Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women

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Abstract

Objective To compare the effect of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment for genuine stress incontinence.
Design Stratified, single blind, randomised controlled trial.
Setting Multicentre.
Participants 107 women with clinically and urodynamically proved genuine stress incontinence. Mean (range) age was 49.5 (24-70) years, and mean (range) duration of symptoms 10.8 (1-45) years.
Interventions Pelvic floor exercise (n = 25) comprised 8-12 contractions 3 times a day and exercise in groups with skilled physical therapists once a week. The electrical stimulation group (n = 25) used vaginal intermittent stimulation with the MS 106 Twin at 50 Hz 30 minutes a day. The vaginal cones group (n = 27) used cones for 20 minutes a day. The untreated control group (n = 30) was offered the use of a continence guard. Muscle strength was measured by vaginal squeeze pressure once a month.
Main outcome measures Pad test with standardised bladder volume, and self report of severity.
Results Improvement in muscle strength was significantly greater (P = 0.03) after pelvic floor exercises (11.0 cm H_2O (95% confidence interval 7.7 to 14.3) before *v* 19.2 cm H_2O (15.3 to 23.1) after) than either electrical stimulation (14.8 cm H_2O (10.9 to 18.7) *v* 18.6 cm H_2O (13.3 to 23.9)) or vaginal cones (11.8 cm H_2O (8.5 to 15.1) *v* 15.4 cm H_2O (11.1 to 19.7)). Reduction in leakage on pad test was greater in the exercise group (−30.2 g; −43.3 to 16.9) than in the electrical stimulation group (−7.4 g; −20.9 to 6.1) and the vaginal cones group (−14.7 g; −27.6 to −1.8). On completion of the trial one participant in the control group, 14 in the pelvic floor exercise group, three in the electrical stimulation group, and two in the vaginal cones group no longer considered themselves as having a problem.
Conclusion Training of the pelvic floor muscles is superior to electrical stimulation and vaginal cones in the treatment of genuine stress incontinence.

Introduction

Urinary incontinence is defined by the International Continence Society as "a condition in which involuntary loss of urine is a social or hygienic problem and is objectively demonstrable."[1] Urinary incontinence is more common in women than in men and affects women of all ages. Prevalence rates in women between 15 and 64 years of age vary from 10% to 30%.[2] Although only a quarter of all women with this problem seek help,[2] the approximate annual cost of the condition in the United States has been estimated at $11.2 billion in the community and $5.2 billion in nursing homes.[2] The most common type of urinary incontinence in women is stress incontinence, defined as the involuntary loss of urine during coughing, sneezing, or physical exertion such as sporting activities or sudden change in position. Genuine stress incontinence is urodynamically proved involuntary loss of urine when the intravesical pressure exceeds that of the urethra with no simultaneous detrusor contraction.[1] Risk factors for genuine stress incontinence are inherently weak connective tissue, vaginal delivery, obesity, strenuous work, and old age.[2]

Urinary incontinence is a socially embarrassing condition, causing withdrawal from social situations and reduced quality of life.[3,4] Genuine stress incontinence may lead to withdrawal from regular physical and fitness activities.[5,6] This withdrawal may be a threat to women's general health and wellbeing as regular moderate physical activity is important in the prevention of osteoporosis, high blood pressure, coronary heart disease, depression, and anxiety.[7]

In 1948 Kegel reported a cure rate of 84% after training of the pelvic floor muscles for women with various types of incontinence.[8] Surgery soon became the first choice of treatment, however, and not until the 1980s was there renewed interest in physical therapies.[9] This renewed interest for conservative treatment may be because of higher awareness among women and cost of and morbidity after surgery. Physical therapies to treat genuine stress incontinence include pelvic floor exercises with or without biofeedback, electrical stimulation, and weighted vaginal cones.[9] Pelvic floor exercise is known to be an effective treatment for

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genuine stress incontinence,[2] but randomised controlled trials evaluating electrical stimulation and vaginal cones have given conflicting and inconclusive results, and many of these studies are flawed because of small sample sizes.[9 10] Though neither electrical stimulation nor vaginal cones have been compared with no treatment, they are commonly used.

We compared the effect of pelvic floor exercises, electrical stimulation, vaginal cones and no treatment in women with genuine stress incontinence.

Methods

This study was a multicentre, single blind, randomised controlled trial with stratified design. Participants were women with genuine stress incontinence who were on the surgical waiting list or women with symptoms of stress incontinence recruited by local newspaper articles. Five centres in southeast Norway participated. A standardised assessment at enrolment included a comprehensive urogynaecological history, urodynamic assessment including uroflowmetry and cystometry, bacteriological examination, and pad test with standardised bladder volume. The study was approved by the local ethics committee, and all women gave written consent.

