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Evaluation of a dementia-specific training in patients with mild to moderate-stage dementia

Submission date
27/08/2012

Recruitment status
No longer recruiting

Registration date
04/09/2012

Overall study status
Completed

Last Edited
12/11/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Patients with dementia suffer from motor as well as cognitive impairment. Motor impairment is a major cause of physical disability and includes muscle weakness and fatigue, impaired sensation and poor balance. Cognitive impairment is when a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life. Based on successful previous studies we have developed a specific training programme to improve cognitive and motor defects which are frequent and early markers of dementia (problems with doing two things at once and planning and performing movements). We use supervised group training and a machine-based approach specifically developed for the patients with mild to moderate dementia

Who can participate?
Patients over 65 with mild to moderate dementia.

What does the study involve?
Participants will be randomly allocated to one of two training programs: either an established training program for older persons (strength and flexibility training), or a specific training program developed to achieve better cognitive/motor performance. Participants will be encouraged to attend two supervised exercise sessions per week for 3 months.

What are the possible benefits and risks of participating?
The specific training will hopefully lead to improved cognitive performance. The risks are low - we expect only harmless effects of training (e.g. getting a little out of breath) as the training intensity is individually tailored and supervised by experienced trainers.

Where is the study run from?
The Bethanien Hospital, Geriatric Center at the University of Heidelberg (Germany).

When is the study starting and how long is it expected to run for?
The study will start in September 2012 and will proceed until June 2014.

Who is funding the study?
The Dietmar Hopp Foundation (Germany).

Who is the main contact?
Prof Klaus Hauer
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Evaluation of a dementia-specific training in patients with mild to moderate-stage dementia: a randomised controlled trial

Study objectives
The dementia-specific training approach will increase dual task performances and executive functions and effect a number of secondary study targets in patients with mild to moderate stage dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Heidelberg, Faculty of Medicine Ethics Committee, May 2012, ref: S-360/2010

Study design
Blinded randomised placebo-controlled interventional single centered study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate stage, diagnostically confirmed dementia

Interventions
Intervention Group (IG) will receive specific motor-cognitive training (dual tasking/ executive function) including individual machine-based motor-cognitive training. Subjects will be encouraged to attend two supervised exercise sessions per week for 1.5 hours for 3 months.

Control Group (CG) will receive unspecific motor training (calistenics and strength training of upper extremities while seated). Subjects will be encouraged to attend two supervised exercise sessions per week for 1 hours for 3 months.

Both study groups will be treated by patient-centered training approach tailored to the needs and abilities of cognitively impaired patients as developed and described by the working group in previous intervention trials for patients with dementia.

Intervention Type
Behavioural

Primary outcome(s)
Improvement of dual task performance (trained and non-trained tasks as measured by electronic gait (Gait rite) and strength analysis (Diagnos 40) and specified cognitive tests) and executive function as measured by biomechanical analyses (DynaPort Hybrid and Physiomat training device) after intervention.

Key secondary outcome(s))
1. MRI-Assessment:
1.1. Association of training induced cerebral modifications with training effects and baseline predictors
1.2. Dual task during ADL: Effect of specific training on habitual dual task performance /frequency as measured in home environment

2. Physical activity:
Physical activity as measured by valid, subjective questionnaire-based measures and objective technical measures allowing quantitative and semi-quantitative analysis optionally including GPs measures

3. Motor Function:
3.1. Timed up and Go - Test
3.2. Performance Oriented Motor Assessment (POMA)
3.3. Psychological / Cognitive Status: Fear of Falling (FESI)
3.4. Geriatric Depression Scale (GDS)
3.5. Short Form Health Survey (SF-12)
3.6. Consortium to establish a registry for Alzheimer´s disease (CERAD)

Trial making test (Zahlenverbindungstest (ZVT), Digit Span test (Zahlennachsprechtest (ZNS), and various other measures.
Validation of assessment tools: Tests for methodological quality of assessment methods including validity, reliability, sensivity to change.

Optional:
Biomarkers: Association of training effects with biomarkers for neural plasticity

Primary as well as secondary outcome measures will be assessed at baseline (T1), at the end of intervention (T2) and at a 3 months follow up (T3)

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Age >65
2. Mild to moderate stage cognitive impairment (MMSE:17-26)
3. Diagnosis of mild to moderate stage dementia based on established international criteria
4. Written informed consent
5. Consent of legal guardian (if assigned)
6. Ability to walk 10 m without aid
7. Living in the vicinity of the study location (<20 km)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Severe psychical disease (substance abuse, psychosis)
2. Severe somatic disease (e.g. heart failure NYHA >3, uncontrolled Diabetes Mellitus)

Date of first enrolment
01/09/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment

Germany

Study participating centre
University of Heidelberg
Heidelberg
Germany
69126

Sponsor information

Organisation
Dietmar Hopp Foundation (Germany)

ROR
https://ror.org/02t2ah669

Funder(s)

Funder type
Charity

Funder Name
Dietmar Hopp Foundation (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/11/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes