A randomized controlled trial of exercise therapy for dizziness and vertigo in primary care

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SUMMARY

Background. *'Vestibular rehabilitation' (VR) is an increasingly popular treatment option for patients with persistent dizziness. Previous clinical trials have only evaluated the effects of specialist therapy programmes in small, selective, or uncontrolled patient samples.*

Aim. *To determine the benefits of VR compared with standard medical care, using a brief intervention for dizzy patients in primary care.*

Method. *Adults consulting their general practitioner (GP) with dizziness or vertigo were randomly assigned to treatment or control groups. Patients in both groups received the same evaluation at baseline, six-week follow-up, and six-month follow-up, comprising examination of nystagmus, postural control, and movement-provoked dizziness, and a questionnaire assessment of subjective status, symptoms, handicap, anxiety, and depression. At baseline and six weeks later, the treatment group also received an individualized 30-minute therapy session, in which they were taught head, eye, and body exercises designed to promote vestibular compensation and enhance skill and confidence in balance.*

Results. *The treatment group (n = 67) improved on all measures, whereas the control group (n = 76) showed no improvement, resulting in a significant difference between the two groups on physical indices of balance and subjective indices of symptoms and distress. Odds ratios for improvement in treated patients relative to untreated patients were 3.1 : 1 at six weeks (95% CI = 1.4–6.8) and 3.8 : 1 at six months (95% CI = 1.6–8.7).*

Conclusion. *VR is a simple, inexpensive, and beneficial treatment, and may be an appropriate first stage of management for many dizzy patients in primary care.*

Keywords: vertigo; dizziness; vestibular rehabilitation; randomized controlled trial.

Introduction

PERSISTENT dizziness or vertigo, which interferes with daily activities, is reported by one in 10 adults, and most of these consult their general practitioner (GP) at some time on account of this complaint.[1,2] Common aetiologies include vestibular, cardiovascular, iatrogenic, and psychiatric disorders, but the proportion of cases that can be ascribed to readily remediable causes is relatively small.[3,4] Only a minority of patients are referred for specialist testing and treatment, as this is costly and by no means certain to result in a definitive diagnosis and course of treatment.[2,5-7]

There is clearly a need to provide some form of therapy for patients with chronic dizziness, as it is associated with significant disability, handicap, and psychological distress, and may contribute to damaging falls in later life.[1,8-10] 'Vestibular rehabilitation' (VR) or 'balance retraining' is recommended for patients whose dizziness may be caused by uncompensated vestibular dysfunction.[11-13] The central element of this therapy is a programme of graded exercises consisting of eye, head, and body movements. These are designed to stimulate the vestibular system and, hence, promote central compensation, while at the same time allowing patients to overcome their fear of activities that may elicit disorientation and to regain both skill and confidence in balance.[14] Chronic dizziness is frequently accompanied by secondary problems, such as anxiety, hyperventilation, neck pain (often caused by adopting a rigid head position in order to avoid provocative head movements), or phobic avoidance of disorienting situations, such as motorways or shopping malls. Consequently, it is sometimes necessary to supplement the core exercises with training in relaxation, breathing control, or progressive exposure to feared situations.

In uncontrolled trials of VR, improvement in over 80% of patients is typically reported.[15-17] Recent small-scale trials have also confirmed the benefits of VR compared with a no-treatment control,[18] a placebo form of exercise therapy,[19] and medication.[19,20] In view of the small and selective samples employed and the limited non-blind outcome measures used, these preliminary findings require confirmation. Therefore, the first objective of the clinical trial described below was to carry out a substantial randomized study of the benefits of VR compared with normal medical care in a heterogeneous sample of dizzy patients. Our second aim was to establish whether treatment could be provided effectively at the primary care level. The programmes of VR assessed in previous trials typically consisted of comprehensive evaluation of balance system function followed by several sessions of therapy with specialist health professionals. As the core exercises used in VR are actually very simple, we wished to determine whether VR might be delivered effectively to the majority of patients using a brief intervention by an appropriately trained nurse.

Method

Sample

The study was conducted in 10 general practices of varying size and composition from throughout the South Thames Region, plus one in the North Thames Region. Ethical approval was obtained from the ethics committee for each participating practice.

