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Effectiveness of Pelvic Floor Muscle Exercise Therapy Supplemented With a Health Education Program to Promote Long-Term Adherence Among Women With Urinary Incontinence

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Aims: A longitudinal randomized controlled trial (RCT) was conducted to evaluate the effectiveness of physiotherapeutic pelvic floor muscle exercise (PFME) therapy supplemented with a health education program to promote long-term adherence among women with stress, mixed, and urge urinary incontinence (UI). **Methods:** Women (n = 129) were evaluated by their general practitioner (GP) and randomized in either the control group (PFME therapy alone) or one of the three experimental groups (PFME therapy with one of the three health education program versions). Therapy consisted of 9–18 individual 30 min sessions with a specialized physiotherapist, over 14–22 weeks. Outcome measures were weekly frequency of wet episodes and adherence behavior. Women were assessed up to 1 year after therapy. **Results:** The health education program had no additional impact to individual contact during PFME therapy on treatment outcome, nor on adherence. However, the individual physiotherapeutic treatment protocol was very effective in reducing weekly frequency of wet episodes from 23 to 8 times a week immediately after therapy, and effects were maintained during the 1-year follow-up period. Adherence was very high; most women followed the behavioral advice on average 6 days/week at posttest and still 4–5 days 1 year after therapy. Results were not different between incontinence types. Women who had relatively frequent wet episodes before and 1 year after therapy had higher adherence levels compared to women who had fewer weekly losses. **Conclusions:** Results suggest that a standardized protocol checklist for physiotherapists covering all treatment aspects of PFME therapy, may optimize long-term treatment outcome and adherence behavior among patients, and outshines the addition of a health education program. *Neurourol. Urodynam. 22:284–295, 2003.* © 2003 Wiley-Liss, Inc.

Key words: adherence; patient education; pelvic floor muscle exercise therapy; urinary incontinence

INTRODUCTION

Urinary incontinence (UI) comprised of three common types stress, urge, and mixed UI [Abrams et al., 1988].

Pelvic floor muscle exercise (PFME) therapy has proven effective for all three [Hay-Smith et al., 2001] and PFME therapy is recommended as the first-choice treatment for women with these types of UI after remediable conditions have been excluded. In prior studies up to 70% of patients were cured or improved after therapy [Berghmans et al., 1998a], but success rates declined during follow-up as adherence to the program deteriorated [Bø and Talseth, 1996; Lagro-Janssen and Van Weel, 1998; Chen et al., 1999]. An intervention aimed at promoting long-term adherence to PFME therapy seems warranted.

Various authors have pointed out that patient education in physiotherapy, and especially the part of encouraging adherence behavior, lacks a systematic behavioral approach [Sluijs et al., 1993]. A literature search was conducted to evaluate approaches designed to improve adherence to PFME therapy. In four studies, the PFME program included adherence-promoting strategies: audiocassette tapes to guide exercising at home, telephone calls as reminders, and follow-up visits to provide feedback and reinforcement. One study found that after 6 weeks of training at home, adherence was significantly better in the group that had used an exercise tape, compared to the group without the tape [Gallo and Staskin, 1997]. Surprisingly, in the other three studies adherence behavior itself was

Abbreviations: PFME therapy, pelvic floor muscle exercise therapy; PFMEs, pelvic floor muscle exercises; UI, urinary incontinence; GP, general practitioner; RCT, randomized controlled trial; ICS, International Continence Society.

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not measured [Burns et al., 1993; Nygaard et al., 1996] or not related to the adherence-promoting strategies [Wyman et al., 1998], thus the efficacy of these strategies remains unclear.

In the current study, a longitudinal randomized controlled trial (RCT) on the effectiveness of PFME therapy supplemented with a theory-driven health education program was set up to promote long-term adherence to PFME therapy. It was hypothesized that better adherence behavior was related to better therapy outcomes, and the study addressed the following two research questions:

1. Does PFME therapy supplemented with a health education program result in better outcomes than PFME therapy alone, 1 year after therapy?
2. Does PFME therapy supplemented with a health education program result in better adherence behavior than PFME therapy alone, 1 year after therapy?

METHODS

PFME Therapy

The content of PFME therapy and the adherence advice were based on usual care in the Netherlands and recommendations of several authors [Lagro-Janssen et al., 1995; Berghmans et al., 1998b; Payne, 2000]. As the Dutch clinical practice guidelines [Berghmans et al., 1998b] were not yet available at the time of this study, a similar protocol for the individual PFME therapy was prepared in cooperation with the participating physiotherapists as a standard for all study conditions.

PFME therapy for stress incontinence focused on the integration of the automatic and subconscious use of the pelvic floor muscles during the daily posture and movement pattern, and on the integration of PFMEs in daily life. For urge and mixed incontinence, the therapy focused first on bladder training in which a normal voiding frequency of approximately seven voidings per day is trained. Second, the therapy included the same program as for stress incontinence with the addition of learning to prevent leakage when feeling an urge, by contracting the pelvic floor muscles. The therapy included teaching about the anatomy and function of the bladder, the pelvic floor muscles, the continence mechanism, toilet behavior, and education on the importance of adherence to the advice.

Adherence to PFME therapy was operationalized as following four behavioral advice:

1) Perform PFMEs regularly: 10 slow twitch contractions (10–30 sec) and 10 fast twitch contractions (2–3 sec), five times a day, each contraction being followed by relaxation. Increase repetitions in each session to the point of fatigue and incorporate different starting positions and functional activities into the exercise program. Check contractions with self-palpation.
2) Perform correct toileting and drinking behavior: sit straight on the toilet and relax the pelvic floor muscles during voiding, and drink 1,500–2,000 ml/day. Women with a deviant voiding frequency should train their bladder by timing their voidings during the day until a normal frequency of seven voidings a day is reached.
3) Utilize the 'knack' technique to prevent incontinent wet episodes by contracting the pelvic floor muscles when feeling a sudden urge to void or when coughing, sneezing, or laughing.
4) Automatically and subconsciously use the pelvic floor muscles, especially during moments of abdominal pressure, in the daily posture and movement pattern to prevent leakage.

These behaviors are expected to be performed during and after therapy, and after a relapse, women need to be able to restart and follow through with these behaviors. Optimal adherence during treatment is expected to be a prerequisite for long-term adherence.

