

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Development and Evaluation of Effectiveness of a Mindfulness-based program on resiliency, rumination, acceptance and improvement of psychological distress of mothers with cancerous children

Protocol summary

Study aim

The results of this study can be Determines whether the package of mindfulness designed to increase resilience, decrease the rumination, acceptance and improve the psychological symptoms of mothers of children with cancer is effective. In practical and practical terms, the results of this research can be used as an intervention to improve the psychological symptoms of mothers of children with cancer, while familiarizing researchers and therapists of the country with the theories, therapeutic approaches, and research areas. Existing, the effectiveness of this method as one of the newest methods of intervention in the treatment of parents of children with cancer in an Iranian sample.

Design

They are available through a sampling method of 30 individuals. They were randomly drawn and drawn in two groups of intervention and control Placed.

Settings and conduct

The statistical population includes mothers of children with cancer who are under treatment in the oncology section of Emam Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Mothers of children with cancer

Intervention groups

30 mothers were randomly selected and assigned to intervention and control group. After pre-test and responding to the questionnaires, the intervention group received mindfulness therapy during 8 90-minute sessions (based on the instructions). The protocol also allows for two sessions per week to be completed, which can be completed for one month). While the control group will not receive any treatment, after the end of the sessions, a two-month follow up will be conducted to measure the efficacy of the treatment at a specified time in both groups. Finally, in order to observe ethical principles in the research, the knowledge of mind will be

provided to the control group.

Main outcome variables

Mindfulness; Resiliency; Rumination; Acceptance; Mothers; Cancerous Children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180830040906N1**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-02, 1397/10/12**

Update count: **0**

Registration date

2019-01-02, 1397/10/12

Registrant information

Name

Zeinab Sinaefar

Name of organization / entity

Shahid beheshti university

Country

Iran (Islamic Republic of)

Phone

+98 21 4466 4341

Email address

sanazsinae@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-15, 1397/09/24

Expected recruitment end date

2019-01-14, 1397/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and Evaluation of Effectiveness of a Mindfulness-based program on resiliency, rumination, acceptance and improvement of psychological distress of mothers with cancerous children

Public title

Development and Evaluation of Effectiveness of a Mindfulness-based program on resiliency, rumination, acceptance and improvement of psychological distress of mothers with cancerous children

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

mothers with cancerous children

Exclusion criteria:**Age**

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

The statistical population includes mothers of children with cancer who are under treatment in the oncology section of Imam Khomeini Hospital in Tehran. They are available through a sampling method of 30 individuals. They were randomly drawn and drawn in two groups of intervention and control Placed.

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 for Bioethics at Shahid Beheshti University

Street address

Institute of Cognitive and Brain Sciences, Shahid Beheshti University, Daneshjoo Blvd, Evin

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2018-12-01, 1397/09/10

Ethics committee reference number

IR.SBU.ICBS.97/1029

Health conditions studied**1****Description of health condition studied**

Children with cancer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Resiliency

Timepoint

Pre-test-Post-test

Method of measurement

CD-RISC

2**Description**

Rumination

Timepoint

Pre-test-Post-test

Method of measurement

RRS

3**Description**

Acceptance

Timepoint

Pre-test-Post-test

Method of measurement

AAQ_II

4**Description**

Psychological Distress

Timepoint

Pre-test-Post-test

Method of measurement

DASS-21

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A package of interventions based on the training of mindfulness skills was performed on the intervention group over 90 minute- 8 sessions.

Category

Lifestyle

2

Description

Control group:Do not get an intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Seyed Mohammad Kazem Nourbakhsh

Street address

Imam Khomeini Hospital, Dr. Gharib Street, End of Keshavarz Blvd

City

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1419733141

Phone

+98 21 6119 0000

Email

dr.nourbakhsh2010@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Dr. Babak Shokri

Street address

Deputy Director of Research and Technology, Presidential Building, Shahid Beheshti University, Daneshjoo Blvd, Evin

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1983963113

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drbabakshokri@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University

Proportion provided by this source

100

Public or private sector

Private

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

Full name of responsible person

Zeinab Sinaefar

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Study documentation will be published after the intervention.

When the data will become available and for how long

september 2019

To whom data/document is available

All undergraduate and postgraduate students

Under which criteria data/document could be used

For researchers and students

From where data/document is obtainable

sanazsinae@gmail.com

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

sanazsinae@gmail.com

Comments