DRKS-ID: **DRKS00013167**
Date of Registration in DRKS: **2018/04/11**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

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

Trial Description

Title

Sensor-based systems for early detection of dementia

Trial Acronym

SENDA

URL of the trial

https://www.tu-chemnitz.de/senda/index.html

Brief Summary in Lay Language

Dementia and cognitive decline are important social problems because of their increasing prevalence in the older population. For an optimal care of the patients it is necessary to detect the illness in an early stage.
Pathological changes in the brain can be found in the early stages of the diseases before cognitive symptoms like memory disorders appear.
The objective of this project is to examine which factors for in the motor (e.g. gait, balance, fine motoric) and sensory system as well as in brain oscillations are associate with symptoms of dementia.
Persons with an age of 80 years and above will be included in this study. They will take part in motor, sensory, neurophysiological and cognitive measurements up to four times within three years.

Brief Summary in Scientific Language

The objective of the SENDA study is to develop a multi-dimensional instrument to detect cognitive decline or dementia with the help of cognitive, sensory, motor and electroencephalogical parameters.
The study will examine the following main question:
- Which cognitive, sensory, motor and neurophysiological parameters are predictors to differentiate people with subjective cognitive declines or with mild cognitive decline from age-matched healthy people?
At the beginning of the study participants will be divided into three groups depending on their cognitive status: 1. cognitive healthy participants, 2. subjectively cognitive impaired participants, 3. participants with mild cognitive impairment. All groups will take part in the same motor, sensory, neurophysiological and cognitive measurements. All measurements will be repeated four times in intervals of eight months to identify associations to cognitive changes over time.

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

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013167**
- Date of Registration in DRKS: **2018/04/11**
- 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.: **V-232-17-KM-SENDA-07112017 , Ethikkommission der Fakultät Human- und Sozialwissenschaften der Technischen Universität Chemnitz, 09107 Chemnitz, Deutschland**

Secondary IDs

Health condition or Problem studied

- Free text: **older healthy people, Mild Cognitive Impairment (MCI)**
- ICD10: **F06.7 - Mild cognitive disorder**

Interventions/Observational Groups

- Arm 1: **At the beginning of the study participants will be divided into three groups depending on their cognitive status: 1. cognitive healthy participants, 2. subjectively cognitive impaired participants, 3. participants with mild cognitive impairment.**
  All measurements will be assessed four times within three years in intervals of eight months to identify associations to cognitive changes over time.
  One time of measurement consists of 3 examination days. The same motor, sensory, neurophysiological, and cognitive measurements will be conducted for each time of measurement.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary endpoint is to identify motor, sensory, neurophysiological and cognitive parameters to predict cognitive decline or dementia in older people.

All measurements will be assessed four times within three years in intervals of eight months to identify associations to cognitive changes over time. One time of measurement consists of 3 examination days. The same motor, sensory, neurophysiological, and cognitive measurements will be conducted for each time of measurement.

Measurements, questionnaires:
- Montreal Cognitive Assessment,
- Consortium to Establish a Registry for Alzheimer`s Disease,
- Questionnaire for subjective assessment of mental performance,
- Digit Symbol Substitution Test,
- gait analysis with OptoGait(R) under single- and dual-task conditions using 3D cameras for video recordings,
- Short physical performance battery,
- hand force dynamometer,
- EEG measurements,
- Eriksen flanker task,
- fine motor measurements e.g. spontaneous finger tapping, force tracking task, foot coordination,
- sensory measurements with shaker or mini-shaker,
- Limits of Stability Test, balance tests on the posturomed under single-task and dual-task conditions

Secondary Outcome

All measurements will be assessed four times within three years in intervals of eight months to identify associations to cognitive changes over time. One time of measurement consists of 3 examination days. The additional measurements will be conducted for each time of measurement. Therefor, functional, cognitive as well as mental health and lifestyle factors, that might be associated with cognitive decline, will be assessed. These include frailty, comorbidities, social support, quality of life, physical activity, depressive symptoms, and fear of falling.

Questionnaires:
- Big Five Inventory,
- Geriatric depression scale,

- Charlson Comorbidity Index,
- Questionnaire for social support,
- BAECKE inventory for physical activity,
- PRISCUS PAQ,
- NAI,
- FRAIL scale,
- Tilburg Frailty Indicator

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Chemnitz und nahe Umgebung**
- other **Zeitungsberichte zur Probandenrekrutierung, Chemnitz und nahe Umgebung**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/02/01**
- Target Sample Size: **240**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **80 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Informed consent for study participation,
- Basics skills in German language,
- Study participant can independently or with the help of an accompanying person visit assessments,
- Study participant can walk independently (a walking aid or a rolling walking is aloud)

Exclusion criteria

- Medically prohibited to be physically active,

- Diagnosed psychological disorders as major depression or neurocognitive disorders as dementia
- Permanent impairments due to a stroke or a brain surgery,
- Other neurological diseases as epilepsy, Parkinson, neuropathy
- Severe diseases of the cardiovascular system (e.g., cardiac arrhythmia, arterial occlusive disease, heart failure)
- Severe diseases of respiratory system (e.g., COPD stage 4, severe asthma)
- Severe diseases of the musculoskeletal system (e.g. arthritis, orthopedic operations in the last 6 months)
- Diabetes with diagnosed neuropathy
- Substance abuse (delirium)
- Difficulties in understanding language or speech
- Participant of other clinical studies e.g. for clinical testing of new anti-dementia drugs

Addresses

■ **Primary Sponsor**

TU Chemnitz, Human- und Sozialwissenschaftliche Fakultät, Institut für Angewandte Bewegungswissenschaften, Professur Sportpsychologie (mit Schwerpunkt Prävention und Rehabilitation)
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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 complete, follow-up continuing**
- 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.*