Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the Effect of a Role Playing-Based Program about Empathy with Patients on Empathy score in Undergraduate Operating Room Students

Protocol summary

Study aim

To investigate the effect of a role playing-based program about empathy with patients on empathy score of operating room students in Isfahan University Of Nursing and Midwifery in 2017-18

Design

A one-side blinded, 2 groups (control, intervention) clinical trial with 77 samples and per-post test and 1 month follow up in 2017-18

Settings and conduct

This is a single-blinded clinical trial (the analyst does not know which data is belonging to which group) on 77 operating room students at Faculty of Nursing and Midwifery in Isfahan with control and intervention groups. In the intervention group, training about empathy with patient is presented in a role-playing technique. Jefferson's scale of empathy was given to samples in 3 stages before, immediately and 1 month after the intervention. Data is analyzed by SPSS.

Participants/Inclusion and exclusion criteria

Inclusion: Student of operating room/2,4,6,8 semesters student who has the experience of clinical practice and working with patients/Absence of obvious psychological problems /Do not attend in communication with patient or empathy workshops. Exclusion: Student of operating room (Discontinuous study)/1st semester operating room student/Students with obvious psychological problems/Students participated in workshops about empathy or communication with the patient

Intervention groups

Intervention: Includes a role-playing based empathy training held in 3 sessions (12 hours). In all sessions, one expert psychologist in empathy, helps researcher. The 1st and 2nd sessions focus on empathy and techniques, and in the 3rd session, the samples implement the techniques learned through role-playing with scenario. A questionnaire was given 3 times before, immediately and 1 month after intervention. Control: participants fill out a questionnaire without receiving intervention

Main outcome variables

Patient's empathy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039726N1**
Registration date: **2018-07-15, 1397/04/24**
Registration timing: **retrospective**

Last update: **2018-07-15, 1397/04/24**
Update count: **0**

Registration date

2018-07-15, 1397/04/24

Registrant information

Name

Negin Larti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3661 3872

Email address

aarabi@nm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date
empty

Scientific title
Study of the Effect of a Role Playing-Based Program about Empathy with Patients on Empathy score in Undergraduate Operating Room Students

Public title
Effect of Patient's Empathy training with Role Playing Method on Empathy score

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Student of undergraduate operating room Second, fourth, sixth or eighth semester student who has the experience of clinical practice and working with patients Absence of obvious psychological problems Do not attend in communication with patient or empathy workshops
Exclusion criteria:
Student of undergraduate operating room (Discontinuous study) First semester operating room student Students with obvious psychological problems Students who previously participated in the workshops about empathy or communication with the patient

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**
Actual sample size reached: **77**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst is unaware of which data is related to which group (control or intervention)

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences and Health Services,Faculty of Nursing and Midwifery, Hezarjarib St., Azadi Square.

City
Isfahan

Province
Isfehan

Postal code
81746-73465

Approval date
2018-02-19, 1396/11/30

Ethics committee reference number
IR.MUI.REC.1396.3.839

Health conditions studied

1

Description of health condition studied
The case in this study is not a disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Patient's empathy score

Timepoint
Before intervention- immediately after intervention- one month after intervention

Method of measurement
Jefferson scale of empathy (JSE)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, a 3-session (12-hour) educational program about empathy with patient, based on role-playing method, in 3 consecutive weeks was conducted for 36 undergraduate operating room students in the Faculty of Nursing and Midwifery, Isfahan. In all the sessions, a psychologist (expert in the field of empathy workshop) helped the researcher. In the first and second sessions, the teaching of empathy topics such as empathy needs, patient empathy techniques and barriers were introduced. In the third session, 36 subjects were divided into 12 groups of 3, and they role-played based on pre-designed scenarios about empathy with patient in the operating room (one of the students played the role of the patient and two others played the

role of the nurse in the room) and practiced empathy techniques.

Category

Behavior

2

Description

Control group: There was no intervention in this group and 41 patients in this group, just responded to the patient's empathy questionnaire in 3 phases. However, in order to comply with the ethics principle in the research, it was suggested to the students that if they want, the training would be carried out for them, after the end of the research.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences

Full name of responsible person

Akram Aarabi

Street address

School of Nursing and Midwifery, Isfahan university of Medical Sciences

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8174673465

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aarabi@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Akram Aarabi

Street address

school of Nursing and Midwifery, Isfahan University Of Medical Sciences, Hezar Jarib Street, Azadi Sq.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Negin Larti

Position

Student

Latest degree

Master

Other areas of specialty/work

Others

Street address

Department of Operating Room, School of Nursing and Midwifery, Isfahan University of Medical Sciences

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8174673465

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surgicaltechnologist89@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Akram Aarabi

Position

Assistant 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
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
Not applicable
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
Title and more details about the data/document
The total potential data can be shared after unidentifiable people.
When the data will become available and for how long
The start of the access period is after publishing the data.
To whom data/document is available
Data will be available to researchers and students working in academic, scientific and clinical settings.
Under which criteria data/document could be used
All people working in science centers have access to data.
From where data/document is obtainable
Refer to the scientific officer for this study. Email: aarabi@nm.mui.ac.ir
What processes are involved for a request to access data/document
It is possible to contact the scientific research officer by Email.
Comments