ISRCTN49243245 https://doi.org/10.1186/ISRCTN49243245

Effectiveness of physical training in persons with mild to moderate cognitive impairment: a randomised controlled trial

Submission date
06/12/2006

Recruitment status
No longer recruiting

Registration date
26/01/2007

Overall study status
Completed

Last Edited
16/06/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
A standardised training regimen of progressive resistance and functional training will improve strength and functional performance (primary outcomes) and cognitive and emotional status, risk of falling and activity level (secondary outcomes) in persons with mild to moderate cognitive impairment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Medical Faculty of the University of Heidelberg, 28/11/2005, application number: 255/2005

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Motor, cognitive, emotional, physical activity status, risk of falling in persons with cognitive impairment

Interventions
Intervention group:
Individually tailored progressive resistance and functional training including attentional demands in supervised training group twice/week (two hours) for 12 weeks.

Control group:
Group training of non relevant motor dimension (basically stretching exercise) while seated twice /week (one hour) for twelve weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Maximal strength and functional performance.

All measurements assessed at baseline, three months, six months, and 12 months by validated, established evaluation tools.

Secondary outcome measures
1. Emotional and cognitive status
2. Physical activity level
3. Risk of falling

Overall study start date
01/04/2006

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Aged over 65
2. No severe or uncontrolled somatic or psychological disease
3. Mini Mental State Examination (MMSE) score 15 to 26
4. Ability to walk 5 metres with assistance
5. Residence within 15 km of study centre
6. Written informed consent
7. No severe language restriction
8. No severe visual deficits

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
120

Key exclusion criteria
Not applicable

Date of first enrolment
01/04/2006

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Germany

Study participating centre
Geriatric Research Department
Heidelberg
Germany
069126

Sponsor information

Organisation
Landesstiftung Baden Württemberg (Germany)

Sponsor details
Im Kaisemer 1
Stuttgart
Germany
70191

Sponsor type
Research organisation

Website
http://www.landesstiftung-bw.de

ROR
https://ror.org/031h5fa94

Funder(s)

Funder type
Research organisation

Funder Name
Landesstiftung Baden-Württemberg (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	12/06/2014		Yes	No