# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The Effectiveness of Internet-Based Mindfulness Training on Parental Stress, Perceived Illness, Coping Styles, and Quality of Life in Families with Newly Diagnosed Autism

## Protocol summary


**Study aim**

Investigating the effectiveness of internet based mindfulness training on parental stress,illness perception,coping styles, and quality of life in parents of children with autism.

**Design**

This is a quasi-experimental study with a pretest–posttest design and a control group; 40 participants will be randomly allocated to intervention and control groups (20 participants per group), and the study will be conducted without blinding.

**Settings and conduct**

The study population consists of all parents of children with Autism Spectrum Disorder in Semnan who are within one year of their child’s confirmed diagnosis by accredited centers.The data will be statistically analyzed using SPSS software (version 26).Descriptive statistics and inferential statistics, including multivariate analysis of covariance (MANCOVA) and univariate analysis of covariance(ANCOVA) on post-test scores while controlling for pre-test scores,will be used.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria:1.Having a child with a confirmed and valid diagnosis of autism spectrum disorder.2.No more than 12 months having elapsed since the child's diagnosis.3.Residency in the city of Semnan.4.Ability to read and write in Persian.Exclusion criteria:1.Absence from more than two intervention sessions.2.Onset of an acute psychiatric disorder or severe illness in the parent or child.3.Occurrence of a family crisis affecting continuation of the study.4.Withdrawal from the research.

**Intervention groups**

Eight sessions of internet based mindfulness training The control group does not receive the intervention during the study period and is assessed after the study concludes.

**Main outcome variables**

Independent variable: Internet information literacy.Dependent variables: Parental stress.Dependent variables: Perceived illness.Dependent variables: Coping styles.Dependent variables: Quality of life


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20260812070633N1**
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**

samaneh gholinezhad

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-08-25, 1405/06/03

**Expected recruitment end date**

2027-02-19, 1405/11/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The Effectiveness of Internet-Based Mindfulness Training on Parental Stress, Perceived Illness, Coping Styles, and Quality of Life in Families with Newly Diagnosed Autism

**Public title**
The Effectiveness of Internet-Based Mindfulness Training on Parental Stress, Illness Perception, Coping Styles, and Quality of Life Among Parents of Children Newly Diagnosed with Autism Spectrum Disorder
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having a child with Autism Spectrum Disorder (ASD) confirmed and registered by accredited centers. A maximum of 12 months (one year) has elapsed since the child's definitive diagnosis. The family's residence in the city of Semnan Ability to read and write in Persian to complete the questionnaires. Willingness and informed consent to participate in all intervention sessions and complete the pre-test and post-test stages. No prior experience participating in formal, internet-based mindfulness training courses.
**Exclusion criteria:**
Failure to actively participate in more than two sessions of the group intervention. A parent suffering from acute psychiatric disorders or instability requiring immediate hospitalization. Occurrence of a family crisis or a severe illness in a parent or child that prevents continued cooperation. Willingness to withdraw at any stage of the research Simultaneous initiation of another structured psychotherapy during the conduct of the study. Need to initiate or make a major change to the parent's psychiatric medication regimen during the intervention period.
**Age**
From **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Upon meeting eligibility criteria and obtaining informed consent, each participant is assigned a code. Participants will be randomly allocated to either the intervention or control group using a random number table via simple randomization. Individuals will be assigned to one of the two groups based on the sequence of random numbers.
**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**
Ethics Committee of Islamic Azad University, Semnan Branch
**Street address**
Km 5, Damghan Road, Islamic Azad University, Semnan Branch, Semnan, Iran
**City**
Semnan
**Province**
Semnan
**Postal code**
۳۷۱۱۱-۳۵۱۳۱
**Approval date**
2026-07-27, 1405/05/05
**Ethics committee reference number**
IR.IAU.SEMNAN.REC.1405.064

## Health conditions studied

### 1

**Description of health condition studied**
Autism
**ICD-10 code**
F84.0
**ICD-10 code description**
Autistic disorder

## Primary outcomes

### 1

**Description**
Parental stress: The level of stress experienced by the parent in relation to the parenting role and the circumstances arising from the child's autism spectrum disorder, measured using the Parenting Stress Questionnaire.
**Timepoint**
After the intervention ended
**Method of measurement**
Standard Parenting Stress Index (PSI) questionnaire; standard "Illness Perception Questionnaire – Parent Version" (IPQ-R); Coping with Stressful Situations

questionnaire; standard World Health Organization Quality of Life (WHOQOL-BREF) questionnaire.

## Secondary outcomes

### 1

**Description**
The level of parental stress in parents of children with autism spectrum disorder, measured using a standardized parental stress questionnaire before and after the intervention.
**Timepoint**
Before the intervention (pre-test) and immediately after completion of the 8-session intervention (post-test).
**Method of measurement**
Parental stress will be measured using the Parenting Stress Index (PSI). The questionnaire will be completed by the parents, and the total score will be considered as an indicator of the level of parental stress. The variable will be assessed at two time points: before the intervention (pre-test) and immediately after completion of the intervention (post-test).

## Intervention groups

### 1

**Description**
Intervention group: Parents in the intervention group receive internet-based mindfulness training over the course of eight sessions. The session content includes mindfulness exercises, meditation, breath awareness, awareness of thoughts and emotions, and stress management.
**Category**
Behavior

### 2

**Description**
Control group: The control group receives no educational or therapeutic intervention during the study period and is placed on a waiting list. Research assessments are also conducted for this group at the scheduled times.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Semnan Autism Center
**Full name of responsible person**
Samaneh Gholinezhad
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Nader Rahbar
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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**
Islamic Azad University
**Proportion provided by this source**
10
**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**
Islamic Azad University
**Full name of responsible person**
Samaneh gholinezhad
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**

Psychology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
The research data include demographic information and results from questionnaires regarding parental stress, illness perception, coping styles, and quality of life. Participants' identifying information will not be disclosed to others.
**When the data will become available and for how long**
پس از پایان پژوهش و انتشار نتایج، در صورت درخواست و با رعایت محرمانگی اطلاعات
**To whom data/document is available**
University researchers
**Under which criteria data/document could be used**
The data may be used solely for research purposes, subject to the preservation of confidentiality and the removal of participants' identifying information.
**From where data/document is obtainable**
The study's principal investigator, via the contact information listed in the IRCT system.
**What processes are involved for a request to access data/document**
Upon receipt of a written request, the researcher will review the proposal—considering the research objective and ensuring the confidentiality of participant data—and, if approved, will provide de-identified data.
**Comments**