



## 2014 Consensus Statement on Improving Pelvic Floor Muscle Training Adherence: International Continence Society 2011 State-of-the-Science Seminar

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**Aims:** To summarize the findings and “expert-panel” consensus of the State-of-the-Science Seminar on pelvic floor muscle training (PFMT) adherence held prior to the 41st International Continence Society scientific meeting, Glasgow, 2011. **Methods:** Summaries of research and theory about PFMT adherence (based on a comprehensive literature search) were presented by subject experts at the 2011 Seminar to generate discussion and guidance for clinical practice and future research. Supplemental research, post-seminar, resulted in, three review papers summarizing: (1) relevant behavioral theories, (2) adherence measurement, determinants and effectiveness of PFMT adherence interventions, and (3) patients' PFMT experiences. A fourth, reported findings from an online survey of health professionals and the public. **Results:** Few high-quality studies were found. Paper I summarizes 12 behavioral frameworks relevant to theoretical development of PFMT adherence interventions and strategies. Findings in Paper II suggest both PFMT self-efficacy and intention-to-adhere predict PFMT adherence. Paper III identified six potential adherence modifiers worthy of further investigation. Paper IV found patient-related factors were the biggest adherence barrier to PFMT adherence. **Conclusion:** Given the lack of high-quality studies, the conclusions were informed by expert opinion. Adherence is central to short- and longer-term PFMT effect. More attention and explicit reporting is needed regarding: (1) applying health behavior theory in PFMT program planning; (2) identifying adherence determinants; (3) developing and implementing interventions targeting known adherence determinants; (4) using patient-centred approaches to evaluating adherence barriers and facilitators; (5) measuring adherence, including refining and testing instruments; and (6) testing the association between adherence and PFMT outcome. *NeuroUrol. Urodynam.*

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**Key words:** consensus statement; exercise; pelvic floor muscle training; treatment adherence

### INTRODUCTION

This consensus statement emanates from the literature review, research and discussions of the multi-disciplinary invited faculty of experts at the August 2011 State-of-the-Science Seminar “*Improving Pelvic Floor Muscle Training Adherence Strategies: from theory to practice*,” a pre-conference seminar to the 41st International Continence Society (ICS)

Christopher Chapple led the peer-review process as the Associate Editor responsible for the paper.

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conference, Glasgow, Scotland. The seminar aim was to review current knowledge of PFMT adherence and to provide recommendations for clinical practice and research.

Level 1 evidence indicates pelvic floor muscle (PFM) training (PFMT) is effective in treating PFM dysfunctions women: stress, urgency or mixed urinary incontinence (UI); pelvic organ prolapse (POP); and lower bowel dysfunctions.<sup>1-4</sup> There are fewer studies in men and the results are controversial. Most studies supporting PFMT to reduce UI incidence and severity, however, a recent large trial found PFMT was not effective at reducing the incidence of post-prostatectomy urinary incontinence.<sup>5,6</sup>

Continued adherence is key to maintaining PFMT effectiveness;<sup>7,8</sup> poor adherence results in a longer term decline in effect.<sup>9-12</sup> PFMT adherence is complex and necessitates behavioral change and active patient participation;<sup>13</sup> over 200 variables correlate with exercise adherence alone.<sup>13,14</sup> Differences exist between short-term adherence (e.g., during supervised PFMT) and long-term adherence (for example, patient training alone after supervised therapy). Clinicians estimate that 64% of patients adhere to PFMT and health advice short term, but only 23% long term.<sup>13,15</sup> Thus, planning and implementing PFMT programs informed by adherence theory and evidence, are potentially critical to achieving and maintaining treatment effect.

Exercise adherence has been identified as an important predictor of overall PFMT effectiveness,<sup>7,8</sup> and cost-effectiveness is dependent upon whether short-term outcomes can be maintained long term.<sup>16</sup> Adherence and its determinants, from initial uptake to longer-term maintenance, need to be understood, measured, and harnessed to maximize PFMT effectiveness.

This consensus statement summarizes the available evidence on PFMT adherence and provides recommendations, based on the evidence and expert opinion, for clinical practice and research.

## MATERIALS AND METHOD

The consensus statement process followed the methodology recommended by the National Institutes of Health (NIH) Consensus Development Program (<http://consensus.nih.gov>). An electronic search for PFMT adherence literature was undertaken (CD + research assistant) in MEDLINE, EMBASE, and CINAHL, using database-adapted keywords for: adherence, compliance (including adherence strategies), pelvic floor, exercise (including exercise therapy, PFMT and pelvic floor muscle exercises (PFME), therapeutic exercises and physiotherapy), education (including health promotion) and behavioral strategies (including brief interventions, motivational interviewing), motivation, and self-efficacy. Results were limited to: English and French languages; randomized-controlled, quasi-controlled, matched-controlled trials, or cohort studies; human subjects; and publications from January 1990 to June 2011. Thirty search records resulted.

The 17-member multi-disciplinary expert panel members were chosen by the seminar's organizing committee (Chantale Dumoulin, Helena Frawley and Doreen McClurg) for their contributions to understanding PFMT adherence in the context of medicine (Frances Mair, general practice; Ted Arnold, urology), nursing (Shu-Yueh Chen), patient education (Dianne Alewijjnse), behavioral psychology (Kathryn Burgio, Sarah Dean), study design and statistics (Suzanne Hagen), and physiotherapy (Kari Bo, Pauline Chiarelli, Sarah Dean, Chantale Dumoulin, Helena Frawley, Jean Hay-Smith, Julia Herbert,

Aishath Mahfooza, Doreen McClurg, Diane Stark, Marijke Van Kampen).

Panel experts received the 30 identified papers 6 weeks prior to the 2011 seminar. Each member presented a paper on an agreed adherence topic based on their literature review, adherence-related research, and knowledge of other research and relevant resources. Presentations were posted to the ICS website: <http://www.ics.org/Documents/Documents.aspx?FolderID=124>

To ensure a broad representation, NIH guidelines (<http://prevention.nih.gov/cdp/about.aspx>) recommend consensus statement panels comprise stakeholder and town-hall style public forums. As members of the public were not included in the seminar, to fulfil this requirement, an online survey of key stakeholders (clinicians and patients) was undertaken. The preliminary results were discussed at the August 2011 State-of-the-Science Seminar.

The 2011 seminar was chaired by Chantale Dumoulin and Helena Frawley. Open discussion among the panel members followed each presentation, although these discussions were closed to non-panel members. Gaps in the existing knowledge were identified and summarized. Any disagreement or differences in opinion were resolved by open discussion among the expert panellists.

Subsequent to the seminar, nominated expert panel members (CD, HF, JHS, DM) led the preparation of four research papers (I-IV) summarizing the reviewed evidence and expert-panel discussions and recommendations. The lead authors of Papers I-III conducted supplementary literature searches and reviewed behavioral theories suited to PFMT research (Paper I); adherence measurement, determinants and interventions (Paper II); and patient experiences of PFMT (Paper III). The online survey continued to collect data for a short period after the seminar, and Paper IV reports the final results regarding health professional and general public opinions about PFMT adherence. Each paper reports on specific methods linked to their research. As the four papers and the consensus statement developed, the nominated expert panel members (CD, HF, JHS, DM) conducted three monthly Skype meetings to critique and edit each manuscript. Finally, the four papers and consensus were distributed to all seminar faculty (n = 17) for expert review prior to the submission for publication.

Key terms used throughout the consensus statement and constituent papers are defined next. **Adherence** is 'the extent to which a patient's behavior matches agreed recommendations/instructions from the prescriber; it is intended to be non-judgmental, a statement of fact, rather than to ascribe blame (to patient, prescriber, or treatment method)'.<sup>17</sup> This definition aligns with the National Institute for Clinical Effectiveness<sup>18</sup> and the World Health Organisation<sup>19</sup> definitions. **Determinants** are variables (substantiated in experimental or observational research) known to influence adherence. Determinants include (pre-treatment) **predictor** variables and **facilitators** and **barriers** to a person's ability to adhere.<sup>7</sup> Determinants of exercise adherence can be subdivided into **moderators** (e.g., age, gender—so not amenable to change through an intervention) and **mediators** (e.g., self-efficacy—which is amenable to change). Our search focused on known **mediators** to PFMT adherence and we also discuss **modifiers** (that have potential to influence adherence but have yet to be investigated in experimental or observational research).<sup>20</sup> **Adherence strategies** include any method or combination thereof designed to improve PFMT adherence (e.g., reminder methods: alarms, diaries) as well as other behavioral strategies (e.g., goal setting).<sup>21</sup>

## RESULTS

### Paper I: Scoping Review of Adherence Promotion Theories in PFMT<sup>22</sup>

Attempts to impact behavior are best made based on knowledge of underlying health behavior theory. Twelve theories/models or behavioral techniques with potential to promote health behavior change and PFMT adherence were identified; 1–6 were used in previous PFMT studies and 7–12 were considered by the panel to be of interest for future PFMT research.

