Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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 Ahvaz 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. Excursion 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

Quality of caring from patients underwent ECT

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
Khouzestan
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
psychaitry

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 staring 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
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Province
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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
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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
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Person responsible for updating data

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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 od 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