ISRCTN87242816 https://doi.org/10.1186/ISRCTN87242816

Adaptation and validation of the Erlangen activities of daily living test to the Latin American cultural area

Submission date
09/10/2025

Recruitment status
Recruiting

Registration date
02/12/2025

Overall study status
Ongoing

Last Edited
22/01/2026

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 because a certain living environment (e.g. independent living or day-care settings) no longer allows participants to perform ADLs spontaneously.

It is therefore very important to be able to measure ADL capabilities with a performance test. Researchers have therefore developed and published 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. In the present study, the validity and reliability of a Spanish version adapted to the Mexican context (E-ADL-LAT) are to be evaluated. On the one hand, the performance test items of the E-ADL were culturally adapted to the Mexican culture. On the other hand, two very easy tasks were replaced by culturally adapted tasks from the ETAM 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) validly and reliably.

Who can participate?
People with mild, moderate, and severe dementia or mild cognitive impairment, living independently or attending day-care services, who speak fluent Spanish and do not have severe motor impairments or current psychosis, are eligible to participate. Participants must have a close caregiver who can also provide informed consent.

What does the study involve?
The study will investigate the validity and reliability of the culturally adapted Spanish version of the Erlangen Test of Activities of Daily Living (E-ADL-LAT) in people with mild cognitive impairment as well as in people with mild to severe dementia in Mexico. Participants will complete the performance test (E-ADL-LAT) either in person or remotely, and caregivers will provide information for the Barthel Index and selected NOSGER subscales. Cognitive abilities will be assessed using the MoCA.

What are the possible benefits and risks of participating?
All participants may benefit from the structured assessment of their remaining ADL capabilities, which may not be recognized in daily life. Identifying these abilities can support more needs-oriented care and appropriate assistance in daily activities. Based on previous validation studies of the E-ADL and ETAM, no risks are expected during participation.

Where is the study run from?
1. Centro Mexicano Alzheimer, CDMX, Mexiko
2. University Clinic Erlangen, Erlangen, Germany

When is the study starting and how long is it expected to run for?
October 2025 to December 2026

Who is funding the study?
There is no external funding. The study is realized with infrastructure and human resources from the Centro Mexicano Alzheimer, the University Clinic Erlangen, and the Universidad Nacional Autónoma de México

Who is the main contact?
1. Prof. Dr. Carolin Donath, carolin.donath@uk-erlangen.de
2. Maestra Regina Altena, regina@cmalzheimer.org.mx
3. Maestra María Teresa Gutiérrez Alanís, teregut2003@yahoo.com.mx

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Donath Carolin

Contact details
University Clinic Erlangen
Psychiatric and Psychotherapeutic Clinic
Schwabchanlage 6
Erlangen
Germany
91054
091318534526
carolin.donath@uk-erlangen.de

Type(s)
Public

Contact name
Ms Regina Altena

Contact details
Centro Mexicano, Alzheimer, Av. Insurgentes Sur 2047 B, San Angel, Alvaro Obgregon
CD DE MEXICO
Mexico
0100
+525519488192
regina@cmalzheimer.org.mx

Type(s)
Public

Contact name
Ms María Teresa Gutiérrez Alanís

Contact details
Universidad Nacional Autónoma de México, Circuito Ciudad Universitaria
CD DE MEXICO
Mexico
04510
+525529409478
teregut2003@yahoo.com.mx

Additional identifiers

Study information

Scientific Title
Objectively and culturally specific assessment of everyday practical skills in people with dementia - adaptation and validation of the Erlangen ADL test (E-ADL) to the Latin American cultural area (E-ADL_LAT)

Study objectives
Primary Objectives:
1. Cultural adaptation of the Erlangen ADL Test (E-ADL) for the Latin American context (E-ADL_LAT):
To develop a culturally appropriate version of the E-ADL for use with people with dementia in Mexico and Spanish-speaking Latin America, enabling objective assessment of daily living skills through a performance-based test. Expected outcome: Obtain a valid, reliable, and culturally adapted Latin American version of the E-ADL test.

Secondary Objectives (Validation Hypotheses):
1. Assessment of test administration objectivity: The E-ADL_LAT will demonstrate high administration objectivity due to a precise test manual.
2. Assessment of scoring objectivity: The E-ADL_LAT will demonstrate high scoring objectivity due to a detailed scoring guide including anchor examples.
3. Test-retest reliability: The E-ADL_LAT will show satisfactory test-retest reliability.

4. Interrater reliability: The E-ADL_LAT will show satisfactory interrater reliability.
5. Internal consistency: The E-ADL_LAT will demonstrate satisfactory internal consistency, measured via Cronbach's Alpha.
6. Convergent validity: The E-ADL_LAT will show substantial correlations with related constructs, including cognitive performance and instrumental activities of daily living (IADL).
7. Concurrent validity: The E-ADL_LAT will show substantial correlations with an established external measure of daily living skills (Barthel Index), indicating it measures the same construct.
8. Discriminant validity: The E-ADL_LAT will demonstrate low correlations with unrelated constructs (agitation/aggression, depression, social behavior), supporting its discriminant validity.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/12/2025, Ethical Commission of the Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU) (Krankenhausstr. 12, Erlangen, 91054, Germany; +49 (0)9131 85-22270; +49 (0) 9131 85-26210; ethikkommission@fau.de), ref: 25-478-ANF

Primary study design
Observational

Study design
Observational validation study

Study type(s)
Other

Health condition(s) or problem(s) studied
Dementia and Mild Cognitive Impairment

Interventions
The E-ADL-LAT is a standardized performance test consisting of six tasks:

Task 1: Making a Bean Taco
(i.e. spreading one spoonful of beans onto a tortilla and rolling the tortilla as if preparing it to be eaten as a taco)
Task 2: Pouring a Beverage
(i.e. opening the bottle and filling the glass up to the marked line)
Task 3: Putting on a T-shirt
(i.e. taking the t-shirt, turning it to the correct side, and putting it on as if getting dressed to go out)
Task 4: Hand Washing
(i.e. washing hands with soap and then drying them afterwards)
Task 5: Making a Phone Call
(i.e. looking up Dr. Orozco's number in a phone list, dialing the number, and listening to the voicemail to find out the office hours on Tuesdays)
Task 6: 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)

Each task is rated by the tester according to a standardized scale from 0 to 6 points. The total score of the E-ADL-LAT ranges from 0 to 36 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 Latin American version of the Erlangen Test of Activities in Daily Living (E-ADL-LAT) at baseline.

Key secondary outcome(s)
Measured at baseline:
1. Cognition measured by the Montreal Cognitive Assessment (MoCA).
2. Behavioral and psychological symptoms (agitation and aggression) measured by the subscale “Disturbing behavior” of the NOSGER-scale
3. Depression measured by the subscale “Mood” of the NOSGER scale.
4. Social behavior measured by the subscale “Social Behavior” of the NOSGER scale.
5. Instrumental Activities of Daily Living (IADL) measured by the NOSGER scale, subscale “IADL”.
6. Activities of Daily Living (ADL) measured by the Barthel-Index.
7. Sociodemographic data: age, gender, education, socio-economic status, former employment, living situation, urban vs. rural place of living, offspring, family status

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Community-dwelling people living with cognitive impairments
2. Symptoms of dementia (any type except Parkinson’s disease dementia) or mild cognitive impairment (MoCA score < 26)
3. Sufficient vision and hearing (use of supporting devices included)
4. No paralysis of upper extremities
5. Fluent oral Spanish sufficient to understand and follow test instructions
6. Availability of a close caregiving relative who provides consent, agrees to participate in the study-related survey and answers the peer-rating scales, supports the participant’s involvement.
7. Provision of informed consent by the participant; if lacking capacity, consent must be obtained from the legally authorized representative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

55 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Parkinson’s disease dementia
2. Severe motor impairments of the upper extremities (paralysis or comparable)
3. Insufficient vision or hearing that cannot be adequately corrected with aids (e.g. glasses, hearing devices)
4. Psychotic disorder
5. Severe depressive episode

Date of first enrolment
01/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Germany

Mexico

Study participating centre
Study Recruitment Center: Centro Mexicano Alzheimer
Av. Insurgentes Sur 2047 – Edificio B
Ciudad de México, CDMX
Mexico
01060

Study participating centre
Study Coordination Center: University Clinic Erlangen, Psychiatric and Psychotherapeutic Clinic
Schwabachanlage 6
Erlangen
Germany
91056

Sponsor information

Organisation
Universitätsklinikum Erlangen

ROR
https://ror.org/0030f2a11

Organisation
Centro Mexicano Alzheimer

Organisation
Universidad Nacional Autónoma de México

ROR
https://ror.org/01tmp8f25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsklinikum Erlangen

Alternative Name(s)
Erlangen University Hospital

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Germany

Funder Name
Centro Mexicano Alzheimer

Funder Name
Universidad Nacional Autónoma de México

Alternative Name(s)
National Autonomous University of Mexico, National Autonomous University, Universidad Nacional Autónoma, National University of Mexico, UNAM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available