Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity

University of Mohaghegh Ardabili

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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
Street address
Daneshgah Avenue
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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
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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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Daneshgah Street, 56199-11367, Ardabil , Iran
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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
Mohammad Narimani
Position
Professor
Latest degree
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Other areas of specialty/work
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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