Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness practice on the stress and Psychological Capital of mothers of premature neonates admitted to the neonatal intensive care unit

Protocol summary

Study aim
Evaluating the effectiveness of mind-awareness training on stress and psychological capital of mothers of premature infants admitted to the neonatal intensive care unit.

Design
Clinical trial with control group without randomization

Settings and conduct
Mindfulness-based stress reduction program for 2 sessions of 1.5 hours every week on Mondays and Wednesdays in the mothers' rest room by the project manager who has obtained the certificate of this course and is held next to the psychologist of Mahdieh Hospital in the training hall of Mahdieh Hospital. There will be lectures, questions and answers, group discussions and practice techniques. In order to continue communicating with the participants, their phone number and home address will be obtained, and communication will be maintained by forming training groups in Telegram and WhatsApp.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the mother's desire to participate in the intervention; mothers with premature babies (28-37 weeks); ability to read and write in Persian; availability of mother; ability to participate in training sessions in case of discharge; having no history of mindfulness training; no chronic neonatal underlying disease and abnormality; no history of taking sedatives and psychotropic drugs before pregnancy; no chronic illness of the mother such as depression and anxiety. Exclusion criteria: absence (even one session) of training sessions; death of a baby.

Intervention groups
The intervention group was selected by the available method and while receiving routine care, mindfulness training sessions were taught for 8 sessions 2 hours for 2 days a week. Mindfulness is a non-invasive and non-pharmacological method that increases the individual's attention. Reduces physiological reactions and regulates a person's emotions.

Main outcome variables
Reducing the stress of mothers

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20210321050755N1**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**
Update count: **0**

Registration date
2021-05-18, 1400/02/28

Registrant information

Name
narhes asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3629 5831

Email address
hasstyass@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of mindfulness practice on the stress and Psychological Capital of mothers of premature neonates admitted to the neonatal intensive care unit

Public title
The effectiveness of mindfulness practice on the stress and Psychological Capital
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The mother's desire to participate in the intervention Mothers with premature babies (28-37 weeks) Ability to read and write in Persian Availability of mother Ability to participate in training sessions in case of discharge No history of mindfulness training (distorter) No chronic neonatal underlying disease and abnormality (distorter) No history of taking sedatives and psychotropic drugs before pregnancy (confounder) No chronic illness of the mother such as depression and anxiety (confounder)
Exclusion criteria:
Absence (even one session) of training sessions Death of a baby
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
So far, no mindfulness training intervention on stress and psychological capital of mothers of neonates admitted to the intensive care unit has been performed.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Nursing and Midwifery and School of Rehabilitation - Tehran University of Medical Sciences
Street address
Tohid Square, Dr. Mirkhani St. (Eastern Nusrat),
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2020-02-18, 1398/11/29
Ethics committee reference number
IR.TUMS.FNM.REC.1398.202

Health conditions studied

1

Description of health condition studied
Stress and psychological capital of mothers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Stress and psychological capital of mothers
Timepoint
The beginning of the study and the end of the study
Method of measurement
Parental Stress Questionnaire and McGee Psychological Capital Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They were selected by the available method and in addition to receiving routine care, they receive mindfulness exercises in 8 sessions for 1 hour two days a week. Mindfulness is a non-invasive and non-pharmacological method that increases a person's attention, decreases Physiological reactions and regulation of emotions.
Category
Lifestyle

2

Description
Control group: Intervention group: Mothers of premature infants admitted to the neonatal intensive care unit who do not receive any training or mindfulness training during this period.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Educational, Health and Medical Center
Full name of responsible person
Narges Asadi
Street address
Shousha Square, Fadaiyan-e-Islam Street, Shishegar Khaneh Alley, Iran
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TEHRAN
Province
Tehran
Postal code
1185817311
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+98 21 5506 2628
Fax
Email
mahdiyeh_hospital@sbmu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Sixth floor, Vice Chancellor for Research and Technology, Tehran University of Medical Sciences, Keshavarz Boulevard
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1419733171
Phone
+98 21 6670 6142
Email
msahrai@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
medical University Tehran
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
Tehran University of Medical Sciences
Full name of responsible person
Narges Asadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Dr. Mirkhani St. (Eastern Nusrat), Tohid Square
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Person responsible for scientific inquiries

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hasstyass@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Narges Asadi

Position

Student

Latest degree

Bachelor

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Except for the name and surname, all the data of the participants will be published

When the data will become available and for how long

Start period 6 months after printing

To whom data/document is available

Researchers working in scientific and academic centers

Under which criteria data/document could be used

Researchers working in scientific and academic centers

From where data/document is obtainable

Ms. Narges Asadi hasstyass@yahoo.com

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

The process is currently unknown

Comments