

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

: effect of quality of life therapy on quality of life and behavioral disorders in mothers with autistic children

Protocol summary

Study aim

determining the effect of quality of life therapy on quality of life and behavioral disorders in mothers with autistic children

Design

Classical experimental (two-group pre-test - post-test) with a control group, with crossed groups, randomized, on 60 participating mothers who met the study entry criteria. A table of random numbers will be used for randomization

Settings and conduct

By receiving a letter of introduction from the university officials and receiving the code of ethics and obtaining permission from the respected officials of the Oghok Clinic in Gonbad Kavus city and providing information and research objectives will be explained to them according to the protocol. Informed consent will be obtained from the mothers of autistic children and the intervention protocol will be fully explained to the mothers.

Participants/Inclusion and exclusion criteria

inclusion criteria: Mastery of Persian language Children aged 6-13 with autism Willingness to cooperate with parents and participate in research Exit criteria: Absence of more than 4 sessions Migration of children from the city

Intervention groups

In the treatment protocol intervention group, the quality of life intervention will be done with 8 treatment sessions and each session will last 90 minutes, and the control group will be given a questionnaire. There is no intervention

Main outcome variables

Quality of life, behavioral disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230311057685N1**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-03, 1402/02/13**

Update count: **0**

Registration date

2023-05-03, 1402/02/13

Registrant information

Name

Sonayaz Hivehchi

Name of organization / entity

The university of aliabad e katoul

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 8143

Email address

hivehchi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-19, 1402/01/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: effect of quality of life therapy on quality of life and behavioral disorders in mothers with autistic children

Public title

: effect of quality of life therapy on quality of life and behavioral disorders in mothers with autistic children

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

person language Autistic children aged 6 to 13
Willingness to cooperate with parents and participate in research

Exclusion criteria:

Healthy children Mothers with mental illnesses Adults

Age

From **6 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study subjects will be divided into 2 control and intervention groups by using simple randomization method and random number table. First, each person is assigned a number. Then, using the table of random numbers, each selected number is randomly assigned to one of the groups, and this work continues until the number of people in each group is completed. Therefore, the researcher will not have the authority to change the assignment status of people or predict it.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of aliabad e katool

Street address

no 3 .sorosh 12 Ave.naharkhoran Blvd.gorgan Town

City

Gorgan

Province

Golestan

Postal code

4917935965

Approval date

2023-03-01, 1401/12/10

Ethics committee reference number

IR.IAU.AK.REC.1401.005

Health conditions studied**1****Description of health condition studied**

autism

ICD-10 code

F84. 0

ICD-10 code description

Childhood autism

Primary outcomes**1****Description**

World Health Organization quality of life score (BREF-QOL WHO)

Timepoint

2 month

Method of measurement

World Health Organization Quality of Life Questionnaire

2**Description**

The child's behavior questionnaire score in the Achenbach questionnaire

Timepoint

2 months

Method of measurement

Achenbach child behavior questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: In the intervention group, the quality of life intervention therapy protocol, which is based on the protocol adopted from the book of psychotherapy based on improving the quality of life of Farish (2006), will be conducted with 8 treatment sessions and each session will last 90 minutes for 2 months. The content of the training includes the definition of quality of life therapy, the introduction of dimensions of quality of life, the introduction of sixteen areas of life that make up the overall quality of a person's life, the discovery of problematic issues for members, a summary of the discussion, providing feedback, introducing CASIO as the five roots for increasing life satisfaction, Education will be the principles of quality of life.

Category
Lifestyle

2

Description

Control group: The control group will be given a questionnaire and no intervention will be done.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Ofogh cilinic center of autism
Full name of responsible person
Abdolrahman Ofogh
Street address
Khorramshahr Ave
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4917935965
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The university of Aliabade Katool
Full name of responsible person
Nafiseh Hekmatipoor
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Pasdaran Ave
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4941793451
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ravabet@aliabadiu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source

The university of Aliabade Katool

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Aliabad Katool
Full name of responsible person
Nafiseh Hekmatipoor
Position
Associate professor
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Bachelor
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Sonayaz Hivehchi
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Person responsible for updating data

Contact

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Islamic Azad University

Full name of responsible person

Sonayaz Hivehchi

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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City

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Phone

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

no more data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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