Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Equine-Assisted Intervention on Psychological and Physiological Outcomes in Mothers of Children with Autism Spectrum Disorder

Protocol summary

Study aim

To evaluate the effectiveness of a structured equine assisted intervention on parenting stress in mothers of children with autism spectrum disorder and its effects on psychological well being, resilience, life satisfaction, depression, anxiety and stress, heart rate, and heart rate variability.

Design

Randomized controlled clinical trial with two parallel groups, 76 participants, 1 to 1 allocation using a random number table and sequentially numbered opaque sealed envelopes. Trial phase is not applicable.

Settings and conduct

The study will be conducted in Mashhad. The intervention will be delivered at the equestrian facility of Ferdowsi University of Mashhad, with assessments at baseline and immediately after the intervention.

Participants/Inclusion and exclusion criteria

Biological mothers of children aged 6 to 12 years with confirmed autism spectrum disorder; residents of Mashhad, able to attend regularly, and providing informed consent. Individuals with medical or psychiatric conditions making participation unsafe, major physical limitations, or regular equine assisted intervention during the previous 6 months will be excluded.

Intervention groups

The intervention group will receive 12 structured equine assisted sessions over 6 weeks, two 45 minute sessions per week. The control group will remain on a wait list and receive the intervention after post test assessment.

Main outcome variables

Parenting stress measured by the Parenting Stress Index, Short Form, at baseline and immediately after the intervention.

General information

Reason for update

Acronym

EAI-ASD

IRCT registration information

IRCT registration number: **IRCT20250822066951N1**
Registration date: **2026-09-03, 1405/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-03, 1405/06/12**
Update count: **0**

Registration date

2026-09-03, 1405/06/12

Registrant information

Name

Zahra Mansourjozan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 156 3578

Email address

zahra_mansuri65@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-24, 1405/04/03

Expected recruitment end date

2026-09-11, 1405/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of Equine-Assisted Intervention on Psychological and Physiological Outcomes in Mothers of Children with Autism Spectrum Disorder

Public title
Effectiveness of Equine-Assisted Intervention on Psychological and Physiological Outcomes in Mothers of Children with Autism Spectrum Disorder

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
* Biological mother of a child with autism spectrum disorder (ASD)* Child's ASD diagnosis confirmed according to DSM-5 by a child and adolescent psychiatrist* Child aged 6–12 years* Living in Mashhad and able to attend the intervention sessions regularly* Ability to read and write in Persian* No regular equine-assisted intervention or hippotherapy during the previous 6 months* Written informed consent to participate in the study* Relative stability of medication status during the previous 4 weeks, if applicable

Exclusion criteria:
* Withdrawal of willingness to participate in the study* Presence of an acute medical condition or psychiatric disorder that makes participation in the intervention unsafe* Major physical limitation that prevents safe participation in equine-assisted activities* Occurrence of a serious adverse event or accident that makes continued participation inappropriate

Age
From **25 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
After confirming eligibility and obtaining written informed consent, participants will be randomly allocated in a 1:1 ratio to either the intervention group or the wait-list control group. The random allocation sequence will be generated using a random number table. To ensure allocation concealment, the group assignments will be placed in sequentially numbered, opaque, sealed envelopes. After completion of the baseline assessment, the envelope corresponding to each participant will be opened in numerical order, and the assigned group will be revealed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is a randomized controlled trial with two parallel groups: an intervention group and a wait-list control group. Following baseline assessment, participants will be randomly allocated in a 1:1 ratio to the two groups. The intervention group will receive a structured equine-assisted intervention consisting of 12 sessions over 6 weeks, while the control group will remain on the wait-list during the study period. Outcome assessments will be conducted at two time points: before the intervention (baseline) and immediately after completion of the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Azadi Street, No. 15, 2nd Floor, Alley 63

City
Mashhad

Province
Razavi Khorasan

Postal code
9197944688

Approval date
2026-06-24, 1405/04/03

Ethics committee reference number
IR.MUMS.NURSE.REC.1405.030

Health conditions studied

1

Description of health condition studied
autism spectrum disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Parenting stress score measured using the Parenting Stress Index, Short Form (PSI-SF), assessed at baseline and immediately after completion of the intervention.

Timepoint
The primary outcome will be measured at baseline, before the intervention, and immediately after completion of the 12 intervention sessions in week 6.

Method of measurement

Parenting stress will be measured using the Parenting Stress Index, Short Form (PSI-SF). Mothers will complete the questionnaire under standardized conditions at baseline and immediately after completion of the intervention. The total parenting stress score will be recorded as the primary outcome.

Secondary outcomes

1

Description

Secondary outcomes include psychological well being, resilience, life satisfaction, depression, anxiety and stress, resting heart rate, and heart rate variability. Psychological outcomes will be assessed using the Ryff Psychological Well Being Scale, 18 item version, the Connor Davidson Resilience Scale, 10 item version, the Satisfaction With Life Scale, and the Depression Anxiety Stress Scale, 21 item version. Physiological outcomes will include resting heart rate and heart rate variability indices, including RMSSD, LF/HF, and SampEn.

Timepoint

Secondary outcomes will be measured at baseline, before the intervention, and immediately after completion of the 12 intervention sessions in week 6.

Method of measurement

Psychological well being will be measured using the Ryff Psychological Well Being Scale, 18 item version; resilience using the Connor Davidson Resilience Scale, 10 item version; life satisfaction using the Satisfaction With Life Scale; and depression, anxiety and stress using the Depression Anxiety Stress Scale, 21 item version. Resting heart rate and heart rate variability will be measured using a 5 minute seated resting recording. Heart rate variability indices will include RMSSD, LF/HF, and SampEn.

Intervention groups

1

Description

Control group: Mothers will be placed on a wait list and will not receive the equine assisted intervention during the study period. Assessments will be performed at baseline and immediately after the intervention period. After completion of the post test assessment, the intervention will be provided to this group according to the study protocol.Intervention group: Mothers will receive 12 structured equine assisted intervention sessions over 6 weeks, two sessions per week, with each session lasting 45 minutes. The intervention includes safety preparation and instruction, structured interaction with the horse, grooming and care of the horse, movement and balance exercises, basic riding, horse guiding, and structured activities targeting emotional regulation, self efficacy, resilience, and reduction of parenting stress. Sessions will be conducted by a qualified instructor with trained horses at the equestrian facility of Ferdowsi University of Mashhad.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ferdowsi University of Mashhad, Equestrian Club

Full name of responsible person
zahra Mansourjozan

Street address
Azadi Square, Ferdowsi University of Mashhad, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۷۴

Phone
+98 51 8802 0004

Email
z.mansur.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Mansourjozan

Street address
Azadi Street, Alley 63, No. 15, 2nd Floor

City
Mashhad

Province
Razavi Khorasan

Postal code
9197944688

Phone
+98 915 156 3578

Email
z.mansur.j@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Ferdowsi University of Mashhad Equestrian Club and Self Funding by the Researchers

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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Ferdowsi University of Mashhad Equestrian Club
Full name of responsible person
zahra Mansourjozan
Position
Non faculty member
Latest degree
Specialist
Other areas of specialty/work
PhD in Motor Behavior (Motor Development, Motor Learning, and Motor Control)
Street address
Azadi Street, Alley 63, No. 15, 2nd Floor
City
Mashhad
Province
Razavi Khorasan
Postal code
91997944688
Phone
+98 915 156 3578
Email
zahra_mansuri65@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ferdowsi University of Mashhad Equestrian Club
Full name of responsible person
Zahra Mansourjozan
Position
Non faculty member
Latest degree
Specialist
Other areas of specialty/work
PhD in Motor Behavior (Motor Development, Motor Learning, and Motor Control)
Street address
Azadi Street, Alley 63, No. 15, 2nd Floor
City
mashhad
Province
Razavi Khorasan
Postal code
91997944688
Phone
+98 915 156 3578
Email
zahra_mansuri65@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Ferdowsi University of Mashhad Equestrian Club
Full name of responsible person
zahra Mansourjozan
Position
Non faculty member
Latest degree
Specialist
Other areas of specialty/work
PhD in Motor Behavior (Motor Development, Motor Learning, and Motor Control)
Street address
Azadi Street, Alley 63, No. 15, 2nd Floor
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Postal code
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Phone
+98 915 156 3578
Email
zahra_mansuri65@yahoo.com

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
Due to confidentiality and privacy considerations, as well as the sensitive nature of the psychological and physiological data, there is no plan to share individual participant data.
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
No data or documents are planned for sharing
When the data will become available and for how long
No data or documents are planned for sharing
To whom data/document is available
No data or documents are planned for sharing
Under which criteria data/document could be used
No data or documents are planned for sharing
From where data/document is obtainable
No data or documents are planned for sharing
What processes are involved for a request to access data/document
No data or documents are planned for sharing
Comments
English: According to the study plan, individual participant data and study documents are not intended

for public sharing.