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

Trial Description

Title

Testing the equivalence/non-inferiority of the digital versus the paper-based measurement method of cognitive impairments

Trial Acronym

Intera-KT-Equivalence

URL of the trial

https://geriatrie.charite.de/forschung/ag_alter_technik/intera_kt/

Brief Summary in Lay Language

The object of this study is to demonstrate the equivalence/non-inferiority of the digital assessment method compared to the conventional paper-based assessment method of established test procedures used in the diagnosis of cognitive impairment (e.g. in the context of dementia).

Brief Summary in Scientific Language

The object of this two-armed study is to demonstrate the equivalence/non-inferiority of the digital survey method compared to the conventional paper-based variant of established test procedures used in the diagnosis of cognitive impairment (e.g. in the context of dementia, after strokes or brain injuries).

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00019114**
- Date of Registration in DRKS: **2019/11/28**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00019114**
Date of Registration in DRKS: **2019/11/28**
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.: **EA1/201/19 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **U51 - [---]***

Interventions/Observational Groups

- Arm 1: **The cognitive performance of inpatient geriatric patients is assessed using the Mini-Mental State Test, the Extended Barthel-Index as well as DIA-S (Depression in the Elderly Scale) or GDS (Geriatric Depression Scale): Tablet/TabletPen or Paper/Pencil-based (RCT)**
  Tests are conducted as part of the in-patient admission interview (each lasting approx. 1 hour). All three test procedures are performed on each patient (according to individual decision).
  Duration of testing October 2019 to April 2020.

- Arm 2: **The cognitive performance of healthy seniors is examined with the Trail Making Test A/B, Clock-Drawing Test and the Rey-Osterrieth Complex Figure Test: with digitized paper/SmartPen and paper/pencil-based (Crossover-Design, randomized).**
  Tests are carried out with participants within the framework of participant tests (duration approx. 1 hour each). All three test procedures are performed with each subject (randomized, either digital or paper-based).
  Duration of testing October to December 2019.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Arm 1: Mini-Mental Status Test (inpatient geriatric patients)
Arm 2: Trail Making Test A/B, Clock-Drawing Test, Rey Osterrieth Complex Figure Test (healthy seniors)

Secondary Outcome

Arm 1: Extended Barthel-Index, Depression in the Elderly Scale, Geriatric Depression Scale (inpatient geriatric patients)

Arm 2: none (healthy seniors)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **EGZB sowie klinikextern, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/10/21**
- Target Sample Size: **245**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2019/10/21**

Target Sample Size: **245**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Arm 1 (inpatient geriatric patients): Age ≥ 65 years, presence of patient information and signed informed consent.

Arm 2 (healthy seniors): Age ≥ 65 years, capacity for consent, presence of subject information and signed informed consent.

Exclusion criteria

Arm 1 (inpatient geriatric patients): legal representative.

Arm 2 (healthy seniors): severe cognitive disorders, psychiatric disorders, severe auditory, visual, linguistic, sensory or motoric impairments, severe systemic diseases, mild or severe pain, CNS diseases and diseases affecting the CNS, cerebrovascular disease, current study participation.

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.)**

Bundesministerium für Bildung und Forschung Dienstsitz Berlin
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10117 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*