

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 Mahdiah Hospital in the training hall of Mahdiah 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

Mahdiah Educational, Health and Medical Center

Full name of responsible person

Narges Asadi

Street address

Shousha Square, Fadaian-e-Islam Street, Shishegar
Khaneh Alley, Iran

City

TEHRAN

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

Email

mahdiyeh_hospital@sbm.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

City

Tehran

Province

Tehran

Postal code

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

66927171

Email

fnm@tums.ac.ir

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

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

Street address

Dr. Mirkhani St. (Eastern Nusrat), Tohid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

hasstyass@yahoo.com

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