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

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Abstract

First-line treatment recommended for pelvic floor disorders is pelvic floor muscle training (PFMT), which is effective, acceptable to patients, and cost efficient. However, PFMT outcomes are mediated by patient variables, such as depression, anxiety, motivation, and health values. The current 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 consecutively female patients who were referred for PFMT were screened for signs of depression and anxiety using the Hospital Anxiety and Depression Scales (HADS), and 31 were identified as having moderate levels of both depression and anxiety. The women had an average age of 50 (range 32 to 72) years, and there were a variety of pelvic floor problems. Patients were randomly divided into two groups: PFMT treatment as usual ($n = 15$), and PFMT plus motivational support ($n = 16$). Patients then received 6-month out-patient physiotherapy. The PFMT plus motivational support group received three 30min group sessions of support after PFMT sessions 2, 3, and 4, using an intervention focused on motivation and values. Significantly more patients (approximately twice as many) in the group with motivational support completed the course, compared to those in the treatment as usual group. 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: Pelvic floor dysfunction; pelvic floor muscle training; motivational support; attendance; treatment compliance.

Pelvic Floor Dysfunction (PFD) refers to conditions including urinary incontinence and lower urinary tract symptoms, pelvic organ prolapses, faecal incontinence, ano-rectal and defecatory dysfunction, voiding problems, and some sexual problems (Davis & Kumar, 2003; Haylen et al., 2010; Slieker-Ten Hove et al., 2009). Prevalence estimates suggest that up to 1 in 3 adult females are affected (Irwin et al., 2011; Milisom, 2009), with the principal causative factors being pregnancy, childbirth, obesity, and menopause (Kepenekci et al., 2011; Memon & Handa, 2012; Milisom, 2009). Current recommendations are that Pelvic Floor Muscle Training (PFMT) should be the first-line treatment in the management of PFD (Dumoulin & Hay-Smith, 2010). PFMT is a cost-efficient physiotherapy intervention, which can be effective in its own regard, as well as being a safe potential alternative and/or aid to surgery (Dumoulin & Hay-Smith, 2010, Imamura et al., 2010). Evidence suggests that supervised PFMT is most successful, and that a minimum of a 12-week supervised course is recommended (NICE, 2006). Supervision means that patients are trained and supported throughout the course of treatment, as well as educated about the anatomy and functions of their pelvic floor.

Research suggests that the clinical outcomes of PFMT are variable, and results from Cochrane reviews support this conclusion, suggesting improvements in function that range between 56-70% (e.g., Dumoulin and Hay-Smith, 2010; Hay-Smith et al., 2002). This variability in outcome implies the influence of additional variables in determining the success of PFMT. However, research shows that the severity of physical dysfunctions does not principally predict the success of PFMT (Dumoulin et al., 2010; Goode et al., 2008). In fact, a key predictor of PFMT success 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 a range of psychiatric co-morbidities with PFD, especially depression and anxiety (Coyne et al., 2012; Khan et al., 2013; Von Gontard et al., 2011). This co-morbidity may not be surprising, as PFD can often be associated with stigma and embarrassment (Davis & Kumar, 2003; Howard & Steggall, 2010; Koch, 2006;), as well as having negative impacts on the quality of life of the people experiencing PFD (Coyne et al., 2012).

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 amongst PFD patients predicted the success of a PFMT programme. They found a strong association between the severity of psychological symptoms and the PFMT outcomes, even when the severity of the physical symptoms were matched between psychologically distressed and non-distressed patients (see also Dumoulin et al., 2010; Goode et al., 2008). One mechanism whereby such psychological problems may impact on the success of PFMT is through impairing patient compliance with their treatment regime (Glazener et al., 2014; Khan et al., 2103). Thus, finding ways in which patients may be supported whilst being on PFMT programmes, in order to overcome the negative effects of any psychological problems associated with PFD, is of some importance to enhancing the effectiveness of this treatment (Alewijanse et al., 2007; McClug et al., 2015, for discussion).

One method by which support may be offered to those undergoing PFMT for PFD is Motivational Interviewing (MI; Miller & Rollnick, 2002). MI is a brief, patient-centred approach that is applicable to numerous behavioural domains (e.g., Bean et al., 2011; Kelly & Lapworth, 2006; see Knight et al., 2006, for a review). MI acknowledges that individuals contemplating health-related behaviour changes often experience some degree of ambivalence regarding that potential change (Hettema et al., 2005; Miller & Rollnick, 2002).

Given this, MI is designed to promote behaviour change by helping patients to discover and resolve their ambivalence towards changing their own behaviours. To do so, this approach focuses on patient values and on increasing the congruence between these values and the sought health behaviours (Wagner & Sanchez, 2002), and by increasing patients' motivation to change (Miller & Rollnick, 2012). In relation to PFMT for PFD, by increasing patients' motivation to change, MI may increase treatment compliance and reduce non-attendance. 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 the patients at physiotherapy sessions.

Method

Participants

Initially, 67 adult females with PFD, who were consecutively referred to an out-patient PFMT programme, were screened for levels of depression and anxiety. Of these patients, 31 scored in the mild to moderate range (a score of 8-14) for either depression and/or anxiety using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). This screening procedure was adopted as it was thought that these patients would benefit most from a motivational support intervention (MIVS) adjunct to their PFMT. It was thought that women reporting no psychological problems on the HADS may not need such support, as their motivation and compliance may not be negatively affected by psychological factors. Those women scoring in the clinical range of the HADS were not thought 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 (\pm 10.98; range = 32 to 72) years, and had a mean BMI of 30.48 (\pm 5.54; range = 21 to 43). The patients were referred to PFMT for a variety of conditions: 6 (19.4%) with stress urinary incontinence but no prolapse; 2 (6.5%) with urge urinary incontinence but no prolapse; 12 (38.7%) with mixed urinary incontinence but no prolapse; 1 (3.2%) with faecal incontinence but no prolapse; 5 (16.1%) with prolapse; and 5 (16.1%) with mixed incontinence and prolapse.

Measure

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). An overall psychological distress score can be computed from the total score of these scales.

Interventions

Pelvic Floor Muscle Training Programme (PFMT): The PFMT programme consisted of 6 x 60min group sessions (with about 7-8 patients per group), and 2 individual appointments, spaced over the course of 6 months. The overall aim of the programme was training in pelvic floor exercises, identifying and isolating the correct muscle group, and to educate patients concerning the anatomy and function of the pelvic floor muscles and the lumbosacral spine region.

The group sessions for the study participants were led by either: a clinical physiotherapy specialist, a senior physiotherapist in women's health, a surgical nurse specialist, or a psycho-sexual counsellor, as appropriate. Each health care professional saw each of the groups, and was not assigned to one particular group. The 6 group sessions each provided training in pelvic floor exercises and advice about the behavioural management of continence, such as fluid intake, bladder drill, how to contract pelvic floor muscles 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) psycho-sexual 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, and were held usually between the 2nd and 3rd group sessions and after the 6th group session of the PFMT programme. 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.

Patients were directed to practice the exercises at home, on a daily basis (mornings and evenings), between the hospital sessions. At the start of the programme, the patients were advised to start with 5 rapid squeezes of their pelvic floor muscles, holding each squeeze between 1-3s, if possible, and then releasing. Patients 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 10s, followed by 10 short squeezes, at least two to three times a day.

Motivational Interviewing and Values Support (MIVS): The MIVS approach, developed by Bean et al. (2011), was adopted as it had been designed for exercise programmes and could be delivered by any health professional. This programme targeted individual values related to health behaviours, and highlighted self-efficacy and autonomy, as well as exploring ambivalence about changing health-related behaviours. There were 3 x 20min MIVS sessions delivered on a group basis (about 7-8 patients per group) by a psychologist, directly following the 2nd, 3rd, and 4th PFMT group sessions.

This approach was not manualised, because it has been found that MI interventions that follow a treatment manual are not as effective as those without a manual (Hettema et al., 2005). Instead, the general structure followed that of Bean et al. (2011), and included in each session: (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 Figure 1.

 Figure 1 about here

In regards to the exploration of the participants' chosen health behaviours and values, 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, 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 personalised means to serve as both motivation and reinforcement. It was designed to especially target the behaviours that participants wished to change – those being, the behaviours that they

themselves, on an individual basis, identified from their MIVS group sessions. Once these health-related behaviours were identified, the patients could record the number of times that they practiced 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 patient wished.

Procedure

Patients with PFD were referred to the out-patient physiotherapy service 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 out-patient PFMT service, and were invited to attend the 1st group session of the next set of PFMT classes to commence. During the 1st group session of the PFMT programme, all 67 invited participants completed the HADS questionnaire to assess their psychological wellbeing (i.e. their levels of anxiety and depression). Data relating to other demographic characteristics (e.g., age, BMI) were also collected from the participants.

After the initial group session of the PFMT, the patients' HADS scores were calculated, and those scoring in the mild to moderate range of the HADS for either anxiety or depression were selected for inclusion in the present study. This produced 31 patients thought suitable for the current trial, who 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 patients were also randomly assigned to one of two PFMT groups ($n = 7$ and $n = 8$), which remained constant throughout the programme. Additionally, 16 participants were assigned to the PFMT + MIVS group. These patients were also randomly assigned to one of two PFMT+MIVS groups (both $ns = 8$),

which remained constant throughout the programme. Figure 2 gives the details of this group-allocation process.

Figure 2 about here

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

Results

Table 1 about here

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 correlations between these scores. Inspection of these scores reveals 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 to 7), 35.8% were in the mild to moderate range (HADS_A = 8 to 14), and 22.4% were in the severe range (HADS_A > 14). The figures for depression were: 61.2% of the sample fell into the normal range (HADS_D = 0 to 7), 31.3% fell into the mild to moderate range (HADS_D = 8 to 14), and 7.5% fell into the severe range (HADS_D > 14).

Table 2 about here

The intake means for the two groups (PFMT and PFMT+MIVS) in terms of age, BMI, anxiety, depression, and total psychological distress are shown in Table 2. Inspection of these data reveals that there was very little difference between the two groups on any of these measures, as might be expected, given the randomisation procedure adopted. In terms of the HADS categories regarding the severity of psychological problems, in the PFMT-only group, there were 10 (66%) mild to moderately anxious participants, and 5 (33%) mild to moderately depressed participants. For the PFMT+MIVS group, there were 10 (63%) mild to moderately anxious participants, and 7 (43%) mild to moderately depressed participants. Of

course, participants could be both anxious and depressed, hence, these figures do not necessarily sum to the total of participants in each group.

Figure 3 about here

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 6 group sessions, attending 5 group sessions, or attending 4 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. In all cases, the difference between the two groups, in terms of attendance/non-attendance, was statistically significant: 6 sessions, $X^2(1) = 4.20, p < .05, Phi = .369$; 5 sessions, $X^2(1) = 3.89, p < .05, Phi = .354$; 4 sessions, $X^2(1) = 4.05, p < .05, Phi = .361$. 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, $t(29) = 2.61, p < .05, d = .940$.

Discussion

The aim of the current study was to investigate whether providing adjunct motivational support for adult females with PFD, who were undergoing an out-patient PFMT programme, would enhance treatment compliance as measured by attendance. The adjunct support employed was a motivational interviewing and values (MIVS) technique derived from that system used by Bean et al. (2011). It was thought that this programme could be adapted easily to the current context, and could be used by many health professionals. The results demonstrated that the group with the additional motivational support, over and above their PFMT, attended significantly more group sessions of PFMT than those without this additional adjunct programme; depending on the particular criterion used to define attendance (treatment compliance), the PFMT+MIVS group attended 100-150% more group sessions than the non-supported group.

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; Osborne et al., 2015). This finding also has been seen in other areas related to treatments for urogynaecological problems (see Basra et al., 2009; McClurg et al., 2015; Tappin et al., 2005). 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% for anxiety and 7% for depression, 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 co-morbid anxiety and depression in this particular population (see Coyne et al., 2012; Von Gontard et al., 2011), and are consistent with previous reports from the same 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, or attempting, to treat these psychological issues, but rather to support patients, who may 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 for PFMT group sessions is an important step, as a key predictor of clinical outcomes in this field is patient adherence to treatment regimes (Alewijns et al., 2005; Lee et al., 1996). 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 health care 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 pelvic floor exercises performed by patients may also be areas of interest. Additionally, the impact of the adjunct MIVS programme on the psychological functioning of patients (such as 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 current RCT was not designed, or conducted, to answer such

‘mechanism’ questions, but to provide an answer to the question, namely: does an adjunct support work in terms of boosting patient attendance for PFMT group sessions?

In summary, the current report has shown that the delivery of a brief adjunct motivational support programme (3 x 20min 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, here, this could mean substantial cost-savings in terms of fewer patients needing surgery following their PFMT.

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Table 1: Means (standard deviation) for the entire sample in terms of age, BMI, anxiety (HADS_A), depression (HADS_D), and total psychological distress (HADS_T), along with the Pearson correlations between these scores

		BMI	Anxiety	Depression	Distress
Age	50.97 (11.98)	-.148	.228	.116	.213
BMI	31.37 (6.21)		-.195	.030	-.106
Anxiety	8.35 (4.51)			.333**	.830***
Depression	6.07 (4.21)				.802***
Distress	14.48 (7.12)				

* $p < .05$; ** $p < .01$; *** $p < .001$

Table 2: Intake means (standard deviation) for the two groups in terms of age, BMI, anxiety (HADS_A), depression (HADS_D), and total psychological distress (HADS_T)

	PFMT	PFMT + MIVS	<i>t</i>
Age	49.12 (10.76)	50.33 (11.56)	< 1
BMI	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

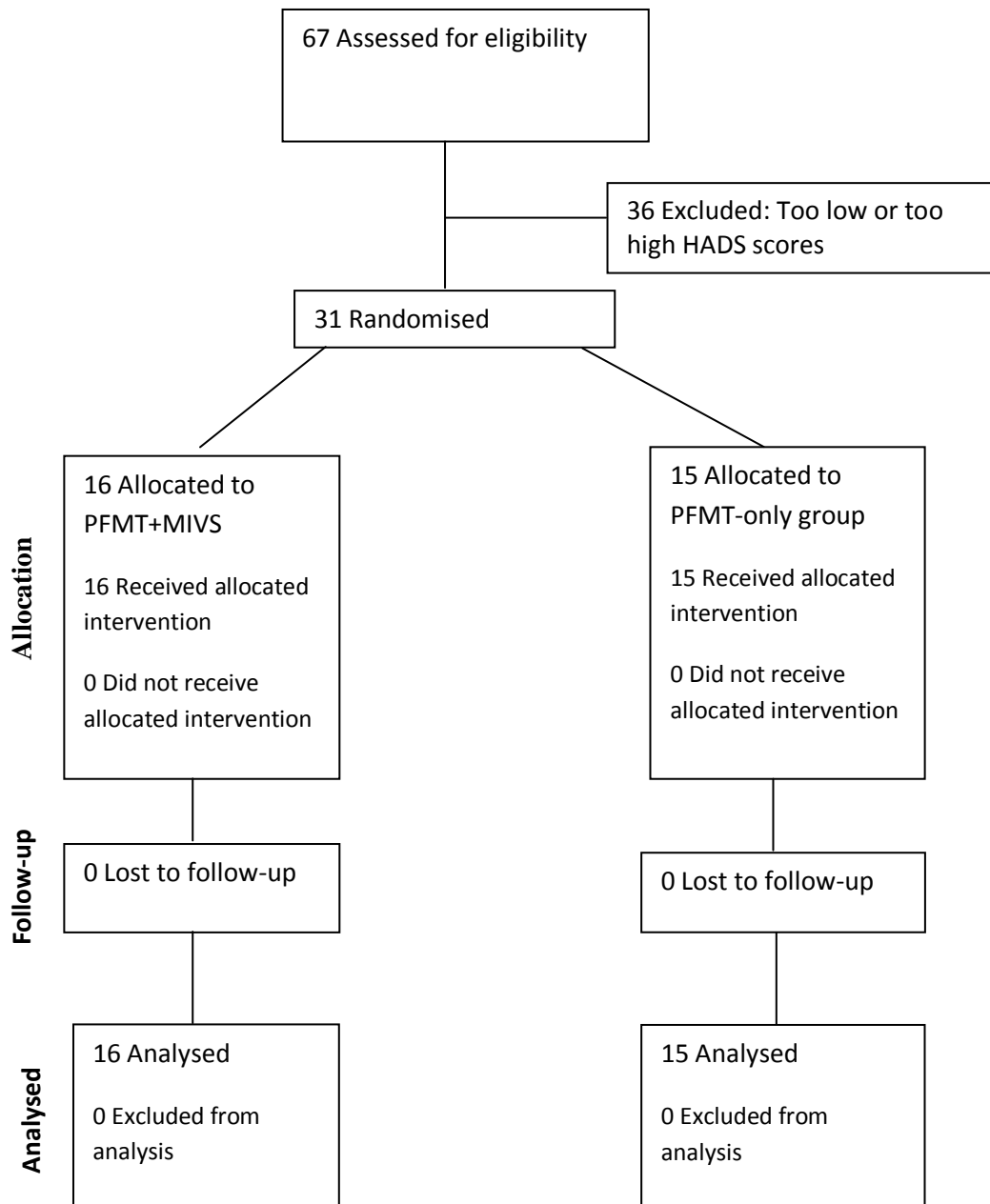


Figure 1: CONSORT diagram showing the flow of participants through each stage of the randomised control trial

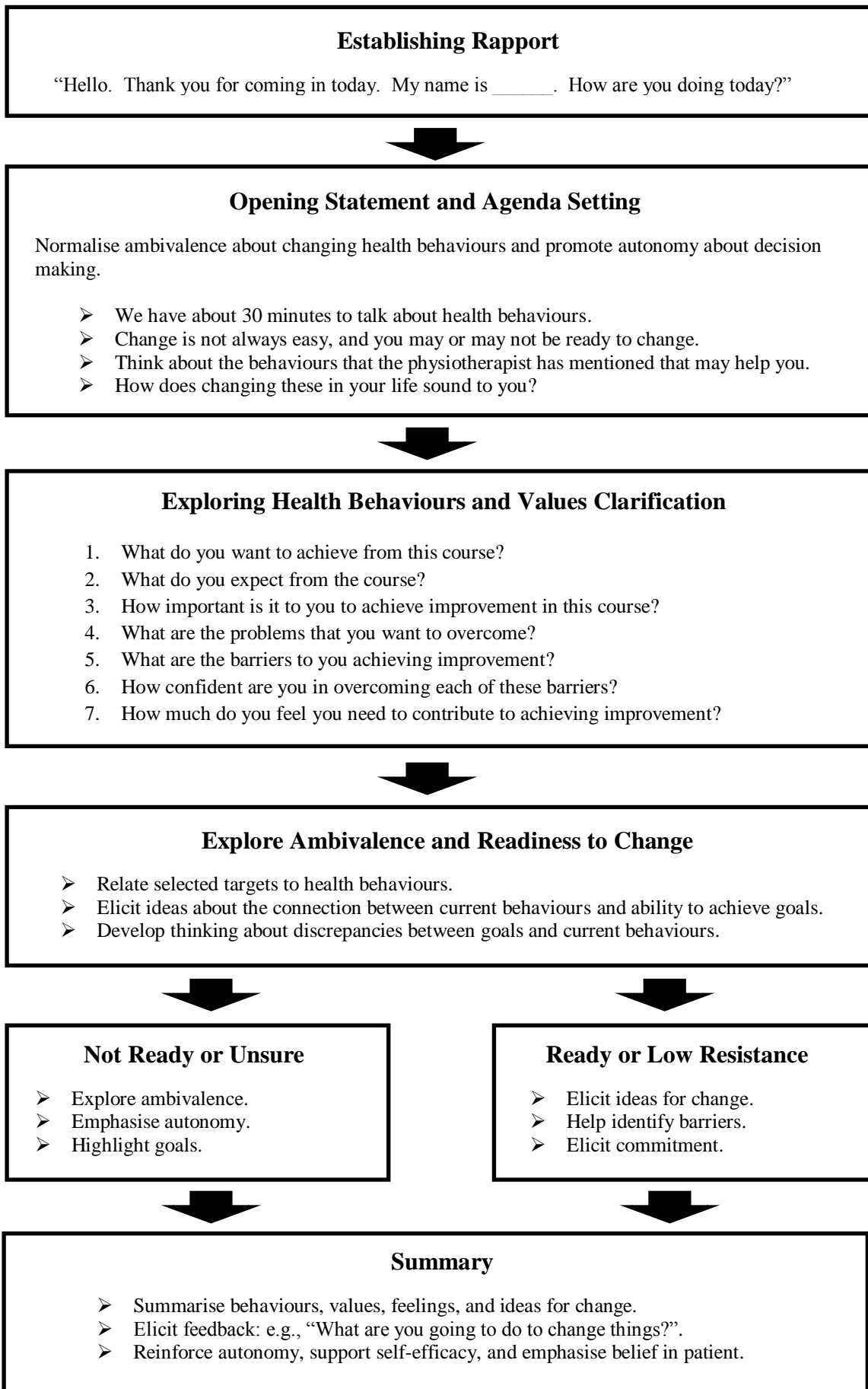


Figure 2: Summary of motivational values session

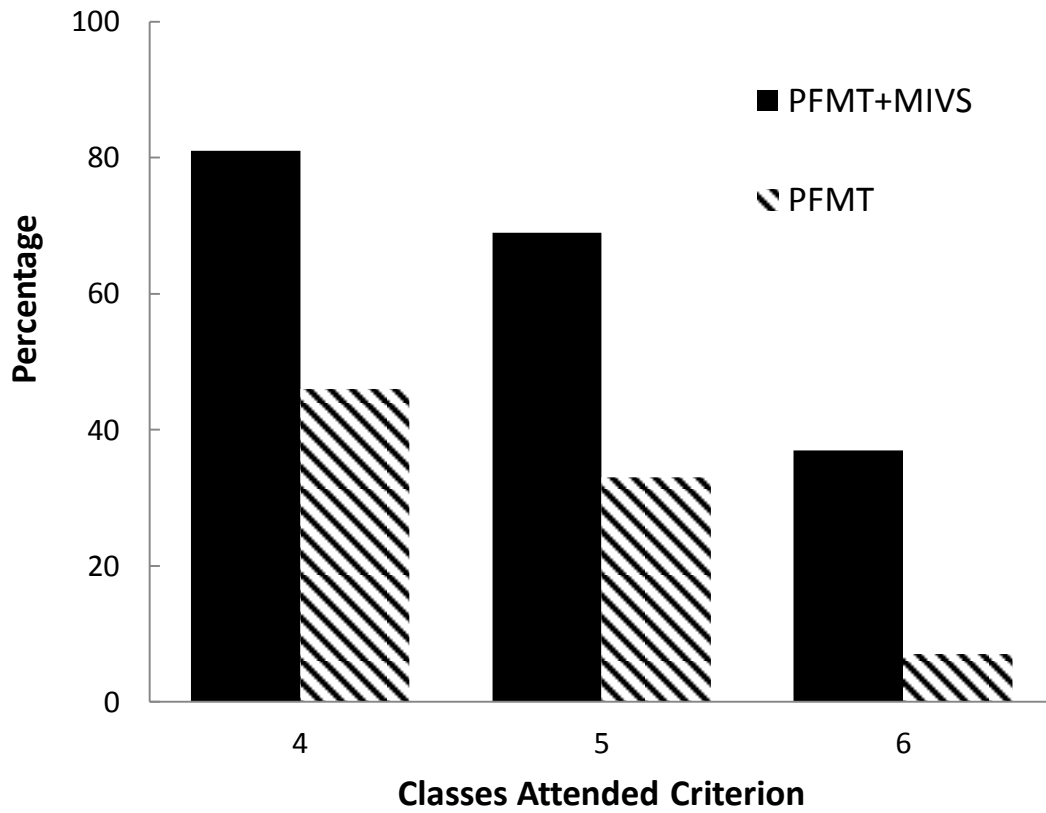


Figure 3: Percentage of participants in each group meeting various criteria of compliance (attendance) with classes: PFMT = pelvic floor muscle training treatment as usual; PFMT + MIVS = pelvic floor muscle training plus motivational interviewing and values support