Patients over 18 years of age were considered eligible if they consulted their doctor with a complaint of dizziness or vertigo.

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Patients were excluded if the performance of vigorous head or body movements during exercise therapy was contraindicated, or if they had a diagnosed non-vestibular cause for the dizziness, or multiple, life-threatening or progressive central disorders.

Basing our estimation on longitudinal data from hospital patients,[21] we estimated that a minimum total sample size of 100 patients was needed in order to detect (with a two-tailed significance level of 5% and a power of 80%) an improvement of at least half a standard deviation in the treatment group on our measure of anxiety and depression, while a sample of 160 would be needed to detect a similar improvement in handicap scores.

General practitioners in participating practices referred patients directly by giving them an information sheet with a consent form (and prepaid envelope) to return to the second author (SB). As the referral rate by this route proved insufficient to meet the requirements of our timetable and required sample size, potentially eligible patients were also identified from computer records by searching for the prescription of common medications for dizziness during the past five years (in four practices in which only medication was recorded), or for a history of dizziness, vertigo, or audiovestibular dysfunction during this period (in four practices in which diagnoses were also recorded). Suitability for the study was confirmed by the patient's doctor from an inspection of the medical records, and these patients were sent a letter inviting them to participate if they were still symptomatic, with an information sheet, consent form, and prepaid envelope enclosed.

Design

The study was a prospective, randomized, controlled trial. All patients received normal medical care and were visited at home for an identical assessment at baseline, six weeks' follow-up, and six months' follow-up. After baseline assessment, patients were randomly assigned by the research nurse (using random number tables) either to 'vestibular rehabilitation' (VR; described below) or to the normal medical care control group who were given VR only after their six-month follow-up assessment. Outcome was assessed by self-ratings of dizziness provoked by a standard set of movements supervised by the therapist, by timed balance on the sharpened Romberg test, and by self-ratings on questionnaires completed and returned in confidence to the first author (LY). Therapy and physical assessment were carried out by the nurse (SB), who had no previous relevant experience, but was given two weeks of training, observation, and supervised practice by the first author and by clinicians at the Royal National Throat, Nose and Ear Hospital

Treatment

A 30- to 40-minute VR session was given after assessment at baseline and six-week follow-up. The therapist explained to the patient (with the aid of written material) how the balance system functions, the causes of dizziness, and the rationale and contraindications for performing the exercises. She then guided patients through eight sets of standard head and body movements to be performed twice daily, which were supplemented as necessary with training in relaxation, slow breathing, and graded resumption of activity. At the six-week follow-up, the instructions were repeated, problems addressed, and additional elements of therapy prescribed.

Patient evaluations

Assessments were based on medical records, physical examination, and completion of a questionnaire booklet at baseline, six weeks, and six months.

Demographic and clinical characteristics. Demographic data comprised age, sex, and occupation. Clinical data comprised diagnosis (from medical records), referral route, and duration of dizziness (assessed by questionnaire). Physical examination consisted of conventional assessments of balance system function,[7] comprising:

- Presence of nystagmus with eyes open, with and without fixation (which was removed by Frenzel glasses), looking for 30 seconds to the centre and 30° to left and right; nystagmus was coded as mild peripheral type if present only without fixation, and as severe peripheral or central if present with fixation.
- Performance on the standard Romberg test; patients were coded as failing the test if they were unable to stand with feet together for 20 seconds, with eyes open and then with eyes closed.
- Performance on the Unterberger test; coded as degrees rotated while attempting to march in place with eyes closed and arms extended.

