Internet-Based Vestibular Rehabilitation for Older Adults With Chronic Dizziness: A Randomized Controlled Trial in Primary Care

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ABSTRACT

PURPOSE Vestibular rehabilitation is an effective intervention for dizziness due to vestibular dysfunction, but is seldom provided. We aimed to determine the effectiveness of an Internet-based vestibular rehabilitation program for older adults experiencing dizziness in primary care.

METHODS We undertook a single-center, single-blind randomized controlled trial comparing an Internet-based vestibular rehabilitation intervention (Balance Retraining, freely available from https://balance.lifeguidehealth.org) with usual primary care in patients from 54 primary care practices in southern England. Patients aged 50 years and older with current dizziness exacerbated by head movements were enrolled. Those in the intervention group accessed an automated Internet-based program that taught vestibular rehabilitation exercises and suggested cognitive behavioral management strategies. Dizziness was measured by the Vertigo Symptom Scale–Short Form (VSS-SF) at baseline, 3 months, and 6 months. The primary outcome was VSS-SF score at 6 months.

RESULTS A total of 296 patients were randomized in the trial; 66% were female, and the median age was 67 years. The VSS-SF was completed by 250 patients (84%) at 3 months and 230 patients (78%) at 6 months. Compared with the usual care group, the Internet-based vestibular rehabilitation group had less dizziness on the VSS-SF at 3 months (difference, 2.75 points; 95% CI, 1.39-4.12; P < .001) and at 6 months (difference, 2.26 points; 95% CI, 0.39-4.12; P = .02, respectively). Dizziness-related disability was also lower in the Internet-based vestibular rehabilitation group at 3 months (difference, 6.15 points; 95% CI, 2.81-9.49; P < .001) and 6 months (difference, 5.58 points; 95% CI, 1.19-10.0; P = .01).

CONCLUSIONS Internet-based vestibular rehabilitation reduces dizziness and dizziness-related disability in older primary care patients without requiring clinical support. This intervention has potential for wide application in community settings.


INTRODUCTION

Dizziness is a highly prevalent symptom¹,² 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.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 aging population, the health burden will steadily increase.⁷ Although dizziness has higher prevalence 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, the mean duration of symptoms was 5.5 years.⁹ Medical and surgical interventions offer limited benefit¹⁰; however, there is evidence that vestibular rehabilitation exercises are the most effective treatment for...
dizziness caused by vestibular dysfunction.9,11 Vestibular rehabilitation promotes central nervous system compensation through sets of simple exercises involving head movements, and research suggests primarily self-directed vestibular rehabilitation interventions can be effective.4,9

Internet use among older adults continues to steadily increase; 59% of individuals aged older than 65 years in the United States reported using the Internet in 2013, compared with just 14% in 2000.12 Consequently, vestibular rehabilitation 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 randomized controlled trial, we aimed to determine the effectiveness of fully automated Internet-based vestibular rehabilitation in improving dizziness symptoms in primary care patients aged 50 years and older.

**METHODS**

**Setting and Participants**

Detailed descriptions of the methods used have been published in the trial protocol.11 We undertook a single-center, single-blind randomized controlled trial among patients from 54 primary care practices in the south of England, United Kingdom. To be eligible for inclusion, patients had to have consulted their general practitioner with symptoms of dizziness over the last 2 years and still be experiencing dizziness made worse by head movements, had to have access to the Internet (and an e-mail account), and had to be aged 50 years or older. On the basis of a search of medical records, patients were excluded by practice staff if they had an identifiable nonlabyrinthine cause of dizziness; medical contraindications that would affect the required head movements, such as a severe cervical disorder; or serious comorbidity, for instance, a life-threatening condition or a progressive central nervous system 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 that 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 maneuver in the previous month, or if they had a future appointment scheduled for this treatment. 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 a National Health Service Research Ethics Committee (REC Reference: 13/SC/0119).

**Randomization and Interventions**

The randomization allocation process was automated and occurred online. Patients were randomized evenly to 2 conditions: Internet-based vestibular rehabilitation or usual care. The randomization sequence was generated by the Internet intervention software and was concealed from the trial team. The automated randomization algorithm stratified patients by dizziness severity using a cutoff of 12 or greater on the Vertigo Symptom Scale–Short Form (VSS-SF). An independent research assistant who collected outcome data over the phone, the trial statistician (B.S.), and a health economist (D.T.) remained blinded to allocation until analyses were complete.

