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CLINICAL PAPER

Randomized control trial of a values-based motivational interview support to promote attendance at pelvic floor muscle training physiotherapy treatment

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Abstract

The recommended first-line treatment for pelvic floor disorders is pelvic floor muscle training (PFMT), which is effective, acceptable to patients and cost-effective. However, PFMT outcomes are mediated by patient variables such as depression, anxiety, motivation and health values. This study examined whether provision of an adjunct values-based motivational interview support for moderately depressed and/or anxious patients would improve attendance at PFMT group sessions. In total, 67 consecutive female patients who were referred for PFMT were screened for signs of depression and anxiety using the Hospital Anxiety and Depression Scale, and 31 were identified as having moderate levels of both conditions. The average age of the women was 50 years (range = 32–72 years), and they suffered from a variety of pelvic floor problems. The participants were randomly divided into two groups: (1) PFMT treatment as usual ($n = 15$); and (2) PFMT plus motivational support ($n = 16$). The patients then received 6 months of outpatient physiotherapy treatment. Those in group 2 (PFMT plus motivational support) received three, 30-min group sessions of support after PFMT sessions 2, 3 and 4, which involved an intervention focused on motivation and values. Significantly more patients (approximately twice as many) in group 2 (PFMT plus motivational support) completed the course, compared to those in group 1 (treatment as usual). These results suggest that adjunct motivational support during PFMT intervention treatment may help some patients by enhancing their motivation to attend sessions and their treatment compliance.

Keywords: attendance, motivational support, pelvic floor dysfunction, pelvic floor muscle training, treatment compliance.

Introduction

Pelvic floor dysfunction (PFD) refers to a wide range of conditions, including urinary incontinence and lower urinary tract symptoms, pelvic organ prolapses, faecal incontinence, anorectal and defecatory dysfunction, voiding problems, and some sexual problems (Davis & Kumar 2003; Slieker-ten Hove *et al.* 2009; Haylen *et al.* 2010). Prevalence estimates suggest that up to one in three adult females are affected (Milsom 2009; Irwin *et al.* 2011), with the principal causative factors being pregnancy, childbirth, obesity and menopause (Milsom 2009; Kepenekci *et al.*

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2011; Memon & Handa 2012). The current recommendations are that pelvic floor muscle (PFM) training (PFMT) should be the first-line treatment in the management of PFD (Dumoulin & Hay-Smith 2010). A cost-effective physiotherapy intervention, PFMT can be beneficial in its own right, and it is also a safe potential alternative and/or aid to surgery (Dumoulin & Hay-Smith 2010; Imamura *et al.* 2010). Evidence suggests that PFMT is most effective when it is performed under supervision, and an organized course lasting for a minimum of 12 weeks is recommended (NICE 2006). Supervision means that patients are trained and supported throughout the duration of treatment, as well as educated about the anatomy and functions of their pelvic floor.

Research indicates that the clinical outcomes of PFMT are variable, and the results of Cochrane Reviews support this conclusion, suggesting improvements in function that range from 56% to 70% (e.g. Hay-Smith *et al.* 2002; Dumoulin & Hay-Smith 2010). This variability in outcome implies that there are additional factors that influence the success of PFMT. However, studies have shown that the severity of physical dysfunctions does not primarily predict the success of PFMT (Goode *et al.* 2008; Dumoulin *et al.* 2010). In fact, a key indicator of the effectiveness of PFMT is patient compliance with the treatment regime (Glazener *et al.* 2014), and research findings have shown that psychological factors may be important in this regard (DiMatteo *et al.* 2000; Khan *et al.* 2013).

A number of studies have shown that a range of psychiatric comorbidities are associated with PFD, especially depression and anxiety (Von Gontard *et al.* 2011; Coyne *et al.* 2012; Khan *et al.* 2013). This comorbidity may not be surprising since PFD can often be associated with stigma and embarrassment (Davis & Kumar 2003; Koch 2006; Howard & Steggall 2010), and it can also have a negative impact on the quality of life of those who suffer from it (Coyne *et al.* 2012).

