

Pelvic-Floor-Muscle Training Adherence: Tools, Measurements and Strategies—2011 ICS State-of-the-Science Seminar Research Paper II of IV

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Aims: This paper on pelvic-floor-muscle training (PFMT) adherence, the second of four from the International Continence Society's 2011 State-of-the-Science Conference, aims to (1) identify and collate current adherence outcome measures, (2) report the determinants of adherence, (3) report on PFMT adherence strategies, and (4) make actionable clinical and research recommendations. **Method:** Data were amassed from a literature review and an expert panel (2011 conference), following consensus statement methodology. Experts in pelvic floor dysfunction collated and synthesized the evidence and expert opinions on PFMT adherence for urinary incontinence (UI) and lower bowel dysfunction in men and women and pelvic organ prolapse in women. **Results:** The literature was scarce for most of the studied populations except for limited research on women with UI. Outcome measures: Exercise diaries were the most widely-used adherence outcome measure, PFMT adherence was inconsistently monitored and inadequately reported. Determinants: Research, mostly secondary analyses of RCTs, suggested that intention to adhere, self-efficacy expectations, attitudes towards the exercises, perceived benefits and a high social pressure to engage in PFMT impacted adherence. Strategies: Few trials studied and compared adherence strategies. A structured PFMT programme, an enthusiastic physiotherapist, audio prompts, use of established theories of behavior change, and user-consultations seem to increase adherence. **Conclusion:** The literature on adherence outcome measures, determinants and strategies remains scarce for the studied populations with PFM dysfunction, except in women with UI. Although some current adherence findings can be applied to clinical practice, more effective and standardized research is urgently needed across all the sub-populations. *NeuroUrol. Urodynam.* 34:615–621, 2015. © 2015 Wiley Periodicals, Inc.

Key words: adherence; determinants; facilitators; pelvic floor muscle training

INTRODUCTION

This paper reviews pelvic-floor-muscle-training (PFMT) adherence literature relating to randomised controlled trials (RCTs) in the prevention and management of urinary incontinence (UI) and lower bowel dysfunction in adults and pelvic organ prolapse (POP) in women. It is the second of four papers, emanating from the State-of-the-Science Seminar "Improving Pelvic Floor Muscle Training Adherence Strategies: from theory to practice" held in Glasgow prior to the 41st International Continence Society (ICS) Annual Conference in 2011. It was instrumental in developing the "2014 Consensus Statement on PFMT Adherence."¹

PFMT is recommended as a first-line treatment for UI; POP; and lower bowel dysfunctions: level 1 evidence.^{2–5} However, potential and sustained benefits are hindered by poor short and

long-term adherence.^{6,7} The cost-effectiveness of PFMT is dependent upon whether short-term outcomes can be maintained;⁸ thus we need to measure short and long-term PFMT adherence and understand its determinants (pre-treatment predictors), facilitators and barriers. Potential determinants of exercise adherence can be subdivided into moderators and

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mediators. In this paper, our search will focus on mediators to PFMT adherence, as they are modifiable.

This review aims to (1) identify and collate adherence-outcome measures used to evaluate PFMT components (clinical visits and home-exercise) and stage (clinical intervention, immediately post-treatment, at follow up), (2) report on PFMT adherence determinants, (3) report on trials specifically comparing PFMT adherence strategies, and (4) make actionable recommendations for clinicians and researchers.

MATERIALS AND METHODS

For full details please refer to the Materials and Method section, 2014 Consensus Statement.¹ Questions guiding the literature review included the identification of (1) PFMT adherence-outcome measures (i.e., tools and measurements), (2) adherence determinants, and (3) strategies to improve adherence. Where no evidence was identified, experts conducted an extended search in their own area (up to June 2013). The primary author (CD) collated and edited the manuscript. The findings were circulated for peer review to the expert panel (from the 2011 seminar).

RESULTS

Women With Urinary Incontinence

PFMT is the recommended first-line treatment for women with stress, urge and mixed UI. There is a large body of literature on its effectiveness;^{2,3} however, while many studies measure and report on adherence, few look at adherence determinants and strategies.

