observed in studies of supervised PFMT.
- Regarding symptom severity and quality of life, treatment effects were similar with both programmes; however, women receiving Internet-based treatment reported greater subjective improvements, larger reductions in the use of incontinence aids, and greater satisfaction with the treatment programme.
- The condition-specific quality of life questionnaire ICIQ-LUTSqol is reliable in women with SUI, and it can be used in either a paper or a web-based version.
- Women appreciated the Internet-based treatment programme, and felt acknowledged and supported without exposure. They gained greater knowledge about how to manage their situation, and felt empowered.
- The Internet-based treatment programme is cost-effective in comparison with both the postal programme and a non-treatment alternative. The cost of delivering the treatments was lower than that of much ordinary care provided today.
- Internet-based treatment for SUI is a new, effective, and appreciated treatment alternative that can increase access to care in a sustainable way.

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Appendices

Appendix A

Reprinted with permission from the ICIQ office.

Patientnummer

Patientens initialer

ICIQ-UI Short Form (Swedish)

KONFIDENTIELLT

Dag

Månad

År

Dagens datum

Många människor drabbas periodvis av urinläckage. Vi försöker ta reda på hur många som har besvär och hur stort problemet är för dem. Vi vore tacksamma om du ville svara på följande frågor om hur du i genomsnitt har haft det, under de SENASTE FYRA VECKORNA.

1 Fyll vänligen i ditt födelsedatum:

DAG

MÅNAD

ÅR

2 Är du (kryssa i ett alternativ):

Kvinna ☐

Man ☐

3 Hur ofta drabbas du av urinläckage? (Kryssa i ett alternativ)

aldrig ☐ 0

ungefär en gång i veckan eller mer sällan ☐ 1

två eller tre gånger i veckan ☐ 2

ungefär en gång per dygn ☐ 3

flera gånger per dygn ☐ 4

alltid ☐ 5

4 Vi skulle vilja veta hur mycket urin som du tror läcker ut.

Hur stor mängd urin är ett normalt läckage för din del (oberoende av om du använder skydd eller ej)? (Kryssa i ett alternativ)

ingen ☐ 0

liten mängd ☐ 2

måttlig mängd ☐ 4

stor mängd ☐ 6

5 På det hela taget, i hur hög grad inverkar urinläckage på ditt normala, dagliga liv?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls våldigt mycket

ICIQ poäng: summa poäng 3+4+5

6 När läcker urin ut? (Kryssa i alla alternativ som stämmer på dig)

aldrig – inget urinläckage ☐

läcker innan du hinner till toaletten ☐

läcker när du hostar eller nyser ☐

läcker när du sover ☐

läcker när du är fysiskt aktiv/tränar ☐

läcker när du har slutat kissa och tagit på dig kläderna ☐

läcker utan synbar anledning ☐

läcker hela tiden ☐

Ett stort tack för att du besvarade dessa frågor.

Appendix B

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Patientnummer

Patientens initialer

ICIQ-LUTSqol (Swedish) 08/04

KONFIDENTIELLT

DAG

MÅNAD

ÅR

Dagens datum

Livskvalitet

Nedan finns några dagliga aktiviteter som kan påverkas av problem med blåsan. Hur mycket påverkar Dina problem med blåsan Dig? Vi skulle vilja att Du svarar på samtliga frågor. Kryssa för det svar som stämmer in på Dig.

Vi är tacksamma om Du vill besvara följande frågor och tänka på hur Du i genomsnitt har haft det under de SENASTE FYRA VECKORNA.

1. Fyll i Ditt födelsedatum:

DAG MÅNAD ÅR

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

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

2b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

3a. Påverkar Dina problem med blåsan Ditt arbete eller Dina normala dagliga aktiviteter utanför hemmet?

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

3b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

4a. Påverkar Dina problem med blåsan Dina fysiska aktiviteter (t.ex. att promenera, springa, sporta, gymnastisera, etc.)?

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

4b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

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

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

5b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

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

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

6b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

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

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

7b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

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

- ej tillämpligt ☐ 8
 inte alls ☐ 1
 lite ☐ 2
 en del ☐ 3
 mycket ☐ 4

8b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
 inte alls mycket

9a. Påverkar Dina problem med blåsan Ditt sexliv?

- ej tillämpligt ☐ 8
 inte alls ☐ 1
 lite ☐ 2
 en del ☐ 3
 mycket ☐ 4

9b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
 inte alls mycket

10a. Påverkar Dina problem med blåsan Ditt familjeliv?

- ej tillämpligt ☐ 8
 inte alls ☐ 1
 lite ☐ 2
 en del ☐ 3
 mycket ☐ 4

10b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
 inte alls mycket

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

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

11b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
 inte alls mycket

12a. Känner Du Dig orolig eller nervös på grund av Dina problem med blåsan?

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

12b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

13a. Har Du dålig självkänsla på grund av Dina problem med blåsan?

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

13b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

14a. Påverkar Dina problem med blåsan Din sömn?

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

14b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

15a. Känner Du Dig sliten/trött på grund av Dina problem med blåsan?

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

15b. Hur mycket besvärar Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

Hur ofta gör eller känner Du något av följande?

16a. Använder skydd för att hålla Dig torr?

aldrig ☐ 1
ibland ☐ 2
ofta ☐ 3
alltid ☐ 4

16b. Hur mycket besväras Du av detta?
Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

17a. Är försiktig med hur mycket vätska Du dricker?

aldrig ☐ 1
ibland ☐ 2
ofta ☐ 3
alltid ☐ 4

17b. Hur mycket besväras Du av detta?
Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

18a. Behöver byta underkläder därför att de blivit våta?

aldrig ☐ 1
ibland ☐ 2
ofta ☐ 3
alltid ☐ 4

18b. Hur mycket besväras Du av detta?
Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

19a. Oroar Dig för att Du kanske luktar?

aldrig ☐ 1
ibland ☐ 2
ofta ☐ 3
alltid ☐ 4

19b. Hur mycket besväras Du av detta?
Ringa in en siffra mellan 0 (inte alls) och 10 (mycket)

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

20a. Blir generad över Dina problem med blåsan?

aldrig ☐ 1

ibland ☐ 2

ofta ☐ 3

alltid ☐ 4

20b. Hur mycket besväras Du av detta?

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

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

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

0 1 2 3 4 5 6 7 8 9 10
inte alls mycket

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Tack så mycket för att du besvarar dessa frågor.

APPENDIX C

Detailed descriptions of the pelvic floor muscle training regimens included in the treatment programmes.

Internet-based treatment programme

Participants were instructed to maintain training at each level for at least 1 week. The urotherapists provided logs for the next level, after participants' reports of the passing of self-monitored tests.

<p>Level 1 3 times daily, supine position: <i>Contractions to identify the correct muscles</i> 10 × 2 s Rest 30 s 10 × 2 s</p> <p>Level 2 3 times daily, supine position: <i>Contractions to identify the correct muscles</i> 5 × 2 s Rest 2 s between individual contractions <i>Maximal contractions, for strength</i> 5 × 6-8 s Rest 6-8 s between individual contractions</p> <p>Level 3 3 times daily, supine, erect, or sitting position: <i>Maximal contractions, for strength</i> 10 × 6-8 s Rest 6-8 s between individual contractions <i>Submaximal contraction, for endurance</i> 1 × >15 s</p> <p>Level 4 3 times daily, sitting position: <i>Maximal contractions, for strength</i> 10 × 6-8 s Rest 6-8 s between individual contractions <i>Submaximal contraction, for endurance</i> 1 × >30 s</p> <p>Level 5 3 times daily, erect position: <i>Maximal contractions, for strength</i> 10 × 6-8 s Rest 6-8 s between individual contractions <i>Submaximal contraction, for endurance</i> 1 × >60 s</p> <p>Level 6 2 times daily, erect position: <i>Maximal contractions, for strength</i> 10 × 6-8 s Rest 6-8 s between individual contractions <i>Submaximal contraction, for endurance</i> 1 × >60 s <i>Maximal contractions, for strength</i> 10 × 6-8 s Rest 6-8 s between individual contractions <i>Maximal quick contractions, for rapidity</i> 10 × 3 s Rest 3 s between individual contractions</p>	<p>Level 7 2 times daily, erect position: <i>Maximal contractions, for strength</i> 10 × 6-8 s, while bending your knees on every other contraction Rest 6-8 s between individual contractions <i>Submaximal contraction, for endurance</i> 1 × >60 s <i>Maximal contractions, for strength</i> 10 × 6-8 s, while bending your knees on every other contraction Rest 6-8 s between individual contractions <i>Maximal quick contractions, for rapidity</i> 10 × 3 s, while coughing on every other contraction Rest 3 s between individual contractions</p> <p>Level 8 3 times weekly, erect position: <i>MaximumMaximal contractions, for strength</i> 12 × 6-8 s, while bending your knees on every other contraction Rest 6-8 s between individual contractions <i>Submaximal contraction, for endurance</i> 1 × >60 s <i>Maximal contractions, for strength</i> 12 × 6-8 s, while bending your knees on every other contraction Rest 6-8 s between individual contractions <i>Maximal quick contractions, for rapidity</i> 10 × 3 s, while coughing on every other contraction Rest 3 s between individual contractions <i>Maximal contractions, for strength</i> 12 × 6-8 s, while bending your knees on every other contraction Rest 6-8 s between individual contractions</p>
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Postal treatment programme

Participants were instructed to increase training gradually, but had access to all exercises from the start.

Level 1

3 times daily, supine position:
Contractions to identify the correct muscles
8 × 2 s
Rest 2 s between individual contractions

Level 2

3 times daily, any position:
Maximal contractions, for strength
8 × 6-8 s
Rest 6-8 s between individual contractions

Level 3

3 times daily, any position:
Maximal contractions, for strength
8 × 6-8 s
Rest 6-8 s between individual contractions
Submaximal contraction, for endurance
1 × >60 s

Level 4

3 times daily, any position:
Maximal contractions, for strength
8 × 6-8 s
Rest 6-8 s between individual contractions
Submaximal contraction, for endurance
1 × >60 s
Maximal quick contractions, for rapidity
8 × 3 s
Rest 3 s between individual contractions

Level 5

3 times daily, any position:
Maximal contractions, for strength
8 × 6-8 s
Rest 6-8 s between individual contractions
Submaximal contraction, for endurance
1 × >60 s
Maximal quick contractions, for rapidity
8 × 3 s
Rest 3 s between individual contractions

Remember to contract your pelvic floor before coughing, sneezing, laughing, lifting, or jumping.