ISRCTN86912968 https://doi.org/10.1186/ISRCTN86912968

Online Dizziness Intervention for Older Adults: A Randomised Controlled Trial

Submission date
24/04/2013

Recruitment status
No longer recruiting

Registration date
25/04/2013

Overall study status
Completed

Last Edited
05/10/2018

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
As people become older, experiencing dizziness becomes more common. For some, dizziness can lead to falls, fear, and poor quality of life. Research has shown that there are specific exercises that can be very helpful for people who experience dizziness, but very few people are currently taught the exercises. The exercises retrain the balance system so as to overcome dizziness and imbalance. Phase 1 of this project worked closely with older people to develop an interactive online intervention which includes videos illustrating how to carry out the exercises at home, advice personalised to the users symptoms, exercise reminders, and help in dealing with fear and stress that can make dizziness worse. The website has been designed specifically so it is easy to use for older adults. In phase 2, we will test if the website is more effective than the usual care for NHS patients, and we will examine whether the intervention provides value for money. The overall aim of this project is to reduce dizziness symptoms and improve quality of life in older adults with dizziness through the use of an Internet intervention. The intention is also to improve our understanding of which features of this intervention, and Internet symptom management interventions in general, are most acceptable, engaging and beneficial for older adults.

Who can participate?
262 adults who are aged 50 years or more, have reported dizziness (that is still current) to their GP in the past two years, and have access to the internet will be recruited from primary care to take part in the study.

What does the study involve?
The study will have two arms; patients in the treatment arm will have access to the online intervention and usual care, while patients in the control arm will have access to usual care only. This will allow us to see how well the intervention works compared to standard primary care practice for older adults consulting with dizziness.
Eligible patients will be given a website address where they can access study information, give informed online consent, complete baseline measures and be automatically randomised to intervention or usual care arms. Patients will be sorted by dizziness severity. Patients allocated to the usual care arm will be informed that they will have access to the intervention after 6 months. Patients in both arms will be emailed at 3 and 6 months to complete automated follow-

up measures online.
Patients in the intervention arm will have access to the website and will be asked to log in and complete modules on a weekly basis. The intervention will consist of 6 modules to be accessed at a rate of one module per week.
The intervention will contain information about and demonstrations of Vestibular Rehabilitation exercises and psychological symptom management. The intervention will be standalone and fully automated. Patients allocated to the intervention will receive automated email reminders to ensure regular use of the intervention.
A diversity sample of 25 patients from the intervention arm, who gave prior consent to be contacted, will participate in in-depth semi-structured interviews following the completion of the intervention. These interviews will provide detailed information regarding the patients experiences and perceptions of using the intervention over the study period.

What are the possible benefits and risks of participating?
All of the participants, in either arm, will be able to benefit from the website intervention as those allocated to usual care alone will be able to access it after they have completed the 6 month outcome measures. As such, participants will have access to information and advice that they may not normally receive as part of their usual care.
The only real cost to participants is the time they will need to spend accessing the online intervention. All participants in the study will have to log on to the website and complete the measures at 3 and 6 months. For those in the intervention arm, they will have to find the additional time to log on to the website and complete modules on a weekly basis.

Where is the study run from?
The study will be run from the University of Southampton, School of Psychology.

When is the study starting and how long is it expected to run for?
Recruitment into this study runs from August 2013 until July 2014.

Who is funding the study?
Dunhill Medical Trust

Who is the main contact?
Rosie Essery
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14234

Study information

Scientific Title
Online Dizziness Intervention for Older Adults: A Randomised Controlled Trial

Acronym
ODIN

Study objectives
Current hypothesis as of 10/09/2013:
As people become older, experiencing dizziness becomes more common. For some, dizziness can lead to falls, fear, and poor quality of life. Research has shown that there are specific exercises that can be very helpful for people who experience dizziness, but very few people are currently taught the exercises. The exercises retrain the balance system so as to overcome dizziness and imbalance. We have worked closely with older people to develop an interactive online intervention which includes videos illustrating how to carry out the exercises at home, advice personalised to the users symptoms, exercise reminders, and help in dealing with fear and stress that can make dizziness worse. The website has been designed specifically so it is easy to use for older adults. We will test if the website is more effective than the usual care for NHS patients, and we will examine whether the intervention provides value for money.

Provision of a stand-alone web-based intervention teaching Vestibular Rehabilitation exercises will be:
1. More effective than routine care in reducing symptoms in dizzy patients over 50 years in primary care
2. More cost-effective than routine care of dizzy patients over 50 years.

Previous hypothesis:
As people become older, experiencing dizziness becomes more common. For some, dizziness can lead to falls, fear, and poor quality of life. Research has shown that there are specific exercises that can be very helpful for people who experience dizziness, but very few people are currently taught the exercises. The exercises retrain the balance system so as to overcome dizziness and imbalance. We will work closely with older people to develop an interactive online intervention which includes videos illustrating how to carry out the exercises at home, advice personalised to

the users symptoms, exercise reminders, and help in dealing with fear and stress that can make dizziness worse. The website will be designed specifically so it is easy to use for older adults. We will test if the website is more effective than the usual care for NHS patients, and we will examine whether the intervention provides value for money.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14234

On 10/09/2013, the following changes were also made to this trial record:
1. The public title was changed from "Online Dizziness Study Phase 2" to "Online Dizziness Intervention for Older Adults: A Randomised Controlled Trial"
2. The scientific title was changed from "Online Dizziness Intervention for Older Adults Phase 2 Randomised Controlled Trial" to "Online Dizziness Intervention for Older Adults: A Randomised Controlled Trial"
3. The anticipated start date was changed from 15/07/2012 to 19/08/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Southampton A,17/04/13, ref:13/SC/0119

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dizziness

Interventions
Intervention 1: Standalone, web-based intervention comprising information about dizziness and the balance system, instructions, advice, video demonstrations and tailored feedback about vestibular rehabilitation exercises, and also advice and instructions about additional psychological techniques that may help improve dizziness symptoms such as controlled breathing, thought control, stress management and relaxation.

2. Usual care for NHS patients

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Vertigo Symptom Scale (short form) measured at baseline, +3 months, +6 months

Secondary outcome measures
Current secondary outcome measures as of 10/09/2013:

Secondary outcome measures will include a single item of subjective improvement in health, the Dizziness Handicap Questionnaire, which measures dizziness-related quality of life, and the Hospital Anxiety and Depression Scale, measuring symptoms of depression and anxiety.

Demographic characteristics, including age, sex and years of education will be taken alongside duration of dizziness symptoms, recorded diagnosis, and previous management.

We will measure potential psychological predictors of outcome including: acceptance using the Acceptance and Action Questionnaire (AAQII), expectations for treatment outcome and exercise self-efficacy.

In addition we will measure adherence and predictors of adherence using the validated Problematic Experiences of Therapy Scale (PETS) and objective measures of website usage.

We will also use the EQ5D as a measure of quality of life.

Previous secondary outcome measures:

Secondary outcome measures will include a single item of subjective improvement in health, the Dizziness Handicap Questionnaire, which measures quality of life, and the Hospital Anxiety and Depression Scale, measuring symptoms of depression and anxiety.

Demographic characteristics, including age, sex and years of education will be taken alongside duration of dizziness symptoms, recorded diagnosis, and previous management.

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In addition we will measure adherence and predictors of adherence using the validated Problematic Experiences of Therapy Scale (PETS) and objective measures of website usage.

Overall study start date
19/08/2013

Completion date
25/07/2014

Eligibility

Key inclusion criteria
1. Reported symptoms of dizziness over the past two years
2. Be over 50
3. Have access to the Internet and an email account

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 262; UK Sample Size: 262

Key exclusion criteria
1. Identifiable non-labyrinthine cause of dizziness
2. Medical contra-indications for making required head movements (e.g. severe cervical disorder)
3. Serious co morbidity (life threatening condition or progressive central disorder)
4. Have taken part in a previous dizziness study

Date of first enrolment
19/08/2013

Date of final enrolment
25/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Aldermoor Health Centre
Aldermoor Close
Southampton
England
United Kingdom
SO16 5ST

Sponsor type
University/education

Website
http://www.southampton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
The Dunhill Medical Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/07/2014		Yes	No

Results article	results	01/05/2017		Yes	No
HRA research summary			28/06/2023	No	No