

A feasibility study of psychologically informed vestibular rehabilitation for persistent dizziness

Submission date 06/04/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/09/2022	Condition category Signs and Symptoms	<input type="checkbox"/> 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?

David Herdman

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

276707

Protocol serial number

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

Study type(s)

Treatment

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 physiotherapist 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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

St George's University Hospitals NHS Foundation Trust

St George's Hospital

Blackshaw Road

Tooting

London

United Kingdom

SW17 0QT

Sponsor information

Organisation

King's College London

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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?
Results article		10/04/2022	11/04/2022	Yes	No

Protocol article		16/08/2021	21/01/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2	09/03/2020	08/04/2020	No	Yes