Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of stress management program on response to stress in nurses at Neonatal Intensive Care Units "

Protocol summary

Summary

This quasi-experimental study utilizes two control and intervention groups to detemination the effect of stress management program on response to stress in nurses working in neonatal intensive care units. The study setting is neonatal intensive care units in teaching hospitals affiliated to Iran University of Medical Sciences, and the study population is 70 nurses who comprises eligible working in these units. intervention and control groups are randomly selected to avoid likelihood of information leakage. Nurses are selected by convenient sampling method, and written consent is obtained from them. Their demographic data are collected and recorded using a questionnaire. In the pretest, all control and intervention groups complete Stress Response Inventory (SRI), containing seven subscales: tension, aggression, anger, depression, fatigue, frustration, and somatization. McNamara stress management teaching method is used in six one-hour sessions during six weeks. In each session, new topics are presented after reviewing previous ones. In this study, education program is not provided for participants in control groups during intervention. However, after completion of the intervention, all educational materials given to intervention groups are also made available to control groups. Eight weeks later, the questionnaire (SRI) is given to the intervention group nurses and inter- and intra-group results are compared.

General information

Acronym

not applicable

IRCT registration information

IRCT registration number: **IRCT201509261788N13**
Registration date: **2015-12-09, 1394/09/18**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-12-09, 1394/09/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences Nursing Care Research Center

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of stress management program on response to stress in nurses at Neonatal Intensive Care Units "

Public title

Stress management to stress in nurses at Neonatal Intensive Care Units "

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Complete personal consent for participation in the study; a minimum of one year's clinical work experience; Bachelor’s degree or higher; no use of psychotropic drugs; working for four to six days per week; or 31 to 40 hours per week. Exclusion criteria: current depression; self-reported acute and chronic somatic or psychiatric disorders; medication.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Iran University of Medical Sciences and Health Services

Street address

Iran, Tehran, Shahid Hemmat Highway West, between the intersection of Sheikh fazlolah Nori and Shahid Chamran

City

Tehran

Postal code

1996713883

Approval date

2015-08-05, 1394/05/14

Ethics committee reference number

IR.IUMS.REC.1394 . 9311451006

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

Primary outcomes

1

Description

Stress managment

Timepoint

before, Immediately after the treatment, after eight week

Method of measurement

SRI Questionnare

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, McNamara stress management is used in six one-hour sessions during six weeks, when NICU nurses receive educational intervention in groups of six. In each session, new topics are presented after reviewing previous ones, and issues discussed are summed up at the end of the session. Session one: Introduction to the importance of learning stress management skills; presenting definitions of stress. Session two: Introducing general effects of stress on various body systems, and examining physical, psychological, and behavioral effects of stress. Session three: Subjective and rational strategies for dealing with stress, and introducing problem-oriented and emotion-oriented methods as coping strategies, examining coping methods adopted by people in stressful situations. Session four: Introducing steps of coping skills, and working on the first stage: being aware of own feelings. Session five: The second step of stress control skills, physical ways of coping with stress: these are concerned with a healthier lifestyle, and include healthy nutrition, and sufficient sleep and exercise, which maintain and strengthen the immune system and increase energy level. Session six: Review of comments expressed by nurses and obtaining feedback, and SRI posttest. Personnel's stress is measured using pretest and posttest, and stress levels in two groups are compared through posttest and follow-up test. Eight weeks later, SRI is made available to nurses in the intervention group (posttest), in order to assess sustainability over time of stress management education provided by the researcher.

Category

Behavior

2

Description
Control group: No action is taken
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Teaching hospitals affiliated with Iran University of Medical Sciences
Full name of responsible person
Lelli Borimnenejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
center for nursing care reaserch Iran University of Medical Sciences
Full name of responsible person
Sedighe Khanjari
Street address
Yasemi Street, Nursing and Midwhery School
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Grant name
مرکز تحقیقات مراقبتهای پرستاری
Grant code / Reference number
94-03-123-26475
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
center for nursing care reaserch Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty