

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Clinical Trial of Acceptance and Commitment Therapy (CHACT) on the Psychological Flexibility in Pain, Function, Quality of life, Internalizing and Externalizing Symptoms of 7 to 12 years - old Children with Chronic Pain

Protocol summary

Summary

According to the criteria of chronic pain and other inclusion criteria such as being in the range age of 7 to 12 and earning a score of 13 to 29 in the Function Disability Inventory, 20 children who according to their parents were prepared to participate in this study, were selected from specialized and subspecialty pediatric hospitals of Tehran. In this study, due to small sample size, sampling method was based on available method. Then, the children were placed in the experimental group (n = 10) and control group (n = 10). The child and parent versions of Function Disability Inventory, the Psychological Inflexibility in Pain Scale and also KID Screen and Child Behavior Checklist was administered on both groups at pretest, post test, the first follow-up (1.5 months after the treatment) and the second follow-up (5.5 months after the treatment).

General information

Acronym

CHACT

IRCT registration information

IRCT registration number: **IRCT2013112815577N1**

Registration date: **2014-04-06, 1393/01/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-06, 1393/01/17

Registrant information

Name

Soheila Ghomian

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

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ghomian_s@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-06-19, 1391/03/30

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Clinical Trial of Acceptance and Commitment Therapy (CHACT) on the Psychological Flexibility in Pain, Function, Quality of life, Internalizing and Externalizing Symptoms of 7 to 12 years - old Children with Chronic Pain

Public title

The Effectiveness of Acceptance and Commitment Therapy on Chronic Pain of Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being in the age range of 7 to 12;

Engagement with education; Obtain a score of 13 to 29 (moderate disability) in Function Disability Inventory (FDI); A history of developing chronic pain for 6 months or more and at least 3 months of the first medical treatment in relation to chronic pain according to viewpoint of physician; the ability to attend meetings according to confirmation of physician. Exclusion criteria: Absence of the above conditions.

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Department of education and graduate, Shahed University

Street address

Shahed University, In front of shrine, Persian Gulf Freeway, Tehran, Iran

City

Tehran

Postal code

.....

Approval date

2012-10-29, 1391/08/08

Ethics committee reference number

130/23217

Health conditions studied

1

Description of health condition studied

Chronic pain

ICD-10 code

R52.1

ICD-10 code description

Chronic intractable pain

Primary outcomes

1

Description

Psychological flexibility in Pain

Timepoint

Before the treatment, after the treatment, first follow-up (1.5 month after the treatment) and second follow-up(5.5 month after the treatment)

Method of measurement

Psychological Inflexibility in Pain Scale (PIPS)

Secondary outcomes

1

Description

Function

Timepoint

Before the treatment, after the treatment, first follow-up (1.5 month after the treatment)and second follow-up(5.5 month after the treatment)

Method of measurement

Function Disability Inventory (FDI)

2

Description

Quality of life

Timepoint

Before treatment, after treatment, first follow-up (1.5 month after treatment)and second follow-up(5.5 month after treatment)

Method of measurement

The Health-Related Quality of Life KIDSCREEN- 27 Questionnaire

3

Description

Internalizing and Externalizing Symptoms

Timepoint

Before the treatment, after the treatment, first follow-up (1.5 month after the treatment)and second follow-up(5.5 month after the treatment)

Method of measurement

Child Behavior Check List (CBCL)

Intervention groups

1

Description

Experimental group: The designed protocol of CHACT was individually implemented for 8 sessions (each session is about one hour) on them. For protocol design, on one hand, the resources associated with acceptance

and commitment therapy and psychological therapy for children, and the other hand, the initial version of acceptance and commitment therapy on children (To consult with Association for Contextual Behavioral Science (ACBS)), were used. The basic components of this protocol include acceptance, cognitive defusion, valuing, behavioral commitment, etc. The objective of the acceptance is that patients are encouraged to welcome unsolicited thoughts and feelings. Thus, there is a way to change avoiding from painful situations. The goal of cognitive defusion is reduction in the true sense of inner experiences. That, thoughts should be considered only as thought and reduced their impact on behavior. In this treatment, the values are considered as elements of life and they stimulate the patients to engage in some specific activity. The patients learn to determine their value orientations in different aspects (Eg, family, spirituality) and act in accordance with them. The behavioral commitments lead to realize the values. they will continue until in person be made the great models of flexible and effective behaviors that are associated with the values. It should be noted that at the end of each session, in accordance with the content of the protocol, a 20-minute session is considered for children`s parent.

Category

Behavior

2

Description

Control group: They received conventional medical treatment in the hospitals

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children`s Hospital

Full name of responsible person

Soheila Ghomian

Street address

Mofid Children`s Hospital, Before Mirdamad Street, Above Hosseiniye Ershad, Doctor Ali Shariati Street, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Soheila Ghomian

Street address

Children's Medical Center, No. 62, Next to Imam Khomeini Hospital, Doctor Mohamed Gharib Street,

Keshavarz Blvd, Tehran, Iran

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3

Recruitment center

Name of recruitment center

Hazrate Ali Asghar Children's Hospital

Full name of responsible person

Soheila Ghomian

Street address

Hazrate Ali Asghar Children's Hospital, Shahid Dastgerdi Street (Zafar), Tehran, Iran

City

Tehran

4

Recruitment center

Name of recruitment center

Bahrami Children`s Hospital

Full name of responsible person

Soheila Ghomian

Street address

Bahrami Children`s Hospital, Shahid Kiani Street, Damavand Street, Imam Hossein Square, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

.....

Full name of responsible person

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Shahed University, In front of Shrine, Persian Gulf Freeway, Tehran, Iran

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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

.....

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Mohammad Reza Shairi

Position

PhD in Clinical Psychology; Associate Professor of
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty