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ORIGINAL ARTICLE

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Can quality of life be improved by pelvic floor muscle training in women with urinary incontinence after ischemic stroke? A randomised, controlled and blinded study

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Abstract The purpose of this study was to evaluate the effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke measured by quality of life (QoL) parameters. Three hundred thirty-nine medical records of stroke patients were searched. Twenty-six subjects were randomised to a Treatment Group or a Control Group in a single blinded, randomised study design. The intervention included 12 weeks of standardised pelvic floor muscle training. The outcome was measured by the Short Form 36 (SF-36) Health Survey Questionnaire and The Incontinence Impact Questionnaire (IIQ). Twenty-four subjects completed the study. The SF-36 and IIQ did not show significant difference between the two groups. Despite the high prevalence of stroke with urinary incontinence, it is difficult to include these patients in such studies. The samples were too small to detect any significant differences. Development of specific instruments for QoL in stroke patients with urinary incontinence can be recommended.

Keywords Pelvic floor muscle training · Quality of life · Stroke · Urinary incontinence · Women

Introduction

Urinary incontinence (UI) [1] after ischemic stroke [2] is an extremely common symptom. The prevalence varies from 32 to 79% at admission, 25 to 28% by discharge and from 12 to 19% 6 months after the stroke [3].

In Denmark the incidence of stroke is two per 1,000 inhabitants per year, corresponding to 10,200 patients per year with a significant increase with age [4].

UI affects the quality of life (QoL) in women through depression [5], functional limitations, social isolation, and negative relation to family, and use of institutions are very frequent [6]. Patients with UI after stroke experience further limitations in their quality of life because this symptom enforces the other consequences of the stroke, which can be deficits such as functional difficulties, depression, dysphasia and cognitive problems [7, 8, 9].

Pelvic floor muscle training (PMFT) is defined by the International Continence Society (ICS) as "repetitive, selective volitional contraction and relaxation of specific pelvic floor muscles. This necessitates muscle awareness in order to be sure that the correct muscles are activated and to avoid unwanted contractions of adjacent muscle groups" [1].

PFMT has been used for treatment in women with UI since Kegel began to use it in 1949 [10]. The effect has been documented in several studies and is now recommended as the first line conservative therapy of UI in women [11, 12]. Although time consuming, it is an inexpensive treatment without any known adverse effects.

The remission of post-stroke functions such as eating, dressing, bathing, using the toilet, and walking in most cases occur during the first 3 months after the stroke. The remission of the most severe stroke symptoms is, however, possible in the following 3–6 months [13]. It is a widely accepted experience that physiotherapy improves the remission after stroke.

Normally stroke patients have urge UI (motor urgency), probably due to central lesions and the uninhibited bladder contraction [14]. As PFMT makes use of the same stimulating methods as ordinary physiotherapy

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for post-stroke remission, it is obvious to do a study of the effect of PFMT in women with UI after ischemic stroke. To our knowledge no studies have been published on this subject.

Prospective, controlled studies of PFMT of UI after the stroke are very few [15] and only rarely fulfill the requirements of modern day research, e.g. no control group and no objective outcome measurements were used.

This study was a part of a large, clinical study evaluating the rehabilitation procedure for stroke patients with UI. The primary aim of the present study was to study the effect of PFMT in women with urinary incontinence after ischemic stroke measured by quality of life parameters.

Materials and Methods

Method

The design was prospective, randomised and single-blinded. All subjects had a 4 week run-in period with baseline registration and the first examination sequence (Pretest). After the run-in period, the subjects were randomised either to a Treatment Group (TG) or to a Control Group (CG) by a randomising procedure using a mathematical table and sealed, numbered envelopes. The randomisation was done by a physiotherapist without any further relation to the study prior to the inclusion of the subjects. The randomisation code remained blinded for the investigators until the last subject was examined.

After 12 weeks a second examination sequence was performed (Post test). The subjects in CG were offered treatment after the study.

Subjects

The sample was recruited from the clinical departments at Copenhagen University Hospital, Glostrup (acute stroke unit, neurological, geriatric, rehabilitation) and general physical therapy clinics and the public rehabilitation centres in The Copenhagen County from 1 January 1999 to 1 March 2001.

