Improving the prognosis of dizzy elderly: a three-arm validation and intervention study in general practice

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44327

Source
ToetsingOnline

Brief title
RODEO: reduction of dizziness in older people

Condition

- Other condition

Synonym
dizziness, spinning sensation

Health condition

Duizeligheid

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Dizziness, older people, prognosis, treatment

Outcome measures

Primary outcome

The primary clinical outcome is dizziness related impairment at follow-up,

which will be assessed using the Dizziness Handicap Inventory (DHI).

Secondary outcome

Secondary outcomes are quality of life (EQ-5D-5L), difference in *Fall Risk

Increasing Drug* count, anxiety/depression, dizziness frequency, fall

frequency, health care utilization.

Study description

Background summary

When treating older patients with dizziness in primary care, the current diagnosis oriented approach is insufficient. Often, it is not possible to diagnose an underlying disease and even if a disease is diagnosed, therapeutic options are often limited. In this study a prognosis oriented approach for dizziness in older people in primary care will be investigated.

Study objective

In this study we want to validate a risk score for chronic dizziness with persistent impairment in older dizzy patients in general practice. Furthermore, we want to investigate the effectiveness of a risk factor-guided, i.e. a prognosis-oriented, intervention for dizzy older patients with a high risk of persistent impairment.

Study design

The study protocol consists of two parts. Firstly, we will perform a validation study to externally validate a 7-item risk score for chronic dizziness with persistent impairment. Secondly, we will perform an intervention study, using a cluster controlled clinical trial. In the intervention study we will compare the effectiveness of a targeted intervention for dizzy older patients with a high risk of persistent impairment with usual care during one year of follow-up.

Intervention

In older patients with a high risk of persistent impairment because of dizziness we will compare a risk factor-guided intervention consisting of one, two, or three of the following interventions: (1) medication adjustment in case of the usage of >= 3 Fall Risk Increasing Drugs (FRIDs), (2) stepped care in case of anxiety/depression, and (3) exercise therapy in case of impaired functional mobility. All three interventions are evidence based and usual care for the above-mentioned risk factors.

Study burden and risks

A group of 125 patients of the validation group will receive 3 questionnaires by mail at baseline and at 6 and 12 months follow-up. The group of 250 patients participating in the intervention study will receive four questionnaires at baseline, 3, 6 and 12 months follow-up, and will keep up a diary to report dizziness frequency and fall frequency. Filling out the questionnaires will take about 30 minutes each time. Keeping up the diary will take 1 minute every week.

All 375 patients will be subjected to a baseline assessment of 30 minutes at their home including a structured interview and a simple test to determine the functional mobility of the patient.

Patients in the intervention group (n=125) will receive - in addition to usual (general practice) care - a targeted intervention, depending on the presence of specific risk-factors. Participating in the intervention 'medication adjustment ' will ask one additional visit to the patients' GP to discuss the outcomes of the medication evaluation. Time investment for the patient when participating in the stepped-care program depends on the severity of the anxiety/depression: the more severe the complaints of the patient, the more time the stepped-care program will cost. We expect an average time investment of of 4 hours per patients in the stepped-care program. The exercise program takes 2 sessions of 50 minutes every week for 8 weeks.

Patients in the control group (n=125) and validation group (n=125) will receive (general practice) care as usual. No treatment will be denied to any participants nor will it be postponed. There are no major medical health risks

for participants in this study. The experimental group may benefit from the intervention by a reduction of impairment due to dizziness and/or a decrease in dizziness frequency.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- being 65 years or older
- consulted a general practitioner for a new episode of dizziness, defined as recurrent dizziness for at least one month, including a giddy or rotational sensation, loss of balance, faint feeling, light-headedness, instability, or tendency to fall
- current dizziness-related impairment (Dizziness Handicap Inventory score >= 30)

- ability to speak, read and write Dutch

Exclusion criteria

- severe cognitive impairment according to the patient*s GP
- serious co morbidity that precludes participation in an exercise program
- current enrolment in interfering study
- if the patient*s GP deems participation of the patient in this study undesirable and/or if participation could damage the doctor-patient relationship for any reason. The GP*s judgement in relation to possible damage of the doctor-patient relationship will always overrule other in- or exclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2015
Enrollment:	375
Type:	Actual

Ethics review

Approved WMO

Date:	11-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	06-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49604.029.14