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<b>Titel proefschrift/thesis</b>	Conservative treatment for women with stress incontinence and bladder overactivity. Thesis University of Maastricht 2000. Promotores: Van Kerrebroeck Ph, van den Brandt PA. Co-promotor: de Bie RA
<b>Samenvatting/abstract</b>	<p><i>Summary</i></p> <p>This thesis focuses on the physiotherapeutic management of lower urinary tract disorders, resulting in stress urinary incontinence, and on the conservative treatment of women with symptoms of urgency, frequency and/or motor urge urinary incontinence due to detrusor instability or bladder overactivity.</p> <p>The aim of this thesis is to make an inventarisation of the current state and the art of the conservative treatment. Next to this, we have tested the efficacy of conservative treatments for women with stress urinary incontinence or bladder overactivity.</p> <p>The International Continence Society defines urinary incontinence as the objectively demonstrable involuntary loss of urine, to such a degree of severity that it is a social or hygienic problem.</p> <p>In The Netherlands (total population 15 millions) the estimated prevalence of urinary incontinence in women of 5 years and older is 8.5% and in men 2.5%. In community dwelling women of 60 years and older, prevalence of UI was 23.5 %. Because urinary incontinence affects women more often than men, this thesis will only focus on women with urinary incontinence, more specific stress urinary incontinence and bladder overactivity.</p> <p>There are various types of urinary incontinence. Stress urinary incontinence is the most common form of urinary incontinence in women. In the literature we found that nearly half of all women with urinary incontinence had stress urinary</p>

incontinence (49%). Stress urinary incontinence is the involuntary loss of urine during physical exertion, e.g., coughing, sneezing, laughing, running, jumping and lifting. Genuine stress urinary incontinence is defined as the involuntary loss of urine which occurs when, in absence of a simultaneous detrusor contraction, the intravesical pressure exceeds the maximum urethral pressure. Besides stress incontinence, bladder overactivity is the most frequently observed disorder in women (22%). Bladder overactivity is defined by the International Continence Society as a disorder of filling/storage in which involuntary bladder contractions are demonstrated while the patient is attempting to inhibit these contractions. The symptoms of bladder overactivity consist of urgency and/or frequency and/or nocturia and/or urge incontinence. They may exist as a single entity or in combination.

Incontinence therapy has mainly been based on multiple surgical methods, a variety of pharmacological agents, and various behavioral methods. In the prevention and the conservative treatment of stress urinary incontinence and bladder overactivity several treatment modalities, like pelvic floor muscle exercises, with or without biofeedback and electrical stimulation, or electrical stimulation alone are performed by physiotherapists. In order to justify in society the rationale for these kind of treatments, there is a growing need to proof that physiotherapy does have clinically relevant effects on the natural course of disease, and impact on the patient's condition.

Widespread application of conservative treatments should be preceded by evidence of improvement in function attributable to their use. Randomized clinical trials can serve this vital purpose. Systematic reviews on the basis of methodological criteria put much emphasis on the quality of the randomized

clinical trials involved and are very useful to support evidence for the effectiveness of therapy.

Guidelines in physical therapy for diagnosis, treatment and prevention in patients with urinary incontinence improve the quality of conservative treatment for these disorders.

After an introduction in chapter 1, chapter 2 holds a systematic review of randomized clinical trials with the aim to assess the efficacy of conservative treatment and prevention in adult women with stress urinary incontinence. Twenty-four randomized clinical trials were identified of which 22 discussed treatment and two prevention. In general, the methodological quality of the included studies was moderate. However, based on the quality of the studies regarding pelvic floor muscle exercises, there is strong evidence that pelvic floor muscle exercises are effective in reducing the symptoms of stress urinary incontinence. There is limited evidence for the efficacy of high intensity versus a low intensity regimen of pelvic floor muscle exercises. Despite significant post test effects of biofeedback as an adjunct to PFME, there is no evidence that biofeedback as an adjunct to pelvic floor muscle exercises is more effective than pelvic floor muscle exercises alone. There is strong evidence that intravaginal electrical stimulation is superior to sham intravaginal electrical stimulation, and there is limited evidence to suggest that there is no difference between electrical stimulation and other physical therapies. The efficacy of pelvic floor muscle exercises with or without other adjuncts to prevent stress urinary incontinence is unclear.

Chapter 3 presents the results of a randomized clinical trial in 40 women, aged 18 to 70 years. The study objective was to assess whether or not a physical therapeutic training program as the standard treatment combined with biofeedback was more effective than the same program without biofeedback in patients with mild or moderate stress incontinence. The results

of the padtest for both the standard treatment and biofeedback showed a mean improvement of 55% ( $p < 0.01$ ) after 12 treatments, however for biofeedback, the same results were reached already after 6 treatments.

After 12 treatment sessions in the group with the standard treatment 3 patients were cured (15%), 14 patients were improved (70%) and 3 patients were worse (15%). In the biofeedback- group 5 patients were cured, 14 were improved and only 1 patient was worse (25%, 70%, 5%). On the symptoms questionnaire the difference in improvement between both groups after 6 and 12 treatment sessions was not significant. The greatest improvement in the biofeedback-group, in comparison with the group with the standard treatment, was realized in the first 6 treatments. This corresponds with the findings of the padtest.

In the patient's diary among other items the pattern of the daily occurrence of involuntary urine loss was noted. The difference in decrease between both groups after 6 and 12 treatment sessions was not significant. Based on the results of the combined measure of effect, there was no difference between both groups. However, after consideration of liquid intake and body weight with the aid of the linear regression analysis, it was apparent that there was a significant difference in favor of biofeedback after 6 treatments. After 12 treatments the findings failed to reach a significant difference. Biofeedback and standard treatment are effective treatment modalities for involuntary urine loss in patients with mild or moderate stress incontinence. It is clear from the analysis that biofeedback as a support to therapy is most important in the first two weeks, during the first 6 treatments. Biofeedback results seem to be achieved faster and could be cost effective.

In chapter 4 evidence-based and systematic guidelines for physiotherapy in women with genuine stress incontinence are

given. Professional co-operation between referring physicians and physiotherapists is required in order to determine the indication for physiotherapy. Based on the diagnostic process, determining the nature of the underlying pathology causing genuine stress incontinence stills remains unclear. Therefore, the question as to whether or not, and to what extent, physiotherapy can be helpful in the management of genuine stress incontinence cannot always be answered definitively. In these cases, physiotherapy is given as a 'pilot treatment'.

The assessment of the efficacy of physical therapies for first-line use in the treatment of urge urinary incontinence in adult women, using a systematic review of randomized clinical trials, is described in chapter 5. Fifteen randomized clinical trials were identified. Generally speaking, the methodological quality of the studies was moderate. Based on the levels-of-evidence criteria there was weak evidence to suggest that bladder training was more effective than no treatment. There was also weak evidence that bladder training was superior to drug therapy. Stimulation types and parameters in the studies of electrical stimulation were heterogeneous. There was insufficient evidence that electrostimulation was more effective than sham electrical stimulation. To date there are not enough studies to evaluate the effects of exercise with or without biofeedback and of toilet training for women with urge urinary incontinence.

In chapter 6 we assessed the efficacy of three physiotherapeutic treatment modalities in 83 women, aged between 22 and 82 years, with bladder overactivity. In a single-blind randomized clinical trial we studied the efficacy of specific lower urinary tract exercises, office and home based electrical stimulation and a combination of the same lower urinary tract exercises and office based electrical stimulation in comparison with a no-treatment group. Based on the objective effectparameter, the Detrusor Activity Index (DAI), office and home based electrical

stimulation seemed to be an effective treatment modality for the treatment of women with bladder overactivity. Lower urinary tract exercises seemed to provide a positive trend in improvement. The combination therapy was not effective. Although there is a positive trend in subjective improvement, as measured by the IIQ-7, an effect parameter regarding the subjective influence of urinary incontinence on daily activities, results have to be interpreted with caution. More research of high methodological quality is required to support the conclusions of this study.

Chapter 7 presents a general discussion and conclusions with respect to the conservative treatment of stress urinary incontinence.

In general, the methodological quality of the included studies in both reviews was moderate. We concluded that more RCTs of high methodological quality, assessing the efficacy of physiotherapy, are necessary. Based on the results of the review and the randomized clinical trial on the efficacy of biofeedback for women with genuine stress incontinence, it was concluded that pelvic floor muscle exercises alone and pelvic floor muscle exercises with biofeedback are equally effective, although there was uncertainty about the most effective program. Biofeedback as an adjunct to pelvic floor muscle exercises did not seem to be more effective than pelvic floor muscle exercises alone, although this strategy might be more effective in the first period of treatment. With respect to all other conservative treatment modalities and prevention no firm conclusions on the efficacy of conservative treatment of stress urinary incontinence could be drawn.

Regarding the efficacy of conservative treatment for women with bladder overactivity, based on the DAI, office- and home based electrical stimulation seemed to be an effective treatment modality for the treatment of women with bladder overactivity.

	<p>Lower urinary tract exercises seemed to provide a positive trend in improvement. The combination of electrical stimulation and lower urinary tract exercises was not effective. Furthermore, there was only weak evidence that bladder (re-)training was more effective than no treatment or drug therapy.</p>
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