# Evaluation of Booklet-Based Self-Management of Symptoms in Ménière Disease: A Randomized Controlled Trial

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**Objective:** This study examined the effectiveness of booklet-based education in vestibular rehabilitation (VR) and symptom control (SC) techniques to manage vertigo and dizziness in Ménière disease. **Methods:** Participants (n=360) were randomized to a waiting list control group or to receive either a VR or an SC self-management booklet. VR involved provoking dizziness in a controlled manner by making repeated head movements in order to promote neurological and psychological habituation. SC involved using applied relaxation, challenging negative beliefs, and lifestyle modification to reduce amplification of dizziness by anxiety. Subjective improvement in health, enablement (ability to understand and cope with symptoms), and adherence were measured at 3 and 6 months. Symptoms, handicap, anxiety and depression, and negative beliefs about symptoms were assessed pretreatment and at 3 and 6 months. **Results:** At 6-month follow-up, 45 (37.5%) of the VR group and 47 (39.2%) of the SC group reported improvement compared with 19 (15.8%) controls; the relative probability of improvement compared with controls was 2.37 (95% confidence interval [CI], 1.48–3.80) for VR and 2.47 (95% CI, 1.55–3.95) for SC. Both intervention groups reported greater enablement than controls (p < .001, d > 0.70). At 3 months, the VR group had reduced symptoms, anxiety, handicap, and negative beliefs about dizziness; the SC group had reduced handicap; but the control group showed no improvement. Reported adherence levels were low and strongly related to outcome. **Conclusions:** Self-management booklets offer an inexpensive and easily disseminated means of helping people with Ménière disease to cope with dizziness symptoms. **Key words:** vertigo, dizziness, vestibular diseases, clinical trial, self-care, cognitive-behavior therapy.

**VR** = vestibular rehabilitation; **SC** = symptom control; **VSS** = Vertigo Symptom Scale; **VSS-SF** = Vertigo Symptom Scale–Short Form; **CI** = confidence interval.

### **INTRODUCTION**

énière disease is a chronic, incurable disorder of the Inner ear, which results in impairment in balance and hearing. Changes in the vestibular organ in the inner ear (which senses balance) lead to recurrent, unpredictable attacks of vertigo, i.e., strong illusions of spinning or other motion (which can lead to falling), accompanied by autonomic symptoms such as nausea and vomiting. Intervals between severe attacks of vertigo can range from weeks to years, but frequent attacks of milder vertigo may be experienced, and persistent dizziness and unsteadiness is common (1). The disease also causes an intermittent sense of pressure in the affected ear(s), tinnitus (a loud ringing, buzzing, or roaring noise), and progressive permanent hearing loss, at first in one ear but often eventually in both (2). No medical treatment has been shown to reliably halt the progression of the disease, although a wide range of treatments is used to attempt to reduce the frequency, duration, and severity of symptoms (3,4).

As might be expected, there is evidence that Ménière disease is often associated with reduced quality of life and high levels of psychological distress (5–8). Vertigo is typically cited as the most distressing symptom (8–11). Vertigo and dizziness in other types of vestibular disorder have also been linked with psychological disturbance, including increased levels of anxiety, depression, panic, and agoraphobia (12–16). Several different mechanisms may be responsible for

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the association between vestibular disorder and psychological disturbance. The sudden, complete disorientation and sense of falling are intrinsically terrifying (10,12,14). Vestibular sensations may also automatically trigger fear and autonomic arousal through central connections between the vestibular and autonomic systems, whereas anxiety arousal may in turn augment symptoms of dizziness and nausea (17-19). Quality of life is impaired by current symptoms and may be further reduced by restriction of activity due to uncertainty about when another attack may occur and fear of provoking symptoms by exertion or stress (8,9,20). Distress may also be intensified by maladaptive responses to vertigo, such as excessive preoccupation with symptoms or catastrophic beliefs about the potential physical and social consequences of attacks (11,21,22). Clinicians caring for people with Ménière disease recognize the psychological impact of the disease and emphasize reassurance, patient education, and psychological support as key components of patient management (4,23). However, the nature of the support given is variable and rarely includes formal psychological evaluation and treatment. There is evidence that some people with Ménière disease feel that they do not receive sufficient information and support from their doctors (8). To date, there has been no evaluation of what specific forms of psychological support might be beneficial for this patient population.

