

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effectiveness of emotion regulation training on compassion fatigue and burnout of intensive and critical care nurses as compared to control group

#### Protocol summary

##### Study aim

1. Effectiveness of emotion regulation training on the compassion fatigue of nurses. 2. Effectiveness of emotion regulation training on the burnout of nurses.

##### Design

Controlled clinical trial. At first, people announced their willingness to participate in the project. Subjects were randomly assigned to draw two groups of intervention and control. The sample size was 60 and in each group was 30.

##### Settings and conduct

This clinical trial was conducted at Alzahra Hospital in Isfahan in 2018. 60 intensive and critical care nurses (8.3% male) were randomly divided into two groups experimental (n = 30) and control (n = 30). The experimental group received 6 sessions of emotion regulation training, while the control group did not receive any interventions. Professional quality of life questionnaire and cognitive emotion regulation questionnaires were completed by both groups before and after the intervention. Data were analyzed by descriptive and inferential statistics in SPSS-22 software.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Conscious willingness and agreement to participate in the research project, occupation in intensive and critical care units, no history of using antidepressants and anti-anxiety drugs on the basis of self-report, lack of experience in teaching emotion regulation training, non-use of psychotropic drugs or substance abuse at the moment based on the self-report  
exclusion criteria: Absence of more than two sessions in the training program and exposure to severe stressful events during the study

##### Intervention groups

1. Experimental group: received 6 sessions of emotion regulation training. 2. Control group: No intervention

##### Main outcome variables

1. Burnout 2. Compassion fatigue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171005036572N3**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **retrospective**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

##### Registration date

2018-10-15, 1397/07/23

##### Registrant information

##### Name

Hamid Kharatzadeh

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2303 1548

##### Email address

h\_kharatzadeh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-26, 1397/04/05

##### Expected recruitment end date

2018-07-06, 1397/04/15

##### Actual recruitment start date

2018-07-01, 1397/04/10

##### Actual recruitment end date

2018-07-13, 1397/04/22  
**Trial completion date**  
2018-09-01, 1397/06/10

**Scientific title**  
Effectiveness of emotion regulation training on compassion fatigue and burnout of intensive and critical care nurses as compared to control group

**Public title**  
Effectiveness of emotion regulation training on compassion fatigue and burnout of intensive and critical care nurses

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Conscious willingness and agreement to participate in the research project Occupation in intensive and critical care units No history of receiving emotion regulation training No history of taking antidepressants and anxiolytics based on self-reported Non-use of psychotropic drugs or substance abuse currently based on self-declaration  
**Exclusion criteria:**  
Missing more than two sessions in the training program Exposure to severe stressful events during the study

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**  
Actual sample size reached: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
At first, people were selected voluntarily and then assigned to one of the two intervention or control groups using the lottery.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**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**  
Hezar jerib St. Isfahan city  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
81746-73461  
**Approval date**  
2018-01-10, 1396/10/20  
**Ethics committee reference number**  
IRMUI.REC.1396.2.087

**Health conditions studied**

**1**  
**Description of health condition studied**  
Burnout  
**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

**1**  
**Description**  
Burnout: is a psychological syndrome due to repeated and prolonged exposure to occupational stress and work-pressure.  
**Timepoint**  
1. pretest & 2. posttest  
**Method of measurement**  
Professional quality of life questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**  
**Description**  
Intervention group: The experimental group received an emotion regulation training course. In this research, emotion regulation training is a 6-session curriculum, and its main components include emotional training, changing emotional excitement, changing attention, changing cognitive assessments and changing the behavioral and physiological outcomes of excitement.  
**Category**  
Behavior

**2**  
**Description**  
Control group: The control group did not receive any intervention.

**Category**

Other

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Hasan Rezvani

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Sofeh Blve. Isfahan

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8174675731

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+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

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Hezar jerib St.

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**Email**

research@mui.ac.ir

**Web page address**<http://research.mui.ac.ir/fa/>**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**

Shahed University

**Full name of responsible person**

Hamid Kharatzadeh

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Not applicable

**Data Dictionary**

Not applicable