Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of supportive nursing care on anxiety, self-esteem and Satisfaction of patients receiving electroconvulsive therapy: A randomized controlled clinical trial

Protocol summary

Summary

The main objective of this study is determining the effect of supportive nursing care on anxiety, self-esteem and satisfaction of patients receiving ECT in Baharan psychiatric hospital of Zahedan. This study is a randomized controlled clinical trial. Firstly, pilot study will be done to determine sample size. The estimated sample size will be allocated randomly into interventional and control groups. Instruments for data gathering and measuring will be Spielberger's Anxiety Questionnaire, Rosenberg's Self-Esteem Scale and Patient Satisfaction Questionnaire. Eligibility criteria for participants are patients receiving ECT and are aged 18 years and older; ability to read and write; lack of physical disease lead to cognitive impairment; lack of perception disorders and impairment in reality test; lack of anxiety disorders; and lack of bipolar disorder with high self-esteem. Exclusion criteria for participants are patients who are in acute phase of psychosis; patients who are refusing to continue to participate in the study; patients who are receiving less than 4 sessions of ECT. In this study, firstly the psychiatric nurses interested in participating in the study will be teaching about supportive nursing care according to the provided booklet. Then, pre-test will be done for both of groups. Intervention group will be taking the supportive nursing care from trained nurses in the duration of ECT sessions. The control group will be taking routine intervention in this duration. Finally, post-test will be done for both of groups. The main outcome variables will be anxiety, self-esteem and satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306036834N6**
Registration date: **2013-07-23, 1392/05/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-23, 1392/05/01

Registrant information

Name
Hossein Ebrahimi
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-07-16, 1392/04/25

Expected recruitment end date

2013-08-16, 1392/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supportive nursing care on anxiety, self-esteem and Satisfaction of patients receiving electroconvulsive

therapy: A randomized controlled clinical trial

Public title
Effect of supportive nursing care on anxiety, self-esteem and Satisfaction of patients receiving electroconvulsive therapy: A randomized controlled clinical trial
Purpose
Prevention
Inclusion/Exclusion criteria
Eligibility criteria for participants: Patients receiving ECT and are aged 18 years and older; ability to read and write; lack of physical disease lead to cognitive impairment; lack of perception disorders and impairment in reality test; lack of anxiety disorders; and lack of bipolar disorder with high self-esteem. Exclusion criteria for participants: Patients who are in acute phase of psychosis; patients who are refusing to continue to participate in the study; patients who are receiving less than 4 sessions of ECT.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Not registered
Secondary trial Id
Nothing
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences, Vice chancellor for research
Street address
Third floor, Central Building- No 2, Golgasht Street
City
Tabriz
Postal code
Approval date
2013-06-23, 1392/04/02
Ethics committee reference number
5/4/2786

Health conditions studied

1

Description of health condition studied
Psychiatric patients receiving ECT
ICD-10 code
F20, F30,
ICD-10 code description
Schizophrenia, Maniaic episode, Bipolar affective disorder, Depressive episode, Recurrent depressive disorder

Primary outcomes

1

Description
Anxiety
Timepoint
Before intervention and six hours after finishing intervention
Method of measurement
Spielberger's Anxiety Questionnaire

2

Description
Self-esteem
Timepoint
Before intervention and six hours after finishing intervention
Method of measurement
Rosenberg's Self-esteem Questionnaire

3

Description
Satisfaction
Timepoint
Before intervention and six hours after finishing intervention
Method of measurement
Webster Satisfaction Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Firstly, the pre-test will be done. Intervention group, during the electroconvulsive therapy proceedings (minimum 4 sessions) will be receiving supportive cares from nurses. Then, the post-test will be done.
Category
Other

2

Description
Control group: Firstly, the pre-test will be done. Control group, during the electroconvulsive therapy proceedings (minimum 4 sessions) will be receiving routine interventions from nurses. Then, the post-test will be done.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharan Psychiatric Hospital
Full name of responsible person
Dr Mohsen Kianpoor
Street address
Imam Khomeini Avenue west end Opposite the grain Organization
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr Kazem Shakouri
Street address
Third floor, No 2 Building of Tabriz University of Medical Sciences, Golgasht Ave
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Hossein Ebrahimi
Position
PhD in nursing
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty