ISRCTN34113243 https://doi.org/10.1186/ISRCTN34113243

Validation of the Chinese version of the Erlangen Test of Activities in Daily Living for people with mild to severe dementia

Submission date
08/05/2025

Recruitment status
No longer recruiting

Registration date
17/06/2025

Overall study status
Ongoing

Last Edited
17/06/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is one of the most common causes of health impairments in older people. Impairments in activities of daily living (ADL) are particularly critical, as they sustainably restrict the independence of those affected. Therefore, the reliable and valid assessment of ADL is of outstanding importance for the diagnosis of dementia, but also in the investigation of the effectiveness of new treatment methods for dementia. Often, limitations in ADL are assessed with proxy-rated instruments, completed by relatives of the affected person or caregivers, sometimes also by self-assessment in cases of mild cognitive impairment (MCI) or mild dementia. However, both self-assessments and proxy-rated assessments are biased in their assessment of what ADLs a person is still capable of performing. This is partly due to the fact that a certain living environment (e.g. institutionalized care environments) no longer allows residents to perform ADLs spontaneously.
It is therefore very important to be able to measure ADL capabilities with a performance test. Researchers have therefore developed the Erlangen Test of Activities of Daily Living (E-ADL), which has proven its validity and reliability, particularly in people with moderate to severe dementia. To ensure that a suitable performance test is also available for people with mild dementia, another test was developed, the Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment (ETAM), which was able to prove its validity and reliability not only in mild dementia but also in mild cognitive impairment. In the present study, the validity and reliability of a Chinese version of the E-ADL are to be evaluated. On the one hand, the performance test items of the E-ADL were culturally adapted to the Chinese culture. On the other hand, two very easy tasks were replaced by – also culturally adapted – tasks from the ETAM in order to create a test instrument that can be used for people with severe dementia as well as for people with mild to moderate dementia. Thus, it should be possible to assess their degree of independence in everyday life (i.e. their level of impairment in ADL) in a valid and reliable manner.

Who can participate?
People with mild, moderate and severe dementia, living in a nursing home in Shenyang and Dalian.

What does the study involve?
The study will investigate the validity and reliability of a culturally adapted, Chinese version of the Erlangen Test of Activities in Daily Living (E-ADL-CN) in people with mild to severe dementia in China.

What are the possible benefits and risks of participating?
At first, all people with dementia in all severity grades could benefit from the E-ADL-CN. People can benefit from the fact that by recording the extent of their impairment in activities of daily living using a performance test, their remaining potential in performing several aspects of ADL is simultaneously recorded. These potentials in capabilities of ADL may no longer be recognized in a structured institutionalized care setting, as certain activities of daily living are no longer performed by the residents at all. This makes it possible to provide care that is more needs-oriented and adapted to the person's potential, with appropriate support for ADLs that may not have been recognized in the past without a valid assessment. The validity and reliability of the E-ADL and the ETAM, which are culturally adapted to the instrument E-ADL-CN, have been proven in inpatient and day-care settings in Germany. There are no risks to be expected during the study participation, based on the results of previous validation studies on the E-ADL and the ETAM.

Where is the study run from?
1. China Medical University (China)
2. University Hospital Erlangen (Germany)

When is the study starting and how long is it expected to run for?
August 2024 to December 2025

Who is funding the study?
Jiangsu Jicui Aging Technology Research Institute (JITRI Aging) (China)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

24-162_1-B

Study information

Scientific Title
E-ADL-CN - validation study to test the convergent and discriminant validity as well as the reliability of the Chinese version of the Erlangen Test of Activities in Daily Living in people with mild to severe dementia in China

Acronym
E-ADL-CN

Study objectives
Primary hypothesis:
1. Convergent validity: significant and high correlations hypothesized with care-index, Lawton ADL, Lawton IADL, MMSE Score
2. Divergent validity: no or only small-sized correlations hypothesized with sociodemographic variables, CMAI-SF, NOSGER mood subscale

Secondary hypotheses:
1. The interrater reliability should be high, tested in n = 30 (subgroup of the study sample, n = 10 with mild dementia, n = 10 with moderate dementia, n = 10 with severe dementia), tested by two independent testers, while the second tester is testing the same person on the day after the first test (same time in the morning)
2. The test-retest reliability should be high, tested in n = 30 (subgroup of the study sample, n = 10 with mild dementia, n = 10 with moderate dementia, n = 10 with severe dementia); retest should be administered 14 days later (same tester for each person), exclusion of participants with an “event” between test and retest like infection, accident, stroke (according to Graessel et al. 2009)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/04/2025, Ethics Committee of the Medical Faculty of the Friedrich-Alexander University Erlangen-Nuremberg (FAU) (Krankenhausstraße 12, Erlangen, 91054, Germany; +49 (0) 91318522270; ethikkommission@fau.de), ref: 24-162_1-B

Study design
Observational validation study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Dementia

Interventions
The E-ADL-CN is a standardized performance test consisting of five tasks:
Task 1: Making Honey Water (i.e. using the spoon to scoop one spoonful of honey into the cup, pour an appropriate amount of water, and stir until evenly mixed)
Task 2: Peeling a boiled egg (i.e. opening the lid of a bowl, taking out the egg, peeling it cleanly, then placing it back into the bowl and putting the lid back on)
Task 3: Handling Finances (i.e. choosing the cheapest price for eggs from three flyers, calculating the total amount required for all the products and taking the necessary amount from a wallet)
Task 4: Pill Sorting (i.e. sorting medications into the corresponding medication boxes according to a schedule)
Task 5: Folding Clothes (i.e. turning a long-sleeved (turned inside out) t-shirt right-side out, folding it neatly, placing it into a box, then closing the lid)
Each task is rated by the tester according to a standardized scale from 0 to 6 points. The total score of the E-ADL-CN ranges from 0 to 30 points, with a higher score indicating a better capability in performing ADL.

Intervention Type
Behavioural

Primary outcome(s)
Activities of Daily living measured with the Culturally adapted, Chinese version of the Erlangen Test of Activities in Daily Living (E-ADL-CN) at baseline

Key secondary outcome(s))
Measured at baseline:
1. Behavioral and psychological symptoms (agitation and aggression) measured by the validated Chinese version of the Cohen-Mansfield Agitation Inventory – Short Form (CMAI-SF)
2. Behavioral and psychological symptoms (depression) measured by the mood subscale of the NOSGER scale
3. Sociodemographic data: age, gender, education, care-index (official care degree of care necessary)
4. Cognition measured by Mini-Mental State Examination (MMSE) at baseline
5. Instrumental Activities of Daily Living (IADL) measured by the Lawton IADL Scale
6. Activities of Daily Living (ADL) measured by the Lawton ADL Scale

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Criteria of the dementia syndrome according to ICD-10
2. Mild to severe dementia according to the Mini-Mental-Status Examination (MMSE): 0 < MMSE score < 24 (CAVE: People with very severe dementia, i.e., MMSE = 0, are excluded)
3. Basic language skills as well as reading and spelling skills (Chinese)
4. Informed consent given

Participant type(s)
Patient, Resident

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Key exclusion criteria
1. Very severe dementia, i.e. MMSE = 0
2. Completely blind or deaf
3. Permanently unable to get out of bed/ immobile
4. Did not graduate from elementary school, i.e. less than 6 years in elementary school
5. Unable to communicate (does not respond to simple closed questions)
6. Diagnosis of another disease that causes cognitive impairment:
6.1. Vascular events (e.g. multiple strokes)
6.2. Parkinson’s disease
6.3. Multiple Sclerosis
6.4. Severe brain disease (e.g. tumor, injury, hydrocephalus)
6.5. Psychosis (e.g. schizophrenia, mania, bipolar psychosis)
6.6. Depression
6.7. Alcohol abuse/drug consumption (addiction) or Korsakoff syndrome
7. Concrete plans/vision to move out of the nursing home

Date of first enrolment
01/03/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
China

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China Medical University, School of Nursing
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Sponsor information

Organisation
Jiangsu Jicui Aging Research Institute of Technology Co., Ltd.

Funder(s)

Funder type
Research organisation

Funder Name
Jiangsu Jicui Aging Research Institute of Technology Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available because we assure in the participant information sheet that data will not be passed to any third party.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes