PELVIC FLOOR MUSCLE TRAINING ADHERENCE: EVALUATING WOMEN'S ADHERENCE TO HOME EXERCISE PRESCRIPTION IN A MULTICENTRE RANDOMISED CONTROLLED TRIAL.

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HYPOTHESIS / AIMS OF STUDY

Urinary Incontinence (UI) is involuntary leakage of urine, with lifetime prevalence for women about 30%. The multicentre randomised controlled trial (RCT) assessed whether standard pelvic floor muscle training (PFMT) for women with stress or mixed (stress and urgency) UI could be enhanced by the addition of electromyography biofeedback (BF). The RCT results showed no additional benefit of BF in UI outcomes observed at two-year follow-up. [1] Process evaluation research showed both RCT groups (PFMT versus PFMT + BF) received a well delivered high quality standard PFMT programme. [2,3] In this study we add to existing knowledge reported from the RCT, specifically investigating diary entries completed by women in response to their exercise prescription: findings not previously reported. Aims were to: quantitively summarise how much home PFMT women reported doing, creating an adherence metric; explore associations between women's self-report of PFMT and their PFMT prescription; identify baseline variables predicting self-reported PFMT adherence; explore and summarise barriers to PFMT adherence reported by women.

STUDY DESIGN, MATERIALS AND METHODS

For RCT details (inclusion/exclusion criteria, randomisation techniques and treatment protocols) see [1]. At each appointment women were issued diaries to complete and return at the next appointment. These were designed as clinical tools for recording exercise prescription with space for women to report their adherence and make free text comments. Prescriptions were summarised [3] and for this study were based on sets of repetitions (number in a set/length of hold) and number of sets per day (days per week also recorded). The PFMT + BF group were given a BF machine; its home use was incorporated into their prescription. Due to the complex nature of data this study focuses on analyses from 1st diaries returned (at the 2nd appointment) meaning only a subset of women from the RCT provided data: those who attended first follow-up, returned their completed diary, and had available prescription data.

Quantitative diary data were subjected to complex data cleaning processes prior to a mean exercise score calculation. These scores were compared to prescribed sets and times per day to create a percentage adherence metric for each woman. An 'a priori' conservative cut-point for adherence versus non-adherence was set at 50%; subsequent review of data meant two additional cut-points (65% and 80%) were added as exploratory analyses. The adherence metric was used in multivariable logistic regression models to determine whether any baseline characteristics (age (dichotomised), incontinence severity, incontinence type, number of deliveries) and treatment group allocation predicted exercise adherence. Free text entries were analysed using Thematic Content Analysis, to summarise barriers to PFMT adherence.

RESULTS

A total of 600 women were randomised, and 409 women returned their 1st diary. Mean adherence percentage was higher in the PFMT + BF group (131%) than the PFMT group (94%). Median adherence across two groups combined was 97%, suggesting women were overall highly adherent. Of the 409 women, only 15 (4%) were less than 50% adherent; 10% were less than 65% adherent to their exercise programme, hence addition of post hoc cut-off adherence thresholds of 65% and 80% for analyses.

Due to missing data when calculating the adherence metric, 395 women were included in regression analyses, 199 from the PFMT group, and 196 from the PFMT + BF group. Baseline characteristics were similar between women in the overall RCT versus this subset, and between the two groups in this subset. We studied baseline characteristics as predictors for adherence. A large percentage of women exhibited adherence at each threshold, with minimal differences between groups (PFMT was the exposure group and PFMT + BF the reference group in the models). Logistic regression modelling results at the 50% adherence threshold revealed only treatment group potentially predicting adherence with weak evidence (odds ratio = 2.8, 95% CI = 0.88; 9.98, p = 0.08). Modelling results at the 65% adherence threshold showed no statistically significant variables predicting adherence. At the 80% adherence threshold, there was little evidence to indicate that baseline characteristics were associated with adherence but there was moderate evidence (odds ratio = 1.75, 95% CI = 1.04, 2.95, p = 0.029) that when compared to the PFMT + BF group, those in PFMT group were less likely to adhere. The odds of non-adherence in the PFMT group were 1.8 times more likely than in the PFMT + BF group.

Thematic Content Analysis identified 7 themes arising from 20 categories. Common reasons for non-adherence to PFMT for both groups related to 'Illness, health and general wellbeing' and 'social and personal commitments'. Issues such as menstruation, stomach pain, back pain, urine leakage and general feelings of ill health were barriers to exercise adherence. 'Social and personal commitments' such as childcare, work and holidays were mentioned equally across both groups. Comments regarding problems with BF equipment occurred 57 times in the PFMT + BF group, a large proportion of their total comments. Despite being intended to increase exercise motivation, comments about BF suggested it caused unnecessary burden: problems with equipment, battery life and difficulty finding both time and privacy to use it.

INTERPRETATION OF RESULTS

Results indicate that women who completed and returned their first diary were highly adherent to the early phase of their PFMT programme, as might be expected. Despite some reported barriers, initial BF use was a positive influence when applying the stricter 80% adherence threshold, even though BF did not show an effect later in the RCT outcomes [1]. This in-depth examination of PFMT exercise diaries, from a large subset of women from the RCT, may help understanding of what factors determine adherence, albeit from the perspective of women reporting high levels of adherence. Learning from such positive (adherent) examples highlights potential importance of not just encouraging women to do their exercises but also to attend appointments, fill out and return their diaries. Even so, these women still encountered barriers to adherence; ill health in general and menstrual symptoms in particular, may warrant therapists discussing with women how to modify or restart their exercises. Research limitations include the degree to which this sample is representative given they were already demonstrating adherent behaviour (this potentially impacts representativeness: they are a self-selected rather than a random, sample) and means results must be interpreted with caution. There was variation in what women recorded, with some women appearing to report number of repetitions instead of sets (diary instructions asked for sets), and this may account for some of the very high levels of adherence. Some women made similar comments on multiple occasions; therefore, number of comments is not indicative of number of women who experience this problem. Finally, percentage cut-off thresholds used to distinguish adherence were initially conservative or decided post hoc, due to lack of research to draw upon when determining levels of therapeutic adherence. Next steps will assess adherence over subsequent appointments in the RCT, examining associations between the adherence metric and the RCT self-efficacy and UI outcomes. Future research could involve women to help better design exercise diaries to avoid variation in reporting and data cleaning problems.

CONCLUDING MESSAGE

Women in this study reported high levels of exercise adherence, and they had completed and returned their diaries: behaviours that also act as markers of adherence. For these women BF use may impact positively upon adherence at the start of their PFMT programme. Future research to improve methods of adherence measurement, including better diary design as research data collection tools, will enhance ability to quantify therapeutic adherence and link these adherence levels with clinical outcomes.

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