Monitoring Adherence

Most RCTs on PFMT for UI in women reported on adherence as: (1) clinical-visit attendance, (2) home exercises during the intervention and (3) PFMT adherence immediately post-treatment and at follow-up.³ Clinical-visit adherence rates were monitored through attendance and home exercise rates using (1) weekly/monthly exercise diaries (number days women followed advice and daily contractions/exercise sets), (2) self-administered questionnaires and/or, (3) self-evaluation scores (e.g., scale 1–10) measuring short- and long-term adherence.³

One study reported psychometric data on adherence-measurement tools by comparing an exercise diary to three items on adherence behavior data from a self-administered questionnaire.⁹ These all correlated moderately ($r_s = 0.388$ to 0.632 , $P < 0.001$) to the diary item, suggesting the diary or the self-administered questionnaire have promise as future measurement tools.⁹

Determinants

Except for Alewijnse^{9,10} and Chen,¹¹ few studies reported on PFMT determinants of adherence. Alewijnse et al.^{9,10} highlighted short- and long-term determinants. Three psychological mediators predicted high short-term adherence, immediately and three months post-treatment: (1) positive intention to adhere, (2) positive self-efficacy expectations, and (3) a perception of high social pressure to engage in PFMT.^{9,10} At 12 months post-treatment, determinants 1 and 2, above, and high short-term-adherence levels significantly predicted high long-term adherence.^{9,10} Women with frequent (weekly)

leakage episodes pre- and post-physiotherapy, were also more likely to demonstrate high adherence, suggesting they adapted adherence behaviours to symptom levels.^{9,10}

Similarly, Chen and Tzeng¹¹ in a nurse and physiotherapist-led PFMT and behavioral intervention study, found women's self-efficacy and severity of urine loss directly affected adherence.¹¹ Participants' attitudes towards the exercises, dyadic cohesion [i.e., feedback from the body or spouses (e.g., PFM exercises during sex)] and perceived benefits also affected adherence when mediated by participants' self-efficacy for the exercises.¹¹

Strategies

Three studies evaluated strategies to improve PFMT adherence in women with UI (Table I).^{10,12,13} One added an audiotape with exercise instructions to support home adherence to a 45-minute PFMT program that included oral and biofeedback instructions from a nurse.¹² After six weeks' training, more women in the audiotape group reported routinely complying with home exercises than in the control group. The second study of PFMT delivered through a pamphlet, assessed the addition of an electronic-chime device (e.g., 2pm, time to exercise)¹³ but failed to measure adherence. However, women who used the electronic device were more likely to be satisfied with treatment outcome (RR 3.17, 95% CI: 1.02–9.88). The third, a longitudinal RCT on physiotherapy outcomes and long-term adherence,¹⁰ added a theory-driven health-education program to PFMT to identify the optimal intensity, in terms of the education component, for adherence. Guided by the Intervention Mapping approach,¹⁴ (refer to paper I of IV) three interventions—minimal, medium and maximum—were developed: reminder stickers (minimal: all groups), a “self-help” guide encouraging self-management (medium: two groups), and a physiotherapist-participant “counseling” guide structuring oral feedback and reinforcement (maximum: one group). The self-help and counseling guides were based on the Transtheoretical Model of Behavior change.¹⁵ The physiotherapist's guide had iterative instructions corresponding to specific PFMT phases and the participant's self-help guide.¹⁶ All physiotherapists used a “protocol checklist” to ensure PFMT standardization.

A process evaluation revealed few had actually used the reminder stickers and the ‘protocol checklist’ had become both a guide and catalyst, stimulating physiotherapists to provide additional guidance across all groups. An effect evaluation found the three interventions had no additional outcome effect (PFMT was successful in all three) nor affected adherence. One year post-physiotherapy, 74.8% of the women ($n = 103$) were cured or improved by 50% (intention to treat for cured or improved 64.4%, $n = 129$), which was higher than in previous studies; adherence behavior was very high: most performed PFMT six out of the seven prescribed days/week during therapy and 4–5 days/week post-treatment.¹⁰ The authors postulated that verifying accomplished-treatment goals each session, as required in the protocol checklist, may have stimulated the physiotherapists to evaluate progress and provide more reinforcement/feedback, negating the effect of the “counseling” guide.¹⁰ Thus, in this study, the protocol checklist, coupled with enthusiastic physiotherapists, seemed to have the greatest impact on long-term outcomes and adherence behaviors.