The psychological factors associated with PFD have been shown to influence the clinical outcomes of PFMT (DiMatteo *et al.* 2000; Khan *et al.* 2013). For example, Khan *et al.* (2013) found that psychological symptoms of depression and anxiety predicted the success of a PFMT programme for patients with PFD. These authors also found a strong association between the severity of psychological symptoms and the outcomes of PFMT, even when the severity of the physical symptoms was matched in both psychologically distressed and non-distressed patients (see also Goode *et al.* 2008; Dumoulin *et al.* 2010). One mechanism whereby such psychological problems may have an impact on the success of PFMT is impairment of patients' compliance with their treatment regime (Khan *et al.* 2013; Glazener *et al.* 2014). Thus, in order to overcome the negative effects of any psychological problems associated with PFD, finding ways in which patients may be supported while they participate in PFMT programmes is of some importance to enhancing the effectiveness of this form of treatment (Alewijnse *et al.* 2007; for a discussion, see McClurg *et al.* 2015).

One method by which support may be offered to those undergoing PFMT for PFD is motivational interviewing (MI) (Miller & Rollnick 2002), which is a brief, patient-centred approach that is applicable to numerous behavioural domains (e.g. Kelly & Lapworth 2006; Bean *et al.* 2011; for a review, see Knight *et al.* 2006). Motivational interviewing acknowledges that individuals contemplating health-related behavioural changes often experience some degree of ambivalence regarding that potential transformation (Miller & Rollnick 2002; Hettema *et al.* 2005). Given this, MI is designed to promote behavioural change by helping patients to discover and resolve their ambivalence towards altering their own behaviours. To do so, this approach focuses on patient values, and on increasing the congruence between these values and the required health behaviours (Wagner & Sanchez 2002) by increasing patients' motivation to change (Miller & Rollnick 2012). In relation to PFMT for PFD, MI may increase treatment compliance and reduce non-attendance by increasing patients' motivation to change. The aim of the present study was to assess the degree of any such impact of MI on PFMT treatment compliance by measuring the attendance of patients at physiotherapy sessions.

Participants and methods

Initially, 67 adult females with PFD, all of whom were consecutively referred to an outpatient PFMT programme at Abertawe Bro Morgannwg University Health Board, Swansea, UK, were screened for their levels of depression and anxiety. Of these patients, 31 were rated as being in the mild to moderate range (score = 8–14) for either depression and/or anxiety using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith 1983). This screening procedure was adopted because it was thought that

these patients would benefit most from an MI and values support (MIVS) intervention adjunct to their PFMT. It was also believed that women who reported no psychological problems on the HADS might not need such support since their motivation and compliance might not be negatively affected by psychological factors. Those women scoring in the clinical range of the HADS were not thought to be suitable for this MIVS intervention, which was not designed for the treatment of psychological problems, but only to support patients' compliance with their PFMT programme. The selected participants had a mean age of 49.71 years [standard deviation (SD) ± 10.98; range = 32–72 years], and a mean body mass index (BMI) of 30.48 (SD ± 5.54; range = 21–43). The patients were referred to PFMT for a variety of conditions: six (19.4%) had stress urinary incontinence, but no prolapse; two (6.5%) had urge urinary incontinence, but no prolapse; 12 (38.7%) had mixed urinary incontinence, but no prolapse; one (3.2%) had faecal incontinence, but no prolapse; five (16.1%) had prolapse; and five (16.1%) had mixed urinary incontinence and prolapse.

Measure

The HADS is a widely used measure of anxiety and depression that has very strong test–retest reliability and validity (Zigmond & Snaith 1983). It focuses on psychological symptoms and excludes somatic symptoms in order to avoid overlap with physical symptoms. The HADS consists of 14 questions (seven for anxiety and seven for depression), and each question is scored from 0 to 3. There are four symptom categories for the overall score: (0–7) normal; (8–10) mild; (11–14) moderate; and (15–21) severe. An overall psychological distress score can be computed from the total score of these scales.

Interventions

Pelvic floor muscle training programme. The PFMT programme consisted of six, 60-min group sessions (which involved approximately seven or eight patients per group), and two individual appointments, spaced over the course of 6 months. The overall aim of the programme was to train patients to perform PFM exercises (PFMEs), and to identify and isolate the correct muscle group, and also to educate them about the anatomy and function of the PFMs and the lumbosacral spinal region.

The group sessions for the study participants were led by a clinical physiotherapy specialist, a senior women's health physiotherapist, a surgical nurse specialist or a psychosexual counsellor, as appropriate. Each healthcare professional saw each of the groups, and was not assigned to one particular set. The six group sessions each provided training in PFMEs, and advice about the behavioural management of continence; for example, regarding fluid intake, bladder drill, how to contract the PFMs before and during increases in abdominal pressure ("the Knack"), double voiding, and helpful activities. The sessions also were structured to provide information and enhance awareness 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) psychosexual issues; (5) the anatomy of the intestines and bowel, and colorectal problems; and (6) physiotherapy management of PFD and available aids.

The individual appointments were taken by one of the clinical physiotherapy specialists. These were held usually between the second and third group sessions, and after the sixth group session of the PFMT programme. The individual appointments established the needs of the patient, and could involve a vaginal examination to assess the vaginal muscles and tissues, and also PFM strength, in order to assess the quality of technique of the PFMEs that the patient was performing.

Participants were directed to practise the exercises at home, on a daily basis (i.e. in the morning and evening), between the hospital sessions. At the start of the programme, the patients were advised to start with five rapid squeezes of their PFMs, holding each squeeze for between 1 and 3 s, if possible, and then releasing. They were encouraged to progressively increase the number and duration of squeezes over the course of the programme, but to primarily focus on the quality of their technique. The goal was to accomplish 10 long squeezes, holding for up to 10 s, followed by 10 short squeezes, at least two or three times a day.

Motivational interviewing and values support (MIVS). The MIVS approach, which was developed by Bean *et al.* (2011), was adopted because it had been designed for exercise programmes, and could be delivered by any health professional. This programme targeted individual values related to health behaviours, highlighted self-efficacy and autonomy, and also explored ambivalence about changing health-related

