

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.

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Steimory28@yahoo.com

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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Full name of responsible person

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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

Psychology

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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