Development of the Health Education Program

On the basis of the Intervention Mapping [Bartholomew et al., 2001] approach, a series of specific steps and procedures for developing health education programs were conducted based on social-cognition theory, empirical findings and real data [Alewijnse et al., 2002]. Encouraging adherence to PFME therapy is viewed as a behavioral change process in which factors such as attitude towards adherence behavior, self-efficacy expectations, perceived severity of symptoms, and all kinds of barriers hampering adherence behavior are considered determinants of adherence to PFME therapy [Prochaska et al., 1994; Leventhal et al., 1998].

For each determinant of adherence behavior identified in the needs assessment [Alewijnse et al., in press], specific aims were formulated and appropriate methods and strategies were selected. For example, for the method of goal setting, the strategy consisted of a filling-in task to write down personal treatment goals, and for the method of modeling, role model stories were the strategy [Bassett and Petrie, 1999]. Furthermore, quality principles for patient education were applied [Mullen et al., 1985]. This implied among others, that information was targeted to women's needs, self-evaluation about changes in symptoms was stimulated, and reinforcement was given for positive behavior changes. In addition, we developed a minimal, a medium, and a maximum intervention that each followed the physiotherapeutic treatment plan in content, to enable investigating what intensity of health education would be necessary to promote adherence effectively. Three health education interventions were developed of which the most important components were reminders, guidance of adherence as self-management process, and structured feedback [Prochaska et al., 1994; Cramer, 1995; Leventhal et al., 1998]:

1) *Reminder intervention*: since forgetting was most often mentioned as a barrier for adherence, this intervention consisted of a folder with information about PFME therapy and adherence behavior and several tips to remember adherence behavior. Stickers were included as reminders.

2) *Reminder and Self-Help Guide intervention*: a guide addressing facts and myths about UI and pelvic floor muscles, coping with UI, tips to tackle all barriers hampering adherence behavior, and relapse prevention strategies to support the self-management process. The self-help guide also contained the stickers of the *Reminder intervention* and reminder tips.
3) *Reminder, Self-Help Guide and Counseling intervention*: identical to the *Reminder and Self-Help Guide intervention*, with the addition of a counseling scheme for physiotherapists, guiding structural oral feedback, and reinforcement to promote adherence behavior.

Participants

The study was approved by both the Medical Ethical Committee of Maastricht University and the Maastricht University Hospital and the Review Committee of the Registration Network Family Practices (RegistratieNet Huisartspraktijken, RNH) [Metsemakers et al., 1992]. Participants were recruited from the RNH, which consists of 23 general practices with 55 general practitioners (GPs), covering a population of around 100,000 persons. Since many women do not seek medical treatment for UI [Shaw et al., 2001], community-dwelling women over 17 years old with at least one of the following risk factors for UI were selected: vaginal delivery, medical history of gynecological operations, asthma, arthritis, and obesity [Milsom et al., 1993]. Selected women received a short questionnaire measuring items on risk factors for UI, continence status, quality of life, and use of health care resources for UI. Women reporting symptoms of stress, urge, or mixed UI were also asked if they were interested in individual PFME therapy and participation in a behavioral intervention study. This procedure was conducted twice; once in 1995 in a study on the prevalence of UI among 2,914 women with risk factors, and once in 1997 among 1,341 women when the present behavioral intervention study was set up. One hundred ninty eight from the first recruitment, 166 women from the second were willing to participate, and a poster recruitment campaign in the participating general practices yielded another 12 women. Thus, a total of 376 women were recruited.

In 1998, 180 of 376 women were actually willing to participate. The primary reasons given for refusal to participate by initially interested women were: insufficient bother (37%), having other more severe health problems (14%), having done PFME therapy or having been operated upon for UI (12%), being too busy with work and/or care activities (10%), no longer having symptoms of UI (5%). Fifteen women had moved or died between the prevalence study and the start of the behavioral intervention study.

Inclusion criteria were: ability to complete questionnaires, full understanding of the Dutch language, and completion of the consent form. Excluded from the study were women (total n = 47) without symptoms of stress, urge, or mixed UI (n = 11) based on their history [Lagro-Janssen et al., 1995], women suffering from neurological conditions such as MS, CVA, and spina bifida or suffering from venereal disease (n = 5), women with viral infections (n = 4), women using medication for UI or using medication that enhances/influences UI (n = 1), women who were pregnant or within 3 months after delivery or women who had been operated upon for UI (n = 20), and women with physical impairments making PFME therapy impossible (n = 6). No women were excluded because of the presence of severe prolapse (grade 3 and 4) or vaginal atrophy. Women with urinary tract infection were treated and included when cured. The GP evaluated the ability to voluntarily contract the pelvic floor muscles through vaginal palpation, and indicated this in the referral letter for the physiotherapist.

Physiotherapists

We recruited 28 experienced female physiotherapists specialized in the field of PFME therapy with an outpatient physiotherapy practice in the residential area of the participating general practices.

Design and Procedures

A longitudinal RCT with three intervention and one control condition was conducted. The control condition consisted of individual physiotherapeutic PFME therapy alone, representing usual care. The intervention conditions consisted of PFME therapy supplemented with one of the three health education interventions. The two primary outcome measures were weekly frequency of wet episodes and number of days per week women had followed the behavioral advice of the physiotherapist, both measured with a 7-day diary.

The four conditions were randomly allocated to the physiotherapists. However, due to a shortage of therapists and to minimize the chance of contamination, the control condition, and *Reminder intervention* were allocated to the same physiotherapists. The 133 eligible women were randomized in one of the four conditions by the GP's assistants, who had been instructed by the researcher. Physiotherapists could not be blinded for the intervention. For practical reasons only, the researcher could not be blinded either.

