

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of group cognitive-behavior based parenting in anxiety and depression symptoms in children with cancer and the role of mechanism of change in treatment

Protocol summary

Study aim

The aim of this study will be to evaluate the effectiveness of group intervention based cognitive-behavioral parenting on the symptoms of depression and anxiety in children with cancer. The role of mediators in treatment as a mechanism of change will also be investigated.

Design

The study population will include all children between 7 and 10 years old with cancer referred to Ali Asghar Hospitals and Children's Medical Center, from which 40 people will be selected by available sampling method. (10 people will be considered for the drop-out). And by simple random method and through lottery, they will be placed in 2 groups of drug therapy and drug therapy in addition to "from Timid To Tiger" parenting intervention.

Settings and conduct

The intervention "from Timid to Tiger" is performed for ten 2-hour group sessions. This study will be performed in the Oncology Clinic of Ali Asghar Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria will include: the child has a type of cancer, and at least 6 months have passed since the diagnosis of cancer and the acute course of the disease, the child's score internalization subscale of CBCL scale should be higher than the cut-off point, and on the basis of the K-SADs scale will receive the diagnosis of major depressive disorder. Exclusion criteria will also include: the child or parent has moderate to severe learning disabilities, the child has psychotic disorder, and the child has end-stage cancer.

Intervention groups

The present study will consist of two groups, one group receiving the treatment as usual, which is pharmacotherapy, and the other group receiving the treatment as usual in addition to parent-based intervention.

Main outcome variables

The severity of anxiety and depression symptoms in children with cancer as a result of treatment will be investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048237N1**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Mehri Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

moradi.me@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-25, 1399/06/04

Expected recruitment end date

2021-01-23, 1399/11/04

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of group cognitive-behavior based parenting in anxiety and depression symptoms in children with cancer and the role of mechanism of change in treatment

Public title
Cognitive-behavioral based parenting effect on depression in children with cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The child has a type of cancer At least 6 months have passed since the diagnosis of cancer and the acute phase of the disease The child's score on the internalization subscale of CBCL scale should be higher than the cut-off point Based on the K-SADs scale, the child is diagnosed with depressive disorder
Exclusion criteria:
 The child or parent has moderate to severe learning disabilities (the parent or child is unable to read and write) The child has psychotic disorder, The child's cancer is in the end stage of the disease

Age
From **7 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The population will include all children between 7 and 10 years old with cancer referred to Ali Asghar hospital and Children's Medical Center.40 people will be selected by available sampling method and by simple sampling and through lottery, they will be allocated in 2 groups of drug therapy and drug therapy plus parenting treatment.

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-11-05, 1398/08/14

Ethics committee reference number

IR.IUMS.REC.1398.851

Health conditions studied

1

Description of health condition studied

depressive disorders

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2

Description of health condition studied

cancer

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Anxiety disorders

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Severity of depressive symptoms

Timepoint

Before the intervention, the fifth session, immediately after the intervention, and two months after the intervention

Method of measurement

Child Depression Inventory

2

Description

Severity of depressive symptoms

Timepoint

Before the intervention, the fifth session, immediately after the intervention, and two months after the intervention

Method of measurement

Spence Children's Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: drug therapy. This group will receive the treatment as usual, which is medication for anxiety disorders and depression, according to the diagnosis of the center's psychiatrist. The prescription drug for these disorders is usually a class of Selective Serotonin Reuptake Inhibitors (SSRIs). Depending on the severity of the disease and the side effects of the drug, the psychiatrist will use the appropriate drug. This treatment is usually used in the relevant group and the researcher will not change it. The psychiatrist visits the clients once a month.

Category

Treatment - Drugs

2

Description

Intervention group: Pharmacotherapy in addition to parenting education. In this group, in addition to the treatment as usual, which is drug therapy, parenting education will be done for parents. The executive protocol includes 10 two-hour sessions that will be held weekly for parents. The treatment is done in groups and children are not present in this intervention. The present intervention is designed to reduce the symptoms of anxiety and depression in children. This intervention is based on the cognitive-behavioral model and its purpose is to cognitive restructuring the thoughts and beliefs of parents and children.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar hospital

Full name of responsible person

Shala Ansari

Street address

Ali Asghar Hospital., No 193., Dastgerdi St., Modares

Highway

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19198167766

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aach@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Abbas Motevalian

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

mehri moradi

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No 1., School of Behavioral Sciences and Mental Health (Tehran Institute of Psychiatry)., Mansouri Ave., Sattarkhan Ave

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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

Yes - There is a plan to make this available

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

The full intervention protocol and informed consent form will be attached to the dissertation. All sessions will be recorded and along with the spss file will be submitted to the department of Clinical Psychology of school of Behavioral Sciences and Mental Health and the supervisor.

When the data will become available and for how long

After completing the dissertation and publishing articles

To whom data/document is available

Supervisors, consultants and other researchers

Under which criteria data/document could be used

The results will be reported in full in the dissertation. And researchers can contact the researcher for meta-analysis to get the information they need.

From where data/document is obtainable

Researchers should refer to Ms. Mehri Moradi and email address moradi.me@tak.iums.ac.ir. The final results will also be mentioned in the dissertation and a copy of the dissertation will be presented in the central library of Iran University of Medical Sciences. The results will also be published in scientific journals.

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

The researcher can correspond with Ms. Moradi via email in order to receive the documents, and if there is no violation of confidentiality and ethical principles, she will be answered within a week

Comments