**Internet-Based Vestibular Rehabilitation**

The Internet-based vestibular rehabilitation intervention, called Balance Retraining (freely available from https://balance.lifeguidehealth.org), has been described elsewhere13 and its development has been detailed by Essery et al.14 Vestibular rehabilitation consists of specific exercises including nodding and shaking the head. Repeated practice of these movements promotes adaptation and the gradual reduction of movement-provoked dizziness. Importantly, the exercises also lead to psychological habituation to the symptoms and reductions in avoidance behaviors. Using vestibular rehabilitation booklets developed by Yardley et al.14,9,15 as a starting point, we created an automated, 6-session, Internet-based intervention to be completed over 6 weeks. The intervention tailored advice and vestibular rehabilitation exercise prescriptions based on individual patients’ symptoms each week, and featured video demonstrations with audio descriptions of all vestibular rehabilitation exercises. Each week, cognitive behavioral coping strategies such as relaxation, breathing techniques, and cognitive restructuring were integrated with the vestibular rehabilitation material. Self-regulation theory16 and cognitive-behavioral theory15 guided the behavior change principles of 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 (http://www.lifeguideonline.org), and was fully automated and delivered online, without therapist support. Patients in the intervention group also had access to usual primary care throughout.

**Usual Care**

As this was a pragmatic trial, patients randomized to the usual care group continued to receive primary care.
for their symptoms as normal over the trial period. Usual primary care for dizziness in the United Kingdom typically consists of reassurance and symptomatic relief (eg, medication for nausea). Some general practitioners may provide additional educational information (eg, leaflets). After completing the trial, patients in this usual care arm were offered access to the Internet-based vestibular rehabilitation intervention.

**Outcome Measures**

Outcomes were measured at baseline and at 3 months and 6 months after randomization. All data were collected online. The primary outcome was the frequency of 15 dizziness-related symptoms at 6 months, as measured by the total score on the VSS-SF.17 The higher scores on the VSS-SF represent higher levels of dizziness. Secondary measures included the vertigo and autonomic symptom subscales of the VSS-SF; the Dizziness Handicap Inventory,18 which measures the functional, physical, and emotional impact of dizziness; a single-item measure of subjective improvement in dizziness;5,17 and the Hospital Anxiety and Depression Scale19 which measures symptoms of anxiety as well as depression. At baseline, we collected demographic information including age, sex, and educational attainment, along with years since diagnosis. Objective website use data were collected to determine adherence to the Internet-based vestibular rehabilitation intervention.

**Statistical Analysis**

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

Data were analyzed using Stata/SE version 13.1 (StataCorp LP). 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 analyzed using quantile regression. Logistic regression analysis was used for binary outcome measures. All analyses controlled for the potential confounding effects of baseline covariates (including severity, age, age when patient 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 regression20 were calculated using Stata’s qreg2 command. Models were fitted backward, retaining only covariates significant at the 5% level. To avoid model overfitting, we eliminated in a stepwise 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 .20. All covariates were included as potential confounders in the multivariate analyses.

The primary analysis was on an intention-to-treat basis, with participants analyzed based on their randomization group. A secondary per-protocol analysis was carried out to explore the effect of the intervention in those who adhered to treatment (defined as completing at least the first exercise test in session 1). To assess the sensitivity of the results to missing data, we completed 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 sociodemographic variables, baseline values, and the outcome measures at all time points. The imputed data sets were then analyzed using nonparametric models as per the primary analysis. This method may have introduced bias, however, particularly given the nonnormality of the data; therefore, we recommend caution in its interpretation. This method is presented here as a sensitivity analysis.

**RESULTS**

**Patients**

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 or clinic was 21 (interquartile range, 11-40). The groups were generally well balanced with a slight difference in the years since diagnosis.

