

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Effectiveness of parent-child interaction therapy on the Improvement of Affective Index in Children

Protocol summary

Study aim

The aim of this study will be investigate the effectiveness of parent-child interactive group therapy (PCIT) on the improvement of affective index in children with methadone-treated parents.

Design

a clinical trial in the form of a semi-experimental study

Settings and conduct

40 mothers and children will be selected through respondent-driven sampling method and will be assigned in two groups by block randomization.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: age range of 5-7 years in children, age range of 18-45 years in mothers, the under methadone treatment with a given dose for at least one of the parents. The exclusion criteria was: More than two absences in treatment sessions.

Intervention groups

PCIT will be in twelve weekly sessions and changes in the level of affection.

Main outcome variables

The Positive and Negative Affect Schedule (PANAS)

General information

Reason for update

Acronym

parent-child interaction therapy (PCIT)

IRCT registration information

IRCT registration number: **IRCT20150503022061N1**

Registration date: **2019-03-01, 1397/12/10**

Registration timing: **prospective**

Last update: **2019-03-01, 1397/12/10**

Update count: **0**

Registration date

2019-03-01, 1397/12/10

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 22081450

Email address

bijanpirnia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-31, 1398/03/10

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2019-09-28, 1398/07/06

Actual recruitment end date

2019-10-23, 1398/08/01

Trial completion date

2020-01-21, 1398/11/01

Scientific title

The Effectiveness of parent-child interaction therapy on the Improvement of Affective Index in Children

Public title

parent-child interaction therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age range of 5-7 years for children age range of 18-45 years for mothers the under methadone treatment with a given dose for at least one of the parents

Exclusion criteria:

More than two absences in treatment sessions

Age

From **5 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **45**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Blocks Randomization: Block randomization works by randomizing participants within blocks such that an equal number are assigned to each treatment. Allocation proceeds by randomly selecting one of the orderings and assigning the next block of participants to study groups according to the specified sequence. A disadvantage of block randomization is that the allocation of participants may be predictable

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**

IR.SBMU. RETECH.REC. 1397.628

Street address

Behavioral Sciences Research Center of Shahid Beheshti University of Medical Sciences, Tehran, Iran

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Postal code

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Approval date

2018-11-04, 1397/08/13

Ethics committee reference number

IR.SBMU. RETECH.REC. 1397.628

Health conditions studied**1****Description of health condition studied**

Affective disorder

ICD-10 code

F34

ICD-10 code description

Persistent mood [affective] disorders

Primary outcomes**1****Description**

affective syndrome

Timepoint

Pre test and post test after 12 sessions therapy.

Method of measurement

The Positive and Negative Affect Schedule (PANAS)

Secondary outcomes**1****Description**

Anxiety

Timepoint

Pre test and post test after 12 sessions therapy

Method of measurement

Beck Anxiety Index (BAI)

Intervention groups**1****Description**

Intervention group: Parent-child interaction therapy (PCIT). PCIT Protocol (UC Davis PCIT Training Center, Sacramento) will be conducted in two phases of child directed interaction (to improve communication) and parent directed interaction (to practice interactive discipline) in twelve sessions. The treatment was presented in the form of 8 weekly sessions.

Category

Behavior

2**Description**

Control group: In this study, the control group was merely receiving routine center therapy and did not receive intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bijan Substance Abuse Treatment Center

Full name of responsible person

Bijan Pirnia

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No 6, West Hafte Tire, Shahrokh Ave

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2**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Alireza Zahiroddin

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Grant name

Behavior Research Centre, Imam Hosein Hospital, Shahid Madani St, Tehran, Iran

Grant code / Reference number

IR.SBMU. RETECH.REC. 1397.628

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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 Beheshti University of Medical Sciences

Full name of responsible person

Bijan Pirnia

Position

phD Student of clinical psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

participant data sets are to be shared (e.g., all collected deidentified IPD, IPD collected for the primary outcome measure only, etc).

When the data will become available and for how long

6 months after publication of manuscript

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

systematic review or meta-analysis

From where data/document is obtainable

b.pirnia@usc.ac.ir

What processes are involved for a request to access

