Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Cognitive-Behavioral Art-Play Therapy, and Cognitive-Behavioral Story Therapy on Pain Perception, Hope, Quality of life, Anxiety and depression among Children with Cancer

Protocol summary

Study aim

The objective was to determine the effect of Cognitive-Behavioral Art-Play Therapy and Cognitive-Behavioral Story Therapy on pain perception, hope, quality of life, anxiety and depression among Children with cancer.

Design

Semi-experimental method and three-group research design, including a group of Cognitive-Behavioral Art-Play Therapy , an Cognitive-Behavioral Story Therapy group and a control group with two stages of pre-test and post-test. A statistical population of 75 Children with Cancer in Shiraz city who were admitted to Amir Hospital in 1397. Of these, 45 people are selected through targeted sampling.

Settings and conduct

Children with cancer who were hospitalized at Amir Hospital in Shiraz City.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Conscious consent to participation in research, Age Range 8 to 12 years, No drug used to reduce anxiety and depression, No other physical and mental illness, In the life of the parents and the lives of both parents with the child, Cancer children are undergoing chemotherapy or have completed the course of chemotherapy, Both sexes. Exclusion Criteria: Unwillingness to attend or refuse to continue working, Sick children who are not able to attend in meetings, Children staying in hospital for less than a week.

Intervention groups

The group of Cognitive-Behavioral Art-Play Therapy was grouped in 12 sessions of 60 to 90 minutes and the Cognitive-Behavioral Story Therapy group was treated as two sessions a week for 12 sessions of 90 minutes. The control group does not receive any treatment during this period.

Main outcome variables

pain perception, hope, quality of life, anxiety and depression

General information

Reason for update

Acronym

خالی

IRCT registration information

IRCT registration number: **IRCT20181117041680N1**
Registration date: **2018-11-28, 1397/09/07**
Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**
Update count: **1**

Registration date

2018-11-28, 1397/09/07

Registrant information

Name

Zohreh Shojaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-20, 1397/03/30

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

2018-06-20, 1397/03/30

Actual recruitment end date

2018-10-22, 1397/07/30

Trial completion date

2018-10-22, 1397/07/30

Scientific title

The Effect of Cognitive-Behavioral Art-Play Therapy, and Cognitive-Behavioral Story Therapy on Pain Perception, Hope, Quality of life, Anxiety and depression among Children with Cancer

Public title

Children with Cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

-Conscious consent to participation in research (by parent and child) -Age Range 8 to 12 years(children of primary school age) -No drug used to reduce anxiety and depression -No other physical and mental illness -In the life of the parents and the lives of both parents with the child -Cancer children are undergoing chemotherapy or have completed the course of chemotherapy -Both sexes(girl and boy).

Exclusion criteria:

-Unwillingness to attend or refuse to continue working -Sick children who are not able to attend in meetings -Children staying in hospital for less than a week

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample Children are selected purposefully, will be assigned to one of the three groups of Art-Play Therapy, Story Therapy, and Control or Testimonial in a random manner(lottery).(Random Assignment).

Blinding (investigator's opinion)

Single blinded

Blinding description

The experimental group, the group of Cognitive-Behavioral Art-Play Therapy, was grouped in 12 sessions of 60 to 90 minutes and the Cognitive-Behavioral Story Therapy Group was treated as a weekly two session for 12 sessions of 90 minutes.The control group will not receive any treatment during this period. In the present study, the results of research implementation with identifiable code are available only to the researcher for the data analyzer and the safety committee and data monitoring. Therefore, these individuals will not be aware of what information is collected about which group and variables. Participants will also not get any information about which variables are being used and how they are clearly and precisely determined by which type of treatment they use from the two treatments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Reseaches of Isfahan Azad University (Khorasgan)

Street address

university Blvd- Arghavaniyeh- East Jey- Esfahan

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Isfehan

Postal code

81551-29998

Approval date

2018-06-03, 1397/03/13

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.022

Health conditions studied

1

Description of health condition studied

children with cancer

ICD-10 code

C79.9

ICD-10 code description

Secondary malignant neoplasm of unspecified site

2

Description of health condition studied

Pain Perception

ICD-10 code

R30.9

ICD-10 code description

Painful micturition, unspecified

3

Description of health condition studied

hope

ICD-10 code

ICD-10 code description

4

Description of health condition studied
quality of life
ICD-10 code
ICD-10 code description

5

Description of health condition studied
anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

6

Description of health condition studied
depression
ICD-10 code
F38.1
ICD-10 code description
Other recurrent mood [affective] disorders

Primary outcomes

1

Description
Pain perception-The range of test scores between 0 to 10 and the higher scores represent the greater pain perception of the accountable person.
Timepoint
Measurment of pre-test pain perception(pre-test) and post test(post-test)
Method of measurement
Oucher Scale

2

Description
Hope -The range of test scores between 6 to 36 and the higher scores represent the greater hope of the accountable person.
Timepoint
Measurment of pre-test hope (pre-test) and post test(post-test)
Method of measurement
Children and adolescent's hope scale

3

Description
Quality of life - The range of test scores between 0 to 100 and the higher scores
Timepoint
Measurment of pre-test quality of life (pre-test) and post test(post-test)
Method of measurement
Child quality of life scale(kid-KINDL)

4

Description
Anxiety - The range of test scores between 0 to 114 and the higher scores
Timepoint
Measurment of pre-test anxiety (pre-test) and post test(post-test)
Method of measurement
Spence children anxiety scale

5

Description
Depression - the smallest average used for diagnose non-depressed children is 60. so subjects with a score of 84 and above are known to be depressed.
Timepoint
Measurment of pre-test depression (pre-test) and post test(post-test)
Method of measurement
Child depression scale - abbreviated

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: The Cognitive-Behavioral Art-Play Therapy Group of 15 patients randomly assigned to this group are treated for 12 sessions at 90 minutes for two months.
Category
Behavior

2

Description
Second intervention group: The group of Cognitive-Behavioral Story Therapy, which was randomly assigned to 15 individuals randomly assigned to this group, was treated for 12 sessions at 90 minutes for two months.
Category
Behavior

3

Description
Control group: This group of 15 randomly selected individuals in this group will receive no treatment for two months. At the same time, the control group, which has been bothering to participate in the research, at the end of the study period is freely and intensively subject to one of the treatments of Cognitive-Behavioral Art-Play Therapy or Cognitive-Behavioral Story Therapy.
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Medical Oncology Hospital
Full name of responsible person
Mohammad Reza Bordbar
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
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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
Islamic Azad 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
Islamic Azad University
Full name of responsible person
Zohreh Shojaei
Position
PhD Student of Psychology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
ethical commitment to participants

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
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Only the statistical analysis results can be shared in the form of an approved scientific article.

When the data will become available and for how long
The beginning of the access period is in late 1397.

To whom data/document is available
According to the subject, the data will only be available to other academic researchers in case of necessity for meta-analysis studies.

Under which criteria data/document could be used
Only in the form of scientific paper approved by the professors of the field studied.

From where data/document is obtainable
Mohsen golparvar and zohreh shojaei mgolparvar@khuisf.ac.ir zohreh_shojaei100@yahoo.com

What processes are involved for a request to access data/document
Apply to Mohsen Golparvar and zohreh shojaei

Comments