

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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)

Phone

+98 41 1475 1709

Email address

ebrahimih@tbzmed.ac.ir

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, Maniac 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

Street address

Psychiatric Nursing Group, Tabriz Nursing and Midwifery Faculty, South Shariati Street

City

Tabriz

Postal code

Phone

+98 41 1475 1709

Fax

Email

Ebrahimih@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Roghaieh Keykha

Position

MSc in Psychiatric Nursing, Student

Other areas of specialty/work

Street address

Psychiatric Nursing Group, Tabriz Nursing and Midwifery Faculty, South Shariati Street

City

Tabriz

Postal code

Phone

+98 41 1475 1709

Fax

Email

Roghaieh.keykha@yahoo.com

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