1. Health Belief Model<sup>23</sup> (HBM), four studies
2. Theory of Planned Behaviour<sup>24</sup> (TPB), one study
3. Social Cognitive Theory<sup>25</sup> (SCT), seven studies
4. Trans-theoretical Model<sup>26</sup> (TTM), one study
5. Self-Regulatory Model<sup>27</sup> (SRM), one study
6. Health Action Approach<sup>28</sup> (HAPA), one study
7. Information-Motivation-Behavioural Skills<sup>29</sup> (IMB)
8. Behaviour Change Techniques (BCTs) taxonomy<sup>30</sup>
9. Capability, Opportunity and Motivation Behaviour<sup>31</sup> (COM-B)
10. Normalization Process Theory<sup>32</sup> (NPT)
11. Motivational Interviewing<sup>33</sup> (MI)
12. Information, Satisfaction, Recall (ISR) Model.<sup>34</sup>

There has been little research to date on health behavior theories or behavior change techniques as a basis for planning or delivering interventions to promote PFMT adherence. The Social Cognitive Theory (which includes self-efficacy) is the only theory that has been subjected to any substantive PFMT research and only among women with UI.<sup>22</sup> Several theories/models, although they have not been studied in PFMT research, show promise.<sup>22</sup> A better theoretically-based understanding of interventions to promote PFMT adherence through changes in health behavior is required. Ideally, future research should explicitly map the theories underpinning interventions intended to improve adherence. In addition, applied behavioral theory requires a process whereby the impact can be evaluated and this means more research designed to investigate the association between outcome and PFMT adherence, and between adherence and its antecedents, moderators and mediators. More urgently, work on behavioral change theories/models is needed in the pre- and early-treatment phases for all PFM dysfunctions and populations, as it is known that significant attrition occurs as a person moves through the process of behavior change, from behavior awareness to agreement to adopt and, finally, to adherence.<sup>35</sup> To maximize long-term adherence, clinicians need to understand all phases and relevant behavior change needs because without “buy-in” to the early phases there is no long-term adherence.

### Recommendations

**Clinical.** Educational institutions should (1) raise clinicians’ awareness of the importance of behavior change in PFMT and (2) provide/recommend appropriate behavior-change theory and skills training for clinicians.

**Research.** Researchers should investigate theory-based health-behavior interventions in relation to PFMT uptake and short-/long-term adherence.

### Paper II: PFMT Adherence Measurement, Determinants, and Interventions<sup>21</sup>

For each condition-specific population (women or men with UI, women with pre- or post-natal UI or with pelvic organ prolapse, and adults with lower bowel dysfunction), the review summarized existing quantitative data regarding PFMT adherence measurement, determinants, and the outcomes of studies investigating PFMT adherence strategies. Some preliminary research was identified for women with UI. Otherwise, literature specific to other populations and conditions was scarce.

### Measurement

Except for women with UI or POP, adherence to PFMT components (clinical intervention, home exercises) for all stages (during intervention, post-treatment, at follow up) was inconsistently monitored or reported, if at all. Where it was reported, adherence data were collected for only one of the study arms, or were pooled for the whole study population, so there were no between group adherence data available. During PFMT and, more infrequently, at a post-intervention follow-up, adherence measurements comprised clinic attendance (individual visits, classes), home-exercise completion, and, to a lesser extent, adherence to day-to-day integration of PFM exercises (e.g., the Knack). Few researchers detailed adherence data collection methods (e.g., session attendance records, participants’ verbal self-reporting formats/questionnaires, diaries), nor how adherence was determined (e.g., exercise days or sets). Among those that did, few described them in adequate detail for cross-study comparison. One study partially assessed the psychometric properties of their adherence measurement tools.<sup>36,37</sup>

Recently, Borello-France et al. (2013) developed a self-administered questionnaire to measure adherence to PFMT and bladder control strategies (frequently taught together); the tool also collated specific PFMT-adherence barriers.<sup>38</sup> Although incomplete, psychometric testing of this promising adherence measuring instrument has begun.<sup>38</sup>