Previous research suggests that two approaches to symptom management have the potential to help people with Ménière disease to tolerate and cope with their illness. Both approaches use cognitive-behavioral methods to influence psychophysiological function and encourage adaptive coping behavior. The first approach, vestibular rehabilitation (VR), entails performing daily exercises that at first provoke vertigo and dizziness but with repeated exposure promote neurological and psychological habituation. The second approach, referred to in this study as symptom control (SC), involves using applied relaxation, controlled breathing, and cognitive-behavioral strategies to reduce the amplification of symptoms by anxiety and psychophysiological arousal.

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The core rationale for VR is to promote central adaptation within the balance system, which can use input from vision, proprioception, and undamaged parts of the vestibular system to correct for abnormal input from the damaged vestibular organ (24,25). Repeated head movement is necessary for adaptation to occur because head movements stimulate the vestibular system. However, until adaptation occurs vestibular stimulation due to head movement causes vertigo and dizziness and is consequently avoided. VR therefore consists of deliberately making head movements that will gradually result in a reduction in movement-provoked dizziness. Intentionally provoking dizziness in a controlled and safe situation can also result in a decrease in anxiety about symptoms (26) and increase confidence in undertaking activities that may have been avoided because of fear of dizziness (25).

VR has been shown to alleviate symptoms and handicap and improve balance in patients with dizziness and vestibular disorder (27,28). Drugs that suppress vestibular symptoms often have central side effects and may retard adaptation, and so VR has been recommended as the treatment of choice for vertigo and dizziness after vestibular damage (29–31). VR cannot prevent acute spontaneous attacks of vertigo in Ménière disease but might provide a useful means of coping with the residual provoked dizziness and unsteadiness reported by most people with Ménière disease (32–34). However, there has been no controlled trial to date of the benefits of VR in Ménière disease.

The rationale for SC is based on the evidence that the experience of symptoms may be worsened by anxiety about symptoms and psychophysiological arousal (11,18,19,21). Anxiety about symptoms could be reduced by using cognitive-behavioral techniques to divert attention from symptoms and challenge catastrophic fears (35,36), whereas arousal could be reduced by methods of applied relaxation (37). There is also evidence that hyperventilation may contribute to vestibular symptoms (38-40) and that controlled breathing can reduce the nausea caused by disorientation (41). It is widely believed by clinicians and patients that stress can contribute to attacks of vertigo (4,10,34), and so stress-reduction techniques such as planning and time management might also prove beneficial. Many of these cognitive-behavioral techniques have been used successfully in conjunction with VR for vestibular disorder, though not specifically for Ménière disease (42–45). However, there has been no controlled trial to date of the benefits of SC alone either in vestibular disorder or specifically in Ménière disease.

Ideally, training in VR and SC should be provided face to face by a specialist who can evaluate the individual's particular symptoms, psychological problems, and circumstances; tailor the symptom-management techniques appropriately; and provide encouragement to persist with the program and advice on how to overcome difficulties. However, in the absence of available resources to provide such support, there is evidence that booklet-based education in self-management using cognitive-behavioral techniques can be of considerable benefit in the management of disorders ranging from anxiety to back pain

(46,47). A successful trial of VR for dizziness used booklet-based self-help, albeit supported by an initial brief face-to-face session with a nurse and telephone follow-up (28,48). Booklet-based therapy offers the advantage of being inexpensive and easily disseminated, but there has been no previous test of the effectiveness of booklet-based VR without support from a health professional. The aim of the present study was therefore to evaluate whether booklet-based education in symptom management techniques could help people with Ménière disease manage their vertigo and dizziness.

Our main hypothesis was that, when compared with a waiting-list control group, both the VR and SC interventions would result in greater improvement in subjective health and perceived ability to understand and cope with symptoms. For our secondary analyses, we predicted that treatment outcomes would be better in those who reported adherence to treatment and that a lower proportion of participants would adhere to VR (because of the dizziness it would provoke). The VR booklet was expected to have a more substantial effect than the SC booklet on symptoms and therefore also on the other outcome measures because it should result in gradual resolution rather than simply management of symptoms, but only in those who did adhere to treatment. Consequently, we anticipated that lower adherence in the VR group would reduce the difference in outcomes between the two booklet groups in the whole sample.

