Cluster randomised control trial of the effect on attendance and outcomes of multi-disciplinary teams involving psychologists during pelvic floor muscle training for pelvic floor dysfunction

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Short title: MDTs and pelvic floor dysfunction.

Abstract

Pelvic floor muscle training (PFMT) is effective, acceptable to patients, and cost efficient as a treatment for Pelvic Floor Dysfunction (PFD). However, PFMT outcomes are mediated by patient variables, such as depression, anxiety, motivation, and health values. The current study examined whether multi-disciplinary provision of PFMT involving a psychologist would improve attendance and outcomes (Clinical Trial Registration: NCT02549157). 88 consecutively referred patients (age 28 - 85 years), with a variety of PFD, were randomised into two groups: PFMT treatment as usual (n = 47), and PFMT with a psychologist involved (n = 41). Patients received 6-month out-patient physiotherapy. More patients with the psychologist completed the course, and there were significantly greater improvements in subjective symptoms (Queensland scale), quality of life (EQ-5D), and anxiety (HADS), although not in objective measures (Oxford Grading) or depression (HADS). These results suggest that an MDT including a psychologist during PFMT intervention treatment may help some patients.

Keywords: Pelvic floor dysfunction; pelvic floor muscle training; psychological support; clinical outcomes; attendance.

Impact Statement

What is already known on this subject?

Pelvic floor muscle training (PFMT) is effective, acceptable to patients, and cost efficient as a treatment for Pelvic Floor Dysfunction (PFD). However, PFMT outcomes are mediated by patient variables, such as depression, anxiety, motivation, and health values. The effectiveness of a multi-disciplinary team delivering both PFMT and psychological support simultaneously to women undergoing PFMT for PFD is unknown.

What do the results of this study add?

Psychological support delivered alongside PFMT increased patient attendance, improved subjective ratings of pelvic floor functioning, health-related quality of life, and reduced anxiety. This is one of the first demonstrations that this can be achieved through a multi-disciplinary team delivering their support simultaneously to the patients.

What are the implications of these findings for clinical practice and/or further research?

Improving subjective functioning and reducing attrition rates in PFD patients has cost implications in terms of reduced need for surgery, and making future surgery more effective. The inclusion of brief, easily delivered psychological support, integrated into the PFMT sessions in a multidisciplinary way may represent an extremely cost effective method of improving the service for these patients.

Pelvic floor dysfunction (PFD) for women can involve stress and/or urge urinary incontinence, faecal incontinence, and prolapse, or a combination of these problems (Haylen, De Ridder, Freeman et al., 2010). Estimates of prevalence suggest 25% of adult women will experience these symptoms, but this figure can be much higher depending on the definition of the symptoms (Kepenekci, Keskinkilic, Akinsu et al., 2011). Pelvic Floor Muscle Training (PFMT) is a safe and effective treatment (Simpson, Garbens, Dossa, 2019; Wallace, Miller, & Mishra, 2019), but clinical outcomes can be sub-optimal due to poor patient take-up (Osborne, Whittall, Edwards et al., 2016; Reed, Mann, & Osborne, 2020). Rates of nonattendance at PFMT appointments average 25% in the UK, and can be as high as 50% (Reed et al., 2020). Additionally, patients can fail to practice their pelvic floor exercises in what can be a lengthy treatment regime, reducing the effectiveness of PFMT (Osborne, Whittall, Emanuel, Emery, & Reed, 2017; Simpson et al., 2019). The consequence is that women fail to seek treatment for, or recover from, PFD making the condition worse, and they later need more expensive and less safe surgery, potentially increasing the costs to the health system (Osborne et al., 2016; Reed et al., 2020).

Women who experience PFD often report psychological comorbidities, such as depression and anxiety (Khan, Whittal, Mansol et al., 2013; Yip & Cardozo, 2007). These psychological comorbidities are associated with higher rates of nonattendance for PFMT appointments (Osborne et al., 2016; Shannon, Adams, Fitzgerald et al., 2018), and a lack of engagement in the ongoing treatment (Osborne et al., 2017; Reed et al., 2020). They are also associated with poorer clinical outcomes for those who do attend, even when physical symptoms are equated with less depressed and anxious individuals (Khan et al., 2013). In addition to the impact of these comorbid psychological conditions, other factors such as the patient's motivation and readiness to change (Hay-Smith, Ryan, & Dean, 2007; Osborne et al., 2016), the value which they place on their own health (Reed, Whittall, Osborne, &

Emery, 2020), and the weight placed on several other life domains (Osborne, Whittall, Hanratty, Emery, & Reed, 2017), all predict attendance and engagement.

Psychological support interventions have been developed to help women engage with PFMT treatment (Osborne et al., 2016; Shannon et al., 2018). These brief interventions have focused on providing psycho-education and bolstering patients' motivation and health values (Osborne et al., 2016). In an RCT, it was found that three, 20min sessions of such support, in addition to the PFMT programmes, boosted PFMT completion rates by 60% (Osborne et al., 2016). A further RCT demonstrated that providing psycho-education and motivational interventions in a single 10min telephone call to the patients, while they were on the waiting list, reduced initial 'did not attend' (DNA) rates by 50% (Osborne et al., 2017). Thus, there is developing evidence that psychological support can improve engagement with treatment, which could have important consequences for improving PFMT treatment outcomes overall.

However, neither of these RCTs took measures of symptom improvement for the patients – either objectively or subjectively. Although previous work has shown that those with better psychological functioning do show better outcomes after PFMT (Khan et al., 2013), it is unclear whether this would have bene the case for the above two interventions, which tended to focus on motivation and health values. Moreover, both of the interventions studies, although very brief, did require extra time input, over and above the PFMT sessions. It may be more effective to have the psychological support for the patients while undergoing PFMT integrated with the PFMT sessions (Albers-Heitner, Lagro-Janssen, Joore et al., 2011). This may also reduce any stigma associated with receiving psychological support, which also can reduce the effectiveness of interventions (Hatzenbuehler, 2016).

Given these considerations, the current study examined the effectiveness of a multidisciplinary team delivering both PFMT and psychological support simultaneously to women undergoing PFMT for PFD. To this end, a randomised cluster design was adopted. Consecutive groups of women undergoing a 6 session group-based PFMT were randomised into receiving PFMT treatment as usual (with no psychologist present), or into receiving PFMT group-sessions with a psychologist in attendance. The psychologist delivered motivation support during the sessions, worked to enhance focus on health values, and provided any individual support requested by the patients after the session. In addition to examining the impact on attendance at sessions during the treatment programme, objective and subjective measures of physical outcomes were taken, along with measures of quality of life (EQ5D) and psychological functioning (depression and anxiety). It was hypothesised that attendance and outcomes would be improved in the group receiving a multi-disciplinary approach to PFMT including a psychologist.

Materials and Methods

Participants

Initially, 130 adult females with PFD, consecutively referred to an outpatient PFMT programme were asked to participate in the study. G-Power analysis suggested that to obtain 80% power, using a rejection criterion of p < .05, with a medium effect size (d = .50, based of previous work; Osborne et al., 2016), a sample size of 128 would be needed. Of the patients approached, 119 (92%) gave their consent to participate prior to their initial PFMT session. Of the patients who gave their consent, 88 (74%) attended for their initial PFMT session. These remaining participants had a mean age of 53.58 (\pm 12.96; range = 28 – 85) years, and had a mean BMI of 29.40 (\pm 6.30; range = 19 – 50). The patients were referred to PFMT for a variety of pelvic floor conditions: 31 (35%) with stress urinary incontinence but no prolapse; 8 (9%) with urge urinary incontinence but no prolapse; 16 (18%) with mixed urinary incontinence but no prolapse; 3 (3%) with faecal incontinence but no prolapse; 13 (15%) with prolapse; and 17 (19%) with mixed incontinence and prolapse. Ethical approval

was granted to this study by the NRES Committee Region - East Midlands, UK. The trial is registered on clinicaltrials.gov (NCT02549157).

Measure

Modified Oxford Grading (Brink, Wells, Sampselle, Taillie, & Mayer, 1994) is a validated objective measure that quantifies the strength of pelvic floor contraction. Patients are scored a scale of between 0–5; 0 = no pelvic floor contraction, 5 = very strong: elevation of examiner's finger against strong resistance. The technique has been demonstrated to be reliable in this context (Brink et al., 1994).

Queensland Pelvic Floor Questionnaire (Baessler, O'Neill, Maher, & Battistutta, 2008) is a self-administered female pelvic floor questionnaire. Sections relate to bladder dysfunction, bowel dysfunction, prolapse, and sexual dysfunction, each producing a score from 0–10, the sum gives overall pelvic floor dysfunction (0–40). Greater scores represent worse function. The internal reliability of the scales (Cronbach α) range between .72 and .95 (Baessler, O'Neill, Maher, & Battistutta, 2010).

EuroQol-5 Dimensional Questionnaire (EQ-5D; Gusi, Olivares, & Rajendram, 2010) is a measure of the impacts of disease on various aspects of health. There are 5 Likert-type, questions addressing the patient's state on the day of assessment, and an overall rating of health (0-100). It has test-retest reliability of .80 (Dorman, Slattery, Farrell, Dennis, & Sandercock, 1998).

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a widely-used measure of anxiety and depression, with very strong test-retest reliability and validity (Zigmond & Snaith, 1983). It focuses on psychological symptoms and excludes somatic symptoms to avoid overlap with physical symptoms. The HADS consists of 14 questions – 7 for anxiety and 7 for depression – each question is scored from 0 to 3. There

are four symptom categories for the overall score: normal (0-7), mild (8-10), moderate (11-14), and severe (15-21).

Interventions

Treatment as Usual: The PFMT programme was delivered over 6, 60min sessions to groups of patients (5-6 patients per group), with 2 individual appointments, spaced over the course of 6 months. The programme sought to provide training in pelvic floor exercises, identifying and isolating the correct muscle groups, and education regarding pelvic floor anatomy and function. Sessions were led by a clinical physiotherapy specialist, a senior physiotherapist in women's health, or a surgical nurse specialist, who each saw all of the groups. Every session provided training in pelvic floor exercises, and advice about behavioural management of continence (fluid intake, bladder drill, 'the knack', double voiding, and helpful activities). Patients were asked to practice pelvic floor exercises on a daily basis. At the start, patients were advised to perform 5 rapid pelvic floor muscles squeezes, holding each squeeze between 1-3s before releasing. Patients were encouraged to progressively increase the number and duration of squeezes over the course of the programme, with a goal to accomplish 10 long squeezes, for 10s, followed by 10 short squeezes, at least two to three times a day. PFMT sessions also provided information regarding: (1) the anatomy and function of the pelvic floor muscles; (2) back and spinal care, as well as posture; (3) medical and surgical management of pelvic floor conditions; (4) psycho-sexual issues; (5) the anatomy of the intestines and bowel, and colorectal problems; and (6) physiotherapy management of PFD and available aids. Individual appointments were taken by a clinical physiotherapy specialist, and were held usually at the start and end of the group sessions. These individual appointments established the needs of the patient, and could involve vaginal examination to assess vaginal muscles and tissues, and pelvic floor strength,

in order to assess the quality of technique of the pelvic floor exercises that the patient was performing.

PFMT and Psychological Support: The PFMT programme for this group was identical to that described above for the TAU group. However, for these sessions a psychologist was present, who had over 5 years experience in working in Women's Health issues. The psychologist provided information and support on two areas, based on previous interventions (Osborne et al., 2016; 2017): motivational support, in the form of Motivational Interviewing style questions asked of the group for their consideration; and focus on health-values of the patients, in an attempt to link any improvements on pelvic floor function to the ability to perform valued activities. The questions typically asked of the group are shown in Table 1. This took about 10min of the PFMT sessions, usually conducted during the first two or three sessions of PFMT, but also revisited as required during the rest of the session. The psychologist would also respond to particular questions from patients during sessions, which tended to be varied and idiosyncratic.

Table 1 about here

Procedure

The patients with PFD were referred to outpatient physiotherapy at the hospital by a range of health practitioners: GPs, consultants/registrars, and continence nurses. The referred patients were placed on a waiting list for the hospital outpatient PFMT service, and were invited to attend the 1st group session of the next set of PFMT classes to commence. Whether the group was to have the psychologist present or not was determined by chance. In total there were 12 groups (mean number of patients = 7.3; range 6 - 8); 6 of these groups had the

psychologist present, and 6 did not. 47 patients received PFMT alone (mean = 7.8 patients per group; range 6 - 8), and 41 patients received PFMT with psychological support (6.8 per group; range 6 - 8). Figure 1 gives the details of the group-allocation process.

Figure 1 about here

At the start of the intervention, participants were given a test of their pelvic floor strength by the physiotherapist in an individual session, and completed the questionnaires to assess their subjective view of their problems (Queensland), their quality-of-life (EQ-5D), and their levels of anxiety and depression (HADS). Data relating to other demographic characteristics (e.g., age, BMI) were collected from the participants. The groups then progressed through their treatment regimes, as described above, and their attendance at the group sessions was monitored. After the intervention, all these measures were collected again.

Results

Table 2 about here

Table 2 shows the mean pre-intervention characteristics of the sets of individuals assigned into the two groups. Inspection of these data shows there was little difference between the groups on any of the characteristics, all ts < 1 (highest d = .08, for EQ-5D).

Participants in the group receiving PFMT alongside psychological support attended for a mean 4.63 ± 1.41) sessions, whereas those receiving PFMT-only attended a mean of 3.13 ± 1.76) sessions. These data were analysed by a one-way analysis of variance

(ANOVA), and the appropriate Bayes statistic was also calculated. This analysis revealed the difference between the groups in attendance to be statistically significant, F(1,86) = 19.18, p < .001, $\eta_p^2 = .182[95\%CI = .057:.320]$, $pH_1/D = .998$.

Of the participants, 17/41 (41%) receiving PFMT and psychology attended all 6 group sessions, but only 8/47 (17%) in the PFMT-alone group attended all 6 sessions, $X^2(1) = 6.42$, p = .011, $\phi = .270$. Using a criterion of attending 5/6 sessions to indicate completion, 23/41 (57%) participants in the PFMT and psychology group completed, but only 12/47 (25%) in the PFMT-alone group completed, $X^2(1) = 8.54$, p = .003, $\phi = .312$.

Figure 2 about here

The change in functioning across all of the variables was calculated by subtracting the pre-intervention scores from the post-intervention scores. The group mean change scores are shown in Figure 2 for the two groups, with improvements displayed as positive changes. Inspection of these data reveals no difference in the objective pelvic floor functioning as assessed by the Oxford Grading system, F(1,38) = 1.68, p = .202, $\eta^2_p = .042[.000:.211]$, $pH_0/D = .706$. However, there was a statistically significant greater improvement in subjective pelvic floor health (Queensland) reported by the group who had the psychology support during their PFMT sessions, F(1,33) = 4.05, p = .050, $\eta^2_p = .109[.000:.316]$, $pH_1/D = .548$. There was also a greater level of improvement in health-related quality of life (EQ-5D), F(1,44) = 3.97, p = .050, $\eta^2_p = .083[.000:.256]$, $pH_1/D = .509$, and anxiety (HADS_A), F(1,43) = 4.23, p = .046, $\eta^2_p = .090[.000:.267]$, $pH_1/D = .548$, for the groups receiving psychological support. Although the change in depression (HADS_D) was not statistically different between the two groups, F(1,43) = 1.26, p = .267, $\eta^2_p = .029[.000:.175]$, $pH_0/D = .778$.

Discussion

The current study demonstrated that psychological support alongside PFMT increased attendance of patients, improved their subjective ratings of their pelvic floor functioning, health-related quality of life, and reduced their anxiety. These data replicate previous work with respect to the impact of psychological support on patient attendance (Osborne et al., 2016; 2017), but show that this support also impacts on the patients' subject experience of their pelvic-floor health, and on their health-related quality of life. This is one of the first demonstrations that this can be achieved through a multi-disciplinary team delivering their support simultaneously to the patients.

There have been previous studies that show the impact of psychological support on attendance of patients with PFD (Osborne et al, 2016). However, these studies have always delivered the psychological support outside the PFMT classes. Likewise, previous studies that have shown stand-alone psychological support can impact on some aspects of PFD (like pain in vaginismus; Engman, Wijma, & Wijma, 2010), but none have shown that pelvic floor function itself can be impacted by psychological support delivered alongside the PFMT. There are positive cost-effectiveness implications of this mode of delivery, in addition to reducing patient resistance to receiving psychological treatment when they are attending for a physical compliant.

The mechanism of action of the psychological support is not apparent from these data, and this was not the primary focus of the current study. The focus of the psychological support was to increase motivation and to increase held health-values, both of which have impacted on attendance (Osborne et al., 2016; Shannon et al., 2018) and outcomes (Reed et al., 2020) for PFMT. It was the case that anxiety levels were reduced by the psychological support. Anxiety symptoms have been related to the experience of pelvic floor symptoms

previously (Khan et al., 2013; Yip & Cardozo, 2007). It may be that anxiety is reduced as the patient's sense of control is increased (Ashworth & Hagan, 1993), although this might have been expected to impact depression also. However, these possibilities warrant further exploration in future studies.