Inclusion criteria were history of stress urinary incontinence and >4 g of leakage measured by pad test with standardised bladder volume. Exclusion criteria were urinary incontinence other than genuine stress incontinence, involuntary detrusor contractions exceeding 10 cm H_2O on cystometry, abnormal bladder function (residual urine >50 ml and maximal uroflow <15 ml/s), previous surgery for genuine stress incontinence, neurological or psychiatric disease, ongoing urinary tract infections, other diseases that could interfere with participation, use of concomitant treatments during the trial, and inability to understand instructions given in Norwegian.

The power calculation of the study was based on the power estimation and results of a previous study designed to detect differences between groups of 1 SD with a power of 80% and an α of 5%.[11] In the previous study significant differences in the same outcomes after the same training programme were shown in groups of 23 and 29 subjects; therefore 30 participants were recruited for each of the four groups in this study.

Randomisation procedure

The participants were stratified into two groups (≤ 20 g and >20 g leakage) according to results of the pad test with standardised bladder volume. Randomisation schemes stratified by degree of incontinence were constructed for all sites by using computer generated random numbers. Participants within each stratum were randomised by using opaque sealed envelopes to one of the four study groups: pelvic floor exercises, electrical stimulation, vaginal cones, or untreated control. Information for decoding randomisation was kept locked in the statistician's office. The main investigator (KB) was not involved in any interventions and was blind to group allocation. Physicians evaluating the effect of the treatments were also blind to allocation of treatments.

Interventions

Participants were taught about the anatomy of the pelvic floor and lower urinary tract, physiology, and continence mechanisms by the local project physical therapist. All were taught to contract the pelvic floor muscles correctly, and this was assessed by vaginal palpation.

Participants in the three treatment groups were told that the three treatments were expected to be equally effective and were discouraged from using other treatments during the 6 month trial period. All patients in the three intervention groups met the physical therapist once a month for motivation, monitoring of pelvic floor muscle strength, and adjustment of treatment if necessary. The untreated control group had no contact during the intervention period but were offered instruction on the use of the continence guard (Coloplast AS).[12]

Pelvic floor muscle training—The protocol has been published previously[11] and followed recommendations for general training to increase strength of skeletal muscle.[13] Participants were asked to conduct 8-12 high intensity (close to maximum) contractions three times a day at home with additional training in groups once a week for 45 minutes with a physical therapist. Group training was performed in lying, standing, kneeling, and sitting positions with legs apart to emphasise specific strength training of the pelvic floor muscles and relaxation of other pelvic muscles. Participants aimed at holding each muscle contraction for 6-8 seconds, three or four fast contractions were then added. The rest period was about 6 seconds. A total of eight to 12 contractions were completed in each position with maximal contraction effort encouraged. Body awareness, breathing, relaxation exercises, and strength training for the abdominal, back, and thigh muscles were performed to music between positions. The participants were encouraged to use their preferred position and perform equally intensive contractions at home. An audiotape with verbal guidance for 12 maximum contractions was available for home training, and a training diary was kept.

Electrical stimulation—An MS 106 Twin (Vitacon AS, Trondheim, Norway) was used according the manufacturer's recommended protocol for 30 minutes of intermittent vaginal electrical stimulation per day. Selected parameters included biphasic intermittent current, frequency 50 Hz, pulse width 0.2 milliseconds, and current intensity between 0-120 mA with individually adapted on-off (duty) cycles on the basis of each woman's ability to hold a voluntary contraction. On time ranged from 0.5 seconds to 10 seconds, and off time from 0 seconds to 30 seconds. If ability to hold the contraction improved the duty cycle was progressed each month. All patients were encouraged to tolerate as high an intensity as possible to get a contraction. Treatment adherence was electronically monitored and recorded. At every monthly visit the physical therapist observed the patients receiving electrical stimulation from their home stimulators in the clinic.

Vaginal cones—Mabella cones (Vitacon AS, Trondheim, Norway) were used for 20 minutes a day according to the manufacturer's recommendations. Patients progressed through three cone weights—20, 40, and 70 g—according to their ability to hold the cones. Adherence was noted in a training diary.

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Adverse effects and tolerance to treatment

Adverse effects and treatment tolerance were monitored with a training diary and during monthly clinic visits.

Main outcome measures

Pad test with standardised bladder volume—After the bladder was emptied by catheter it was refilled with 200 ml saline. Women wore preweighed pads and ran on the spot for 30 seconds followed by 30 seconds of jumping with legs in subsequent adduction and abduction (jumping jacks) at a preset metronome rate of 132 beats per minute. After the test the pad was reweighed.

Subjective assessment—Women recorded how they perceived the condition before and after treatment on a 5 point scale (unproblematic, minimal problem, moderate problem, problematic, very problematic).[1]

Secondary outcome measures

Three day leakage episodes—The number of episodes of involuntary leakage in 3 days was recorded in a home voiding diary before and after the intervention period. Mean number of episodes was calculated.

