Acta Obstet Gynecol Scand 1998; 77: 671–677
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Acta Obstetricia et Gynecologica Scandinavica
ISSN 0001-6349

ORIGINAL ARTICLE

A population based, randomized, controlled trial of conservative treatment for urinary incontinence in women

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Acta Obstet Gynecol Scand 1998; 77: 671–677. © Acta Obstet Gynecol Scand 1998

Background. Urinary incontinence remains a hidden and inadequately treated problem in a high proportion of women.
Methods. Ninety women 50–74 years of age were recruited to a population-based, randomized, controlled clinical trial of conservative treatment for urinary incontinence, with delayed treatment for the control group. The study was performed in general practice in three north-Norwegian municipalities, in cooperation with two local departments of gynecology. Three patients were found protocol deviant and analysis was based on 87 patients.
Intervention. Local estrogen, physiotherapy and electrostimulation combined with close follow-up.
Main outcome measures. 1. Change in severity of incontinence from start of treatment (index range 0–8). 2. Change in impact from start of treatment (index range 0–4). 3. Quantitative measures in relation to micturition. 4. Criteria based classification into cured, improved, unchanged, worse.
Results. Treatment reduced severity (index change 1.8 in the intervention group vs. 0.1 in the control group at six months) and impact (index change 0.8 vs. 0.0) of leakage. Almost one third of the patients did not complete all micturition tests, but in those who did, average number of wet episodes per 24 hours decreased with treatment, and so did average number of micturitions in urge and mixed incontinence. Forty-nine patients (56%) were cured or improved after one year.
Conclusion. Women 50 to 74 years of age with urinary incontinence may improve considerably through conservative treatment in general practice.

Key words: electrostimulation; general practice; pelvic floor exercise; randomized controlled clinical trial; urinary incontinence

Submitted 5 December, 1997
Accepted 16 March, 1998

Urinary incontinence remains a hidden and inadequately treated problem in a high proportion of women, although modern treatment may be given by the general practitioner, reducing unnecessary referral (1). Two randomized, controlled studies in general practice settings showed a 60%–68% improvement rate from information and pelvic floor exercises for stress incontinence and bladder training for urge incontinence (2, 3). Another study adding estriol for atrophic vaginitis and weight reduction advice for overweight women showed similar results (4).

The International Continence Society (ICS) defines urinary incontinence as involuntary loss of urine which is objectively demonstrable and a social or hygienic problem (5). Incontinence may cause reduced social and mental well-being, embarrassment, in particular fear of unpleasant odor,

and sometimes sexual difficulties (6, 7). However, such disability may correlate poorly with the degree of incontinence.

The present study evaluates a general practice treatment regimen in females 50–74 years of age with urinary incontinence.

Material and methods

Six hundred and ninety-eight women, 50–74 years of age, randomly selected from population registers in three North-Norwegian municipalities, were invited by mail to two gynecological examinations one year apart in the office of their general practitioner in 1994–95. There was no mention of incontinence. Women with urinary incontinence were invited to the treatment study and informed that some of them haphazardly would be assigned to delayed treatment 6 months later. After inclusion, the randomization result to 'now'-group or 'wait'-group was given by phone from the university department.

Sample size was based on calculations of necessary number of patients in the clinical trial (8), published prevalences of incontinence, and results from a small pilot study in a different municipality. Sample size in the three trial municipalities was 9.1%, 12.5% and 16.7%, respectively, varying with the number of doctors available. Most general practitioners in each municipality participated in the study after attending a locally held seminar with the authors. Findings were recorded on a three-page questionnaire after the consultation (including gynecological examination) at zero, six and twelve months. The patient completed a short questionnaire about urinary and gynecological health.

In each practice a nurse or a medical secretary had been instructed in treatment details by one of three urotherapist nurses who visited each practice. The practice nurses would make appointments with the patients, be available for questions and worries and encourage continuing treatment. After about three months of treatment the nurses completed a preliminary report of progress.

Inclusion/exclusion

Inclusion criteria were fulfillment of the ICS definition, with a quantitiative addition specifying a history of 'regular incontinence', i.e. two or more leakage episodes per month (9). Leakage was objectively demonstrated in at least one of three ways: visible leakage on coughing during the gynecological examination; a positive 48 hour pad test with at least 3 grams of pad weight increase when physical activity was encouraged; or recording of 'wet' on a 48 hour frequency/volume chart recorded while doing ordinary activities. The patient's written, informed consent to take part in a treatment study after the initial consultation with history taking and examination was accepted as a confirmation that the patient experienced a social or hygienic problem. Exclusion criteria were cardiac pacemaker, dementia or psychological or medical problems so severe that the doctor doubted the patient could follow the treatment scheme, or conditions that should not wait for referral to the gynecologist.

Treatment (Fig. 1)

Treatment was free of charge for the women and consisted of:

1. Information and fitting of pads and pants.
2. Estriol to all women unless they refused or were well estrogenized. In case of severe atrophy, initial treatment with tablets was recommended. Subsequent treatment could be tablets or local vagitories or estrogen jelly.
3. Up to six individual treatment sessions with a physiotherapist with a special interest in incontinence treatment. All patients were instructed in pelvic floor exercises (10). Patients with urge or mixed incontinence were also instructed in bladder training (11) through oral and written instructions conforming with Norwegian guidelines (12).
4. Demonstration and training, and subsequent home use of a portable battery-driven plug device for electrostimulation of the pelvic floor (13, 14). Patients diagnosed with urge incontinence received vaginal maximal stimulation in series of 20 minutes. They were encouraged to treat themselves once daily or every other day for one to two

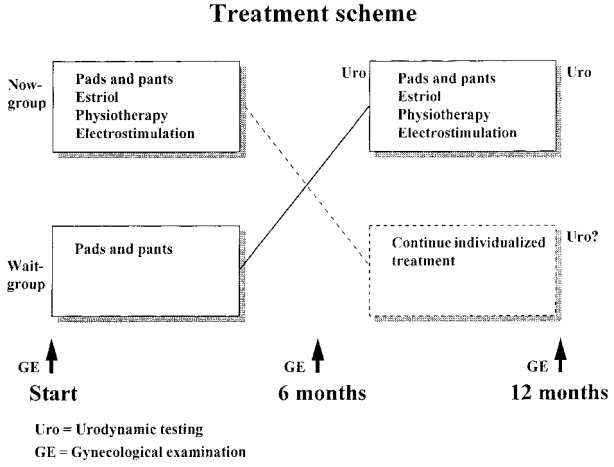

Fig. 1. The urinary incontinence treatment scheme for the two groups of patients.

months. Patients with stress incontinence used vaginal long-term stimulation. The plug device was carried initially for an hour or two, rapidly increasing duration in order to tolerate stimulation during sleep every night for 7–8 hours. Women were encouraged to pursue treatment for four to six months. Patients having mixed incontinence started with maximal stimulation and then eventually continued with long-term stimulation.

After six months the wait-group was offered the same treatment elements. In addition, they were invited to a standardized urodynamic assessment before and after treatment. While treatment in the now-group followed the general practitioners' classification into stress, urge or mixed incontinence, treatment for the wait-group would be modified to suit the gynecologist's diagnosis. Now-group patients were referred for urodynamic testing after twelve months if they were still bothered by their incontinence.

Outcome measurement

1. Change in severity of incontinence from start of treatment, using a validated severity index, classifying leakage as slight, moderate or severe (15). (Table I).

2. Change in impact from start of treatment, using a four-level ordinal index scale which had been tried out in the pilot study (Table I).

Table I. Severity index and impact index

I. Severity index, based on frequency and amount recorded by patient:

Frequency:
How often do you experience urinary leakage?
1. Not more than once a month
2. Twice or more a month
3. One or several times a week
4. Every day and/or night

Amount:
How much urine do you lose each time?
1. Drops or less
2. More

The severity index is found by multiplying the results of the two questions
Severity index 1–2=slight
Severity index 3–4=moderate
Severity index 6–8=severe

II. Impact index, based on primary care physician's recording at the end of consultation with patient, after reading aloud the four possibilities and letting the patient choose:

Little leakage, only slightly bothering =slight (1)
Bothersome, but does not disturb daily activities=moderate (2)
Bothersome, disturbs daily activities =disturbing (3)
Much leakage, makes me stay home =incapacitating (4)

The numbers in brackets correspond to the values used for calculation of mean changes in Impact.

3. Micturition data from the 48 hour frequency/volume chart and the subsequent pad test. The latter was omitted at six months.

4. Criteria based classification as:
Cured: No reported leakage and zero wet episodes. **Improved:** Improvement in at least two of the four elements frequency, amount, impact, wet episodes, consistent with any pad test results and with comments from health workers. **Unchanged:** None of the three others. **Worse:** Reported worsening of severity or of impact.

Statistics

Data were recorded in Epi-Info (16) and analyzed in SAS (17). Ordinal variables were analyzed both as categorical and continuous data, with 95 % confidence intervals (CI) or a significance level of 0.05. Chi square, two-sample *t*-test, Wilcoxon two-sample rank sum test were used. Severity change and impact change at twelve months were used as dependent variables in a multiple regression model with various patient data as independent variables.

Ethics

The Norwegian data inspectorate approved sampling and registration of patient data. Written informed consent was obtained on the basis of oral and written information, and the Regional Ethics Committee approved the study.

Results

Five hundred and seven women (72.6% of all invited) met for the first gynecological examination. Two hundred and forty (47.3% of the 507) reported involuntary leakage. Eighty-five (16.8%) of these did not leak more than once a month, and 65 (12.8%) were not considered for randomization because they declined participating, did not demonstrate leakage or had medical or social reasons. Ninety patients were thus randomized. Leakage was demonstrated in one or more ways in each patient; 13 had visible leakage, 69 had a positive pad test and 66 at least one 'wet'-recording on the frequency/volume chart. Two now-patients and one wait-patient had been randomized without objective demonstration of leakage; they were considered protocol deviant and excluded from the analyses which are based on the remaining 87 patients (17.2%), 42 now-patients and 45 wait-patients.

Forty-two of the 45 wait-patients had urodynamic testing, five of them declined the repeat testing. Twelve now-patients came to urodynamic testing after the last consultation in general practice.

Table II. Background data. Means with standard deviation (s.d.), or number of patients

	Now-group		Wait-group	
	n=42	s.d.	*n*=45	s.d.
Means				
Age in years	61.2	7.5	60.0	6.3
Number of births	3.0	1.6	3.2	1.6
Age at menopause[1]	48.8	5.6	48.9	3.9
Body Mass Index	26.4	3.6	26.8	4.1
Severity index	3.9	1.9	4.3	2.1
Impact	1.8	0.6	1.9	0.7
Wet episodes per 24 hours[2]	2.2		2.5	
Number of urinations[2]				
per 24 hours	7.0		7.8	
Stress	6.1		7.3	
Urge+Mixed	8.5		8.4	
Pad weighing test[3], grams in				
wettest pad	15		13	
Number of patients				
Primary care physician's classification of incontinence				
Stress	26		24	
Urge	4		2	
Mixed	12		19	
Previous hysterectomy	5		5	
Previous operation for genital prolapse and/or urinary incontinence	8		4	
Pelvic floor contraction found satisfactory[4]	22		22	

[1] Not recorded for 6 women 50–57 years of age with <6 months since last menstruation period, and for one older woman.
[2] Home recordings performed by 69 patients before start, measured for 48 hours (24 hours in 6 cases). Patients pursued ordinary daily activities.
[3] Home recordings for 75 patients before start. Patients were encouraged to do increased physical activity.
[4] Not recorded for 3 now-patients and 6 wait-patients.

Table III. Outcome at six months. Index changes (means with 95% confidence intervals), micturition data (means) and classification of change. *n*=number of patients

	Treatment group *n*=36		Control group *n*=44		*p* value[1]
Change in severity index[2]	1.8 (1.0 to 2.6)		0.1 (−0.6 to 0.8)		<0.001
5-year age groups:					
50–54	1.5 (*n*=10)		−2.0 (*n*=7)		
55–59	1.6 (*n*=8)		0.6 (*n*=14)		
60–64	2.6 (*n*=8)		0.6 (*n*=12)		
65–69	2.2 (*n*=6)		1.2 (*n*=6)		
70–74	0.8 (*n*=4)		−0.6 (*n*=5)		
Change in impact index[2]	0.8 (0.5 to 1.1)		0.0 (−0.2 to 0.2)		<0.001
5-year age groups:					
50–54	1.0 (*n*=10)		−0.1 (*n*=7)		
55–59	0.6 (*n*=8)		−0.1 (*n*=14)		
60–64	0.9 (*n*=8)		0.2 (*n*=12)		
65–69	0.8 (*n*=6)		0.2 (*n*=6)		
70–74	0.8 (*n*=4)		−0.2 (*n*=5)		
Wet episodes per 24 hours[3]	0.3		1.8		<0.001
Number of urinations[3]	6.5		7.4		
Stress	6.3		6.7		n.s.
Urge+Mixed	6.4		8.4		<0.01
	n	%	*n*	%	
Cured[4]	8	22	0	–	
Improved	14	39	4	9	
Unchanged	10	28	27	61	
Worse	4	11	13	30	

