

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effectiveness of the Web-Based Barkley Behavioral Training Model on the Caregiving Burden and Resilience of Mothers of Children with Attention Deficit Hyperactivity Disorder (ADHD)

#### Protocol summary

##### Study aim

Determining the effectiveness of the Barkley web-based behavioral training model on the caregiving burden and resilience of mothers of children with Attention Deficit Hyperactivity Disorder (ADHD)

##### Design

A clinical trial with parallel groups, single-blind design, and randomization using Random Allocation Software.

##### Settings and conduct

Mothers of children with ADHD who visit Ibn Sina and Akbar Hospital in Mashhad during the study will be included if they meet the criteria and will be randomly assigned to intervention and control groups using block randomization methods. This study is designed as a single-blind study, meaning that the outcome assessors or data analysts will not be aware of the type of intervention. The interventions will be conducted over 8 sessions in the Eitaa application and 2 question-and-answer sessions in Sky-room. After the intervention is completed, the educational files will also be provided to the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: The mother has a child diagnosed with ADHD. She is the primary caregiver of the child. She has not previously participated in family education sessions. Exclusion Criteria: The mother has a specific mental illness such as depression or bipolar disorder. The child has severe ADHD with a history of frequent hospitalization in psychiatric emergency services.

##### Intervention groups

In the intervention group, the Barkley educational model will be delivered through the Iranian messaging app Eitaa over 8 sessions, each lasting 90 minutes, across 4 weeks to mothers of children diagnosed with Attention Deficit Hyperactivity Disorder (ADHD). The control group will receive standard therapeutic interventions. At the end of the study, the educational files will also be

provided to the control group.

##### Main outcome variables

Resilience, Caregiving Burden

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250322065141N1**

Registration date: **2025-05-15, 1404/02/25**

Registration timing: **prospective**

Last update: **2025-05-15, 1404/02/25**

Update count: **0**

##### Registration date

2025-05-15, 1404/02/25

##### Registrant information

##### Name

Parisa Rahmani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3840 8876

##### Email address

rahmanip4033@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-06-07, 1404/03/17

##### Expected recruitment end date

2026-03-08, 1404/12/17

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of the Web-Based Barkley Behavioral Training Model on the Caregiving Burden and Resilience of Mothers of Children with Attention Deficit Hyperactivity Disorder (ADHD)

**Public title**

The effectiveness of the Web-Based Barkley Behavioral Training Model

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The mother has a child diagnosed with Attention Deficit Hyperactivity Disorder . (The official diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) should be made by a psychiatrist or clinical psychologist based on the criteria outlined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), or other valid diagnostic tools.) The mother is considered the primary caregiver of the child and holds all responsibilities for them. The mother has the physical and mental capacity to care for a child with Attention Deficit Hyperactivity Disorder (ADHD). The mother is interested in and willing to participate in the study. The mother is able to speak, read, and write in Persian The mother does not have an addiction to drugs or other psychoactive substances. The mother has not previously participated in family training sessions (other research in this area). The child should be aged between 6 to 9 years The child should not have any other debilitating conditions besides Attention Deficit Hyperactivity Disorder (ADHD), such as physical or mental disabilities, autism, etc. The child's GARS (Gilliam Autism Rating Scale) test result should be negative. (The GARS test is a definitive diagnostic tool for autism.)

**Exclusion criteria:**

The mother suffers from a specific mental illness such as depression or bipolar disorder, which negatively affects her judgment, behavior, and cognitive functioning. The child's severe and uncontrollable behaviors resulting from hyperactivity are such that they have led to prolonged and frequent hospitalizations in the psychiatric emergency department, significantly disrupting the child's normal life. Lack of access to a smartphone or inability to use one by the mother.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, the block randomization method will be used to allocate samples to the intervention and control groups, ensuring a proper balance between confounding variables such as the child's age and gender. Initially, the samples will be divided into small blocks (e.g., groups of 5 individuals) based on these variables, and then they will be randomly allocated to one of the two groups (intervention or control) using the Random Allocation Software. The order of allocation in blocks of six will be determined randomly. To prevent bias, the allocation process will be conducted by an individual independent of the research team, and participants and evaluators will not be provided with information about the group assignments (blinded randomization). To prevent bias in the allocation of samples to the intervention and control groups, the method of allocation concealment will be employed. The randomization process and sample allocation will be conducted by an individual independent of the research team to ensure that researchers and participants are unaware of the group distribution.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Blinding Description: Blinding type: Outcome assessor / Data analyst blinding (single-blind) In this study, blinding of the data analyst and outcome assessor was employed to reduce bias and increase internal validity. The individual responsible for entering, processing, and analyzing the data was kept unaware of the group allocations (intervention vs. control). To ensure proper blinding, participants' data were coded anonymously, and the final dataset provided to the analyst contained no labels indicating group assignment. Additionally, the person responsible for extracting and interpreting outcome measures (e.g., caregiver burden and resilience scores) was also blinded to group assignment. Due to the behavioral nature of the intervention, it was not possible to blind the participants or the intervention provider. However, through blinding of the outcome assessor and data analyst, the risk of bias in analysis was minimized.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the School of Nursing and Midwifery, Mashhad

**Street address**

Shahid Dr. Kharazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Razavi Khorasan Province, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177939-25

**Approval date**

2025-04-22, 1404/02/02

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1404.019

**Health conditions studied****1****Description of health condition studied**

Attention Deficit Hyperactivity Disorder (ADHD)

**ICD-10 code**

F90

**ICD-10 code description**

Attention-deficit hyperactivity disorders

**Primary outcomes****1****Description**

The score obtained from the Connor-Davidson Resilience Scale questionnaire.

**Timepoint**

Measuring the score obtained from the Connor-Davidson Resilience Scale questionnaire before the intervention, after the completion of the intervention, and one month after the completion of the intervention (follow-up)

**Method of measurement**

The standard questionnaire of the Connor-Davidson Resilience Scale (2003).

**2****Description**

The score obtained from the Zarit Caregiver Burden Scale questionnaire.

**Timepoint**

Measuring the score obtained from the Zarit Caregiver Burden Scale questionnaire before the intervention, after the completion of the intervention, and one month after the completion of the intervention (follow-up).

**Method of measurement**

The Zarit Caregiver Burden Scale (1986)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention Group: Mothers in the intervention group will be divided into groups of five, and groups will be formed for them in the Iranian application Eitaa. They will then receive Barkley's educational sessions over 8 sessions, each lasting 1.5 hours, within one month. After each educational session, 3 to 4 questions will be administered as a quiz to ensure the mothers have learned the content. Additionally, discussions will take place in the Eitaa group regarding the session content. The session materials will be provided to participants in the form of podcasts, educational videos, and PowerPoint presentations. A summary of the session content, the objective of each educational session, and the assignments for each session are as follows: 1. Session One :Objective: Change parents' perceptions of the disorder and problematic behaviors. Content: Explanation of the disorder, etiology, symptoms, common treatments, and identification of positive parenting methods. Assignment: Techniques for praise and attention. 2. Session Two: Objective: Application of rewards and points. Content: Explanation of positive and differential reinforcement, identification of types of reinforcers in behavior management. Assignment: Completing a positive reinforcement table. 3. Session Three: Objective: Learning techniques for encouragement and praise. Content: Teaching methods to increase desirable behaviors through praise techniques and reduce undesirable behaviors through reinforcement interruption. Assignment: Techniques for praise and reinforcement interruption. 4. Session Four: Objective: Teaching parents behavioral management and behavior control, effective use of ignoring. Content: Training on positive attention to compliance with parental commands. Assignment: Tasks for paying attention and ignoring. 5. Session Five :Objective: Improving child behavior at school, kindergarten, and home, and reducing aggressive behaviors. Content: Explanation of shaping specific behaviors by parents, using deprivation for risky and aggressive behaviors. Assignment: Techniques for punishment and deprivation. 6. Session Six :Objective: Preventing severe misbehavior. Content: Developing a token economy program at home. Assignment: Using techniques for removing rewards and points. 7. Session Seven: Objective: Reforming the mindset of parents who use punishment as the primary disciplinary method. Content: Application of corporal punishment. Assignment: Using submission, completing assignments (home-school communication), and summarizing learned content. 8. Session Eight: Objective: Reviewing learned materials and correcting learning, managing future problems. Content: Summarizing learned content, teaching submission to problems. Assignment: Regularly completing assignments (home-school or kindergarten communication). After the first four sessions and then the last four sessions, two online sessions will be held on the Sky-room platform, where a child and adolescent

