Trial Description

Title

The influence of multimodal physical activity on cognition and everyday life competence in patients with early Alzheimer's disease

Trial Acronym

Sport & KOG

URL of the trial

http://www.uni-due.de/rke-ap/SportUndCog.shtml

Brief Summary in Lay Language

There is evidence that physical activity and cognitive activation retards the development of Alzheimer's disease. Only few trails have already examined the influence of a combined physical and cognitive activity on cognitive function in patients with early Alzheimer's disease.

Brief Summary in Scientific Language

The aim of the trail is to analyse if multimodal physical activity significantly improves cognitive function and everyday life competence of patients with early Alzheimer's disease. Primary endpoints are the measurement of cognitive reduction with ADAS-Cog. Activities of daily living are measured using the ADCS-ADL.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000100**
- Date of Registration in DRKS: **2009/03/24**
- 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.: **08-3818 , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

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Secondary IDs

Health condition or Problem studied

- ICD10: **G30 - Alzheimer's disease**
- ICD10: **F00 - Dementia in Alzheimer's disease**

Interventions/Observational Groups

- Arm 1: **Intervention**
  -Motor activity anamnesis
  -1-3 times a week combined physical and cognitive activity programme
  -1-2 times a month telephone counselling (month3-6)
- Arm 2: **Control intervention - Stretching**
  -Motor activity anamnesis
  -1-3 times a week stretching programme
  -1-2 times a month telephone counselling (month3-6)

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **[---]***
- Assignment: **Parallel**
-

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Purpose: **[---]***

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Primary endpoints are measured at T0 (after screening), T1 (month 6) and T2 (month 12)
-measurement of cognitive reduction with ADAS-Cog
-Activities of daily living are measured using the ADCS-ADL

Secondary Outcome

Secondary endpoints are measured at T0 (after screening), T1 (month 6) and T2 (month 12)
-MWT-B (Mehrfachwahl-Wortschatztest)
-SKT (Syndrom-Kurz-Test)
-Clinical Dementia Rating (CDR)
-DEMQOL (Smith, et al., 2005)
-SF12 (Quality of life)
-HPS (Häusliche Pflegeskala)
-NPI (Neuropsychiatric Inventory)
-BDI (Beck Depression Inventory)
-PASE (physical activity)
-GPAQ (physical activity)
-measurement of physical activity by pedometer

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2009/04/01**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

-diagnosis of Alzheimer's dementia according to NINCDS-ADRDA respectively ICD 10
-Mini-Mental-State-Test (20 - 25) at screening
-Hachinski Ischemia Scale <=4 at screening
-CT or MRT, maximal 2 years old, compatible with Alzheimer's dementia
-Geriatric Depression Scale (GDS) <=4 (15-item scale)
-ambulant patients
-exercise ECG analysed by specialist in internal medicine
-caregiver (contact 3 times a week, overall 5 hours a week), who can report the patient's state of health
-informed consent form signed by patient and caregiver

Exclusion criteria

-diagnosis of a possible, probable or certain vascular dementia NINDS-AIREN criteria
-missing approval ability, missing ability to take part in intervention programme or missing compliance
-intake of following drugs with change of dosage during the last 3 months before baseline: antidepressants, tranquilizer / sleeping pills, anti-psychotica or anti-epileptica
-excessive alcohol, drug or medicament abuse. Diagnosis of drug abuse or drug addiction (ICD-10) as a primary clinical diagnosis, which indicates the initiation or continuation of a medical treatment of this disorder
-clinically relevant neurologic or psychiatric diseases, such as severe depression, schizophrenia, epilepsy or Parkinson's disease
-participation in a pharmaceutical trail 2 months before baseline
-decompensated or poorly regulated diabetes
-decompensated or poorly regulated hypertonia
-cardiovascular event during the last 3 months e.g. cardiac catheterization, vascular surgery, acute coronary syndrome, myocardial infarction or unstable angina, clinical relevant cardiac dysrhythmia, cardiac surgery, angiography with stent implantation
-other clinically significant aberrances in clinical, neurologic, laboratory medicine examination, clinically relevant ECG changes, which could impair the patient's

health related to the trail
-cardiologically relevant anaemia

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and**

Research (BMBF), etc.)

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*