

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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)

##### Phone

+98 21 8801 0623

##### Email address

zargarinejad.gh@iums.ac.ir

##### 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/](http://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

Tehran

##### Province

Tehran

##### 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**

Ghazale Zargarinejad

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### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammad Shams Mehrabadi

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No 1, mansoori Alley, Niaiesh St, Satarkhan Ave

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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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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Other areas of specialty/work**

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### Person responsible for updating data

**Contact****Name of organization / entity**

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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**