[1] Two-sample *t*-test. Same results for Wilcoxon two-sample rank sum test.
[2] Paired data not including the six now-patients and the one wait-patient not examined after six months.
[3] Home recordings performed by 63 patients, measured for 48 hours (24 hours in 3 cases). Patients pursued ordinary daily activities.
[4] Cured: No reported leakage and zero wet episodes. Improved: Improvement in at least two of the four elements frequency, amount, impact, wet episodes, consistent with comments from GP, practice nurse, physiotherapist. Unchanged: None of the three others. Worse: Reported worsening of severity or of impact.

Baseline data for the two groups are presented in Table II. The wait-group on average had slightly more severe leakage. Overall, 17% had slight leakage, 59% moderate and 24% severe leakage at start. Severity and impact did not differ significantly between five-year age-groups.

Outcome

After six months[1], average severity index had decreased from 3.9 to 1.9 in the treatment group and remained stable at 4.3 in the control group ($p<0.001$). Similarly, average impact index decreased in the treatment group from 1.8 to 1.0 and remained at 1.9 in the control group ($p<0.001$) (Table III). On average, the treated group changed from moderate severity and impact to slight severity and impact. Average number of wet episodes per 24 hours decreased with treatment, and so did average number of micturitions in urge and mixed incontinence, but almost one third of the patients did not complete all micturition tests.

After twelve months[2] there were no longer significant differences between now-group and wait-group (Table IV). Most of the improvement at six

[1] Of the 87 patients, seven were not examined at six months. Six of them were now-group-patients: one woman who withdrew from the study soon after having started treatment, one who had a mammary cancer diagnosed two months after start of treatment, one 73 year old woman who took estriol but felt too weak for follow-up or other treatment, and three patients in one practice who had treatment and follow-up delayed because of illness in the practice. The seventh patient was a wait-group-patient who had a benign ovarian tumor diagnosed. Her leakage stopped after operation.

[2] Two of the 87 patients had no examination at twelve months: the now-patient who withdrew from the study, and a wait-patient who withdrew from the study after having started treatment.

Table IV. Outcome at twelve months after both groups had received treatment. Index changes (means with 95% confidence intervals), micturition data (means) and classification of change. *n*=number of patients

	Now-group *n*=41	Wait-group *n*=44
Change in severity index	1.6 (0.8 to 2.4)	1.4 (0.7 to 2.2)
5-year age groups:		
50–54	2.3 (*n*=10)	0.5 (*n*=8)
55–59	1.8 (*n*=8)	2.8 (*n*=14)
60–64	1.7 (*n*=10)	0.9 (*n*=11)
65–69	1.3 (*n*=7)	2.0 (*n*=6)
70–74	0.5 (*n*=6)	0.0 (*n*=5)
Change in impact index	0.7 (0.4 to 1.0)	0.6 (0.4 to 0.9)
5-year age groups:		
50–54	0.9 (*n*=10)	0.9 (*n*=8)
55–59	0.4 (*n*=8)	0.6 (*n*=14)
60–64	0.6 (*n*=10)	0.7 (*n*=11)
65–69	0.9 (*n*=7)	0.8 (*n*=6)
70–74	0.8 (*n*=6)	−0.2 (*n*=5)
Wet episodes per 24 hours[1]	0.4	0.9
Number of urinations per 24 hours[1]	6.4	6.6
Stress	6.1	6.3
Urge+Mixed	6.9	6.9
Pad weighing test[2], grams in wettest pad	10	10

	n	%	*n*	%
Cured[3]	4	10	3	7
Improved	20	49	22	50
Unchanged	9	22	13	30
Worse	8	20	6	14

[1] Home recordings performed by 63 patients at 12 months, measured for 48 hours (24 hours in 2 cases). Patients pursued ordinary daily activities.

[2] Home recordings for 63 patients at 12 months. Not performed at 6 months. Patients were encouraged to do increased physical activity.

[3] Cured: No reported leakage and zero wet episodes. Improved: Improvement in at least two of the four elements frequency, amount, impact, wet episodes, consistent with pad test results and with written comments from GP, practice nurse, physiotherapist, gynecologist. Unchanged: None of the three others. Worse: Reported worsening of severity or of impact.

months had been maintained. More severe leakage at start ($p<0.001$) and lower age ($p=0.02$) were associated with greater reduction in severity at one year (R square 0.31), higher impact at start ($p<0.001$) and satisfactory pelvic floor contraction at twelve months ($p=0.02$) with greater reduction in impact (R square 0.33). Duration of leakage, body mass index, smoking habits, or municipality did not significantly influence severity or impact at one year. There were non-significant tendencies for a poor result when the women had a previous operation for uterine prolapse or incontinence, and for a better result with previous hysterectomy.

Fourteen patients had worsening of severity, impact or both. In about half of these patients intercurrent or major chronic illness made treatment difficult. This was far less common in the other patients.

Seventy women completed at least four sessions of physiotherapy. Forty-two women completed at least 12 weeks of overnight long term electrostimulation for stress incontinence, at least 15 sessions of maximal electrostimulation for urge incontinence, or at least one of the two for mixed incontinence. Twenty patients reported they stopped long-term electrostimulation before they intended because of discomfort, and four stopped maximal stimulation. Asked about the best treatment alone or in combination 12 patients reported long-term stimulation, seven maximal stimulation, 54 pelvic floor exercises, two bladder training, and 20 patients mentioned estrogen. Twenty-four of the patients mentioned a combination of treatment elements. Most now-patients continued using estriol and practising pelvic floor exercises, and 18 prolonged their electrostimulation beyond the examination at six months. Repeat urodynamic testing confirmed reported change for most of the 38 wait-patients who were tested twice. After the last urodynamic testing, four wait-patients and one now-patient have been operated for their incontinence, and two patients started using a vaginal ring for genital prolapse. One woman at repeat testing had a benign ovarian cyst diagnosed and removed.

Discussion

This study confirms that women 50 to 74 years of age with urinary incontinence may improve considerably through conservative treatment in general practice. It shows that treatment is feasible when the practice takes an interest in incontinence problems. Some patients became less motivated to complete the micturition tests at the end of the study, some because they felt better. When performed, these tests pointed in the same direction as the subjective changes in severity and impact. Untreated incontinence seems to have little tendency for spontaneous improvement. The wait-group showed no change at six months, even with slightly higher baseline leakage and thus greater potential for improvement. Approximately two-thirds of the patients had not previously tried medical treatment, and this is in accordance with a study from New Zealand (18).

The study was not designed to compare single treatment elements, and it is therefore difficult to judge the precise contribution to improvement of each treatment element. Pelvic floor exercise contributed much to the total improvement according to the patients' answers, and illustrated by the association between impact change and an increased ability to contract pelvic floor muscles. It is con-

sistent with findings in other studies (2, 3). However, most patients started physiotherapy before they received the electrostimulator and thus got the initial treatment effect through physiotherapy along with the general teaching effect and estriol. In one case where physiotherapy was incidentally delayed, electrostimulation and estriol had already cured the patient. There is seldom any haste to operate, and treatment helps select patients who finally will be best helped by surgery. A conservative treatment scheme is costly particularly in terms of the time and effort spent by the patients and by the doctors, nurses and physiotherapists who treat, but not treating at all carries important costs in terms of pads, laundry and psychosocial problems like shame and the fear of odor.

The ICS standardized test is the one hour pad test, but the 48 hour test is in current use and is more practical in general practice. Recent literature (19, 20) suggests that it is also more sensitive than the one hour test, but that our cut-off point of three grams weight gain per pad may be insufficient for objective demonstration of incontinence. More than 8 grams increase per 24 hours gives high specificity, and high predictive value even in populations with moderate leakage. None of the tests guarantee against false negative test results, since leakage is not always possible to provoke there and then, but for objective demonstration additional measures are necessary if pad weight increase is lower. In most of our patients leakage was higher and confirmed by more than one of the three leakage criteria, but 10 patients had less leakage than 9 g/24 hours. In six of them, objective leakage was demonstrated at a later time during the study period. For four patients we have only the patient's own history and pad weight increase less than 9 grams. We probably would not have included these four patients with our present knowledge about the 48 hour test, but our main conclusions are not affected by keeping them in the analysis.

Because incontinence was not mentioned in the invitation, we do not think the prevalence (21) of incontinence was much different in the 191 non-responders, whose mean age was 63 years. As expected, severe leakage was less frequent in our population based sample than in more selected samples (15). Impact of incontinence has been measured on ordinal scales quantifying the patient's worries or restriction of activities (22, 23) or measuring quality of life (24, 25), but unlike for severity we do not know of any validated scales for impact. Our impact scale was tried out in the pilot study with slightly different categories, and on the basis of this experience we arrived at the one we used in the present study. None of our patients reported incapacitating leakage on our scale, but it exists in selected populations.

Important comorbidity made treatment difficult in several cases. However, with less important comorbidity, our study shows that reduced leakage and more normal micturition is a realistic goal for treatment even in higher age groups. The association between severity and degree of improval may reflect a weakness in the rating scale, but perhaps more that definite cure is difficult to achieve. Commonly, the goal of treatment could be to keep leakage in check, minimizing its impact on daily activities. Our study confirms previous findings that conservative treatment is feasible and often effective even in high age groups, that a majority of the patients may improve from pelvic floor excercises, that some motivated women improve with electrostimulation and that estriol is important for some women with incontinence. But we cannot conclude that all women with urinary incontinence in our age group should have all three treatment elements in addition to being better informed. Rather, our study demonstrates the need for individualized treatment when the patient is obliged to play a very active role. Without this, our population based sample might not have achieved results comparable with results in studies dealing with patients who have consulted on their own initiative in general practice or have been referred to specialized departments. Our rather simple treatment elements may be tried one at a time or in different combinations. It is clearly shown that treatment is necessary to improve.

It is encouraging that what had been gained in the now-group was not lost during the last six months of the trial. The results are in agreement with three other studies (1, 10, 25), one with longer follow-up, but, to our knowledge, ours is the first population based study of this kind.

Acknowledgments

Primary care physicians: Tor Anvik, Berit Bartnes, Mari K. Johansen, Gerd Teigland, Mette Lerfaldet, Nils Fikke, Bjørg Evjenth, Egil Eliassen, Åse Schrøder, Karin Nilsen, Terje Tollåli, Bernt Markussen, Jan-Petter Lea, Torfinn Endresen, Tore Tveraabak, Bernt-Inge Embrå, Leif-Erik Traasdahl, Terje Erikstad, Elisabeth Teig Wium, Tove Skjelbakken, Karin Breckan, Knut Lappegård, Jan Johansen, Olaug Vassbotn, Gudmundur Pálsson, Fred Zahl, Anne Østmo Scott, Astrid Holm, Egil Myklebust, Bjørn Tansem, Kjetil Ryan, Samuel Hykkerud, Ellinor Heitmann, Vibeke Nissen, Søren Nissen, Ann Rydberg, Olav Ballo, Svein Svendsen, Jørn Ingvaldsen, Nina Stewart, Ingvil Vik, Jan Eggesvik, Babak Irandoust. Also, for pilot project participation Randi Nesje Myhr, Anne Sofie Chaboud, Ranil Roche – and Steinar Hunskår for comments. *Physiotherapists:* Marina Larsen, Bente Haugmo, Inger Reinholdtsen, Wenche Dølør. *Urotherapist nurses:* Guri Berg, Målfrid Gabrielsen, Gudrun Norvik, Randi Nylund. *Practice nurses:* Rita Flygt Nilsen, Karin Eriksen, Oddveig Johansen, Berill Dåbakk,

Ellen Mathisen, Elna Simonsen. *Medical secretaries:* Halldis Skjørseter, Grethe Klette Nilsen, Gretha Leivseth, Nina Angell, Inger Sjøhaug, Janne Johansen, Turid Fagerland, Kirsti Erikstad.

The study received unconditional financial and material (pads, estriol) support from The Norwegian Medical Association Fund no. 1, Odd Berg Medical Research Fund, Finnmark County Research Fund, Medicon A/S, Organon A/S, Coloplast A/S, SABA Mölnlycke A/S, LIC Hygiene A/S. Portable electrostimulators are available on loan to women with incontinence when requested by a physician in Norway, with expenses paid by Social Security.

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