

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)

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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

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Daneshgah Avenue

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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

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Number 1891, Kargare Shomali st., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mohaghegh Ardabili University

Full name of responsible person

Davood Seifzadeh

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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

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

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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