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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
06/12/2006		☐ Protocol		
Registration date 26/01/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 16/06/2014	Condition category Mental and Behavioural Disorders	☐ Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Klaus Hauer

Contact details

Geriatric Research Department Bethanien-Krankenhaus at the University of Heidelberg Rohrbacherstr 149 Heidelberg Germany 069126

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

Maximal strength and functional performance.

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

Key secondary outcome(s))

- 1. Emotional and cognitive status
- 2. Physical activity level
- 3. Risk of falling

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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)

ROR

https://ror.org/031h5fa94

Funder(s)

Funder type

Research organisation

Funder Name

Landesstiftung Baden-Württemberg (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	12/06/2014		Yes	No