### **METHODS**

### Participant Recruitment and Selection

Participants were recruited in 2003 by sending members of the Ménière's Society (n=4800) an information sheet and consent form and screening questions for stratification. Members were eligible for participation if they had experienced symptoms of dizziness or imbalance over the past 12 months, had not had any severe vertigo attacks within the last 6 weeks, had consulted their GP to check there were no medical reasons why they should not take part in the trial, and could be contacted by post for the key stages of the trial. Members were excluded if they reported having a vestibular disorder other than Ménière disease.

Findings from a previous clinical trial in patients with dizziness (48) suggested that with a sample size of 86 patients per group we should be able to detect an effect size of 0.5 on the Vertigo Symptom Scale–Short Form (VSS-SF) with a two-tailed significance level of 5% and 90% power. However, we anticipated that variability in symptoms and outcome would be higher in people with Ménière disease because of spontaneous fluctuations in the severity of their disease. We therefore recruited 120 participants per group (Figure 1). The protocol was approved by the Ethical Committee of the School of Psychology, University of Southampton. Written informed consent was given by all participants before enrollment.

#### **Interventions**

Participants were randomized to three intervention arms: VR booklet, SC booklet, or waiting list control. The booklets were closely matched for style and length and were both professionally produced and designed using principles of behavior change derived from cognitive-behavior theory and self-regulation theory (49–51). To ensure positive but realistic beliefs, a question-and-answer format was used to provide evidence of treatment relevance and efficacy and to address common concerns. To promote self-efficacy and adherence, the booklets required participants to make a specific graded goal plan and written commitment and to actively adapt the intervention to their symptoms, capabilities, and lifestyle.

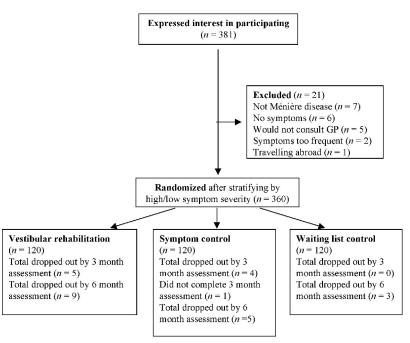


Figure 1. Flow of participants through the trial.

The VR booklet explained in lay terms how inadequate central compensation could contribute to symptoms and why balance training should facilitate habituation. Details were given of daily balance training exercises to carry out in the home and how to tailor these to the particular symptoms experienced. Participants were encouraged to resume activities in their daily lives that they had avoided because of dizziness, to promote generalization of habituation.

The SC booklet explained in lay terms how stress could augment symptoms of dizziness and nausea and why stress-reduction techniques should facilitate a reduction in symptoms. Details were given concerning how to carry out daily relaxation and controlled breathing exercises and how to use distraction to reduce attention to symptoms. Participants were encouraged to identify and challenge unrealistic expectations and catastrophic thoughts and reduce stress by planning and prioritizing.

### **Procedure**

Participants were stratified by symptom severity into blocks of 30 and then sent baseline questionnaires to complete. When all baseline questionnaires in a block had been returned, an independent research administrator allocated participants to the intervention arms using a computer randomization program and sent each participant a letter informing them which intervention group they had been assigned to. Those in the VR and SC groups were also sent the corresponding self-management booklet to use for 3 months. At the end of the 3-month intervention period, a follow-up questionnaire pack was sent. A final follow-up questionnaire pack was administered at 6 months. Participants in all groups were then sent the booklet(s) they had not received.

#### Measures

At baseline, single items were used to assess age, gender, and length of time since first symptoms were experienced. Symptoms during the past year were evaluated using the vertigo and anxiety subscales of the Vertigo Symptom Scale (VSS; long version) (19), the hearing disability scale (52), and single-item questions assessing tinnitus and fullness in the ear (53).

Our primary outcome measures were assessed at 3 and 6 months after baseline. Subjective improvement in health was assessed by a previously validated single item (48) asking whether, during the past week, the participant had felt better, much the same, or worse than when completing the baseline assessment. The Patient Enablement Instrument (PEI) (54) was used

to assess the extent to which participants felt more able to understand and cope with their illness than at baseline.