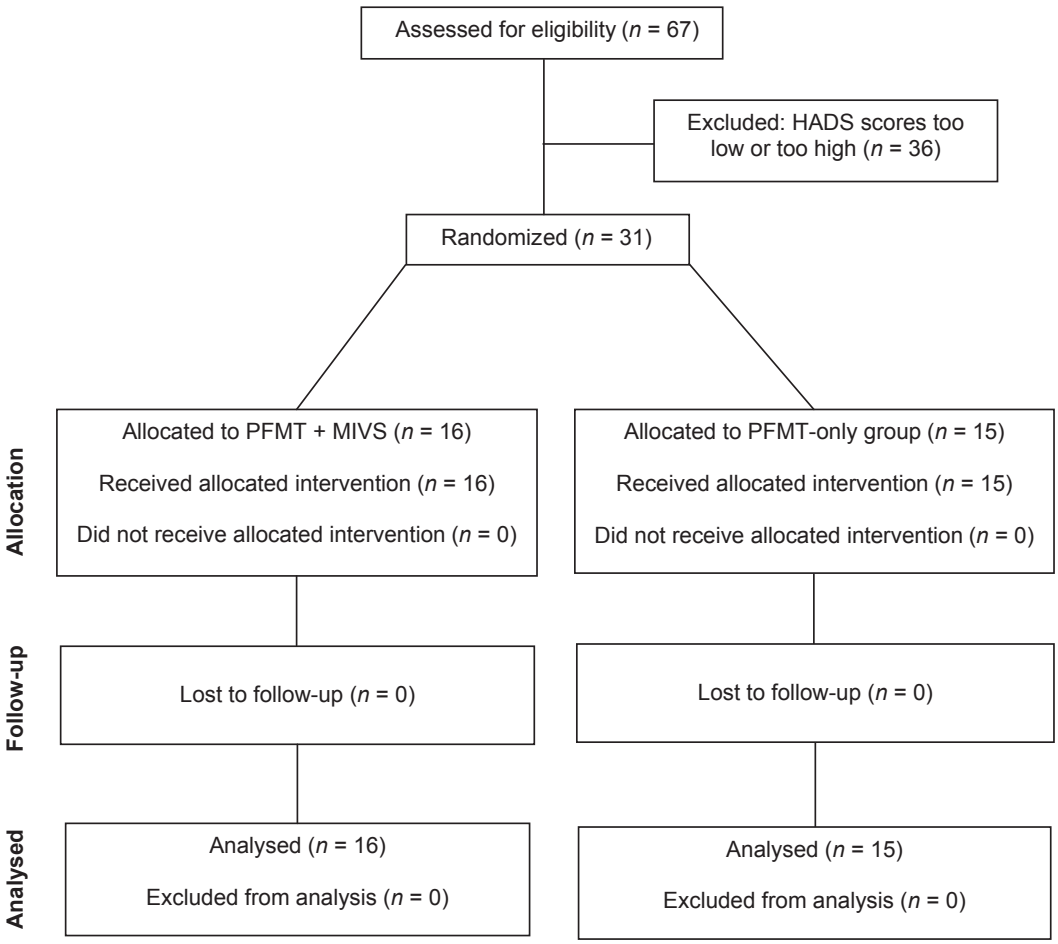

Figure 1. Consolidated Standards of Reporting Trials diagram showing the flow of participants through each stage of the randomized controlled trial: (HADS) Hospital Anxiety and Depression Scale; (PFMT + MIVS) pelvic floor muscle training plus motivational interviewing and values support; and (PFMT) pelvic floor muscle training treatment as usual.

behaviours. Three, 20-min MIVS sessions were delivered on a group basis (which involved approximately seven or eight patients per group) by a psychologist, directly following the second, third and fourth PFMT group sessions.

This approach was not manualized because it has been found that MI interventions that follow a treatment manual are not as effective as those without one (Hettema *et al.* 2005). Instead, the general structure followed that of Bean *et al.* (2011), and each session included: (1) establishing rapport; (2) an opening statement and setting an agenda; (3) exploring chosen (target) health behaviours, and health-related values exploration and clarification; (4) exploration of ambivalence and readiness to change; (5) negotiation of a plan to change and eliciting commitment; and (6) a summary. A schematic representation of the structure of a session is displayed in Fig. 1.

With regard to the exploration of the patients' chosen health behaviours and values, the participants were given a set of questions that concentrated on their health-related values. These questions were given to each patient to work through individually while they were attending the group MIVS session. The questions aimed at focusing each patient's attention on their own health-related goals by specifically asking:

(1) "What do you want to achieve from this course?";
(2) "What do you expect from the course?";
(3) "How important is it to you to achieve improvement in this course, on a scale of 1–10 (1 being not important and 10 being very important)?";
(4) "What are the problems that you want to overcome (e.g. leakage, not going to the toilet until you have a full bladder)?";
(5) "What are the barriers to you achieving improvement in this course?";
(6) "How confident are you in overcoming each of these barriers in order to achieve success in this course?"; and
(7) "How much do you feel you need to contribute successfully in completing this course and achieving improvement?"

The participants' responses to these questions were then briefly discussed with the psychologist who delivered all of the MIVS group sessions in order to help the patients clarify their goals and objectives, and identify any barriers obstructing the achievement of their objectives.

In addition, a diary system was introduced, which was a simple and personalized means to serve as both motivation and reinforcement. It was especially designed to target the behaviours that participants wished to change, those being the behaviours that they themselves, on an individual basis, identified in their MIVS group sessions. Once these health-related behaviours were identified, the patients could record the number of times that they practised the behaviours, or when they had achieved their set goals. These successes could then be shared and discussed with their health professionals and/or the group, if and when the patients wished.

Interventions

Patients with PFD were referred to the outpatient physiotherapy service at the hospital by a range of health practitioners, including general practitioners, 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 first group session of the next set of PFMT classes to commence. During the first group session of the PFMT programme, all 67 invited participants completed the HADS questionnaire to assess their psychological well-being (i.e. their levels of anxiety and depression). Data relating to other demographic characteristics (e.g. age and BMI) were also collected from the participants.

After the initial group PFMT session, the patients' HADS scores were calculated, and those scoring in the mild to moderate range for either anxiety or depression were selected for inclusion in the present study. This produced 31 patients who were thought suitable for the current trial, and these individuals were randomly divided into two groups using a random number generator between 0 (PFMT) and 1 (PFMT + MIVS). Of these 31 patients, 15 were assigned to a PFMT-only group, and these participants were also randomly assigned to one of two PFMT groups ($n = 7$ and $n = 8$, respectively), which remained constant throughout the programme. Additionally, 16 patients were assigned to the PFMT + MIVS group. These participants were also randomly assigned to one of two PFMT + MIVS groups ($n = 8$ for both), which remained constant throughout the programme. Figure 2 gives the details of this group allocation process.

The groups then progressed through their treatment regimes, as described above, and their attendance at the group sessions was monitored.

Results

The means for the entire sample ($n = 67$) in terms of age, BMI, anxiety (HADS_A), depression (HADS_D) and total psychological distress (HADS_T) are shown in Table 1, along with the Pearson product-moment correlation coefficients between these scores. Inspection of the latter results revealed little relationship between age or BMI with the psychological variables (all of the psychological variables correlated with one another). In terms of anxiety levels, 41.8% of the sample were in the normal range (HADS_A = 0–7), 35.8% were in the mild to moderate range (HADS_A = 8–14) and 22.4% were in the severe range (HADS_A > 14). The figures for depression were as follows: 61.2% of the sample were in the normal range (HADS_D = 0–7), 31.3% were in the mild to moderate range (HADS_D = 8–14) and 7.5% were in the severe range (HADS_D > 14).

The intake means for the PFMT and PFMT + MIVS groups in terms of age, BMI, anxiety, depression and total psychological distress are shown in Table 2. Inspection of these data revealed that there was very little difference between the two groups on any of these measures, as might be expected, given the randomization procedure adopted. In terms of the HADS categories for the severity of psychological problems, there were 10 (66%) mild to moderately anxious and five (33%) mild to moderately depressed participants in the PFMT-only group. For the PFMT + MIVS group, there were 10 (63%) mild to moderately anxious and seven (43%) mild to moderately depressed participants. Of course, individuals could be both anxious and depressed, and hence, these figures do not necessarily sum to the total number of participants in each group.

Figure 3 shows the percentage of participants in each group who were defined as compliant with the course, based on their attendance, according to a number of definitions: attending all six group sessions, attending five group sessions or attending four group sessions. Irrespective of the definition employed, the participants from the PFMT + MIVS group had higher attendance rates than those from the PFMT-only group.

