Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of anartificial intelligence-based self-management educational intervention on the empowerment and resilience of mothers with children suffering from attention deficit/hyperactivity disorder (ADHD): A randomized controlled clinical trial

Protocol summary

Study aim
Determining the effect of an artificial intelligence-based self-management educational intervention on the empowerment and resilience of mothers with children suffering from attention deficit/hyperactivity disorder (ADHD)

Design
A randomized, controlled, parallel-group clinical trial including 100 patients, with randomization performed using a block randomization method.

Settings and conduct
Study setting: The psychiatry department of Shahid Rajaei Hospital in Yasuj. Study population: Mothers of children diagnosed with attention-deficit/hyperactivity disorder (ADHD). Blinding: No blinding will be performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: mothers aged 25–45; having a 6–12-year-old child with a confirmed ADHD diagnosis by a specialist; willingness to participate; signed informed consent. Exclusion criteria: the mother’s severe or disabling psychiatric disorders (e.g., schizophrenia, acute bipolar disorder); unwillingness to participate; changes in the child’s treatment status (such as new therapies or major medication adjustments); the presence of marital conflicts.

Intervention groups
Intervention group: Mothers receive brief training from the researcher on using ChatGPT, then carry out the 5-week home-based intervention. Control group: No training or intervention is provided.

Main outcome variables
Score on the Koren et al.'s Family Empowerment Scale (FES); Score on the Connor-Davidson Resilience scale-10 (CD-RISC-10)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200107046044N9**
Registration date: **2025-12-14, 1404/09/23**
Registration timing: **prospective**

Last update: **2025-12-14, 1404/09/23**
Update count: **0**

Registration date
2025-12-14, 1404/09/23

Registrant information
Name
Mohammadsajjad Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-01-21, 1404/11/01
Expected recruitment end date
2026-04-14, 1405/01/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Effect of anartificial intelligence-based self-management educational intervention on the empowerment and resilience of mothers with children suffering from attention deficit/hyperactivity disorder (ADHD): A randomized controlled clinical trial

Public title
Effect of an artificial intelligence-based self-management educational intervention on the empowerment and resilience

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The ability to communicate and respond to questions Being between 25 and 45 years of age Having a child aged 6–12 years Willingness to participate in the study and signing the informed consent form A definitive diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) in the child by a relevant specialist physician Simultaneously obtaining a score of 102 or lower on the Koren et al.'s Family Empowerment Scale (FES) and a score of 20 or lower on the Connor-Davidson Resilience scale-10 (CD-RISC-10)

Exclusion criteria:
Prior training and participation in studies similar to the current research within the past six months Presence of a severe or disabling psychiatric disorder in the mother that would prevent effective participation in the intervention (e.g., severe psychiatric disorders, schizophrenia, acute bipolar disorder). Significant changes in the child’s condition (e.g., receiving new treatments or major medication changes) Having marital conflicts Having mood and emotional disorders Using narcotic substances

Age
From **25 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible study participants will be selected through convenience sampling and randomly assigned to one of the two groups (intervention and control) using block randomization. Two-group blocks of sizes 2, 4, and 6 will be utilized. For example, when the block size is 2, the possible sequences are AB and BA (where A and B represent the intervention and control groups, respectively). An online platform will be used to generate the allocation sequence and ensure concealment. A dedicated randomization code will be generated, and a block randomization allocation list will be prepared. After fully explaining the study objectives, eligible participants will be assigned a unique code according to the order of their referral. By matching this code with the block randomization allocation list, participants will be allocated to either the intervention or control group. This process will continue until the estimated sample size is achieved.

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 Yasuj University of Medical Sciences

Street address
Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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Approval date
2025-11-19, 1404/08/28

Ethics committee reference number
IR.YUMS.REC.1404.174

Health conditions studied

1

Description of health condition studied
Attention Deficit/Hyperactivity Disorder (ADHD)

ICD-10 code
F90.0

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

Primary outcomes

1

Description
The Empowerment score is derived from the Koren et al.'s Family Empowerment Scale (FES)

Timepoint
Before the implementation of the interventions and one month after the completion of the interventions
Method of measurement
Koren et al.'s Family Empowerment Scale (FES)

2

Description
The Resilience score is derived from the Connor-Davidson Resilience scale-10 (CD-RISC-10)
Timepoint
Before the implementation of the interventions and one month after the completion of the interventions
Method of measurement
Connor-Davidson Resilience scale-10 (CD-RISC-10)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, interventions will be conducted according to the protocol, summarized in 10 sessions as outlined below:Session 1: Introduction of participants, brief overview of the 10 sessions, and instruction on how to use artificial intelligence tools.Session 2: Introduction to the concept of self-management, understanding Attention-Deficit/Hyperactivity Disorder (ADHD) and its symptoms.Session 3: Training in mother–child principles and interactive mother–child play, identifying stressors, basic stress-reduction techniques, and practicing simple relaxation techniques.Session 4: Cognitive flexibility through the “Hearts and Flowers” game, introduction to the concept of resilience, familiarity with the SMART technique for goal setting, and formulation of short-term and long-term goals.Session 5: Cognitive flexibility through the “Cards” game, introduction to service systems, principles of time management, creation of daily and weekly schedules, and techniques for overcoming procrastination.Session 6: Cognitive flexibility through the “Quadrato” game, introduction to social-political systems, recognition of emotions and their impact on behavior, strategies for anger management and emotional control, and practicing healthy emotional expression.Session 7: Enhancement of executive functions, including working memory, through the “Tapping” game; cognitive flexibility through the “Knuckle-Shoulder-Knee” game; importance of self-care for mothers; physical and psychological self-care methods; and planning daily and weekly activities to maintain mental health.Session 8: Enhancement of executive functions, including working memory, through the “Inside and Outside” game; cognitive flexibility through the “Rush Hour” game; problem-solving stages; logical decision-making techniques; and practice with sample problems and appropriate solutions.Session 9: Enhancement of executive functions, including working memory, through the “Locking” game; cognitive flexibility through the “Shape and Color” game; practical strategies for managing challenging behaviors; and collaboration with teachers and specialists.Session 10: Review of experiences and overall conclusions.Following the sessions, telephone follow-ups will be conducted to monitor the completion of home exercises. Interventions, once taught by the researcher, will be carried out individually by participants at home. The 10 sessions will each last 50 minutes, conducted twice weekly over a total of 5 weeks, in line with similar studies.Prior to the intervention, artificial intelligence tools, including ChatGPT, will be introduced to participants by the researcher. The researcher will provide complete instructions on using these tools, including initial training, guidance, and troubleshooting technical issues. Thus, in case of any questions, participants will consult only these AI tools to obtain answers. The intervention protocol itself will also be selected and implemented using the aforementioned AI tools.
Category
Lifestyle

2

Description
Control group: non-intervention; There will be no intervention in this group.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital
Full name of responsible person
MohammadSajjad Mousavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person

Cirruse Salehnasab

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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
Yasouj 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
Ahvaz University of Medical Sciences

Full name of responsible person
MohammadSajjad Mousavi

Position
Faculty instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available