Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Parent-Child Interaction Therapy on reducing behavioral problems and improving the parent-child relationship in children with attention deficit hyperactivity disorder

Protocol summary

Study aim

At present, no research has investigated the effectiveness of coaching and behavioral coding treatment in Iran, and the results of this study can be used to evaluate the effectiveness of PCIT for children with ADHD, improve parenting styles. This treatment will be the pioneer of other researches and effective therapeutic interventions at this field.

Design

This research will be an RCT with a pre-test and post-test design with a control group and two four-month test and follow-up groups: the first group of father-child pairs receiving PCIT, the second group of mother-child pairs receiving PCIT, and the third group of the control group (list waiting) who do not receive intervention until the end of the research.

Settings and conduct

it will be held in Sanandaj city and in Afra psychological counseling center under the management of Mr. Samad Hamidi (PCIT therapist) equipped with closed-circuit camera and one-way mirror. Sampling will be block randomization.

Participants/Inclusion and exclusion criteria

Children aged 3 to 7 years should score at or above the borderline on the Conner's Parent-Teacher Scale. parents who have special medical conditions or active substance dependence or do not want to record and videotape therapy sessions, do not have enough time to participate in sessions and do exercises at home, are not motivated enough to participate in sessions. Children with co-morbid Autism Spectrum Disorders and other developmental disabilities or mental retardation

Intervention groups

The first experimental group of 40 father-child pairs The second experimental group of 40 mother-child pairs Waiting group for father/mother-child pairs of 40 people

Main outcome variables

Effectiveness of PCIT on improving father-child and mother-child relationships, fathers and mother's parenting capacity, and reducing behavioral problems in children will be investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160530028182N12**
Registration date: **2024-02-20, 1402/12/01**
Registration timing: **retrospective**

Last update: **2024-02-20, 1402/12/01**
Update count: **0**

Registration date

2024-02-20, 1402/12/01

Registrant information

Name

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Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-07-07, 1402/04/16

Actual recruitment start date
2022-12-22, 1401/10/01
Actual recruitment end date
2023-07-07, 1402/04/16
Trial completion date
empty

Scientific title
Effectiveness of Parent-Child Interaction Therapy on reducing behavioral problems and improving the parent-child relationship in children with attention deficit hyperactivity disorder

Public title
Effectiveness of Parent-Child Interaction Therapy on attention deficit hyperactivity disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
3-7 year old children diagnosed with moderate and severe ADHD through a child and adolescent psychiatrist and the Connors scale of parents and teachers
Exclusion criteria:
Parents with specific medical conditions or substance dependence Parents who do not wish to record and videotape therapy sessions, Parents who do not have enough time to participate in meetings and practice at home. Patients who are not motivated enough to attend meetings. Children with autism spectrum disorders and other developmental disabilities or mental retardation based on clinical interview.
Age
From **3 years** old to **7 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the restricted randomization method of the block randomization type. Blocking is usually used to balance the number of samples allocated to each studied group. Random allocation software will also be used for randomization. We will utilize allocation concealment, which is a method for performing a random sequence on research subjects such that the allocated group is unknown prior to the individual's allocation. Using sequentially numbered, opaque sealed envelopes (SNOSE) is a cheap and effective way to disguise the randomization sequence, despite the fact that numerous methods of randomization are known to do so. In this method, each of the generated random sequences is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of the registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened, and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, we will use the restricted randomization method of the block randomization type. Blocking is usually used to balance the number of samples allocated to each studied group. Random allocation software will also be used for randomization. We will utilize allocation concealment, which is a method for performing a random sequence on research subjects such that the allocated group is unknown prior to the individual's allocation. Using sequentially numbered, opaque sealed envelopes (SNOSE) is a cheap and effective way to disguise the randomization sequence, despite the fact that numerous methods of randomization are known to do so. In this method, each of the generated random sequences is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of the registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened, and the assigned group of that participant will be revealed.
Placebo
Not used
Assignment
Crossover
Other design features
Therapeutic interventions are implemented based on the "treatment manual" on the participants of the two experimental groups. The participants of the control group are placed on the waiting list and receive intervention services at the end of the study. After the last meeting, the post-test is done on the experimental and waiting group, and the follow-up of the groups is done four months after the last meeting. The quality of parent-child interaction will be measured based on a parent-child interaction questionnaire and behavioral observations of parent-child interaction using a one-way mirror as well as 15-minute video observations. To code the behavioral observations, the DPICS-III third edition parent-child interaction coding system will be used. All parent-child interactions are coded in four groups: verbalization, vocalization, physical contact, and answer. Parents and children play on a table in a playroom equipped with a closed-circuit camera and a one-way mirror, and trained therapist and coders observe, evaluate, and coach the sessions, and the sessions are filmed, and at the end of each session and these films

reviewed by two people who are familiar with the DPICS coding system (who were not present during the intervention and did not observe the sessions live) and all parent-child dialogues are written on a sheet and coded based on this coding system and finally Inter-rater reliability is also scored (based on the DPICS coding system). In this treatment, the parent is coached by the therapist every moment and his verbal and non-verbal mistakes are corrected instantly. Parents use a bug-in-ear device to hear the therapist's instructions. In each session, an observer evaluates the therapist's "fidelity to the guidelines" in the "Clinical Guide to Therapy". The therapist is responsible for both coaching and coding sessions. So far in Iran, PCIT research has not been done in the form of "direct coding and coaching by the therapist". And the treatment in the form of direct "coaching" is the first time that it is implemented in Iran. The therapist of this research will be Mr. Samad Hamidi, and he has complete expertise in the coaching and coding of the sessions, and the sessions are conducted under the direct supervision of Dr. Cheryl McNeil, will be implemented from Florida International University . Mr. Hamidi will implement this approach in Iran for the first time under his clinical supervision.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
No. 1, Pasdaran Blvd. Sanandaj Town

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Sanandaj

Province
Kurdistan

Postal code
6617713446

Approval date
2023-10-17, 1402/07/25

Ethics committee reference number
IR.MUK.REC.1402.220

Health conditions studied

1

Description of health condition studied
Attention-Deficit Hyperactivity Disorder

ICD-10 code
F90.0

ICD-10 code description
Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description
Improving parent-child interactions based on the DPICS coding system, the international PCIT system, mastery criteria based on the treatment guide, 10 behavioral descriptions, 10 feedback and 10 titled rewards, and 3 or less negative sentences, reducing children's behavioral problems based on ECBI less than 114.

Timepoint
Before the start of the two baseline interventions, the week 1 and 2, the middle of the treatment after the implementation of the CDI phase, the first stage of the treatment, the 10th week, and the end of the treatment, the 20th week and 4 months after the end of the treatment for follow-up.

Method of measurement
The Dyadic Parent-Child Interaction Coding System, Eyberg child behavior inventory, Therapy Attitude Inventory, Conners' Parent Rating Scales, Early Intervention Parenting Self-Efficacy, Difficulties in Emotion Regulation Scale, Parenting stress index - short form, Alabama Parenting Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: father-child pair. 40 fathers with their children aged 3 to 7 years with ADHD are randomly placed in this group. They will receive treatment in weekly sessions for 20 weeks. Father-child pairs will play in the treatment room and will be observed by a trained therapist in the room and coached from behind a one-way mirror using the bug in ear system.

Category
Treatment - Other

2

Description
Intervention group 2: mother-child pair. 40 mother with their children aged 3 to 7 years with ADHD are randomly placed in this group. They will receive treatment in weekly sessions for 20 weeks. Mother-child pairs will play in the treatment room and will be observed by a trained therapist in the room and coached from behind a one-way mirror using the bug in ear system.

Category
Treatment - Other

3

Description
Control group: parent couple (mother/father)-child. 40

parents (mothers/fathers) with children aged 3 to 7 years with ADHD are randomly placed in this waiting group. Until the end of the research, this group will not receive any intervention, but after the end of the research, they will receive weekly sessions for 20 weeks. Parents-child pairs will play in the treatment room and will be observed by a trained therapist in the room and coached from behind a one-way mirror using the bug in ear system.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital Sanandaj
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Soliman Mohammadzadeh
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
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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

Not applicable

Title and more details about the data/document

Individual data of participants

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Researchers in this field

From where data/document is obtainable

dr.mohammadzadeh86@muk.ac.ir

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

2 Month

Comments