The inclusion criteria were: 1) women diagnosed with first-ever ischemic stroke according to the definition of the World Health Organisation and verified by CAT scan [2]; 2) stroke symptoms in at least 1 month; 3) normal cognitive function (Mini-mental state examination a.m. Folstein >25) [16]; 4) urinary incontinence according to the definition of ICS [1] that started in close relation to the stroke; 5) independent walking abilities indoors >100 meters with/without aids; 6) independence in toilet visits; and 7) age between 40–85 years.

Exclusion criteria were: 1) urinary tract infection; 2) symptoms of descensus urogenitale; 3) chronic respiration diseases; 4) psychiatric diseases; 5) other neurological diseases; and 6) do not speak Danish

The subjects received written and verbal information and signed an informed consent. The ethical committee for The Copenhagen County had approved the study.

The subjects were outpatients at the time of the study and were offered free transportation for examinations and intervention visits at the hospital.

The medical records of the subjects were screened and subjects were included in the study based on inclusion and exclusion criteria. The UI-status of the subjects was determined by interview and subjects not fulfilling the UI inclusion criteria were excluded (Fig. 1).

Measurements

Two instruments measured the outcomes:

1. A generic questionnaire: The Short Form 36 (SF-36) Health Survey Questionnaire [17]. The SF-36 consists of 36 items grouped in eight health-related domains: physical functioning (ten items); role limitations due to physical problems (four items); body pain (two items); general health perceptions (five items); vitality (four items); social functioning (two items); role limitation because of emotional problems (three items); general mental health (psychological distress and psychological well-being (five items). A single item is added to assess any change in health compared with 1 year before. Each scale was ranged from 0 (worst case) to 100 (best case). The reliability and validity of SF-36 had been studied in several populations [18, 19].
2. A specific questionnaire: The Incontinence Impact Questionnaire (IIQ) [20]. The IIQ questionnaire measured UI impact on different activities and feelings. The questionnaire consists of 30 items grouped (emerged) in four subclasses: physical activities (six items); travel (six items); social relationships (ten items); and emotional health (eight items). Each subscale ranges from 0 (best case) to 100 (worst case). IIQ had been tested for reliability and validity [20].

The questionnaires were in a Danish version, and the permission for using the Danish version of SF-36 had been acquired. All QoL interviews were performed by two trained neurological and gynaecologic physiotherapists.

Intervention

The subjects in TG were treated in a systematic, controlled, intensive PFM programme in 12 consecutive weeks by the same specialist physiotherapist. The procedure is presented in Table 1.

The treatment program consist of:

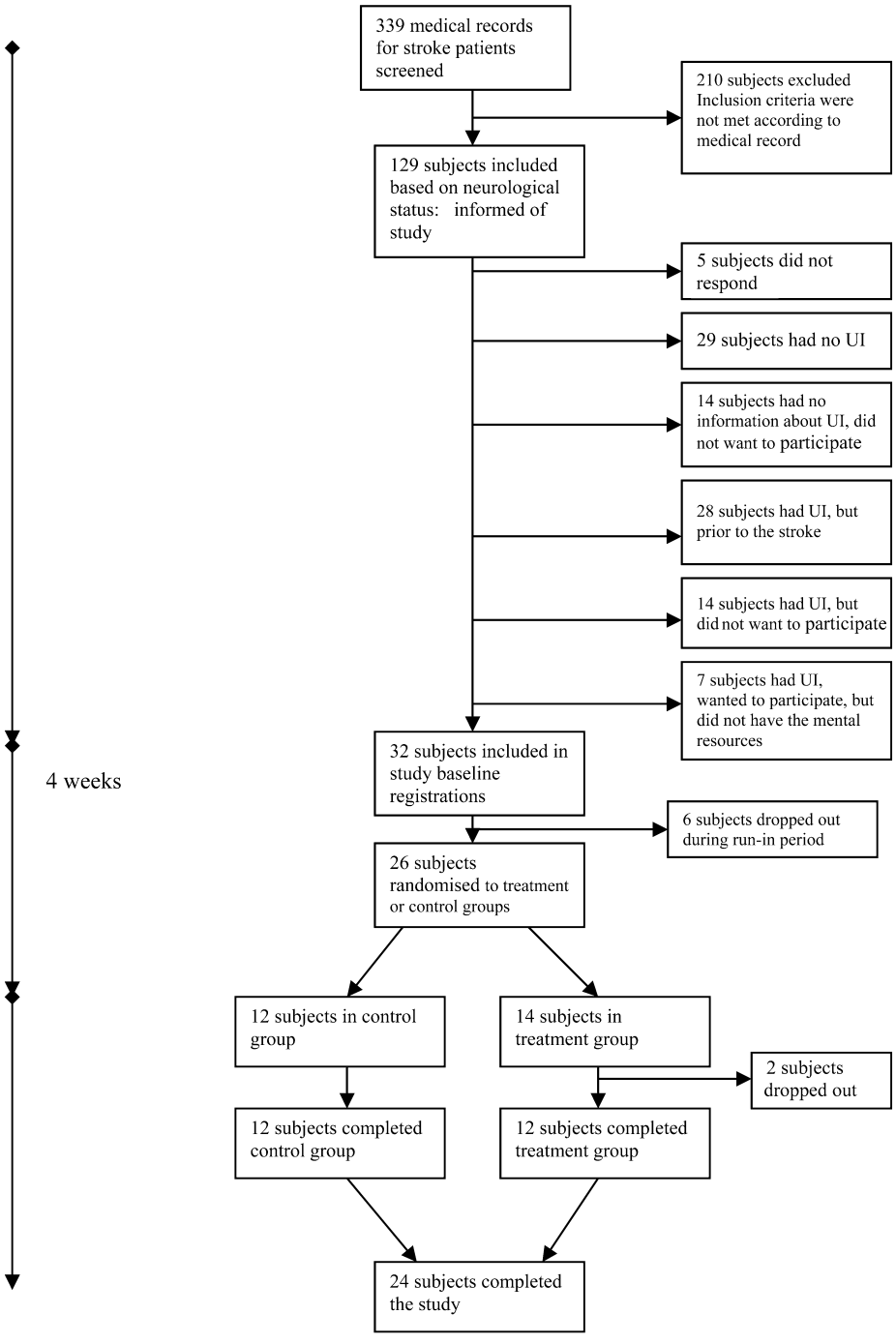
1. Introduction: a) group conversation about UI problems, duration and experiences; b) definition of UI types; c) anatomy and physiology of the bladder and the PFM; d) instruction in self-palpation of PFM; e) motivation and instruction in home exercises.
2. Home exercises: a) strength PFM exercise by performing close to maximum contraction (6 s contraction/ 6 sec rest) [12]; b) endurance PFM exercise by performing at least 30% of maximum contraction as long as possible (max 30 s contraction/30 s rest). All exercises repeated gradually 6–10 times in lying, standing and sitting positions, 1–2 times daily.
3. Group treatment: a) isolate PFM contraction (6 s contraction/ 6 s rest); b) strength exercises (3 s contraction/3 s rest, and 6 s contraction/6 s rest); c) endurance exercises (max 30 s contractions/30 s rest). All techniques were graduated repeated 4–8 times in lying, standing and sitting positions; d) PFM contractions before and during daily activities such as rising, sitting and walking; e) vaginal palpation of PFM was performed to control correct contraction, and to give continual feed-back to the subjects and to evaluate the strength. The training programme is a Modified version of a standard training programme for group treatment of stress incontinence.

The subjects in CG followed the normal, standard programme of rehabilitation without any specific treatment of urinary incontinence.

Statistics

Statistical calculation was done by means of SPSS (Statistical Package of Social Science), version 10.1. Median and quartile ranges are presented. The null-hypothesis are tested by Mann Whitney U-test between groups and by Wilcoxon test within groups. The level for statistical significance was set at $p < 0.05$.

Fig. 1 Study profile



Results

A total of 339 medical records of women with stroke were screened, 210 of which were excluded based on their neurologic status. The remaining 129 subjects were invited to participate in the study but 28 (23%) subjects had UI before the stroke, 14 (11%) subjects with UI did not want to participate, and seven (5%) subjects with UI wanted to participate but did not have the resources. As seen in Fig. 1, the total number was reduced to 26 subjects to be included. Two subjects from TG dropped out, and no subjects from CG dropped out during the treatment period. The reasons for termination were abdominal diseases (n = 1) and social problems (n = 1). The median age for the remaining 24 subjects was 60 years, interquartile range 56–74.

