# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The Effect of Mindfulness-Based Education on the Burden of care and Psychological Capital of Parents of Children with ADHD.

## Protocol summary

**Study aim**

Determination the Effect of Mindfulness-Based Education on the Burden of Care and Psychological Capital of Parents of Children with ADHD.

**Design**

Convenience sampling was used to select the participants among the parents of children ADHD referring to Zare Hospital. Then will be selected using the excel software Randbetween function.To put the samples in one of two group (intervention or group),the coin will be used.finally,they will be divided into two groups of 40 intervention and control.

**Settings and conduct**

The intervention group will attend eight 90-minute sessions twice a week at a classroom in Zare Hospital equipped with audio- visual instruments. The researcher will teach them Mindfulness and at the end of the eighth session after receiving the last training, both groups will be re-evaluated.

**Participants/Inclusion and exclusion criteria**

Entry criteria: Age of parents 18 to 65 years old, Having a child of 3 to 12 years old with ADHD ,Passing of at least 6 months after diagnosis of a child's illness by a psychiatrist, No severe mental illness in the parent's, Willingness participate in the study by the main parent (father/ mother or both) ,Ability to speak and read and write in Persian ,Not being under the psychotherapy simultaneously . Exclusion criteria :Simultaneous care for another patient in the family by the parent, Absence from more than two sessions , Reluctance to continue collaborating in the study ,Coincidence of other illnesses along the ADHD for the child.

**Intervention groups**

The intervention group receive eight 90-minute sessions of Mindfulness-Based Education twice a week while the control group will receive no specific intervention and will receive routine treatment.

**Main outcome variables**

the Burden of care and Psychological Capital

## General information

**Reason for update**

**Acronym**

اختلال کم توجه/بیش فعال با حروف ADHD

**IRCT registration information**

IRCT registration number: **IRCT20180924041109N1**
Registration date: **2018-11-21, 1397/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-21, 1397/08/30**
Update count: **0**

**Registration date**

2018-11-21, 1397/08/30

**Registrant information**

**Name**

Yadollah Jannati

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 11 3310 9808

**Email address**

jannati.yadollah@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-10-23, 1397/08/01

**Expected recruitment end date**

2018-11-22, 1397/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
The Effect of Mindfulness-Based Education on the Burden of care and Psychological Capital of Parents of Children with ADHD.

**Public title**
Mindfulness on the Burden of care and Psychological Capital of Parent

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age of parents 18 to 65 years old Having a child of 3 to 12 years old with ADHD Passing of at least 6 months after diagnosis of a child's illness by a psychiatrist No severe mental illness in the parent's Willingness participate in the study by the main parent (father/ mother or both) Ability to speak and read and write in Persian Not being under the psychotherapy simultaneously

**Exclusion criteria:**
Simultaneous care for another patient in the family by the parent Absence from more than two sessions Reluctance to continue collaborating in the study Co-infection of the child with other illnesses Coincidence of other illnesses along the ADHD for the child

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**
Actual sample size reached: **62**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Eligible names were prepared and then the groups were selected using the Rand Between in Excel (a function that determines random numbers in a specified range). In order to assign the samples in either control or intervention group, we used tossing a coin.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
•Ethics committee of Mazandaran University of Medical Sciences

**Street address**
Teachers 'Street - Teachers' Square - Deputy of Research and Technology of Mazandaran University of Medical Sciences

**City**
Sari

**Province**
Mazandaran

**Postal code**
4815733971

**Approval date**
2018-08-12, 1397/05/21

**Ethics committee reference number**
IR.MAZUMS.REC.1397.151

## Health conditions studied

**1**

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

**ICD-10 code**

**ICD-10 code description**
F90-0

## Primary outcomes

**1**

**Description**
The Score of Psychological Capital in the Luthanz Questionnaire

**Timepoint**
Before and immediately after the intervention

**Method of measurement**
Psychological Capital Luthanz Questionnaire

**2**

**Description**
The Score of Burden of care in the Zarit questionnaire

**Timepoint**
Before and immediately after the intervention

**Method of measurement**
Zarit questionnaire

## Secondary outcomes

**1**

**Description**
self-efficacy

**Timepoint**
Before and immediately after the intervention

**Method of measurement**
Luthanz Psychological Capital questionnaire

**2**

**Description**
optimism
**Timepoint**
Before and immediately after the intervention
**Method of measurement**
Luthanz Psychological Capital questionnaire

**3**

**Description**
hope
**Timepoint**
Before and immediately after the intervention
**Method of measurement**
Luthanz Psychological Capital questionnaire

**4**

**Description**
flexibility /elasticity
**Timepoint**
Before and immediately after the intervention
**Method of measurement**
Luthanz Psychological Capital questionnaire

## Intervention groups

**1**

**Description**
Intervention group:will receive eight 90-minute sessions of Mindfulness-Based Education twice a week.
**Category**
Other

**2**

**Description**
Control group: will receive no specific intervention and will receive routine treatment.
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Zare hospital
**Full name of responsible person**
jannati yadollah
**Street address**
Sari Neka Road
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815733971
**Phone**
+98 11 3328 3886
**Fax**
+98 11 3336 2569
**Email**
zarehospital@yahoo.com
**Web page address**
http://zarehospital.mazums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Majid Saeedi
**Street address**
Sari, Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815733971
**Phone**
+98 11 3304 4001
**Fax**
+98 11 3336 2569
**Email**
mazums.ac.ir@yahoo.com
**Web page address**
https://www.mazums.ac.ir
**Grant name**
---
**Grant code / Reference number**
---
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Sari University of Medical Sciences
**Proportion provided by this source**
70
**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

**2**

**Sponsor**
**Name of organization / entity**
Zare hospital
**Full name of responsible person**
Majid Saeedi

**Street address**
5 Sari Road, Neka
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4815733971
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+98 11 3326 8915
**Email**
zarehospital@yahoo.com
**Web page address**
http://zarehospital.mazums.ac.ir/

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Zare hospital

**Proportion provided by this source**
30

**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**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Yadollah Jannati
**Position**
Assistant Professor
**Latest degree**
Ph.D.
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Nursery
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**
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**Other areas of specialty/work**
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**Web page address**

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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