

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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		Secondary Ids	empty
Public title	The Effect of Mindfulness-Based Stress Reducing Intervention on the Rate of Chronic Sorrow and Coping Behaviors	Ethics committees	
Purpose	Education/Guidance	1	
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.	Ethics committee	
Age	From 20 years old	Name of ethics committee	Ethics Committee of the Faculty of Pharmacy, Nursing and Midwifery - Shahid Beheshti University of M
Gender	Female	Street address	Shahid Beheshti school of nursing and midwifery,in front of Shahid Rajaei hospital,Valiasr street
Phase	N/A	City	Tehran
Groups that have been masked	No information	Province	Tehran
Sample size	Target sample size: 40	Postal code	19857174443
Randomization (investigator's opinion)	Randomized	Approval date	2020-05-03, 1399/02/14
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.	Ethics committee reference number	IR.SBMU.PHARMACY.REC.1399.034
Blinding (investigator's opinion)	Not blinded	Health conditions studied	
Blinding description		1	
Placebo	Not used	Description of health condition studied	Leukemia
Assignment	Parallel	ICD-10 code	C91.0
Other design features		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

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

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Web page address

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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

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Email

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Web page address

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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

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Web page address

http://nm.sbm.ac.ir/

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