Interventions for Urinary Incontinence in Women
To Thomas, Marit, Ellen och Erik
Interventions for Urinary Incontinence in Women
Survey and effects on population and patient level
Abstract


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Several of these knowledge gaps have been the starting points for the projects in this thesis. The overall aim has been to study the impact of different interventions for urinary incontinence in women on the population level but also on the patient group level, for assessing the significance of UI on general living conditions and to validate instruments to measure quality of life to be used as part of the evaluation of treatment effectiveness.

Paper I: A population-based study where UI amongst women was found to be commonly associated with different psychosocial problems and an expressed feeling of vulnerability.

Paper II: A population-based study where informative material on UI to the general public in order to increase knowledge and encourage self-management was found promising for meeting increasing demands and optimizing healthcare resources.

Paper III: A randomized controlled trial where both electrical stimulation and drug therapy reduced the number of micturitions and improved QoL in women with urge or urge incontinence, but electrical stimulation was not found to be superior to drug therapy.

Paper IV: A prospective cohort study where the international questionnaires UDI-6 and IIQ-7 after translation and validation, showed good responsiveness and were easy to administer and to fill out. The UDI-6 scale did not accomplish the same solid result in the psychometrical analysis as the IIQ-7 scale but both scales showed good responsiveness and can thereby be recommended for clinical use.

Keywords: Urinary incontinence, female, general living conditions, self-management, electrical stimulation, quality of life questionnaire.

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Original papers

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Introduction

Urinary Incontinence is a common health problem that can cause both severe medical and social problems, resulting in negative impact on different aspects of Quality of Life. In 2000, the Swedish Council on Health Technology Assessment (SBU) published a systematic review, “Treatment of Urinary Incontinence” where the importance of finding methods for improving the general knowledge on UI amongst the general public and to encourage self-management when suitable to meet the increasing demands and to optimize healthcare resources, was pointed out. The need for pragmatic intervention studies in clinical practice, and the need for instruments to assess quality of life as part of the evaluation of treatment effectiveness were other important areas where gaps in current knowledge were identified, together with the need to enhance the general knowledge on UI in relation to different psychosocial aspects.

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Background

Definition, prevalence and economic consequences

Urinary incontinence (UI) is a common disorder. In 2002, the International Continence Society updated the definition of UI: "Urinary incontinence is the complaint of any involuntary leakage of urine." ICS also stated that in each specific circumstance, urinary incontinence should be further described by specifying relevant factors such as type, frequency, severity, social impact and effect on quality of life. The measures used to contain the leakage should be described together with whether or not the individual sought or desired help because of urinary incontinence [1]. This wide definition, together with different methodologies used plus differences in populations surveyed, are possible reasons for the wide range of prevalence estimates reported in different studies.

The prevalence of UI among women is approximately twice the prevalence in men. The prevalence increases with age, from 7 to 37% at 20-39 years, 31 to 48% at 40-59 years, 30 to 61% at 60-79 years and 37 to 63% at 80+. The annual incidence of any new urinary incontinence ranges from 3% to 11%, increasing with age. Rates of complete remission range from 0% to 13% per year [2-7].

In the SBU systemic review from 2000 [8] it was estimated that around 500,000 persons in Sweden were affected by urinary incontinence and the total cost of UI to society was estimated to 2.8 to 4.4 billion SEK per year. The dominating cost items were for nursing care and sanitary protection (>90%). Drug therapy, electrical stimulation treatment and surgery accounted altogether for less than 8%. With increasing demands and growing awareness of UI as an important health issue, both in the medical literature and in the popular media, but most importantly as a consequence of an ageing population, this economic burden is likely to escalate [8, 9].

Types of urinary incontinence and patophysiology

Several subtypes of UI have been described in the literature. The three most common subtypes of UI amongst women are stress urinary incontinence (SUI) which is characterized by involuntary leakage on effort, sneezing or coughing. Urge urinary incontinence (UUI) is defined as the complaint of involuntary leakage accompanied by or immediately preceded by a sudden strong desire to void and mixed urinary incontinence (MUI), which is a combination of SUI and UUI.

Stress urinary incontinence arises when the bladder pressure exceeds the urethral pressure in situations with a sudden increase of intra-abdominal pressure.
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pressure (ie coughing), due to bladder neck hypermobility and/or low pressure urethra (intrinsic sphincter deficiency).

The prevalence of SUI in women peaks between ages 40 and 60 years whereas both UUI and MUI continue to increase with age [5].

UUI often coexists with urgency (sudden strong desire to void without urinary leakage), frequency (to void > 8 times/24h), and nocturia (awake at night ≥ once to void) which together can be described as the overactive bladder syndrome (OAB) [1]. OAB is mostly regarded as an idiopathic bladder oversensitivity but can also occur in cases of deterioration of CNS control of urine storage such as spinal cord injury and in neurological diseases such as Parkinson’s disease [5].

The estimated prevalence of OAB in women in two large population-based surveys were 12.8 % and 17.4 %, respectively [10, 11]. Overactive bladder syndrome is in turn a subset of LUTS (lower urinary tract symptoms) that are divided into three groups; storage, voiding and post micturition symptoms [1].

In a large population-based study from 2009 [12] they found that LUTS were highly prevalent both among men and women >40 years. The most prevalent symptom reported among both men and women were terminal dribble (prolonged final part of micturition) (45% and 38%, respectively), but this was at the same time reported as one of the least bothersome symptoms. The least prevalent symptom and reported as being the most bothersome both among men and women were incontinence during sexual activity (0.3% and 2.0%, respectively).

Risk factors
The best studied risk factors for UI are parity, age and obesity [5]. Vaginal delivery is the most important lifetime risk factor, caesarean delivery is partly protective. About 15 to 30 % of new mothers become incontinent after their first vaginal delivery [2, 5].

Obesity is associated with all types of UI. Other described risk factors are diabetes mellitus, previous hysterectomy, oral estrogen replacement therapy, impaired physical function, restricted mobility, cognitive impairment and dementia. Family history of UI is another risk factor as well as constipation, faecal incontinence, genital prolapse, congestive heart failure, use of diuretics and childhood enuresis [2, 5, 6, 13-15].

Lifestyle, living conditions and psychosocial factors
The literature concerning surveys looking into UI in relation to lifestyle, living conditions, and socioeconomics is limited. A population-based study
by Hannestad et al [16] showed that heavy smoking, high intake of tea, and high BMI were related to UI; whereas increased hours of low intensity physical activity were associated with decreased risk of UI. Possible associations between UI and educational level, housing tenure, employment status, and domestic situation were negated by Roe et al [17].

A survey by Fultz et al showed that the incontinent responders reported being lonelier, sadder and more depressed than the continent responders [18]. Methods of coping with UI included avoidance, limiting behaviour and social isolation, which could explain why depression and anxiety may be associated with UI [19, 20].

Perry et al [21] found in their prospective longitudinal postal survey that a significant proportion of women with urge incontinence reported symptoms of anxiety (57%) and depression (38%) and that incident cases of urge incontinence were predicted by anxiety at baseline, but not depression. Anxiety and UUI appeared to interact and exacerbate each other.

Helpseeking behaviour
In spite of the fact that urinary incontinence is a common health problem that can cause severe medical and social problems, resulting in a negative impact on the quality of life (QoL), it has been shown that approximately 70% of individuals with UI do not seek help for their complaints [8, 22]. The reasons for this are not all clear but are likely to be multifactorial. One reason may be that the individual does not perceive UI as a major problem requiring treatment or that incontinence is experienced as a normal part of aging in spite of sometimes severe symptoms. Other important reasons are lack of knowledge, both concerning available treatment options and where to seek care, fear of treatments and embarrassment to discuss UI [23-29]. Those with more severe UI measured as frequency of leakage, greater self-perceived severity and functional limitations are most likely to seek treatment [6, 22, 25].

Evaluation of urinary incontinence
The traditional methods to assess the diagnosis and symptom severity of urinary incontinence are through clinical measures such as history taking, physical examination, bladder diary or frequency volume chart and urodynamics [1].

Physical examination includes abdominal, pelvic, focused neurological examination and stress test, the latter to observe urinary leakage when the woman is asked to cough or strain in lying, sitting or standing position.
Bladder diary includes times for micturitions and voided volumes, incontinence episodes, fluid intake and the degree of urgency and incontinence. Bladder diary also includes pad usage which is usually evaluated by weighing the pads before and after use. The leakage of urine is measured in gram/24 hours.

Frequency volume charts record the volumes voided as well as the times of each micturition day and night, for at least 24 hours.

Urodynamics is used to investigate the urethra and bladder’s functional status; it normally is performed in the urodynamic laboratory and involves filling the bladder with a specified liquid (NaCl) via a catheter [1].

In recent years it has been acknowledged that even if some kind of objective method to assess UI is necessary and important, these clinical measures alone are poor indicators of the effect on individual lives and that the extent of this impact varies greatly among individuals [5, 6, 30, 31, 32].

It has also been shown that compared with stress incontinence sufferers, persons with urge incontinence that must cope with the unpredictability of urgency symptoms and also often experience a greater urine loss experience a greater negative impact on QoL [33-36]. To comprehensively assess the impact of incontinence it is necessary to measure the level of symptoms in an individual together with the extent to which these symptoms impair QoL.

**Quality of life**

In the last two decades a considerable number of instruments to assess lower urinary tract symptoms and impact on QoL have been developed. In 2004 the Symptom and Quality of Life Subcommittee of the Second International Consultation on Incontinence (ICI) reviewed published literature on psychometrically based self-report questionnaires, both generic (measurement of general health) and those specific for the disease (condition specific), that had been used to assess the symptoms and effect on Quality of Life of urinary and anal incontinence in adults [37]. The report was revised in 2007 and upgraded to include material published from 2001 to 2004. The report graded the questionnaires as grade A- highly recommended - if the instrument/questionnaire could provide published rigorous data on validity, reliability and responsiveness to change in several clinical studies. All together 18 condition specific questionnaires for men and women achieved grade A level [31]:

- Questionnaires/instruments that address combined symptoms and QoL impact of UI:
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**Questionnaires/instruments that address combined symptoms and QoL impact of UI:**
- ICIQ (International Consultation on Incontinence Questionnaire)
- BFLUTS-SF (Bristol Female LUTS Questionnaire- short form)
- SUIQQ (Stress and Urge Incontinence Quality of life Questionnaire)
- ICSmaleSF (International Continence Society male Short Form)
- OAB-q (Overactive bladder-questionnaire)

**Questionnaires/instruments that address UI symptoms:**
- UDI (Urogenital Distress Inventory)
- UDI-6 (Urogenital Distress Inventory-6, short form)
- Incontinence severity index
- BFLUTS (Bristol Female Lower Urinary Tract Symptoms)
- ICSmale LUTS primarily (International Continence Society male)
- Danish Prostatic Symptom Score

**Questionnaires/instruments that address QoL impact of UI:**
- I-QoL (Quality of Life in persons with UI questionnaire)
- SEAPI-QMM (Stress-related leaks Emptying ability Anatomy (female) Protection Inhibition –Quality of Life Mobility Mental status)
- KHQ (King’s Health Questionnaire)
- IIQ (Incontinence Impact Questionnaire)
- IIQ-7 (Incontinence Impact Questionnaire-7 short form)
- UISS (Urinary Incontinence Severity Score)
- Contilife (Quality of Life Assessment Questionnaire Concerning Urinary Incontinence)

The two most commonly used generic measures of QoL used for urinary incontinence were SF-36 and EQ-5D, but these generic measures were found to be relatively insensitive to changes in incontinence [37, 38, 39]. Instruments to assess the impact of anal incontinence, vaginal and pelvic problems were by far fewer and none reached grade A level [31].

The majority of the instruments listed are originally developed in an English-speaking population. The current number of Swedish translated instruments available is difficult to find out. Only a few Swedish translated instruments to be used in female UI are listed in the ProQolid database [40]; namely the ICIQ[41], OAB-q[42], I-QoL[43], KHQ[44] and Contilife[45]. The ProQolid (Patient Reported and Quality of Life Instruments Database) is a database that provides an overview of existing PRO instruments (currently > 600). The listing in ProQolid does however not guarantee that the translations have undergone a full linguistic validation process.
It is proposed that the process of translation and validation of an instrument into a foreign language must be appropriate and rigorous to ensure validity and make cross cultural comparisons possible [46]. It might be tempting but is not enough to translate a questionnaire literally. There are two main approaches for translation: the forward-backward translation and the dual panel approach, both methods are time consuming and costly [47, 48]. The challenge is to adapt the questionnaire in a culturally relevant and comprehensible form while maintaining the meaning and intent of the original items, a fact that is said often to be neglected and even unknown by many clinicians [46].

When choosing a questionnaire for use in clinical practice or research, the first step is to make a brief review of the questionnaire’s content and structure. Is it feasible to use? A long and detailed questionnaire intended for research use might be too burdensome and time consuming to use in clinical practice. Does it measure what you want to measure? In what context and in which population was the questionnaire originally and later translated versions validated? If this extensively differs from the intended target population further validation is usually necessary even for a validated translated version.

To assess reliability and validity and responsiveness there are several commonly used concepts to consider [49].

Validity
Face validity:
Subjective assessment by an expert panel and/or patient focus group as to whether the instrument appears to measure what it intends to measure. The questions should make sense.

Content validity:
Subjective assessment by an expert panel and/or patient focus group as to the extent that the domain of interest is comprehensively sampled by the questions in the instrument.

Construct validity:
An assessment as to whether the instrument has appropriate relationship with other variables or measures. That is, the instrument correlates or agrees with other tests or measures of the same construct (convergent validity) and has little or no correlation or agreement with measures of different construct (discriminant or divergent validity).
Known-groups validity assesses the instrument’s ability to differentiate between subgroups (i.e. different diagnose groups within urinary incontinence). This requires an assumption/hypothesis.

Criterion validity:
Extent to which an instrument correlates with an established criterion standard (or “gold standard”). For Health Related QoL questionnaires in UI, no such gold standard exists.

Reliability
Internal consistency:
The extent to which the items on a scale are related to one another. Often assessed with the statistic Cronbach’s alpha (values of > 0.70 demonstrate adequate internal consistency).

Test-retest reliability:
An assessment of the repeatability; the correlation between instrument scores on two separate occasions. Repeat measurements should be made far enough apart in time so earlier responses are forgotten, yet not so far apart that the construct measured might have changed.

Responsiveness
An assessment as to whether the instrument can detect clinically meaningful change. Methods for assessing responsiveness can broadly be separated into two groups: distribution-based methods that measure the relative amount of change from baseline score of an instrument after treatment (effect size, standardized response mean (SRM)) and anchor-based methods that compare the change in an instrument to some other measure that has clinical relevance (i.e. incontinence episodes)

There are two more concepts that have to be explained; effect indicators and causal indicators. The traditional psychometrical analysis and psychometric scale construction is based on the assumption that all items are effect indicators (i.e. depression, frustration etc.) reflecting the latent construct; in this case QoL, thus leading to high correlation structure and high internal consistency. Scales constructed to measure severity of symptoms that differ, in this case between the different subtypes of UI, are called clinimetric scales. Such scales contain items on symptoms that can cause deterioration in QoL (so called “causal indicators”). Causal indicators are usually more heterogeneous than effect indicators and thereby consequently leading to lower correlation structure and lower internal consis-
tency. Validation of clinimetric scales should be based more on content validity and clinical usefulness. The clinimetric scale construction also makes it more difficult to differentiate between different subtypes of UI when summation of score (total score calculation) is made [50].

**Treatment of urinary incontinence**

There are several different treatment alternatives for urinary incontinence. The treatment alternatives are different for the different subtypes of incontinence and also depend on the severity and impact, as well as the patients’ individual preferences.

**Surgical treatment options**

Surgery is used mainly in treatment of stress urinary incontinence. Minimally invasive synthetic suburethral sling operations are today the dominating surgical procedure. The TVT (tension-free vaginal tape) procedure was introduced in the mid-90’s and have been shown to be safe, easy to perform, with low complication rates and with cure rates between 80% to 90% during follow-up periods of more than 3 years and 77% subjective cure after 11.5 years [51,52].

In order to avoid the blind passage through the retropubic space, two alternative ways of putting the sling through the obturator membrane instead have been developed: the “inside out” tension-free vaginal tape obturator (TVT-O) and the “outside-in” tension-free vaginal tape obturator (TOT).

In the Cochrane collaboration review from 2009 [53] the obturator route was found to be less favourable than the retropubic route in objective cure (84% versus 88%; RR 0.96 (95%CI 0.93 - 0.99), 17 trials, n = 2434), although there was no difference in subjective cure rates. There was less voiding dysfunction, blood loss, bladder perforation (0.3% versus 5.5%), and shorter operating time, but more groin pain (12% versus 1.7%) with the obturator route.

The surgical procedure of trans- or periurethral injection of different bulking agents into the wall of urethra show according to a Cochrane collaboration review from 2007[54] unsatisfactory basis for practice. The review of 12 trials including 1318 women found some but only limited evidence that the method in the short-term can relieve stress urinary incontinence in women. The conclusion was that other methods might be preferable.
Non-surgical treatment options

Pelvic floor muscle training (PFMT) is the most commonly used physical therapy treatment for women with stress urinary incontinence. It is sometimes recommended for mixed and less commonly for urge urinary incontinence. According to a Cochrane collaboration review from 2010[55] women who performed PFMT were more likely to report they were cured or improved and experienced a positive impact on QoL. They also reported fewer urinary leakage episodes per day, and less amount of leakage compared with women on no or inactive treatment. PFMT helps women with all types of incontinence although women with stress urinary incontinence who exercise for three months or more benefit the most.

Bladder training and behavioural modifications is the basic form of treatment for urgency and overactive bladder. The patient is taught strategies to improve control of urgency and voiding regimen to increase time interval between voiding. According to a Cochrane collaboration review from 2004[56]this treatment may be helpful for treatment of urinary incontinence but the conclusion is tentative due to limited data, and more research is needed.

Obesity (BMI > 30) is associated with all types of UI, but especially stress urinary incontinence. Weight reduction of 5% has been shown to reduce the number of incontinence episodes [57].

Estrogen therapy According to a Cochrane collaboration review from 2009 [58] there is some evidence that estrogens administered locally in the vagina may improve incontinence in terms of less frequency and urgency (RR 0.74, 95% CI 0.64 - 0.86). There were no available data on long-term effects.

Systemic hormone replacement initiated by other reasons than incontinence might on the other hand induce urinary incontinence [59].

Pharmacotherapy for urgency/urge incontinence includes drugs that suppress bladder contractions through the parasympathetic nervous input via muscarenic receptors of the bladder wall where acetylcholine is the transmitter substance.

The drug efficacy, measured as the reduction in leakage episodes over 24 hours (weighted mean difference (WMD) -0.54; 95% CI -0.67 to -0.41) and the difference in number of voids in 24 hours (WMD -0.69; 95% CI -0.84 to -0.54) were statistically significant favouring medication. These results correspond to roughly five less trips to the toilet and four less leakage episodes per week on average for a patient on anthicholinergic medication compared with placebo. Side effects are common, especially dry mouth, but there was no significant difference in withdrawal (RR 1.11, CI 95% 0.91 to 1.36) compared to placebo [60].
Comparisons between different antimuscarenics should be interpreted cautiously due to different inclusion and exclusion criteria plus differences in populations surveyed. However, new agents have greater tolerability and better dose flexibility and once-a-day dosage seem to be better tolerated [61].

**Pharmacotherapy** for stress urinary incontinence includes Duloxetine a serotonin and noradrenaline reuptake inhibitor (SNRI). A systemic review from 2007 [62] showed that duloxetine 80mg/daily had better results compared to placebo in terms of subjective cure and improvement in incontinence, but the effect was very modest. A considerable amount of participants reported an adverse effect, most commonly nausea. Approximately 17% discontinued treatment. The evidence that duloxetine alone or in combination with PFMT (pelvic floor muscle training) would be more efficient than PFMT alone was limited.

**Electrical stimulation treatment**
Another treatment option for urgency/urge incontinence but not as frequently used is electrical stimulation. The treatment is thought to induce a reflex contraction of the striated para- and periurethral muscles, accompanied by a simultaneous reflex inhibition of the detrusor muscle [33].

Electrical stimulation is administered vaginally and/or transanally and is usually delivered by a specialized nurse (urotherapist) at the outpatient clinics. Over a time period of 5-7 weeks, all together ten stimulation treatments are applied 1-2 times per week for 20 minutes with a frequency of 5-10 Hz. The maximum electrical stimulation is done with maximum tolerable intensity, which is adjusted up to the level of tolerable discomfort.

Another form of electrical stimulation treatment is the long-term stimulation which is delivered below the sensory threshold. Devices are to be used for 6-8 h per day for at least 3 months; this form of treatment is usually used in stress urinary incontinence [63].

The literature reveals a large variation in treatment results, probably due to a large heterogeneity in study design, in choice of outcome parameters and mode and duration of treatment. The overall results regarding improvement measured both as incontinence episodes and as subjective improvement, vary from 17% to 100% (mean 70%) among patients completing the treatment [64-72]. However, the discontinuation rate is relatively high (20%) [64]. The long-term effect seems to be relatively good, showing a continuing effect 6 to 24 months after completion of the electrical stimulation treatment [68].

