

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Preparation and Study of the efficacy of mindfulness-based training package to improve attention, self-regulation and interpersonal relationships in Elementary School students with ADHD symptoms.

#### Protocol summary

attention,self regulation,interpersonal relationship

##### Study aim

Prepare a mindfulness-based educational package for children with attention deficit hyperactivity disorder and then study its effectiveness for the same statistical population.

##### Design

Using the available sampling method, 15 students with symptoms of attention deficit hyperactivity disorder are selected, Then they fall into a group called the intervention group and first taken pre test from students and then They will be taught mindfulness-based training packages, then taken post test from students,The pre-test and post-test results will be compared.

##### Settings and conduct

Statistical population includes fourth, fifth and sixth grade elementary school students with symptoms of attention deficit / hyperactivity disorder, Intervention at Tasnim Elementary School, first taken pre test from student and Then the intervention will be done and then taken post test, So that we can compare pre-test and post-test

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Elementary school students with attention deficit hyperactivity disorder,Gender:male  
Exclusion criteria: having a mental disorder at the same time not being at the same time under psychological treatment

##### Intervention groups

With informed consent, 15 children with symptoms of attention deficit / hyperactivity disorder were selected and Fall into one group then taken pre-test and then They will be taught mindfulness-based training packages, then taken post test from students,The pre-test and post-test results will be compared.If effective, the intervention will improve the symptoms of students with attention deficit hyperactivity disorder.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200303046687N1**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **prospective**

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

Update count: **0**

##### Registration date

2020-04-06, 1399/01/18

##### Registrant information

##### Name

parnian rezaei

##### Name of organization / entity

Shahid Beheshti University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7623 1872

##### Email address

pa.rezaee@mail.sbu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-09, 1399/02/20

##### Expected recruitment end date

2020-06-19, 1399/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Preparation and Study of the efficacy of mindfulness-based training package to improve attention, self-regulation and interpersonal relationships in Elementary School students with ADHD symptoms.

**Public title**  
Preparation and Study of the efficacy of mindfulness-based training package to improve attention, self-regulation and interpersonal relationships in Elementary School students with ADHD symptoms.

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Children 10 to 12 years old with symptoms of attention deficit hyperactivity disorder Gender: Male

**Exclusion criteria:**

having a mental disorder at the same time not being at the same time under psychological treatment

**Age**

From **10 years** old to **12 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **15**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee Of Shahid Beheshti University

**Street address**

Institute of Cognitive and Brain Sciences, Shahid Beheshti University, Daneshjoo Blvd, Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2020-02-22, 1398/12/03

**Ethics committee reference number**

IR.SBU.REC.1398.041

**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**

Attention

**Timepoint**

before the intervention, two week after the intervention

**Method of measurement**

Strop test

2

**Description**

self-regulation

**Timepoint**

before the intervention, two week after the intervention

**Method of measurement**

ERQ-CA

3

**Description**

Interpersonal Relationships

**Timepoint**

before the intervention, two week after the intervention

**Method of measurement**

Child Self-efficacy Questionnaire in Interpersonal Relationships with Peers

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: mindfulness-based training package for eight 45-minute sessions for the intervention group,First, this package is tailored for elementary

school student, Before the intervention, we will pre-test to determine the baseline level of children, and Then we will do mindfulness-based intervention and then we take the post-test so we can compare it with the pre-test, If this package is effective, it will improve the performance of children with ADHD.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tasnim School

**Full name of responsible person**

Rahim porhashemi

**Street address**

Tasnim School., Sahar Ave., Sepah St

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Pardis

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1655113592

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parirez309@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid beheshti University

**Full name of responsible person**

Babak Shokri

**Street address**

Deputy Director of Research and Technology,  
Presidential Building, Shahid Beheshti University,  
Daneshjoo Blvd, Evin

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+98 21 29901

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drbabakshokri@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid beheshti University

**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**

Shahid Beheshti University

**Full name of responsible person**

Jalil fath abadi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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Velenjak St

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University

**Full name of responsible person**

Parnian Rezaei

**Position**

MS

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Bachelor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

The participants data without identifying information will be available after completion of the study. Clinical study report: The clinical study report will be available after completion of the study.

**When the data will become available and for how long**

September 2020

**To whom data/document is available**

For researchers and students

**Under which criteria data/document could be used**

Using study data for systematic reviews and meta-analysis studies is permitted.

**From where data/document is obtainable**

Dr Jalil fath abadi.Shahid beheshti university

**What processes are involved for a request to access data/document**

parirez309@gmail.com

**Comments**