

BMJ Open Internet-based vestibular rehabilitation for adults aged 50 years and over: a protocol for a randomised controlled trial

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ABSTRACT

Introduction: Dizziness is highly prevalent in older adults and can lead to falls, fear of falling, loss of confidence, anxiety and depression. Vestibular rehabilitation (VR) exercises are effective in reducing dizziness due to vestibular dysfunction, but access to trained therapists is limited. Providing dizzy patients with booklets teaching them how to carry out VR exercises has been shown to be a cost-effective way of managing dizziness in primary care. Internet-based intervention delivery has many advantages over paper-based methods, including the provision of video instructions, automated tailoring and symptom-related feedback. This trial will examine whether an internet-based VR intervention is (1) effective in reducing dizziness and (2) a cost-effective primary care treatment option.

Methods/analysis: This will be a single blind, randomised controlled trial carried out in UK primary care. A stand-alone internet-based VR intervention will be compared with routine care in 262 dizzy patients aged 50 years and over. Measures will be taken at baseline, 3 and 6 months. Our primary outcome measure will be the effectiveness of the intervention in reducing dizziness symptoms compared with routine care at 6 months. Cost-effectiveness will be examined along with the effect of the intervention on dizziness-related disability and symptoms of depression and anxiety. Psychological process variables including expectancy, self-efficacy and acceptance will be explored in relation to adherence and symptom reduction.

Ethics/dissemination: This trial has undergone ethical scrutiny and been approved by an NHS Research Ethics Committee, Southampton A REC Reference: 13/SC/0119. The findings of this trial will be disseminated to the scientific community through presentations at national and international conferences, and by publishing in peer review journals. Findings will be disseminated to the public through targeted press releases. This trial will provide valuable information on the role of internet interventions in facilitating self-management in older adults.

Trial registration number: ISRCTN: 86912968.

Strengths and limitations of this study

- This protocol describes a fully powered trial to determine the effectiveness of internet-based vestibular rehabilitation in primary care patients aged 50 years and over.
- Cost-effectiveness of the internet-based intervention will be examined in comparison with usual care.
- Internet access and use may still be limited in older adults, so this mode of delivery will not be accessible for all older patients experiencing dizziness.

INTRODUCTION

Dizziness affects more than 1 in 5 adults above the age of 60¹ and is associated with falls, fear of falling, loss of independence, anxiety and depression.^{2–4} A screening test for poor balance due to vestibular dysfunction revealed deficits in 50% of those aged over 60.⁵ Experiencing dizziness as an older adult can lead to significant disability, medical consultation or medication use,¹ as well as avoidance of physical activity to not provoke symptoms. This avoidance behaviour leads to increased frailty, reduced confidence in balance and vulnerability to falling.^{4 6–8}

In those who present to primary care, a very common cause of dizziness is peripheral vestibular disorder. Serious sinister pathology in patients with no other symptoms is rare.^{9–13} Treatment typically consists of reassurance and medication for symptomatic relief.^{9–11 14} Medications prescribed for dizziness due to vestibular disorder do not have well-established preventative or curative effects, thus exercises designed to facilitate vestibular rehabilitation (VR) are now recommended as the treatment of choice.^{10 15–17} VR involves the patient

carrying out graded exercises for 10–20 min daily for 6–12 weeks, consisting of specific combinations of eye, head and body movements that stimulate the vestibular system so as to promote neurological adaptation to the altered input from the damaged labyrinth.^{14 18 19} Performing these exercises also helps patients to overcome fear and avoidance of activities that provoke dizziness, thus regaining skill and confidence in balance and subsequently reducing the risk of falls.^{20 21} VR has been shown to be an effective treatment for dizziness in older people^{2–23} and has been successfully combined with cognitive behavioural therapy, highlighting the potential for integration of additional psychotherapeutic techniques within VR programmes.^{22 23}

The delivery of VR remains severely limited. Access can involve lengthy referrals to secondary care and it is often difficult to locate suitably trained therapists. In a previous trial of VR, only 3% of patients had been previously offered VR despite a mean 8-year duration of dizziness.²⁴ Booklet-based self-management programmes have been developed to increase access to VR by facilitating the practice of rehabilitation exercises alone or with limited guidance. Self-management programmes increase the likelihood of getting treatment for those who do not have access to therapists, and might never have access due to limited resources. Booklet-based VR has been shown to effectively reduce dizziness in two large primary care trials^{24 25} as well as in a trial using volunteers recruited from the Meniere's Society.²⁶ Additionally, a booklet without VR, focusing on symptom management and relaxation has also been shown to significantly reduce symptoms and dizziness handicap,²⁶ suggesting that psychotherapeutic techniques may also provide a useful addition to primarily unguided VR self-management programmes.

Internet interventions are increasingly being used as an alternative to paper-based self-management materials^{27–29} and present many advantages: they can be rolled out to a very large population at very little cost; they can provide reminders and personalised progress-relevant feedback to promote adherence; they can feature videos demonstrating exactly how to complete exercises and utilise audio to present text. Automated tailoring allows users to enter current symptoms and be provided with symptom specific advice and exercise prescriptions. Booklet-based VR material is ideally suited to transfer into an internet format. Booklet sections can be developed into weekly modules with video VR demonstrations and patients can be provided with individually tailored feedback and encouragement.

Older adults' use of the Internet for health information is increasing rapidly. In 2010, 72% aged 55–64 and 32% aged 65+ had accessed the Internet within the past 3 months in the UK, and of those individuals, 59% aged 65+ reported using the Internet 'almost every day'.³⁰ Critically, growth in Internet access from 2006 to 2010 was highest in the 65+ group at 113%.³⁰ A recent review reported that Internet interventions targeting lifestyle

change in over 50s can be effective³¹ and previous research has shown that a falls prevention website, designed specifically for use by older adults, was effective in promoting strength and balance training.³² As access to the internet and internet literacy continue to grow among older adults,³³ internet interventions may provide an important resource to supplement usual primary care treatment for common conditions.

This trial has been designed to determine whether an automated internet-based VR intervention is an effective care option for reducing dizziness in adults aged 50 years and over that is also cost-effective. In addition, we will explore the relationship between patient-level psychological variables including expectancy, self-efficacy and acceptance and adherence/outcome. Patients' expectations about the effectiveness of interventions have been shown to predict outcome following treatments for pain, depression and anxiety.^{34 35} In dizzy patients, expectations of benefit can provide reassurance and reduce anxiety, which may directly affect symptoms.³⁶ Self-efficacy refers to beliefs in one's ability to carry out certain behaviours.³⁷ Self-efficacy is a strong predictor of adherence to exercise in older adults,³⁸ and has been included as a potential predictor of adherence to the VR exercises in this trial. Hayes *et al* define acceptance as a willingness to accept internal events (thoughts and feelings) while still moving toward valued goals.³⁹ As a treatment-related construct, acceptance has been the focus of psychological interventions for dizziness and tinnitus.^{40 41} VR exercises deliberately provoke temporary dizziness, thus baseline measures of acceptance may be predictive of patients' willingness to tolerate symptoms and adhere to exercises to complete the rehabilitation programme.

In sum, if an automated internet intervention reduces dizziness and is shown to be cost-effective, it could provide an early inexpensive first-line treatment as part of a stepped care approach and be rolled out rapidly for patients. This will allow limited resources and therapist time to be diverted to those patients who most require therapist contact.

Aims and hypotheses

The broad aim of this project is to reduce dizziness symptoms and improve quality of life in adults aged 50 years and over with dizziness through the use of a stand-alone internet intervention. The most recent VR booklet trial²⁵ tested two models of intervention: stand-alone booklets versus booklets with brief structured telephone support from a vestibular therapist. Yardley *et al*²⁵ reported similar outcomes for almost all measures for both models at 12 months, and both were significantly more effective in reducing dizziness symptoms than routine care at the 12-month follow-up point. Providing the additional live support element adds to the complexity and the cost of a self-directed intervention. As the telephone support did not significantly add to the benefit of the booklet alone on dizziness

symptoms, we will trial the internet intervention as a stand-alone treatment. This form of delivery is suited to rapid rollout with high access at potentially low cost.

We hypothesise that provision of a stand-alone internet-based intervention teaching VR exercises will be (1) more effective than routine care in reducing symptoms in dizzy patients 50 years and over in primary care and (2) more cost-effective than routine care of dizzy patients 50 years and over.

METHODOLOGY

We will use a single blind, single-centre randomised controlled trial to compare effectiveness and cost-effectiveness of the internet-based VR intervention to routine general practitioner (GP) care for dizziness in adults aged 50 years and over. Patients will be followed up at 3 and 6 months. This design is comparable with the series of booklet-based VR trials on which this trial builds.^{24–26} The trial will be carried out in 50–80 UK primary care practices in the south of England. Practices will be sampled to include a broad spectrum of patients, including rural and urban practices and practices from across the social deprivation range.

