

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Investigating the effectiveness of pain's cognitive-behavioral therapy and its computerized version in the reduction of pain intensity, depression, anger and anxiety in children with cancer

Protocol summary

Study aim

The Effectiveness of Common Cognitive-behavioral Pain Therapy and its Computerized Version in Reducing Pain Severity, Depression, Anger, and Anxiety in Children with Cancer

Design

The study's objectives were described to the participants, and written consent was taken from the child's parents. The selected individuals signed an agreement including the number of sessions and the estimated duration. All the three groups received medical treatment as usual, but the two experimental groups received psychological interventions as a complementary treatment. In addition, at the end of the study, the control group received intervention.

Settings and conduct

To reduce the bias, the data (i.e., a pre-test and a post-test) was collected by a master student of Clinical Psychology, who did not know the aim of the study. The results were analyzed through ManCova, Anova, and T_test by SPSS software, version20.

Participants/Inclusion and exclusion criteria

The population of this study included all patients with cancer who referred to Ahvaz Shahid Baghee Hospital from the beginning of October of 2018 to the end of December 2018. Inclusion criteria of this study: They suffered from one type of cancer; their age ranged from 9 to 12 years, they were literate, and they were fluent in Persian. Exclusion criteria included neurodevelopmental disorders, autism spectrum disorders (according to the diagnosis of a psychiatrist), and a history of seizure.

Intervention groups

The individuals willing to participate in the study were randomly (using the lottery method) assigned to three groups (i.e., conventional Pain Cognitive- behavior Therapy, computerized Pain Cognitive- behavior Therapy, and control group).

Main outcome variables

Pain,Children, Psychological intervention, Cancer, Anger, Anxiety, Depression.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191225045896N1**

Registration date: **2020-05-18, 1399/02/29**

Registration timing: **retrospective**

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Vajiheh Hamedi

Name of organization / entity

Shahid chamran university

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 6848

Email address

v.hamedi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-07, 1396/10/17

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2018-01-07, 1396/10/17
Actual recruitment end date
 2018-02-19, 1396/11/30
Trial completion date
 2018-02-19, 1396/11/30

Scientific title
 Investigating the effectiveness of pain's cognitive-behavioral therapy and its computerized version in the reduction of pain intensity, depression, anger and anxiety in children with cancer

Public title
 Investigating the effectiveness of pain's cognitive-behavioral therapy and its computerized version in the reduction of pain intensity, depression, anger and anxiety in children with cancer.

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 They were 9-12 years old. They were literate They had one type of cancer. They were fluently in Persian.
Exclusion criteria:
 They had neuro-developmental disorders They had autism spectrum disorders (according to the diagnosis of a psychiatrist). They had a history of seizure.

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

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
 Target sample size: **50**
 Actual sample size reached: **45**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Balanced block randomization

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The Participants were not aware of the type of intervention of other groups, and the aim objective of the study. The Intervention's evaluators did not know the purpose of the study.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee for Research in Ahvaz Jundishapur University

Street address

Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-01-06, 1396/10/16

Ethics committee reference number

IR.AJUMS.REC.1396.820

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

ICD-10 code description

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

ICD-10 code description

4

Description of health condition studied

Anger

ICD-10 code

R45.4

ICD-10 code description

Irritability and anger

5

Description of health condition studied

Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain score in Jung and Baker's scale

Timepoint

Before the intervention, the last session of the intervention, one month after the intervention

Method of measurement

Jung and Baker's pain scale

2

Description

Spilberger's State -Trait Anxiety Scale

Timepoint

Before the intervention, the last session of the intervention, one month after the intervention

Method of measurement

Spilberger's State -Trait Anxiety Scale

3

Description

Children's Depression Inventory Score

Timepoint

Before the intervention, the last session of the intervention, one month after the intervention

Method of measurement

Children's Depression Inventory

4

Description

Spilberger's State-Trait-Anger Expression Inventory score

Timepoint

Before the intervention, the last session of the intervention, one month after the intervention

Method of measurement

Spilberger's State-Trait-Anger Expression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

The first experimental group: Six sessions of cognitive-behavioral therapy in terms of private sessions for each participant were held weekly. The first session included a review of the rules of the meetings (i.e., the principle of anonymity, timely attendance, and assignments), cancer education tutorials and changes which cancer has made in the activities, the introduction of a sensory thermometer to measure the degree of emotion, the introduction to the meetings' processes and the skills which were to be learned ,next session's assignments, and the last part of the session which was a fun activity with the therapist. The second session included the

review of the assignments the investigation of the challenges and possible problems, introducing Pain Gate Control Theory and the factors which help closing the pain gates, abdominal breathing exercises, relaxation exercises, next session's assignments, and the last part of the session which was a Pleasurable activity with the therapist. The third session included the review of the assignments, statements on the relationships of thought, feeling, behavior and cognitive errors, positive self-esteem and cognitive reconstructions, reinforcement and self-rewarding, the subsequent session's homework, the last part of the session which was performing a fun activity. The fourth section included The review of the challenges, problem solving training, attention deviation strategies training, positive mental imagery, countdown), next session's assignments, and the last part of the session which was doing a fun activity. The fifth session included the review of the assignment, anger control, effective communication training, and next session's assignment. The last part of the session which was doing one pleasant activity with the therapist. The sixth session included reviewing the pre-treatment task, activating the behavior, presenting the instruction booklet, and a summary of the practical treatment tips, and doing a fun activity with the therapist as the final part of the session.

Category

Behavior

2

Description

The second experimental group's intervention included using computer training software and performing its tasks on a weekly basis. This version included a compact disc (including 6 sessions) and a parents' manual and handbook designed as a computer program. The program is a computer program consisting of educational materials which are in accordance with the educational content similar to in-person intervention designed based on prior research. The program was designed and developed by the researchers. The program includes sections on psycho-education, animation, and computer games. The participant inserted the CD into the computer or laptop and then observed the contents of each session according to the instructions in the manual. At the beginning of the program, a list of sessions was specified on the page where they could see the content of that meeting by clicking on the icon of each session. Meanwhile, they performed a series of assignments in the booklet. At the end of each session, after viewing the training material and performing the assignments, the student could play one or more computer games on his/her own choice. In the computer version, all of the above mentioned materials were provided as an educational program in the form of animation with a manual. Each week the participants observed a part of the program and performed the exercises related to that part.

Category

Behavior

3

Description

The control group: They received no intervention. However, at the end of the treatment sessions of the experimental groups, the control group received the computer program for ethical considerations.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Baghaei 2 Ahvaz Hospital

Full name of responsible person

Bijan Keikhaei Dehdezi

Street address

Golestan Blvd

City

Ahvaz

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Khouzestan

Postal code

15794-61357

Phone

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Email

info@ajums.ac.ir

Web page address

<https://h-baghaei2.ajums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Chamran University of Ahvaz

Full name of responsible person

Ibrahim Haji Dolu

Street address

Golestan Blvd

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Ahvaz

Province

Khouzestan

Postal code

1939714956

Phone

+98 61 3333 0019

Email

Public@scu.ac.ir

Web page address

<http://scu.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Chamran University of Ahvaz

Proportion provided by this source

50

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

Shahid Chamran University of Ahvaz

Full name of responsible person

Vajihe Hamed

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

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1939714956

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v.hamedi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Chamran University of Ahvaz

Full name of responsible person

Vajiheh Hamed

Position

Phd Student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Position

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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

Research colleagues disagree

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The protocol and informed consent form are published in the form of a thesis and a copy of it is available to researchers at Iran Documentation Center, Iran Duck.

When the data will become available and for how long

The following information is available after the date of defense October 2018).

To whom data/document is available

Researchers, Students

Under which criteria data/document could be used

Any scientific use without commercial purpose is permitted.

From where data/document is obtainable

You can access the following information by visiting the university, Iran Duck website or the National Library.

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

It is sufficient to use a university or student ID card to use the university version. For Access to the National Library version, the membership in the library is required. Membership and payment are required to access the site version of Iran Duck.

Comments