INFORMED CONSENT FORM

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

NCT Number	Not yet assigned
Document Date	July 14, 2025
Study Site	Pamukkale University Hospital, Department of Psychiatry

Invitation to Participate

You are invited to take part in a research study titled "Turkish Validation and Reliability Study of the Electroconvulsive Therapy Cognitive Assessment (ECCA) and Comparison With Other Cognitive Assessment Tests in Patients Receiving Electroconvulsive Therapy." This study is being conducted for research purposes. Participation is entirely voluntary. Before you decide whether to participate, it is important that you understand why the study is being done, what it involves, how your information will be used, and what your rights are as a participant. Please read the following information carefully and ask any questions you may have. If you agree to participate after being fully informed, you will be asked to sign this form.

What are the purpose of the study and how many people will participate?

The purpose of this study is to evaluate the Turkish validity and reliability of the Electroconvulsive Therapy Cognitive Assessment (ECCA), a cognitive assessment tool developed specifically for patients receiving electroconvulsive therapy (ECT), and to compare it with other cognitive assessment tests currently used in clinical practice.

Approximately 100 volunteer patients who have a clinical indication for ECT are planned to be included. The study is planned as a single-center study.

Do I have to take part in this study?

No. Whether or not you participate is entirely your decision. If you decide to participate, you will be asked to sign this written informed consent form. Even after signing, you are free to withdraw from the study at any time and for any reason without giving an explanation. If you decide not to participate, or if you later withdraw, your medical care and your relationship with your physicians will not be affected in any way.

What will happen if I participate?

If you agree to participate, a brief introductory interview lasting approximately 10 to 15 minutes will first be conducted. After the study has been explained to you and a sociodemographic data form has been completed, the following assessments are planned:

Before ECT:

- ECCA
- Montreal Cognitive Assessment (MoCA)
- Mini-Mental State Examination (MMSE)
- Addenbrooke's Cognitive Examination-Revised (ACE-R)
- PEBL-Victoria Stroop Test
- Trail Making Test
- Digit Span Test

After the 4th ECT session:

- ECCA
- MoCA
- MMSE
- ACE-R

After completion of the ECT course:

- ECCA
- MoCA
- MMSE
- ACE-R
- PEBL-Victoria Stroop Test
- Trail Making Test
- Digit Span Test

Some tests, including the Trail Making Test, PEBL-Victoria Stroop Test, and Digit Span Test, may be administered using a computer. The duration of testing may vary from person to person because the study evaluates cognitive performance.

What are the possible benefits of taking part?

This study is mainly intended to generate scientific knowledge. You are not expected to receive a direct medical benefit from participation. However, the findings may help improve the assessment of cognitive functioning in patients receiving ECT in Turkey and may support the use of a Turkish version of an ECT-specific cognitive assessment tool in future patients.

What are the possible risks or inconveniences?

Because this is a non-interventional observational study, no additional treatment-related risk is expected beyond your routine clinical care. The main inconvenience is the time and attention required to complete the cognitive assessments. If you become tired or uncomfortable during testing, you may inform the research team.

Will participation cost me anything, or will I be paid?

You will not have to make any payment to participate in this study, and you will not receive any payment for participating.

How will my personal information be used?

The research team will use your personal information only for the purposes of conducting this study and performing statistical analyses. Your identity and personal information will be kept confidential. Without your written permission, your personal information will not be disclosed to others except where required by law or ethical oversight. The results of the study may be presented in scientific meetings or publications, but your identity will not be revealed. No participant names will be included in documents uploaded for public posting.

Who can I contact for more information?

If you have questions about the study or need additional information, please contact:

Name: Sinem Zeynep Yildiz

Title: Research Assistant, M.D.

Phone: +90 258 296 46 13

Participant Declaration

I have been informed that a medical research study will be conducted at the Department of Psychiatry, Pamukkale University, by Dr. Sinem Zeynep Yildiz, and the information above has been explained to me. I have read this form, or it has been read to me, and I have had the opportunity to ask questions.

I understand that:

a. I have the right to refuse to participate, and this will not affect my medical care or my relationship with my physician.

b. I may withdraw from the study at any time without giving any reason, provided that I inform the responsible researcher/physician. My withdrawal will not affect my current or future medical care.

c. The researcher/physician may withdraw me from the study, without causing harm to my medical condition, if continuation is no longer appropriate.

d. Study results may be presented at scientific meetings or in publications, but my identity will remain confidential.

e. I will not assume any financial responsibility related to this study, and no payment will be made to me.

f. I will receive a signed copy of this form.

Under these conditions, I voluntarily agree to participate in this study of my own free will, without pressure or coercion.

Signatures

Participant - Name and Surname	
Address / Phone	
Signature	
Date	
Interview Witness (required for psychiatric studies) - Name and Signature	
Researcher Providing Information - Name, Title, and Signature	

Note: For participants under guardianship or lacking decision-making capacity, consent must be obtained from the legally authorized representative in accordance with local ethical and legal requirements.