

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Reduce mental workload of neonatal intensive care units nurses through a self-designed educative class: A randomized controlled trial.

#### Protocol summary

##### Study aim

Therefore the present study was conducted aiming to investigate and compare the effect of a conventional educative class and a self-designed educative class on NICU (Neonatal Intensive Care Units) nurses' mental workload at educational hospitals of Isfahan.

##### Design

The clinical trial has two groups of control and intervention, with parallel and random groups.

##### Settings and conduct

This study was a randomized controlled trial administered on 68 nurses. They were divided into two intervention and control groups. Then the intervention was administered through designing a class with the content of reinforcing social awareness as one of the dimensions of emotional intelligence. NASA -TLX (national aeronautics and space administration- Task load Index)'s mental workload questionnaire was applied in order to collect data. The collected data will analyze by SPSS software.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: 1. having at least Bachelor of sciences in nursing. 2. Job precedency for at least six months in NICU. 3. Not having suffered from anxiety and depression recently according to self-confirmation and 4. Not using antianxiety and antipsychotic drugs.

##### Intervention groups

Both groups (nurses of NICU) participate in an educative class according to the routine NICU nurses continues educational schedule that in this research we call it "conventional educative class" entitled "respiration management in neonates". The intervention group participate in an additional class designed by the researcher after a week. In holding this class an experienced psychology expert who had the license of emotional intelligence training is employed. The nurses in the intervention group took part in a self-designed educative class entitled "Emotional intelligence with emphasizes on social awareness" for four hours.

#### Main outcome variables

mental workload

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180511039604N1**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **retrospective**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

##### Registration date

2018-05-27, 1397/03/06

##### Registrant information

##### Name

Akram Aarabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7565

##### Email address

fbf1370@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2016-08-21, 1395/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Reduce mental workload of neonatal intensive care units nurses through a self-designed educative class: A randomized controlled trial.

**Public title**

Reduce mental workload of neonatal intensive care units nurses through a self-designed educative class: A randomized controlled trial.

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

having at least Bachelor of sciences in nursing. Job precedency for at least six months in NICU. Not having suffered from anxiety and depression recently according to self confirmation Not using antianxiety and antipsychotic drugs

**Exclusion criteria:****Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Nurses at first selected by simple sampling method and then randomly allocated in control and intervention groups. For randomization we first labeled every nurse with a number and then we provided separated vote labels for each number and put all the numbers in a vase and randomly select the numbers one by one. If the selected number were even she were put in control and if it was odd she were put in intervention group.

**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 Isfahan University Of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73465

**Approval date**

2016-05-21, 1395/03/01

**Ethics committee reference number**

IR.MUI.REC.1395.3161

**Health conditions studied****1****Description of health condition studied**

mental workload

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

mental workload

**Timepoint**

after and before intervention

**Method of measurement**

NASA -TLX (national aeronautics and space administration- Task load Index)'s mental workload questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The intervention group: They participated in an additional class designed by the researcher after a week. In holding this class an experienced psychology expert who had the license of emotional intelligence training is employed. Social awareness is selected for training and the nurses in the intervention group took part in a self-designed educative class entitled "Emotional intelligence with emphasizes on social awareness" for four hours. Because we have not been permitted to raise a class with more than 30 person we convene two separate but the same content classes with 17 nurses for intervention

group. Content of the self-designed educative class are included the definition of emotional intelligence and its dimensions, strategies for improvement of social awareness such as personality identification and personality categories base on colors (for example orange personality green personality etc.). The self-designed educative class raise a week after the conventional educative class for intervention group.

**Category**

Behavior

**2**

**Description**

Control group: The control group participate in an educative class according to the routine continues educational schedule that in this research we call it "conventional educative class" entitled "respiration management in neonates".

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**  
Alzahra Hospital of Isfahan

**Full name of responsible person**  
Akram Aarabi

**Street address**  
Soffeh Blvd., Isfahan, Iran

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aarabi@nm.mui.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**  
Shahid Beheshti Hospital of Isfahan

**Full name of responsible person**  
Akram Aarabi

**Street address**  
shahid motahari St. Isfahan. Iran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
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**Full name of responsible person**  
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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**  
Akram Aarabi

**Position**  
faculty member

**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

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**Full name of responsible person**  
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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

Not applicable

### Informed Consent Form

No - There is not 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

### 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 6 months after the results are published.

### To whom data/document is available

The data from this study will be available to researchers working in academic, scientific and clinical settings.

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

All people in the science centers are allowed to request access to the data.

### From where data/document is obtainable

Refer to the scientific officer for this study.

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

Through correspondence with the academic studying officer.

### Comments