Sample size and power calculation

In the most recent primary care trial²⁵ the VR booklet alone without guidance produced an effect of $d=0.45$ compared with routine care at 12 months. Assuming our unguided Internet intervention produces an effect of the same magnitude we will need 105 patients per group to test a two-tailed hypothesis with 90% power and 5% significance level. Attrition from previous primary care trials has been low (8.8%), however, attrition can be higher from internet interventions⁴² so we will recruit a minimum of 131 participants per group (262 total sample) to allow for up to 20% attrition.

Recruitment

The trial is eligible for UK National Institute for Health Research Clinical Research Network support, allowing us to work with the Primary Care Research Networks (PCRN, South-Central, East and North Hubs) in recruiting a broad range of practices to take part in the trial. Following the protocol from previous successful VR booklet trials, practices will be asked to screen patient lists for eligible patients (see below for eligibility criteria). Lists of patients created by practice staff will be screened by a GP. The screened lists of patients will be sent a pack containing a letter from their GP and a trial information sheet. Interested patients are asked to contact the trial manager by phone, email or by returning the study reply slip in a provided stamped addressed envelope. Once contact has been made, the trial manager will contact the patient by phone and confirm eligibility by asking:

1. If they still experience dizziness made worse by head movements (if this is not the case dizziness is not

likely to be caused by vestibular imbalance and is thus unlikely to respond to VR)?

2. If they have any neck pain/injury which might prevent them from carrying out the exercises?
3. If they had the Epley Manoeuvre⁴³ performed in the previous month or if they have a future appointment scheduled for this?

If they answer yes to the first question and no to the second two questions, patients will be emailed a link to the trial website. On this website they will provide online consent, complete online baseline measures and will be automatically randomised to the intervention or routine care arms. See figure 1 for participant flow through the trial.

Eligibility criteria

Inclusion: Patients will have reported symptoms of dizziness above the past 2 years, be aged 50 years and over, and will have access to the internet and an email account. *Exclusion:* On the basis of searched medical records exclusion criteria will be identifiable non-labyrinthine cause of dizziness; medical contraindications for making required head movements (eg, severe cervical disorder); and serious comorbidity (life-threatening condition or progressive central disorder). Previous primary care trials^{24–26} have established that these criteria can be used to safely identify those likely to benefit from VR exercises.

Randomisation and blinding

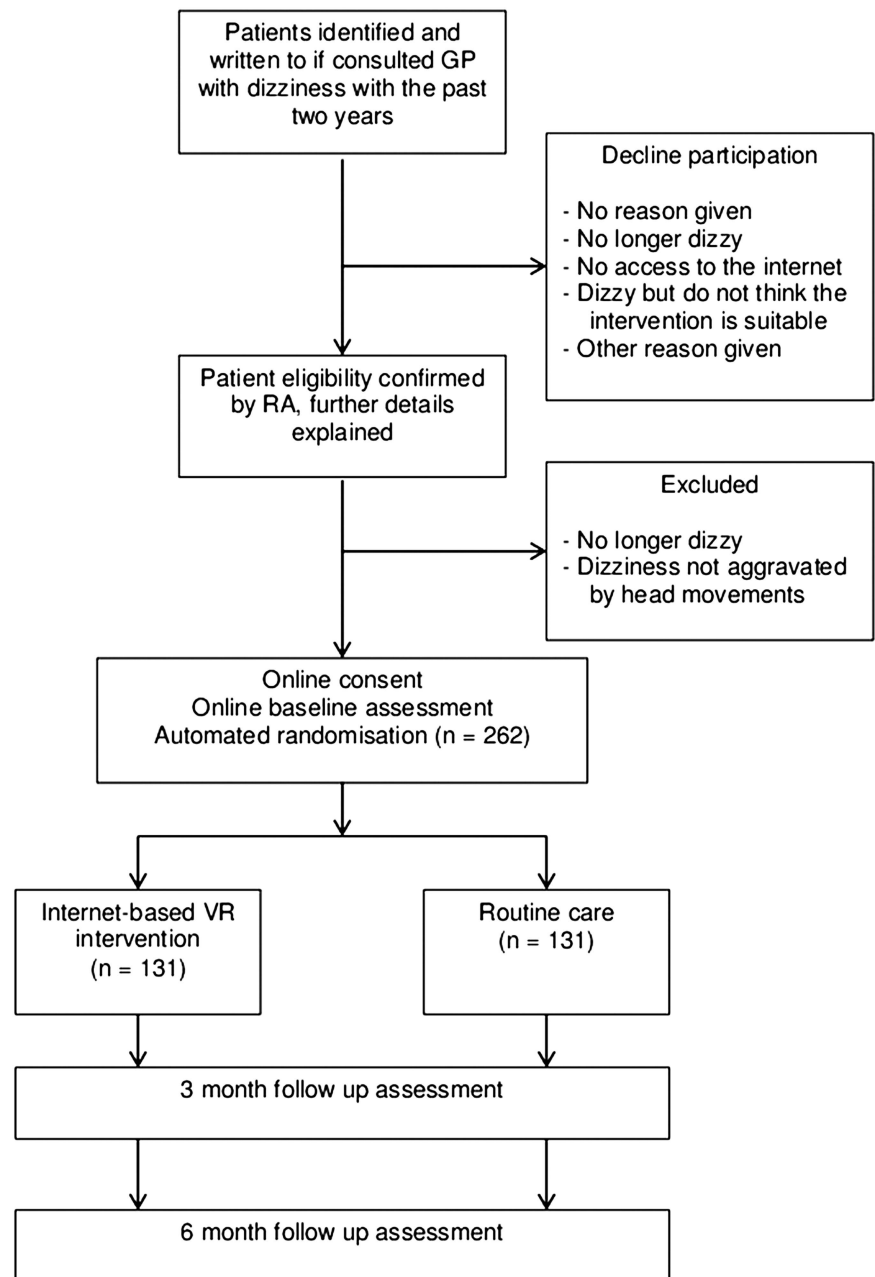
The randomisation sequence will be generated automatically by the LifeGuide internet intervention software. The automated randomisation algorithm will stratify patients by dizziness severity (≥ 12 on the Vertigo Symptoms Scale-Short Form (VSS-SF⁴⁴). As randomisation will be an automated process, sequencing will remain concealed to the trial team. Allocation will occur via the internet; patients will be automatically informed of their allocated group on their computer or device used to access the trial website. As VR is a behavioural intervention, it is not possible for patients to be blind to allocation. An independent research assistant blind to treatment allocation will contact patients to collect telephone outcome data. The trial statistician will remain blind until analyses are complete.

Trial arms

The intervention

VR involves specific exercises that are designed to target vestibular pathology by maximising central nervous system compensation.⁴⁵ VR exercises such as nodding and shaking of the head ensure the movement necessary for adaption, and continued practice of these movements will result in movement-provoked dizziness being gradually reduced.²⁶ Additionally, deliberately provoking dizziness in a controlled context functions as a form of exposure-based behaviour therapy.²⁰ The exercises will promote psychological habituation to symptoms,

Figure 1 Diagram of flow through the trial.



reducing avoidance behaviours. Persistent avoidance behaviours may reduce the likelihood of exposure and adaption through everyday activities and increase anxiety and depressive symptoms.

The internet-based VR intervention content is based closely on the effective booklet-based VR (the booklet is available here: <http://www.menieres.org.uk/information-and-support/treatment-and-management/vestibular-rehabilitation>). All material from the booklet was developed following principles of behaviour change, derived from self-regulation theory and cognitive-behaviour theory.^{26 46} Self-efficacy is targeted through graded goal setting and tailored feedback alongside stating the importance of setting goals that fit with everyday life. The intervention is structured over six sessions; patients are advised to log in each week across the 6-week intervention

period (see [table 1](#) for details and [figure 2](#) for screenshots). Session one provides information about dizziness and a rationale for the VR exercises. It also provides video demonstrations of all the exercises, alongside written instructions. The weekly 'timed exercise scoring test' ('TEST') is explained in session 1 and instructions are provided for how to do the exercises for specified times (eg, nod your head up and down and back again 10 times in 10 s). VR exercises should be tailored to patients' specific symptoms and balance capabilities; the online TEST approach allows this tailoring to be automated. Patients move through the exercises in turn (shake; shake eyes closed; shake stare; nod; nod eyes closed; nod stare). As they complete the 'TEST', patients input whether they did the exercise sitting or standing and provide a score for how dizzy each respective exercise

Table 1 Example internet-based VR intervention session 1–6 content

Session number	Summary content
Session 1	<ul style="list-style-type: none"> ▶ Welcome to balance retraining and overview of session content ▶ Dizziness and the balance system ▶ Intro to VR exercises—how do they work, contraindications, extra info for Meniere's patients ▶ Planning exercises ▶ Exercise demonstration videos ▶ Timed exercise scoring test (long version) ▶ Exercise 'prescription' for the following week ▶ Dealing with side effects ▶ Session recap and access to main menu.
Session 2	<ul style="list-style-type: none"> ▶ Welcome to session 2 and overview of session content ▶ Tailoring of exercises to current capabilities:(ie, <i>Review of last week's exercises</i>) ▶ <i>Information about how to deal with possible difficulties with exercises</i> ▶ <i>Timed exercise scoring test (option to do short or long version)</i> ▶ <i>Exercise 'prescription' for the following week)</i> ▶ Stress and dizziness—exacerbation of symptoms ▶ Introduction to symptom control techniques: controlled breathing ▶ Session recap and access to main menu
Session 3	<ul style="list-style-type: none"> ▶ Welcome to session 3 and overview of session content ▶ Tailoring of exercises to current capabilities ▶ Increasing difficulty of exercises ▶ Symptom control techniques: relaxation ▶ Session recap and access to main menu
Session 4	<ul style="list-style-type: none"> ▶ Welcome to session 4 and overview of session content ▶ Tailoring of exercises to current capabilities ▶ Visual environments and dizziness—exercises and techniques to help ▶ Symptom management techniques: stress management ▶ Session recap and access to main menu
Session 5	<ul style="list-style-type: none"> ▶ Welcome to session 5 and overview of session content ▶ Tailoring of exercises to current capabilities ▶ Everyday situations/activities and dizziness—exercises and techniques to help ▶ Symptom management techniques: thought control ▶ Session recap and access to main menu
Session 6	<ul style="list-style-type: none"> ▶ Welcome to session 6 and overview of session content ▶ Tailoring of exercises to current capabilities ▶ Adding general exercises to VR ▶ Maintaining a healthy balance system ▶ Session recap and access to main menu.

VR, vestibular rehabilitation.

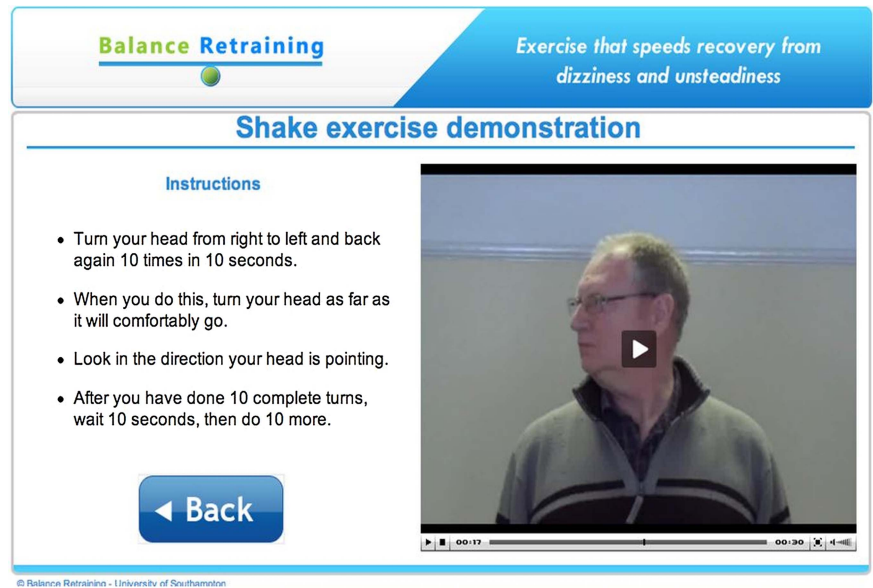
made them feel. These scores are used by the intervention to automatically provide an exercise prescription for the coming week, tailored to the individual patient's dizziness symptoms. Each week features the TEST and then provides symptom specific feedback—this represents the core of the intervention. Patients can choose to go through the TEST, exercise by exercise with videos or simply enter their scores into a table. The intervention suggests patients carry out the exercises for 10 min twice a day.

In addition to the VR exercises, the internet intervention incorporates information and advice on cognitive behavioural coping strategies. A previous trial demonstrated that a booklet focusing on such symptom control strategies rather than VR led to significant subjective health improvement and significantly reduced dizziness

handicap compared with a waiting list control.²⁶ Cognitive restructuring (challenging negative dizziness-related thoughts) and problem solving can help to address dizziness-provoking anxiety, and progressive muscle relaxation and breathing techniques can lessen dizziness-associated psychophysiological arousal.

More generally, the internet intervention included particular features to target increased engagement. Scientific studies supporting the effectiveness of VR were presented in brief lay language to increase patients' expectations regarding the intervention content. Patient VR success stories were included wherever possible to enhance self-efficacy. Stories were drawn from qualitative research with patients who had taken part in the previous VR trial.²⁵ Email reminders were used to bring patients back to the intervention each week. To ensure

Figure 2 A screenshot from the internet-based intervention.



accessibility for older adults, the look/design of the intervention was kept simple with large font sizes and use of bullet points instead of paragraphs wherever possible. The internet intervention was piloted with 14 adults aged 50 years and over experiencing dizziness recruited from primary care, the Meniere's Society and an older adult research volunteer list held by the Department of Psychology at the University of Southampton. Users gave detailed feedback on the content and the usability of the intervention via 'think aloud' interviews,⁴⁷ and the intervention was modified accordingly.

Importantly, the internet intervention will be offered to patients in addition to their usual GP care.

Routine care

Patients allocated to the routine care arm will continue with their care as usual from their GP for their symptoms. After 6 months, patients in this group will be offered access to the intervention.

Fidelity

Internet interventions have many advantages over traditional face-to-face intervention delivery methods with regard to fidelity. Automated digital delivery ensures equivalent information is available to all patients in the intervention group. There can be no live therapist 'drift' from intervention protocol or intervention manuals. Data is automatically collected by the intervention software on all aspects of intervention use, including which sections and pages are viewed, how often and for how long. This enables comprehensive analysis of the relationship between intervention use and symptom reduction following the trial, for instance, examining dose-response curves and whether viewing some sections in particular appeared to be critical to beneficial outcome.

Adverse events

Adverse events are rare following VR. However, there is the possibility that VR could have serious medical consequences such as perilymph fistula, vertebrobasilar ischaemia or cervical damage. If participants experience any of the following symptoms they are advised at multiple points in the intervention to stop and not continue with VR until they have consulted with their GP. The symptoms are: (1) a sharp or prolonged pain in the neck, head or ear, (2) a feeling of fullness in the ear, (3) deafness or noises in the ear, (4) fainting with a loss of consciousness or blacking out, (5) double vision, and (6) numbness and weakness or tingling in the arms or legs. Most problems that occur when patients undertake the exercises can be remediated by advising patients to do the exercises more gently and slowly. Any adverse events that occur during the trial will be recorded and reported to the Ethics Committee and the Trial Steering Committee (TSC).

Data collection and storage

Primarily, data will be collected online using LifeGuide software. LifeGuide integrates an intervention platform with a data management system. Data collected during the intervention period will be stored securely in compliance with NHS standards, and will include dizziness symptoms used to inform the weekly exercises prescription, logins, page views and time spent on each page. Patients in both trial arms will complete baseline measures online. They will be automatically emailed at 3 and 6 months and asked to complete follow-up measures online. Failure to respond to two emails and a written letter will lead to the patient being called by an independent research assistant, blind to treatment allocation, who will collect the primary outcome measure (VSS-SF) and the single-item measure of subjective improvement over the telephone at the 3 and 6-month

time points. Following 6 months all patients who were randomised will have their medical notes reviewed to inform the cost-effectiveness analysis. All patient data will be kept in strict confidence and managed in accordance with the Data Protection Act 1998. The University of Southampton will store the data for 10 years following the end of the study, after which time it will be disposed of securely.

Measures

See [table 2](#) for a list of measures and when they will be collected throughout the trial.

Primary outcome. The primary outcome measure for this trial will be dizziness symptoms at 6 months, as measured by the VSS-SF.⁴⁴ The full Vertigo Symptoms Scale consists of two subscales measuring vertigo and autonomic symptoms. Both subscales have high internal consistency with Cronbach's α ranging from 0.76 to 0.88 and high test-retest correlations of 0.94–0.95.⁴⁴ The short-form version of the scale was developed and validated as an efficient clinical outcome⁴⁸ and has been used effectively in previous VR trials.^{24 25} A more recent study has confirmed the two-factor structure of the VSS-SF and demonstrated that it retains the strong psychometric properties of the original scale, with high internal consistency, Cronbach's $\alpha=0.90$ and test-retest correlations ranging between 0.88 and 0.90.⁴⁹

Health economic outcomes: To measure cost-effectiveness, quality of life will be assessed using the EuroQol EQ-5D.⁵⁰ The EQ-5D requires patients to rate their current health state on a self-administered health index covering five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D also includes a visual analogue component where patients visually rate their state of health on a 'thermometer', from worst imaginable health to best imaginable health. Dizziness-related NHS resource use will be recorded by a retrospective analysis of GP notes carried out by a researcher blind to study group. If it is unclear whether healthcare resource use is dizziness related then this will be decided by clinical experts on the study

steering committee. Alternative and complementary medicine and time off work will be collected by means of a participant completed questionnaire at the 6-month follow-up. Resource use will include: GP and primary care visits, referrals to secondary care; and medicines.

Secondary outcomes: A single-item measure of subjective improvement will be included as in previous VR trials.^{25 26} This item asks patients to indicate whether, during the past week, they had felt better, much the same or worse with regard to their dizziness symptoms than at baseline. The item may allow for the collection of simple outcome data in patients who require telephone follow-up and are reluctant to complete the longer measures. The Dizziness Handicap Questionnaire (DHQ)^{25 26} will be used to measure the effect dizziness has on patients' lives. The DHQ consists of three subscales covering the functional, emotional and physical aspects of dizziness and unsteadiness. Internal consistency for the subscales range from 0.72 to 0.89 (Cronbach's α), with test-retest correlations for the subscales ranging from 0.92 to 0.97.⁵¹ The Hospital and Anxiety and Depression Scale (HADS)⁵² will be used to measure depression and anxiety. The validity of the HADS has been widely demonstrated in hospital, primary care and community settings.⁵³

Psychological process measures: Expectancy will be measured using the Credibility and Expectancy Questionnaire (CEQ). The CEQ was developed for psychotherapy trials, but has since been used in trials of behavioural interventions for symptoms such as pain.⁵⁴ In the initial validation study, scores loaded onto two related factors, credibility and expectancy, and the overall scale had high internal consistency (0.85, Cronbach's α).⁵⁵ Self-efficacy will be measured using an exercise self-efficacy scale originally developed by Resnick *et al*,⁵⁶ and modified for the study of adherence to physiotherapy exercises by Tijou *et al*.⁵⁷ The scale measures patients' confidence to carry out physiotherapy exercises (in this case VR exercises) in a number of circumstances such as if they were tired, stressed or busy. Tijou *et al*⁵⁷ report high internal consistency for the scale at 0.91 (Cronbach's α).

Table 2 Measures and their placement within the trial

Measure	Baseline	Postfirst-session	3 month follow-up	6 month follow-up
Demographics	×			
VSS-SF	×		×	×
DHI	×		×	×
SI			×	×
HADS	×		×	×
AAQ-II	×		×	×
EQ-5D	×		×	×
Healthcare usage				×
PETS			×	×
Self-efficacy		×	×	
CEQ		×	×	

AAQ-II, Acceptance and Action Questionnaire II; CEQ, Credibility and Expectancy Questionnaire; DHI, Dizziness Handicap Inventory; EQ-5D, EuroQual Quality of life Scale; HADS, Hospital Anxiety and Depression Scale; PETS, Problems and Experiences of Therapy Scale; SI, Subjective Improvement in Dizziness Symptoms; VSS-SF, Vertigo Symptom Scale-Short Form.

A dizziness specific acceptance scale is under construction, (Kirby S, 2014, personal communication) but has not yet been validated and so for the present trial we will use the revised version of the Acceptance and Action Questionnaire-II (AAQ-II).³⁹ The seven-item AAQ-II is a general measure of acceptance, experiential avoidance and psychological inflexibility. The AAQ-II is unidimensional and has a reported internal consistency ranging from 0.78 to 0.88 (Cronbach's α) and test-retest correlations of 0.79–0.81.³⁹

The Problematic Experiences of Therapy Scale (PETS)⁵⁸ will be used as a subjective measure of adherence. The PETS was developed specifically as a quantitative measure of patient adherence to home-based rehabilitation and is comprised of four subscales. The subscales measure the degree to which patients agree that they have been prevented from carrying out the intervention due to: (1) symptom severity or aggravation, (2) uncertainty regarding how to carry out the treatment, (3) doubts about treatment efficacy and (4) practical problems such as lack of time. High internal consistency is reported across the subscales ranging from 0.84 to 0.96 (Cronbach's α).⁵⁸

In addition to the above measures, LifeGuide software will automatically collect detailed data regarding intervention usage and weekly dizziness symptoms. We will also collect demographic data (gender, age and education) along with data on duration of dizziness symptoms and diagnosis.

Qualitative data

A diversity sample of 20 patients from the intervention arm, who gave prior consent to be contacted, will be invited to participate in in-depth semistructured telephone interviews following the completion of the intervention. All interviews will be recorded and fully transcribed. These interviews will provide detailed information regarding the patients' experiences and perceptions of using the intervention over the trial period, allowing further insight into possible reasons for outcome and adherence results. Thematic analysis will be applied to the qualitative data. Emerging themes will be identified to comprehensively describe and provide insight into the experiences of patients as they used the intervention.

Trial management and steering committee

Team members directly involved with the day-to-day running of the trial will meet twice monthly to discuss trial progress. Email communication will be primarily used to consult the broader team as issues arise. ATSC will oversee the conduct of the trial and advise on any difficulties experienced. The TSC will be made up of an independent Chair (a senior primary care academic) and two additional independent members (Director and Research Lead for the Meniere's Society). The Committee including AWAG, LY, SK and AB will meet annually to discuss trial progress.

ANALYSIS

Quantitative analysis will begin following cleaning and inspection of the data. Descriptive analysis will be conducted to determine outliers and distributions of the data. Where necessary, if data are not normally distributed, non-parametric tests or transformations will be applied. The main analysis of the primary outcome measure (VSS-SF) will use multiple linear regression comparing the intervention group with the control group and controlling for baseline symptom severity and any other potential confounders. Analysis of secondary outcomes will also be conducted using linear regression for continuous outcomes and logistic regression for dichotomous outcomes, again controlling for baseline symptom severity and any potential confounders. Multiple regression will be used to determine the relationship between predictors, process measures and outcome. We will examine the structure and pattern of missing data and, if appropriate, will present a sensitivity analysis based on data imputed using a multiple imputation model. Data will be analysed on an intention-to-treat basis; however, as a secondary analysis we will also conduct a per protocol analysis. It is not anticipated that there will be significant practice level effects but we will test this assumption by comparing a fixed effect model to a random effects model. If there are significant practice level effects then participants will be treated as clustered by practice for the analysis.

To conduct the cost-effectiveness analysis, we will record all resources required to implement the online intervention as part of the trial. The GP notes review will be used to identify all resources associated with dizziness care in the follow-up period. Any resources identified will be costed using appropriate local and national data, for example NHS reference costs⁵⁹ and Unit Costs of Health and Social Care. The perspective of the analysis will be that of the NHS. However, we will examine some non-NHS costs, such as time off work and complementary healthcare use.⁶⁰

The main outcome measure in the economic evaluation will be the quality adjusted life year (QALY), obtained from the EQ-5D instrument using the published UK tariff. Estimates of QALY generated in each group will be adjusted for baseline EQ-5D scores. In addition, we will also carry out a cost-effectiveness analysis using the study primary outcome measure (VSS-SF), that is, we will estimate cost per point change in VSS-SF. If one intervention is more costly and more effective than the other we will calculate the incremental cost-effectiveness ratio, that is, cost per QALY. Bootstrapping will be used to calculate cost-effectiveness acceptability curves. These will illustrate the effect of uncertainty on study results. Major assumptions made in the analysis will be tested by means of sensitivity analysis. In particular, we will explore assumptions made during the costing of the intervention such as the number of individuals who will be using the website.

ETHICS AND DISSEMINATION

All patients will receive detailed information about the trial before providing consent to take part. Patients will be asked to give consent to take part in the study, to have their medical records accessed, to have their GPs informed that they are taking part, to data provided being used unless they ask otherwise and to take part in a qualitative interview when they complete the trial. All patients will be informed that they can withdraw from the trial at any point.

The results of this trial will be widely disseminated to GPs, lay people experiencing dizziness, practitioners and academics working in balance disorders and internet intervention researchers. Press releases and media interviews will be used to communicate with the general public. We will target dissemination to GPs through leading medical journals and reports submitted to magazines such as Pulse. Those working in e-health will be targeted through publications in journals focusing on internet health research. Additionally, our findings will be presented at relevant national meetings such as the British Academy of Audiology Conference. UK Clinical Commissioning Group boards will be engaged to discuss the trial's findings and how the intervention might be implemented. We will also consult with and present to major charities, including the Meniere's Society.

DISCUSSION

Internet-based VR may represent a novel, easily delivered, high accessible treatment option to support the management of dizziness in older adults in primary care. The current intervention will provide access to a simple and effective version of VR exercises, which we anticipate will reduce the need for referral to often very limited specialist physiotherapist services. An additional key benefit of internet interventions is that unlike paper-based materials, or therapist time, they represent a non-consumable resource.⁶¹ Once maintenance and hosting are covered, costs are unlikely to differ substantially whether 1000 or 10 000 patients are accessing the intervention. The potential of internet interventions to be cost-effective is often discussed⁶²—we will examine this potential directly through a full cost-effectiveness analysis.

Examining psychological process variables such as expectancy and self-efficacy in this trial will allow us to determine how these potentially modifiable patient-level factors influence adherence and symptom reduction. This information will be useful when considering implementation; if expectations are predictive of adherence and reductions in dizziness, GPs could be advised to discuss the rationale for the intervention in some detail with patients in order to bolster those expectations. Additionally, if self-efficacy is important, extra self-efficacy enhancing tailored sections could be added to a modified version of the intervention.

By focusing on primary care patients aged 50 years and over, the current trial stands to make an important

contribution regarding the use and effectiveness of internet technologies in the management of a common health issue for older adults. With an ageing population, the need for cost-effective interventions for symptoms such as dizziness will increase. Evidence-based internet interventions may be well placed to play a significant role in ensuring access to effective behavioural treatments.

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