Five other trials used PFMT-adherence strategies but did not compare them to PFMT without adherence strategies (audiotape for home PFMT, telephone calls/reminders, test and reinforcement and pamphlet).^{2,3}

TABLE I. Studies Comparing Strategies to Improve PFMT Adherence

Study	Participants	Comparison	Results
For UI in women			
Gallo & Staskin ¹²	n = 86 Women with stress UI	(n = 43) audiotape + home PFMT exercise programme (after 45-min. of oral instruction and biofeedback) vs. (n = 43) no audiotape + same home PFMT exercise programme	Women who used the audiotape with exercise instructions were more likely to be performing the PFMT exercises twice daily as per instruction during the 6 weeks of home exercises (RR 7.05; 95% CI: 2.78–17.88).
Sugaya ¹³	n = 41	(n = 21) Electronic device to cue PFMT + PFMT exercise programme vs. (n = 20) no electronic device + same PFMT exercise programme	No measure of adherence. Women who used the electronic device to cue PFMT were more likely to be satisfied with treatment outcome (RR 3.17, 95% CI: 1.02–9.88). Dropouts: 2 in electronic device, 3 in no device.
Alewijnse ¹⁰	n = 103	Aimed to identify the required optimal intensity of a health education component to promote effective adherence. Methodology: Longitudinal RCT with pre- & post-test, 3- and 12-month follow-up, measuring adherence behaviour and determinants and severity of UI symptoms. One control (n = 29) and three intervention groups (n = 22) minimal, (n = 25) medium, (n = 27) maximum)	All groups improved significantly, no difference btw intervention groups. Positive effect on adherence. Positive effect on UI. Severity of symptom, self-efficacy, positive intention to adhere and no sex education at school predicted adherence behaviour explaining up to 50% of variance in long-term adherence (adjusted R ²). Dropouts: 26 2 in control group 7 in minimal 9 in medium 7 in maximum
For UI in men			
Ip ³⁰	n = 16 men post-operatively, after TURP and radical prostatectomy.	(n = 8) Refrigerator reminder magnet (a visual prompt) + home PFM exercise vs. (n = 8) printed copy of the same reminder + home PFM exercise	Adherence questionnaire, by telephone, before and every two weeks for 3 months after the surgery. No difference in continence rate, but participants in magnet group perceived it as an excellent idea. A negative point to the magnet was the cost: 12 times higher than the printed copy of reminder.
For UI in post-natal women with UI			
Chiarelli ⁴⁴	n = 676	(n = 328) Physiotherapy visits ×2 and followed-up guided by the Health Belief Model vs. (n = 348) Usual care	Significantly more women in the physiotherapy group (83.9%) adhered to PFMT (at least three or more times/week) compared to the control (57.6%) (P < 0.01).

Summary

There is a small, yet stimulating, body of evidence on PFMT-adherence determinants (moderators and mediators) and strategies for women with UI but no commonly-agreed adherence outcome measures. The tools utilized include (1) weekly/monthly exercise diaries, (2) self-administered questionnaires and/or (3) self-evaluation score.

Two studies^{9,10,11} evaluated PFMT-adherence determinants, some of which were mediators (amenable to change through an intervention and with clinician support): (1) positive intention to adhere, (2) positive self-efficacy expectations, (3) perception of high social pressure to engage in PFMT, (4) attitude towards the exercises, (5) dyadic cohesion, and (6) perceived benefits of the exercises; additionally, and as expected (7) high short-term adherence levels were linked to post-treatment adherence.

Comparisons of different PFMT-adherence strategies/techniques support the use of a structured PFMT protocol with goal setting, coupled with enthusiastic physiotherapists, and an audiotape for home PFMT. These are indicative of elements that could comprise useful adherence strategies in women with UI; more studies are needed to better understand short- and long-term PFMT-adherence strategies.

Men With Urinary Incontinence

PFMT is the first-line treatment for post-prostatectomy UI in men.^{2,17} Although patients generally experience spontaneous

recovery, most studies show PFMT reduces UI incidence and severity.¹⁷ However, in two recent parallel randomized trials, not yet incorporated in the Cochrane review¹⁷, one-to-one conservative physical therapy for men after prostatectomy did not reduce UI incidence.¹⁸

Monitoring Adherence

In the identified RCTs on PFMT and male incontinence, few measured adherence to PFMT. Among those that did^{18,19} weekly home diaries or research participant’s report were generally used and adherence measured as the frequency/number of contractions/day or home PFMT days/week during the intervention stage.

Determinants

No RCT studied or reported on determinants.

Strategies

Only one RCT³⁰ specifically compared strategies, exercise-reminders printed on fridge magnets versus printed copies (Table I), but the study was underpowered and no differences were detected. Most studies did not specifically refer to adherence strategies; however, ten described techniques to improve PFMT adherence but did not evaluate them.^{20–29} Strategies included verbal instructions combined with one of

the following: written instructions, exercise-reminder checklists, self-administered adherence questionnaires, information leaflets, DVDs, and diaries.

Summary

Little is known about PFMT-adherence outcome measures, predictors and strategies for UI in men. Although different techniques encouraging PFMT adherence are described in some studies, only one, inconclusive, study actually compared strategies. More studies investigating short- and long-term PFMT adherence are required.

Pre- and Post-Natal Urinary Incontinence

Around a third of pregnant women will develop UI postpartum.² A Cochrane Review⁴ concluded that pregnant women without a prior UI history who received intensive antenatal PFMT were around 30% less likely to report UI 6 months postpartum than women who received no PFMT or usual care. Similarly, women with persistent UI 3 months postpartum who received PFMT were around 40% less likely to report UI at 12 months. The effect increased with more intensive PFMT programs.⁴ The literature review was expanded to June 2013 using a subject search of PubMed, PEDro and the Cochrane library: PFMT or exercise AND UI AND pregnancy or postpartum. Fifteen out of 20 identified studies were relevant.³¹⁻⁴⁵

Monitoring Adherence

Studies provided few details on outcome measures or tools. Information in eight studies³¹⁻³⁸ was gathered through general questionnaires,^{31,35} self-report³² or physiotherapist/group attendance,³⁷⁻³⁸ or home exercise diaries.^{32,33,34,36,38}

Determinants

No RCT studied or reported on determinants.

Strategies

Only Chiarelli and Cockburn⁴³ utilized a specific behavioral theory to improve adherence (Table I). Within 48 hr of delivery, one group of women received usual care while a second received two physiotherapist visits and follow-up guided by the Health Belief Model.¹⁵ Strategies included tailoring PFMT exercises to each woman's PFM functional abilities and specifically negotiating exercise times. Visual supports included an exercise-reminder poster and stickers, a partner information sheet and a booklet containing information on PFMT, perineal care, good bladder habits, effects of childbirth on PFMs, and constipation-avoidance instructions. Significantly more women in the intervention group 84% (80-88%) adhered to PFMT as measured by their self-report of PFM exercise performance frequency—at least three or more times/week—compared to the control 58% (52-63%) ($P < 0.01$).

Multiple factors were postulated for the intervention's success: it was based on an established behavior-change theory, incorporated known principles of anatomy and physiology, and included consumer input in the design and treatment phases. Behavioral principles may also have encouraged PFMT adherence (mitigating attrition) and exercise performance (effectiveness). The fact that the PFMT was designed to exercise specific muscles and accommodate the woman's daily routine may have added to its acceptability.

Summary

Information on adherence measures, if provided, was gathered through questionnaires, participants' or physiotherapist/instructors' reports, or home exercise diaries.

In the only adherence strategy study, the multi-faceted intervention varied significantly from the control, rendering it difficult to determine which factor had the greatest impact on adherence. However, the results suggest that established behavior-change theories, incorporating known principles of anatomy and physiology, and user consultations in the design and treatment phases can increase adherence and exercise performance (effectiveness).