Figure 1 shows the flow of patients through the trial. Dropout varied between the groups and was higher in the intervention group at both 3 months (23.1%, 37 of 160 patients) and 6 months (30.0%, 48 of 160 patients) compared with the usual care group at 3 months (6.6%, 9 of 136 patients) and 6 months (13.2%, 18 of 136 patients). The majority of the dropout occurred by 3 months. Differences between those who completed all follow-up assessments and those who did not are shown in the Supplemental Table (available at http://www.annfammed.org/content/15/3/209/suppl/DC1). Allocation to the intervention group was the only significant predictor of noncompletion.
VESTIBULAR REHABILITATION

Table 1. Baseline Characteristics (N = 296)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention Group (n = 160)</th>
<th>Usual Care Group (n = 136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, No. (%)</td>
<td>107 (66.9)</td>
<td>90 (66.2)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>67.3 (9.0)</td>
<td>67.5 (11.5)</td>
</tr>
<tr>
<td>Age at leaving school, mean (SD), y</td>
<td>16.2 (1.2)</td>
<td>16.1 (1.1)</td>
</tr>
<tr>
<td>Time since diagnosis, mean (SD), y</td>
<td>6.5 (7.8)</td>
<td>8.2 (11.3)</td>
</tr>
<tr>
<td>VSS-SF scores, median (IQR)</td>
<td>Total score</td>
<td>14 (8-22)</td>
</tr>
<tr>
<td></td>
<td>Vertigo subscale score</td>
<td>8 (5-13)</td>
</tr>
<tr>
<td></td>
<td>Autonomic symptoms subscale score</td>
<td>5 (2-9)</td>
</tr>
<tr>
<td></td>
<td>DHI score, median (IQR)</td>
<td>32 (22-48)</td>
</tr>
<tr>
<td>HADS scores, median (IQR)</td>
<td>Anxiety score</td>
<td>7 (4-10)</td>
</tr>
<tr>
<td></td>
<td>Depression score</td>
<td>4 (2-6)</td>
</tr>
</tbody>
</table>

DHI = Dizziness Handicap Inventory; IQR = interquartile range; VSS-SF = Vertigo Symptoms Scale–Short Form; HADS = Hospital Anxiety and Depression Scale.

a Higher scores indicate higher levels of dizziness. Ranges of scores in this trial: total score: 0-48; vertigo subscale score: 0-32; autonomic symptoms subscale score: 0-25.

b Higher scores indicate greater dizziness-related disability. Range of scores in this trial: 0-96.

c Higher scores indicate higher levels of anxiety and depression. Ranges of scores in this trial: anxiety score: 0-20; depression score: 0-20.

Primary Outcome

In all, 250 patients (84%) completed the VSS-SF at 3 months and 230 (78%) did so at 6 months. The intervention group showed statistically significant improvements in dizziness symptoms compared with the usual care group (Table 2). In multivariate analysis, 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; \( P < .001 \)) at 3 months and by 2.26 points (95% CI, 0.39 to 4.12; \( P = .02 \)) at 6 months.

Repeating the analysis with missing data replaced based on a multiple imputation model, as a sensitivity analysis, yielded more modest differences. The median VSS-SF score was 2.57 points (95% CI, 0.85 to 4.28; \( P = .003 \)) lower in the intervention group compared with the usual care group at 3 months, and 1.86 points (95% CI, −0.59 to 4.32; \( P = .14 \)) lower in the intervention group compared with the usual care group at 6 months (data not shown).

For the 160 patients in the intervention group, per protocol was defined as completing at least the first exercise test in session 1. Objective data on use of the intervention showed that 99 patients (61%) reached this point in the intervention. In the 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 all those in the usual care group) at 3 months (1.27 points; 95% CI, −0.31 to 2.85; \( P = .12 \)), but it had reached significance at 6 months (2.11 points; 95% CI, 0.23 to 3.99; \( P = .03 \)) (data not shown).

Secondary Outcomes

As shown in Table 2, there was a significantly greater 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 significantly greater reduction in symptoms at 3 months, but this difference did not persist at 6 months. There were also significant differences between the intervention and usual care groups on the Dizziness Handicap Inventory at 3 and 6 months, showing substantially greater reductions in dizziness-related disability for the former group. The intervention group had a greater reduction in anxiety at 3 months, but this difference was not sustained at 6 month. There were no significant differences between groups in depression at either time point.

Compared with the usual care group, the intervention group reported significantly greater subjective improvement in dizziness at both 3 months and 6 months (Table 2). At 3 months, 62.3% of the intervention group (76 of 122 patients) reported their dizziness symptoms felt a little or much better, compared with 32.8% (42 of 128 patients) in the usual care group. These findings were replicated at 6 months with 64.2% (70 of 109 patients) in the intervention group feeling a little or much better, compared with 41.0% (50 of 122 patients) 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 they were a little or much worse, respectively (see Supplemental Figure 1, available at http://www.annfammed.org/content/15/3/209/suppl/DC1).

Exploratory Analysis by Age

Although our trial 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 according to participant age above and below the median of 67 years (Table 3). At 6 months, in the younger age-group, the effect of the intervention compared with usual care was not significant (univariate median difference = 1.00, 95%, CI, −1.77 to 3.77; \( P = .48 \)); however, in the older age-group, the effect of the intervention compared with usual care was significant (univariate median difference = 3.00, 95% CI, 0.14 to 5.86; \( P = .04 \)). This pattern suggests the improved dizziness in the intervention group was
Figure 1. Patient flow through the trial.

5,854 Patients identified via general practitioner database search, screened, and invited to trial

5,192 Did not respond

662 Assessed for eligibility

318 Total excluded
200 No longer dizzy
80 No access to a computer or Internet
21 Declined
8 Neck pain/injury
5 Serious comorbidity
3 Registered blind
1 Not contactable after multiple attempts

344 Eligible for registration

39 Did not complete registration
9 Did not complete baseline measures

296 Randomized

160 Intervention group

3-month follow-up
123 Completed
3 Primary outcome missing
22 Withdrew
12 Not contactable

6-month follow-up
112 Completed
1 Primary outcome missing
33 Withdrew (cumulative)
14 Not contactable

3-month analysis
123 Included in primary outcome analysis

6-month analysis
112 Included in primary outcome analysis

136 Usual care group

3-month follow-up
127 Completed
1 Primary outcome missing
6 Withdrew
2 Not contactable

6-month follow-up
118 Completed
5 Primary outcome missing
9 Withdrew (cumulative)
4 Not contactable

3-month analysis
127 Included in primary outcome analysis

6-month analysis
118 Included in primary outcome analysis

more likely to be sustained at 6 months among the older adults (aged >67 years) in our sample.

Adverse Events
A total of 18 non–dizziness-related hospitalizations were identified in a review of general practitioner notes undertaken at the end of the trial (8 in the usual care group, 10 in the intervention group). No dizziness- or intervention-related serious adverse events were reported during the trial or identified from the notes review.

DISCUSSION
Access to an unsupported Internet-based vestibular rehabilitation intervention significantly reduced chronic dizziness and dizziness-related disability compared with usual primary care among the older adults in our study. This benefit persisted for at least 6 months. With the increasing Internet use being seen in older adults, our Internet-based vestibular rehabilitation 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, suggesting that provision via digital technology may not be barrier to effectiveness in older adults, particularly if attention is paid to accessibility when developing such interventions.

Our findings are consistent with the findings of trials of booklet-based vestibular rehabilitation. 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.
Table 2. Primary and Secondary Outcome Measures at 3 and 6 Months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention, Median (IQR)</th>
<th>Usual Care, Median (IQR)</th>
<th>Univariate Difference, Median (95% CI)a</th>
<th>Multivariate Difference, Median (95% CI)b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>VSS-SF total score</td>
<td>6 (3-12)</td>
<td>9 (5-15)</td>
<td>2.52 (1.17 to 3.87; P &lt; .001)</td>
<td>2.75 (1.39 to 4.12; P &lt; .001)</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSS-SF vertigo subscale score</td>
<td>3 (1-7)</td>
<td>4 (2-9)</td>
<td>1.42 (0.50 to 2.33; P = .003)</td>
<td>1.49 (0.54 to 2.43; P = .002)</td>
</tr>
<tr>
<td>VSS-SF autonomic symptoms</td>
<td>3 (0-6)</td>
<td>4 (2-6)</td>
<td>1.19 (0.37 to 2.01; P = .005)</td>
<td>1.03 (0.12 to 1.94; P = .03)</td>
</tr>
<tr>
<td>VSS-SF subscale score</td>
<td>6 (12.5-38)</td>
<td>28 (16-52)</td>
<td>5.33 (1.41 to 9.26; P = .008)</td>
<td>6.15 (2.81 to 9.49; P &lt; .001)</td>
</tr>
<tr>
<td>HADS anxiety score</td>
<td>6 (3-9)</td>
<td>6 (3-9)</td>
<td>0.88 (0.02 to 1.75; P = .046)</td>
<td>0.82 (0.03 to 1.61; P = .04)</td>
</tr>
<tr>
<td>HADS depression score</td>
<td>3 (1-5)</td>
<td>4 (1-7)</td>
<td>0.55 (–0.06 to 1.15; P = .08)</td>
<td>0.55 (–0.18 to 1.28; P = .18)</td>
</tr>
<tr>
<td>Patient-reported improve-</td>
<td>76/122 (62.3)</td>
<td>42/128 (32.8)</td>
<td>0.28 (0.18 to 0.45; P &lt; .001)</td>
<td>0.27 (0.17 to 0.44; P &lt; .001)</td>
</tr>
<tr>
<td>ment, No. (%)</td>
<td></td>
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</table>