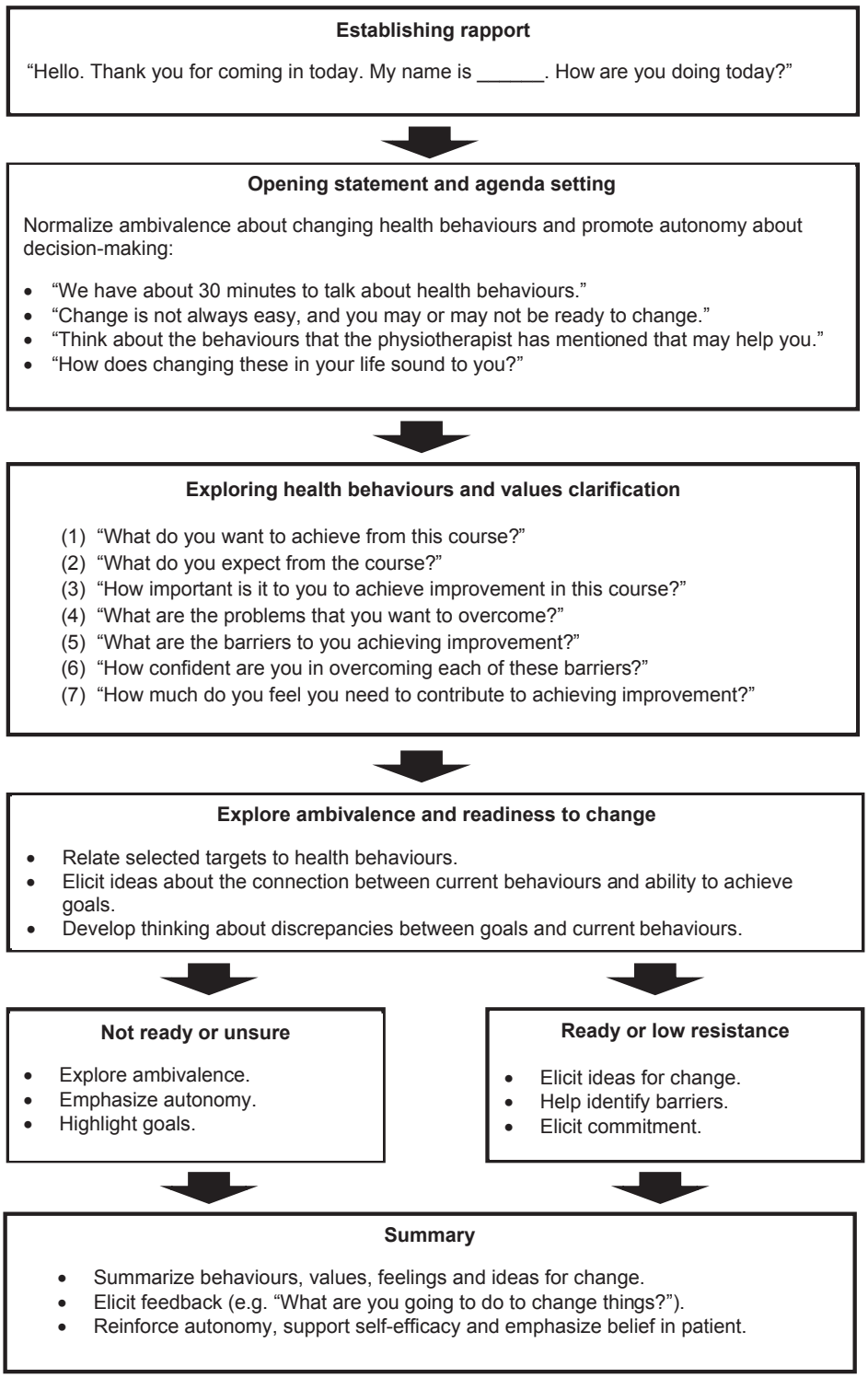

Figure 2. Summary of the motivational values session.

In all cases, the difference between the two groups, in terms of attendance/non-attendance, was statistically significant: for six sessions, $\chi^2_{(1)} = 4.20$, $P < 0.05$ and $\varphi = 0.369$; for five sessions, $\chi^2_{(1)} = 3.89$, $P < 0.05$ and $\varphi = 0.354$; and for four sessions, $\chi^2_{(1)} = 4.05$, $P < 0.05$ and $\varphi = 0.361$. The mean number of classes attended by the PFMT + MIVS group was 4.75 (± 1.39), compared to 3.33 (± 1.63) for the PFMT-only group, which was a large-effect-sized statistically significant difference [$t_{(29)} = 2.61$, $P < 0.05$, $d = 0.940$].

Discussion

The aim of the present study was to investigate whether providing adjunct motivational support for adult females with PFD who were undergoing an outpatient PFMT programme would enhance treatment compliance, as measured by attendance. The adjunct support employed was

Table 1. Means [± standard deviations (SDs)] for the entire sample in terms of age, body mass index, and Hospital Anxiety and Depression Scale (HADS) anxiety (HADS_A), depression (HADS_D) and total psychological distress (HADS_T) scores, along with the Pearson correlations between these scores

	Mean ± SD	Body mass index	Anxiety	Depression	Distress
Age (years)	50.97 ± 11.98	–0.148	0.228	0.116	0.213
Body mass index	31.37 ± 6.21		–0.195	0.030	–0.106
Anxiety	8.35 ± 4.51			0.333**	0.830***
Depression	6.07 ± 4.21				0.802***
Distress	14.48 ± 7.12				

*$P < 0.05$.
**$P < 0.01$.
***$P < 0.001$.

Table 2. Intake means [± standard deviations (SDs)] for the two groups in terms of age, body mass index and Hospital Anxiety and Depression Scale (HADS) anxiety (HADS_A), depression (HADS_D) and total psychological distress (HADS_T) scores: (PFMT) pelvic floor muscle training treatment as usual; and (PFMT + MIVS) pelvic floor muscle training plus motivational interviewing and values support

	Mean ± SD		
	PFMT	PFMT + MIVS	*t*-value
Age (years)	49.12 ± 10.76	50.33 ± 11.56	< 1
Body mass index	30.94 ± 5.08	30.00 ± 6.13	< 1
Anxiety	7.00 ± 2.48	7.00 ± 2.53	< 1
Depression	5.81 ± 2.37	5.73 ± 2.55	< 1
Distress	12.81 ± 2.11	12.73 ± 2.40	< 1

a MIVS technique derived from the system used by Bean *et al.* (2011). It was thought that this programme could be adapted easily to fit the current context, and also used by many health professionals. The results demonstrate that the group with the additional motivational support over and above their PFMT attended significantly more group training sessions than those without this additional adjunct programme. Depending on the particular criterion used to define attendance (i.e. treatment compliance), the PFMT + MIVS group attended 100–150% more group sessions than the non-supported group.

