

# Efficacy of Physical Therapeutic Modalities in Women with Proven Bladder Overactivity

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## Abstract

**Objective:** To assess the efficacy of physiotherapeutic treatment modalities in women with proven bladder overactivity.

**Methods:** One hundred and twelve women received ambulatory urodynamics. Based on both urodynamic variables of ambulatory cystometry (ACM) and the micturition diary, the Detrusor Activity Index (DAI) for each patient was calculated. After randomization, 68 women with a DAI  $\geq 0.50$  were defined as having proven bladder overactivity. In a single blinded RCT patients were randomized over four treatment groups, i.e. lower urinary tract exercises (LUTE); office- and home-based functional electrostimulation (FES); office-based FES and LUTE; no treatment. Patients treated received nine treatment sessions, once weekly. The primary outcome variable was the DAI, measured before randomization and, as soon as possible within a maximum of 14 days after the end of the study period.

**Results:** Intention to treat analysis in the group of 68 patients showed a statistically significant decrease of DAI-scores in the FES group ( $p = 0.032$ ) in comparison with no treatment, while this decrease was not statistically significant in the LUTE group ( $p = 0.105$ ) and the LUTE + FES group ( $p = 0.672$ ).

**Conclusions:** Our conclusion is that, based on the DAI, in the homogeneous set of 68 patients, only FES seemed to be effective.

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**Keywords:** Bladder overactivity; Urge urinary incontinence; Electrical stimulation; Pelvic floor muscle exercises; Bladder (re)training

## 1. Introduction

Urinary incontinence and voiding disorders, specifically due to bladder overactivity are highly prevalent disorders that greatly impact the lives of millions of people worldwide. Next to stress incontinence, bladder overactivity is the most frequently observed disorder of the storage function in women [1]. The symptoms of bladder overactivity consist of urgency and/or frequency and/or nocturia and/or urge incontinence. Urgency or

urge incontinence has greater impact on quality of life than stress incontinence, probably because it is a highly unpredictable phenomenon [2,3], and has the greatest effect on quality of life in the younger population [4]. The underlying etiology is only partially understood [5]. Also the clinical terminology used in connection with this storage dysfunction is confusing [5]. To date, the International Continence Society (ICS) has provided no clear definition of the term bladder overactivity [6]. Therefore, it is suggested to describe bladder dysfunction which is related to symptoms of frequency, urgency and urinary incontinence as follows; “bladder overactivity is a dysfunction of the bladder in which a subject has no or decreased control over suddenly occurring

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contractions of the detrusor muscle in such a way that this leads to premature passage of urine” [7]. Most of the terms only allow for a qualitative state of the patient, while research demands the need for a quantitative assessment of bladder overactivity [7]. In our review on urge urinary incontinence, in none of the studies the investigators achieved to apply a quantitative validated urodynamic measure both as an inclusion criterion and as an effect measurement [5]. A quantitative assessment provides not only a more specific diagnosis of bladder overactivity but also an evaluation of the effects of the various possible therapies. The Detrusor Activity Index (DAI) model is very useful to quantify the severity of bladder overactivity during storage objectively [7].

At present, only a few studies are performed regarding the efficacy of physiotherapeutic treatment modalities for bladder overactivity [8]. Our review revealed only weak evidence on the efficacy of bladder (re)training and insufficient evidence on the efficacy of PFME, of electrical stimulation alone or in combination with PFME for women with UUI [5].

However, these findings do not prove the ineffectiveness of physical therapy as a treatment modality for urinary incontinence and voiding disorders as a whole. It is our assumption that the lack of efficacy is most likely caused by methodological flaws like heterogeneity of study groups and suboptimal research designs.

Our main study objective was to assess the efficacy of various physical therapeutic treatment modalities, i.e. lower urinary tract exercises (LUTE), functional electrostimulation (FES) and a combination of LUTE and FES in women with proven bladder overactivity as indicated by an ambulatory urodynamic investigation. These treatment modalities theoretically stimulate

the detrusor inhibition reflex (DIR) and pacify the micturition reflex, resulting in a decrease of overactive bladder dysfunction [9].

## 2. Materials and methods

In a single blind randomized clinical trial, we studied the efficacy of LUTE (group II), office- and home-based FES (group III) and LUTE and office-based FES (group IV) versus a no-treatment group (group I).

Patients were recruited by general practitioners, urologists from our department and by announcements in local papers and other media. During a 2-week qualification period inclusion and exclusion criteria were checked, medical history was taken and a pad test was obtained. At the end of the standardized intake, the observer selected all relevant candidates for a micturition diary test. Using the results of the micturition diary the observer was able to get a reliable impression whether or not the candidate might have an overactive bladder. Only candidates with a positive result of this test were selected for the ambulatory urodynamic test in order to quantify and eventually to prove bladder overactivity.

Table 1 presents the inclusion and exclusion criteria. At the end of the intake period all preliminary included women had to sign informed consent. Finally, to ensure homogeneity of the study population, all women underwent ambulatory urodynamics, using the DAI [7]. Only DAI-values larger than 0.50 were considered, i.e. proven bladder overactivity. This model uses the results of extramural ambulatory cystometry (ACM) and a micturition diary to quantify detrusor activity during several consecutive filling phases. The model has been validated and applied in several drug trials [10–12]. Preceding this ambulatory investigation, urine analysis with a bacterial count was carried out to exclude urinary tract infection (UTI). When proven suitable the patient was extensively briefed about the intent and proceedings of the trial. The data obtained at the end of each qualification period formed the baseline values.

### 2.1. Sample size and randomization

With the assumption of a one-sided effect (H1 hypothesis: Treatment patients are on the average better off than no-treatment patients),

**Table 1**

Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
DAI $\geq$ 0.5	Mechanical intravesical obstruction
Sex: female	Urinary calculus
Age: >18 years	Repetitive symptomatic UTI (>3 $\times$ per year)
Drug free interval of at least 4 weeks before start of the study for the following drugs: anticholinergic, beta-sympathomimetic, alpha-blocker and psychopharmacological agents	Colpitis
Willingness to participate	Clinical evidence of disordered action of heart (Lown III)
Able to fill out forms	Pacemaker
	Pregnancy or lactating period
	Inability to comply with follow up
	Treatment with physical therapies within 3 months before start of therapy
	Neurogenic or congenital disorders resulting in urinary incontinence (e.g. spina bifida)
	Psychological disorders
	Irritation of the vagina (consult with general practitioner and patient)
	Poor adjustable diabetes mellitus: last HbA1C > 10
	Contra-indication for the use of an intra-vaginal or anal electrode
	Not able to understand Dutch
	Not able to travel

a level of significance of 95% ( $\alpha = 0.05$ ), a power of 80% ( $\beta = 0.20$ ), an expected drop-out rate of 10%, and an expected improvement of bladder overactivity status of treatment groups in comparison with the no-treatment group, expressed as a decrease of approximately 30% in the DAI, 20 patients in each of the four groups had to be recruited. Therefore, the intended sample size was set on 80 persons.

Randomization was done in blocks of four, using opaque and sealed envelopes, containing a note with group allocation. Besides the patient and the physical therapist all others, involved in randomization, registration and evaluation were blinded for group allocation.

## 2.2. Interventions

In the Dutch health care system, after referral, insurance companies basically only reimburse patients for a maximum of nine physiotherapeutic treatment sessions a year. Therefore, it was decided that each patient should receive nine treatment sessions, once weekly.

For each individual patient an optimal LUTE program was provided consisting of the following components:

- Patient information about the lower urinary tract function, the function of the pelvic floor and the way to contract and relax the pelvic floor.
- Bladder (re)training (BIT) consisting of four components. The first is an educational program that addresses lower urinary tract function. The next component involves training to inhibit the sensation of urgency and to postpone voiding. The third is to urinate according to a timetable in patients with an interval less than two hours between two consecutive micturitions in order to reach an interval of at least three hours between two consecutive voidings and to reach larger voided volumes. As a fourth step, reinforcement of patient motivation by the physical therapist.
- Specific PFME training in order to *probably* facilitate and restore the DIR by selective contraction of the pelvic floor muscles [13]. In many patients with an overactive bladder, the level of activation is so high [14] that selective contraction of the pelvic floor muscles in order to achieve reciprocal inhibition of the bladder is very difficult or not possible. Teaching selective contraction and relaxation of the pelvic floor muscles is an important first step. Once this is achieved, selective contraction of the pelvic floor muscles focuses on facilitation of the DIR. In this study, after testing a patient's ability to hold contractions for at least 20 seconds by digital palpation by the physiotherapist, patients were instructed to do so, followed by a relaxation period of 10 seconds. A more functional training (pelvic floor exercises during daily living activities) completed the exercise program.
- Toilet behavior aiming at the aspects of the micturition process itself.

Full details of the LUTE-program may be obtained from the first author on request.

FES was applied vaginally through plug mounted electrodes. The maximum level of the electrical stimulation was 100 mA ( $I_{\text{eff}} = 6$  mA). The patient was instructed to use the maximal tolerable level during stimulation. Treatment characteristics were: frequency modulation of 0.1 s trains of rectangular biphasic 200  $\mu$ s long pulses which varied stochastically between 4 and 10 Hz. In this study, a special version of the ProSeco system of Innocept™ Medizintechnik Inc., Gladbeck, Germany, i.e. the ProUrge system, was used. This portable microprocessor controlled system is a combined FES and EMG (electromyography) device that can be used for the treatment of bladder overactivity in (para)medical centers and at home.

The combination of LUTE + clinic-based FES consisted of the same LUTE-program with additional weekly clinic-based FES.

At the start of each treatment session, the patient's compliance was checked by discussing adherence to, performance and fixed goals of the weekly home-program.

## 2.3. Outcome measures

In this study, we used the DAI as the primary outcome measure. The DAI was measured before randomization (during the first ambulatory urodynamic investigation) and, within a margin of 2 weeks, after the end of the study period (second ambulatory urodynamic investigation). The DAI is a combined parameter that quantifies bladder overactivity by using variables from the analysis of ACM during the filling phase (mean number of contractions/h, mean duration of a contraction and mean amplitude of a contraction) and from the micturition diary: drinking (mean volume drunk/h) and voiding behavior (mean number of micturitions/h and mean volume voided per micturition) in a logistic regression equation. The DAI represents a score between 0 and 1, where '0' represents no activity of the bladder during the filling phase and '1' represents severe overactivity of the bladder. The DAI was used both as an inclusion criterion and as the primary measure of effect. The nursing staff of the urodynamic laboratory carried out ACMs in accordance with the ICS standards [15]. If measurements did not fulfill our quality criteria, the results were deemed not reliable for evaluation and were therefore discarded. In such cases, patients either had to undergo a new ACM or were excluded because of unreliable results in the first DAI measurement. If a second ACM failed, the measurement was repeated again or we classified the data as missing.

## 2.4. Statistics

All collected data were stored in a database. Data analysis was done with SPSS/PC, Version 9.0 [16]. Results were expressed as means  $\pm$  S.D. Data were analyzed using a repeated measures ANOVA as a first step and ANCOVA, done as a dummy regression analysis, using the difference of pre- and post-DAI measurements as a dependent variable. To correct for multiple comparisons in ANOVA, the Dunnett test was used.

The efficacy of physical therapy for women with bladder overactivity was also assessed by calculating the standardized effect for each therapy group versus the control group [17]. If ' $d$ ' expresses the differences between two sample means in standard deviation units,  $d = (\bar{X}_1 - \bar{X}_2)/s$ , where  $d$  is the effect size index,  $\bar{X}_1$  and  $\bar{X}_2$  are the DAI-score progression group means and  $s$  is the square root of the mean of squares of  $s_1$  and  $s_2$  (standard deviations of both groups). The  $s$  can be calculated as:  $\{(s_1^2 + s_2^2)/2\}^{0.5}$ . A ' $d$ ' effect of 0.20 is considered to be a 'small effect', that of 0.50 a 'medium effect' and 0.80 a 'large effect' [17].

