# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparsion 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**
Comparsion 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 Mshhhad 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

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Ghasem Abad, Mashhad.

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Ziba Emamdoust

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student

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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**
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