PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Cognitive and motor training in mild cognitive impairment: an MRI study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Although mild cognitive impairment is considered a risk factor for subsequent dementia of the Alzheimer type (AD), there is currently no drug treatment option. In this study, the influence of a combined memory and exercise training should be investigated for memory and attention processes in people with mild cognitive impairment.
The subjects were 12 weeks of cognitive-motor training undergone compared to a control group that did not train.
Further tasks should be handled at home. Before and after completion of the three-month training phase, a detailed neuropsychological testing of memory and attention performance was carried out.

Brief Summary in Scientific Language

Memory dysfunction is the first and leading symptom of dementia of the Alzheimer type. In the context of improved early detection of the concept of mild cognitive impairment was introduced. This requires a subjective memory impairment that can be objectified in a cognitive test that exist in the absence of evidence of manifest dementia.
In addition to pharmacological therapies, there is a possibility of a cognitive intervention.
For this purpose, the effect of a 12-week combined memory and motor skills training was examined on memory performance in subjects with mild cognitive impairment:
- Impact on memory performance measured by a neuropsychological test battery.
- Impact on cortical morphology, structural integrity and functional plasticity as measured by MRI.
- The dependence of the observed changes of biological and genetic markers, such as homocysteine, apolipoprotein E phenotype Dopaminrezeptorpolymorphismen, asymmetric dimethylarginine (ADMA), brain-derived neurotrophic factor (BDNF) polymorphism and plasma levels.

Organizational Data

- DRKS-ID: **DRKS00007858**
- Date of Registration in DRKS: **2015/03/09**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **04/09 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1167-7319**

Health condition or Problem studied

- ICD10: **F06.7 - Mild cognitive disorder**

Interventions/Observational Groups

- Arm 1: **-20 Subjects with MCI: 12-week cognitive-motor training**
  - 1 time weekly 120-135 min
- Arm 2: **20 subjects with MCI: without 12-week cognitive-motor training**
- Arm 3: **21 healthy volunteers**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment, Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Episodic memory performance:

At the beginning and at the end of the training phase is detailed neuropsychological testing by VLMT (Verbal learning and memory test)

Secondary Outcome

- BDNF plasma levels by ELISA:
At the beginning and at the end, and once after training

- Identification of the hippocampus volume by MRI:
at the beginning, after completion of the initial training period at 3 months and 6 months.

- Test for Attentional Performance: Rey-Osterrieth figure, logo test number range and block span, Verbal Fluency, Boston Naming Test, Trail-Making Test A and B, TAP

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Neurologie, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/02/16**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- MCI

Exclusion criteria

- Probable dementia,

- History of severe diseases such as stroke or psychiatric disease,

- Treatment with antipsychotics and antidepressants,

- The existence of a relevant depressive mode with a value above 13 by the Beck Depression Inventory

- Unstable medical conditions

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/03/31**

Trial Publications, Results and other documents

- Paper **Poster Presentation Alzheimer's Association International Conference (AAIC) 2012**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*