

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**  
26/01/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ 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

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Heidelberg  
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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?
<a href="#">Results article</a>	results	12/06/2014		Yes	No