Our secondary outcome measures were administered at baseline and at 3 and 6 months after baseline to assess change following treatment. Symptom severity during the past month was assessed by the short form of the VSS-SF (48), and current handicap was assessed by the Dizziness Handicap Inventory (DHI) (55). Beliefs about likely negative consequences of an attack of dizziness were assessed by the Dizziness Beliefs Questionnaire (DBQ) (21), and anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS) (56).

To reduce social desirability effects on reporting of adherence at 3 months, participants completed a 12-item Problematic Experiences of Therapy Scale (PETS) that asked them to what extent they agreed that they had been prevented from carrying out the intervention by socially acceptable reasons: symptoms too severe or aggravated by therapy, doubts about treatment efficacy, uncertainty about how to carry out the treatment, practical problems (lack of time or opportunity, forgetting). They were then asked for how many weeks they carried out the therapy and whether they stopped because they were asymptomatic. Participants were considered to adhere to treatment if they carried out the exercises for the recommended period (9–12 weeks) or until asymptomatic.

### **Statistical Analysis**

For the intention-to-treat analyses of the primary outcome measure, subjective improvement in health was dichotomized into improvement versus not improved (combining no change or worse), and all cases with missing data were designated as not improved. Where missing data could not be imputed, the number of participants from whom data were obtained is given in the relevant table. For between-group comparisons, we used the  $\chi^2$  test for categorical variables and one-way ANOVA or independent t tests (for two-group comparisons) for continuous measures.

Pre-/posttreatment change using the measures administered at baseline and at 3 and 6 months was determined by a repeated-measures ANOVA with intervention group as a between-subjects factor, using Pillai's trace to examine multivariate effects. To permit intention-to-treat analysis, we brought forward the baseline scores of participants lost to follow-up, imputing no change. The Greenhouse-Geisser correction was used for univariate follow-up *F*-test comparisons when Mauchly's test of sphericity was significant. Paired

t tests were then used to identify significant change from baseline within groups. These analyses were repeated including only adherent participants in the intervention groups. To determine the effect of adherence on outcome, a further repeated-measures ANOVA was carried out, with the secondary outcome measures as the dependent variables but with adherence versus nonadherence as the between-subjects factor.

### **RESULTS**

There were no differences between the control and the two intervention groups on any of the baseline participant characteristics (see Table 1). Dropout was very low, with only 17 participants out of the sample of 360 failing to complete the final follow-up (Figure 1).

## **Between-Group Differences on Primary Outcome Measures**

There was a significant difference in subjective improvement in health between the three groups at 3 months and at 6 months (Table 2). At 3 months, only 23 (19.2%) people in the control group reported improvement compared with 42 (35.0%) in the VR group and 42 (35.0%) in the SC group. Both intervention groups therefore differed significantly from the control group ( $\chi^2 = 7.6$ , df = 1, p = .006) but not from each other, and the relative probability of improvement compared with controls was 1.83 (95% confidence interval [CI], 1.18–2.84) for both groups. By 6 months, the number of people in the control group who reported improvement had fallen to 19 (15.8%), whereas the number who had improved

had risen to 45 (37.5%) in the VR group and 47 (39.2%) in the SC group. Both intervention groups therefore continued to differ significantly from the control group (VR group,  $\chi^2$  = 14.4, df = 1, p < .001; SC group,  $\chi^2 = 16.4$ , df = 1, p < .001) but not from each other, and the relative probability of improvement compared with controls was 2.37 (1.48 to 3.80) for VR and 2.47 (95% CI, 1.55-3.95) for SC. Enablement scores were also much higher in the intervention groups (which did not differ significantly) than in the control group at 3 months (F(2, 347) = 17.94, p < .001) and 6 months (F(2, 340) =17.09, p < .001). The effect size (Cohen's d) for improvement in enablement compared with the controls was 0.74 and 0.72 for VR and SC, respectively, at 3 months and 0.72 and 0.71 at 6 months. Table 2 shows that the proportion of those in the intervention groups who reported feeling worse was lower than in the control group.

### Between-Group Differences on Secondary Outcome Measures

Multivariate tests of within-subjects effects revealed a significant interaction between intervention group and time (F (20, 2812) = 1.56, p = .05), indicating that change in symptoms from pre- to posttreatment differed in the three intervention groups. Univariate ANOVAs confirmed that there was a significant interaction between intervention group and change over time for anxiety (F (3.83, 2489.1) = 2.69, p = .03), depression (F (3.93, 2716.0) = 3.01, p = .02), and handicap

TABLE 1. Baseline Characteristics of Participants in the Three Intervention Groups

	$VR Group^a$ $(n = 120)$	SC Group <sup>b</sup> $(n = 120)$	Control Group $(n = 120)$	Total $(n = 360)$
Female, No. (%)	87 (72.5)	75 (62.5)	85 (70.8)	247 (68.6)
Age	58.0 (11.4)	60.0 (13.6)	59.7 (11.8)	59.2 (12.3)
Vertigo Symptom Scale–Vertigo	2.13 (0.76)	2.15 (0.76)	2.03 (0.72)	2.10 (0.74)
Vertigo Symptom Scale–Anxiety	2.43 (0.86)	2.46 (0.85)	2.40 (0.80)	2.43 (0.83)
Hearing Scale	12.6 (7.18)	14.3 (7.55)	13.6 (8.08)	13.5 (7.63)
Frequent severe tinnitus, No. (%)	90 (75.0)	88 (73.3)	92 (76.7)	270 (75.0)
Frequent incapacitating fullness in ear, No. (%)	79 (65.8)	74 (61.7)	82 (68.3)	235 (65.3)

Data are given as mean (SD) unless otherwise noted.

TABLE 2. Post-intervention Response on Single-Item Measure of Subjective Health Improvement and Enablement Score\*

	VR Group		SC C	Group	up Control Group	
	3 mo (n = 115)	6 mo (n = 111)	3 mo (n = 115)	6 mo (n = 115)	3 mo (n = 120)	6 mo (n = 117)
Subjective health						
Better	42 (36.5)	45 (40.5)	42 (36.5)		23 (19.2)	19 (16.2)
No change	50 (43.5)	50 (45.0)	58 (50.4)	49 (42.6)	66 (55.0)	69 (59.0)
Worse	23 (20.0)	16 (14.4)	15 (13.0)	19 (16.5)	31 (25.8)	29 (24.8)
Enablement						
PEI score	3.04 (3.71)	3.49 (3.96)	2.69 (3.07)	3.26 (3.49)	0.87 (1.90)	1.17 (2.34)

<sup>\*</sup> Subjective health data reported as No. (%). Enable scores reported as mean (SD). PEI = Patient Enablement Instrument.

<sup>&</sup>lt;sup>a</sup> VR Group = Vestibular Rehabilitation Group.

<sup>&</sup>lt;sup>b</sup> SC Group = Symptom Control Group.

TABLE 3. Level and Change in Pre-/Posttreatment Change Measures as a Function of Time in the Three Intervention Groups<sup>a</sup>

Intervention Group/Measure	Baseline (Mean, SD)	3 mo (Mean, SD)	6 mo (Mean, SD)	Change Between Baseline and 3 mo (With 95% CI)	Change Between Baseline and 6 mo (With 95% CI)
VR booklet					
Symptoms (VSS-SF)	15.36 (11.22)	13.76 (10.56)	13.71 (11.23)	-1.6 (-3.09 to -0.10)*	-1.64 (-2.96 to -0.32)*
Anxiety (HADS-A)	8.64 (4.09)	7.98 (3.88)	7.89 (4.51)	-0.66 (-1.24 to -0.08)*	-0.69 (-1.39 to 0.01)
Depression (HADS-D)	5.66 (3.56)	5.46 (3.75)	5.16 (4.02)	-0.22 (-0.71 to 0.28)	-0.42 (-0.98 to 0.14)
Handicap (DHI)	52.24 (21.19)	47.37 (22.95)	47.54 (23.31)	-4.79 (-6.72 to -2.86)***	-4.45 (-6.72 to -2.86)***
Beliefs (DBQ)	51.14 (9.23)	48.24 (9.02)	47.40 (10.57)	-2.93 (-4.45 to -1.42)***	-3.72 (-5.27 to -2.18)***
SC booklet					
Symptoms (VSS-SF)	14.52 (11.27)	13.31 (10.31)	13.38 (11.02)	-1.20 (-2.54 to 0.14)	-1.13 (-2.48 to 0.22)
Anxiety (HADS-A)	7.84 (4.02)	7.58 (4.32)	8.04 (4.37)	0.20 (-0.36 to 0.76)	0.20 (-0.36 to 0.76)
Depression (HADS-D)	5.49 (3.18)	5.20 (3.71)	5.62 (3.71)	-0.29 (-0.72 to 0.15)	0.13 (-0.33 to 0.58)
Handicap (DHI)	49.00 (19.27)	45.67 (21.12)	44.95 (20.96)	-3.30 (-5.43 to -1.18)**	-4.02 (-5.93 to -2.10)***
Beliefs (DBQ)	48.70 (8.76)	47.53 (10.24)	47.14 (10.60)	-1.18 (-2.52 to 0.16)	-1.57 (-3.07 to -0.06)*
Controls					
Symptoms (VSS-SF)	14.83 (11.11)	13.99 (11.06)	15.07 (11.19)	-0.84 (-2.17 to 0.48)	0.22 (-1.08 to 1.53)
Anxiety (HADS-A)	8.39 (4.92)	8.66 (4.84)	8.61 (4.78)	0.22 (-0.26 to 0.69)	0.16 (-0.37 to 0.69)
Depression (HADS-D)	5.78 (3.59)	5.46 (3.75)	5.16 (4.02)	0.38 (-0.11 to 0.86)	0.41 (-0.07 to 0.89)
Handicap (DHI)	49.60 (21.26)	48.49 (22.67)	48.61 (22.64)	-1.18 (-3.06 to 0.69)	-1.17 (-3.40 to 1.06)
Beliefs (DBQ)	49.09 (10.38)	48.17 (11.76)	47.82 (10.99)	-0.93 (-2.27 to 0.42)	-1.28 (-2.54  to  -0.02)*

<sup>\*</sup> p < .05; \*\* p < .01; \*\*\* p < .001.

(F (3.78, 2511.4) = 2.71, p = .03), a nearly significant interaction for beliefs (F (3.89, 2666.2) = 2.10, p = .08), but no significant interaction for symptoms (F (3.69, 2398.1) = 1.17, ns). The VR group improved significantly relative to baseline on four of the five measures at 3-month follow-up (all except depression) and three of the five measures at 6-month follow-up, whereas the control group improved only on beliefs at 6 months (see Table 3). The SC group improved on handicap at both follow-ups and on beliefs at 6 months.

### Adherence to Therapy

As expected, adherence to the intervention differed significantly between the intervention groups ( $\chi^2=4.27,\,df=1,\,p=.03$ ), with 60 (50.0%) of the SC group reporting adherence compared with only 45 (37.5%) of the VR group. Also as predicted, change from pre- to posttreatment was greater in those who reported adherence, i.e., there was a significant interaction between adherence level and change over time on the pre-/posttreatment secondary outcome measures (F (10, 882) = 2.35, p = .01). The analyses reported below therefore examine the effects of the interventions on change on the pre-/posttreatment secondary outcome measures for those in the intervention groups who reported adhering to the interventions

Multivariate tests of within-subjects effects confirmed that, as in the analysis of the total sample, the change in symptoms from pre- to posttreatment differed in the three intervention groups since a significant interaction was observed between intervention group and time (F(20, 1764) = 2.94, p < .001). Univariate ANOVAs indicated that when considering only those adhered, there was a significant interaction between

intervention group and change over time for all of the secondary outcome measures: symptoms (F (4, 1768) = 6.25, p = .002), anxiety (F (3.88, 1662.2) = 4.04, p = .003), depression (F (4, 1768) = 5.27, p < .001), handicap (F (3.58, 1415.2) = 7.81, p < .001), and beliefs (F (3.83, 1621.2) = 2.98, p = .02). From Table 4, it can be seen that at 3 months the adherent VR group members had improved significantly relative to baseline on all measures except anxiety, whereas the adherent SC group members had only improved on handicap. By 6 months, the adherent VR group members had improved significantly relative to baseline on all five secondary outcome measures, and the adherent SC group members had improved on symptoms, handicap, and negative beliefs.

The high- and low-adherence groups differed on all of the dimensions of the Problematic Experiences of Therapy Scale. Symptom severity or aggravation was the principal reason given for nonadherence in the VR group, whereas practical obstacles were reported as the principal problem in the SC group (Table 5).

