STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Turkish Validation and Reliability Study of the Electroconvulsive Therapy Cognitive Assessment (ECCA) and Comparison With Other Cognitive Assessment Tests in Patients Receiving Electroconvulsive Therapy

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Study Site	Pamukkale University Hospital, Department of Psychiatry

1. Rationale and Objectives

Electroconvulsive therapy (ECT) is one of the earliest biological treatments used in psychiatry and remains an effective option for severe psychiatric disorders, particularly severe major depression, catatonia, schizophrenia, and mania. Despite its clinical efficacy, ECT may be associated with subacute cognitive adverse effects, including anterograde and retrograde memory impairment. Because some of these effects may persist after treatment, careful cognitive monitoring before, during, and after ECT is recommended.

Commonly used cognitive screening tools such as the Montreal Cognitive Assessment (MoCA) and the Mini-Mental State Examination (MMSE) are useful for general cognitive screening, but they were not specifically developed to detect ECT-related cognitive changes such as autobiographical memory disturbance and subjective memory complaints. The Electroconvulsive Therapy Cognitive Assessment (ECCA) was developed as a structured 30-item instrument specifically designed to assess ECT-related cognitive effects across subjective memory, informant-rated memory, attention, autobiographical memory, and delayed verbal recall.

The primary objective of this study is to translate and culturally adapt the ECCA into Turkish and to evaluate its validity and reliability in adult patients receiving ECT in Turkey. A secondary objective is to compare ECCA performance with other cognitive assessment instruments used in routine clinical and research settings, including the MoCA, MMSE, Addenbrooke's Cognitive Examination-Revised (ACE-R), PEBL-Victoria Stroop Test, Trail Making Test, and Digit Span Test.

2. Study Design

This is a non-interventional, prospective observational validation study. Participants will be recruited from psychiatric inpatients who have already been given a clinical indication for ECT by their treating clinicians. The research team will not influence the clinical decision to administer ECT, the ECT parameters, or the anesthetic management. The study will focus on serial cognitive assessments conducted as part of the observational research protocol.

3. Study Setting and Duration

The study will be conducted at Pamukkale University Hospitals, Habip Kiziltas Psychiatry Hospital / Department of Psychiatry. Recruitment is planned to start after Ethics Committee approval and continue during the approved study period. The anticipated study period is approximately 10 months, with completion targeted between August 18, 2025 and June 15, 2026, subject to Ethics Committee approval and recruitment pace.

4. Study Population

Approximately 100 adult patients are planned to be enrolled. Because the ECCA contains 30 items, at least 90 participants are required to support psychometric analyses, and recruitment may continue beyond 90 participants to compensate for missing data or withdrawals.

4.1 Inclusion Criteria

- Age 18 to 65 years
- Inpatient at Pamukkale University Hospitals, Department of Psychiatry
- Clinical indication for ECT determined by the treating psychiatrist according to routine practice
- Able to read and write sufficiently to complete the study procedures, directly or with standard administration support where appropriate
- Willingness to participate and provision of written informed consent by the participant, or by the legally authorized representative when the participant lacks decision-making capacity

4.2 Exclusion Criteria

- Intellectual disability
- Pre-existing major cognitive disorder or known dementia
- History of major neurological disease that may substantially affect cognition
- Active substance use likely to interfere with assessment
- Illiteracy preventing completion of the planned assessment battery
- Physical or cognitive impairment severe enough to preclude valid communication or testing

5. Assessment Schedule and Measures

Participants will undergo a structured assessment process at three main time points:
T0 - before the first ECT session
T1 - after the 4th ECT session
T2 - after completion of the ECT course

At T0, T1, and T2, the following measures will be administered:

- Electroconvulsive Therapy Cognitive Assessment (ECCA)
- Montreal Cognitive Assessment (MoCA)
- Mini-Mental State Examination (MMSE)

- Addenbrooke's Cognitive Examination-Revised (ACE-R)

At T0 and T2, the following additional neuropsychological tests will be administered:

- PEBL-Victoria Stroop Test
- Trail Making Test
- Digit Span Test

A sociodemographic and clinical data form developed by the investigators will also be completed. This form will record variables such as age, sex, education level, marital status, employment status, place of residence, psychiatric diagnosis, medications used during treatment, anesthetic agent used during ECT, seizure duration, and relevant medical comorbidity.

6. Outcome Measures

Primary outcome:

- Validity and reliability of the Turkish version of the ECCA in patients receiving ECT

Secondary outcomes:

- Correlation of ECCA scores with MoCA, MMSE, ACE-R, PEBL-Victoria Stroop Test, Trail Making Test, and Digit Span Test
- Change in cognitive test scores across the ECT course
- Description of the pattern of cognitive changes observed before and after ECT

7. Translation and Cultural Adaptation Procedure

Permission for Turkish adaptation of the ECCA has been obtained from the original developer, Dr. Adriana P. Hermida. During the adaptation process, the ECCA was translated independently from English into Turkish by five individuals who were unaware of one another's translations. The reconciled Turkish version was then back-translated into English independently by five different individuals who were similarly blinded to one another's work. A sworn translator also reviewed the translations to support linguistic consistency. The final Turkish wording was determined after evaluation of semantic and conceptual equivalence.

8. Statistical Analysis Plan

All analyses will be performed using SPSS version 25.0 and AMOS version 23.0, or equivalent software. Continuous variables will be summarized as mean ± standard deviation or median (interquartile range), as appropriate. Categorical variables will be summarized as frequencies and percentages. A two-sided p-value below 0.05 will be considered statistically significant.

Psychometric evaluation of the Turkish ECCA will include:

- Internal consistency analysis using Cronbach's alpha
- Corrected item-total correlations
- Cronbach's alpha if item deleted
- Test-retest reliability using the intraclass correlation coefficient where applicable
- Construct validity using exploratory factor analysis and confirmatory factor analysis

- Assessment of suitability for factor analysis using the Kaiser-Meyer-Olkin measure and Bartlett's test of sphericity
- Parallel-form / convergent validity using Pearson or Spearman correlation coefficients with comparator cognitive tests, depending on distributional assumptions

For longitudinal comparisons of cognitive scores across the ECT course, repeated-measures methods or non-parametric equivalents will be used as appropriate. Missing data will be reported, and analyses will be based on the available data; additional handling methods may be applied if the extent and pattern of missingness justify them.

9. Ethical Considerations

This study will be conducted in accordance with the Declaration of Helsinki and applicable national regulations. Written informed consent will be obtained from all participants with intact decision-making capacity. For participants who are under guardianship or who lack the capacity to provide valid informed consent, permission will be obtained from the legally authorized representative in accordance with local ethical and legal requirements. Participation is voluntary, and refusal to participate or later withdrawal will not affect the patient's treatment or rights. All data will be handled confidentially, and no participant names will be included in publicly shared trial documents.

10. Risks and Benefits

This is a non-interventional observational study. The study does not introduce an additional therapeutic intervention beyond routine clinical care. The main burden is the time required to complete the assessment battery. Participants are not expected to receive direct medical benefit from participation. However, the study may contribute to improved cognitive monitoring of Turkish-speaking patients receiving ECT and may support the availability of an ECT-specific cognitive assessment tool in Turkey.

11. Funding

No specific external financial support is required for this study.

12. References

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