There are only a few randomised controlled trials where electrical stimulation treatment has been compared to other conservative treatments or no
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Another form of electrical stimulation treatment is the long-term stimulation which is delivered below the sensory threshold. Devices are to be used for 6-8 h per day for at least 3 months; this form of treatment is usually used in stress urinary incontinence [63].

The literature reveals a large variation in treatment results, probably due to a large heterogeneity in study design, in choice of outcome parameters and mode and duration of treatment. The overall results regarding improvement measured both as incontinence episodes and as subjective improvement, vary from 17% to 100% (mean 70%) among patients completing the treatment [64-72]. However, the discontinuation rate is relatively high (20%) [64]. The long-term effect seems to be relatively good, showing a continuing effect 6 to 24 months after completion of the electrical stimulation treatment [68].

There are only a few randomised controlled trials where electrical stimulation treatment has been compared to other conservative treatments or no treatment amongst patients with urinary incontinence. Brubaker et al 1997 [73] and Barroso et al 2004 [74] compared the use of an active transvaginal electrical device with use of a sham device, and found the active treatment more effective. Smith et al 1996 [75] in a study including 38 patients with detrusor instability randomized to electrical stimulation or drug therapy found that 72% improved in the electrical stimulation group but could not show a significant difference between the two active treatment groups. Arruda et al 2008 [76] in a three-armed randomized controlled trial of all together 64 women with overactive bladder and detrusor overactivity compared electrical stimulation, drug therapy, and pelvic floor muscle training, and found that all three treatments improved the number of leakage episodes and the number of pads used. In the group with electrical stimulation, consisting of 21 women, 52% reported resolved urgency. However, also this study failed to demonstrate difference between the treatment groups. There is still insufficient evidence for the efficacy of electrical stimulation compared to drug therapy [33].

Treatment of mixed incontinence
First line treatments are bladder training and behavioural modifications and PFMT that will help both the stress urinary incontinence and the urge urinary incontinence. Further treatment is usually aimed at the symptoms that cause the most bother. If the two types of incontinence are equally bothersome, treatment of the urge component is usually initiated before considering surgery [5].
Rationales for the thesis

It has been shown that only a minorit y of patients with urinary incontinence seek treatment. As discussed before the reasons for this are multifactorial but important aspects are psychosocial factors and coping strategies with UI including avoidance, limiting behaviour, and social isolation which probably influence patients' tendency to not seek help. The first study was designed to enhance knowledge around these aspects and the second study was designed to study if it would be possible to spread knowledge and encourage self treatment through a postal brochure on UI.

The third study focuses on patients with urge and mixed incontinence who usually are more bothered compared to patients with stress urinary incontinence and experience a larger negative impact on quality of life. There is a shortage of pragmatic studies comparing different treatments for urgency/urge incontinence. In this randomized controlled trial we studied the efficacy and Quality of Life impact of electrical stimulation compared with drug therapy (tolterodine) among women with urgency/urge incontinence.

In the fourth study we validated two condition specific self-report questionnaires that address symptom severity and QoL impact of urinary incontinence. The instruments are short and comprehensive tools, feasible for the use in clinical practice.
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Aims of the thesis

The overall aim of this thesis is to study the effect of different interventions for urinary incontinence in women on both population and patient level and to study UI in relation to different psychosocial aspects as well as to validate and test an instrument to assess impact on QoL.

The specific aims are:

To study the presence of female urinary incontinence in relation to psychosocial factors in the population.

To study and evaluate the effect of an information campaign in the form of a brochure on UI directed to the general public concerning knowledge, individual health behaviour, self-reported health care utilisation and how the information was perceived.

To study the effect of electrical stimulation compared with drug treatment for treatment of urge/urge incontinence amongst women in a randomized controlled trial.

To validate and study responsiveness of a Swedish version of Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6); two condition specific self-report questionnaires that address symptom severity and QoL impact of urinary incontinence.
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<table>
<thead>
<tr>
<th>Study</th>
<th>Aim</th>
<th>Design</th>
<th>Data collection</th>
<th>Subjects</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study I</td>
<td>To analyze differences in general health and living conditions between women with and without urinary incontinence</td>
<td>Population-based cross-sectional study</td>
<td>The postal public health &quot;Life&amp; Health&quot;(87 questions) answered by all participants and the urinary incontinence questionnaire (12 questions), answered by people with UI</td>
<td>15,360 randomly selected individuals living in Örebro County: data from 4,609 female respondents of whom 1,332 had completed both questionnaires and 3,277 had completed only the Life&amp; Health questionnaire</td>
<td>Binary logistic regression analysis</td>
</tr>
<tr>
<td>Study II</td>
<td>To study and evaluate the effect of an information campaign in the form of a brochure on UI directed to the general public</td>
<td>Population-based cross-sectional study</td>
<td>A postal questionnaire (20 questions) answered by all participants that had received the brochure “Treatment of Urinary incontinence”</td>
<td>3,658 randomly selected individuals in Laxå community, stratified for gender and age. Data from 1,738 men and women (782/956) who had returned the questionnaire</td>
<td>Descriptive statistics</td>
</tr>
<tr>
<td>Study III</td>
<td>To study the effect of electrical stimulation compared with drug treatment for treatment of urge/urge incontinence amongst women</td>
<td>Randomized Controlled Trial</td>
<td>Data on frequency of micturition, patient assessed improvement and QoL were measured at baseline and 6 months</td>
<td>37 women were randomized to electrical stimulation and 35 women to drug therapy-tolterodine. Sixty-one women were included in the final analysis</td>
<td>Chi square test, Independent and paired t-test with 95% CI</td>
</tr>
<tr>
<td>Study IV</td>
<td>To validate two condition specific self-report questionnaires that address symptom severity and QoL impact of urinary incontinence.</td>
<td>Prospective cohort study/Questionnaire</td>
<td>Clinical data including age and subtype of UI. Scores of UDI-6 and IIQ-7 at baseline and 6 months. “Satisfied with treatment” score at 6 months</td>
<td>Pilot study: 18 women with UI. Prospective study: 96 women with UI. Data from 77 women available at 6 months</td>
<td>Psychometric analysis: Content validity, Test-retest reliability, Weighted Kappa, Internal consistency, Cronbach’s alpha, Effect size, Standardized response mean, Convergent validity – Spearman rho</td>
</tr>
</tbody>
</table>
Methods and Results

The first two studies in this research project were population based studies. The third study is a randomised controlled trial. The fourth study is a prospective cohort study where validation of two condition specific questionnaires that address symptom severity and QoL impact of urinary incontinence was performed. Table 1.
In March 2000, a comprehensive public health questionnaire known as “Life and Health” was sent to randomly selected residents within a well-defined geographical area in the middle of Sweden. The purpose of this questionnaire was to assess issues of public health and general living conditions in order to obtain information for future health care planning. The sample was randomly selected from the Population Registry in Sweden and stratified for geographical area, age, and sex.

In Örebro County, an additional section entitled “For Persons with Problems with Involuntary Urine Loss” was enclosed with the Life and Health questionnaire. Only respondents with UI were asked to complete this section.

The sample and respondents, Figure 1.

15,360 Life and Health surveys and UI questionnaires
9,836 returned questionnaires
670 incomplete questionnaires
4,557 men excluded
Final study population 4,609
1,332 women who completed both questionnaires (defined as UI)
3,277 women who only completed the Life and Health survey (defined as not UI)
5,279 female respondents
Study I

Participants
In March 2000, a comprehensive public health questionnaire known as “Life and Health” was sent to randomly selected residents within a well-defined geographical area in the middle of Sweden. The purpose of this questionnaire was to assess issues of public health and general living conditions in order to obtain information for future health care planning. The sample was randomly selected from the Population Registry in Sweden and stratified for geographical area, age, and sex.

In Örebro County, an additional section entitled “For Persons with Problems with Involuntary Urine Loss” was enclosed with the Life and Health questionnaire. Only respondents with UI were asked to complete this section.

The sample and respondents, Figure 1.

<table>
<thead>
<tr>
<th>15 360 Life and Health surveys and UI questionnaires</th>
</tr>
</thead>
<tbody>
<tr>
<td>9836 returned questionnaires</td>
</tr>
<tr>
<td>4557 men excluded</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>5279 female respondents</td>
</tr>
<tr>
<td>670 incomplete questionnaires</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Final study population 4609</td>
</tr>
<tr>
<td>1332 women who completed both questionnaires (defined as UI)</td>
</tr>
<tr>
<td>3277 women who only completed the Life and Health survey (defined as not UI)</td>
</tr>
</tbody>
</table>
Questionnaires
The Life and Health questionnaire consisted of 87 multiple-choice questions on broad aspects of general and psychiatric health. It included questions on the presence or absence of chronic disease but did not include detailed questions on specific diseases. Questions concerning general living conditions (housing tenure, level of education, occupation, employment status, finances, social relations, need for aid in daily living, security in the neighbourhood) and personal habits (exercise, diet, weight and height, smoking and drinking habits) were included in addition to specific questions on the use of health care, dentistry, and medication. A few questions addressed general aspects of quality of life, but this was not assessed in detail by any of the standard global instruments since quality of life was not the main focus of the study.

The incontinence questionnaire consisted of 12 questions concerning different aspects of UI; such as frequency, duration, type of leakage, desire for treatment, and degree of inconvenience. Only respondents with UI were asked to complete this section. The questionnaire had been developed based on International Continence Society recommendations for community-based questionnaire studies. All questions were multiple-choice.

Data analysis
The data were entered into the SPSS statistical program (version 11.5). Data from respondents and non-respondents to the incontinence questionnaire (comprising the dependant variable) were compared using binary logistic regression. The non-dependant variables comprised all the questions from the Life and Health questionnaire. These were analyzed in relation to the dependent variable using a contingency table and univariate logistic regression. The statistical threshold for inclusion in further analysis was set at $p<0.25$. Variables within close areas were unified/recoded and the answers made binary.

Next, a stepwise deletion with a likelihood ratio and chi-squared test was used to reduce the model, resulting in a model in which all remaining variables had a p-value $<0.01$. The final model is presented using p-values and odds ratios with 95% confidence intervals. The statistic model has been presented previously [77, 78].

Results
We found associations between UI and the occurrence of musculoskeletal pain, fatigue and sleeping disorders, feelings of humiliation, financial problems, and reluctance to seek medical care. We also confirmed the strong associations between age and body mass index and UI. With one exception
(musculoskeletal pain) these associations were all strengthened when looking at women with more severe UI (leakage at least once per week), suggesting that increased severity leads to increased inconvenience.

We also found that persons with urge and mixed incontinence when analyzed separately from those with stress incontinence tended to be older and had a higher degree of psychosomatic problems (tiredness, weakness, sleeping disorders) but the differences were small with overlapping CI. The results of the final logistic regression analysis, showing the variables associated with urinary incontinence are shown in Table 2.
### Study II

Participants

Within the community of Laxå, situated in the southern part of the county of Örebro, Sweden, a random sample of the population, ages from 18 years and up, was selected from the Population registry. Laxå community is geographically well defined and primary health care is only available at the Laxå Primary Health Care Centre.

The population of Laxå community at the time of the study was 6,600 of which 1,500 > 65 years (22%). A random sample, stratified for gender and weighted for age included everyone older than 50 years, every other person between 35 and 49 years and every fourth person between 18 and 34 years. This made a total sample of 3658 persons. Persons living in nursing homes or other institutions were not included.

In figure 2 flow chart for study II is shown.

**Figure 2**

<table>
<thead>
<tr>
<th>Variable/question</th>
<th>Any leakage (n=1332) OR (95%CI)</th>
<th>Leakage &gt;= once per week (n=520) OR (95%CI)</th>
<th>Stress UI (n=565) OR (95%CI)</th>
<th>Urge + Mixed UI (n=593) OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65-79</td>
<td>6.60 (5.13-8.50)</td>
<td>13.89 (8.84-21.84)</td>
<td>6.70 (4.50-9.98)</td>
<td>8.47 (5.88-12.21)</td>
</tr>
<tr>
<td>50-64</td>
<td>5.50 (4.34-6.98)</td>
<td>8.62 (5.54-13.40)</td>
<td>7.46 (5.13-10.85)</td>
<td>6.06 (4.27-8.59)</td>
</tr>
<tr>
<td>35-49</td>
<td>3.22 (2.53-4.09)</td>
<td>5.38 (3.45 - 8.40)</td>
<td>4.2 (3.38-7.16)</td>
<td>3.10 (2.16-4.45)</td>
</tr>
<tr>
<td>18-34</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Body mass index (kg/m²)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obese (&gt;30)</td>
<td>2.11 (1.74-2.56)</td>
<td>3.26 (2.52-4.21)</td>
<td>2.33 (1.80-3.00)</td>
<td>2.39 (1.86-3.07)</td>
</tr>
<tr>
<td>Overweight (25-30)</td>
<td>1.23 (1.06-1.43)</td>
<td>1.29 (1.03-1.63)</td>
<td>1.22 (0.99-1.51)</td>
<td>1.29 (1.05-1.60)</td>
</tr>
<tr>
<td>Low/normal (&lt;25)</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Musculoskeletal pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During the last couple of months, have you been bothered more than once by pain in your back, hips, hands, arms, legs, knees, or feet?</td>
<td>1.45 (1.20-1.76)</td>
<td>1.20 (0.90-1.59)</td>
<td>1.33 (1.02-1.73)</td>
<td>1.38 (1.05-1.81)</td>
</tr>
<tr>
<td>Have not been bothered by musculoskeletal pain.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Psychosomatic problems</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During the last 3 months, have you been bothered more than once by tiredness, weakness, and sleeping disorders?</td>
<td>1.59 (1.30-1.95)</td>
<td>1.85 (1.33-2.55)</td>
<td>1.37 (1.04-1.82)</td>
<td>2.23 (1.62-3.08)</td>
</tr>
<tr>
<td>Have not been bothered by these symptoms.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Medical care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you, during the last 3 months, felt the need to seek medical care but have ignored it?</td>
<td>1.43 (1.21-1.68)</td>
<td>1.58 (1.25-1.99)</td>
<td>1.61 (1.29-2.09)</td>
<td>1.48 (1.19-1.84)</td>
</tr>
<tr>
<td>Have not ignored medical care.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Economical problems</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you, during the last 3 months, had problems managing your day-to-day expenses and/or would you be unable to raise 18 000 SEK (≈ €1800) within 1 week?</td>
<td>1.36 (1.11-1.66)</td>
<td>1.55 (1.18-2.05)</td>
<td>1.27 (0.97-1.67)</td>
<td>1.44 (1.10-1.87)</td>
</tr>
<tr>
<td>Have not had these financial problems</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Humiliation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you, during the last 3 months, felt humiliated or ridiculed?</td>
<td>1.29 (1.12-1.50)</td>
<td>1.42 (1.14-1.75)</td>
<td>1.22 (1.00-1.49)</td>
<td>1.41 (1.15-1.72)</td>
</tr>
<tr>
<td>Have not had this experience.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 2
Study II

Participants
Within the community of Laxå, situated in the southern part of the county of Örebro, Sweden, a random sample of the population, ages from 18 years and up, was selected from the Population registry. Laxå community is geographically well defined and primary health care is only available at the Laxå Primary Health Care Centre.

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Figure 2
Questionnaire

The study group was sent the brochure “Treatment of Urinary Incontinence-Questions and answers” in March 2003. It comprised extensive facts collected from SBU’s systematic review [8] concerning aetiology of UI, diagnostic procedures and available treatments (40 pages long). The brochure had been developed by the Swedish Council on Health Technology Assessment (SBU) in cooperation with the Swedish state pharmacy in 2001. Together with the brochure a prenotification letter was sent explaining the aim of the study and that a questionnaire would be sent 1-2 months after the brochure was received.

A new questionnaire was created and validated by testing and re-testing in a group of men and women representative of the general population before taken into use. The questionnaire consisted of 20 questions of which 19 were multiple-choice and one open question where the respondent could suggest other subjects for brochures that he/she would like to receive.

Data-analysis

The data were entered into the statistical program SPSS version 13.0 and analyzed by using descriptive statistics; the results are presented as proportions.

Results

The resulting response rate was 47.5%. The response rate differed according to age groups. It was highest in age group 65-79 years.

Table 3 Send outs and response rate presented according to age and gender

<table>
<thead>
<tr>
<th>Age group</th>
<th>Send outs (n)</th>
<th>Male / Female (n)</th>
<th>Response rate % / (proportion women)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-34 years</td>
<td>450</td>
<td>195 / 255</td>
<td>45 / (52)</td>
</tr>
<tr>
<td>35-49 years</td>
<td>637</td>
<td>330 / 307</td>
<td>31 / (58)</td>
</tr>
<tr>
<td>50-64 years</td>
<td>1280</td>
<td>651 / 629</td>
<td>49 / (54)</td>
</tr>
<tr>
<td>65-79 years</td>
<td>1029</td>
<td>473 / 556</td>
<td>61 / (56)</td>
</tr>
<tr>
<td>≥80- years</td>
<td>262</td>
<td>146 / 116</td>
<td>35 / (47)</td>
</tr>
<tr>
<td>Total</td>
<td>3658</td>
<td>1795 / 1863</td>
<td>47.5 / (55)</td>
</tr>
</tbody>
</table>

Eighty percent of those who responded stated UI as an important health problem in society, while 51% stated UI as an important personal health problem. New and important knowledge on UI reported 66% of the re-
sponders that they had received from the brochure. Of the responders, 28% reported a current or previous history of UI. Occurrence among age groups ranged from 7% to 37%, Table 4.

Table 4  Reported current or previous history of UI among age groups

<table>
<thead>
<tr>
<th>Age groups (years)</th>
<th>Current or previous history of UI n (%)</th>
<th>Male / Female n / (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-34 years</td>
<td>66 (30)</td>
<td>169 / 326 (34 / 66)</td>
</tr>
<tr>
<td>35-49 years</td>
<td>35 (17)</td>
<td></td>
</tr>
<tr>
<td>50-64 years</td>
<td>154 (23)</td>
<td></td>
</tr>
<tr>
<td>65-79 years</td>
<td>233 (37)</td>
<td></td>
</tr>
<tr>
<td>≥80- years</td>
<td>7 (7)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>495 (28)</td>
<td></td>
</tr>
</tbody>
</table>

In the group who reported UI, 57% had had a previous wish to receive help and advice concerning UI; of these little over 1/3 had not sought healthcare. The remaining 43% in the UI group reported no wish for help or advice. Additionally, 49% of the responders who reported UI felt that they had received useful information for self-treatment and 21% reported that they had begun self-treatment (mainly pelvic floor muscle exercises) and 30% experienced that they had gotten good advice concerning sanitary protection.

Study III

Study design

In this randomised controlled trial patients were recruited from three centres in Sweden; the Department of Obstetrics & Gynaecology at Örebro University Hospital, the Department of Obstetrics & Gynaecology and Urology at Karlstad Hospital, and the Department of Urology at Torsby Hospital. The target population was women 18 years of age with urgency/urge incontinence presenting to the gynaecology/urology outpatient clinics. At Örebro University Hospital, additional recruitment of a few patients took place through an advertisement in the local newspaper.

The patients were randomized to receive either electrical stimulation treatment or drug therapy. Electrical stimulation was administered vaginally and/or transanally with the MS-310 Device, MIC Rehab AB and delivered by a specialized nurse (urotherapist) at the outpatient clinics. Over a time period of 5-7 weeks, all together ten stimulation treatments
were applied 1-2 times per week for 20 minutes with a frequency of 5-10Hz. The control group received tolterodine SR 4 mg orally once daily.

The patients had an equal probability of assignment to the two groups. The randomization was made on blocks of variable length for each of the centres separately. The randomization sequence was developed centrally, using a computer random number generator. The assignment was enclosed in sequentially numbered opaque sealed envelopes by a person not involved in the study. Patients were included into the study and allocated to treatment group by the clinical staff responsible for the study at each participating centre, by opening the lowest numbered envelope. Blinding of study personnel and participants to treatment assignment for the duration of the study was not possible due to the nature of the interventions.

**Power calculation and sample size**

Our hypothesis was that electrical stimulation treatment in women with urgency/urge incontinence would give 1) greater reduction of frequency of micturition per 24 h, 2) greater degree of patient-assessed symptomatic improvement, and 3) greater improvement in QoL, compared to drug treatment (tolterodine).

The power analysis was calculated on the basis of the primary outcome measure; reduction of micturitions per 24 h. There is a large uncertainty regarding the efficacy that can be expected for both electrical stimulation treatment and drug treatment. In the literature, improvements ranging from 17% to 100% (mean 70%) are reported for electrical stimulation, with the corresponding range for drug treatment being 30 to 50%. Under the assumption of a difference between treatments of 20%, a Chi-square test with a 2-sided significance level of 5% yielded a power of 80% for a sample size of 103 patients in each group. If the assumption was an even larger difference in efficacy (30%), the sample size with an additional 10% to compensate for drop outs would be 55 patients in each group. Taking into consideration the large uncertainty concerning efficacy, our goal was to include at least 55 patients in each group.

In spite of extended recruitment period from 2001 to 2003 to December 2005 we did not reach this goal. Seventy-two women were randomized to the two study groups, thirty-seven patients to the electrical stimulation group and thirty-five patients to the tolterodine group. Sixty-one patients were included in the final analysis. A flow chart is given in Figure 3.
Interventions for Urinary Incontinence in women

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Power calculation and sample size

Our hypothesis was that electrical stimulation treatment in women with urgency/urge incontinence would give 1) greater reduction of frequency of micturition per 24 h, 2) greater degree of patient-assessed symptomatic improvement, and 3) greater improvement in QoL, compared to drug treatment (tolterodine).

The power analysis was calculated on the basis of the primary outcome measure; reduction of micturitions per 24 h. There is a large uncertainty regarding the efficacy that can be expected for both electrical stimulation treatment and drug treatment. In the literature, improvements ranging from 17% to 100% (mean 70%) are reported for electrical stimulation, with the corresponding range for drug treatment being 30 to 50%. Under the assumption of a difference between treatments of 20%, a Chi-square test with a 2-sided significance level of 5% yielded a power of 80% for a sample size of 103 patients in each group. If the assumption was an even larger difference in efficacy (30%), the sample size with an additional 10% to compensate for drop outs would be 55 patients in each group. Taking into consideration the large uncertainty concerning efficacy, our goal was to include at least 55 patients in each group.

In spite of extended recruitment period from 2001 to 2003 to December 2005 we did not reach this goal. Seventy-two women were randomized to the two study groups, thirty-seven patients to the electrical stimulation group and thirty-five patients to the tolterodine group. Sixty-one patients were included in the final analysis. A flow chart is given in Figure 3.

Figure 3

72 Women randomized

- 3 refused to participate before start of treatment
  - Electrical stim. 37 patients
    - 1 study withdrawal
    - 1 excluded due to incomplete protocol
    - 6 weeks 33 patients
      - 6 months 32 patients (2 had stopped taking tolterodine)
        - 1 excluded due to incomplete protocol
        - Final study group Electrical stim. 31 patients
  - Tolterodine 35 patients
    - 2 refused to participate before start of treatment
    - 6 weeks 32 patients
      - 6 months 31 patients (8 had stopped taking tolterodine)
        - 1 lost to follow up
        - 1 excluded due to incomplete protocol
        - Final study group Tolterodine 30 patients

3 refused to participate before start of treatment
Data analysis
The two groups were evaluated at baseline, at 6 weeks, and 6 months. The study ended after 6 months, but to evaluate the long-term effect of the treatments the patients were also assessed after 12 and 24 months. At baseline, 6 weeks, 6 months, 12 months and 24 months the patients were asked to complete a 48 h bladder diary along with a questionnaire concerning the use of pads, occurrence of side effects, the use of estrogen and other medications, general health status, degree of symptomatic improvement, and compliance with the drug therapy. A condition-specific QoL instrument, the Swedish version of the King’s Health Questionnaire (KHQ), was used to assess QoL [44, 79].

All the data analyses were carried out according to intention to treat and according to the pre-established analysis plan. The data were entered into the SPSS statistical program (version 11.5).

Proportions were compared with the Chi-square test. An independent samples t-test with 95% confidence intervals (CI) was used to compare changes between groups, while a paired t-test with 95% CI was used to analyze changes within groups. Two-sided significance tests were used throughout.

Results
There was no significant difference between the two treatment groups when analyzing the number of micturitions per 24 h from baseline to 6 months (primary outcome) and no significant difference between the two treatment groups when analysing the mean volume of urine voided per micturition from baseline to 6 months. There was, however, a clearly significant reduction in the number of micturitions per 24 h from baseline to 6 months and a clearly significant increase in the mean volume of urine voided per micturition when analyzing the two treatments separately (Table 5).
The two groups were evaluated at baseline, at 6 weeks, and 6 months. The study ended after 6 months, but to evaluate the long-term effect of the treatments the patients were also assessed after 12 and 24 months. At baseline, 6 weeks, 6 months, 12 months and 24 months the patients were asked to complete a 48 h bladder diary along with a questionnaire concerning the use of pads, occurrence of side effects, the use of estrogen and other medications, general health status, degree of symptomatic improvement, and compliance with the drug therapy. A condition-specific QoL instrument, the Swedish version of the King’s Health Questionnaire (KHQ), was used to assess QoL [44, 79].

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Table 5. Change from baseline in number of micturitions per 24 h (MN) and mean volume (ml) voided per micturition (MV) for electrical stimulation treatment and tolterodine treatment; differences within groups and mean difference between treatment groups at 6 weeks and 6 months

<table>
<thead>
<tr>
<th></th>
<th>Electrical stimulation</th>
<th>Tolterodine</th>
<th>Difference Electricalstim-Tolterodine</th>
<th>Mean diff (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0-6 w</td>
<td>0-6 m</td>
<td>0-6 w</td>
<td>0-6 m</td>
</tr>
<tr>
<td>n</td>
<td>32</td>
<td>30</td>
<td>31</td>
<td>31</td>
</tr>
<tr>
<td>MN (95%CI)</td>
<td>-2.6 (-3.5 to -1.8)</td>
<td>-2.8 (-3.7 to -1.9)</td>
<td>-2.9 (-3.6 to -2.2)</td>
<td>-3.2 (-4.1 to -2.4)</td>
</tr>
<tr>
<td>MV (95%CI)</td>
<td>55 (30 to 80)</td>
<td>54 (28 to 80)</td>
<td>38 (20 to 50)</td>
<td>55 (36 to 74)</td>
</tr>
</tbody>
</table>

At 6 months, 73% of the electrical stimulation group and 71% of the tolterodine group reported a lesser degree of bother from bladder symptoms, compared to baseline. In the tolterodine group, 6% reported a higher degree of bother at 6 months compared to baseline. For the remaining study population, the degree of bother was unchanged. See Figures 4a and 4b.
For analysis of the result of the King's Health Questionnaire QoL symptom score, at 6 weeks and 6 months, the level of minimal patient-perceivable change defined as a reduction of at least 5 score points compared to baseline was chosen [80]. There were no significant differences between treatment groups.

We also evaluated the patients at 12 and 24 months; at these time points, there was a considerable loss to follow up, changing between treatment groups, incomplete protocols, and additional treatments. At 12 months, data were available from 52 patients, and at 24 months data were available from 46 patients. When analyzing the two treatments separately, there was a continued significant difference in the number of micturitions per 24 h from baseline to 12 months, the mean difference being -3.1 (95% CI: -4.0 to -2.1) in the electrical stimulation group and -3.1 (95% CI: -4.3 to -1.9) in the tolterodine group. At 24 months, the corresponding results were -3.4 (95% CI: -4.6 to -2.2) in the electrical stimulation group and -3.7 (95% CI: -4.8 to -2.6) in the tolterodine group. There were no significant differences between the two treatment groups when analyzing the change in number of micturitions per 24 h from baseline to either 12 or 24 months, respectively, according to intention to treat or per protocol. When analyzing the King's Health Questionnaire domain scores at 12 and 24 months, respectively, defining an improved patient as one seeing a reduction of at least 5 score points, we found that both treatment groups had a continuing positive impact on QoL. There were no significant differences between treatment groups.

**Figure 4**

(a) Electrical stimulation group: patient-assessed degree of bother by bladder symptoms at baseline compared to at 6 months.

<table>
<thead>
<tr>
<th>Degree of bother at 6 months</th>
<th>Total number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4</td>
</tr>
<tr>
<td>Mild</td>
<td>1</td>
</tr>
<tr>
<td>Severe</td>
<td>2</td>
</tr>
</tbody>
</table>

(b) Tolterodine group: patient-assessed degree of bother by bladder symptoms at baseline compared to at 6 months.

<table>
<thead>
<tr>
<th>Degree of bother at 6 months</th>
<th>Total number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>3</td>
</tr>
<tr>
<td>Mild</td>
<td>1</td>
</tr>
<tr>
<td>Severe</td>
<td>2</td>
</tr>
</tbody>
</table>

Study IV

Participants and study design

The purpose of this study was to translate, modify, and psychometrically evaluate two condition specific self-report questionnaires that address symptom severity and QoL impact of urinary incontinence: The Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) from American English to Swedish [81,82].
For analysis of the result of the King’s Health Questionnaire QoL symptom score, at 6 weeks and 6 months, the level of minimal patient-perceivable change defined as a reduction of at least 5 score points compared to baseline was chosen [80]. There were no significant differences between treatment groups.

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A translation from American English to Swedish was made by an experienced non-professional bilingual translator not familiar with the IIQ-7 and UDI-6. The provisional Swedish versions of the two instruments were administered to eight women suffering from UI by in-person interviews where they were asked to complete the draft version and were asked for possible ambiguous wordings. After final modifications the Swedish versions of the instruments were completed. Appendix 1
In a pilot study 31 women with UI who had been referred to the outpatient clinic at the Department of Obstetrics and Gynaecology, Örebro University Hospital, were asked to complete the questionnaire. Twenty-three questionnaires were returned, of which 19 (61%) were fully completed. To assess test-retest reliability 19 questionnaires were sent out 2-3 weeks after the first questionnaires had been completed.

After the pilot study the UDI-6 and IIQ-7 were introduced in a prospective study, including 97 female patients who were referred to the Department of Obstetrics and Gynaecology, Örebro University Hospital with UI as their main problem, regardless of subtype of UI. Patients suffering from both UI and pelvic organ prolapse were not included.

Of those, 96 completed the UDI-6 and IIQ-7 at baseline, 77 (79%) at 6 months, 61 (63%) at 12 months and 48 (49%) at 24 months. Mean (SD) age in the study sample was 64.8 (±16) years. Thirty-one percent were diagnosed with SUI and 69% were diagnosed with UUI or MUI.

**Data analysis**
To analyze test-retest reliability, weighted kappa coefficients were calculated. To estimate internal consistency reliability of scale scores Cronbach’s alpha was calculated.

To assess construct validity, “known groups validity” analysis of baseline scores for the different diagnose groups SUI and UUI+MUI was performed with Mann Whitney U test. Effect sizes within groups as standardized response mean (SRM) were calculated to be able to determine the magnitude of group change over time. Correlation between the total scores of the UDI-6 and IIQ-7 and the “treatment satisfaction” score in two different subgroups, SUI and Mixed UI + UUI, was performed with Spearman’s rho. Two-sided significance tests were used throughout and a p-value < 0.05 was considered as statistically significant. The data were entered into the SPSS statistical program (version 11.5).

**Results**
Nineteen questionnaires were sent out 2-3 weeks after the first questionnaires had been completed and 18 were returned with no missing responses on individual items. Weighted kappa coefficients showed moderate to almost perfect agreement.

In the following prospective study the alpha coefficient was 0.39 for UDI-6 and 0.83 for IIQ-7. Alpha coefficients within subscales for the UDI-6 ranged from 0.24 to 0.44. Removal of single items did not improve the alpha coefficient. Alpha within subscales for IIQ-7 ranged from 0.51 to 0.76.
The difference in mean total score at baseline for UDI-6 and IIQ-7 respectively, within the diagnose groups SUI and UUI+MUI (to assess known groups validity) was not statistically significant.

Analysis of responsiveness, change in UDI-6 and IIQ-7 scores over time for the different diagnose groups was determined by calculating the effect size. In the SUI group, the effect size was moderate to large (0.74 for UDI-6 and 0.85 for IIQ-7) after 6 months compared to small in the UUI+MUI patients (0.39 for UDI-6 and 0.38 for IIQ-7) Table 6.

The “treatment satisfaction” score at 6, 12 and 24 months for the different diagnose groups showed that the surgically treated patients reported high satisfaction with treatment and SUI patients were more satisfied than UUI+MUI patients. The strength of the association between the UDI-6 and IIQ-7 scores and the treatment satisfaction score over time for the different diagnose groups showed moderate to strong correlation and were statistically significance throughout.
**Table 6.** Mean (SD) UDI-6, IIQ-7 and “treatment satisfaction” scores over time in the total sample and different diagnose groups. Mean (SD) UDI-6 and IIQ-7 change scores and effect size for within-group changes are given at 6 months.

<table>
<thead>
<tr>
<th></th>
<th>Total sample</th>
<th>SUI</th>
<th>Mixed+UUI</th>
<th>p-value SUI vs MUI+UUI</th>
<th>Surgically treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score UDI-6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) baseline n</td>
<td>55 (17)</td>
<td>51 (18)</td>
<td>56 (16)</td>
<td>0.14</td>
<td>52 (20)</td>
</tr>
<tr>
<td></td>
<td>96</td>
<td>30</td>
<td>66</td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>6 months</td>
<td>43 (22)</td>
<td>31 (21)</td>
<td>48 (19)</td>
<td>0.002</td>
<td>17 (12)</td>
</tr>
<tr>
<td></td>
<td>76</td>
<td>25</td>
<td>51</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>12 months</td>
<td>42 (20)</td>
<td>36 (23)</td>
<td>46 (17)</td>
<td>0.06</td>
<td>22 (18)</td>
</tr>
<tr>
<td></td>
<td>61</td>
<td>22</td>
<td>39</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>24 months</td>
<td>45 (21)</td>
<td>36 (22)</td>
<td>50 (18)</td>
<td>0.035</td>
<td>22 (14)</td>
</tr>
<tr>
<td></td>
<td>48</td>
<td>18</td>
<td>30</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Score IIQ-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) baseline n</td>
<td>49 (25)</td>
<td>42 (24)</td>
<td>53 (25)</td>
<td>0.057</td>
<td>50 (24)</td>
</tr>
<tr>
<td></td>
<td>96</td>
<td>30</td>
<td>66</td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>6 months</td>
<td>33 (29)</td>
<td>16 (24)</td>
<td>42 (28)</td>
<td>0.000</td>
<td>6 (11)</td>
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<tr>
<td></td>
<td>77</td>
<td>25</td>
<td>52</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>12 months</td>
<td>29 (26)</td>
<td>14 (23)</td>
<td>38 (24)</td>
<td>0.000</td>
<td>3 (5)</td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>21</td>
<td>39</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>24 months</td>
<td>32 (28)</td>
<td>20 (26)</td>
<td>40 (24)</td>
<td>0.013</td>
<td>8 (15)</td>
</tr>
<tr>
<td></td>
<td>48</td>
<td>18</td>
<td>30</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Score Treatment Satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) 6 months n</td>
<td>3.2 (1.5)</td>
<td>2.2 (1.3)</td>
<td>3.7 (1.4)</td>
<td>0.000</td>
<td>1.6 (0.99)</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>24</td>
<td>46</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>12 months</td>
<td>3.5 (1.8)</td>
<td>2.8 (1.9)</td>
<td>3.9 (1.5)</td>
<td>0.015</td>
<td>1.7 (1.7)</td>
</tr>
<tr>
<td></td>
<td>59</td>
<td>22</td>
<td>37</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>24 months</td>
<td>3.3 (1.7)</td>
<td>2.7 (1.6)</td>
<td>3.6 (1.7)</td>
<td>0.08</td>
<td>1.8 (1.3)</td>
</tr>
<tr>
<td></td>
<td>49</td>
<td>18</td>
<td>31</td>
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<td>10</td>
</tr>
<tr>
<td>Difference score UDI baseline-6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) 95% CI n</td>
<td>12 (23)7-17</td>
<td>19 (26)</td>
<td>8 (21)2-14</td>
<td>35 (25)21-49</td>
<td></td>
</tr>
<tr>
<td></td>
<td>76</td>
<td>25</td>
<td>51</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Difference score IIQ baseline-6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD) 95% CI n</td>
<td>16 (31)9-23</td>
<td>27 (32)</td>
<td>11 (29)3-19</td>
<td>46 (29)29-63</td>
<td></td>
</tr>
<tr>
<td></td>
<td>76</td>
<td>25</td>
<td>51</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Effect Size 6 months</td>
<td>UDI-6</td>
<td>0.51</td>
<td>0.39</td>
<td>1.40</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IIQ-7</td>
<td>0.53</td>
<td>0.38</td>
<td>1.59</td>
<td></td>
</tr>
</tbody>
</table>

UDI-6 and IIQ-7 are scored on a 0-100 scale where a higher value indicates more symptoms/ lower quality of life. The “treatment satisfaction” scale is scored on a 7-point Likert scale from 1= very satisfied to 7= very dissatisfied. Mann Whitney U-test was used for significance testing between groups.
Summary of findings

In paper I a population-based cross-sectional study, associations between UI and the occurrence of musculoskeletal pain, fatigue and sleeping disorders, feelings of humiliation, financial problems and reluctance to seek medical care were found. Our results indicate that respondents who lacked financial or cognitive resources were likely to find UI more bothersome and thus impose a social and emotional burden. A fear of feeling humiliated might prevent women from discussing UI with their doctor and also cause a general reluctance to seek medical care. Still, as the study was cross-sectional, we cannot show any cause and effect relationship but can only describe independent associations between UI and the different variables examined.

In paper II, a population-based study within a well defined geographical area, we found that the distribution of a brochure on Urinary Incontinence to the general public was well received and can be an efficient method to spread knowledge on UI. A high percentage (80%) of the responders stated UI as an important health problem in society but stated to a lesser extent (51%) UI as an important personal problem. Two thirds of the responders reported that they had received new and important knowledge on UI and a substantial number of individuals claimed that they had initiated some form of self-management for UI due to information received from the brochure. However in our study we found that spreading information on UI through a postal brochure did not seem to be efficient among the oldest age group (>80 years).

In paper III I a randomized controlled trial was conducted where both electrical stimulation and drug treatment (tolterodine) was found to reduce the number of micturitions and improve subjective symptoms and quality of life in women with urgency/urge incontinence. We could also show a continuing long-term effect at 12 and 24 months in both treatment groups. However, the hypothesis that electrical stimulation treatment would be more efficient and give a greater positive impact on QoL compared to drug treatment (tolterodine) could not be confirmed.

In paper IV we translated and validated a Swedish version of Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) by analyzing reliability, validity and responsiveness in a clinical sample of 96 women with UI. The test-retest reliability coefficients showed moderate to almost perfect agreement. The internal consistency measures as Chron-
bach's alpha was poor for the UDI-6 but satisfactory for the IIQ-7. The effect size calculation of change after treatment demonstrated good responsiveness and a larger effect size for patients in the SUI group, especially in the group that had undergone surgical treatment compared to patients in the UUI/MUI group. A moderate to strong correlation between UDI-6 and IIQ-7 scores and treatment satisfaction scores was also demonstrated.
Ethical considerations

Paper I: The study was performed according to Swedish regulations for surveys directed towards the general public. The participants were guaranteed anonymity. After the data were coded and entered into the statistical software, all identifying information on individuals was erased.

Paper II: The study protocol was approved by the regional ethics committee. The participants were guaranteed anonymity. After the data was coded and entered into the statistical software, all identifying information on individuals were erased.

Paper III: The study protocol was approved by the regional ethics committee and all participants gave written informed consent before start of the study.

Paper IV: The study protocol was approved by the regional ethics committee and all participants in the pilot study gave written informed consent before start of the study. In the following prospective study a letter was sent together with the questionnaire explaining the aim of the study and that the participation was voluntary.
Discussion

The different choices of design and methods in this research project were ruled by the research question. The first two studies were population-based cross-sectional studies that provide information about extent and distribution of the question surveyed and allows comparisons among groups but not on individual/patient level. The cross-sectional design cannot show any cause and effect relationship but can describe independent associations between the different variables examined. To ensure the study sample is representative of the whole population different methods of selecting a random sample are used.

In the first paper (Life and Health) the study sample was randomly selected from the Population Registry in Sweden using a method for sampling and analysis developed by SCB Statistics Sweden. The method is used for large population-based studies to make reliable estimates for different population groups and to correct for variations in response rates [83]. The somewhat low response rate in the female study population (60%) may presumably be of less concern due to this method of correction and the response rate is also comparable with other large population-based investigations [84]. A strength of the study is that it was a large public health study based on a survey containing a large number of questions on general health, general living conditions, personal habits and socioeconomic factors to which we had the unique opportunity to attach a UI questionnaire. Data from respondents and non-respondents to the incontinence questionnaire were compared using logistic regression analysis where all the questions from the Life and Health questionnaire comprised the non-dependant variables.

The results in our study suggest that UI among women is commonly associated with different psychosocial problems and expressed feeling of vulnerability, indicating that respondents who lacked financial or cognitive resources were likely to find UI more bothersome and thus impose a social and emotional burden.

The literature concerning surveys looking into UI in relation to such a broad spectrum of lifestyle–factors, living conditions, and socioeconomics is limited [16, 17].

In the Laxå study (second paper) a random sample was selected from the Population Registry, stratified for gender and weighted for age. The resulting response rate was 47.5%. The method to correct for variations in response rates was not applied in this study. The aim of this study was to evaluate the impact of an information campaign in contrast to surveys...
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In the Laxå study (second paper) a random sample was selected from the Population Registry, stratified for gender and weighted for age. The resulting response rate was 47.5%. The method to correct for variations in response rates was not applied in this study. The aim of this study was to evaluate the impact of an information campaign in contrast to surveys.
focused on UI as a health problem. When taken into consideration that the brochure was sent to an unselected population group with no known expressed wish for this kind of information, the response rate must be considered as acceptable. The response rate is also similar to other population-based surveys focused on general health problems, including UI, and population based studies investigating the response rate to variations in questionnaire design [23, 24, 27, 29, 84-87]. Additionally, the large sample size strengthens the study. Hence we believe, in spite of the low response rate, the results to be applicable to the general public.

In the study half of the responders that reported a current or previous history of UI felt that they had received useful information for self treatment and a significant proportion had begun self treatment, mainly pelvic floor muscle training. A limitation of the study design is the lack of possibility for objective confirmation of the respondents’ urinary incontinence and effect of self treatment. According to a Cochrane collaboration review [55] PFMT helps women with all types of incontinence although women with stress urinary incontinence who exercise for three months or more benefit the most. It is most likely, however, that the maintenance of pelvic floor muscle training is sporadic at best. Milne J L et al[88] looked into factors impacting self care for urinary incontinence and found that self-care efforts were motivated by desire for a normal daily lifestyle/ to live as well as possible and that the recommended therapy must not be more troublesome than UI itself. They also found that participants were motivated to maintain strategies by the ability to visualize progress and by knowledge that they were progressing (follow up visits). The latter is of course difficult to achieve through a brochure.

There is however a need to try and find alternative ways to spread knowledge to the 2/3 of persons with UI that do not seek help for their complaints in order to reduce the negative impact of UI on the individual, but also to meet increasing demands and to optimize the use of limited health care resources.

The postal brochure on UI seemed to be most well received in age groups 65-79 years and age group 50-64 years who had the highest response rates. To be more efficient, perhaps future information campaigns on UI should focus on men and women in these age groups.

The same age groups also reported the highest prevalence of current or previous history of UI. It is well known from previous studies that the prevalence of UI increases with age both among women and men. The high numbers make it reasonable to believe that persons suffering from UI found the brochure more interesting and therefore were more likely to read the brochure and answer the questionnaire. However, this does not seem to
apply to the oldest age group in our study (>80 years). The response rate was very low, only 35%. Only 7% reported current or previous history of UI, where one would have expected a much higher prevalence. The explanation for this is unclear. One explanation might be that the elderly do not perceive UI as an important problem in comparison to other more severe health problems that they might suffer from, or that they consider UI as part of “normal” aging [26, 28, 29, 89-91]. Further research is needed to find efficient methods to spread knowledge on UI to the elderly.

The third study was a randomised controlled trial (RCT). This form of experimental study is considered to represent and correspond to the highest level of scientific evidence. When properly executed the RCT is the only method that minimizes the risk for selection and confounding biases and can be used to test a hypothesis [92].

Due to inadequate reporting of randomised controlled trials the CONSORT (Consolidated Standards of Reporting Trials) statement was introduced in 1996 [93]. The latest update from 2010 [94] includes a 25 item checklist, a flow diagram and provides guidance for reporting all randomised controlled trials.

We have tried to perform and report our study following the principles of the CONSORT statement. There are, however, limitations to our study. We were not able to recruit the estimated number of patients, despite prolonging the planned recruitment period from 2001–2003 to 2005, and we had a drop out rate of 15%. There are several possible reasons for this; new anticholinergic drugs were introduced on the market during the study period. The study was performed in routine practice, with many caregivers involved. Since it was an academic study, performed without any support from the industry, financial or otherwise, the patients did not receive any monetary or other kind of compensation for participating in the study. It is also possible that the acceptability to randomization was lowered due to the fact that recruiting clinicians and patients might have felt that the two allocated treatments were too dissimilar and that some recruiting clinicians may have had a preconceived option of which treatment might be best suitable for a specific patient [95].

Our study was designed to show superiority, founded on the previously existing information in the literature, but we could not demonstrate any difference between the two treatment arms. This, in combination with the small study sample, raises the question of the possibility of a Type II error. Although this cannot be completely excluded, we believe this to be of minor concern since the confidence interval for the difference was narrow.
around zero, and the limits of the confidence interval did not correspond to a clinically important difference in any direction. A larger study could of course give a more reliable estimation of the effect, but could not be expected to give a result outside the limits of confidence interval found in our study. We therefore believe our results to be reliable. Another flaw in our study was that we did not manage, as our intention was, to collect data to report the number of women eligible for the study. This was also due to practical circumstances. However, since the study was conducted within a routine clinical practice setting, the results should be generalizable to other patients with the same clinical findings and degree of bother as in our study.

If we were to perform the same study again we would consider including evaluation of leakage episodes in the study protocol. We were neither able to measure the severity and magnitude of urgency, because when this trial was initiated there was no fully-developed questionnaire for urgency perception [96]. It would also have been interesting to use the Swedish translations of UDI-6 and IIQ-7 together with KHQ (Kings health questionnaire) [44] to measure the symptom severity and impact on QoL and be able to compare validity, reliability and responsiveness among the instruments, but the Swedish versions of UDI-6 and IIQ-7 had not been validated at the time of initiation of this study.

The fourth study is a prospective cohort study, where validation of two condition specific self-report questionnaires that addresses symptom severity and QoL impact of urinary incontinence was performed. As mentioned before the process of translation and validation of an instrument into a foreign language must be appropriate and rigorous to insure validity and make cross cultural comparisons possible [46]. Validity can never be formally proven, but acceptance for the validity of an instrument can be accumulated over time by surveys showing support for the instruments validity and reliability.

In our study Cronbach’s alpha at baseline was 0.39 for UDI-6 and 0.83 for IIQ-7, showing internal consistency to be poor for the UDI-6 and satisfactory for the IIQ-7. Alpha values for the UDI-6 scale are considerably lower compared to the original instrument (long form) [81]. The unexpected low alpha raises the question whether an explanation might be found in the somewhat less rigorous translation manner in our study and thereby possible small aberrations from the English version. We did not have two, but one, independent forward translator and a back translation was not performed. The importance of back-translation is however debatable; we did have what is regarded as a more important part in the transla-
tion process the in-person interviews with women suffering from UI. The unexpected low alpha can also be related to sample size which we have discussed in paper IV and cultural differences in the study populations. We do believe however that the original study population of well-educated, upper-middle income women ≥ 45 years and 95.7% white, with at least one episode of UI per week, to be relatively similar to the Swedish study population. Instead, a more likely explanation of the low alpha value might be found in the scale construction of the UDI-6, being more a clinimetric scale as described in the background chapter. It should also be noted that the moderate to high alpha on the original instrument (long form) were on subscale levels where a higher correlation structure is expected, if the items are grouped properly.

To add support or disapproval to this Swedish version of Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6), they need to be used in different clinical settings in Sweden and tested regarding responsiveness, validity and reliability.

There is quite a large focus today on stress urinary incontinence both in the medical literature and in the popular media; the treatments we have to offer are usually uncomplicated, safe and effective. Patients that undergo surgical treatment can be included in the Swedish national quality register of gynaecological surgery [97] where outcomes after surgery within healthcare production are made available and can be compared.

There is a much lesser focus on patients suffering from mixed and urge urinary incontinence. As mentioned earlier they are usually more bothered compared to patients with stress urinary incontinence and experience a larger negative impact on quality of life, which we also have found in this research. At the same time the treatments we have to offer for urge urinary incontinence are usually less effective than available treatments for stress urinary incontinence. We have found that electrical stimulation treatment can be an optional treatment to drug therapy in this patient group. There is a need for further pragmatic studies comparing different treatments for urgency/urge and mixed incontinence to help clinicians find the best treatment for the specific patient.

The treatments need to be evaluated both from a cost-effectiveness and health-effectiveness view. As mentioned in the background chapter the prevalence of SUI in women is peaking between ages 40 and 60 years where as both UUI and MUI continue to increase with age. So the solution to the growing burden of UI that comes with an ageing population will most likely not be found in redoubling the amount of surgical treatments.
Conclusions

Urinary incontinence amongst women is commonly associated with different psychosocial problems and an expressed feeling of vulnerability. Spreading knowledge and encouraging self management through informative material on Urinary Incontinence to the general public may be beneficial for meeting increasing demands and optimizing healthcare resources.

Both electrical stimulation and drug therapy were found to reduce the number of micturitions and improve QoL in women with urge or urge incontinence, but electrical stimulation was not found to be superior to drug therapy.

The translated form of UDI-6 and IIQ-7 from English to Swedish showed good responsiveness and were easy to administer and to fill out. The UDI-6 scale did not accomplish the same solid result in the psychometrical analysis as the IIQ-7 scale but both scales showed good responsivity and can thereby be recommended for clinical use.
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Clinical implication and future research

In a time with increasing and competing demands on limited healthcare resources it is important to use the resources wisely. With further research we can gain a better understanding of UI in relation to psychosocial aspects and living conditions and how these factors influence patients to seek help. In this aspect initial care at the right level is an important issue where district nurses in the primary care play an important role.

The efficiency of self care treatments and methods to improve the general knowledge on UI needs to be further studied. Perhaps different strategies for spreading knowledge in different age groups would be more efficient, through the internet for the younger and through television for the elderly?

There is a need for pragmatic studies comparing different treatments for urgency/urge and mixed incontinence evaluated both from a cost-effectiveness and health-effectiveness view to meet increasing and competing demands on limited healthcare resources.

It would also be desirable to create registers within healthcare production of outcomes after non-surgical treatments as a source for quality assessment.

To assess the impact of incontinence it is necessary to measure the level of symptoms in an individual together with the extent to which these symptoms impair QoL. A Swedish version of Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) is now available and can be recommended for clinical use in different clinical settings in Sweden. Further research regarding testing of the Swedish version of the instruments responsiveness, validity and reliability is needed as well as research concerning development of even simpler/shorter instruments to be used in everyday clinical practice.
Clinical implication and future research

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Svensk sammanfattning (Swedish summary)

Urininkontinens är ett folkhälsoproblem som berör en stor del av befolkningen. SBU (Statens beredning för medicinsk utvärdering) utkom år 2000 med en systematisk översikt om urininkontinens där det konstateras att cirka 500 000 personer iverige är drabbade av urinläckage. Problemet ökar med ökande ålder och är vanligare hos kvinnor än hos män. Förutom ett medicinskt problem kan urininkontinens vara ett allvarligt socialt händikapp för den drabbade, med betydande negativ inverkan på livskvaliteten. Det är därför viktigt att livskvalitetsmätning ingår i bedömningen av patienter med urininkontinens, dels vid bedömning av allvarlighetsgraden av urininkontinens, dels vid värdering av effekten av olika behandlingsåtgärder. Man påpekar också behovet av pragmatiska behandlingsstudier där olika terapeutiska metoder studeras i den kliniska miljö de är avsedda att användas, med fokus på total patientnytta men även på kostnadeffektivitet.

Urininkontinens kan vara ett dolt problem i hälso- och sjukvården och det är inte känt hur många som söker och behandlas för urininkontinens då detta inte alltid registreras som en enskild diagnos. Tillståndet kan vara både underdiagnosticerat och underbehandlat. Genomgående anges i litteraturen att betydligt färre, mot svarande cirka 20-50%, söker hjälp än de som uppger att de har urininkontinens. Det kan vara relaterat till graden av läckage och graden av påverkan på det sociala livet. Urinläckage kan upplevas som en del av normalt åldrande eller något som inte kräver behandling, men okunskap om vilka behandlingsmöjligheter som står till buds, rädsla för undersökningar och ingrepp samt ovilja att diskutera problemet kan också spe le roll. Typen av urininkontinens har också betydelse för graden av negativ inverkan på den drabbades livskvalitet. Ansträngningsinkontinens kan i många fall korrigeras operativt med gott resultat medan däremot trängningsinkontinens i många fall är en mer kronisk sjukdom där behandlingsmetoderna och behandlingsresultaten är mer begränsade och därmed ofta ger en större negativ inverkan på livskvaliteten. I det idag befintliga nationella kvalitetsregister inom gynekologisk kirurgi registreras och sker uppföljning på patienter som undergått inkontinenskirurgi, däremot registreras ej urininkontinenta patienter som erhållit icke-kirurgisk behandling.

Det finns tecken på att efterfrågan på behandling ökar och fler använder hjälpmedel. En ökande uppmärksamhet finns också i massmedia. Trots detta beräknas ändå en betydande underbehandling föreligga. Enligt uppgifter från brittiska studier skulle, omräknat till svenska förhållanden, cirka...
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300 000 vuxna svenskar önska behandling. Detta antal får också antas öka i en framtid då andelen äldre i befolkningen ökar. I SBU rapportens slutsatser anges som ett av förslagen till åtgärder att det är väsentligt att kartlägga i vilken utsträckning allmänheten har kunskap om tillgängliga behandlingsmetoder och möjligheten att få hjälp. Det anges också som angeläget att utforma informationsmaterial om urininkontinens med allmänheten som målgrupp.

Samhällets kostnader är också stora. I SBU rapporten beräknas de totala kostnaderna till mellan 2,8 – 4,4 miljarder SEK per år, där omvårdnadskostnader inom äldrevården och kostnader för hjälpmedel dominerar.

För att kunna möta en ökad efterfrågan på behandling och optimera utnyttjandet av hälsovårdens resurser är det angeläget att finna sätt att öka befolkningens kunskap om urininkontinens samt i lämpliga fall uppmuntra till egenvård.

Avhandlingsarbetet har tagit sin utgångspunkt i flera av dessa ovanstående frågeställningar. Följande delstudier ingår i avhandlingen:

1. Förekomsten av urininkontinens i relation till psykosociala faktorer i befolkningen.
2. Effekten av en informationskampanj till befolkningen avseende kunskap, upplevt vårdbehov, vårdutnyttjande samt egenvårdsinsatser.
3. Effekten av elstimuleringsbehandling jämfört med läkemedelsbehandling hos kvinnor med trängningsinkontinens i form av en randomiserad kontrollerad studie.
4. Validering av ett sjukdomsspecifikt livskvalitetformulär för uppföljning och värdering av olika behandlingsåtgärder vid urininkontinens.

Från avhandlingens arbeten kan följande slutsatser dras i sammanfattning: Urininkontinens utgör ett vanligt hälsoproblem hos kvinnor som kan påverka livskvaliteten och som kan vara associerat till ett flertal psykologiska besvär samt en känsla av utsatthet. Interventioner på befolkningsnivå kan öka medvetenhet om besvärens orsaker och vilka möjliga behandlingsalternativ som finns, och kan även stimulera till egenvårdsåtgärder. För gruppen med trängningsinkontinens, som oftast rapporterar högre grad av livskvalitetspåverkan av UI kan elektrostimulering utgöra ett behandlingsalternativ till läkemedelsbehandling.
Tack (Aknowledgement in Swedish)
Det är många som på olika sätt har varit betydelsefulla för denna avhandlings tillkomst. Jag vill särskilt nämna:

Mina handledare Kerstin Nilsson och Jan Erik Johansson som med er stora kunskap, outtröttlig energi och positiv uppmuntran har lotsat mig igenom detta avhandlingsarbete. ”I would have been lost without you”.

Jan Karlsson som genom sin stora kunskap inom psykometrisk värdering av frågeinstrument varit till ovärderlig hjälp i mitt fjärde arbete.

Mia Kling och Anders Magnusson samt Niklas Pettersson för all värdefull hjälp med statistiska beräkningar.

Eva Sahlberg-Blom för kloka synpunkter vid våra forskargruppsmöten samt tipset om att gå kursen ”Mät och testteori- Utvärdering och utveckling av mätinstrument i vård- och omsorgsforskning”. Den blev en ögonöppnare.

Vibeke Jonsson, Inger Lauridsen, Jill Canelid och Bengt Heiwall för det strävsamma arbetet med elstimeringsstudien.

Marit Moisanen för all sektreterarhjälp med livskvalitetstudien

Kristina Crafoord min forskningskollega, arbetskollega och goda vän som var den som först fick mig intresserad av urogynekologi.

Karin Zetterström min arbetskollega och forskningskollega för alla bra tips och råd.

Gunnel Andersson min forskningskollega och medförfattare för alla värdefulla samtal

Stort tack till min tidigare verksamhetschef Ingrid Östlund och nuvarande verksamhetschef René Bangshøj för positiv uppmuntran och att ni möjliggjort detta arbete med tid.

Stort tack till Margareta Landin och övrig personal på medicinska biblioteket
Alla mina arbetskollegor på kvinnoklinken för visat intresse och uppmuntran för min forskning.

CAMTÖ samt forskningskommittén, Örebro Läns landsting för ekonomiskt stöd

Mina föräldrar Grethe och Martin Franzén som alltid trott på och uppmuntrat min förmåga.

Sist men inte minst, de viktigaste personerna i mitt liv, min kära man Thomas och mina älskade barn Marit, Ellen och Erik och våra hundar Freja och Minto som tjatat sig till långpromenader när de tyckt jag jobbat för länge vid datorn.
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93. www.consort-statement.org


97. www.gynopregistret.se
## Appendix

Frågeformulär angående livskvalitet och urinläckage

<table>
<thead>
<tr>
<th>Personnr</th>
<th>Datum</th>
<th>Namn</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Har Du besväv av och i så fall i vilken omfattning?</th>
<th>Inte alls</th>
<th>Lite</th>
<th>Måttligt</th>
<th>Mycket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poäng:</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1. Behöva gå på toaletten mycket ofta?</td>
<td></td>
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<td></td>
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<tr>
<td>2. Urinläckage i samband med starkt behov av att urinera?</td>
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<tr>
<td>3. Urinläckage i samband med fysisk aktivitet, hosta eller nysning?</td>
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<tr>
<td>4. Små mängder av urinläckage (droppar?)</td>
<td></td>
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<tr>
<td>5. Svårigheter att tömma urinblåsan?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Smärta eller obehag i bukens nedre del eller i underlivet?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Påverkar urinläckage och/eller framfall Dig vad avser:</th>
<th>Inte alls</th>
<th>Lite</th>
<th>Måttligt</th>
<th>Mycket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poäng:</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1. Förmågan att utföra hushållssysslor (matlagning, städning, tvätta kläder)?</td>
<td></td>
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<td></td>
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<tr>
<td>2. Fritidssysselsättning som promenader, simning eller andra fysiska aktiviteter?</td>
<td></td>
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<tr>
<td>3. Nöjen (t ex bio, konserter )?</td>
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<td></td>
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<tr>
<td>4. Förmågan att resa med bil eller buss mer än 30 minuter hemifrån?</td>
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<tr>
<td>5. Deltagande i sociala aktiviteter utanför hemmet?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6. Psykisk hälsa (nervositet, nedstämdhet etc.)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Frustration, jag känner mig förhindrad att göra vad jag vill</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

\[ \text{UDI-6} = \times 33,3 \]  \[ \text{IIQ-7} = \times 33,3 \]
Vilken/vilka typer av behandling har Du fått mot dina urinläckagebesvär?  
(flera svarsalternativer möjliga)

☐ 1. Bäckenbottenträning (knipträning)
☐ 2. Livsstilsförändring (minskad dryck, viktnedgång och liknande)
☐ 3. Blåsträning

Läkemedelsbehandling
☐ 4. a Yentreve
☐ 4. b Detrusitol, Ditropan, Vescicare, Kentera, Emselex
☐ 4. c Östrogen
☐ 4. d Annat läkemedel, vilket…………………………………………

☐ 5. Elstimuleringsbehandling
☐ 6. Inkontinensskydd (bindor, blöjor, trosskydd)
☐ 7. Kontinensbåge (Contrelle)
☐ 8. Urinrörspropp (Viva)
☐ 9. Injektionsbehandling (sprutbehandling)
☐ 10. Operation

Är du nöjd med resultatet av den/de behandlingar Du fått mot dina urinläckagebesvär?

☐ 1. Mycket nöjd
☐ 2. Nöjd
☐ 3. Inte helt nöjd
☐ 4. Varken nöjd eller missnöjd
☐ 5. Delvis missnöjd
☐ 6. Missnöjd
☐ 7. Mycket missnöjd

Egna kommentarer
……………………………………………………………………………………
……………………………………………………………………………………
Table 4. Correlation between the total UDI-6 and IIQ-7 scores and the “treatment satisfaction” score in the 2 diagnose groups SUI and MUI+UUI at 6, 12 and 24 months. (r, p-value, and number of patients)

<table>
<thead>
<tr>
<th>Diagnostic Group</th>
<th>Treatment Satisfaction Score at 6 Months</th>
<th>Treatment Satisfaction Score at 12 Months</th>
<th>Treatment Satisfaction Score at 24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUI</td>
<td>0.762 (0.000) 25</td>
<td>0.615 (0.002) 25</td>
<td>0.548 (0.008) 22</td>
</tr>
<tr>
<td>MUI+UUI</td>
<td>0.451 (0.002) 44</td>
<td>0.457 (0.002) 45</td>
<td>0.557 (0.000) 36</td>
</tr>
</tbody>
</table>

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