### DISCUSSION

Both self-help booklets resulted in greater subjective improvement in health and confidence in understanding and coping with illness, relative to the waiting-list control group. Moreover, improvement in reported health and confidence in coping had increased by 6-month follow-up. Because similar effects were obtained with both booklets, it is impossible to exclude the possibility that this subjective improvement was due partly or wholly to the nonspecific psychological effects of participating in the intervention. These include an increase in expectations for improvement, receiving attention and re-

<sup>&</sup>lt;sup>a</sup> Analyses are based on data from 118 participants in the VR group, 118 participants in the SC group, and 119 participants in the control group. VSS-SF = Vertigo Symptom Scale-Short Form; HADS = Hospital Anxiety and Depression Scale; DHI = Dizziness Handicap Inventory; DBQ = Dizziness Beliefs Questionnaire.

TABLE 4. Level and Change in Pre-/Posttreatment Change Measures as a Function of Time in Adherent Patients in the VR and SC Groups<sup>a</sup>

Intervention Group/Measure	Baseline (Mean, SD)	3 mo (Mean, SD)	6 mo (Mean, SD)	Change Between Baseline and 3 mo (With 95% CI)	Change Between Baseline and 6 mo (With 95% CI)
VR booklet					
Symptoms (VSS-SF)	14.38 (11.02)	10.64 (9.87)	10.89 (10.29)	−3.73 (−6.25 to −1.22)**	-3.49 (-5.99 to -0.99)**
Anxiety (HADS-A)	8.31 (4.25)	7.29 (3.93)	6.60 (4.42)	-1.02 (-2.15 to 0.10)	-1.71 (-2.94 to -0.48)**
Depression (HADS-D)	5.82 (3.97)	4.82 (3.77)	4.40 (3.65)	−1.00 (−1.96 to −0.04)*	-1.42 (-2.30 to -0.54)**
Handicap (DHI)	51.64 (22.81)	41.20 (23.89)	42.40 (25.38)	-10.44 (-13.91 to -6.98)***	-9.24 (-13.44 to -5.05)***
Beliefs (DBQ)	50.73 (9.94)	46.80 (9.02)	45.09 (11.43)	−3.93 (−6.50 to −1.36)**	-5.64 (-8.30 to -2.99)***
SC booklet					
Symptoms (VSS-SF)	14.67 (10.65)	13.00 (11.17)	12.42 (10.11)	-1.68 (-3.59 to 0.25)	-2.25 (-4.20 to -0.26)*
Anxiety (HADS-A)	6.82 (3.86)	6.52 (4.16)	7.00 (4.24)	-0.30 (-1.03 to 0.43)	0.18 (-0.69 to 1.05)
Depression (HADS-D)	4.58 (2.79)	4.25 (3.29)	4.75 (3.74)	-0.33 (-0.84 to 0.18)	0.17 (-0.45 to 0.79)
Handicap (DHI)	48.13 (18.94)	43.90 (21.17)	42.47 (20.95)	-4.23 (-7.31 to -1.15)**	-5.67 (-8.50 to -2.83)***
Beliefs (DBQ)	48.47 (8.82)	46.85 (11.03)	45.75 (11.28)	-1.62 (-3.76 to 0.52)	-2.72 (-4.86 to -0.58)*

<sup>\*</sup> p < .05; \*\* p < .01; \*\*\* p < .001.

TABLE 5. Comparison of Problematic Experiences of Therapy Scale (PETS) Scores Between Those With High and Low Levels of Adherence and Between Those in the VR and SC Groups<sup>a</sup>

	Adhere	ence Level	Interven	Intervention Group		
	High (n = 105)	Low (n = 118)	VR Group (n = 112)	SC Group (n = 113)		
PETS: Symptoms severe/aggravated	1.38 (0.77)	2.36 (1.43)***	2.38 (1.44)	1.41 (0.80)***		
PETS: Uncertain how to perform	1.23 (0.62)	1.56 (0.96)**	1.33 (0.72)	1.46 (0.93)		
PETS: Doubt about efficacy	1.43 (0.82)	2.16 (1.14)***	1.84 (1.07)	1.81 (1.06)		
PETS: Practical obstacles	1.96 (1.13)	2.47 (1.23)**	1.98 (1.20)	2.46 (1.17)**		

