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A study investigating the possibility and practicality of assessing and treating dizziness after traumatic brain injury

Submission date
10/02/2020

Recruitment status
No longer recruiting

Registration date
13/02/2020

Overall study status
Completed

Last Edited
31/05/2024

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Dizziness affects the majority of traumatic brain injury (TBI) survivors and can have a burdensome impact on individuals, their families and on wider society. However, evidence suggests dizziness and imbalance problems are not well managed in acute TBI (i.e whilst patients are still in hospital). The researchers will train hospital staff to assess and treat the most common form of dizziness (Benign paroxysmal positional vertigo [BPPV]). The researchers will ask patients with this type of dizziness to take part in the study.

The researchers aim to find out how many patients have this type of dizziness and whether it is possible and practical for ward staff to assess and treat this type of dizziness whilst patients are still in hospital following a traumatic brain injury.

Who can participate?
Patients over the age of 18 years with a closed head injury and benign paroxysmal positional vertigo [BPPV]. Members of ward staff.

What does the study involve?
The researchers will train ward staff to be able to diagnose and treat one specific form of dizziness, 'Benign paroxysmal positional vertigo [BPPV]' which affects approximately 50% of acute TBI patients.
Those taking part will be asked to complete some questionnaires about their symptoms and to complete some tests of their balance. These tests are non invasive and are well tolerated. The researchers will then randomly allocate patients to three different treatments; repositioning manoeuvres, Brandt-Daroff exercises and advice. Study participants will be followed up in face to face appointments at 4 weeks and 12 weeks following treatment.

What are the possible benefits and risks of participating?
The researchers expect the results of the study to benefit future patients. Patients taking part in

the study will receive reimbursement for their time at follow up assessments. There is a risk patients may feel dizzy or nauseated during tests or treatments, where required tests or treatments will be stopped at the patient's request.

Where is the study run from?
1. Imperial College London Department of Medicine (UK)
2. St. Mary's Hospital (UK)
3. King's College Hospital (UK)
4. St George's Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2022

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

Who is the main contact?
Rebecca Smith
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
249678

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 41229, IRAS 249678

Study information

Scientific Title
A feasibility study investigating different interventions for the treatment of benign paroxysmal positional vertigo in acute traumatic brain injury patients

Study objectives
Assessing and treating benign paroxysmal positional vertigo is feasible in acute traumatic brain injury patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/04/2019, East of England Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8068; nrescommittee.eastofengland-essex@nhs.net), ref: 19/EE/0052

Study design
Interventional randomized feasibility study

Primary study design
Interventional

Secondary study design
Randomised feasibility study

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
Benign paroxysmal positional vertigo

Interventions
PATIENT ASSESSMENTS
Following consent patients will undergo ward-based assessments comprising a clinical history and examination, subjective questionnaires and balance tests, prior to randomisation to one of three treatment group. Following randomisation, patients will receive treatment as per their

allocated group. At the end of treatment, the researchers will ask patients to participate in interviews to explore their thoughts of taking part in the trial.

CLINICAL HISTORY AND EXAMINATION
Participants will be assessed using routine clinical history and examination. This will comprise bedside eye movement and vestibular testing.
At this point, the researchers will also note baseline data including:
- Demographic data (age and gender)
- Past medical history
- Date and nature of injury
- Severity and location of injury
- Surgical interventions
- Duration of hospital stay
- Falls during hospital stay
- Anti sickness or dizziness medications during hospital stay
- Type of BPPV
- Presence and length of post-traumatic amnesia
- Functional status as measured by the Functional Ambulation Category

SUBJECTIVE QUESTIONNAIRES AND BALANCE TESTS
The researchers will ask participants to complete questionnaires regarding their symptoms, mood and function and complete objective tests of their balance (see below)

Timepoint 0 - Questionnaires
Dizziness Handicap inventory
UCLA Dizziness questionnaire
Activities Specific Balance Confidence Scale
Hospital Anxiety and Depression Scale
Euro QoL 5D
Montreal Cognitive Assessment
Awareness Questionnaire

Timepoint 0 - Balance tests
Modified Dynamic Gait Index
Modified Clinical test of sensory integration in balance
Balance tests will include tests of walking and balancing by the bedside, tests routinely used on the ward. These are commonly used measures of balance. For the walking test, a researcher will walk alongside the subject to ensure that there is no risk of falling.
The researchers will ask patients and their carers to keep a falls diary during the period between discharge from hospital and follow up. This will be collected at the follow-up appointment.

RANDOMISATION
Following assessment, participants will be randomly allocated to one of three treatment groups using computer software (sealed envelope). A minimisation procedure will ensure equal allocation between groups of the following factors:
Age: (≤ 40 years Vs > 40 years)
Initial TBI severity: Glasgow coma scale (GCS) GCS ≥9 Vs GCS <9
Ability to complete balance outcome measures: Yes Vs No
Participants will be randomly allocated to one of three groups using computer software (sealed envelope).

BLINDING
The trial participants and outcome assessors will be blinded to the intervention groups. The care providers (i.e. the ward therapists) completing the diagnostic and intervention procedures will not be blinded (due to the physical nature of the different intervention procedures).

Unblinding
Final unblinding will occur at 12 week follow up when the outcome assessor will be required to interview participants to discuss their thoughts and views about participating in the trial. This will necessitate unblinding.

TREATMENTS FOR PATIENTS
Following completion of outcomes, patients will be randomly allocated to a treatment group. All interventions will be completed by ward therapists. Patients will be blinded to treatment allocation. Due to the physical nature of the interventions, therapists will not be blinded to treatment. In some cases, the researchers will video diagnostic manoeuvres and treatment. There will be a clause in the participant consent form for this purpose. This will help us analyse the fidelity of the intervention.
1. Repositioning manoeuvres:
Therapists will complete repositioning manoeuvres with patients as per recent clinical guidelines, up to 3 manoeuvres per session. Re-positioning manoeuvres can be completed at the bedside and are physical manoeuvres, take little time, are non-invasive and do not require any additional equipment.
2. Brandt - Daroff exercises:
Therapists will teach patients to perform Brandt Daroff exercises (exercises completed on the bed, by the patient) as per clinical recommendations (Bhattacharyya et al. 2017). The researchers will ask patients to continue with the exercises twice a day for 2 weeks. The researchers will provide each patient with a home exercise diary to record their adherence to the exercises.
3. Advice:
Ward therapists will provide patients with written and verbal advice regarding maintaining normal movements of the head and body.

FOLLOW UP
The researchers will follow up patients at 4 and 12 weeks following treatment in a face to face outpatient clinic. Repeat subjective
questionnaires and objective balance tests will be completed, as well as repeat diagnostic tests for BPPV.
Follow up 1 - 4 weeks post-treatment date
Questionnaires as completed at Timepoint 0 PLUS
Work Status and Stability questionnaire
Glasgow Coma Score Extended
Quality of Life after Brain Injury
Follow up 2 - 12 weeks post-treatment date
All questionnaires completed at Timepoint 0 and Follow up 1
Semi-structured interview (see below)

LABORATORY TESTING
At Follow up 1 and / or 2, patients will also be asked if they are willing to undertake further balance tests at the balance laboratory at Charing Cross Hospital, Imperial College London. These tests will include tests of balance perception and sway, used in previous studies. Those eligible to take part in these tests will fit the primary inclusion criteria AND:
- Will not have sustained lower limb trauma affecting the patient's balance or precluding patient's ability to stand unaided

Those willing to take part in laboratory tests will complete:
Static Balance:
The researchers will record static balance using posturography. Participants will be asked to stand with their feet together on solid or a foam surface with their eyes open or closed for one-minute intervals. Subjects will be tethered by a harness and supervised by a researcher for safety purposes.
Balance perception:
Subjects will be moved on whole-body motion devices (in axes aligned to earth vertical and tangential to earth vertical) whilst sitting in a comfortable seat with a safety harness, and will be required to indicate - by button press, or verbally – their perceived sensation of motion or orientation. The researchers routinely use these whole-body motion devices in the clinic and previous research projects. These tests are non-invasive and well-tolerated.

INTERVIEWS WITH PATIENTS AND STAFF
A qualitative methodology will explore the thoughts and experiences of study participants, those who declined to take part in the trial and ward staff. This part of the study aims to identify potential barriers and facilitators to participant recruitment and retention. This will be achieved by undertaking individual semi-structured interviews, which is the most effective strategy to overcome barriers to recruitment.
Purposive sampling will be used for the interviews to obtain a sample of 18 patient participants; six from each group (re-positioning manoeuvres; Brandt-Daroff exercises and advice)for interviews. This sampling strategy will ensure that a range of ages and initial TBI severity are represented. This sample size is in line with other studies utilising a framework approach. All those recruited to the feasibility study will be eligible to participate. A purposive sampling strategy will also be used for decliner and clinician interviews.
Patient interviews: Semi-structured interviews will be conducted with patient participants using interview topic guides developed and informed by the literature and Patient and public involvement. Interviews will be audio-recorded, transcribed verbatim and anonymised. This will occur 12 weeks post-treatment after the last objective data collection.
This ensures the outcome assessor will remain blinded to the group allocation up to this point.
Staff interviews: Up to ten staff members will also be interviewed including the treating therapist(s), those involved in screening participants and ward managers/ matrons. Semi-structured interviews or a focus group (depending on staff preference) will evaluate whether staff perceive the subsequent RCT to be achievable within an acute environment. This will help inform and direct a future randomised controlled trial. There will be a separate information sheet and consent form for this purpose.
Decliner and withdrawal interviews: Patients may decline to take part in the study without giving reasons. If however, they are willing to discuss their reasons for declining to take part, up to ten people who declined to participate, or withdrew from the study, will be interviewed. The aim of this is to explore their reasons for declining/withdrawing to inform and optimise recruitment /retention for the subsequent main study. Data collection will occur within three days of declining/withdrawal, either on the ward or in a quiet environment, depending on patient preference. There will be a separate information sheet and consent form for this purpose. A short (5 minute) semi-structured interview using a topic guide will be undertaken.

Intervention Type
Other

Primary outcome measure

1. Trial recruitment and retention rates measured at the end of the trial
2 .Acceptability and fidelity of the intervention examined at the end of the trial
3. Incidence of adverse events measured at the end of the trial

Secondary outcome measures
1. Frequency of BPPV measured at baseline, 4 and 12 weeks
2. Dizziness handicap measured using Dizziness handicap inventory at baseline, 4 and 12 weeks
3. Balance confidence measured using the Activities specific balance confidence scale at baseline 4 and 12 weeks
4. Mood measured using the hospital anxiety and depression scale at baseline, 4 and 12 weeks
5. Static and dynamic balance measured using the mCTSIB and mDGI at baseline and 4 and 12 weeks
6. Quality of life measured using quality of life after brain injury questionnaire at 4 and 12 weeks
7. Brain injury recovery measured using the glasgow outcome scale extended at 4 and 12 weeks

Overall study start date
21/01/2018

Completion date
01/04/2022

Eligibility

Key inclusion criteria
Patient Inclusion criteria:
1. Over the age of 18 years
2. Closed head injury as defined by CT imaging
3. Inpatient on major trauma or outlying ward
4. Able to give informed consent or consultee consent
5. Sufficient grasp of English to consent and complete outcome measures

Staff inclusion criteria:
1. Members of ward staff involved in the trial
2. Able to consent to an audio-recorded interview

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 95; UK Sample Size: 95

Total final enrolment
75

Key exclusion criteria
Patients exclusion criteria:
1. History of previous or current substance abuse
2. Orthopaedic or vascular cervical spine instability
3. Pregnant
4.Glasgow Coma Score at assessment less than 14
5. Medically unstable
6. Current prescription of Phenytoin
7. Active psychiatric disease, including those with a current or past history of active psychotic disease but not those with a past history of psychiatric disease

Staff exclusion criteria:
Does not meet inclusion criteria

Date of first enrolment
03/02/2020

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Mary's Hospital
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
St George's Hospital
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SW17 0QT

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2017-03/070

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/09/2020	21/09/2020	Yes	No
Interim results article	Qualitative results on healthcare professionals' perceptions of barriers or facilitators	02/01/2023	03/01/2023	Yes	No
HRA research summary	Baseline results		28/06/2023	No	No
Other files			24/07/2023	No	No
Results article		28/05/2024	31/05/2024	Yes	No