For each experimental condition, a standardized protocol checklist was supplemented with instructions on how and when to use the health education intervention during treatment. The *Reminder intervention* and *Reminder and Self-Help Guide intervention* had to be given to the women at the onset of therapy. The instruction for the guide was, whenever a woman would like to do so, to read about what she had learned during the sessions at home, to use it as a diary by writing down the behavioral advice, and/or to use it as a reminder during and after therapy. The *Reminder, Self-Help Guide and Counseling intervention* was used in a similar way as the *Reminder and Self-Help Guide intervention*, with the difference that the instruction was more directive. Physiotherapists had to instruct women to read pages x to y of the guide that corresponded with the content of that particular therapy

session. Furthermore, these physiotherapists had been instructed by the researcher to follow a counseling scheme with oral instructions corresponding to the design of the guide and to the iterative phases of the physiotherapeutic treatment plan [Verhulst et al., 1994]. This counseling process was supposed to structurally guide patients from the awareness of the need for adherence, to taking up adherence behavior after relapses by providing oral feedback and reinforcement [Prochaska et al., 1994].

Questionnaire and Diary

Outcome variables for the effect evaluation were collected with self-administered questionnaires and 7-day diaries before (pretest), immediately after (posttest), and at 3 and 12 months after therapy. Process evaluation items were included in the posttest and in the 12-month follow-up. Initial non-responders were phoned and asked to complete the surveys and return them in the prepaid envelope. Reasons for the delay and other aspects related to PFME therapy discussed in the call, were recorded.

UI symptoms. The 7-day diary assessed frequency and amount (droplets, dashes, whole bladders) of wet episodes, and the number of protective garments used (nothing, panty shields, sanitary towels, incontinence pads) [Nygaard and Holcomb, 2000]. In the questionnaire, these three aspects were also assessed on the basis of the PRAFAB score [Vierhout, 1990], for validation of the diary assessment. The three items correlated significantly with the diary assessment ($r_s = 0.551-0.766$, $P < 0.001$). Another three items measured the duration of symptoms, the type of UI and daily voiding frequency. Symptom distress was assessed with the Incontinence Quality of Life scale [IQOL, scale 22–110, $\alpha = 0.92$; Wagner et al., 1996], and symptom impact with the Incontinence Impact Questionnaire [IIQ-7, scale 0–15, $\alpha = 0.79$; Uebersax et al., 1995]. Higher IQOL scores indicate a better quality of life in relation to incontinence symptoms, whereas higher IIQ-7 scores indicate a larger impact of symptoms in daily life. Satisfaction and perceived improvement were assessed with five-point scales.

Adherence behavior. The 7-day diary assessed adherence in terms of number of days per week women had followed the behavioral advice of the physiotherapist at posttest and follow-ups (item A, Table I). Three items (B–D, in Table I) on adherence behavior in the questionnaire were used as validation for the diary assessment [Kerssens et al., 1996], that all correlated highly and significantly ($r_s = 0.388-0.632$, $P < 0.001$) with the diary item. These three items assessed how often women had adhered to the behavioral advice the day and the week before, and a self-evaluation score for adherence on a scale from 1 to 10. Four other items in the questionnaire assessed with seven-point scales how difficult or easy women found the adherence

TABLE I. Instruments for Assessment of Adherence Behavior and Cross-Sectional Results at Posttest, 3- and 12-Months Follow-Up (t2, t3, t4)

Item	Respond categories	t2 (n = 90)	t3 (n = 99)	t4 (n = 103)
7-day diary:	Choose the statement that corresponds best to your behavior: Today . . . (score 1–3 = not adherent; 4–5 = adherent)	Filled in 609 times[a]	Filled in 676 times[a]	Filled in 657 times[a]
A: During the therapy several behavioral advice have been given to you by the physiotherapist	1. I forgot to do them	43 (7.1)	70 (10.4)	83 (12.6)
	2. I didn't feel like doing them	13 (2.1)	22 (3.5)	43 (6.5)
	3. I didn't find it necessary to do them	10 (1.6)	50 (7.4)	71 (10.8)
	4. I followed the advice now and then	256 (42.0)	321 (47.5)	282 (42.9)
	5. I followed the advice regularly	287 (47.1)	213 (31.5)	178 (27.1)
Questionnaire items for validation:		n = 87	n = 98	n = 102
B: How often did you follow the behavioral advice of the physiotherapist yesterday?	1. I did not do them	12 (11.7)	33 (32.0)	52 (50.2)
	2. Only a few times, namely ..... times	6 (5.8)	13 (12.6)	13 (12.6)
	3. Now and then, namely ..... times	26 (25.2)	34 (33.0)	23 (22.3)
	4. Regularly, namely ..... times	43 (41.7)	18 (17.5)	14 (13.6)
C: How many days last week did you follow the behavioral advice?	None, 1–7 days	5.6 (1.6)	4.3 (2.3)	3.4 (2.5)[b]
D: Give yourself a report mark for following the behavioral advice of your physiotherapist	1 (very bad)–10 (very good)	6.8 (1.7)	5.8 (2.3)	5.0 (2.5)
E: Could you describe what behavioral advice the physiotherapists has given you and when and how often it is best to perform them?	Open answer			

Number (%) or M (SD).

[a]Most women answered this question every day in the 7-day diary, thus the maximal number of answers is the number of women completing that diary item × 7.

[b]Kruskal–Wallis test revealed difference among conditions; control > R-SHGi, $P = 0.024$; rest of comparisons are not significant.

advice to integrate the adherence behavior in daily life and the advice on toileting and drinking behavior.

Background variables. Social desirability was assessed using the Social Desirability scale [Visser and Breemhaar, 1989; $\alpha = 0.63$]. Ten items such as 'If I make a mistake, I will always be prepared to admit it,' were measured on a VAS scale (true–false, 0–10), and summed to form an index score ranging from 0 to 100. Subjective general health was assessed with the abbreviated 13-item 'Inventory of Subjective Health' [VOEG; Sikkel, 1980]. The 13 items about chronic physical complaints were summed to form one index score (0–13). Two items of the Dutch National Health Survey assessed women's perception of their health on a five-point scale from very bad to very good (1–5), and which chronic conditions they had other than UI (index, 0–26) [Van den Berg, 1992]. In addition, sociodemographics were assessed.

Process evaluation. Both participants and physiotherapists completed a process evaluation assessing satisfaction with and level of implementation of the health education program. Twenty-two structured and open items assessed women's experience and satisfaction with the therapy, and whether the therapy had lived up to women's expectations. Women's opinion about and satisfaction with the health education program was assessed with another 22 structured and open questions. For women in the experimental conditions, level of implementation was assessed with 15 items asking whether women had read the health education materials and to what extent they had used the filling-in tasks, the tips, and reminder stickers.