psychologist will be present for mothers to ask their questions. The Zarit Caregiver Burden Scale and the Connor-Davidson Resilience Scale will be administered to mothers in the intervention group before the intervention starts, immediately after the intervention ends, and one month after the intervention concludes. Then, the results will be analyzed using SPSS software version 26.

#### Category

Lifestyle

## 2

#### Description

Control Group: Mothers who are randomly assigned to the control group will not receive any specific educational intervention during the study and will only benefit from routine therapeutic care. The usual care includes periodic visits to a psychiatrist, monitoring the child's medication treatment, prescribing necessary medications at the physician's discretion, and receiving general therapeutic and supportive recommendations according to the current protocols of treatment centers (including psychiatric hospitals and relevant private clinics). In this group, no educational sessions, structured psychological counseling, or parenting training will be provided. Additionally, control group members will not have access to the educational content of the intervention, Sky-room sessions, or online groups (Eitaa) to prevent data contamination and ensure a valid comparison between the groups. To control for confounding variables, research tools including demographic questionnaires, the Zarit Caregiver Burden Scale, and the Connor-Davidson Resilience Scale will be administered at the same times and under equal conditions for both the intervention and control groups. These assessments will take place during the pre-test and post-test phases. Since providing an effective intervention to one group while completely depriving the other group could raise ethical concerns, at the end of the study, the complete content of Barkley's cognitive-behavioral training provided to the intervention group (including files, podcasts, PowerPoints, and educational videos) will be made available to the control group in a summarized offline format. This action is in line with research fairness and adherence to ethical principles in research. Then, the results will be analyzed using SPSS software version 26.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ibn Sina Children's Psychiatric Clinic

##### Full name of responsible person

Parisa Rahmani

##### Street address

Next to Astan Quds Razavi Transportation Office, Hor Ameli Street, Mashhad, Razavi Khorasan Province,

Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

919583134

##### Phone

+98 51 3711 2701

##### Fax

+98 51 3711 2545

##### Email

ISH.IT@MUMS.AC.IR

##### Web page address

<https://sina.mums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Akbar Specialized Children's Hospital

##### Full name of responsible person

Parisa Rahmani

##### Street address

Opposite Kaveh 14, Shahid Kaveh Boulevard, Shahid Javan Square, Shahid Faghori Boulevard, Mashhad, Razavi Khorasan Province, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91177897107

##### Phone

+98 51 3871 3801

##### Fax

##### Email

ak.pr@mums.ac.ir

##### Web page address

<https://akbar.mums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Research and Technology Vice Presidency ,Central Building of Mashhad University of Medical Sciences ,Daneshgah Street,Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

**Email**

Tafaghodim@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Parisa Rahmani

**Position**

Master's student in Pediatric Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Dr. Kharazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Razavi Khorasan Province, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3884 6730

**Email**

RahmaniP4033@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Naghme Razaghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Dr. Kharazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Razavi Khorasan Province, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3884 6730

**Email**

RazaghiN@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Parisa Rahmani

**Position**

Master's student in Pediatric Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Dr. Kharazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Razavi Khorasan Province, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3884 6730

**Email**

RahmaniP4033@mums.ac.ir

**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