Adherence needs to be systematically reported in all PFMT studies, both during and after supervised interventions. Research is needed to develop, standardise and evaluate the psychometrics of PFMT adherence measurement instruments in populations with different PFM dysfunctions; exercise diaries and the already-developed adherence questionnaires offer potential starting points.<sup>21</sup>

### Determinants

Research on adherence determinants is limited so far to secondary analyses of RCTs involving women with UI; two have evaluated short- and long-term adherence determinants.<sup>21</sup> Short-term determinants, as documented in one or more studies, include positive intentions to adhere, self-efficacy expectations, attitudes towards and perceived benefits of the exercises, and high perception of social pressure to adhere.<sup>7,37</sup> Positive adherence intentions and self-efficacy expectations also appear to predict better long-term adherence.<sup>37</sup> These are promising findings as clinicians can intentionally influence these determinants.

Consistent with the Trans-theoretical Model,<sup>26</sup> in which strategies are tailored to phases of behavior change, one study demonstrated that addressing short-term adherence determinants may be inadequate for promoting long-term adherence. Clinicians and researchers, guided by general exercise

adherence theories,<sup>22</sup> need to identify adherence determinants and appropriate strategies across the continuum of behavior change to ensure appropriate selection of effective long-term adherence determinants.

### Interventions

Few trials studied or compared adherence strategies; among these, all but two<sup>37,39</sup> were likely underpowered. In women with UI, PFMT combined with enthusiastic clinicians (those that evaluate progress and provide feedback) appeared to increase adherence, and pre-recorded audio prompts appeared to increase routine practice of home exercises.<sup>37,40</sup> In post-partum women, the use of established theories of behaviour change (Health Belief Model), incorporating known principles of anatomy and physiology, and consumer consultations in both the design and treatment phases increased exercise adherence and performance.<sup>39</sup>

### Recommendations

**Clinical.** Clinicians should (1) assess PFMT adherence in all patients and, at a minimum, during and at the end of supervised treatment; (2) employ, as part of good clinical practice, patient-focused adherence strategies targeting different stages of PFMT adoption and maintenance, specifically, strategies influencing intention to adhere, self-efficacy, positive attitudes towards and perceived benefits of the exercises, and the integration of PFMT into daily activities; and (3) utilize general exercise-adherence theories as a clinical guide in selecting appropriate patient-focused adherence strategies for PFMT stages (Paper I).

**Research.** Researchers must (1) consistently monitor and report adherence for all study participants, regardless of group assignment, and during and after intervention (clinical intervention, immediately post-treatment and at follow-up); (2) describe in study methods the adherence-measurement instrument (including administration, psychometric properties if available and data analysis) and clearly and completely report adherence data in the results; (3) undertake psychometric evaluations of adherence-measurement instruments to identify robust measures; (4) undertake primary or secondary analysis of adherence determinants in all RCTs and sufficiently large observational studies; (5) study previously identified determinants (mediators) (e.g., intention to adhere, self-efficacy, etc.) in all populations with PFM dysfunction; and (6) design robust experimental and observational studies to test the effects of the identified adherence strategies (in Paper II) as an added intervention to PFMT.

### Paper III: Patient Experiences of PFMT<sup>20</sup>

A review of qualitative studies elucidated six adherence modifiers based on the cognitive, physical and affective PFMT experiences of patients. Twelve of the 13 studies recruited only women. The six modifiers generated by the thematic analysis were: knowledge; physical skill; feelings about PFMT; cognitive analysis, planning and attention; prioritisation; and service provision.<sup>20</sup>

Post-analysis, these six modifiers were mapped to an overarching framework of health behaviour, the Capability, Opportunity and Motivation Behaviour (COM-B) system,<sup>31</sup> to identify appropriate targets for enhancing adherence in practice and testing in research. COM-B offers a starting point for designing behavior change interventions based on three

interacting factors: capability (knowledge and physical skills), opportunity (external context facilitating or impeding a behavior such as service provision) and motivation (conscious, habitual, affective and automatic processes that animate and direct behavior such as feelings about PFMT). A mapping of the six modifiers showed women experienced difficulties with PFMT capability, opportunity and motivation (especially, substantive cognitive demands, negative feelings and problems in prioritizing PFMT). The expert consensus concluded that appropriate behavior-change techniques directed at these modifiers might improve PFMT adherence, hence outcomes, and were worthy of further investigation.<sup>20</sup>

### Recommendations

**Clinical.** Clinicians should: (1) judiciously offer sufficient accurate information to grow patient “*knowledge*,” (2) teach the “*physical skills*” of a correct PFM contraction, then enhance performance and develop patient confidence, (3) promote positive and decrease negative “*feelings about PFMT*” and counter negative with positive PFMT role models, (4) enable constructive “*cognitive analysis, planning and attention*” to problem solve common barriers to and enhance PFMT facilitators in daily life, (5) boost the “*prioritisation*” of PFMT in patients’ lives.

**Research.** Future work must (1) address the absence of primary qualitative research exploring PFMT experiences in men, antenatal women, and those with faecal incontinence, (2) examine the predictive value of the six PFMT adherence modifiers, (3) directly compare the effects of an intervention based on the above clinical recommendations versus ‘usual care’, and (4) investigate whether PFMT adherence mediates incontinence and prolapse outcomes.

### Paper IV: Clinicians’ and Patients’ Perspectives on PFMT Adherence<sup>41</sup>

A survey for health professionals and the general public on PFMT adherence determinants was posted on the ICS website (Paper IV). Survey questions sought opinions about the extent to which patient, therapy, physical/condition, and socio-economic factors were PFMT adherence barriers or facilitators, including the relative importance of each. Of 566 responses, 515 were health professionals and 51 were general public. In the health professional cohort there were few responses from non-English speaking countries or discipline other than physiotherapy.

Both cohorts agreed that “patient-related” factors were the most important adherence barrier; “patients forgetting to exercise” and “minimal perceived benefits” were the key influences for clinicians and general public respectively. Congruent with qualitative studies, health professionals also felt patients prioritized the needs of others above their own.<sup>20,42</sup>

Health professionals rated “patient-related” factors as the most important facilitators while the public identified “therapy-related” factors. Both rated the perception of significant benefit as the most important long-term facilitator. Contrary to published findings, symptom severity did not rank highly as a facilitator.<sup>21,43</sup> Patient self-efficacy, identified in previous studies,<sup>21,43</sup> ranked more highly for the public than for health professionals.

Most respondents felt barriers and facilitators did not differ between PFM conditions. Response variability regarding the effects of age, sex, and ethnicity suggests a need for individualization of therapy and a patient-centred approach.<sup>21,43</sup> A slight majority supported the notion that

research participants are more PFMT-adherent than clinical patients, however, accompanying open-text responses suggested the opposite.

### Recommendations

**Clinical.** Clinicians should (1) identify and address patient-related factors to PFMT adherence, (2) provide tangible evidence or feedback to patients on PFMT benefits, (3) undertake follow-up appointments and re-assess barriers and facilitators to progress, and (4) design individualized treatment approaches based on a person's age, sex and ethnicity.

**Research.** Researchers must: (1) increase research into effective long-term PFMT-adherence facilitators, including sub-population investigations to inform demographic variations and (2) investigate the use of technology (such as electronic-based resources to assist exercise adherence) and relevant behavior change theories/models in maximizing PFMT adherence.

### CONCLUSION AND RECOMMENDATIONS

The prescription of a PFMT program based on sound exercise science and a correct PFM contraction is central to effective training. Equally important to achieving and maintaining the therapeutic effect is the process of behavior change, from awareness to agreement to adoption to adherence. However, there are (1) few documented or adequately detailed examples of health-behavior theory-based interventions and PFMT protocols describing the applied behavioral change techniques; (2) few instruments that measure PFMT adherence, with minimal psychometric testing; (3) few studies investigating determinants of adherence or their association with treatment outcomes; (4) few trials testing adherence strategies; and (5) no qualitative descriptions of PFMT experiences other than among women with UI.

Specific recommendations for practice and research arising from the three literature reviews (Papers I, II, II) and a survey of health professional and general public opinions (Paper IV), are reported. Overall, we find considerable opportunity and need to advance research and practice in the field of PFMT adherence because adherence is central to short- and longer-term PFMT effect. More attention and explicit reporting is needed regarding: (1) the application of health behavior theory and models to underpin PFMT program planning; (2) developing interventions targeting known determinants, such as PFMT self-efficacy (confidence in the behavior and short and longer-term outcome expectations); (3) using and documenting adherence strategies in treatment delivery; (4) measuring adherence, including instrument refinement and testing; (5) identifying and assessing other adherence determinants; and (6) investigating the association between adherence and PFMT outcome, and between determinants and adherence. Greater attention is also needed on patient perspectives regarding all aspects of adherence and how to support it.

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