Baseline characteristics of the subjects who completed the trial are presented in Table 2 and baseline, neurological characteristics in Table 3. Mann-Whitney U-test was used to check that there were no differences between TG and CG. The test showed no significant difference between the groups regarding the number of smokers,

Table 1 Treatment program of pelvic floor muscle exercise in women with urinary incontinence after stroke

Introduction (theory)	1 h
Group treatment	6–8 patients/group
Frequency	1 h/week
Duration	12 weeks
Attendance in group treatment sessions	Minimum eight times
Vaginal palpation	2–3 times
Home exercises	1–2 times daily

medication intake, muscle strength and sensory disorder within the two groups. No subjects used incontinence medication.

Twenty-four subjects completed the trial, twelve in CG and twelve in TG. The attendance for treatment was 90% (66–100%).

SF-36

In SF-36 all 24 (100%) subjects completed the questionnaire (Table 4). Seven scales in TG had changed: three scales increased, four scales decreased and one scale was unchanged. Six scales in CG had changed: three scales increased, three scales decreased and two scales were unchanged. There were no significant differences between the groups.

IIQ

The IIQ was completed by 24 subjects (100%) (Table 5). The levels of scores in the test are low: 14 is the median before intervention and 29 after intervention on a scale ranging from 0 (best case) to 400 (worst case). Of the answers to most of the individual questions, 60–90%

Table 2 Baseline characteristics of stroke patients with urinary incontinence

Characteristics	Treatment group n = 12	Control group n = 12	*p*
Age (years)	59 (56–72)	62 (52–75)	0.799
Childbirth (number)	2 (1–3)	2 (2–3)	0.713
Gynaecological surgery			
None	7 (58%)	5 (42%)	-
One or more	5 (42%)	7 (58%)	-
Urinary incontinence type			
Stress	1 (8%)	2 (17%)	-
Urge	5 (42%)	3 (25%)	-
Mixed	6 (50%)	7 (58%)	-
Urinary incontinence loss: pad test (g/24 h)	7.5 (2–22)	7.5 (2–72.5)	0.663
Mobility: walking distance (m)	1000 (500–5000)	3500 (400–5750)	0.688
Cycling distance (km)	0 (0–4)	0 (0–9,5)	0.353
Walking stairs (amount of steps)	60 (20–100)	40 (23–90)	0.733
Sport/exercises (minutes per week)	0 (0–30)	68 (0–113)	0.65
Walking aids, rollator/food braces, Klensax	0 (0–1)	0 (0–3)	-

Median (quartile range) or number (%)

Table 3 Baseline, neurological characteristics of stroke patients with urinary incontinence

Neurological characteristics	Treatment group n = 12	Control group n = 12	*p*
Since stroke, months	12 (2–20)	13 (2–50)	0.579
Size of Ischemic infact on CAT scan: small	2 (17%)	4 (33%)	-
Moderate	0 (0%)	0 (0%)	-
Large	1 (8%)	1 (8%)	-
No information	9 (75%)	7 (58%)	-
Localisation: left, hemisphere	3 (25%)	7 (58%)	-
Right, hemisphere	6 (50%)	4 (33%)	-
Bilat	2 (17%)	1 (8%)	-
No information	1 (8%)	0 (0%)	-
Mini-Mental State Examination (maximum score = 30)	30 (29–30)	30 (29–30)	0.568

Median (quartile range) or number (%)

Table 4 Results of Short Form (SF-36) Health Survey Questionnaire in 24 women with urinary incontinence after stroke

		Pre-test	Post-test	*P*
Total	TG	598 (362–713)	629 (455–692)	0.147
	CG	655 (477–692)	656 (487–729)	0.722
Physical functioning	TG	63 (43–88)	60 (48–89)	0.470
	CG	70 (43–89)	67 (50–90)	0.671
Role limitation due to physical problems	TG	88 (6–100)	75 (50–100)	0.524
	CG	50 (6–100)	88 (13–100)	0.498
Body pain	TG	62 (44–100)	76 (44–100)	0.753
	CG	84 (63–100)	76 (52–100)	0.600
General health perceptions	TG	70 (41–91)	60 (43–87)	0.877
	CG	82 (56–92)	64 (42–90)	0.083
Vitality	TG	65 (50–74)	55 (45–78)	0.753
	CG	70 (45–89)	83 (56–85)	0.472
Social functioning	TG	88 (53–100)	100 (88–100)	0.058
	CG	100 (100–100)	100 (100–100)	0.276
Role limitation because of emotional problems	TG	100 (8–100)	100 (33–100)	0.180
	CG	100 (75–100)	100 (75–100)	1.000
Mental health	TG	68 (57–96)	82 (64–96)	0.292
	CG	84 (73–92)	86 (64–96)	0.610

The scales ranges from 0 (worst case) to 100 (best case). Median, quartile range are presented. *TG* treatment group (n = 12), *CG* control group (n = 12)

Table 5 Results of the Incontinence Impact Questionnaire (IIQ) in 24 women with urinary incontinence after stroke

	Pre-test	Post-test	*P*	
Total	TG	14 (8–99)	29 (2–67)	0.374*
	CG	17 (5–80)	18 (4–116)	0.721*
Physical activity	TG	0 (0–11)	6 (0–15)	0.832*
	CG	0 (0–14)	0 (0–21)	0.414*
Travel	TG	6 (0–36)	8 (1–25)	0.445*
	CG	3 (0–26)	0 (0–29)	0.752*
Social relationships	TG	2 (0–17)	3 (0–9)	0.288*
	CG	0 (0–11)	2 (0–13)	0.799*
Emotional health	TG	8 (4–22)	8 (1–20)	0.518*
	CG	8 (1–28)	13 (4–21)	0.959*

The scales range from 0 (best case) to 100 (worst case).*TG* treatment group (n = 12), *CG* control group (n = 12)

were ''no impact/no problem''. Only three questions of 30 (travelling more than 30 min, visiting places with unknown toilet facilities and impact on sleep) were answered more varied.

Overall, the changes were very small and Wilcoxon matched pairs test showed no significant difference between scores at pre-test and at post-test within groups.

Mann-Whitney U-test did not show significant differences between groups.

Discussion

Present study

In the present study a total of 339 medical records of stroke patients were screened during a period of 2 years. Of these 339 patients, 210 were excluded as potential participants in the study because of their neurological status. There was no information regarding UI. The remaining 129 subjects were informed about the study, but 103 were left out for various reasons (see Fig. 1), leaving only 26 subjects to be randomised to the study.

This marked reduction to 8% of the potential candidates was unexpected. The reasons for this are partly due to the rather strict inclusion criteria that had been introduced to make sure that the subjects were able to complete the training as outpatients and participate during a long period. The great reduction clearly indicated that stroke patients are a vulnerable group having to fight many other deficits, which prevent the subjects from participating in a study like the present. As the frequency of UI increases with the severity of the stroke [12], the strict inclusion criteria have probably ruled out several UI subjects, but the exact number is unknown as the UI-status of these subjects have not been systematically recorded.

The resulting number of patients completing the study was far less than planned and the sample became too small to get significant statistical power when using the QoL-questionnaire as the measurement instruments. Furthermore, there was a considerable inter-subject variation.

The SF-36 questionnaire was chosen, as this is an acknowledged method for a QoL-measurement for stroke patients [21]. The IIQ questionnaire was chosen, as this was the only available QoL-questionnaire specific towards UI in women in Danish [22]. The use of the combination of SF-36 and IIQ to stroke patients with UI is new and an unproven method.

As a consequence of the above-mentioned problems, the use of the SF-36 and IIQ questionnaires did not reveal any significant effects of the intervention in the treatment group.

SF-36 showed increased scores for TG on three scales: body pain (TG/CG: 62 to 76/ and 84 to 76); social functioning (88 to 100/ and 100 to 100); and mental health (68 to 82 and 84 to 86).One scale was unchanged: role limitation because of emotional problems (TG/CG) 100/100 to 100/100. Four scales decreased: physical functioning (TG/CG) 63/70 to 60/67; role limitation because of physical problems 88/50 to 75/88; general health perception 70/82 to 60/64; and vitality 65/70 to 55/83.

Although there were no significant differences between the two groups before or after intervention, a trend to some effect of active intervention appeared.

The IIQ showed the same tendency with a trend to stabilisation. One scale was unchanged (TG/CG): emotional health (8/8 to 8/13). Three scales changed a little, but not to a significant degree: physical activity (0/0 to 6/0); travel (6/3 to 8/0); and social relationship (2/0 to 3/2).

These results allow no firm conclusions about the effect of PFMT in women with UI after stroke. The lack of significant results can of course be true, but it could also mean that SF-36 and IIQ questionnaires, as the primary instruments to document the effect of the intervention, are not the optimal choice. The reasons for this could be:

1. If the effect of the intervention measured by SF-36 and IIQ questionnaires gives small changes on the eight SF-36 scales and four IIQ-scales, the sample must be very large to prove any significant statistical difference.
2. The IIQ questionnaire seems not to be sensitive towards patients with urge UI, which is one of the dominant types of UI for this group of patients. According to Lagro-Jansson et al. [23], the impact of urge UI is seen as disturbance of sleep, emotional disturbances and social isolation. The IIQ has only a few items related to the special situation of women with urge UI, although the present answers to these shows some sensitivity towards urge UI.
3. The IIQ questionnaire has a basic error because the possibility of answering ''not relevant'' is missing. This misleads the subject to answer ''no impact/no problem'' when asked to indicate the impact of UI on a certain activity which the subject does not perform. As an example of this, only one patient of the present sample did actually have a job, but nevertheless most subjects answered ''no impact on job situation''! As the questionnaire gives no possibility to leave out irrelevant items during the calculation, this results in a one-side bias indicating thereby a too optimistic result.

Previous studies

Likewise, in a very recent double blinded, controlled study by Rasmussen [24] where the effect of Sertraline on the post-stroke depression was measured in a parallel group design with 21 subjects in a placebo group and 24 subjects in a treatment group, no significant effect was measured by the SF-36 questionnaire.

In their study from 2000, Sanders et al. [22] also used SF-36 together with IIQ to assess the effect of a vaginal vice on 41 women with stress UI. Similar to our study, they did not find the sensitivity of SF-36 sufficient to detect alterations in QoL in women with stress UI.

By means of The Nottingham Health Profile questionnaire, Lagro-Jansson et al. [23] noted in a controlled study that urge incontinence had a more profound impact on quality of life than stress incontinence.

Methodology

Stroke patients have many other deficits than UI after the stroke. This means that when we measure the general Quality of Life with an SF-36 Questionnaire, we expect only very small changes in the scores. In the case that the general health of the patients is worsening because of other post-stroke complications, decreasing scores will be recorded by the SF-36 scales, illustrating the necessity of a matched control group.

Using the SF-36 questionnaire on a group of patients who suffer from many different deficits relating to stroke creates a major problem when only one deficit is studied in detail. This study focuses only on UI and offers a treatment for this, but even if this treatment is a success the other deficits may widely be unchanged. The eight SF-36 scores reflect the general health status of the patients. If, as in this study, there is no significant difference between scores taken before and after the intervention, it is not possible to determine whether the treatment has no effect or the effect is overruled by the general progression in the patients' health. By having a third group of patients with the same baseline characteristics and deficits except the focused subject, one may demonstrate whether the treatment effects are ''overshadowed'' by a general progression. On the other hand, such a study would be quite complicated and the statistical power further reduced.

After this study was started a shorter version of the SF-36 questionnaire, the SF-12, was developed. A recent study indicates that the SF-12 may be used without substantial loss of information in stroke patients [25].

A new version of IIQ, U-IIQ, has also been developed to be specific to the assessment of urge incontinence [26, 27]. Further work on this scale is reported to be underway.

Conclusion and perspectives

In this study the use of two QoL-questionnaires (a general and a specific) were tested on a group of stroke patients having primary urge and mixed UI after stroke, but the instruments proved to be insufficient to determine whether PFMT had any or no effect on the QoL for this very restricted group of patients.

The use of a general QoL-questionnaire like the SF-36 will give an indication of the general health status but can not give any information about a specific symptom such as UI. Using SF-36 must therefore be regarded as a supplement to other, more robust measurements and more sensitive instruments should be developed.

The specific IIQ-questionnaire turned out to be rather insensitive towards women with urge UI. In our experience it seems possible to gather information from women

with urge UI with this type of questionnaire, but the new version of IIQ focussing on urge urinary incontinence in women has to be tested in therapeutic trials.

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Editorial comment

This study uses quality of life parameters to evaluate the effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke. The authors should be commended on studying this very important group of patients that historically have been difficult to treat. The small study size makes it impossible to draw significant conclusions.