

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of Modified Mindfulness-based Cognitive Therapy for hospitalized Children Hospitalized with Cancer compared to control group in attention problems and internalizing problems.

Protocol summary

Study aim

The aim of this study is the enhancement of emotional regulation in children with cancer.

Design

Forty children (ages 11 to 13) diagnosed with cancer were randomly assigned to either a modified MBCT-C group (n = 20) or treatment-as-usual (TAU) control group (n = 20). To meet the needs of hospitalized participants, the manualized MBCT-C protocol was adapted to consist of 20 sessions, each lasting 45-minutes. Sessions were conducted 5 times weekly for 4 weeks.

Settings and conduct

The study was conducted at the Mahak Hospital and Rehabilitation Complex, located in Tehran, Iran.

Participants/Inclusion and exclusion criteria

Hospitalized patients were eligible to participate in the MBCT-C if they were 11 to 13 years of age. Patients who were determined to be diagnosed with a terminal illness were excluded.

Intervention groups

The primary aim of MBCT-C is to improve effective self-regulation through the development of mindful attention and to decenter from thoughts and emotions. The main component of this therapy is awareness of the present moment, which helps them decide more wisely. Unlike cognitive therapy, no effort is made to restructure or change existing thoughts and emotions. Individuals in this program learn to be mindful in daily life. The control group was 20 children with cancer hospitalized and were not under any psychological and psychiatric therapy.

Main outcome variables

Change in internalizing and attention problems.

on the reduction in internalizing and attention problems as well as enhancement in emotional regulation. So, we decided to assess the variables which had more support in the literature review. We selected internalizing and attention problems because more studies examined them. Moreover, we found out in hospitalized children who could stay in the hospital for one month, internalizing and attention problems are more evident than adjustment problems. Hence, we decided to change the independent variable from adjustment to attention and internalizing problems. Besides, parents in the initial interviews reported that their children's internalizing and attention problems are more frequent than the adjustment problems. It became another reason to change the "adjustment" variable to the internalizing and attention issues.

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120614338N1**

Registration date: **2013-12-06, 1392/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-02, 1399/10/13**

Update count: **1**

Registration date

2013-12-06, 1392/09/15

Registrant information

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General information

Reason for update

Mindfulness-Based Cognitive Therapy has been focused

Recruitment status
Recruitment complete
Funding source
Funded by researcher

Expected recruitment start date
2013-09-01, 1392/06/10
Expected recruitment end date
2014-03-11, 1392/12/20
Actual recruitment start date
2013-08-31, 1392/06/09
Actual recruitment end date
2014-03-10, 1392/12/19
Trial completion date
2014-03-10, 1392/12/19

Scientific title
The effectiveness of Modified Mindfulness-based Cognitive Therapy for hospitalized Children Hospitalized with Cancer compared to control group in attention problems and internalizing problems.

Public title
The Effectiveness of an Adapted Mindfulness-based Cognitive Therapy for Children with Cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized patients were eligible to participate in the Mindfulness-Based Cognitive Therapy for Children (MBCT-C) program in addition to receiving TAU if they were (a) 11 to 13 years of age; (b) had at least average fluency in Persian; (c) had received the first diagnosis of any type of cancer except brain cancers; (d) were undergoing radiation therapy and/or chemotherapy through the hospital's oncology division; and (e) had not received any psychological interventions or psychiatric medications in the six months preceding the study. Diagnostic inclusion criteria were: (f) a diagnosis of Autism spectrum disorder (ASD) (Diagnostic and Statistical Manual of Mental Disorders (IV) (DSM-IV (American Psychiatric Association, 2000); and (g) at least two comorbid diagnoses in any of four diagnostic categories (anxiety, depression, psychosomatic, or attention deficit disorders). Diagnoses were ascertained using the Kiddie Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Persian version (K-SADS-PL-P). Additionally, patients needed to be: (h) in the borderline or clinical range for internalizing problems (T-score ≥ 60) and attention problems (T-score ≥ 57) on at least two of four subscales of the Child Behavior Checklist (CBCL) or Youth Self-Report (YSR) (depression/anxiety, withdrawal/depression, somatic complaints, and attention problems) at the screening assessment.

Exclusion criteria:

Patients who were determined to (i) have a major cognitive dysfunction or developmental disability, or (j) was diagnosed with a terminal illness (defined as having a prognosis of fewer than six months) were excluded. Moreover, Brain cancers were excluded based on research suggesting that these may affect attention

(Raghubar et al., 2017), a key outcome variable.

Age
From **11 years** old to **13 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
We utilized simple randomization through the excel file of random numbers. The unit of randomization was individual.

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

Shahid Beheshti University

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Shahid Beheshti University, Evin, Tehran.

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Province

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Approval date

2013-08-27, 1392/06/05

Ethics committee reference number

58/850/ص

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

F06.30

ICD-10 code description

Mood disorder due to known physiological condition,

unspecified

2

Description of health condition studied

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3

Description of health condition studied

depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

4

Description of health condition studied

somatic complaints

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

5

Description of health condition studied

attention problems

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

internalizing and attention problems

Timepoint

Before and 4 weeks after the treatment as well as 2-month follow-up

Method of measurement

CBCL and YSR

Secondary outcomes

1

Description

more cooperation in medical treatments in participants

Timepoint

Before and after the treatment as well as at follow-up point

Method of measurement

Interviews

Intervention groups

1

Description

Forty children (ages 11 to 13) diagnosed with cancer were randomly assigned to either a modified MBCT-C group (n = 20) or treatment as usual (TAU) control group (n = 20). To meet the needs of hospitalized participants, the manualized MBCT-C protocol was adapted to consist of 20 sessions, each lasting 45 min. Sessions were conducted 5 times weekly for 4 weeks. Primary outcome measures were the Child Behavior Checklist, Parent Report and its companion instrument, and the Youth Self-Report (YSR). Data were collected at pre-intervention, post-intervention, and at 2 months following the intervention.

Category

Treatment - Other

2

Description

Forty youth were age and gender-matched, and then randomly assigned to either a modified MBCT-C group (n = 20) or treatment-as-usual (TAU) control group (n = 20). Mahak hospital provided some welfare services and social work services. Welfare services as well as social work services was equal for both experimental and control group. Social workers were assigned to accompany the child and help the family to become acquainted with the cancer, available services, hospital procedure and personnel, and disjunctive treatment. Moreover, they facilitated a shared playroom that every child welcomed to join. They could use from various toys there and made friend with others. Parents could accompany their children there. And the group was lead by social workers. The room was open 2 hours daily from 2 pm to 4 pm. Children could use from snacks there and remaining there was not mandatory.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahak Hospital and Rehabilitation Complex

Full name of responsible person

Shima Shirafkan

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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The main researcher (samaneh abedini)
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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

to respect to confidentiality, we do not aim to share our

participants' names or pictures, but we can share their general demographic features as well as the results of their assessments through our publications or presentations at conferences.

When the data will become available and for how long

The results of data analysis will be available for everyone in google scholar when we could publish them in one scientific journal. it seems that in February of 2021 the article derived from the results will be published.

To whom data/document is available

The results of data analysis will be available for the public.

Under which criteria data/document could be used

Persons who want to use the results of data analysis have to cite us and our research as a reference.

From where data/document is obtainable

The results of data analysis can be downloaded from google scholar. Individuals interested in reading the article derived from these data can contact the corresponding author to receive the full-text article. Other researchers can contact Samaneh Abedini through the following email to receive the main article: samaneh.abedini88@gmail.com

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

Academic persons who need the data can send an email to the researchers. If they contacted the corresponding author, they could receive the article within one week.

Comments