

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effectiveness of Small Group Discussion with Simulation Training versus routine instruction on Quality of Care in Electroconvulsive Therapy

#### Protocol summary

Quality of caring from patients underwent ECT

##### Study aim

Determination of the effect of simulation training in small groups on improving the quality of patient care under electroconvulsive therapy in nurses working in the psychiatric ward of Golestan hospital of Ahwaz

##### Design

This study is a clinical trial with two groups of pre-test and post-test. Samples will be assigned in the randomized sampling method in two groups include intervention and control.

##### Settings and conduct

In this study, the research environment includes the hospitals affiliated to Ahwaz Jundishapur University of Medical Sciences that have psychiatric wards and the research population includes all nurses working in these psychiatric Wards. Individuals will attend a 2-hour session and will be informed about the basics, benchmarks and study framework as well as the checklist of the research. Then, they participate in the 4 complete ECTs procedure in each of the three steps before, during and after the patient's bedside process will be present in the presence of the researcher and will be evaluated by the observer in order to identify possible ambiguities in the assessment process.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) Work experience for 6 months or more as a direct provider of patient care. 2) Stable presence in the sector as permanent personnel and in coordination with assistants and individuals. 3) willingness to participate in simulated group discussions and participate in pre-test and post-test. Exclusion Criteria: 1) Not participating in 1 or more session.

##### Intervention groups

Intervention group: Nurses who work in the psychiatric ward of women and men underwent training with small groups discussion. The control group: Nurses who work in the psychiatric ward of men and women not underwent training with small groups discussion.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181210041915N1**

Registration date: **2019-01-03, 1397/10/13**

Registration timing: **retrospective**

Last update: **2019-01-03, 1397/10/13**

Update count: **0**

##### Registration date

2019-01-03, 1397/10/13

##### Registrant information

##### Name

Kourosh Zarea

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3373 8071

##### Email address

zarea\_k@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

2018-03-21, 1397/01/01

##### Actual recruitment end date

2018-12-31, 1397/10/10

##### Trial completion date

2019-01-21, 1397/11/01

### Scientific title

The effectiveness of Small Group Discussion with Simulation Training versus routine instruction on Quality of Care in Electroconvulsive Therapy

### Public title

The effectiveness of Training on Quality of Caring

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Work experience in ECT for 6 months or more as a direct provider of patient care stable present in the psychiatric ward The volunteer to participate in simulated group discussions and participate in pre-test and post-test

#### Exclusion criteria:

The reluctance or withdrawal of participation in the study at any time.

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: **80**

Actual sample size reached: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple Randomization with random number table

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

no

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

##### City

Ahvaz

### Province

Khuzestan

### Postal code

6135715794

### Approval date

2018-06-30, 1397/04/09

### Ethics committee reference number

IR.AJUMS.REC.1397.288

## Health conditions studied

### 1

#### Description of health condition studied

Psychiatric patients caring

#### ICD-10 code

F00-F99

#### ICD-10 code description

psychiatry

## Primary outcomes

### 1

#### Description

Quality of Caring

#### Timepoint

Before intervention and 1 month after intervention

#### Method of measurement

Quality of care before, during and after ECT questionnaire

## Secondary outcomes

### 1

#### Description

quality of patient care

#### Timepoint

Before starting of study and 4 weeks after study

#### Method of measurement

Quality of care checklist

## Intervention groups

### 1

#### Description

Intervention group: Education with simulated small group training

#### Category

Behavior

### 2

#### Description

Control group: without training in small group

#### Category

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

golestan, sina, salamt

**Full name of responsible person**

kourosh zarea

**Street address**

educational hospital of ahvaz jundishapur university  
of medical sciences

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8333

**Email**

zarea\_k@ajums.ac.ir

**Web page address**

<http://ajums.ac.ir>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

research and technology affair of university

**Street address**

ahvaz jundishapur univeristy of medical sciences,  
Ahvaz, Iran

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

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**Phone**

+98 61 3373 8333

**Email**

zarea\_k@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

kourosh zarea

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Ahvaz jundishapur university of medical sciences,  
Ahvaz, Iran

**City**

Ahvaz

**Province**

Khouzestan

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<https://orcid.org/0000-0001-5124-6025>

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Kourosh Zarea

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychiatrics

**Street address**

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**Email**

zarea\_k@ajums.ac.ir

**Web page address**

<http://ajums.ac.ir>

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Kourosh Zarea

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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**Fax**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Our data without name of participant can be available

**When the data will become available and for how long**

after publication

**To whom data/document is available**

researcher and health policymakers

**Under which criteria data/document could be used**

Statistics analysis

**From where data/document is obtainable**

Ahvaz Nursing and Midwifery School

**What processes are involved for a request to access data/document**

by Email

**Comments**