Data analysis took place according to the intention-to-treat principle. A  $p$ -value of  $< 0.05$  was considered to be statistically significant.

## 3. Results

Shortly before the end of the inclusion period, as a result of a quality improvement project that was simultaneously executed, we discovered a software bug in the computer program that we use for calculating the input variables for the DAI model. Although this bug occurred only under certain technical circumstances, it caused an overestimation of the DAI in some cases. This

had no effect on our analysis of the urodynamic curves but led to a classification problem. After repair of the software bug all DAI calculations were re-checked. After comparison of the recalculated DAI results with the former results, from the total group of 80 randomized women, 12 patients turned out to be included erroneously, leaving 68 patients, mean (S.D.) [range] age 55.2 (14.4) [23–82], with DAI-score  $\geq 0.50$  after the first ambulatory urodynamic investigation.

Next to this unexpected problem, a total number of 10 women dropped out of the trial for various reasons. One woman stopped before start of therapy, because she considered the burden of investigation too high. During the treatment period, five women stopped because of illness (two in group II and two in group III) or allegedly reasons of too much burden felt (one in group IV). On completing treatment, four women had no second ambulatory urodynamic investigation for reasons allegedly too much burden expected (three in group II) or non-compliance in the investigation session (one in group IV). For these 10 patients (five in group II, three in group III and two in group IV) missing data in the set of post-treatment DAI-scores were substituted by post-treatment means of the

empirical data according to the intention-to-treat principle. Of the 486 scheduled therapy sessions 448 (92%) were completed.

Further protocol deviations were almost non-existent. Harmful side-effects were neither reported by patients, nor by therapists.

Comparing the four groups on medical history and individual baseline characteristics, no significant differences between groups were found (Table 2).

In Table 3, baseline urological characteristics of the set of 68 patients with DAI  $\geq 0.50$  before start of therapy can be found. There were no significant differences between the groups.

In repeated measures ANOVA of DAI-score differences between pre-treatment and afterward treatment conditions for the 68 randomized patients with DAI  $\geq 0.50$  there were statistically significant differences between therapy groups and controls ( $F = 3.56$  by 3 and 64 d.f.;  $p = 0.019$ ) and mean DAI-scores were post-treatment lower over all groups than pre-treatment DAI-scores ( $F = 17.41$  by 1 and 64 d.f.;  $p < 0.001$ ). Specified to the differences between treatment groups and controls only the FES group showed a significant decrease in DAI-scores ( $p = 0.032$ ) (see Tables 4 and 5).

**Table 2**

Group comparison based on medical history

	Controls (N = 14)	LUTE (N = 18)	FES (N = 17)	LUTE + FES (N = 19)
Age				
Mean	50.5	55.6	61.9	52.3
S.D.	11.8	14.8	13.5	15.4
Range	36–74	25–80	42–82	23–74
Frequency of urine loss <sup>a</sup>				
0	2	1	2	3
$\leq 1$ per week	3	3	0	3
2–7 per week	2	4	2	2
2–3 per 24 h	5	6	5	4
$> 4$ per 24 h	2	4	6	7
Quantity of urine loss/a time <sup>a</sup>				
Nothing	1	0	0	2
Drops	2	2	1	1
Dashes	3	8	6	8
To the last drop	8	7	7	7
Use of pads <sup>a</sup>				
No	3	4	0	3
Yes	10	14	14	13
Mean number of changes pads/24 h (S.D.)	3.5 (2.6)	3.7 (2.9)	5.9 (3.9)	5.3 (5.0)
Mean number of times to toilet daytime (S.D.)	13.1 (5.4)	14.7 (7.2)	13.9 (3.7)	12.4 (4.4)
Mean number of times to toilet nighttime (S.D.) <sup>a</sup>	2.4 (2.2)	4.3 (3.5)	2.8 (2.0)	2.6 (1.2)
Mean number of months of urine loss (S.D.)	122 (129)	101 (127)	122 (172)	196 (205)
Period after first visit GP for OAB (months) (S.D.)	87 (151)	61 (84)	120 (127)	91 (166)
Number of Patients with hysterectomy	1	2	3	5
Number of Patients with surgery for UI	4	0	4	4
Mean number of children (S.D.)	1.6 (1.2)	1.6 (1.9)	1.7 (1.5)	1.8 (1.3)

With ANOVA or loglikelihood  $\chi^2$  for two-way tables; no significant differences ( $p < 0.05$ ) between groups on anamnestic data were found.

<sup>a</sup> Missing values or answer: 'do not know' or 'not applicable'.

**Table 3**Comparison of baseline characteristics ( $N = 68$ , DAI  $\geq 0.50$ )

	Controls ( $N = 14$ )	LUTE ( $N = 18$ )	FES ( $N = 17$ )	LUTE + FES ( $N = 19$ )
Pad test MUDO (ml), mean (S.D.)	65 (87)	51 (82)	107 (205)	99 (159)
Frequency voidings/h, mean (S.D.)	1.28 (0.52)	1.26 (0.58)	1.19 (0.68)	1.10 (0.44)
Volume/voiding (ml), mean (S.D.)	144 (74)	148 (73)	126 (67)	109 (53)
DAI-1, mean (S.D.) (0–1)	0.85 (0.15)	0.84 (0.16)	0.84 (0.18)	0.87 (0.17)

$\alpha = 0.05$ .

**Table 4**Statistical characteristics/results pre- and post-treatment DAI ( $N = 68$ , DAI-1  $\geq 0.50$ )

Egroup	DAI-1 means	S.D.	DAI-2 means	S.D.	Diff. DAI	S.D.	$N$
Control	0.85	0.15	0.80	0.26	0.06	0.19	14
LUTE	0.85	0.17	0.62	0.33	0.22	0.32	18
FES	0.85	0.17	0.57	0.33	0.28	0.33	17
LUTE + FES	0.86	0.17	0.84	0.27	0.02	0.26	19
Total	0.85	0.16	0.71	0.32	0.15	0.30	68

$F$  time: 17.41 by 1 and 64 d.f.,  $p < 0.001$ ;  $F$  time  $\times$  therapy: 3.56 by 3 and 64 d.f.,  $p = 0.019$ .

**Table 5**

ANOVA and multiple comparisons results

Effect	Dunnnett			
I $\Rightarrow$ II	0.17	(0.10)	$p = 0.105$	(0.119)
I $\Rightarrow$ III	0.23	(0.10)	$p = 0.032$	(0.039)
I $\Rightarrow$ IV	-0.04	(0.10)	$p = 0.672$	(0.863)
I $\Rightarrow$ II–IV	0.35	(0.26)	$p = 0.177$	–

Even corrected by Dunnnett's  $t$ -test the FES group showed remarkable progress ( $p = 0.039$ ) (Tables 4 and 5).

Specified to the differences over treatment groups, repeated measures ANCOVA also showed a statistically significant decrease of DAI-scores in the FES group ( $p = 0.029$ ) (Table 6).

The standardized effect for the FES group versus the control group was calculated [12]. For the difference between the control group and the FES group  $d = 0.80$ , defined as a 'large' effect [17].

The decrease of DAI-scores in the LUTE group was evident, but not significant ( $p = 0.097$ ). There was no effect in the LUTE + FES group compared to the no-treatment group ( $p = 0.664$ ).

**Table 6**Parameters of dummy regression model ( $N = 68$ , DAI-1  $\geq 0.50$ )

Variable	$B$	$B$ (S.E.)	$\beta$	$t$	$p$
DAI-1	0.342	0.214	0.18	1.60	0.115
D12 (LUTE-con)	0.169	0.100	0.25	1.69	0.097
D13 (FES-con)	0.227	0.102	0.33	2.23	0.029
D14 (LUTE + FES-con)	-0.043	0.099	-0.07	-0.43	0.664
Intercept	-0.234	0.197	–	-1.19	0.240

ANCOVA:  $F_{\text{overall treatment}} = 3.71$  by 3 and 63 d.f. ( $p = 0.016$ ).

## 4. Discussion

The ICS-Standardisation Sub-Committee of the ICS for ambulatory urodynamic studies recognizes ambulatory urodynamic testing as an important scientific tool in diagnosing bladder overactivity [15]. The DAI, as a result of ambulatory urodynamic monitoring, is very useful to quantify the severity of bladder overactivity during storage [7]. The development of the DAI model and report of the findings and experiences during validation of the DAI have been described previously [7,18]. Although the DAI is not yet a completely reliable 'gold standard' to determine whether or not patients suffer from bladder overactivity, this diagnostic and evaluation tool has sufficient accuracy and responsiveness to be used as a primary measure of outcome [19]. However, disadvantage is the complicated way of collecting the necessary data. The preparation, the instruction of the patient, and the analysis of the data are time-consuming. A 'quality-control' protocol for the ambulatory urodynamic monitoring was used to optimize the results of the test and its acceptance by the patient.

The randomization was successful. The relevant prognostic data appeared to be equally divided between the groups (see Tables 2 and 3). In the FES group, mean age and mean number of changes of pads appeared to be slightly higher in comparison with the other groups but not significant.

Blinding was not possible at all levels. Because exercises were performed in the LUTE group and because of the use of an intra-vaginal or intra-anal electrode during FES no blinding of patient and thera-

pist was possible. Often in physical therapy it is unrealistic to aim for a double blind study design [20].

During the 1-year inclusion period, 248 persons with possible bladder overactivity applied as candidates for the trial. Only candidates with a positive result of the micturition test were selected for the ambulatory urodynamic test in order to quantify and eventually to prove bladder overactivity. Of the 114 persons with a positive result on the micturition test, 86 had involuntary bladder contractions during ACM (76%) of which 68 had proven bladder overactivity ( $DAI \geq 0.50$ ), indicating that this micturition test can serve as a sensitive tool in the diagnosis of bladder overactivity. In most cases, after diagnosing bladder overactivity based on history taking and physical examination, the general practitioner refers patients directly to the physical therapist without urodynamic evaluation. Because the general practitioner normally has limited direct access to urodynamics and only can rely on symptoms, there is no proof that patients with symptoms of urgency, frequency and/or urge incontinence really suffer from bladder overactivity. The micturition test, used in this study, could be very useful for general practitioners especially in diagnosing and referring patients with mild or moderate bladder overactivity.

A separate comparison for those patients continuing and withdrawn from the study showed no difference in baseline characteristics. Of the 10 patients who withdrew from the study, five did not wish to undergo an ambulatory investigation because this diagnostic procedure meant too much burden, and four had a non-urinary incontinence related illness that forced them to discontinue the study. Only one woman stopped because of too much burden expected from the therapy itself. Overview and analysis of other non-clinical data of the withdrawals showed a same trend in results as the empirical data. So, it was decided to use the post-treatment mean of the empirical data to serve as a substitute for missing data for patients who withdrew from the study.

The literature suggests that combination of different therapies or therapy modalities show more effect than each therapy (modality) separately [21,22]. However, in this study the combination of LUTE and FES was (almost) non-effective in comparison with no-treatment. It seems that FES, applied directly after LUTE, neutralizes the effect of the intensive LUTE-program. Separately, LUTE is suggested to provide central inhibition of bladder overactivity by reciprocal inhibition, FES regional inhibition by spinal reflexes [23,24]. It is possible that a combination of these two different pathways interfere negatively,

which was clearly the case in this study if we look at the negative results of the LUTE + FES group in comparison with the control group.

For the treatment of women with bladder overactivity, this is the first RCT comparing LUTE or *center- and home-based* FES with no treatment. In our review on the efficacy of conservative treatment modalities for women with UUI, two RCTs of sufficient [25,26] and two of lower methodological quality [27,28] were identified comparing bladder (re)training with no treatment (controls), suggesting that there is only weak evidence that bladder (re)training is more effective than no treatment (controls). However, the LUTE protocol used in this study differed from these studies, because it also included pelvic floor muscle exercises focused on *selective contraction* of the pelvic floor in order to increase the detrusor inhibition reflex. We only could identify four RCTs [29,30–32] comparing intra-vaginal ES versus sham intra-vaginal ES. Three trials reported results in favor of ES [29–31], whereas the low quality study of Sheperd reported that ES was not more effective than sham ES [32]. In the well-designed study of Yamanishi, 32 patients in the active group and 28 in the sham group completed the study. On the cystometrogram, the bladder capacity at the first desire to void and the maximum desire to void increased significantly in the active group, but not in the sham group. It was concluded that FES was superior to sham treatment and proved its efficacy for the treatment of UI due to bladder overactivity [29]. Because there was no consistency between the trials in terms of types and parameters of FES, it seems that no standard protocol or ‘best’ methodology of FES for the treatment of women with bladder overactivity exists [33]. The treatment parameters of electrical stimulation in this study were empirical and in accordance with FES protocols usually employed in studies with the choice for a high intensity treatment [5].

Finally, there is always the possibility that the significant results of the FES group compared to the no-treatment group were merely due to chance. However, the large standardized effect for the FES group versus the no-treatment group ( $d = 0.80$ ) seemed to support our results.

## 5. Conclusions

Although results have to be interpreted with caution, based on the objective effect parameter, combined center- and home-based FES seems to be an effective treatment modality for the treatment of women with proven bladder overactivity.