Twenty four hour pad test—Twenty four hour pad weighs were conducted by patients at home before trial entry and after the last clinic visit. Women chose a typical day that mirrored their average level of activity.

Leakage index—Patients indicated on a 5 point scale (5 always, 4 often, 3 sometimes, 2 seldom, 1 never) the frequency of urinary leakage during sneezing, coughing, laughing, walking, walking downhill, running, jumping, and lifting. The mean was calculated as an index of leakage frequency before and after treatment.[14]

Social activity index—Perceived problems in participating in nine different social situations were recorded on a 10 cm visual analogue scale (0 impossible to participate, 10 no problem taking part). As an overall index of quality of life the mean was calculated before and after treatment.[14] After treatment participants also rated improvement on a 5 point scale (worse, unchanged, improved, almost continent, continent)[11] and stated whether they wanted further treatment.

Muscle function and strength

Pelvic floor muscle function was assessed by the physical therapist with vaginal evaluation during contraction. Muscle strength was evaluated by a vaginal balloon catheter (balloon size 6.7 × 1.7 cm) connected to a pressure transducer (Camtech AS 1300, Sandvika, Norway). The middle of the balloon was placed 3.5 cm inside the vaginal introitus.[15] Only contractions with simultaneous observable inward movement of the perineum were considered valid.[16]

Resting maximum urethral pressure and maximum urethral closure pressure were measured before and after treatment with a fibreoptic microtransducer. All terminology conforms to International Continence Society standards.[1]

Statistical methods

The primary analysis was carried on data from treated participants, with exclusion of data from those without final evaluation on efficacy variables. Additional intention to treat analyses were also done for all randomised patients including those who dropped out. The missing last values were considered as equal to baseline values. Results are given as mean values with 95% confidence intervals. As several variables were not normally distributed, however, the Kruskal-Wallis analysis of variance was chosen as the global test of differences between groups on visual analogue scales and other interval scaled variables. Pair-wise comparisons were made with the Mann-Whitney U test to compare each group with the control and one intervention group with another. Cochran-Mantel-Haenszel tests or χ^2 tests were used if data were nominal or categorical. P values < 0.05 were considered significant.

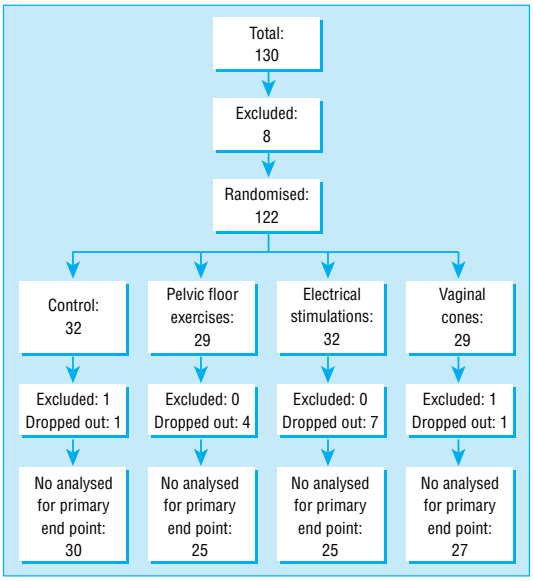


Fig 1 Trial profile of 130 women recruited to study of treatment of stress incontinence

Results

One hundred and twenty two patients were randomised. Three women could not complete the study (asthma, change of work, and death in the family), and two were excluded because they used other treatments during the trial. Ten women dropped out with motivation problems or adverse effects: two from pelvic floor muscle training (one motivation problem, one because of travel time to the training group), seven from electri-

Table 1 Background and outcome variables before treatment. Values are means (SD) unless stated otherwise

Detail	Control (n=30)	Exercise (n=25)	Electrical stimulation (n=25)	Cones (n=27)
Age (years)	51.7 (8.8)	49.6 (10.0)	47.2 (10.1)	49.2 (10.6)
Body mass index (kg/m^2)	25.8 (3.7)	25.1 (2.8)	24.9 (3.2)	25.3 (4.4)
Parity	2.4 (0.9)	2.3 (0.8)	2.4 (1.0)	2.6 (1.0)
Duration of symptoms (years)	9.9 (7.8)	10.2 (7.7)	13.3 (9.7)	10.1 (7.7)
Maximum urethral pressure (cm H_2O)	59.4 (19.8)	61.3 (18.7)	62.2 (13.5)	59.5 (15.1)
Maximum closure pressure (cm H_2O)	39.7 (19.8)	40.9 (20.7)	40.3 (14.8)	41.9 (17.1)
No (%) undertaking regular exercise	9 (30)	10 (40)	10 (40)	13 (48)
No (%) postmenopausal	19 (63)	15 (60)	13 (52)	14 (52)
No (%) using oestrogen	15 (50)	7 (28)	8 (32)	9 (33)
Pelvic floor muscle strength (cm H_2O)	14.6 (7.4)	11.0 (8.2)	14.8 (9.7)	11.8 (8.7)
Episodes of leakage in 3 days	2.9 (2.9)	2.0 (1.8)	2.3 (2.0)	2.7 (2.4)
Stress pad test (g)	51.4 (48.2)	38.6 (34.7)	56.0 (53.7)	48.4 (51.2)
24 h pad test (g)	42.5 (116.1)	14.5 (15.2)	20.9 (15.5)	52.3 (158.3)
Leakage index	3.0 (0.7)	2.8 (0.6)	2.7 (0.5)	3.0 (0.6)
Social activity index	8.1 (2.3)	8.7 (1.2)	8.2 (1.2)	8.3 (1.1)

