Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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)
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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
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Isfahan
Province
Isfehan
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

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Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Isfahan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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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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