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## References

- [1] Resnick NM. Urinary incontinence. *Lancet* 1995;346:94–9.
- [2] Hunskaar S, Vinsnes A. The quality of life in women with urinary incontinence as measured by the sickness impact profile. *J Am Geriatr Soc* 1991;39:378–82.
- [3] Grimby A, Milson I, Molander U, Wiklund I, Ekelund P. The influence of urinary incontinence on the QOL of elderly women. *Age Ageing* 1993;22:82–9.
- [4] Norton PA, MacDonald LD, Sedgwick PM, Stanton SL. Distress and delay associated with urinary incontinence, frequency and urgency in women. *Br Med J* 1988;297:1187–9.
- [5] Berghmans LCM, Hendriks HJM, de Bie RA, Van Waalwijk van Doorn ESC, Bø K, Van Kerrebroeck PhEV. Conservative treatment of urge urinary incontinence in women: A systematic review of randomized clinical trials. *Br J Urol* 2000;85:254–63.
- [6] Hampel C, Wienhold D, Dahms SE, Thuroff JW. Heterogeneity in epidemiological investigations of bladder control problems: A problem of definition. *Br J Urol* 1999;83(Suppl 2):10–5.
- [7] Van Waalwijk van Doorn ESC, Ambergen AW. Diagnostic assessment of the overactive bladder during the filling phase: The Detrusor Activity Index. *Br J Urol* 1999;83(Suppl 2):16–21.
- [8] Mattiasson A. Discussion: bladder and pelvic floor muscle training for overactive bladder. *Urology* 2000;55(5a):12–3.
- [9] Eriksen BC. Electrostimulation of the pelvic floor in female urinary incontinence. Thesis. Trondheim (Norway): University of Trondheim, 1989.
- [10] Van Waalwijk van Doorn ESC, Remmers A, Janknegt RA. Extramural ambulatory urodynamic monitoring during natural filling and normal daily activities: Evaluation of one hundred patients. *J Urol* 1991;146:124.
- [11] Van Waalwijk van Doorn ESC, Remmers A, Janknegt RA. Conventional and extramural ambulatory urodynamic testing of the lower urinary tract in female healthy volunteers. *J Urol* 1992;147:1319.
- [12] Van Waalwijk van Doorn ESC, Ambergen AW, Janknegt RA. Detrusor Activity Index: Quantification of detrusor overactivity by ambulatory monitoring. *J Urol* 1997;157:596–9.
- [13] Houston KA. Incontinence and the older woman. *Clin Geriatr Med* 1993;9:157–71.
- [14] Messelink EJ. The overactive bladder and the role of the pelvic floor muscles. *Br J Urol* 1999;83(Suppl 2):31–5.
- [15] Van Waalwijk van Doorn ESC, Anders K, Khullar V, Kulseng-Hanssen S, Pesce F, Robertson A, Rosario D, Schäfer W. Standardisation of ambulatory urodynamic monitoring: Report of the Standardisation Sub-Committee of the International Continence Society for ambulatory urodynamic studies. *Neurourol Urodyn* 2000;19(2):113–25.
- [16] SPSS/PC, version 9.0. Chicago (IL): SPSS Inc. 1998.
- [17] Portney LG, Watkins MP. Power analysis and determination of sample size. In: Portney LG, Watkins MP, Mehalik CL, editors. *Foundations of Clinical Research*. 1st ed. Norwalk (CT): Appleton and Lange, 1993. p. 651–67 [Appendix C].
- [18] Van Waalwijk van Doorn ESC. Ambulatory urodynamics. Thesis. Maastricht (The Netherlands): University of Maastricht, 1990.
- [19] Van Waalwijk van Doorn ESC, Zwiers W, Wetzels LLAN, Debruyne FMJ. A comparative study between standard and ambulatory urodynamics. *Neurourol Urodyn* 1987;6:159.
- [20] Deyo RA, Walsh NE, Schoenfeld LS, Rama-Murthy S. Can trials of physical therapy be blinded? The example of transcutaneous electrical nerve stimulation for chronic pain. *Am J Phys Med Rehabil* 1990;69:6–10.
- [21] Fantl JA, Newman DK, Colling J, et al. Urinary incontinence in adults: Acute and chronic management. AHCPR publication 96-0682, Clinical Practice Guideline No. 2, 1996 Update, Rockville (MD): US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, 1996.
- [22] Van Kerrebroeck PhEV. A treatment algorithm for the overactive bladder. *Br J Urol* 1999;83:29–30.
- [23] Vodusek DB, Plevnik S, Vrtacnik P, Janez J. Detrusor inhibition on selective pudendal nerve stimulation in the perineum. *Neurourol Urodyn* 1988;6:389–93.
- [24] Holstege G. Neuronal organisation of micturition. In: *Lower Urinary Tract Dysfunction: From All to Clinical Approach*. Microsymposium, Erasmus University Rotterdam, Rotterdam, The Netherlands, 1998.
- [25] Fantl JA, Wyman JF, McClish DK, Harkins SW, Elswick RK, Taylor JR, Hadley EC. Efficacy of bladder training in older women with urinary incontinence. *JAMA* 1991;265(5):609–13.
- [26] Wyman JF, Fantl JA, McClish DK, Harkins SW, Uebersax JS, Ory MG. Quality of life following bladder training in older women with urinary incontinence. *Int Urogynecol J* 1997;8:223–9.
- [27] Jarvis GJ, Millar DR. The treatment of incontinence due to detrusor instability by bladder drill. *Female Incontinence* 1981;341.
- [28] Lagro-Janssen ALM, Debruyne FMJ, Smits AJA, van Weel C. The effects of treatment of urinary incontinence in general practice. *Fam Pract* 1992;9(3):284–9.
- [29] Yamanishi T, Yasuda K, Sakakibara R, Hattori T, Suda S. Randomized, double-blind study of electrical stimulation for urinary incontinence due to detrusor overactivity. *Urology* 2000;55(3):353–7.
- [30] Tsinar B, Kralj B. Maximal electrical stimulation in children with unstable bladder and nocturnal enuresis and/or daytime incontinence: A controlled study. *Neurourol Urodyn* 1996;15:133–42.
- [31] Brubaker L, Benson JT, Bent A, Clark A, Shott S. Transvaginal electrical stimulation for female urinary incontinence. *Am J Obstet Gynecol* 1997;177:536–40.
- [32] Shepherd AM, Tribe E, Bainton D. Maximal perineal stimulation. A controlled study. *Br J Urol* 1994;56:644–6.
- [33] Wilson, et al. Conservative management of in women. In: Abrams P, Khoury S, Wein A, editors. *Incontinence*. 1st Consultation on Incontinence, Monaco 1998. Plymouth (UK): Plymridge Publishers Ltd., 1999.