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Table 2 Mean change (95% confidence interval) in measures of stress incontinence from baseline to 6 months

Outcome measure	Control (n=30)	Exercise (n=25)	Electrical stimulation (n=25)	Cones (n=27)	P value*
Episodes of leakage in 3 days	0.3 (–0.5 to 1.1)	–1.2 (–2.0 to –0.4)	–0.7 (–1.5 to 1.1)	0.8 (–1.2 to 2.8)	0.01
Stress pad test (g)	–12.7 (–27.2 to 1.8)	–30.2 (–43.3 to –16.9)	–7.4 (–20.9 to 6.1)	–14.7 (–27.6 to –1.8)	0.038
24 h pad test (g)	–7.1 (–20.2 to 6.0)	–6.6 (–12.1 to –1.1)	–0.5 (–8.9 to 7.9)	–22 (–55.7 to 11.7)	0.684
Leakage index	0.1 (–0.1 to 0.3)	–0.9 (–1.1 to –0.7)	–0.2 (–0.4 to 0)	–0.3 (–0.5 to –0.1)	0.001
Social activity index	–0.2 (–0.8 to 0.4)	0.6 (0.2 to 1.0)	0.6 (0.2 to 1.0)	0.1 (–0.3 to 0.5)	0.001

*Kruskal-Wallis test for comparison between groups.

cal stimulation (two because of pain, one for bleeding, and four through lack of motivation), and one from vaginal cones (vaginal bleeding). This left 107 participants: 30 in the control group, 25 in the pelvic floor exercise group, 25 in the electrical stimulation group, and 27 in the vaginal cones group (fig 1).

At baseline there were no significant differences between the groups in any of the background characteristics such as age, body mass index, duration of symptoms, pelvic floor muscle strength, urodynamic assessment, or degree of leakage (table 1).

Compliance with treatment

Mean (SE) adherence with treatment was 93% (1.5%) for pelvic floor muscle training, 75% (2.8%) for electrical stimulation, and 78% (4.4%) for vaginal cones. Adherence with pelvic floor muscle training was significantly greater than with electrical stimulation or vaginal cones ($P<0.001$ and <0.002, respectively). The difference between the electrical stimulation and cone groups was not significant.

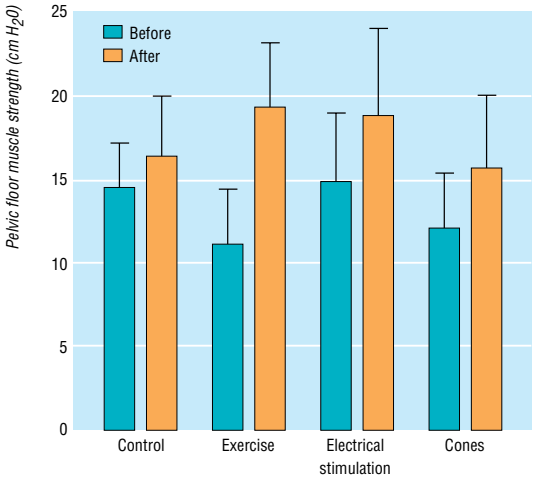


Fig 2 Change in strength of pelvic floor muscles in control group and treatment groups

Table 3 Differences (95% confidence intervals) between active and control treatment in change in stress incontinence measured by efficacy variables from baseline to 6 months

Variable	Exercise *v* control	Electrical stimulation *v* control	Cones *v* control
Episodes of leakage in 3 days	–1.5 (–2.6 to –0.4)	–1 (–2.1 to 0.1)	0.5 (–2.4 to 3.4)
Stress pad test	–17.5 (–36.5 to 1.5)	5.3 (–14.5 to 25.1)	–2.0 (–21.4 to 17.4)
24 h pad test	0.5 (–15.3 to 16.3)	6.6 (–9.0 to 22.2)	–14.9 (–51.1 to 21.3)
Leakage index	–1.0 (–1.3 to 0.7)	–0.3 (–0.6 to –0.1)	–0.4 (–0.7 to –0.1)
Social activity index	0.8 (0.1 to 1.5)	0.8 (0.3 to 1.4)	0.3 (–0.3 to 0.9)