Outcome measures. Subjective improvement was assessed at follow-up by a single questionnaire item asking patients to indicate whether, during the past week, they had felt better, much the same, or worse than when they first completed the questionnaire. Symptoms were assessed by a shortened (14-item) version of the validated Vertigo Symptom Scale[22] (score range 0–60, reliability at baseline as indicated by alpha coefficient 0.88, test–retest reliability in the control group over a six-week period 0.60), which measures frequency of dizziness, vertigo, imbalance, and related autonomic symptoms (nausea, sweating, etc.) during the past month. Anxiety/depression was assessed using the composite score of the validated (14-item) Hospital Anxiety and Depression Scale (score range = 0–42, reliability = 0.86, test–retest = 0.85), which measures non-somatic symptoms of anxiety and depression during the previous week.[23] As anxiety and depression were highly correlated (0.60), the scales were combined as a measure of emotional distress. Handicap was assessed by a shortened (14-item) version of the validated Vertigo Handicap Questionnaire[24] (score range = 0–56, reliability = 0.86, test–retest = 0.67), which measures restriction of activity caused by dizziness at the time of completion and the social effects of this activity restriction. Provocative movements were assessed using a standard subset of seven exercises from those used in therapy, and the number of exercises after which the patient reported dizziness was recorded (score range = 0–7, reliability = 0.80, test–retest = 0.72). Sharpened Romberg tests (standing for up to 20 seconds with feet placed heel-to-toe) were carried out, twice with the eyes open and twice with the eyes closed, and the total time in seconds for which the patient maintained balance on the four tests was summed (score range = 0–80, reliability = 0.85, test–retest = 0.66).

Statistics

The chi-squared test was used to compare the frequency of subjective improvement in the treatment and control groups, and odds ratios were calculated to indicate the comparative likelihood of improvement for individuals in each group. ANCOVA (analysis of covariance) was used to test for differences between the mean group scores on the five outcome measures at each follow-up, controlling for differences in group scores at baseline. Within-group change is shown as 95% confidence intervals for changes in mean scores from baseline to follow-up (Table 4).

Results

Participation and dropout

Participants included 41 (69.5%) of the 59 patients referred directly by their GP who agreed to take part, three self-referred patients, and 115 (35%) of the 327 patients identified from computer records. Of these 159 patients, 16 dropped out of the study before follow-up and were excluded from the analysis. Some individuals failed to complete either the physical or the questionnaire assessments at the six-week or six-month follow-ups, and so precise figures are given for the sample size in all the analyses below. The only variable on which completers and non-completers differed significantly at baseline was the number of movements provoking symptoms, which was higher in non-completers than in completers in the treatment group (mean difference = 1.1, 95% CI = 0.6–2.1).

Baseline characteristics

Baseline measures and data from at least one follow-up assessment were obtained for 67 patients in the treatment group and for 76 in the control group. The groups did not differ significantly on any demographic or clinical characteristic at baseline (see Table 1). The duration of illness was under two years in only 49 (34.3%) cases, and 54 (37.8%) participants had been dizzy for more than five years. Less than a third of the sample had specific diagnosed audiovestibular conditions; these included Ménière's disease (6), labyrinthitis (12), benign paroxysmal positional vertigo (7), ear disease (9), and aural surgery (5).

Outcome measures

The proportions of the treatment and control groups who indicated on the two single-item measures of improvement that they felt better, unchanged, or worse than they had at baseline are shown in Table 2. There was a significant trend towards greater improvement in the treatment group at six weeks ($\chi^2 = 7.9$, df = 2, $P = 0.02$), which became more marked at six months ($\chi^2 = 12.0$, df = 2, $P = 0.002$). When the categories 'worse' and 'unchanged' were collapsed to allow comparison of those who did and did not report improvement, the odds ratio for improvement in treated patients relative to untreated patients was 3.1 : 1 at six weeks (95% CI = 1.4–6.8) and 3.8 : 1 at six months (95% CI = 1.6–8.7).

Mean scores on the five principal outcome measures at baseline, six weeks, and six months are shown in Table 3. Mean changes in outcome measures at the six-week and six-month assessments are shown in Table 4. There was a consistent trend towards improvement in scores on all the measures in the treatment group, resulting in a significant change at the six-month follow-up on every measure. The control group did not show consistent signs of improvement on any measure. The control group had slightly, but not significantly, worse scores on all measures at baseline but, by the six-month follow-up, had significantly worse scores on measures of symptoms, anxiety and depression, provocative movements and the sharpened Romberg test. After controlling for baseline levels of each outcome measure, ANCOVA confirmed a statistically significant difference at

Table 2. Proportion of treatment and control groups who rated themselves 'worse', 'much the same', or 'better' at six-week and six-month follow-ups (percentages, with numbers in brackets).

