Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of Animal-Assisted Therapy and Applied Behavior Analysis on Behaviors and Social Skills of Children with Autism Spectrum Disorder, a randomized controlled trial

Protocol summary

Study aim
the effectiveness of animal-assisted therapy in the main symptoms of autism spectrum disorders, namely communication, social skills, self-care behaviors, and reduction of repetitive and stereotyped behaviors.

Design
single blind randomized controlled trial

Settings and conduct
Children with level 1 autism spectrum disorders referring to the Child and Adolescent Psychiatry Clinic of Zare Hospital, Bu-Ali Sina Hospital, and Tooba Clinic in Sari will be selected. They will be randomly assigned to 4 groups: Group 1: Animal-based intervention (parrot), Group 2: Applied Behavior Analysis intervention, Group 3: Applied Behavior Analysis intervention with the passive presence of a pet, and Group 4: Waiting list without the presence of a pet. A demographic questionnaire (including age, gender, etc.) will be completed for all participants.

Participants/Inclusion and exclusion criteria
Study inclusion criteria: Having DSM-5 criteria for diagnosing autism spectrum disorder (KSADs interview) No other concomitant psychiatric disorders Having written parental and verbal consent from the child to participate in the study Study exclusion criteria Disagreement to continue participating in the study Emergence of parrot phobia Emergence of physical or mental conditions that prevent the study from continuing.

Intervention groups
Group 1: therapeutic intervention with an animal (parrot), Group 2: intervention using the applied behavior analysis method, Group 3: intervention with applied behavior analysis with the passive presence of a pet, Group 4: waiting list without the presence of a pet.

Main outcome variables
Signs and symptoms are assessed with the Aberrant Behavior Checklist-C and the Children's Social Skills Profile Questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121225011885N9**
Registration date: **2025-03-21, 1404/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-21, 1404/01/01**
Update count: **0**

Registration date
2025-03-21, 1404/01/01

Registrant information

Name
Samaneh Farnia

Name of organization / entity
Mazandaran University of Medical Sciences

Country
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-04, 1403/10/15

Expected recruitment end date
2025-05-05, 1404/02/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Animal-Assisted Therapy and Applied Behavior Analysis on Behaviors and Social Skills of Children with Autism Spectrum Disorder, a randomized controlled trial

Public title

Effect of parrot in assissted treatment on autism

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

KSADS-PL SCREEN INTERVIEW: Autism Spectrum Disorders Absence of other concomitant psychiatric disorders Having written parental and verbal consent from the child to participate in the research No concomitant use of psychiatric medications

Exclusion criteria:

Unwillingness to continue participating in the study Occurrence of parrot phobia The occurrence of physical or mental conditions that prevent continued participation in the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly allocate subjects to either the four groups, the following steps will be undertaken in the current study: we need random numbers for 40 children in 4 intervention group (each group 10 participant) the numbers are generated by https://www.randomizer.org/ 4 data sets, 10 number per set, with unique numbers place markers within. The numbers 1 to 40 will correspond to the consecutive numbers of the referring patients based on the date of the medical record. (example: Set #1 p1=4, p2=16, p3=13, p4=22, p5=28, p6=33, p7=30, p8=36, p9=35, p10=21 Set #2 p1=21, p2=4, p3=40, p4=15, p5=3, p6=35, p7=34, p8=23, p9=37, p10=7 Set #3 p1=34, p2=28, p3=9, p4=40, p5=20, p6=36, p7=7, p8=3, p9=5, p10=2 Set #4 p1=10, p2=5, p3=38, p4=24, p5=27, p6=30, p7=25, p8=7, p9=36, p10=34)

Blinding (investigator's opinion)

Single blinded

Blinding description

regarding blinding procedures, Statistics expert colleague will be blind of intervention assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Zare Sari Psychiatry and Burn Center,5th kilometer of Sari-Neka Road

City

sari

Province

Mazandaran

Postal code

۴۸۴۳۱۸۵۷۷۴

Approval date

2023-07-16, 1402/04/25

Ethics committee reference number

IR.MAZUMS.REC.1402.253

Health conditions studied

1

Description of health condition studied

Autism spectrum

ICD-10 code

autism

ICD-10 code description

autism spectrum

Primary outcomes

1

Description

Aberrant Behavior Checklist –C and Children's Social Skills Profile Questionnaire

Timepoint

All participants will be assessed immediately before the start of the study, at the end of the study (week 8), and 4 weeks after the end of the study.

Method of measurement

Aberrant Behavior Checklist –C and Children's Social Skills Profile Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1: therapeutic intervention with a parrot
Category
Treatment - Other

2

Description
Intervention group: Group 2: intervention using the applied behavior analysis method
Category
Behavior

3

Description
Intervention group: Group 3: intervention using applied behavior analysis with the passive presence of a parrot
Category
Behavior

4

Description
Control group: waiting list
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Zare Hospital
Full name of responsible person
Samaneh Farnia
Street address
Zare Sari Psychiatry and Burn Center,5th kilometer of Sari-Naka road
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Sponsors / Funding sources

1

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Name of organization / entity
Mazandaran University of Medical Sciences
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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
Mazandaran University of Medical Sciences
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
Mazandaran University of Medical Sciences
Full name of responsible person
Samaneh Farnia
Position
Associate professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
here is no further information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data will be made available to requesting researchers in an encrypted and non-identifiable form upon reasonable request from the principal investigator.

When the data will become available and for how long
6 months after publication

To whom data/document is available
this only available for people working in academic institutions

Under which criteria data/document could be used
Use for academic research with ethical approval

From where data/document is obtainable
contacting by E-mail

What processes are involved for a request to access data/document
sm.farnia@gmail.com

Comments