

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 determine 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

Name

Leili Borimnejad

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6150 4212

Email address

borimnej@iums.ac.ir

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 management

Timepoint
before, Immediately after the treatment, after eight week

Method of measurement
SRI Questionnaire

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 Borimnejad

Street address

Nursing and midwifery School

City

Tehran

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

City

Tehran

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

Iran University Of Medical Sciences

Full name of responsible person

Leili Borimnejad

Position

Ph.D / Educational Affair

Other areas of specialty/work

Street address

Yasemi Street , Nursing and Midwhery School

City

Tehran

Postal code

1996713883

Phone

+98 21 8888 2886

Fax

Email

l.borimnejad@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leili Borimnejad

Position

Ph.D / Associate Professor

Other areas of specialty/work

Street address

Yasemi Street, Nursing and Midwifery School

City

Tehran

Postal code

1996713883

Phone

+98 21 8888 2886

Fax

Email

l.borimnejad@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran university of Medical Sceinec

Full name of responsible person

Leili Borimnejad

Position

Ph.D

Other areas of specialty/work

Street address

Nursing and Midwifery School

City

Tehran

Postal code

19994

Phone

+98 21 8820 1880

Fax

Email

l.borimnejad@gmail.com

Web page address

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