Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Mindfulness-Based Stress Reducing Intervention on the Rate of Chronic Sorrow and Coping Behaviors in Mothers of Children with Cancer

Protocol summary

Study aim
Determining the effect of "mindfulness-based stress reduction" intervention on chronic sorrow and coping behaviors in mothers of children with cancer in Mofid Children's Hospital

Design
Clinical trial with control and intervention groups, parallel groups, randomized, on 80 mothers of children with cancer. Random number table is used for randomization.

Settings and conduct
The study site is the oncology ward of Mofid Children's Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Mother over 20 years old; 6 months have passed since the child was diagnosed with cancer and the mother is aware of the diagnosis; The child's cancer is in the extinction stage; Be Persian-speaking and literate; Physically and mentally able to answer questions and communicate. Non-inclusion criteria:The mother or first-degree relatives (except the child) have cancer; Have cognitive, speech or hearing problems; Have a mental illness or anxiety disorder based on the child's records; have a degree in psychology and medical science.

Intervention groups
Intervention group: The members of this group undergo the mindfulness-based stress reduction intervention and learn relaxation and meditation techniques in 4 sessions. Control group: in the control group, mothers will not participate in mindfulness-based stress reduction sessions

Main outcome variables
Chronic Sorrow, Coping Behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200610047721N1**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-23, 1399/06/02**
Update count: **0**

Registration date
2020-08-23, 1399/06/02

Registrant information

Name
Mahsa Moslem

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3374 9035

Email address
m.moslem@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2020-11-20, 1399/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Mindfulness-Based Stress Reducing

Intervention on the Rate of Chronic Sorrow and Coping Behaviors in Mothers of Children with Cancer

Public title
The Effect of Mindfulness-Based Stress Reducing Intervention on the Rate of Chronic Sorrow and Coping Behaviors

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Be over 20 years old Have a diagnosis of pediatric cancer by a oncologist doctor with a definite record in the patient's file Mothers are aware of the diagnosis of their child's cancer. Being the biological mother of the child. The child's cancer is in the extinction stage. At least 6 months have passed since the diagnosis of child cancer. Being literate, have the ability to speak Persian. Being physically and mentally able to answer questions and communicate. Have consent to participate in the study. Have the desire and ability to participate in face-to-face meetings. Have access to mobile phones and familiarity with Mobogram or Talagram software.

Exclusion criteria:
The mother or first-degree relatives (except the child) have cancer. The mother has cognitive, speech, or hearing problems. Have a mental illness or anxiety disorder based on the child's records. Have a degree (being educated) in psychology and medical sciences.

Age
From **20 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample selection is done in such a way that all eligible samples are listed, then each of them is given a number that was randomly derived from the table of random numbers. There is no special order in writing these numbers. Next, the required number of samples is randomly selected from the numbers by drawing numbers. In placing people in the control and intervention groups, the block randomization method is used, in which 16 blocks of size 5 are selected and then patients are divided into two groups of 40 people as control and intervention groups based on the sequence of numbers created from block randomization.

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 the Faculty of Pharmacy, Nursing and Midwifery - Shahid Beheshti University of M

Street address
Shahid Beheshti school of nursing and midwifery,in front of Shahid Rajaei hospital,Valiasr street

City
Tehran

Province
Tehran

Postal code
19857174443

Approval date
2020-05-03, 1399/02/14

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1399.034

Health conditions studied

1

Description of health condition studied
Leukemia

ICD-10 code
C91.0

ICD-10 code description
Acute lymphoblastic leukemia [ALL]

2

Description of health condition studied
Brain tumors

ICD-10 code
C71

ICD-10 code description
Malignant neoplasm of brain

3

Description of health condition studied
Bone tumor

ICD-10 code
C40

ICD-10 code description
Malignant neoplasm of bone and articular cartilage of limbs

4

Description of health condition studied
Wilms tumor

ICD-10 code
C64

ICD-10 code description

Malignant neoplasm of kidney, except renal pelvis

5

Description of health condition studied
lymphoma
ICD-10 code
C77
ICD-10 code description
Secondary and unspecified malignant neoplasm of lymph nodes

Primary outcomes

1

Description
Mother's coping behaviors
Timepoint
Before the intervention (before the start of the first session of mindfulness-based stress reduction program) and after the intervention (four weeks after the intervention, ie after four sessions of mindfulness-based stress reduction program once a week).
Method of measurement
The McCobin's Coping Health Inventory for Parents (CHIP) Questionnaire

2

Description
Mother's chronic sorrow
Timepoint
Before the intervention (before the start of the first session of mindfulness-based stress reduction program) and after the intervention (four weeks after the intervention, ie after four sessions of mindfulness-based stress reduction program Once a week).
Method of measurement
Kendall Chronic Sorrow Instrument (Persian version)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The purpose of the intervention in this study is to hold four sessions with the content of stress reduction based on mindfulness for mothers. The content of the sessions is the first session including introduction, expression of feelings and thoughts, body scan meditation, the second session includes body scan exercise, Three-minute breathing, the third session includes repeating the previous sessions and doing yoga movements. Finally, in the fourth session, the exercises will be reviewed and after completing the sessions, the questionnaires will be completed again. The sessions will be held once a week for a period of 45-120 minutes.
Category
Behavior

2

Description
Control group: in the control group, mothers will not participate in mindfulness-based stress reduction sessions and will only complete the Coping Health Inventory for Parents (CHIP)and Kendall Chronic Sorrow Instrument Questionnaire.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid children's hospital
Full name of responsible person
Mahsa Moslem
Street address
Before Mirdamad street, near by Hosseinieh Ershad; Shariati street
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Tehran
Postal code
1546815514
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+98 21 2222 0254
Email
info-mch@sbmu.ac.ir
Web page address
http://en.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahrokh Dolatian
Street address
Shahid Beheshti school of nursing and midwifery,in front of Shahid Rajaei hospital,Valiasr street
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
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+98 21 8865 5363

Email

mhdolatian@gmail.com

Web page address

http://nm.sbmu.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Moslem

Position

Master student of pediatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti school of nursing and midwifery,in front of Shahid Rajaei hospital,Valiasr street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Moslem

Position

Master student of pediatric nursing

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Questionnaire information and only part of the main outcome information

When the data will become available and for how long

six months

To whom data/document is available

Nursing students and nurses

Under which criteria data/document could be used

Use in related research and similar to research title

From where data/document is obtainable

Contact with Mahsa Moslem via email: mahsa.moslem20n@gmail.com

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

Data will be available up to ten days after receiving the email.

Comments