

Exploratory trial of antidepressant therapy for dizziness

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| Submission date 30/09/2005 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/09/2005 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 20/09/2013 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0530147182

Study information

Scientific Title

Study objectives

In primary care attendees with symptoms of dizziness and associated psychological symptoms, a) antidepressants and b) vestibular rehabilitation exercises reduces symptoms of dizziness when either treatment is delivered singly or together in a factorial design. Prior to testing this hypothesis, in this study the researchers propose to conduct an exploratory trial in which they will examine the effects of varying doses of antidepressants, on the symptoms of dizziness amongst general practice attendees visiting their GP for this purpose.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Signs and Symptoms: Dizziness

Interventions

1. Low dose antidepressant (Citalopram) therapy and self-help leaflet
2. Full dose antidepressant (Citalopram) and self-help leaflet
3. A control group receiving no antidepressant treatment, but receiving self-help leaflet

Added 20/09/2013: this trial never took place as there was no sponsorship agreed.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Citalopram

Primary outcome(s)

The community prevalence of dizziness ranges from 16-35%. One quarter of such sufferers report chronic handicapping symptoms and psychological distress. There are currently no evaluations of treatment for dizziness in the community. This study is the first step in evaluating a treatment that has been previously examined in a hospital setting.

This study will provide:

1. Information on the acceptability and feasibility of using antidepressants for people with dizziness in primary care.
2. Estimates of the numbers of people with dizziness who can be recruited to the study from

each practice and hence assist with planning in a main trial.

3. Information on people's preferences for each intervention.

4. Preliminary estimates of the effect on clinical, psychological and physical outcomes in people with dizziness in primary care treated with low dose or full dose of antidepressants, which will inform sample size calculations for a main trial.

In addition, the results of this study will allow the researchers to finalise their assessment and treatment schedule for people with dizziness in primary care.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/05/2005

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

GP attendees with acute symptoms of dizziness, vertigo, lightheadedness, dysequilibrium, presyncope, and other types of balance problems for more than 2 months, associated with associated psychological symptoms.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Below 18 years old and above 85 years old
2. Too ill to take part (i.e serious physical illness or terminal disorder)
3. First episode of dizziness
4. Acute dizziness
5. Vertebral basilar insufficiency
6. Cardiovascular diagnoses
7. Severe neurological disorders

Date of first enrolment

01/06/2003

Date of final enrolment

31/05/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Free and University College Medical School

London

United Kingdom

NW3 2PF

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

North Central London Research Consortium (UK) NHS support funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration