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A feasibility study of psychologically informed vestibular rehabilitation for persistent dizziness

Submission date
06/04/2020

Recruitment status
No longer recruiting

Registration date
08/04/2020

Overall study status
Completed

Last Edited
30/09/2022

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
Dizziness can be treated with exercises called vestibular rehabilitation. The exercises retrain the balance system so as to overcome dizziness and imbalance. There is evidence to show that not everyone improves with this treatment. Research shows that what starts the dizziness is not always the same thing that perpetuates the symptoms. The way people cope with the symptoms may contribute to their illness. Treatment outcomes could be improved by including cognitive behavioural therapy (CBT). This helps patients to understand their dizziness, tackle the understandable fears they have about activity, and to learn how to manage and reduce the symptoms. The aim of this study is to assess whether it is possible to conduct a full-scale main study. To do this the researchers will collect important information that is needed to design a larger study alongside interviews with participants.

Who can participate?
Participants will need to be over the age of 18 and have had dizziness for 3 months or longer. They must have a minimum level of dizziness-related disability, and not be receiving treatment. Participants will not be included if they have ongoing investigations, have other active health conditions that limit their capacity to complete the study, or cannot speak English.

What does the study involve?
Forty participants will be recruited. Consenting participants will be randomly allocated to undergo six sessions of psychologically informed physiotherapy or six sessions of physiotherapy as usual over 4 months. Participants will complete self-report questionnaires about their physical and mental health and a test of their balance before and after the treatments.

What are the possible benefits and risks of participating?
All of the participants, in either group, will still receive active treatment for their condition. The only real cost to participants is the time they will need to spend attending therapy, completing the questionnaires and balance tests needed for the study. For those in the intervention group, they will receive physiotherapy treatment from a qualified physiotherapist who has taken the extra training required for them to deliver it. When undergoing vestibular rehabilitation, dizziness may worsen in the short term.

Where is the study run from?
St George's University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2015 to October 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276707

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44952, IRAS 276707

Study information

Scientific Title
INVEST: A feasibility randomised controlled trial of psychologically informed vestibular rehabilitation for chronic dizziness

Acronym
INVEST

Study objectives
Integrating cognitive-behavioural therapy and vestibular rehabilitation will be feasible and acceptable for people with persistent dizziness and warrant a full-scale randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2020, Wales Research Ethics Committee 4 (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7976 982591; Wales.REC4@wales.nhs.uk), REC ref: 20/WA/0089

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chronic dizziness / Persistent Postural Perceptual Dizziness (PPPD)

Interventions
This is a randomised controlled feasibility trial. It also includes nested qualitative interviews with participants. The objective is to gather preliminary information in preparation for conducting a full-scale trial in the future.

Participants will be recruited from the audiovestibular (balance) clinic at St George's Hospital, London. They will be given an information sheet and approached to screen for eligibility by a member of the healthcare team. Eligible participants wishing to take part in the trial will sign a

written consent form indicating that they have read and understood the information sheet and have opportunity to answer any further questions. Participants will then attend a testing appointment, where they will complete a set of baseline self report questionnaires and a test of their balance/walking. Once they have completed the baseline measures they will be randomly allocated to either the intervention and usual care physiotherapy, by a computer. A total of 20 participants will be allocated to each arm, who will complete 6 sessions of physiotherapy over 12-14 weeks. Sixteen weeks after they were randomised they will attend another appointment to complete the same questionnaires and balance test they did at baseline to see if there has been any changes. A proportion of participants in the intervention group will be invited to participate in semi-structured interviews to discuss the acceptability and feasibility of the trial, including the recruitment processes, randomisation, retention, and outcome measures.

The treatment in the intervention arm will mirror the best practice physiotherapy (vestibular rehabilitation) guidelines but also include elements of cognitive-behavioural therapy (CBT). The purpose of this intervention is to target individual's dizziness beliefs and behaviours in order to facilitate their engagement with exercise and vestibular rehabilitation. The development of the intervention was systematic, based on findings of a review and prospective studies, with substantial input from six patient and public representatives and a multidisciplinary team of health psychologists, physiotherapists and Audiovestibular physicians. Participants will be provided with a structured therapy manual including worksheets. The primary researcher (DH) is the principal physiotherapists at St George's Hospital and will deliver the intervention.

The treatment as usual will be delivered by another senior specialist physiotherapist at St George's and will comply with the best practice guidelines outlined by the American Academy of Physical Therapy.

Intervention Type
Behavioural

Primary outcome measure
Primary feasibility outcomes collected at the end of the trial:
1. Suitability of eligibility criteria measured by recording the number of people excluded from the trial
2. Willingness to participate measured by the proportion of eligible patients who agree to participate
3. Retention rates measured by the proportion of participants who were randomised that completed follow-up assessment as well as recording of attendance at therapist sessions
4. Time needed to collect and analyse data measured by timesheets
5. Acceptability of the intervention measured at 4 months up using a questionnaire based on the component constructions in the theoretical framework of acceptability

Secondary outcome measures
Secondary feasibility outcomes measured at baseline and 4 months:
1. Dizziness handicap is measured using the Dizziness Handicap Inventory (DHI)
2. Visually induced dizziness is measured using the Visual Vertigo Analogue Scale (VVAS)
3. Dizziness interference is measured using the visual analogue scale (VAS)
4. Health-related quality of life is measured using the European Quality of Life questionnaire EQ5D (EuroQol)
5. Balance is measured using the mini-Balance Evaluation Systems Test (mini-BEStest)

Process outcome measures measured at baseline and 4 months:
1. Illness perceptions are measured using the Brief Illness Perception Questionnaire (B-IPQ)
2. Cognitive and behavioural responses to dizziness are measured using the Cognitive and Behavioural Responses to Symptoms Questionnaire (CBRSQ)
3. Anxiety is measured using the Generalised Anxiety Disorders-7 Questionnaire (GAD-7)
4. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9)

Overall study start date
01/02/2015

Completion date
30/10/2022

Eligibility

Key inclusion criteria
1. Patients attending the neuro-otology balance clinic at St George's University Hospitals Foundation Trust with symptoms of chronic dizziness (>= 3 months) made worse by movement of the self and/or the environment
2. Dizziness Handicap Inventory (DHI) > = 40
3. Aged > = 18 years
4. Not currently participating in vestibular rehabilitation or psychological treatment (talking therapies)
5. Able to provide consent and willing to comply with the proposed training and testing regime

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
40

Key exclusion criteria
1. Patients with incomplete diagnosis or ongoing investigations
2. Patients with vestibular migraine or other headache/migraine disorder with > = 3 headaches a month and/or MIDAS (Migraine Disability Assessment) > = 6
3. Patients with active Meniere's disease or BPPV (Benign Paroxysmal Positional Vertigo)
4. Patients with central vestibular disorders (excluding migraine and functional disorders), other

neurological disorders, significant systematic illness or known psychiatric disorders
5. Patients with acute orthopaedic disorders influencing balance control and gait
6. Insufficient grasp of written/spoken English

Date of first enrolment
06/07/2020

Date of final enrolment
24/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's University Hospitals NHS Foundation Trust
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2015-01-079

Results and Publications

Publication and dissemination plan
The full protocol will be uploaded pending publication in a peer-reviewed journal. Planned publication of the study results in a high-impact peer-reviewed journal in 2021.

Intention to publish date
01/03/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	09/03/2020	08/04/2020	No	Yes
Protocol article		16/08/2021	21/01/2022	Yes	No
Results article		10/04/2022	11/04/2022	Yes	No
HRA research summary			28/06/2023	No	No