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
City
Tehran
Province
Tehran
Postal code
1981999751
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
Street address
No 6, West Hafte Tire, Shahrokh Ave

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https://www.linkedin.com/authwall?trk=ripf&trkInfo=AQG1Y-_HdcZ4DgAAAWj6vrnw3ia6JxCcu3rRn9ir8w7mCn1RdiJGub9zPdv9z8gw8ojina3aApENt1FdNFHd64qZJBE71H2TjPNM1LLFbHIH2qput3GraebwCXiVuX7EZu229J8=&originalReferer=https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=2ahUKEwiAxaC9t8LgAhXFh7QKHV_uCK8QFjABegQIBBAB&url=https%3A%2F%2Fir.linkedin.com%2Fin%2Fbijan-pirnia-3088b491&usg=AOvV&sessionRedirect=https%3A%2F%2Fir.linkedin.com%2Fin%2Fbijan-pirnia-3088b491

2

Recruitment center
Name of recruitment center
Bijan Substance Abuse Treatment Center
Full name of responsible person
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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
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phD Student of clinical psychology
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Person responsible for scientific inquiries

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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

data/document

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Comments