

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Effectiveness of Reality Therapy on Psychological Capital, Emotional Self-Regulation and Anxiety Sensitivity in Mothers of Children With Autism

Protocol summary

Study aim

Determining the effectiveness of reality therapy on psychological capital, emotional self-regulation and anxiety sensitivity in children mothers with autism

Design

Clinical trial with control group (15 participants) and experimental group (15 participants), community-based, pragmatic, parallel groups, randomised controlled

Settings and conduct

Thirty mothers referred from the Autism Spectrum Association of Rasht city, will be selected by available sampling method and will be randomly divided into two experimental and control groups. After performing the pre-test for all participants, the virtual reality therapy group training course in a virtual training channel with voice and image and presenting written summaries with interaction and receiving feedback in the experimental group for 8 sessions, 90 minutes will be held in 4 weeks. There will be no intervention in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers between 25 and 35 years old, Children with autism 3-10 years old, Severity of high-functioning autism according to psychiatrist; Exclusion criteria: Psychiatric problems.

Intervention groups

The intervention group consisted of 15 mothers referred from the Autism Spectrum Association who were randomly placed in the experimental group with the inclusion criteria. No intervention was performed for the control group that will refer from autism Spectrum Association.

Main outcome variables

Psychological Capital; Emotional Self-Regulation; Anxiety Sensitivity

General information

Reason for update

Acronym

RT

IRCT registration information

IRCT registration number: **IRCT20210619051622N1**

Registration date: **2021-08-10, 1400/05/19**

Registration timing: **prospective**

Last update: **2021-08-10, 1400/05/19**

Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Seyedeh Masoumeh Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3213 3959

Email address

sami.bagheri78@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-11, 1400/05/20

Expected recruitment end date

2021-09-11, 1400/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Reality Therapy on Psychological Capital, Emotional Self-Regulation and Anxiety Sensitivity in Mothers of Children With Autism

Public title

The effectiveness of reality therapy on psychological variables in mothers with children with autism spectrum disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers' consent to participate in the study Age of mothers between 25 and 40 years, Age of child with autism 3-10 years, Severity of high-functioning autism according to psychiatrist.

Exclusion criteria:

History of psychiatric problems, Distortion of questionnaires, Lack of entrance criteria.

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method in this research, in terms of selecting the sample to enter the research, it is done by sampling and being in the intervention and control group is a simple random and by lottery.

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 - Lahijan Branch

Street address

No. 4, Eskan Building, First Alley, Taleghani Alley,

Moallem Blvd, Rasht, Gilan

City

Rasht

Province

Guilan

Postal code

4157933809

Approval date

2021-05-26, 1400/03/05

Ethics committee reference number

IR.IAU.LIAU.REC.1400.022

Health conditions studied

1

Description of health condition studied

Mothers of children with autism spectrum disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Miller and Brown's self-regulation scale (SRQ)

Timepoint

Assessment will be done once at the beginning of the study and once after the intervention.

Method of measurement

Miller and Brown's self-regulation scale (SRQ)

2

Description

Anxiety Sensitivity Index (ASI)

Timepoint

Assessment will be done once at the beginning of the study and once after the intervention.

Method of measurement

Anxiety Sensitivity Index (ASI)

3

Description

Luthans Psychological Capital Questionnaires (PCQ)

Timepoint

Assessment will be done once at the beginning of the study and once after the intervention.

Method of measurement

Luthans Psychological Capital Questionnaires (PCQ)

Secondary outcomes

empty

Intervention groups

1

Description

This research consists of two control groups and an experimental group. In each group, 15 people participate. First, a questionnaire is given to both groups. After separating the groups, the reality therapy training intervention was used for the experimental group. Reality therapy has been based on choice theory. Workshops for the experimental group consisted of 8 sessions for one month in which participants received training twice a week for 90 minutes by presenting videos, booklets, flashcards, audio and video content. Then, in order to evaluate the effectiveness of the intervention, a questionnaire was given to both groups again to compare the changes obtained from training in the training group with the control group. It should be noted that no drug treatment was used in this

Category

Behavior

2

Description

There was no intervention on the control group and this group completed the study questionnaires in only two stages.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besharat Exceptional School

Full name of responsible person

Kobra Alijanpour

Street address

Besharat Exceptional School, Gilan Boulevard, Rasht, Gilan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Gholamreza Vaghar

Street address

Islamic Azad University., Lahijan

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Guilan

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1616

Phone

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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

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

Islamic Azad University

Full name of responsible person

Seyedeh Masoumeh Bagheri

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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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

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