

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 74 3322 4673

Email address

zohreh.shojaei@khuisf.ac.ir

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
City
 esfahan
Province
 Isfahan
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

Street address

Amir Medical Oncology Hospital, 11 Station, Culture City, Shiraz

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3632 3731

Fax

+98 71 3632 5655

Email

amirhp@sums.ac.ir

Web page address

http://amirhosp.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohsen Golparvar

Street address

Arghavanieh, Jey St., Esfahan, Iran. Post Code : 81551-39998. P.O.BOX:81595-158

City

Esfahan

Province

Isfahan

Postal code

81551-39998

Phone

+98 31 3535 4001

Email

mgolparvar@khuisf.ac.ir

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

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Faculty of Psychology and Educational Sciences, Islamic Azad University, Isfahan (Khorasgan)

City

Esfahan

Province

Isfahan

Postal code

81551-29998

Phone

+98 31353540019

Email

zohreh_shojaei100@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohsen Golparvar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Faculty of Psychology and Educational Sciences, Islamic Azad University, Isfahan (Khorasgan)

City

Esfahan

Province

Isfahan

Postal code

81551-29998

Phone

+98 31353540019

Email

mgolparvar@khuisf.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zohreh Shojaei

Position

PhD Student of Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Department of Psychology , Faculty of Psychology and Educational Sciences, Islamic Azad University, Isfahan (Khorasgan) Branch, Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

81551-29998

Phone

+98 31353540019

Email

zohreh_shojaei100@yahoo.com

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