Table 3. Post Hoc Exploratory Analysis of Intervention Effectiveness by Age

<table>
<thead>
<tr>
<th>VSS-SF Total Score</th>
<th>Aged ≤67 Years</th>
<th>Aged &gt;67 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention, Median (IQR)</td>
<td>Usual Care, Median (IQR)</td>
</tr>
<tr>
<td>6 months</td>
<td>8 (4-15)</td>
<td>9 (5-20)</td>
</tr>
<tr>
<td>3 months</td>
<td>8 (5-15)</td>
<td>10 (6-19)</td>
</tr>
</tbody>
</table>

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

a Difference between groups controlling for baseline value and clustering.

b Difference between groups controlling for baseline value, clustering, and other significant covariates.

c No other covariates were significant.

d DHI = Dizziness Handicap Inventory; IQR = interquartile range; VSS-SF = Vertigo Symptoms Scale–Short Form; NA = not applicable.

e Difference between groups controlling for baseline values and clustering.

f Difference between groups controlling for baseline value, clustering, and other significant covariates.

of chronic dizziness. The size of the effect on the primary outcome, the VSS-SF, was comparable to the effects achieved in a trial by Yardley et al, where booklets were provided with health care professional support (1.79 to 2.52 points). It is also comparable to mean VSS-SF reductions after a 9-week, face-to-face group session vestibular rehabilitation intervention (2.4 points).23

Although the difference in dizziness symptoms remained significant, the size of the difference between the intervention and usual care groups decreased from 3 months to 6 months. This diminishing difference was driven by improvements in the control group rather than by worsening symptoms in the intervention group, where improvements in dizziness persisted. Our trial’s pre-randomization entry procedures for all patients may have been reassuring, describing vestibular rehabilitation as simple head movements that may reduce dizziness. Dizziness is closely related to anxiety and avoidance behaviors; therefore, reassurance is a key component in management strategies for dizziness.6

This trial had some limitations. Loss to follow-up in the intervention group 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 patients engage in this program. Although the difference between groups in the multiple imputation analysis was significant at 3 months, it did not reach significance at 6 months. 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 because of the nonnormality of the patient data. As with previous vestibular rehabilitation trials, overall uptake after our primary care list search and mailing was low (fewer than 10% of patients offered participation enrolled); however, it is possible that a large proportion of nonresponders were no longer dizzy or simply did not want to take part in a research trial. We were unable to consider our results in relation to specific diagnoses, as those data were not obtained. Nonetheless, our trial approach 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. Finally, harms data were examined primarily through a review of family practice notes, or when reported directly to the study team. As minimal contact was made with the trial team, some harms may have gone unreported.

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

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Key words: behavioral medicine; chronic care; ear, nose, and throat (ENT); vertigo; Meniere disease; primary care; practice-based research

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Author contributions: L.Y., S.K., P.C., G.A., and A.G. conceived of the study. A.G., L.Y., S.K., D.T., and P.L. designed the study and secured funding. R.E., A.G., L.Y., and S.K. developed the intervention. F.L. and A.B. were responsible for ensuring the clinical safety of the design and the potential for appropriate implementation. B.S. carried out the statistical analysis. A.G. drafted the manuscript with input from all authors. All authors approved the final manuscript. A.G. had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Supplementary materials: Available at http://www.AnnFamMed.org/content/15/3/209/suppl/DC1/

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