Changes after treatment

Figure 2 shows details of the change in strength of the pelvic floor muscles. There was no significant change in the control group, but significant improvement was seen after treatment in the other groups. Only in the pelvic floor exercise group, however, was the improvement significant when it was compared with the control group ($P<0.01$). The change in the strength of pelvic floor muscle was significantly greater ($P=0.03$) in the pelvic floor exercise group (11.0 cm H_2O (95% confidence interval 7.7 to 14.3) before test *v* 19.2 cm H_2O (15.3 to 23.1) after test) compared with electrical stimulation (14.8 cm H_2O (10.9 to 18.7) *v* 18.6 cm H_2O (13.3 to 23.9)) and vaginal cones (11.8 cm H_2O (8.5 to 15.1) *v* 15.4 cm H_2O (11.1 to 19.7)). There was no difference in changes of strength between the electrical stimulation and vaginal cones groups ($P=0.90$). Intention to treat analyses did not change the results.

Analysis with Kruskal-Wallis test showed significant differences between groups in changes in all outcome variables except the 24 hour pad test (table 2). Table 3 shows the difference between active and control treatment in changes from baseline to 6 months with 95% confidence intervals for efficacy variables.

There were also significant differences in change between the pelvic floor exercise group and the control group according to the results of the pad test with standardised bladder volume ($P=0.02$), episodes of leakage in 3 days ($P<0.01$), social activity index ($P<0.01$), and leakage index ($P<0.01$). The difference between electrical stimulation and control was significant for episodes of leakage in 3 days ($P=0.02$), social activity index ($P<0.01$), and leakage index ($P<0.04$) (table 3). The difference between the vaginal cones group and the control group was significant for social activity index ($P=0.04$) and leakage index ($P=0.02$) (table 3). The pelvic floor exercise group improved significantly more than the electrical stimulation group measured by pad test with standardised bladder volume (reduction in urine leaked 30.2 g *v* 7.4 g; difference 22.8 (3.8 to 41.8); $P=0.02$) and leakage index (0.9 *v* 0.2 lower; difference –0.7 (–0.4 to –1.0); $P<0.01$) and significantly more than the vaginal cones group in pad test (reduction in urine leaked 30.2 g *v* 14.7 g; difference –15.5 (–34.1 to 3.1); $P<0.01$), episodes of leakage over 3 days (1.2 fewer *v* 0.8 more; difference –2.0 (–41.0 to 0.1); $P=0.03$), and leakage index (0.9 *v* 0.3 lower; difference –0.6 (–0.9 to –0.3); $P<0.01$). There were no significant differences between the electrical stimulation and vaginal cones groups in any outcome variable. There were no significant changes in maximum urethral pressure or maximum closure pressure for any group.

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Table 4 Subjective assessment of improvement in stress incontinence according to treatment

Outcome	Control	Exercise	Electrical stimulation	Cones
Continent	0	2	1	0
Almost continent	1	10	2	5
Improved	0	11	13	12
Unchanged	26	2	7	10
Worse	3	0	2	0

Objective cure (≤2 g leakage on the pad test with standardised bladder volume) was achieved by two women in the control group, 11 in the pelvic floor exercise group, seven in the electrical stimulation group, and four in the vaginal cones group ($P = 0.02$).

Subjective cure (number of women stating that the condition was "unproblematic" after the treatment) was reported by one woman in the control group, 14 in the pelvic floor exercise group, three in the electrical stimulation group, and two in the vaginal cones group. When corrected for baseline values the change in the pelvic floor exercise group was significantly greater than the change in the other groups ($P < 0.001$).

Table 4 shows subjective improvement after intervention. Significantly more women in the exercise group reported being continent or almost continent ($P < 0.001$) than in the other groups. Fourteen of the 30 participants in the control group chose to use the continence guard. Four felt completely dry when wearing the guard, and five felt somewhat better. Three participants in the control group and two in the electrical stimulation group considered themselves worse after treatment.

Twenty eight women in the control group, four in the pelvic floor exercise group, 19 in the electrical stimulation group, and 23 in the vaginal cones group wanted further treatment, apart from the one they had been randomised to, after the trial period. The difference between groups was significant in favour of the pelvic floor exercises ($P < 0.001$).

The results according to the intention to treat analysis showed virtually the same results as the treatment analyses. The only group that came out somewhat weaker when compared with the control group was the electrical stimulation group. Only the variable of leakage in 3 days showed nominally significant differences in change from baseline compared with the control group ($P = 0.047$). Improvement on the social activity index also became significant in favour of exercises compared with electrical stimulation.

Adverse effects and treatment tolerance

There were no side effects reported for pelvic floor exercises. In the electrical stimulation group two participants reported smarting (one tenderness and bleeding, one discomfort), and eight women reported motivation problems and difficulties in using the stimulator. Of those participants who used vaginal cones, one reported abdominal pain, two vaginitis, and one bleeding, and 14 reported motivation problems and trouble in using the cones.

Discussion

To our knowledge, this is the first study to compare three of the most commonly used conservative treatments with no treatment for genuine stress incontinence. We have shown that pelvic floor muscle training was a more effective treatment for genuine stress incontinence than no treatment, electrical stimulation, or vaginal cones. Compared with women in the control group only women in the pelvic floor exercise group increased pelvic floor muscle strength and reduced urinary leakage significantly when it was measured by pad test with standardised bladder volume. In addition, significantly more women in the pelvic floor exercise group stated that after the intervention the condition was no longer a problem.

Pragmatic study

This was a pragmatic study reflecting current practice. The intention was to give the optimal treatment in each group on the basis of current theory and recommendations. Because the exercise group met once a week for training the women had more attention than those in the the two other treatment groups. Electrical stimulation and vaginal cones, however, are advertised as treatments that patients can undertake at home after introduction by health staff. In an attempt to give equal individual attention and motivation all participants met once a month for individual follow up by a skilled physical therapist. On the other hand, both the electrical stimulation group and cone group spent more time per day with the treatment than the exercise group (30, 20, and less than 10 minutes, respectively). From the present study we cannot conclude which part of the three treatment packages caused the results. A decision to exclude the control group from monthly visits to measure strength of the pelvic floor muscles was taken to prevent this acting as a stimulus for training—that is, the "avis effect." The electrical stimulation and vaginal cones groups were not protected from this effect either, although they were specifically asked not to undertake pelvic floor exercises during the trial.

The use of this structured programme of pelvic floor exercise has previously been reported to be more effective than exercise carried out just at home.[11] Our results confirm that such a programme is more effective than no treatment for genuine stress incontinence, as have other well designed randomised controlled studies.[17 18]

The finding that pelvic floor exercises are more effective than electrical stimulation confirms the results of Henalla et al, who found pelvic floor exercise was more effective than electrical stimulation or oestrogen therapy in the treatment of genuine stress incontinence,[18] but contrasts with other studies that did not find any differences in outcome between the two interventions.[9 10] These studies, however, were of small samples, and non-significant results may be due to type II error. The effectiveness of the exercise regimens used can also be questioned.[19] Interestingly, two well designed, randomised controlled trials that compared electrical stimulation with sham electrical stimulation (placebo) have shown conflicting results,[20 21] and Brubaker et al found a 49% cure rate after electrical stimulation for urge incontinence but no effect for genuine stress incontinence.[22]

That regular exercises seem to be more effective than electrical stimulation is not surprising from a physiological perspective. Several consensus statements have concluded that electrically stimulated muscle

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contractions in humans are less effective than voluntary contractions for strengthening.[23 24] In addition, Bø and Talseth showed that voluntary contraction of pelvic floor muscle was twice as effective as an electrically stimulated contraction at increasing urethral pressure.[25] By attributing baseline values to all participants who dropped out in an intention to treat analysis the effect of electrical stimulation diminished further.

The theoretical basis of vaginal cones has been questioned. They may produce prolonged isometric contractions of the pelvic floor muscles, and in other muscles this may cause injuries due to overuse.[26] Our results showed pelvic floor exercises to be superior to vaginal cones in increasing muscle strength and reducing urinary leakage.

We found no differences in effect between electrical stimulation and vaginal cones, although both were more effective than no treatment measured by some secondary outcome measures. Many women, however, found electrical stimulation and vaginal cones difficult to use, and adverse effects were reported with both methods. Adverse effects have also been reported by other research groups.[20]

Outcome

Lack of reproducible and valid tests to measure urinary leakage makes the choice of outcome measures difficult. The Urodynamic Society and the standardisation committee of the International Continence Society have recommended use of measures for urinary leakage and self report to evaluate treatment effect,[27] although there is no agreement about the most appropriate measures to date. Because of the need for inclusion of randomised controlled trials in future meta-analyses we used a range of outcome measures used in clinical practice and research that have been previously tested for reproducibility.[11 14] A pad test with standardised bladder volume was chosen as the primary outcome measure because it has been shown to be more reproducible than pad tests with no standardisation.[28] The pad test used in our study, however, entailed movements likely to cause leakage. Some women who leak urine with this test may consider themselves subjectively cured. Few women may include such rigorous physical activity as part of their everyday life. Therefore an outcome that assesses how problematic incontinence is during daily life may be the most appropriate measure of cure.

It can be questioned as to whether 56% is a satisfactory cure rate. As these women do not then need surgery we suggest that this is highly acceptable. Although all the women who participated in this study had genuine stress incontinence, there can be several causes for this condition. DeLancey considers that if the cause is rupture of ligaments or facias or severe peripheral nerve damage training may not be effective.[29] Future imaging techniques may improve our ability to give a more specific diagnosis and thus improve the results of conservative treatments.