Implementation of the oral counseling intervention that was supposed to be implemented in the therapy by the physiotherapists, were assessed among women in the *Reminder, Self-Help Guide and Counseling intervention* and all physiotherapists. Thirteen items assessed whether physiotherapists had discussed, for example, what treatment goals a woman wanted to reach in order to set small subgoals, pros and cons of continuous adherence behavior, or possibilities of taking up adherence behavior after relapses. The process evaluation for physiotherapists further assessed their satisfaction with the use of the health education interventions during the PFME therapy and their estimate of what aspects of the interventions are most effective in promoting adherence. Experiences with the implementation of the protocol checklist for PFME therapy in general, were assessed among all physiotherapists.

Analyses

Data were analyzed using SPSS version 9.0, and procedures for data screening, randomization check, and selectivity of dropouts, were applied. Descriptive statistics were used to describe sociodemographic variables and process evaluation findings. Univariate one-way analysis of variance and Kruskal–Wallis tests were used to compare outcome variables at posttest, 3- and 12-month follow-up between conditions. Univariate analysis of covariance controlling for pretest values was used to compare the efficacy of the experimental conditions to the control condition on outcome variables at 12-month follow-up. When homogeneity of variances was lacking, or when group sizes were unequal and small, Kruskal–Wallis tests with the change scores were applied.

No significant interactions of condition and weekly frequency of wet episodes with possible confounders were found through linear multiple regression analyses. Repeated measurement analyses of variance were used to detect changes over time with post hoc paired samples *t*-test with Holm's bonferroni correction ($\alpha = 0.05$/n tests) to reveal differences between measurements. Subgroup analyses for diagnostic groups were performed using the diagnosis of the physiotherapist as that determined therapy content.

An a priori power analysis indicated that a sample size of 192 (48 per group) was needed to provide at least 90% power to detect a minimum difference between experimental conditions and control condition of 25% in weekly wet episodes ($P = 0.05$) at 12-month follow-up, when women in the control condition would improve by 50% [Lagro-Janssen et al., 1992; Mouritsen, 1994]. Although a size of 192 participants was not reached, analysis with n = 103 would still provide a power of 79% when predicted data from initial power analyses were found.

RESULTS

Participants and Non-Response

Four women never started the research project. Three because of medical problems and one never started.

Loss to follow-up numbers were not significantly different between intervention groups; control 3/32, *Reminder intervention* 7/29, *Reminder and Self-Help Guide intervention* 9/34, *Reminder, Self-Help Guide and Counseling intervention* 7/34. Twenty-six women (20% of 129) withdrew either immediately after randomization (n = 10), during the treatment period (n = 4), or during the follow-up measurements (n = 12). Reasons or combinations of reasons for withdrawal included personal illness (n = 12) and/or an ill relative (n = 3), stressful life or busy schedule (n = 8), transportation problems (n = 2), symptoms not improved (n = 2), lack of interest (n = 7). One women died and one decided that she no longer needed PFME therapy.

The 26 women lost to follow-up differed from the women who completed the study on two variables at pretest. They had more frequent (U = 978.5, $P = 0.029$) and more severe (U = 1036.5, $P = 0.045$) wet episodes. All analyses, except intention to treat (last observation carried forward), were performed with the 103 women who completed the 12-month follow-up measurements. Of those, the posttest of 15 and the 3-month follow-up of two were not returned.

Sociodemographic characteristics and as outcome variables at pretest of the 129 remaining participants are presented in

TABLE II. Characteristics of Participants, N = 129

Characteristics of study population	Number of women	Percentage of population	Mean (SD)
Age			55.6 (10.9)
Having a partner	107	82.9	
Having children	118	91.5	
Number of children			2.1 (1.2)
Having a paid job	45	34.9	
Hours of paid labor per week			22.0 (11.3)
Education level (n = 127)			
Low[a]	96	75.6	
Medium[b]	16	12.4	
High[c]	15	11.8	
Had sex education at school	43	33.3	
Social health insurance	98	76.0	
Recruitment phase 1995	69	53.5	
Recruitment phase 1998	60	46.5	
Body mass index			26.9 (4.8)
VOEG			7.2 (3.2)
General health status			
Good	46	35.7	
Moderate	52	40.3	
Poor	31	24.0	
Other chronic conditions (0–26)			2.5 (1.9)
Sexual violence in youth	22	17.1	
Sexual violence in adult life	16	12.4	
Diagnosis of physiotherapist (n = 99)			
Stress	48	37.2	
Urge	11	8.5	
Mixed	40	31.0	
Missing	30	23.3	
Duration of symptoms (n = 127)			
Less than 2 years	11	8.7	
2–7 years	72	56.7	
Over 7 years	44	34.6	
Frequency of wet episodes			
Max 1 × per week	27	20.9	
2–7 × per week	54	41.9	
Several times a day	48	37.2	
Amount of urinary loss			
Droplets	21	16.3	
Droplets and dashes	76	58.9	
Dashes	23	17.8	
Dashes and whole bladders	8	6.2	
Whole bladders	1	0.8	
Weekly frequency of wet episodes			
7-day diary (n = 125)[d]			24.5 (25.0)
IQOL (n = 128)			83.9 (15.8)
IIQ-7			2.2 (2.7)

[a]Low education level: completed primary school and vocational school.
[b]Medium education level: completed secondary (vocational) school.
[c]High education level: completed the highest level of secondary (vocational) school or university.
[d]The median of weekly frequency of wet episodes was 15.0.

Table II. Most women reported having symptoms of moderate severity for several years and the majority of women lost droplets and dashes several days per week. Mean weekly frequency of wet episodes was 24.5 (SD 25.0, median 15.0). Women occasionally worried about their incontinence symptoms (IQOL) and wet episodes had some negative impact on daily life activities (IIQ-7).

Significant differences between conditions at pretest were as follows: women in the control condition used heavier pads than women in the *Reminder and Self-Help Guide intervention* (H (3) = 9.143, $P = 0.027$), and women in the *Reminder intervention* experienced more symptom distress than women in the *Reminder, Self-Help Guide and Counseling intervention* (F (3.124) = 3.079, $P = 0.030$) and more symptom impact than women in the *Reminder and Self-Help Guide intervention* (F (3.124) = 3.105, $P = 0.029$). Further, fewer women in the control condition had sex education at school than women in the *Reminder and Self-Help Guide intervention* (H (3) = 4.098, $P = 0.043$). With n = 129, no differences were found among groups on any of the other variables at pretest. However, with n = 103, pretest scores of weekly frequency of wet episodes were significantly higher (H (3) = 8.943, $P = 0.030$) in the control (M 27.6, SD 21.9) condition than in the *Reminder and Self-Help Guide intervention* (M 12.8, SD 12.4) (see Table III).

Implementation of Health Education Interventions

Neither the reminder nor the counseling intervention had been implemented as planned. Only two in five women of the *Reminder intervention* and the *Reminder, Self-Help Guide and Counseling intervention* actually used a few stickers, and only two women in the *Reminder and Self-Help Guide intervention* did so. No relation was found between the use of stickers and adherence behavior.

All 13 key aspects of oral counseling had been equally applied by the physiotherapists in all conditions, although only the therapists in the *Reminder, Self-Help Guide and Counseling intervention* had actually been trained in applying the specific counseling scheme to provide structural oral feedback and reinforcement. Thus, having had a self-help guide remained as the only distinction between the study groups. Therefore secondary analyses were conducted in which women in the two self-help guide groups were compared with women in the other two groups (Control condition + *Reminder intervention*), to study the possible surplus value of the self-help guide on adherence behavior and determinants. To check for consistency of the results, women in the self-help guide groups were also compared with women in the control condition alone.

Effect on Incontinence Symptoms

The effectiveness of PFME therapy on incontinence symptoms was compared between the four intervention conditions, as well as between the group with and the group without the self-help guide. After adjustment for pretest scores, no significant differences were found between conditions in weekly frequency of wet episodes at posttest, 3- and 12-month follow-up. Mean weekly frequency of wet episodes was drastically

TABLE III. Mean (SD) of Weekly Frequency of Wet Episodes (7-Day Diary) and Adherence Behavior as Number of Days per Week Women Followed the Behavioral Advice, for Each Condition and Total Group

Variable	Control (n = 29)	Ri (n = 22)	R-SHGi (n = 25)	R-SHG-Ci (n = 27)	Total (n = 103)	Between groups P [a]
Wet episodes	n = 29	n = 21	n = 25	n = 27	n = 102	0.030 C > SHGi
t1	27.6 (21.9)	31.2 (31.1)	12.8 (12.4)	20.7 (25.8)	22.9 (24.1)	
	n = 24	n = 18	n = 22	n = 23	n = 87	
t2	7.6 (11.5)	10.0 (13.2)	5.2 (9.2)	6.7 (18.9)	7.3 (13.6)	0.175
	n = 29	n = 20	n = 25	n = 25	n = 99	
t3	11.1 (14.9)	13.1 (18.5)	5.2 (8.7)	6.6 (13.6)	8.8 (14.3)	0.356
	n = 29	n = 22	n = 25	n = 26	n = 102	
t4	8.8 (13.0)	12.2 (16.6)	4.2 (5.5)	6.5 (10.8)	7.8 (12.2)	0.812
In time, P [b]	F = 10.021, $P < 0.001$; t1 > t2,t3,t4 < 0.001 t3 > t4, 0.013	F = 3.664, $P = 0.039$; t1 > t2, 0.009 t1 > t3, 0.002 t1 > t4, 0.003	F = 6.805, $P = 0.003$; t1 > t2,t3,t4 < 0.001	F = 4.912, $P = 0.010$; t1 > t2,t3 0.002 t1 > t4, 0.001	F = 23.186, $P < 0.001$; t1 > t2,t3,t4 < 0.001	
Adherence	n = 24	n = 18	n = 22	n = 23	n = 87	
t2	6.3 (1.1)	6.5 (1.2)	6.2 (1.2)	6.0 (1.4)	6.2 (1.2)	0.497
	n = 28	n = 20	n = 23	n = 25	n = 96	
t3	5.2 (2.0)	5.5 (2.1)	6.1 (1.6)	5.4 (2.1)	5.5 (2.0)	0.464
	n = 28	n = 20	n = 24	n = 25	n = 97	
t4	5.3 (2.3)	5.3 (2.3)	4.4 (2.5)	4.4 (2.3)	4.8 (2.4)	0.419
In time, P [b]	F = 3.790, $P = 0.039$ [c]; t2 > t3, 0.027 [c]	F = 3.285 $P = 0.070$; t2 > t3, 0.031 [c]	F = 5.651, $P = 0.013$; t2 > t4, 0.006 t3 > t4, 0.001	F = 5.694, $P = 0.011$; t2 > t4, 0.002	F = 14.323, $P < 0.001$; t2 > t3, 0.002 t2 > t4, < 0.001 t3 > t4, 0.001	
IQOL	n = 23–29	n = 18–22	n = 22–25	n = 23–27	n = 86–103	
t1	81.1 (14.0)	79.8 (18.0)	87.2 (12.1)	89.8 (10.4)	84.5 (14.2)	0.030 SHG-Ci > Ri
t2	94.6 (11.9)	94.1 (12.8)	93.9 (13.5)	95.1 (8.4)	94.4 (11.6)	0.985
t3	95.0 (14.0)	96.3 (9.4)	97.8 (10.7)	96.8 (10.3)	96.4 (11.4)	0.833
t4	92.8 (14.2)	92.8 (15.0)	94.6 (13.3)	94.7 (11.9)	93.7 (13.4)	0.923
In time, P [b]	F = 7.364 $P = 0.002$; t1 > t2,t3,t4 < 0.001	F = 7.683 $P = 0.003$; t1 < t2,t3, 0.001 t1 < t4, < 0.001	F = 6.677 $P = 0.003$; t1 < t3, 0.003	F = 3.836 $P = 0.027$; t1 < t2, 0.003 t1 < t3, 0.008 t1 < t4, 0.007	F = 24.296 $P = 0.001$; t1 < t2,t3,t4 < 0.001 t2 < t3, 0.004	

Differences between conditions and changes between pretest (t1), posttest (t2), 3- and 12-month follow-up (t3 and t4). Ri, Reminder intervention group; R-SHGi, Reminder and Self-Help Guide intervention group; R-SHG-Ci, Reminder, Self-Help Guide and Counseling intervention group.

[a]One-way ANOVA, comparison between intervention groups per measurement with post hoc Dunnet's C test or Kruskal–Wallis (wet episodes, adherence).

[b]One-way Repeated Measurement ANOVA with post hoc paired t-test with Holm's bonferroni correction for multiple comparisons.

[c]Post hoc paired t-test was not significant after Holm's bonferroni correction for multiple comparisons; 0.05/3 = 0.016; 0.027 and 0.031 > 0.016, thus not significant.

reduced from an average of 23 losses per week to an average of 8 losses per week, and remained fairly stable up to 1 year after therapy (Table III). Further, relative cure and improvement rates of weekly frequency of wet episodes are presented in Table IV. There were no differences between women with and without the self-help guide. Overall, 74.8% (intention to treat 64.4%) of the women were cured or improved by 50% or more 1 year after therapy.

After adjustment for pretest scores there were no differences between diagnostic groups at posttest, 3- and 12-month follow-up or diagnostic groups in frequency of wet episodes at pretest between women with stress (M 21.2, SD 25.1, n = 41), mixed (M 22.5, SD 24.0, n = 34), and urge UI (M 27.6, SD 20.7, n = 9), nor at posttest, 3- and 12-month follow-up. Analyses based on women's self-diagnosis revealed the same results. Thus, PFME therapy yielded similar results for women with either stress, urge, or mixed incontinence.

Using regression analyses, no significant interactions were found between intervention conditions and the weekly frequency of wet episodes and possible confounders. The number of treatment sessions attended was not related to weekly frequency of wet episodes at pretest and had no influence on treatment outcomes. Mean number of treatment sessions was 8.5 (SD 2.9), although most women found fewer sessions enough (M 6.6, SD 2.8; t (88) = 7.402, $P < 0.001$).

Adherence Behavior

Overall, adherence behavior was very high with women following the behavioral advice on average 6 days per week at

TABLE IV. Relative Cure and Improvement Rates Between Pretest and 1 Year After Therapy Based on Weekly Frequency of Wet Episodes, for Women in the Group Without and in the Group With the Self-Help Guide (shg), and for the Total Number of Women Followed up and Intention to Treat

Change	Group without shg[a] (%), n = 51	Group with shg[a] (%), n = 52	Women followed up (%), n = 103	Intention to treat (%), n = 129
100% (dry)	21 (41.2)	17 (32.7)	38 (36.9)	41 (31.8)
75–99%	8 (15.7)	9 (17.3)	17 (16.5)	20 (15.5)
50–74%	8 (15.7)	14 (26.9)	22 (21.4)	22 (17.1)
1–49%	10 (19.6)	6 (11.5)	16 (15.5)	19 (14.7)
0% or deteriorated	3 (5.9)	5 (9.6)	8 (7.8)	22 (17.0)
Missing	1 (2.0)	1 (1.9)	2 (1.9)	5 (3.9)

[a]No significant differences in relative change scores between women in the group without and women in the group with the self-help guide; Mann–Whitney test; U = 1076.0, $P = 0.163$.

posttest and 4–5 days per week 1 year after therapy (Table III). A significant decrease in adherence behavior over time was found for the two groups with the self-help guide, and not in the two groups without the guide. No significant differences were found between the four study conditions in the number of days per week women had followed the behavioral advice at posttest, 3- and 12-month follow-up. Short- and long-term adherence behavior, or the change in adherence between posttest and follow-ups was not different for the group with the self-help guide compared to the group without the self-help guide. Overall, 67% of the women followed the behavioral advice 4–7 days per week 1 year after therapy. After adjustment for pretest frequency of wet episodes, adherence behavior at posttest, 3- and 12-month follow-up, did not differ between conditions for women with either, stress, urge, or mixed UI.

Table I presents details on adherence behavior for the total group.

Overall, voiding frequency significantly decreased from eight (range 2–18) to six or seven (range 3–15) voidings per day (F (3.71) = 15.202, $P < 0.001$) between pretest and posttest, and remained stable afterwards. Women with mixed UI voided more often per day (M 9.4, SD 2.8) before therapy than women with stress UI (M 7.3, SD 2.9) (F (2.67) = 4.376, $P = 0.016$), but after therapy no differences in voiding frequency were found between diagnostic groups. More than half of the women (55.3%) found that their toilet behavior had improved a little, while the others had remained the same or their toilet behavior was already as recommended at the onset of therapy.

Relation Between Outcome Variables

When assessed with the total group scores, higher pretest weekly frequency of wet episodes were significantly related to higher adherence levels 1 year after therapy ($r_s = 0.385$, $P < 0.001$). To further analyse the relation between frequency of wet episodes and adherence behavior, the total group of women was split up into four subgroups on the basis of pretest scores of weekly frequency of wet episodes and compared with changes in adherence behavior. Because of pretest differences in the weekly frequency of wet episodes between conditions, we checked distribution of conditions among the four quartiles (Table V). Regardless of the treatment condition, women with the lowest weekly frequency of wet episodes at pretest and also at 12-month follow-up, had reduced adherence levels between posttest and 12-month follow-up, while women with a higher weekly frequency of wet episodes at pretest and at 12-month follow-up, retained their high adherence levels at all measurements. These findings should be interpreted with caution because the numbers per group were very small. Thus, the fact that women in the two groups with the self-help guide had significantly lowered their adherence levels over time (see Table III), is a consequence of the fact that more women (n = 31) from the self-help guide conditions were present in the lowest two quartiles of the weekly wet episodes than in the highest two quartiles (n = 18), as compared to 19 women from the control condition or *Reminder intervention* in the lowest two quartiles and 29 in the highest two quartiles. This indicates that most women learned to adapt their adherence behavior to their symptoms.

Weekly frequency of wet episodes was significantly related to symptom distress (IQOL) and symptom impact (IIQ-7). Women who had more frequent wet episodes had more symptoms distress ($r_s = -0.389$, $P < 0.001$), and experienced a greater impact of symptoms on daily life activities ($r_s = 0.316$, $P < 0.001$). The quality of life scales IQOL and IIQ-7 were highly correlated ($r_s = -0.594$, $P < 0.001$); women who had more worries about their symptoms, also experienced a greater impact of symptoms on daily life activities. Overall, adherence behavior was not related to these condition-specific quality of life scales. Women who had experienced more symptom distress at pretest, had higher adherence levels at posttest ($r_s = -0.267$, $P = 0.012$), and 1 year after therapy ($r_s = -0.270$, $P = 0.007$). After adjustment for pretest weekly frequency of wet episodes, no significant differences in IQOL or IIQ-7 scores were found between intervention conditions at either measurement, or between women with stress, urge, or mixed UI.

TABLE V. Adherence at Posttest, 3- and 12-Month Follow-Up (t2, t3, t4) per Quartile Subgroup of Pretest Weekly Frequency of Wet Episodes and per Treatment Condition

Quartile mean (SD) frequency from pretest to t4	Treatment condition	Adherence at t2, no. women mean (SD)	Adherence at t3, no. women mean (SD)	Adherence at t4, no. women mean (SD)	Differences in adherence in time per quartile and condition[a]	
1: 2.0 (1.4) → 1.0 (1.6)	Control	3: 6.0 (1.0)	4: 4.3 (1.0)	4: 5.0 (2.4)	0.135	
	Ri	3: 7.0 (0.0)	4: 5.8 (1.9)	4: 4.7 (2.1)	0.368	0.050[b]
	R-SHGi	8: 6.1 (1.4)	8: 5.8 (2.5)	8: 3.5 (2.7)	0.059	
	R-SHG-Ci	9: 5.1 (1.7)	9: 4.3 (2.4)	9: 3.1 (2.3)	0.024	0.002[b]
2: 9.7 (2.7) → 3.0 (3.8)	Control	6: 6.3 (1.0)	6: 5.8 (1.3)	7: 4.1 (2.3)	0.024	
	Ri	5: 6.8 (0.4)	5: 6.0 (1.0)	4: 6.0 (1.2)	0.264	0.013[b]
	R-SHGi	7: 6.6 (0.8)	8: 6.1 (1.1)	8: 4.3 (2.3)	0.034	
	R-SHG-Ci	6: 6.8 (0.4)	6: 6.3 (0.5)	6: 4.8 (1.5)	0.014	0.001[b]
3: 24.1 (6.3) → 7.3 (10.0)	Control	9: 6.6 (0.9)	9: 5.8 (1.6)	9: 5.1 (2.8)	0.193	
	Ri	6: 6.0 (2.0)	6: 5.7 (2.8)	6: 5.2 (2.8)	0.472	0.122[b]
	R-SHGi	6: 6.0 (1.5)	5. 6.4 (0.5)	6: 5.2 (2.8)	0.867	
	R-SHG-Ci	4: 6.0 (0.8)	5: 5.2 (3.0)	6: 4.5 (2.9)	0.779	0.810[b]
4: 60.0 (20.9) → 22.7 (15.8)	Control	6: 5.8 (1.5)	9: 4.7 (2.5)	8: 6.5 (0.9)	0.076	
	Ri	4: 6.5 (1.0)	4: 4.5 (2.9)	6: 6.2 (1.6)	0.368	0.062[b]
	R-SHGi	1: 6.0 (0.0)	2: 6.5 (1.0)	2: 6.0 (2.0)	—	
	R-SHG-Ci	4: 7.0 (0.0)	5: 6.6 (0.9)	4: 6.5 (1.0)	0.368	0.999[b]
Differences in adherence between conditions per quartile[c]		1: 0.224	1: 0.294	1: 0.565		
		2: 0.806	2: 0.942	2: 0.408		
		3: 0.550	3: 0.976	3: 0.922		
		4: 0.193	4: 0.384	4: 0.916		

Ri, Reminder intervention group; R-SHGi, Reminder and Self-Help Guide intervention group; R-SHG-Ci, Reminder, Self-Help Guide and Counseling intervention group.

[a]Friedman paired samples test, change in adherence behavior in time, per intervention condition.

[b]Friedman paired samples test, change in adherence behavior in time, with or without self-help guide.

[c]Kruskal–Wallis test comparing differences between conditions per quartile.

Mean IQOL and mean IIQ scores improved significantly for women in all conditions (see Table III). This means that effective PFME therapy with or without extra health education decreased symptom distress and symptom impact significantly. Mean item scores indicated that women were hardly worried about symptoms after therapy, and perceived little or no impact on daily life activities.

Perceived Improvement and Satisfaction

Perceived improvement and satisfaction with treatment outcomes at 12-month follow-up were not significantly different between intervention conditions. One year after therapy, 29 women (28.1% of n = 103) reported being dry, 44 women (40.8%) perceived much improvement of symptoms, 20 women perceived little improvement (19.4%), 9 women found that they had remained the same, and 2 found that their symptoms had deteriorated since they had started PFME therapy. Seventy women (68%) were very satisfied with the treatment effects on incontinence symptoms and toilet behavior, 14 women were a little satisfied, 11 were neutral, and 6 women were dissatisfied. According to the judgment of the women, PFME therapy had no influence on their physical or mental health, social life, job related activities, or care activities, but 38 women (36.9%) expressed that their self-esteem had improved.

DISCUSSION AND CONCLUSIONS

This study assessed the effectiveness of PFME therapy supplemented with a theory-driven health education program on therapy outcome and long-term adherence behavior. The health education interventions, and in particular the self-help guide alone, had no significant additional impact on symptom outcome, nor on adherence behavior. Intention to treat analyses did not change the results. However, the individual PFME therapy was very successful. Weekly frequency of wet episodes drastically decreased during therapy, and results were maintained during the 1 year follow-up. The symptom cure and improvement rates we found 1 year after therapy, including intention to treat data, exceed those found in other studies on physiotherapeutic PFME therapy as reported in reviews [for example, Mouritsen and Schiøtz, 2000; Hay-Smith et al., 2001].

Adherence behavior of the women in this study was higher than found in other studies during a 1 year follow-up [Ferguson et al., 1990; Lagro-Janssen et al., 1992; Janssen et al., 2001]. An important finding of our study was that women with more frequent losses before and after therapy, more likely retained a higher adherence level 1 year after therapy, than women with less frequent losses. Thus, most women seem to have learned to adapt their adherence behavior to their symptoms. A similar adaptation pattern was found in the study of

Burns et al. [1993], who argued that women with mild symptoms may not perceive their incontinence as a problem warranting sustained effort, while women with many daily losses recognize it as an ongoing problem and make a persistent effort as positive response occurs. As stated, adherence level was high, but it is unclear whether women in this study had fewer wet episodes because their previous adherence (between pretest and posttest) was high or whether women had high adherence levels although they were dry or had mild UI symptoms. In contrast to others [Bø and Talseth, 1996; Lagro-Janssen and Van Weel, 1998; Chen et al., 1999], we did not find that women with higher adherence levels had fewer wet episodes at follow-up.

An interesting explanation for the lack of impact of the health education program was found in the process evaluation. According to the remarks of the physiotherapists, working with the standardized protocol checklist for PFME therapy structured the content of their therapy sessions. This structure coupled with enthusiastic physiotherapists, seems most important for realizing long-term effects and optimal adherence behavior. This might explain why the written health education program had no significant additional influence.

Some flaws of the present study should be considered though. A Hawthorne effect may have biased our findings. All therapists in our study knew that they were in a trial evaluating the effectiveness of additional health education to regular PFME therapy. They may unintentionally have given more and structured attention to the regular patient education part of their therapies. Social desirability may also have played a role, but this was not assessed among physiotherapist. Among the participating women, social desirability scores were high (80%), which might explain the reporting of high adherence levels. Nevertheless, social desirability scores were equal between conditions and would therefore have influenced all scores in the same direction. Moreover, an attempt was made to minimize social desirability by using a five-point scale instead of a dichotomous scale in the diary question on adherence behavior, in which the first three options referred to reasons for non-adherence, the fourth to moderate adherence, and the fifth to optimal adherence. Another possibility is that the measurement of adherence itself could have functioned as a reminder for adherence behavior, thereby significantly raising adherence levels in all conditions. If so, then it may be expected that the reminder phone calls for sending back the measurements would also have raised adherence levels [Burns et al., 1993; Nygaard et al., 1996]. However, this was checked and no significant correlation was found between the number of calls per person and adherence behavior. Memory bias is not likely to have played a role in this study, because diaries are expected to prevent memory bias.

In studies on PFME therapy, adherence is most often associated with doing PFMEs, seldom with bladder training and never with the functional use of pelvic floor muscles in daily life, nor is it operationalized into such specific behaviors. Actual adherence behavior remains a black box. We tried to open this black box by asking additional information about adherence activities as presented in Table I, but it was not reliable enough because of missing values or indistinct answers. Clearly, further studies on the assessment of adherence behavior are warranted.

We had anticipated a 25% larger relative reduction in symptoms when the control condition had improved by 50% at 1 year follow-up [Lagro-Janssen et al., 1992; Mouritsen, 1994]. The fact that we had much fewer women in the study than we had planned to have on the basis of the power analysis, was not the problem, as we would still have found the expected difference with a power of 79%. Furthermore, relative to other studies in this field, we were still able to include a large number of women in our study up to the last assessment at 1 year after therapy [Hay-Smith et al., 2001]. It may be that it is much more difficult to reduce symptoms even further when they are already low after therapy (floor effect), which is reflected in the effects remaining stable after posttest, regardless of high adherence levels, which may explain why the health education program had no additional long-term effect.

With respect to the external validity, some comments should be made. Women were first recruited on the basis of risk factors for UI, and those with symptoms of UI were asked to participate in the study. This recruitment procedure was probably responsible for the fact that the general health status and co-morbidity of women in our study was slightly worse than that of the general population of women with UI. However, co-morbidity is often seen in women with UI, especially in older women [Resnick, 1995], so our population might also reflect the true heterogeneous picture of women with UI seen in clinical practice [Mouritsen and Schiøtz, 2000]. In addition, a lot of the recruited women in our study did not want to participate because their symptoms did not bother them so much to start therapy as yet. Thus, the women who wanted to participate were probably highly motivated, which may explain their high adherence levels. This may point towards selection bias. However, that is a problem that all studies in this field encounter.

Implications for Practice

Although we lack data about whether the protocol checklist for PFME therapy optimized care, the physiotherapists confirmed that they worked more consiously and systematically when using the protocol checklist. We believe that a RCT should be conducted to compare PFME therapy with and without a checklist protocol. In the interim, we recommend further implementation in practice of clinical procedure guidelines [Berghmans et al., 1998b]. Therapists in our study claimed that our guideline summary made their therapy sessions more efficient because they could see at a glance what treatment aspects they had or hadn't attended with a patient.

Physiotherapists in our study found that the frequency of treatment sessions over time should remain individually

targeted. This means that our optimal results were found with a therapy of normal length, which was prolonged only for those women who could benefit further from additional sessions. Further research should evaluate the effectiveness of long-term follow-up treatment sessions, and determine at which moments they could best be provided. In addition, the organizational and financial consequences should be evaluated as well, in cooperation with paramedical organizations and insurance companies.

Implementation of the health education program in the form of a self-help guide with sticker-reminders does not seem warranted as it does not improve clinical outcomes when using it together with a standardized protocol checklist, and the effect on adherence behavior remains unclear. However, process evaluation revealed that these 28 physiotherapists would like to continue to work with the guide, and most women in the study had appreciated the information very much and would recommend it to others.

Process evaluation findings also offered recommendations for the adaptation of the guide: leave more place for personal notes; diary pages on which women can write the behavioral or exercise advice of the therapist after each session should be replaced by texts and drawings of the most important exercises, or better, physiotherapists should give the personal behavioral and exercise advice on paper for every women appropriate to her situation.

To conclude, the results of this study show that symptoms of UI drastically reduced after individual PFME therapy relative to the severity of symptoms before therapy, and remained stable up to 1 year follow-up. This means that health professionals such as GPs, can tell their female patients with symptoms of UI that success can be expected when they invest sustainable time and effort in PFME therapy and adherence behavior.

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