Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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Psychology
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Person responsible for updating data

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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