<sup>\*\*</sup> p < .01 (Significant difference between groups compared on independent t test), \*\*\* p < .001 (significant difference between groups compared on independent t test).

assurance, and the implicit situational demand to report a positive outcome from an intervention that they had committed to. However, such effects are likely to be much smaller with anonymous receipt of a booklet and completion of questionnaire measures than after face-to-face contact with therapists and clinicians and would not be expected to be sustained for 6 months. Moreover, clinicians often openly acknowledge that many of the treatments they provide for Ménière disease, including drugs and surgery, may be beneficial partly or principally for these reasons (4,57,58). Self-help symptom management booklets could, therefore, at a minimum offer an inexpensive, nontoxic, and effective means of supplying patients' unmet needs for information and increasing their sense of well-being and control over illness.

The findings from the secondary analyses of measures administered before and after treatment suggest that the effects of the intervention may not have been entirely nonspecific. As predicted, small but significant effects of the interventions on change after treatment were observed in the whole sample, with more extensive benefits from the VR than the SC intervention. This pattern of findings was stronger when comparing those patients who reported adhering to treatment with controls. VR is the most direct and best validated method of reducing vestibular symp-

toms and, in this study, resulted in the greatest improvements in symptoms and vertigo-related handicap. VR also resulted in a reduction in anxiety and feared negative consequences of dizziness. In Ménière disease, carrying out exercises that provoke limited vertigo symptoms may help patients to distinguish provoked symptoms from signs of the onset of a fresh attack, thus reducing concern about mild residual symptoms. Because people with Ménière disease know they are likely to have future spontaneous vertigo attacks, learning techniques for speeding recovery from these attacks may also be helpful for reducing anxiety. Nevertheless, the SC intervention also led to a reduction in handicap, even though little decrease in symptoms was observed. This suggests that the most effective component of this intervention may have been the advice on planning and engaging in activity, whereas the education in applied relaxation and controlled breathing techniques may not have achieved the intended psychophysiological effects on symptoms.

The small size of the effects of the interventions on symptoms in the whole sample is partly to be expected due to the much larger variations in symptoms that will inevitably occur due to spontaneous attacks of severe vertigo. However, because those who reported adherence had much better outcomes, it seems likely that the effects of the interventions were

<sup>&</sup>lt;sup>a</sup> Analyses are based on data from 45 participants in the VR group and 60 participants in the SC group.

<sup>&</sup>lt;sup>a</sup> Data are given as means (SD).

also limited by the low levels of adherence, particularly in the VR intervention. Symptom severity or aggravation by therapy was the main reason given for nonadherence to VR. Some participants may have been prevented from carrying out VR because of spontaneous severe attacks of vertigo, and for these people the SC intervention, although less effective, may be most appropriate. However, some people may have been unable to tolerate the milder symptoms provoked by head movement or may have misinterpreted provoked symptoms as initial signs of a spontaneous attack. Therapist support and advice (for example, regarding grading exposure to provocative head movements) might reduce dropout and improve outcomes in people who are concerned about symptoms provoked by VR.

This study was carried out in a volunteer sample from a self-help group, who therefore cannot be regarded as representative of all people with Ménière disease. Although the age and gender profile and symptom levels were broadly similar to those observed in unselected hospital samples (59), it is likely that participants felt themselves particularly in need of the interventions offered and may therefore have been more likely to benefit. Uptake from members of the self-help group was very low, although it is impossible to estimate what proportion of members might have been potentially eligible for the trial. Many members had very longstanding illness and were likely to feel that they had been provided with or obtained the information and support they needed at some time in the past. Many may have been in remission or had too frequent spontaneous attacks to be eligible for the trial. Some of those experiencing symptoms may have mistakenly interpreted these as spontaneous attacks and concluded that they did not meet our eligibility criteria. It is therefore possible that uptake of these interventions might be considerably higher if they were suggested to appropriate people by a therapist.

Despite the limitations of this study, it provides a clear demonstration that self-management booklets offer an inexpensive and easily disseminated means of improving well-being and coping in people with Ménière disease who feel in need of information about controlling their symptoms. It also provided a useful first test and comparison of the effects of VR and SC on physical symptoms and psychological disturbance in Ménière disease. Further research is needed to determine whether therapist support for these interventions might result in better adherence and larger treatment effects.

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