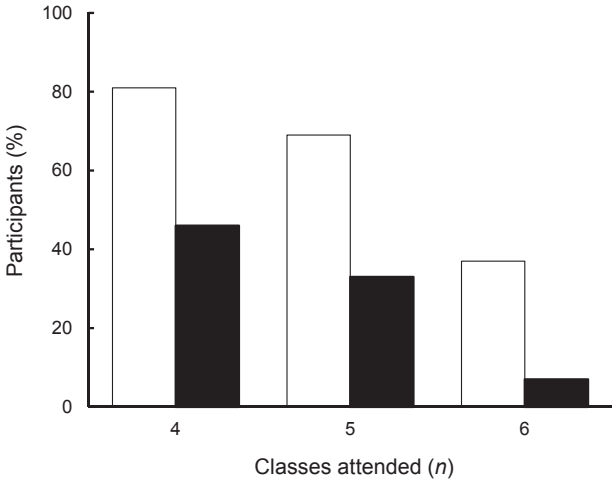

Figure 3. Percentage of participants in each group meeting the various criteria of compliance with classes (i.e. attendance): (□) pelvic floor muscle training plus motivational interviewing and values support; and (■) pelvic floor muscle training treatment as usual.

These data add to the growing literature that suggests that the addition of some form of psychological and/or motivational support, along with physiotherapy treatment as usual, will enhance the chances of patient compliance with the physiotherapy treatment for PFD (see McClurg *et al.* 2015). This finding has also been seen in other areas related to treatments for urogynaecological problems (see Tappin *et al.* 2005; Basra *et al.* 2009; McClurg *et al.* 2015). The mechanisms of action for adjunct support programmes are still not entirely clear, although improvements in patient motivation, or an amelioration of the motivational deficits associated with psychological distress, such as anxiety and depression, are both possible.

The latter suggestion gains some support from an analysis of the levels of anxiety and depression found in the current sample as a whole. These levels were noted to be 22% and 7% for anxiety and depression, respectively, when considering the most severe cases; and 60% and 40%, respectively, when including mild to severe cases of anxiety and depression. These figures correspond with a range of estimates for comorbid anxiety and depression in this particular population (see Von Gontard *et al.* 2011; Coyne *et al.* 2012), and are consistent with previous reports from the hospital where the current study was conducted (Khan *et al.* 2013). However, it should be noted that the present adjunct support programme was specifically not designed, nor attempting, to treat these psychological issues, but rather, to support patients who might have these problems while they were undergoing their PFMT group sessions.

Given that the current study suggests that attendance for PFMT programmes can be improved by implementing such adjunct support schemes, a number of questions may be considered for further research into this area. Clearly,

improving attendance at PFMT group sessions is an important step since a key predictor of clinical outcomes in this field is patient adherence to treatment regimes (Lee *et al.* 1996; Alewijnse *et al.* 2007). However, whether these improvements in attendance translate into clinical gains in terms of pelvic floor function needs to be fully established. Additionally, there are questions to be asked concerning the MIVS programme, such as: can it be integrated into a PFMT programme itself, rather than being presented as an adjunct to such sessions, which would be more time-efficient; and can it be delivered by a healthcare professional who is not a psychologist?

The measure of treatment compliance used here was a simple and objective one of patient attendance, but the impacts of MIVS on the quantity and quality of PFMEs performed by patients may also be areas of interest. Additionally, the impact of the adjunct MIVS programme on the psychological functioning of patients (e.g. the effects on their levels of anxiety and depression, and their motivation to change) could also be studied. Both or either of these improvements could effectively drive increased patient attendance at PFMT sessions. The present randomized controlled trial was not designed, or conducted, to answer such "mechanism" questions, but to provide an answer to a specific question, namely: does an adjunct support work in terms of boosting patient attendance at PFMT group sessions?

In summary, the current report has shown that the delivery of a brief adjunct motivational support programme (three, 20-min group sessions) can boost attendance for PFMT. If this increased attendance/compliance translates into greater clinical gains for patients with PFD, then, given the very large boost seen in attendance in the present study, this could mean substantial cost savings in terms of fewer patients needing surgery following their PFMT.

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