Women With Pelvic Organ Prolapse

The evidence-base for PFMT effectiveness for POP in women has increased over the last decade; level-1 evidence indicates it can reduce both symptoms and severity.^{2,5}

The literature review for this section was extended to June 2013 and a total of eight RCTs were identified.⁴⁶⁻⁵³

Monitoring Adherence

Seven of the eight studies measured adherence outcomes, generally expressed as the percentage of women adhering to the prescribed clinical visits and/or home exercises.⁴⁸⁻⁵⁴ Predominantly, researchers recorded the clinical visits^{49-51,53} and women reported on exercise sets, verbally^{47-49,53} or in daily exercise diaries.⁴⁹⁻⁵³ In two studies, verbal information, alone⁴⁹ or combined with participants' diaries,⁴⁸ was used to classify women into adherence categories (i.e., poor, moderate, good) based on the number of daily contractions or exercise sets. The completeness and accuracy of the diaries were not reported.

Only five studies reported adherence results for home exercises;⁴⁹⁻⁵³ two others measured but did not report results.⁴⁷⁻⁴⁸

Determinants

No RCT reported on or studied determinants.

Strategies

No RCT reported on or studied adherence strategies.

Summary

There are few RCTs on PFMT for POP and even fewer follow-up studies, limiting adherence data. Seven out of eight RCTs measured adherence through attendance lists and/or exercise diaries and patient reports; however, only six reported data on adherence. Predominantly, researchers recorded the number of clinical visits women attended and the women reported on the exercise sets. No study reported on determinants or strategies.

Adults With Lower Bowel Dysfunction

Lower-bowel dysfunction symptoms include anal or faecal incontinence, constipation and difficulty with defecation;⁵⁴ these may occur concurrently. Depending upon symptom aetiology, PFMT can be a first-line treatment for adults.⁵⁴⁻⁵⁵

Monitoring Adherence

One RCT and its follow up, (discussed previously in the Pre- and Post-natal Urinary Incontinence section) studied fecal incontinence and reported adherence to PFMT.^{40,56} Home exercise performance adherence among perinatal women with and without fecal incontinence was self-reported and collected via a postal questionnaire.

Determinants

No RCTs reported on or studied determinants.

Strategies

No RCTs reported on or studied adherence strategies.

Summary

In the only study that monitored adherence to PFMT, participants recorded the number of days they followed lifestyle advice and daily contractions and/or exercise sets and this was collected via postal questionnaire. No research on adherence determinants or strategies was identified, which may, in part, be due to the complexity of the aetiologies and treatments linked to lower bowel dysfunction.

DISCUSSION

Except for women with UI (including pre and post-natal women), for which some preliminary research was identified, literature on PFMT adherence in other populations with PFM dysfunctions was scarce. Research generally focused on incontinence outcomes (e.g., UI signs/symptoms), few recognized adherence to PFMT as a key determinant to UI outcome.

Monitoring Adherence

Adherence to PFMT components and stages was inconsistently monitored or inadequately reported on, if at all, except in a few studies of women with UI or POP. When reported, it comprised attendance to clinical interventions (visits, classes, etc.); adherence with home PFMT and, to a lesser extent, behavioral advice; and, less frequently, adherence to PFMT in post-intervention or follow-ups stages.

Few studies provided detailed descriptions of adherence measurement methodology: tools (e.g., questionnaires, diaries, etc.) and adherence measurements (e.g., exercise sets, number of contractions). Fewer still described them in adequate detail for cross-study comparisons. Exercise diaries were the most widely-used tool.⁹ Only one study attempted partial assessment of the psychometric properties of an adherence questionnaire and an exercises diary.⁹

Encouragingly, Borello-France has recently developed a self-administered questionnaire to measure adherence to PFMT and bladder control strategies at different stages. In addition to measuring the number of PFM contraction/day, number of days/week and months of home exercise, it monitors integration of stress strategies into day-to-day life (e.g., the Knack) while collating specific PFMT-adherence determinant. Although, yet to be completed, part of the psychometric testing of this promising adherence measuring instrument was initiated.⁵⁷

Clearly, adherence needs to be studied and systematically reported for all PFMT components and stages. Research is needed to develop, standardize and evaluate the psychometric

properties of PFMT adherence-outcome measures in different populations with PFM dysfunctions; exercise diaries, and the already-developed adherence questionnaires discussed previously above offer potential starting points.

