

Internet-based vestibular rehabilitation for older adults with chronic dizziness: A randomised controlled trial in primary care

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Abstract

Purpose: Vestibular Rehabilitation (VR) is an effective intervention for dizziness due to vestibular dysfunction, but is seldom provided. We aimed to determine the effectiveness of internet-based VR for older adults experiencing dizziness in primary care.

Methods: A single centre, single blind randomised controlled trial comparing an internet-based VR intervention with usual primary care was conducted with patients from 54 primary care practices in southern England (ISRCTN: 86912968). Patients aged 50 years and over with current dizziness exacerbated by head movements were included in the trial. Patients accessed an automated internet-based intervention that taught VR exercises and suggested cognitive behavioural management strategies. Dizziness was measured by the Vertigo Symptom Scale Short-Form (VSS-SF) at baseline, 3 and 6 months. The primary outcome was VSS-SF score at 6 months.

Results: A total of 296 patients were randomized into the trial (66% female, median age 67). The VSS-SF was completed by 250 participants at 3 months (84%: 123 intervention (77%), 127 usual care (93%)) and 230 participants at 6 months (78%: 112 intervention (70%), 118 usual care (87%)). At 3 and 6 months dizziness symptoms were significantly lower in the internet-based VR group compared to usual care (2.75, 95% CI, 1.39 to 4.12; $p < 0.001$ and 2.26, 95% CI, 0.39 to 4.12; $p = 0.018$ respectively). Dizziness-related disability was also significantly lower in the internet-based VR condition, at 3 (6.15 95% CI, 2.81 to 9.49; $p < 0.001$) and 6 month (5.58, 95% CI, 1.19 to 10.0; $p = 0.013$).

Conclusions: Internet-based VR improves dizziness and reduces dizziness-based disability in older primary care patients without requiring clinical support, and has potential for wide application in community settings.

Key words: Behavioural medicine; Chronic care; Ear, nose, throat (ENT)

Introduction

Dizziness is a highly prevalent symptom (1, 2) responsible for nearly 7 million consultations per year in the United States (3). In primary care the majority of dizziness is caused by vestibular dysfunction, including benign paroxysmal positional vertigo (BPPV) (4). Dizziness in older adults is associated with falls, fear of falling, anxiety and depression, contributing to substantial disability, increased frailty and loss of independence (5, 6). With a growing ageing population, the health burden will steadily increase (7). While more prevalent in older adults, more than 1 in 10 people of working age experience dizziness that causes dysfunction or leads to medical consultations (8). Often going untreated, dizziness can become chronic; in a recent primary care trial including adults of all ages mean duration of symptoms was 5.5 years (9). Medical and surgical interventions offer limited benefit (10), however there is evidence that Vestibular Rehabilitation (VR) exercises are the most effective treatment for dizziness caused by vestibular dysfunction (9, 11). VR promotes central nervous system compensation through sets of simple exercises involving head movements, and research suggests primarily self-directed VR interventions can be effective (4, 9).

Internet use in older adults continues to steadily increase; 59% of over 65 year olds in the US reported using the internet in 2013 compared to just 14% in 2000 (12). Consequently, VR delivered via the internet, if shown to be effective, could potentially have a major impact in increasing access to low-cost treatment for dizziness. However, it is critical to determine the effectiveness of unguided internet-supported self-management in older adults.. In this randomised controlled trial we aimed to determine the effectiveness of fully automated internet-based VR in improving dizziness symptoms in primary care patients aged 50 and over.

Method

Setting and participants

Detailed descriptions of the methods used have been published in the trial protocol (13). This was a single centre single blind randomised controlled trial conducted with patients from 54 primary care practices in the south of England, UK. To be eligible for inclusion patients had to have consulted their General Practitioner (GP) with symptoms of dizziness over the last two years and still be experiencing dizziness made worse by head movements; have access to the internet (and an email account); and be aged 50 years or over. Based on searched medical records, patients were excluded by practice staff if they had an identifiable non-labyrinthine cause of dizziness; medical contraindications that would affect the required head movements, such as severe cervical disorder; or serious comorbidity, for instance a life threatening condition or progressive central disorder. Eligible patients were then sent information about the study (including a trial information sheet). Interested patients contacted the research team, and were further screened over the telephone to ensure they were still currently experiencing dizziness, and that this dizziness was made worse by head movements (indication of vestibular pathology). Patients were also excluded if their dizziness had been treated by the Epley Manoeuvre in the previous month, or if they had a future appointment scheduled for an Epley Manoeuvre to be performed. Patients provided consent online before completing baseline measures, and were recruited and followed-up between September 2013 and June 2014. This trial was approved by an NHS Research Ethics Committee (REC Reference: 13/SC/0119).

Randomisation and interventions

The randomisation allocation process was automated and occurred online. Patients were randomised to one of two conditions, internet-based VR or usual care. The randomisation sequence was generated by the internet intervention software, and was concealed from the trial team. The automated randomisation algorithm stratified patients by severity (≥ 12 on the VSS-SF). An independent research assistant who collected outcome data over the phone, the trial statistician (BS) and health economist (DT) remained blind to allocation until analyses were complete.

Internet-based VR

The internet-based VR intervention has been described elsewhere (13) and its development detailed by Essery et al. (14). VR consists of specific exercises including nodding and shaking the head. Repeated practice of these movements promotes adaption and the gradual reduction of movement-provoked dizziness. Importantly, the exercises also lead to psychological habituation to the symptoms and reductions in avoidance behaviours. Using VR booklets developed by Yardley et al. (4, 9, 15) as a starting point, we created an automated six-session internet-based intervention to be completed over 6 weeks. The intervention tailored advice and VR exercise prescriptions based on individual patients' symptoms each week, and featured video demonstrations with audio descriptions of all VR exercises. Each week, cognitive behavioural coping strategies such as relaxation, breathing techniques and cognitive restructuring were integrated with the VR material. Self-regulation theory (16) and cognitive-behavioural theory (15) guided the behaviour change principles contained within the intervention, and self-efficacy was targeted by encouraging graded goal setting and tailored feedback. The intervention was developed and delivered using the freely available LifeGuide software (see www.lifeguideonline.org), and was fully automated and delivered online, without therapist support. Patients in the intervention condition also had access to usual primary care throughout.

Usual care

As this was a pragmatic trial, patients randomised to this group continued to receive primary care for their symptoms as normal over the trial period. Usual primary care for dizziness in the UK typically consists of reassurance and symptomatic relief (e.g. medication for nausea). Some GPs may provide additional educational information (e.g. leaflets). After completion of the trial, patients in this arm were offered access to the internet-based VR intervention.

Outcome measures

Outcomes were measured at baseline, and at three and six months following randomisation. All data was collected online. The primary outcome was the frequency of 15 dizziness related symptoms at six months, as measured by a total score on the Vertigo Symptom Scale-Short Form (VSS-SF (17)). Higher scores on the VSS-SF represent higher levels of dizziness. Secondary measures included the vertigo and autonomic symptom sub-scales of the VSS-SF; the Dizziness Handicap Inventory (DHI (18)) which measures the functional, physical and emotional impact of dizziness; a single item measure of subjective improvement in dizziness (15); and the Hospital Anxiety and Depression Scale (HADS (19)) to measure symptoms of depression and anxiety. At baseline demographic information including age, gender and educational attainment, along with years since diagnosis was collected. Objective website usage data was collected to determine adherence to the internet-based VR intervention.

Statistical analysis

The sample size was based on an effect size 0.45 (Cohen's *d*) drawn from the findings of previous booklet-based VR trials (9). With 90% power and a 5% significance level, this requires 105 per group. We allowed for 20% loss to follow up, giving a total sample size of 262 participants (131 per group).

Data were analysed using Stata/SE version 13.1. The distribution of the primary outcome measure and its residuals were examined for deviations from normality and tested using the Shapiro-Wilk test. The same tests were carried out on the continuous secondary outcome measures. The outcome data were not approximately normally distributed and were therefore analysed using quantile regression. Logistic regression was used for binary outcome measures. All analyses controlled for the potential confounding effects of baseline covariates (including baseline severity, age, age left education, sex and time since diagnosis) and the standard errors were adjusted to allow for any clustering by practice. Cluster robust standard errors for quantile regression (20) were calculated using Stata's `qreg2` command. Models were fitted backwards, retaining only covariates significant at the 5% level. To avoid model overfitting, we eliminated in a step-wise fashion the least significant variables. To avoid removing variables that might have a weak effect on the model as true confounders, we retained any that were associated with the outcome with a p-value of at least 0.20. All covariates were included as potential confounders in the multivariate analyses.

The primary analysis was on an intention to treat basis, with participants analysed based on their randomisation group. A secondary analysis was carried out to explore the effect of the intervention in those who adhered (i.e. completed at least one intervention session). To assess the sensitivity of the results to missing data, we completed a multiple imputation analyses based on a linear multiple imputation model with 50 imputations. The imputations were undertaken using chained equations (21). A linear model was assumed for missing outcome data and appropriate distributions for any missing covariates. The model included

all socio-demographic variables, baseline values and the outcome measures at all time points. The imputed datasets were then analysed using non-parametric models as per the primary analysis. However, this method may have introduced bias, particularly given the non-normality of the data, thus we recommend caution in its interpretation. This method has been presented as a sensitivity analysis.

Results

We recruited 296 patients from 54 general practices. Table 1 gives the baseline characteristics of the intervention and usual care groups. The median number of patients participating at each practice/clinic was 21 (IQR 11, 40). The groups were generally well balanced with a slight difference in the years since diagnosis. Figure 1 shows the flow of participants through the trial. Dropout varied between the arms, and was higher in the intervention arm at both 3 (23.1%, 37/160) and 6 months (30.0%, 48/160) compared to the usual care arm at 3 (6.6%, 9/136) and 6 months (18%, 18/136). The majority of the dropout occurred after 3 months. See supplementary appendix for a table showing differences between those who completed all follow-up assessments and those that did not. Allocation to the intervention arm was the only significant predictor of non-completion.

[INSERT TABLE 1 ABOUT HERE]

[INSERT FIGURE 1 ABOUT HERE]

Primary outcome

The Vertigo Symptom Scale – Short Form (VSS-SF) was completed by 250 (84%) participants at 3 months and 230 (78%) participants at 6 months. The intervention group showed statistically significant improvements in dizziness symptoms compared with the usual care group. At both 3 and 6 months the median VSS-SF score in the intervention group was lower than in the usual care group by 2.75 points (95% CI, 1.39 to 4.12; $p < 0.001$) and by 2.26 points (95% CI, 0.39 to 4.12; $p = 0.018$) respectively, see Table 2.

[INSERT TABLE 2 ABOUT HERE]

Sensitivity analysis for primary outcome

Repeating the analysis with missing data replaced based on a multiple imputation model indicated that this approach was more conservative. The median VSS-SF score was 2.57 (95% CI, 0.85 to 4.28; $p = 0.003$) points lower in the intervention condition compared to usual care at 3 months, and 1.86 points lower (95% CI, -0.59 to 4.32; $p = 0.135$) in the intervention condition compared with usual care at 6 months.

For the 160 patients in the intervention group, per protocol was defined completing as at least as far as the first exercise test in session one. Objective intervention usage data showed that 99 (61%) patients reached this point in the intervention. In a per protocol analysis the VSS-SF score was not significantly lower in those who had reached this point in the intervention than in those who had not (including the usual care group) at 3 months (1.27, 95% CI, -0.31 to 2.85; $p = 0.115$), but it had reached significance at six months (2.11, 95% CI, 0.23 to 3.99; $p = 0.028$).

Secondary outcomes

As shown in Table 2, there was a significant reduction in the intervention group on the autonomic symptoms subscale of the VSS-SF at both 3 and 6 months. On the vertigo subscale there was a significant reduction in symptoms at 3 month but this did not persist at 6 months. There were large significant differences between the intervention and usual care groups on the Dizziness Handicap Inventory (DHI) at 3 and 6 months, suggesting substantial reductions in dizziness-related disability. There was a significant difference suggesting a reduction in anxiety at 3 months in the intervention group compared to usual care, but this was not sustained at 6 month. There were no differences in depression at either time-points.

The intervention group reported significantly greater subjective improvement in dizziness than the usual care group at 3 and 6 months. At 3 months 62.3% (76/122) of the intervention group reported their dizziness symptoms felt a little or much better, compared to 32.8% (42/128) in the usual care group. These findings were replicated at 6 months with 64.2% (70/109) of the intervention group feeling a little or much better compared to 41.0% (50/122) in the usual care group feeling a little or much better. There were low rates of perceived harm in both groups at 3 and 6 months, with 9.8% and 6.4% of the intervention group and 14.8% and 20.5% of the usual care group reporting that that they were a little or much worse respectively (see Figure 1 in the supplementary appendix).

[INSERT FIGURE 2 ABOUT HERE]

Exploratory analysis by age

Although this study was not powered to detect interactions, we carried out a planned exploratory analysis to see whether there were any differences in the response to the intervention by participants above and below the median age (67 years) (see Table 3). At 6 months, in the younger age group the effect of the intervention compared to usual care was

not significant (univariate median difference = 1.00, 95% CI, -1.77 to 3.77; p=0.476).

However, in the older age intervention group the effect of the intervention compared to usual care was significant (univariate median difference = 3.00, 95% CI, 0.14 to 5.86; p=0.040).

This suggests the improved dizziness in the intervention group was more likely to be sustained at 6 months in the older adults in our sample (> 67 years old).

[INSERT TABLE 3 ABOUT HERE]

Adverse events

18 non-dizziness related hospitalisations were identified in a GP notes review undertaken at the end of the trial (8 in the usual care arm, 10 intervention in the intervention arm). No dizziness/intervention related serious adverse reactions were reported.

Discussion

Access to an unsupported internet-based VR intervention significantly reduced chronic dizziness and dizziness-related disability compared to usual primary care. This result persisted for at least 6 months. With the increasing internet access seen in older adults (12), our internet-based VR intervention could enable clinicians to provide broad and rapid access to low cost, evidence-based treatment for their patients experiencing dizziness. The mean age of our sample was 67 years old; provision via digital technology may not be barrier to effectiveness in older adults, particularly if attention is paid to accessibility in development (14).

The findings of this trial are consistent with the booklet-based VR trials conducted by Yardley et al. (4, 9, 15, 22). Provision via the internet has substantial benefits over use of booklets, which may have limited penetration even in clinical settings and even less in community settings, reducing the likelihood of a significant impact on the health burden of chronic dizziness. The size of the effect on the primary outcome, the VSS-SF, was comparable with the effects achieved in Yardley et al.'s (9) trial where booklets were provided with health care professional support (-1.79 to -2.52). It is also comparable to mean VSS-SF reductions following a 9 week, face-to-face group session VR intervention (23), (-2.4).

Although remaining significant, the size of the difference in dizziness symptoms between the intervention group and usual care reduced from 3 months to 6 months. This was driven by improvements in the control group, rather than worsening symptoms in the intervention group, where improvements in dizziness persisted. Our trial pre-randomisation entry procedures for all patients may have been reassuring, describing VR as simple head movements that may reduce dizziness. Dizziness is closely related to anxiety and avoidance behaviours; as such reassurance is a key component in management strategies for dizziness (6).

This trial has some limitations. Loss to follow-up in the intervention arm was relatively high. Some patients may have found the dizziness inducing head movements off-putting and dropped out. The Balance Retraining intervention provides explicit reassurance regarding these dizziness symptoms; nonetheless, it is important that physicians provide reassurance regarding what to expect when engaged with VR. Although retaining significance at 3 months, the multiple imputation analysis was more conservative at 6 months, and differences between the intervention and usual care did not reach significance. We suspect that the prominence of patients' baseline score in the imputation model (other covariates were

limited) and the extent of the imputation required may have attenuated differences; we also reiterate that caution is required in the interpretation of these analyses due to the non-normality of the patient data. As with previous VR trials (9), overall uptake following our primary care list search and mailout was low (<10%), however, it possible that a large proportion of non-responders were no longer dizzy (9), or simply not wanting to take part in a research trial. We were unable to consider our results in relation to specific diagnoses, as these data were not obtained. Nonetheless, this was consistent with the conduct of a pragmatic trial in primary care, where definitive diagnoses of dizziness symptoms are rare in day-to-day practice (24). Finally, harms data were examined primarily through family practice notes reviews, or when reported directly to the study team. As minimal contact was made with the trial team it is possible other harms may have gone unreported.

In conclusion, this trial has demonstrated that internet-based VR is effective in reducing dizziness symptoms and dizziness-related disability in primary care patients. Internet-based interventions may provide a promising route to greatly increasing the provision of evidence-based self-management strategies for older adults in primary care.

Access *Balance Retraining* using the link provided below:

<https://balance.lifeguidehealth.org>

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Table 1. Baseline characteristics.

	Intervention	Usual Care
Female	107/160 (66.9%)	90/136 (66.2%)
Mean age yrs (s.d.)	67.3 (9.0)	67.5 (11.5)
Mean age left school yrs (s.d.)	16.2 (1.2)	16.1 (1.1)
Mean years since diagnosis	6.5 (7.8)	8.2 (11.3)
(s.d.)		
Median VSS-SF total (IQR)	14 (8, 22)	13 (7, 22)
- Median Vertigo subscale	8 (5,13)	8 (5, 12)
(IQR)		
- Median autonomic symptoms subscale (IQR)	5 (2,9)	5 (2, 8)
Median Dizziness Handicap	32 (22, 48)	32 (20, 55)
Inventory (IQR)		
Median HADS anxiety (IQR)	7 (4,10)	6 (4, 10)
Median HADS depression	4 (2, 6)	4 (2, 7)
(IQR)		

VSS-SF = Vertigo Symptoms Scale – Short Form; HADS = Hospital Anxiety and Depression Scale

Table 2. Primary and secondary outcome measures at 3 and 6 months.

	3 months				6 months			
	Intervention	Usual	Univariate	Multivariate	Intervention	Usual	Univariate	Multivariate
	median	Care	difference	difference	median	care	difference	difference
	(IQR)	median	(controlling	(controlling	(IQR)	median	(controlling	(controlling
		(IQR)	for baseline	for other		(IQR)	for baseline	for other
			value and	significant			value and	significant
			clustering)	covariates)			clustering)	covariates)
Primary outcome								
VSS-SF total	6 (3,12)	9 (5,15)	2.52 (1.17,	2.75 (1.39,	6 (3,14)	7 (4,17)	2.38 (0.31,	2.26 (0.39,
			3.87;	4.12;			4.46;	4.12;
			p<0.001)	p<0.001)			p=0.025)	p=0.018)
Secondary outcome								
- Vertigo	3 (1,7)	4 (2,9)	1.42 (0.50,	1.49 (0.54,	4 (1,6)	4 (2,11)	1.00 (-0.25,	0.93 (-0.24,
subscale			2.33;	2.43;			2.25;	2.10;
			p=0.003)	p=0.002)			p=0.117)	p=0.120)

- Autonomic symptoms subscale	3 (0,6)	4 (2,6)	1.19 (0.37, 2.01; p=0.005)	1.03 (0.12, 1.94; p=0.026)	3 (1,6)	4 (1,7)	1.38 (0.62, 2.14; p<0.001)	1.33 (0.63, 2.03; p<0.001)
Dizziness	24 (12.5, 38)	28 (16, 52)	5.33 (1.41, 9.26; p=0.008)	6.15 (2.81, 9.49; p<0.001)	22 (8, 40)	26 (12, 46)	5.58 (1.19, 10.0; p=0.013)	5.58 (1.19, 10.0; p=0.013)
HADS anxiety	6 (3,9)	6 (3,9)	0.88 (0.02, 1.75; p=0.046)	0.82 (0.03, 1.61; p=0.042)	6 (3,9)	6 (3,9)	0.17 (-0.83, 1.16; p=0.741)	0.10 (-0.97, 1.16; p=0.860)
HADS depression	3 (1,5)	4 (1,7)	0.55 (-0.06, 1.15; p=0.078)	0.55 (-0.18, 1.28)	2 (1,6)	4 (1,6)	0.29 (-0.23, 0.80; p=0.273)	0.24 (-0.25, 0.73; p=0.330)
Patients reporting subjective improvement	49/122 (40.2%)	26/128 (20.3%)	0.35 (0.21, 0.60; p<0.001)	0.34 (0.19, 0.60; p<0.001)	43/109 (39.5%)	35/122 (28.7%)	0.63 (0.39, 1.02; p=0.060)	0.66 (0.40, 1.10; p=0.113)

VSS-SF = Vertigo Symptoms Scale – Short Form; HADS = Hospital Anxiety and Depression Scale

Table 3. Post-hoc exploratory analysis of intervention effects by age.

	Below median age				Above median age			
	Intervention median (IQR)	Usual Care median (IQR)	Univariate difference (controlling for baseline value and clustering)	Multivariate difference (controlling for other significant covariates)	Intervention median (IQR)	Usual care median (IQR)	Univariate difference (controlling for baseline value and clustering)	Multivariate difference (controlling for other significant covariates)
VSS-SF total at 6 months	8 (4,15)	9 (5, 20)	1.00 (-1.77, 3.77; p=0.476)	1.08 (-1.66, 3.82; p=0.436)	5 (1, 12)	6 (3,15)	3.00 (0.14, 5.86; p=0.040)	N/A (no other covariates were significant)
VSS-SF total at	8 (5, 15)	10 (6, 19)	2.79 (0.74, 4.83;	3.03 (0.99, 5.08;	6 (1,10)	8 (4, 12)	3.19 (1.03, 5.35;	3.33 (1.29, 5.38;

3	p=0.008)	p=0.004)	p=0.004)	p=0.002)
months				

VSS-SF = Vertigo Symptoms Scale – Short Form; HADS = Hospital Anxiety and Depression Scale

Figure 1. Patient flow through the trial.



