Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the Effectiveness of Group Emotion-Focused and Behavioral Interventions for mothers in Children with Attention Deficit/Hyperactivity Disorder

Protocol summary

Study aim

Comparing the effectiveness of group Emotion-focused and Behavioral interventions for mothers in children with Attention Deficit/Hyperactivity Disorder, before intervention, after intervention and follow up Comparing the effectiveness of group Emotion-focused and Behavioral interventions for mothers in mothers of children with Attention Deficit/Hyperactivity Disorder, before intervention ,after intervention and follow up

Design

Randomized Clinical Trail with pre-test, post-test and follow-up assessment with intervention and control groups

Settings and conduct

Participants are mothers who have children diagnosed with Attention Deficit/Hyperactivity Disorder The study is performed in Tehran Psychiatric Institute clinic

Participants/Inclusion and exclusion criteria

Diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) based on Kiddie schedule for Affective Disorder and Schizophrenia-Present and Lifetime Version (K-SADS-PL), Age range for children is between 6 to 10, Minimum education for mothers is diploma, Comorbidity with Autism Spectrum Disorders and Mental Retardation, Non Pharmaco-Therapeutic intervention for mothers or children 6 months before intervention, Starting Pharmacotherapy for mothers or children in accordance with the intervention or during it, Diagnosis of Psychotic Disorders or being in Major Depression / Mania Episodes in mothers

Intervention groups

Emotion-focused intervention group Behavioral intervention group

Main outcome variables

Attention Deficit/Hyperactivity Disorder symptom severity in children Externalizing problems in children Emotion regulation in children Maternal emotion socialization Maternal well being Parenting stress in mothers Maternal Emotion regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190915044776N1**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **retrospective**

Last update: **2020-04-06, 1399/01/18**
Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Ghazaleh Zargarinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-29, 1398/08/07

Expected recruitment end date

2019-11-28, 1398/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Group Emotion-Focused and Behavioral Interventions for mothers in Children with Attention Deficit/Hyperactivity Disorder

Public title

Comparing the Effectiveness of Group Emotion-Focused and Behavioral Interventions for mothers in Children with Attention Deficit/Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) based on Kiddie schedule for Affective Disorder and Schizophrenia- Present and Lifetime Version (K-SADS-PL) Age range for children is limited to 6 to 10 years Minimum education for mothers is diploma

Exclusion criteria:

Comorbidity with Bipolar Spectrum Disorders, Autism Spectrum Disorder and Mental Retardation in children Non-pharmacological interventions for mothers or children 6 months before intervention starting Pharmacotherapy for mothers or children in accordance with the intervention or during it Diagnosis of Psychotic Disorders or being in Major Depression / Mania Episodes in mothers

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are randomly assigned using blocked randomization to three groups (two intervention groups and one control group). Randomization is performed using //www.sealedenvelope.com/. Considering the number of groups (three groups), the block size is 6 and fixed. We have 9 blocks. In each block, two participants are randomly assigned to the first intervention group (Emotion Focused), two participants to the second intervention group (Behavioral) and two participants to control group(waiting list).

Blinding (investigator's opinion)

Single blinded

Blinding description

Statistical Analyst is unaware of the personal codes of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

5th floor, Iran University of medical Sciences, Hemmat Highway, Tehran, Iran

City

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Postal code

1449614535

Approval date

2019-10-01, 1398/07/09

Ethics committee reference number

IR.IUMS.REC.1398.701

Health conditions studied

1

Description of health condition studied

Attention Deficit/Hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Symptoms of Attention Deficit/Hyperactivity Disorder

Timepoint

Pretest, Post test and 2-month Follow-up

Method of measurement

Swanson, Nolan and Pelham–IV Questionnaire (SNAP-IV)

2

Description

Child's Externalizing Behaviors

Timepoint

Pretest, Post test and 2-month Follow-up

Method of measurement

Eyberg Child Behavior Inventory (ECBI)

3

Description
Child's Emotion Regulation
Timepoint
Pretest, Post test and 2-month Follow-up
Method of measurement
Emotion Regulation Checklist (ERC)

4

Description
Emotion Socialization
Timepoint
Pretest, Post test and 2-month Follow-up
Method of measurement
Coping with Children's Negative Emotions Scale (CCNES)

5

Description
Psychological Symptoms: Anxiety, Depression and Stress
Timepoint
Pretest, Post test and 2-month Follow-up
Method of measurement
Depression Anxiety Stress Scales (DASS-21)

6

Description
Parenting Stress
Timepoint
Pretest, Post test and 2-month Follow-up
Method of measurement
Parenting Stress Index-Short Form (PSI-SF)

7

Description
Mother's Emotion Regulation
Timepoint
Pretest, Post test and 2-month Follow-up
Method of measurement
Difficulties in Emotion Regulation Scale (DERS)

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention Group (Emotion Focused Intervention): In this study, Emotion Focused Intervention is applied using "Emotions Program" which was developed by Shortt and Eddy (2014). The objective of the "Emotions Program" was to teach emotion regulation and emotion coaching parenting skills to mothers. The Emotion Focused Intervention is consisted of 15 2-hr group weekly sessions for mothers. Nine of the sessions focus on strengthening emotion regulation skills and the remaining six sessions target emotion coaching skills. The parent emotion-regulation component was informed by key ideas and strategies from Dialectical Behavior Therapy (DBT) which was developed by Linehan (1993). The content of the sessions is focused on being aware of emotions and thoughts, mindfulness, experiencing emotions without making judgment, calming down strong emotions, healthy coping and responding effectively to life's events. The emotion coaching component was derived from the Tuning In to Kids (TIK) which was developed by Havighurst & Harley (2007). Emotion coaching reflects a unique parenting behavior and socialization process whereby parents provide guidance to their children in understanding and coping with emotions. Some handouts and practices are presented to mothers each sessions which are related to the session content.
Category
Behavior

2

Description
Second Intervention Group (Behavioral Parenting): Behavioral parenting in this research is implemented using the Level 4 of Positive Parenting Program (Triple P) which was developed by Sanders & his colleagues (2000) for parents of children with more severe behavioral difficulties. This is an 8-session group parenting program (5 sessions for 2 hours and 3 telephone sessions for 15-30 minutes) for each mothers. Behavioral parenting programs, such as Triple P are based on behavioral approach and learning theory. Sessions of Triple P involve monitoring problem child behavior, stimulus control (e.g., identifying antecedents to problem behavior, promoting a more positive environment) , rewards for appropriate behavior, directed discussion , giving clear instructions and behavior-consequences (e.g., time-out, planned ignoring). Some handouts and practices are presented to mothers each sessions which are related to the session content.
Category
Behavior

3

Description
Control Group (Waiting List): Waiting list in this research includes mothers of children diagnosed with Attention deficit hyperactivity disorder which are selected based on inclusion criteria. They do not receive the intervention until the intervention phase of the research is finished. It is explained for mothers on the waiting list that their sessions would begin after five months due to research purpose. The mothers are asked to complete the same questionnaires using the same instruments and concurrent with intervention groups.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Child Psychiatric Clinic of Tehran Psychiatric Institute

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Ghazaleh Zargarinejad

Position
Ph.D Candidate

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data will be presented in the statistical analysis section in the future articles
When the data will become available and for how long
Nearly six months to one year after the termination of the project
To whom data/document is available
All mental health practitioners who will read the articles
Under which criteria data/document could be used
Researchers who aim to conduct any related studies on the data
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Sending email and explaining about the research aims
Comments