	Treatment group	Control group
Six weeks		
Worse	10.4 (5)	19.7 (12)
Much the same	35.4 (17)	52.5 (32)
Better	54.2 (26)	27.9 (17)
Six months		
Worse	2.4 (1)	17.7 (11)
Much the same	28.6 (12)	45.2 (28)
Better	69.0 (29)	37.1 (23)

Table 1. Baseline characteristics of patients in treatment and control groups (figures are the number of patients with percentage of group in brackets, unless otherwise stated).

	Treatment group (*n* = 67)	Control group (*n* = 76)
Demographic characteristics		
Sex		
Men	15 (22.4%)	13 (17.1%)
Women	52 (77.6%)	63 (82.9%)
Age (mean and SD)	60.1 (15.2)	59.6 (15.9)
Occupational category		
Classes I–III	21 (31.3%)	33 (43.4%)
Classes IV–VI	14 (20.9%)	6 (7.9%)
Retired/student/unemployed	32 (47.8%)	37 (48.7%)
Clinical characteristics		
Diagnosis		
Vertigo/audiovestibular disorder	48 (71.6%)	44 (58.8%)
Dizziness, unknown origin	19 (28.4%)	32 (42.1%)
Referral route		
Direct GP referral	17 (25.3%)	19 (25.0%)
Computer/self-referral	50 (74.7%)	57 (75.0%)
Duration of dizziness in weeks (mean and SD)	338 (371)	422 (561)
Nystagmus		
Mild peripheral type	14 (20.9%)	23 (30.2%)
Severe peripheral or central	21 (31.3%)	17 (22.4%)
Failed Romberg test (eyes open or closed)	7 (10.4%)	8 (10.5%)
Degrees rotated on Unterberger test (mean and SD)	75.3 (125)	69.5 (129)

SD = standard deviation.

Table 3. Scores on outcome measures in the treatment and control groups at baseline and at six-week and six-month follow-ups (for patients completing all three assessments).

Outcome measure	Treatment group	Control group	95% CI for difference between means
Symptoms (43:54)[a]			
Baseline	10.9 (9.3)	13.0 (12.4)	-2.4 to 6.7
Six weeks	7.9 (6.4)	12.9 (11.8)	1.0 to 9.0
Six months	7.7 (8.2)	12.5 (11.0)	0.8 to 8.8
Anxiety/depression (44:60)			
Baseline	11.8 (7.3)	13.7 (7.0)	-0.9 to 4.7
Six weeks	9.4 (5.9)	13.8 (7.2)	1.7 to 7.0
Six months	9.3 (6.0)	13.6 (7.7)	1.5 to 7.1
Handicap (43:52)			
Baseline	17.0 (10.6)	19.1 (11.0)	-2.3 to 6.6
Six weeks	16.0 (9.9)	19.4 (10.6)	-0.8 to 7.6
Six months	14.8 (9.7)	18.4 (11.1)	-0.6 to 7.9
Provocative movements (47:62)			
Baseline	2.8 (2.1)	3.5 (2.4)	-0.2 to 1.6
Six weeks	2.3 (2.3)	3.7 (2.5)	0.5 to 2.3
Six months	1.7 (2.2)	3.9 (2.6)	1.3 to 3.2
Sharpened Romberg test (47:61)[b]			
Baseline	48.6 (25.6)	46.2 (28.1)	-12.8 to 8.0
Six weeks	52.0 (26.8)	42.1 (28.7)	-20.6 to 0.8
Six months	55.0 (26.0)	43.3 (28.4)	-22.2 to -1.1

The means for each group are shown with standard deviations in brackets and 95% confidence intervals for the difference between group means. [a]Figures in brackets following outcome measure indicate the numbers of patients in the treatment and control groups respectively, on which analysis based. [b]Note that an elevation in scores on this test corresponds to better balance, i.e. an increase in the number of seconds for which the patient was able to balance.

Table 4. Magnitude of improvement in outcome measures in treatment and control groups for all patients who completed at least one follow-up assessment.

Outcome measure	Six-week follow-up				Six-month follow-up			
	Treatment group		Control group		Treatment group		Control group	
	Mean (CI)	*n*	Mean (CI)	*n*	Mean (CI)	*n*	Mean (CI)	*n*
Symptoms	2.1 (-0.2 to 4.3)	48	-0.1 (-2.8 to 2.5)	62	2.7 (0.5 to 5.0)	47	0.7 (-2.2 to 3.6)	56
Anxiety/depression	2.2 (1.0 to 3.4)	51	-0.3 (-1.2 to 0.6)	67	2.1 (1.0 to 3.3)	48	0.2 (-1.1 to 1.5)	61
Handicap	1.1 (-0.8 to 3.0)	51	-0.4 (-2.6 to 1.9)	60	2.3 (0.1 to 4.5)	47	0.7 (-2.1 to 3.6)	53
Provocative movements	0.8 (0.3 to 1.3)	47	-0.3 (-0.7 to 0.2)	73	1.0 (0.3 to 1.6)	50	-0.4 (-0.1 to 0.9)	63
Sharpened Romberg test	3.3 (-1.5 to 8.2)	60	-4.0 (-9.1 to 1.0)	71	5.5 (0.2 to 10.9)	49	-3.2 (-9.6 to 3.2)	63

Figures show absolute improvement between baseline and follow-up scores (with 95% confidence interval in brackets) and number of patients included in each comparison.

follow-up between the treatment and control group in symptoms ($F_{1,94} = 8.2$, $P = 0.005$), anxiety and depression ($F_{1,101} = 19.0$, $P<0.001$), provocative movements ($F_{1,106} = 19.9$, $P<0.001$) and the sharpened Romberg test ($F_{1,105} = 6.8$, $P = 0.01$), but the difference in handicap did not reach significance ($F_{1,92} = 2.2$, $P>0.05$).

Discussion

The outcome of this clinical trial clearly indicates a potential role for the delivery of basic VR in primary care. There was significant improvement in the treatment group on virtually every index, from objective measures of postural control to subjective reports of symptoms and emotional status. Improvement was already evident at the six-week follow-up and was enhanced at the six-month follow-up. In contrast, during this period, the control patients had no reduction in symptoms or anxiety and depression, and no improvement in balance. Overall, the likelihood of subjective improvement was nearly four times greater in the treatment group than in the control group. These findings compare very favourably with the results of clinical trials of medication and surgery for dizziness and vertigo, which have repeatedly failed to demonstrate any difference in rates of recovery in treatment relative to control groups.[25,26]

While these findings are encouraging, the reduction in symptoms and improvement in balance observed in this trial were relatively modest. VR is not expected to effect a total elimination of symptoms in the majority of cases,[15,27] as the underlying organic causes of dizziness and imbalance often persist or recur. Nevertheless, there is evidently a need for further research in order to determine whether a greater reduction in symptoms can be achieved and to identify the optimal treatment package. The very basic treatment programme used in this study might be upgraded in a number of respects, for example by providing reg-

ular group support and feedback sessions and by tailoring the therapy programme more precisely to the patients' individual needs. Moreover, problems of motivation were revealed in this trial by the dropout rate from treatment of one in four patients and the observation by the therapist that very few patients performed the exercises vigorously enough to maximize vestibular compensation. Motivation is a key ingredient in the success of VR, which requires the patient to induce dizziness deliberately. Better results may be attained in future with more positive endorsement of VR (which we described to patients in this trial as an experimental treatment) followed up by closer monitoring and additional advice and encouragement.

Although no formal cost–benefit analysis was undertaken, our brief intervention, consisting of two 30- to 40-minute therapy sessions with a trained nurse, is likely to prove cost-effective in comparison with either long-term prescription of medication or referral to specialist clinics, especially if it can be delivered in group sessions. Moreover, early provision of VR may prevent the development of the difficult secondary psychosocial and physiological problems often seen in patients who are referred to hospital after suffering dizziness for several years. VR could be provided at the primary care level either by a suitably trained member of the practice staff or as a liaison service, and may be an appropriate first stage of management for many dizzy patients in primary care, reserving referral for specialist testing and treatment for those with sinister, complex, or recalcitrant symptoms.

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