

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Developing a family-centered eclectic model and comparing its effectiveness with parent-child interaction therapy in improving parent-child relationship and reducing behavioral problems in children with autism

#### Protocol summary

##### Study aim

The present study aimed to answer the question of whether teaching techniques of ACT, Mindfulness approach and using Glasser's theory of choice, in addition to behavioral techniques are effective on reducing children's behavioral problems and improvement of parent-child relationship between children with autism spectrum, and is there a difference between family therapy with eclectic approach and other common treatments for autism?

##### Design

Thirty-six children with autistic syndrome were randomly selected and divided into three groups: parent-child interaction program (PCIT), eclectic family-centered model and control group.

##### Settings and conduct

The statistical population of this study includes all mothers of children with autism spectrum disorders in Tehran Autism Medical Center.

##### Participants/Inclusion and exclusion criteria

Children aged 4 to 7 years who have received a diagnosis of autism and their overall Garz scale score is between 85 and 99 were included in this study (high-performance category)

##### Intervention groups

People in the first experimental group are treated with parent-child interaction therapy. People in the second experimental group go through the same general treatment as the first group. In addition, Mindfulness and ACT techniques will be applied in child-centered and parent-centered sessions to make the intervention eclectic family therapy.

##### Main outcome variables

The family system is an important factor in the parent-child relationship. This model is based on the assumption that improving parent-child interactions can lead to

improved child-family functioning. Both methods are effective in improving parent-child relationships, but eclectic family-centered model, by considering more components such as parents' mindfulness and acceptance of situations with ACT technique, is more effective in improving parent-child relationships and reducing children's behavioral problems.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220214054019N1**

Registration date: **2022-06-21, 1401/03/31**

Registration timing: **retrospective**

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

##### Registration date

2022-06-21, 1401/03/31

##### Registrant information

##### Name

Noushin Fayezi

##### Name of organization / entity

University of Mohaghegh Ardabili

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8877 2360

##### Email address

nooshin.fayezi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2019-09-23, 1398/07/01

**Expected recruitment end date**

2022-02-20, 1400/12/01

**Actual recruitment start date**

2019-09-23, 1398/07/01

**Actual recruitment end date**

2022-03-11, 1400/12/20

**Trial completion date**

2022-03-11, 1400/12/20

**Scientific title**

Developing a family-centered eclectic model and comparing its effectiveness with parent-child interaction therapy in improving parent-child relationship and reducing behavioral problems in children with autism

**Public title**

Family Therapy and Autism

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

All mothers of children who referred to Tehran Autism Clinic Children 4 to 7 years old who have received a formal diagnosis of autism Their overall Garz scale score is between 85 and 99 (light, high-performance category)

**Exclusion criteria:**

Mothers with acute psychiatric disorders Children with mental retardation

**Age**

From **4 years** old to **7 years** old

**Gender**

Male

**Phase**

0

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

Actual sample size reached: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was assigned to three groups of PCIT intervention, family-centered eclectic model and control group through two-stage lottery. First, 36 people were selected by available sampling based on inclusion criteria and then were drawn to be in one of the three groups. First, the name of each person was selected from 36 people, and in the next lottery, it was determined which of the three groups he would belong to. It should be noted that there were 12 people in each group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of University of Mohaghegh Ardabili

**Street address**

Daneshgah Avenue

**City**

Ardabil

**Province**

Ardabil

**Postal code**

1313156199

**Approval date**

2022-04-25, 1401/02/05

**Ethics committee reference number**

IR.UMA.REC.1401.001

**Health conditions studied****1****Description of health condition studied**

Autistic Spectrum disorder

**ICD-10 code**

F84.0

**ICD-10 code description**

Autistic disorder

**Primary outcomes****1****Description**

Measuring a Parent-Child Relationship

**Timepoint**

Pre-test before the intervention and post-test after the intervention

**Method of measurement**

Pianta Child Parent Relationship Scale (CPRS) consists of 17 items of conflict, 10 items of intimacy and 6 items of dependence. The total score of the positive relationship is calculated by total scores of all three items.

**2****Description**

Children's Behavioral Problems

**Timepoint**

On a weekly basis. In each session, the parents were treated by necessary intervention training and then performed the relevant intervention tasks at home for a week and completed a questionnaire at the end of the week.

**Method of measurement**

Eyberg Child Behavior Inventory (ECBI): This questionnaire is designed in two scales of severity and difficulty. A score of 151 on severity and a score of 19 on the scale of difficulty are placed in autistic spectrum syndrom.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Parent Child Interaction Treatment

#### Category

Behavior

### 2

#### Description

Intervention group: Eclectic family-centered model

#### Category

Behavior

### 3

#### Description

Control group: Parents of autistic children who did not receive any treatment or intervention

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The Center for the Treatment of Autistic Disorders (CTAD)

##### Full name of responsible person

Mohammad Narimani

##### Street address

Number 1891, Kargare Shomali st., Tehran, Iran

##### City

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##### Province

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##### Email

info@ctad.ir

##### Web page address

<https://ctad.ir/contact-us/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mohaghegh Ardabili University

##### Full name of responsible person

Davood Seifzadeh

##### Street address

Daneshgah Street, 56199-11367, Ardabil , Iran

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info@uma.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mohaghegh Ardabili 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

Mohaghegh Ardabili University

##### Full name of responsible person

Mohammad Narimani

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Psychology

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## Person responsible for updating data

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Mohaghegh Ardabili University

**Full name of responsible person**

Nooshin Fayezi

**Position**

PhD student of Psychology

**Latest degree**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

All data will be published considering the confidentiality of participants' information

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

About a year after the article was published

**To whom data/document is available**

All researchers and students of psychology and psychiatry

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

For more accurate data analysis for the practical use of that treatment method

**From where data/document is obtainable**

To the first author and corresponding author of the article

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

The applicant has access to the data after sending the request and the reason for it to the e-mail of the first author or the responsible author.

**Comments**