So far there are no long term results available from this study and as participants were offered other treatment options after cessation of the trial a follow up study will be difficult. A 5 year follow up of a previous clinical study that used the same pelvic floor exercise programme has been published.[30] Five years after cessation of the organised training three of 23 women had been treated surgically; of the 20 remaining, 14 were still satisfied with the results of pelvic floor exercises and did not want other treatment, 15 had no leakage on urodynamic cough test, and 14 were still doing pelvic floor exercises once or more a week.[30] No long term follow up data after cessation of treatment have so far been published for electrical stimulation and vaginal cones.

Key messages

- Training to increase the strength of pelvic floor muscles was superior to electrical stimulation and vaginal cones in treatment of genuine stress incontinence
- Adverse effects were reported with use of electrical stimulation and vaginal cones but not with exercises
- Patients' tolerance for electrical stimulation and vaginal cones was low
- Pelvic floor exercise should be first choice of treatment for genuine stress incontinence

Conclusion

Pelvic floor exercises are more effective than electrical stimulation, vaginal cones, and no treatment for women with genuine stress incontinence. As such exercise seems to be safe and effective it should be offered as first choice of treatment for genuine stress incontinence.

In addition to the authors the Norwegian Pelvic Floor Study Research Group comprised Ruth Dyresen, Tom Engebretsen, Hanne Borg Finckenhagen, Magne Halvorsen, Anke Helgar, Kjersti Dybvig Jensen, Marit Nicolaisen, Anne Sophie MacLeod, Ann Brit Sangvik, Latis Sadek, Hjalmar Schiøtz, Trine Lise Urnes, and Bjørg Wandås (project secretary). E Jean Hay-Smith has given valuable help with the English revision of the manuscript.

Contributors: KB was the main investigator. She initiated and planned the study, supervised the physicians and physical therapists, administered the whole trial, and wrote the manuscript. TT was in the planning group with KB from the beginning of the study. He was responsible for the planning and administration of the inclusion and exclusion criteria and was head of all urodynamic investigations. He supervised the other physicians in the inclusion and exclusion procedures, urodynamic assessment, and pad testing. In addition, he was the physician in one of the five centres and assessed the patients himself. He has revised the manuscript thoroughly several times, specifically the results from urodynamic investigations. IH advised on the study design and was responsible for stratification and randomisation procedures and planned and supervised all the statistical analysis. He carried out the more advanced statistical analyses, thoroughly revised the manuscript several times, and wrote details on statistical analyses. All participants in the research group contributed throughout the trial period with inclusion, exclusion, assessments, and treatments. KB is the guarantor of the study.

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1 Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardisation of terminology of the lower urinary tract function. *Scand J Urol Nephrol Suppl* 1988;114:5-19.

2 Fantl J, Newman D, Colling J, DeLancy JOL, Keeys C, Loughery R, et al. *Urinary incontinence in adults: acute and chronic management*. 2nd update. Rockville, Maryland: Department of Health and Human Services, Public

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Health Service, Agency for Health Care Policy and Research, 1996; (Clinical Practice Guideline, 96-0682.)
3 Norton P, MacDonald LD, Sedgwick PM, Stanton SL. Distress and delay associated with urinary incontinence, frequency, and urgency in women. *BMJ* 1988;297:1187-9.
4 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.
5 Bø K, Hagen R, Kvarstein B, Larsen S. Female stress urinary incontinence and participation in different sport and social activities. *Scand J Sports Sci* 1989;11:117-21.
6 Nygaard I, DeLancey JOL, Arnsdorf L, Murphy E. Exercise and incontinence. *Obstet Gynecol* 1990;75:848-51.
7 Bouchard C, Shephard R, Stephens T, eds. *Physical activity, fitness, and health. International proceedings and consensus statement*. Champaign: Human Kinetics Publishers, 1994.
8 Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. *Am J Obstet Gynecol* 1948;56:238-49.
9 Berghmans LC, Hendricks HJ, Bø K, Hay-Smith EJ, de Bie RA, van Waalwijk van Doorn ES. Conservative treatment of stress urinary incontinence in women. A systematic review of randomized clinical trials. *Br J Urol* 1998;82:181-91.
10 Bø K. Effect of electrical stimulation on stress urinary incontinence. Clinical outcome and practical recommendations based on randomized controlled trials. *Acta Obstet Gynecol* 1998;77(suppl 168):3-11.
11 Bø K, Hagen RH, Kvarstein B, Jørgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. III: Effects of two different degrees of pelvic floor muscle exercise. *Neurourol Urodyn* 1990;9:489-502.
12 Thyssen H, Lose G. Long-term efficacy and safety of a disposable vaginal device (continence guard) in the treatment of female stress incontinence. *Int Urogynecol J* 1997;81:30-3.
13 American College of Sports Medicine. Position stand. The recommended quantity and quality of exercise for developing and maintaining cardiorespiratory and muscular fitness in healthy adults. *Med Sci Sports Exerc* 1990;22:265-74.
14 Bø K. Reproducibility of instruments designed to measure subjective evaluation of female stress urinary incontinence. *Scand J Urol Nephrol* 1994;28:97-100.
15 Bø K. Pressure measurements during pelvic floor muscle contractions: the effect of different positions of the vaginal measuring device. *Neurourol Urodyn* 1992;11:107-13.
16 Bø K, Kvarstein B, Hagen R, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. II: Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. *Neurourol Urodyn* 1990;9:479-87.
17 Lagro-Janssen TLM, Debruyne FMJ, Smits AJA, Van Weel C. Controlled trial of pelvic exercises in the treatment of urinary stress incontinence in general practice. *Br J Gen Pract* 1991;41:445-9.
18 Henalla S, Hutchins C, Robinson P, MacVicar J. Non-operative methods in the treatment of female genuine stress incontinence of urine. *J Obstet Gynaecol* 1989;92:22-5.
19 Bø K. Pelvic floor muscle exercise for the treatment of stress urinary incontinence. An exercise physiology perspective. *Int Urogynecol J* 1995;6:282-91.
20 Sand PK, Richardson DR, Staskin SE, Swift SE, Appell RA, Whitmore KE, et al. Pelvic floor stimulation in the treatment of genuine stress incontinence: a multicenter placebo controlled trial. *Am J Obstet Gynecol* 1995;173:72-9.
21 Luber K, Wolde-Tsadik G. Efficacy of functional electrical stimulation in treating genuine stress incontinence: a randomized clinical trial. *Neurourol Urodyn* 1997;16:543-51.
22 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.
23 Dudley GA, Harris RT. Komi PV, eds. Use of electrical stimulation in strength and power training. In: *Strength and power in sport*. Oxford: Blackwell Scientific Publications, 1992:329-37.
24 Bouchard C, Shephard RJ, Stephens T, ed. Physical activity, fitness and health. Consensus statement. In: *Physical activity, fitness, and health: status and determinants. Adjuvants to physical activity*. Champaign: Human Kinetics Publishers, 1993:33-40.
25 Bø K, Talseth T. Change in urethral pressure during voluntary pelvic floor muscle contraction and vaginal electrical stimulation. *Int Urogynecol J* 1997;8:3-7.
26 Bø K. Vaginal weight cones. Theoretical framework, effect on pelvic floor muscles strength and female stress urinary incontinence. *Acta Obstet Gynecol Scand* 1995;74:87-92.
27 Blaivas J, Appell R, Fantl J, Leach G, McGuire E, Resnick N, et al. Standards of efficacy for evaluation of treatment outcomes in urinary incontinence: recommendations of the urodynamic society. *Neurourol Urodyn* 1997;16:147.
28 Lose G, Rosenkilde P, Gammelgaard J, Schroeder T. Pad weighing test performed with standardized bladder volume. *Urol* 1988;32:78-80.
29 DeLancey J. Stress urinary incontinence: where are we now, where should we go? *Am J Obstet Gynecol* 1996;175:311-9.
30 Bø K, Talseth T. Long term effect of pelvic floor muscle exercise five years after cessation of organized training. *Obstet Gynecol* 1996;87:261-5.

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Assessment of competence to complete advance directives: validation of a patient centred approach

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Abstract

Objective To develop a patient centred approach for the assessment of competence to complete advance directives ("living wills") of elderly people with cognitive impairment.
Design Semistructured interviews.
Setting Oxfordshire.
Subjects 50 elderly volunteers living in the community, and 50 patients with dementia on first referral from primary care.
Main outcome measures Psychometric properties of competence assessment.
Results This patient centred approach for assessing competence to complete advance directives can discriminate between elderly persons living in the community and elderly patients with dementia. The procedure has good interrater ($r=0.95$) and test-retest ($r=0.97$) reliability. Validity was examined by relating this approach with a global assessment of competence to complete an advance directive made by two of us (both specialising in old age psychiatry). The data were also used to determine the best threshold score for discriminating between those competent and those incompetent to complete an advance directive.
Conclusion A patient centred approach to assess competence to complete advance directives can be reliably and validly used in routine clinical practice.

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Introduction

Advance directives ("living wills") for medical care have been widely advocated as a means of extending the autonomy of patients to situations when they are incompetent. However, their impact has been surprisingly small. Despite legislation in the United States aimed at encouraging the completion of advance directives, less than 10% of healthy Americans have completed one.[1] The question remains as to how advance directives can be developed and effectively implemented in clinical practice. A pressing ethical problem in their use is that competent people may not always be well placed to make decisions concerning their future incompetent selves.[2] It is difficult for healthy people to imagine the whole range of situations that might befall them. It seems more worthwhile for advance directives to be completed at a time

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