

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of video based education on fear and anxiety of patient candidates for Electroconvulsive therapy at psychiatric ward

Protocol summary

Study aim

Determining the effect of video training on fear and anxiety in patients undergoing electroconvulsive therapy admitted to a psychiatric ward

Design

The present study is a randomized two-group clinical trial study that will be performed with the participation of 72 patients. The research units will be selected by available sampling method and will be randomly divided into two groups of control and test.

Settings and conduct

This study is a randomized clinical trial that will be conducted to investigate the effect of video training on fear and anxiety of patients undergoing electroconvulsive therapy admitted to psychiatric ward of Sina hospital in Hamadan on 72 patients. patients will be randomly divided into two groups of control and intervention. The intervention group will be provided with an instructional video on the method of electroconvulsion therapy. Educational intervention for the intervention group will be done in 3 sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Do not have vision or hearing problems, Patients must be fully conscious, Patients who are first-time candidates for electroconvulsive therapy.
Exclusion criteria: Patients in the psychotic phase.

Intervention groups

Intervention group: In the intervention group will be provided with educational materials on the method of electrical convulsion therapy by educational video. The content of the film will include: steps, complications, introduction to the environment, before and after nursing care. The film will be broadcast the day before the electroconvulsive therapy. Control group: There will be no special intervention

Main outcome variables

Fear and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033378N9**

Registration date: **2021-09-11, 1400/06/20**

Registration timing: **prospective**

Last update: **2021-09-11, 1400/06/20**

Update count: **0**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

Efat Sadeghian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

sadeghian_e@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of video based education on fear and anxiety of patient candidates for Electroconvulsive therapy at psychiatric ward

Public title

The effect of video based education on fear and anxiety of patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are first-time candidates for electroconvulsive therapy. Patients must be fully conscious. Do not have vision or hearing problems.

Exclusion criteria:

Patients in the psychotic phase

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by available method with considering inclusion criteria, then divided into two intervention and control groups by randomized allocation. Random allocation will be by permuted block randomization. It is individual randomization. First, a random list is generated using R software in which the intervention group (A) and the control group (B) are based on blocks such as ABAB. And AABB, ABBA and ... are randomly generated based on the number of samples. Then these lists are put into an envelope and one of the envelopes is randomly selected by referring patients and then individuals are assigned to group A Or B are allocated. Due to the educational intervention and having the control and experimental group there is no possibility of blinding the participants.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2021-07-30, 1400/05/08

Ethics committee reference number

IR.UMSHA.REC.1400.350

Health conditions studied

1

Description of health condition studied

Mood disorders

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description

Fear

Timepoint

Before intervention and before receiving electroconvulsive therapy

Method of measurement

Visual analog scale

2

Description

Anxiety

Timepoint

Before intervention and before receiving electroconvulsive therapy

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In the intervention group will be provided with educational materials on the method of electrical convulsion therapy by educational video. The content of the film will include: steps, complications, introduction to the environment, before and after nursing care. The film will be broadcast the day before the electroconvulsive therapy. Control group: There will be no special intervention.

Category

N/A

2

Description

Control group: No special intervention will be taken other than routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Efat Sadeghian

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Deputy of research and technology

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available