There was no reliable impact of the psychological support on the objective symptoms observed in the patient in terms of the Oxford Grading system. The lack of impact may result from the structure of the PFMT, either in terms of time given during or after the intervention before reassessing physical functioning. It may also have been a function of the particular set of somatic issues presented by a mixed group of patients. It has been shown that patient motivation and health-values when targeted separately from the PFMT session can improve this aspect of functioning (Osborne et al., 2016). However, whether the primary goal of PFMT should be improvement of objective symptoms, or improvement in patient reported functioning, is a debatable issue. Moreover, it may be that the Oxford Grading system is not entirely sensitive to detecting such improvements and this remains an area in need of exploration.

A number of limitations should be noted with the study. The sample size fell below that indicated by the G-Power calculation, which might be responsible for the lack of significance for some measures, such as objective symptoms. Moreover the current sample was quite diverse in their presentations, meaning it is not possible to be specific about which forms of PFD for which psychological support will be most helpful. More information regarding the patients, such as the duration of their PFD, their use of specific medication, their previous experience of PFMT or psychological support, would also be helpful to develop understanding of the effects of psychological support.

Improving subjective functioning and reducing attrition rates in PFD patients has import cost implications, as patients who are successful with PFMT have reduced need for

surgery, and any future surgery may be more effective after PFMT. Attrition rates have long been recognised as an issue for this treatment form (Reed et al., 2020). The inclusion of brief, easily delivered psychological support, integrated into the PFMT sessions in a multidisciplinary way may represent an extremely cost effective method of improving the service for these patients.

Disclosures

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Disclosures of Interest: The authors report no conflict of interest.

Data: Data may be obtained by contacting the corresponding author.

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Table 1: Summary of questions posed to group to support motivation and values

We've been telling you what you should or could do, but I'd like to listen to what you would like to do. You know, it's up to you what you would like to do – after all, it is your health, and your life.

- 1. What would you like to get out of this some of the reasons why you want to do this your goals?
- 2. What are some of the negatives about not doing this some of the things you wouldn't like if you didn't do this the future?
- 3. What are the barriers to doing this some reasons why you may not be able to do this obstacles?
- 4. What strategies can you think of that would help you overcome these barriers/obstacles?
- 5. What benefits would there be if you did this how would your life be different how would this affect your life, now and in the future?

Table 2: Mean (standard deviation) for characteristics of the two groups pre intervention.

	PFMT ONLY	PFMT + PSYCH
N	47	41
AGE	51.51 (10.22)	53.94 (13.52)
BMI	27.70 (6.82)	29.62 (6.32)
OBJECTIVE (OXFORD)	2.51 (.46)	2.57 (.71)
SUBJECTIVE	69.74 (15.44)	73.09 (14.76)
(QUEENSLAND)		
QOL (EQ-5D)	68.86 (19.24)	66.38 (17.40)
ANXIETY (HADS_A)	7.80 (4.57)	7.82 (4.538)
DEPRESSION (HADS_D)	6.14 (4.20)	5.32 (4.17)

Figure captions

Figure 1: CONSORT diagram showing the flow of participants through each stage of the randomised control trial.

Figure 2: Mean improvement scores for objective (Oxford Grading) and subjective (Queensland) pelvic dysfunction, quality of life (EQ-5D), and anxiety and depression (HADS) for both groups. Error bars = 95% confidence limits.

Figure 1:

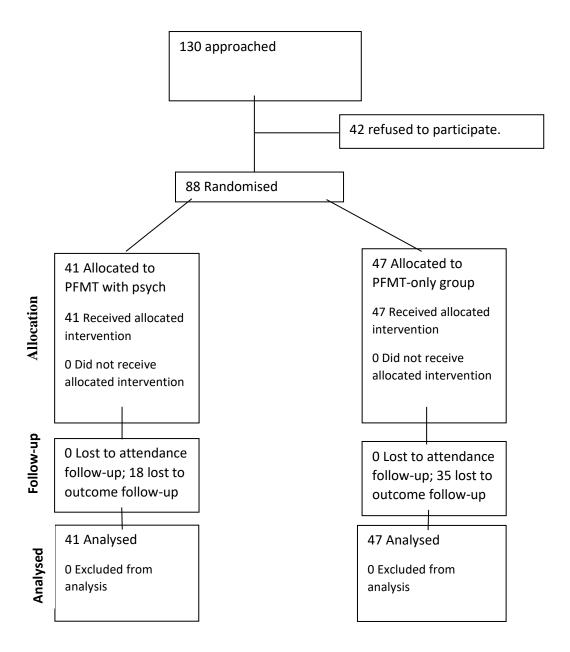


Figure 2:

