

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparision between efficacy of reality therapy and mindfulness -based cognitive therapy on psychological well-being and cognitive emotion regulation and mother's attitude towards child's with autism spectrum disorders.

#### Protocol summary

##### Study aim

Comparison between efficacy of reality therapy and mindfulness -based cognitive therapy on psychological well-being and cognitive emotion regulation and mother's attitude towards child's with autism spectrum disorders.

##### Design

three parallel group randomized trial. 45 participants, the study design in two therapy intervention group and one control group

##### Settings and conduct

The study population consisted of mothers of students with autism in the first to fifth grade of a special school in Mashhad. The purposeful sampling method was to select 45 mothers from the mothers and then randomly divided into two experimental groups and control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: not having a mental disorder, Not participating in psychotherapy, do not take psychotropic drugs or drug abuse for the past six months, Completion of the informed consent form and attending the meetings. exclusion criteria Attending therapeutic sessions or psychotherapy training concurrently, Absence of more than two sessions, Not willing to continue attending meetings.

##### Intervention groups

One experimental group will receive reality therapy and the second experimental group will receive Mindfulness-Based Cognitive Therapy in 10 weeks and the control group will receive no treatment.

##### Main outcome variables

psychological well-being

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N30**

Registration date: **2019-09-25, 1398/07/03**

Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**

Update count: **0**

##### Registration date

2019-09-25, 1398/07/03

##### Registrant information

###### Name

Raheleh Nejati

###### Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina  
Psychiatric Hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3711 2540

###### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison between efficacy of reality therapy and mindfulness -based cognitive therapy on psychological well-being and cognitive emotion regulation and mother's attitude towards child's with autism spectrum disorders.

## Public title

Comparison between efficacy of reality therapy and mindfulness -based cognitive therapy mother's attitude towards child's with autism spectrum disorders.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

not having a mental disorder Not participating in psychotherapy do not take psychotropic drugs or drug abuse for the past six months Completion of the informed consent form and attending the meetings.

### Exclusion criteria:

Attending therapeutic sessions or psychotherapy training concurrently Absence of more than two sessions Not willing to continue attending meetings

## Age

No age limit

## Gender

Female

## Phase

2-3

## Groups that have been masked

- Participant

## Sample size

Target sample size: 45

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted block randomization, randomly allocate a participant to a treatment group, while maintaining a balance across treatment groups. prepared a list of all permutations for the block size. selected one of them and based on arrangement allocated participants to a treatment and control groups with sealed envelope. Participants will be unaware of the type of intervention.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

After obtaining informed consent, participants were classified into intervention groups and were not aware of the type of intervention.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of Islamic Azad University Mshhhd Branch

##### Street address

Central building Ethics Committee of Islamic Azad University ,Emamyieh Street, Ghasem Abad, Mashhad.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9187147578

#### Approval date

2019-06-12, 1398/03/22

#### Ethics committee reference number

IR.IAU.MSHD.REC.1398.047

## Health conditions studied

### 1

#### Description of health condition studied

Autism Spectrum disorders

#### ICD-10 code

F84.0

#### ICD-10 code description

Childhood autism

## Primary outcomes

### 1

#### Description

Psychological Wellbeing Scale

#### Timepoint

Before intervention and after intervention and 1 month after intervention

#### Method of measurement

REF Questionier

### 2

#### Description

Cognitive Emotion Regulation Questionnaire

#### Timepoint

Before intervention and after intervention and 1 month after intervention

#### Method of measurement

CERQ Questionnaire

### 3

#### Description

Mother's attitude towards child's

#### Timepoint

Before intervention and after intervention and 1 month

after intervention  
**Method of measurement**  
Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: reality therapy

#### Category

Treatment - Other

### 2

#### Description

Intervention group: mindfulness -based cognitive therapy

#### Category

Treatment - Other

### 3

#### Description

Control group:no treatment

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad Exceptional children School

##### Full name of responsible person

Saeid Teymori

##### Street address

mashhad

##### City

Ghasem Abad, Mashhad.

##### Province

Razavi Khorasan

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9187147578

##### Phone

+98 51 3525 1022

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Steimory28@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Saeid Teymori

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Central building Ethics Committee of Islamic Azad University ,Emamyieh Street, Ghasem Abad, Mashhad.

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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

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Islamic Azad University

##### Full name of responsible person

Saeid Teymori

##### Position

Associate Professor

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

##### Street address

Ostad Yusofi Street, Emamieh Boulevard ,GhasemAbad, Mashhad, Iran.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Saeid Teymori

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ziba Emamdoust

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Province**

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**Email**

zibaemamdoost@yahoo.com

## 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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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**

No - There is not a plan to make this available