

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of behavioral activation treatment on the level of depression and quality of life and psychological well-being of the family of children with Cancer

Protocol summary

Study aim

The Effectiveness of behavioral activation treatment on the level of depression, quality of life and psychological well-being of the family of children with cancer

Design

24 parents have a cancerous child and will be randomly assigned into two groups of tests and controls.

Settings and conduct

After approving the subject in the Department of Psychology and obtaining the Ethics Code from the Ethics Committee of Arsanjan University of Azad University, referring to the Anikology Hospital of Amir, 24 children with cancer have been selected and randomly divided into two groups of research, the experimental group underwent 7 sessions of behavioral activation therapy will be placed.

Participants/Inclusion and exclusion criteria

Entry requirements: Having a child with cancer in the family, the age range of children under the age of 12, having a medical record of the child suffering from a doctor, informed consent about entering the research, the absence of other medical problems, the lack of a child or parent's backwardness. ; Conditions of non-entry: one of the parents suffers from disorders such as addiction and psychotic disorders, taking psychiatric drugs, having serious suicidal thoughts, having certain medical conditions

Intervention groups

The experimental group will be trained under 7 sessions of behavioral activation therapy, weekly for 90 minutes per session, the content of each session will be formed by presenting explanations, exercises and group discussions, providing homework assignments and summing up, at the beginning At the end of the research, both research groups are evaluated by questionnaires. At the end of the research, in order to observe ethics in the research, a course of behavioral activation therapy for

the control group will be implemented if this group wishes.

Main outcome variables

Depression, psychological well-being, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181114041659N1**

Registration date: **2018-12-10, 1397/09/19**

Registration timing: **retrospective**

Last update: **2018-12-10, 1397/09/19**

Update count: **0**

Registration date

2018-12-10, 1397/09/19

Registrant information

Name

Maede Ahmadzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5382 2120

Email address

maedeahmadzade4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2018-11-26, 1397/09/05

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of behavioral activation treatment on the level of depression and quality of life and psychological well-being of the family of children with Cancer

Public title
The effect of behavioral activation treatment on the family of children with cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having a child with cancer in the family The age range of children with cancer is less than 12 years old Having a doctor's medical record for a child with cancer Conscious Consent to Entering Research The absence of other medical problems Lack of child or parent backwardness
Exclusion criteria:
One of the parents is afflicted with disorders such as addiction and psychosis Taking psychiatric medications Serious suicidal thoughts Having certain medical conditions

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized method: Limited randomization: This method is used if the researcher tends to have all the study groups having an equal volume. The method used between finite randomization methods is block randomization method. Block randomization method: Blocking is usually used to balance the number of specimens assigned to each of the study groups.
Random unit: Individual Random allocation cloaking: Random allocation cloaking is used in the method used to execute the random sequence on the participants in the study, so that before the assignment of the individual, the assigned group is not specified.
Randomization Tool: Non-transparent sealed envelopes with random sequences

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 Islamic Azad University, Arsanjan Branch
Street address
Fars, Arsanjan, University Blvd, Educational Complex, Islamic Azad University, Arsanjan Branch
City
Arsanjan
Province
Fars
Postal code
7376153161
Approval date
2018-11-14, 1397/08/23
Ethics committee reference number
IR. IAU. A. REC. 1397.002

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
P91.4
ICD-10 code description
Neonatal cerebral depression

Primary outcomes

1

Description
Depression, the score that the subject will receive in the depression, anxiety, and stress questionnaire.

Timepoint
Before the onset of behavioral activation therapy sessions, and after the end of treatment sessions, a questionnaire for depression, anxiety, stress will be provided to the control and testing group to complete.

Method of measurement
Depression, Anxiety, Stress Scale - 21questions

2

Description
Quality of Life, the score that a subject will receive on a short-term assessment of the quality of life of the World Health Organization.

Timepoint

Before the start of treatment for behavioral therapy sessions and after the end of treatment sessions, the WHO World Health Organization's Quality of Life Scale will be provided to the control and testing team to complete.

Method of measurement

The World Health Organization's Quality of Life Scale 26 questions

3

Description

Psychological well-being, the score that a subject will get in the psychological well-being psychology reef.

Timepoint

Before the onset of behavioral activation therapy sessions and after the end of treatment sessions, the psychological well-being questionnaire will be provided to the control and test group to complete.

Method of measurement

Psychological well-being questionnaire Rif 84 questions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be trained on a weekly basis for up to 90 minutes per treatment session for 7 sessions of Behavioral Activation therapy by clinical psychologist trained in behavioral activation therapy. Content of each session is also formed by providing explanations, exercises and group discussions, homework assignments and summing up, and the reception of the group will also be held in the meetings. At the beginning and the end of the research, the intervention group will be evaluated by questionnaires.

Category

Treatment - Other

2

Description

Control group: The control group will not receive any psychological intervention. At the beginning and the end of the study, the control group will be evaluated by questionnaires. In order to observe the ethics in the study, a course of behavioral activation therapy should be provided to the group Will be implemented.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir oncology Hospital

Full name of responsible person

Samad Freidooni

Street address

Station 11, Farhang City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Saeed Mohtashamnia

Street address

Fars, Arsanjan, University Blvd, Educational Complex, Islamic Azad University, Arsanjan Branch

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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

Islamic Azad University of Arsanjan Branch

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

Islamic Azad University

Full name of responsible person

Maede Ahmadzade

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the research after the completion of the research are published in a group without mention.

When the data will become available and for how long

After completing the research and publishing through the publication of the article

To whom data/document is available

The results are published collectively without mentioning names and scholars working in academic and academic institutions can access it.

Under which criteria data/document could be used

If you use the results obtained in the health system and set up a psychology unit and equip the hospitals that have cancer patients admitted to the psychology department and assist these people through experienced psychologists.

From where data/document is obtainable

Islamic Azad University, Arsanjan Branch, info@iaua.ac.ir, Maedeh Ahmadzadeh, maedeahmadzade4@gmail.com

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

After assuring that the claimant will use the results correctly, the results will be presented to him in a group without mention.

Comments