Determinants

Research on adherence determinants is limited to secondary analyses of two RCTs¹⁰⁻¹² on women with UI; both included short- and long-term determinants.

Short-term determinants, as documented in at least one of the two identified studies, include positive intentions to adhere, self-efficacy expectations (two studies), attitudes towards and perceived benefits of the exercises and high social pressure to engage in PFMT. Positive adherence intentions and self-efficacy expectations also appear to predict high long-term adherence. Long-term adherence is also influenced by UI symptom severity, suggesting women modulate exercise adherence to symptom severity.

The importance and durability of adherence determinants to PFMT success and post-treatment continuation found in this paper is supported by the 2013 Borello-France study.⁵⁷ A higher SF-36 mental score pre-treatment and diminishing frequency of UI leaks subsequent to PFMT predicted exercise adherence: at three months post-randomisation, dropouts were noted to have had weaker PFM strength at baseline; at 12 month, only 'trouble remembering' was associated with lower long-term adherence.

Many of the determinants to PFMT adherence found were mediators therefore amenable to change through clinician's intervention. However, effective adherence mediators could vary according to specific stages, which is consistent with the Transtheoretical Model:¹⁵ behavioral change occurs across a continuum from pre-contemplation, through treatment and on to exercise maintenance. Individuals will likely vary progression through stages based on performance outcomes (refer to paper I out of IV). Clinicians and researchers, guided by general exercise adherence theories¹⁵ and by these preliminary results on adherence determinants, need to identify strategies across the continuum of behavior change and treatment phases.

Strategies

Few trials studied adherence strategies and all but three were likely statistically underpowered.^{10,12,44} In women with UI, structured PFMT with goal setting combined with enthusiastic physiotherapists appeared to increase adherence;¹⁰ audio prompts (e.g., audiocassette) appeared to increase routine home-exercise practice.¹² In post-partum women, the use of established theories of behavior change, incorporating known principles of anatomy and physiology, and user-consultations in both the design and treatment phases increased exercise adherence and performance (effectiveness).⁴⁴

In the future, strategies involving more functional trainings and the use of new technologies, such as personal apps and virtual reality rehabilitation, could play an important role in short- and long-term adherence. Preliminary results of small cohort studies in older women with UI appears to be promising.⁵⁸

CONCLUSION AND RECOMMENDATIONS

The literature on adherence measurements, tools, determinants and strategies is scarce for most populations with a PFM dysfunction. Studies of women with UI are the exception but limited to preliminary research. To render PFMT more effective,

research is urgently needed on all populations with a PFM dysfunction.

Recommendations

Clinical. (1) PFMT adherence should be monitored for all components (attendance to clinical visits with home-exercises adherence) and stages (clinical intervention, immediately post-treatment, follow-up). (2) Patient-focused strategies targeting different PFMT stages should underpin good clinical practice; specifically, strategies influencing the intention to adhere, self-efficacy, positive attitude towards exercises, perceived benefits, and integration of PFMT into daily activities. (3) General exercise-adherence theories should be used as a clinical guide in selecting appropriate patient-focused adherence strategies for PFMT stages.¹⁵

Research. (1) Adherence should be consistently monitored for all study groups. (2) PFMT adherence should be monitored for all components (clinical visits, home-exercises) and stages (clinical intervention, immediately post-treatment, follow-up). (3) Adherence tools and outcome measurements should be judiciously described (method section) and systematically reported on (results and discussion sections). (4) Adherence outcome measurements should be reported on as an overall percentage of all participants for each study group, not just those completing PFMT. (5) More robust and extensive psychometric testing of adherence-measurement outcomes should be undertaken to identify the best outcomes for assessing PFMT adherence components across all stages. (6) The identification of adherence determinants (specifically mediators) for different stages and populations should be undertaken in all RCTs. (7) Previously-identified patient-focused strategies should be validated in post-natal women and women with UI; specifically, strategies to influence the intention to adhere, self-efficacy, a positive attitude towards the exercises, perceived benefits, and ability to integrate PFMT into daily activities. (8) Quantitative studies guided by general behavior change theories on exercise adherence should be undertaken to identify adherence mediators at each stage in all populations with PFM dysfunctions.

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