Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of remote health education on general health, sleep quality and resilience of mothers of children with autism

Protocol summary

Study aim

The purpose of the study is to determine the effect of remote health education on general health, sleep disorders and resilience of mothers of children with autism referred to autism centers in Shiraz.

Design

The clinical trial with control and intervention groups; with parallel design; double-blind; on 80 people; randomized by simple lottery method.

Settings and conduct

This research is conducted in Tabsem and Mehrandish Center of Shiraz. The studied population is mothers with children with autism. This study is double-blind because the mothers do not know which one is in the control group and which one is in the intervention group. Also, the person who analyzes the data does not know who is in the intervention and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the research; having an autism disorder for the child that has been approved by a psychiatrist; having the ability to read and write; having a smartphone and the ability to use communication software ; the ability to use virtual education. Exclusion criteria: passing a similar training program; suffering from acute and chronic problems and mental disorders that prevent participation in training sessions; moving to another city.

Intervention groups

Intervention group: For the intervention group, 9 online sessions of 60 minutes will be held twice a week. Control group: No intervention is done for the control group, and at the end of the study, electronic content is provided to them

Main outcome variables

General health, Sleep quality and Resilience In mothers with autistic children

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20160404027216N12**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name
Fatemeh Vizeshfar
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 71 3647 4258
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vizeshfarf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2024-03-29, 1403/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of remote health education on general health, sleep quality and resilience of mothers of children with autism

Public title
The impact of distance health education on general health, sleep quality and resilience

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction with participation in research Autism disorder in the child confirmed by a psychiatrist Having at least reading and writing literacy Having a smartphone and the ability to use communication software Ability to use virtual training

Exclusion criteria:
Completing a similar training program Suffering from acute and chronic problems and mental disorders that prevent participation in training sessions Moving to another city

Age
From **20 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Two centers are selected under the direct supervision of the welfare of the Statistical Society by a simple lottery method (in this way, the name of each center is written separately in the middle of the note sheet and folded on both sides. One University professors are asked to choose one of the leaves) the name of the center chosen as the first center in the lottery is allocated as the intervention group and the other center is allocated as the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Because the questionnaire is given to all participants, no one knows that they are in the control and intervention groups. The person analyzing the data also does not know who is in the intervention and control group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Central building of Shiraz University of Medical Sciences; next to Red Crescent institution; Zand street

City
Shiraz

Province
Fars

Postal code
84471-71946

Approval date
2024-01-09, 1402/10/19

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.114

Health conditions studied

1

Description of health condition studied
The subject of study is not a disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
General health score in Goldberg and Hiller general health questionnaire

Timepoint
Before the start of the intervention - immediately after the intervention - 2 months after the intervention

Method of measurement
Goldberg and Hiller general health questionnaire

2

Description
Sleep quality score in the Pittsburgh Sleep Quality Questionnaire

Timepoint
Before the start of the intervention - immediately after the intervention - 2 months after the intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

3

Description
Resilience score in Kenner and Davidson's resilience questionnaire

Timepoint

Before the start of the intervention - immediately after the intervention - 2 months after the intervention

Method of measurement

Kenner and Davidson's resilience questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, 9 online sessions of 60 minutes will be held twice a week. Topics include: two sleep hygiene sessions; three sessions of resilience and ways to create it; other sessions of self-awareness skills; empathy skills; self-expression skills; Problem solving skills

Category

Rehabilitation

2

Description

Control group: No intervention is done for the control group and electronic content is provided to them at the end of the study.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehrandish Autism Center

Full name of responsible person

Zohre Hassas

Street address

1 Alley; Shahid Haraf Street

City

Shiraz

Province

Fars

Postal code

7349171441

Phone

+98 71 3383 0214

Email

shiraz.autism.mehrandish@gmail.com

2

Recruitment center

Name of recruitment center

Tabsem Autism Rehabilitation and Training Center, Shiraz

Full name of responsible person

Zohre Karami

Street address

6 Alley; South Chehel Magham Blvd.

City

Shiraz

Province

Fars

Postal code

7349171321

Phone

+98 71 3231 9746

Email

zohre.karami@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Central building of Shiraz University of Medical Sciences; in front of Felestin Street; Zand Street

City

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71348-14336

Phone

+98 71 3481 4336

Email

info@sums.ac.ir

Grant name

research grant

Grant code / Reference number

10450

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

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Vizeshfar
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Hazrat Fatemeh Nursing and Midwifery School; Namazi Square
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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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available