Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of tele psychologic - based mindful- parenting on anxiety and resilience of mothers of children ages 6-12 with attention deficit hyperactivity disorder (ADHD) during covid-19 outbreak.

Protocol summary

Study aim

This study aims to determine the effect of tele psychologic -based mindful- parenting on anxiety and resilience of mothers of children ages 6-12 with attention deficit hyperactivity disorder (ADHD) during covid-19 outbreak

Design

This study is a randomized clinical trial with two groups (experimental and control) in three phases (per-test, post-test and follow up). Forty children with ADHD diagnosis and their mothers will assign in two groups randomly (mindful parenting and control) The data will be analyzed by spss-21, using One-way ANOVA repeated measure.

Settings and conduct

Children with ADHD diagnosis, Will be referred by the child psychiatrist at Kargarnejad Hospital in Kashan, Iran. Forty children and their mothers who are eligible for inclusion and exclusion are selected. Children and their mothers will assign in two groups randomly. participants of both group fill out Beck Anxiety Inventory; Connor and Diodson resilience inventory scale; as per-test, post-test and two month after intervention as follow- up. The intervention (mindful parenting) will be done for mothers.

Participants/Inclusion and exclusion criteria

Inclusion: Children are having with attention deficit hyperactivity disorder according to a psychiatrist; age 6-12 years; receiving regular pharmacotherapy by risperidone or Ritalin; their mothers are having minimum education level of diploma. Exclusion criteria: Mother or child having intellectual disability, psychosis or major mood disorder; receiving pharmacotherapy unregularly

Intervention groups

The intervention consist of 8 sessions (each session last 90 minutes) of mindful parenting training based on Kabat-Zinn protocol in experimental group. The control group doesn't receive any psychotherapy. Participants of both group receive pharmacotherapy (risperidone or Ritalin).

Main outcome variables

Main outcome measures variables are Resilience and Anxiety mothers

General information

Reason for update

Acronym

ADHD

IRCT registration information

IRCT registration number: **IRCT20210712051858N1**
Registration date: **2022-01-08, 1400/10/18**
Registration timing: **retrospective**

Last update: **2022-01-08, 1400/10/18**
Update count: **0**

Registration date

2022-01-08, 1400/10/18

Registrant information

Name

Bahman Heidarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

heidarianc@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date
2021-08-06, 1400/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of tele psychologic - based mindful- parenting on anxiety and resilience of mothers of children ages 6-12 with attention deficit hyperactivity disorder (ADHD) during covid-19 outbreak.

Public title
The effect of mindful- parenting on anxiety and resilience of mothers have children with attention deficit hyperactivity in covid-19 pandemic.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children are having with attention deficit hyperactivity disorder according to a psychiatrist The age of children with ADHD is 6-12 years receiving regular pharmacotherapy by risperidone or Ritalin their mothers are having minimum education level of diploma
Exclusion criteria:
Mother or child having intellectual disability psychosis or major mood disorder Changes in the dose of medication received by the child
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
First, all the files of individuals were examined in terms of entry and exit criteria; Than, each eligible file was assigned a specific number, and using SPSS software, two sets of 20 file number were selected by simple random sampling. One group was considered the intervention group and the other included the control group.
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
Ethics Committee of Kashan University of Medical Sciences
Street address
Kargarnejad Hospital, Qutb Ravandi Blvd., kashan Town
City
kashan
Province
Isfehan
Postal code
8713783981
Approval date
2021-06-23, 1400/04/02
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1400.057

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder, Resilience and Anxiety
ICD-10 code
F90.0
ICD-10 code description
Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description
Anxiety
Timepoint
per-test, post-test and two month after intervention as follow- up
Method of measurement
Beck Anxiety Inventory (BAI)

2

Description
Resilience
Timepoint
per-test, post-test and two month after intervention as follow- up
Method of measurement
Connor and Diodson resilience inventory scale (RIS_CD)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All the children receive pharmacotherapy with either risperidone or Ritalin. The intervention group receive 8 sessions(1 session each week, each session lasting 90 minutes) of mindful parenting training based on the Kabat-Zinn protocol.
Category
Treatment - Other

2

Description
Control group: All the children receive pharmacotherapy with either risperidone or Ritalin
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kargarnejad hospital
Full name of responsible person
Fatemeh Assarian
Street address
Kashan University of Medical Sciences and Health Services, Kashan, 5Qotbe Ravandi Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza Banafsheh
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Kashan University of Medical Sciences and Health Services, Kashan, 5th Qotbe Ravandi Blvd
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Email
Heidarianc@gmail.com
Grant name
Vice chancellor for research Kashan University of Medical Sciences and Health Services
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research Kashan University of Medical Sciences and Health Services
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
Kashan University of Medical Sciences
Full name of responsible person
Bahman Heidarian
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person
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Position
Mental Health expert

Latest degree
Master

Other areas of specialty/work
Psychology

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Bushehr University of Medical Sciences and Health Services, Bushehr, Yadegar Imam St., in front of Bahman Cinema

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Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Biostatistics

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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
Part of the data, such as information about the main outcome or the like, can be shared

When the data will become available and for how long
Unknown date

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data will be available only to researchers working in academic and scientific institutions

From where data/document is obtainable
by Email: Heidarianc@gmail.com

What processes are involved for a request to access data/document
The person must have a letter of introduction from a university or scientific institute.

Comments