

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the Effect of Education based on Leventhal's Self-Regulation Model on The Psychological Distress of Parent's of Children with Autism in Qazvin, 1397

Protocol summary

Study aim

Determining the Effect of Education Based on Leventhal's Pattern of Self-Regulatory Pattern on Psychological Distribution of Parents of Children with Autism in Qazvin, 1397

Design

Clinical trials with control group, Randomized

Settings and conduct

The research environment is Sina Autism Home located at Vali Asr Crossroads, Shahed Street, the only Autism Spectrum Dispensary Training and Rehabilitation Center, and Leventhal's training for the test group during 4 sessions of 75 minutes in person and in the community at Sina's Autism Home Qazvin will be done.

Participants/Inclusion and exclusion criteria

In this study, the parents of children with autism who are referred to the home of Autism Sina in Qazvin will be included in the research. Inclusion criteria: • Complete satisfaction of the company in the research • Ability to speak and understand Persian language • No psychiatric disorder • Not receiving other educational interventions simultaneously with the plan • The availability of children's parents • Do not use Psychotropic drugs • Having reading and writing skills Having at least one child with autism • Life with a child's autism in a home
Exclusion criteria: • The presence of parents of autistic children in a psychotherapy or other counseling process, while conducting research • The parents of children with autism are reluctant to continue to cooperate and withdraw from the research project • Lack of more than one session of training sessions

Intervention groups

Parents using Random Allocation Rule (assigning couple or individual scores to selected files and then a simple draw) will be divided into two groups of control and test and the Leventhal pattern training for the test group during the four sessions of 75 minutes in face and group

At home of Autism Sinai City of Qazvin will be held

Main outcome variables

Leventhal's self-regulation model ; Psychological Distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040549N1**

Registration date: **2018-10-17, 1397/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-17, 1397/07/25**

Update count: **0**

Registration date

2018-10-17, 1397/07/25

Registrant information

Name

Marzieh Hajikarimbaba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3252 3405

Email address

m.hajikarimbaba@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-09, 1397/04/18

Expected recruitment end date

2018-11-09, 1397/08/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Education based on Leventhal's Self-Regulation Model on The Psychological Distress of Parent's of Children with Autism in Qazvin, 1397

Public title

Evaluation of the Effect of Education based on Leventhal's Self-Regulation Model on The Psychological Distress of Parent's of Children with Autism in Qazvin, 1397

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete satisfaction of the company in the research • • • • • Ability to speak and understand Persian language No psychiatric disorder (parental report of having a history of mental illness and hospitalization) Not receiving other educational interventions simultaneously with the plan The availability of children's parents Do not use Psychotherapeutic drug Having reading and writing skills Having at least one child with autism Life with a child's autism in a home

Exclusion criteria:

The presence of parents of autistic children in a psychotherapy or other counseling process, while conducting research (during the period of this project, do not receive training on the subject of research and psychological training) The parents of children with autism are reluctant to continue to cooperate and withdraw from the research project Lack of more than one session of training sessions

Age

No age limit

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

After entering 60 mothers of eligible children with autism, they are assigned to the control and test groups using a randomized four-way parents method. So by randomly selecting 15 blocks of 4 blocks of 6 blocks, we will eventually reach the equalization of the control and the test of 30 people. After this stage, the parents will be divided into two groups of control and test using random allocation using the Random Allocation Rule method (assigning paired or individual scores to selected files and then simple drawings)It will be divided into two groups of control and test.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics Committee of Qazvin University of Medical Sciences

Street address

Valiasr Street, Shahed Street, Sinai Autism House

City

Qazvin

Province

Qazvin

Postal code

59811 -34197

Approval date

2018-04-30, 1397/02/10

Ethics committee reference number

IR.QUMS.REC.1397.021

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**

Psychological Distress: Psychological distress is a state of emotional distress and pain that is defined by symptoms of depression (such as loss of interest, sadness and despair) and anxiety (such as restlessness and tension), and may be associated with physiological signs Such as insomnia, headache and lack of energy), and disturbance in social function and everyday life of individuals. In this study, the psychological distress is the mean scores that will be examined by the Kessler Psychological Distress Questionnaire.

Timepoint

Before intervention and every month up to 6 months

after intervention
Method of measurement
Kessler Psychological Distress Scale (K10)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training based on Leventhal's self-regulation model in the present study in four sessions of 75 minutes in group

Category

Other

2

Description

Control group: Do not attend these training sessions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Home Autism Sinai Qazvin

Full name of responsible person

Tayyaba Emami

Street address

Qazvin - Vali Asr Crossroad, Shahed Street No. 15 -
Sinai Autism House

City

Qazvin

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59811 -34197

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+98 28 3322 9675

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m.hajkarimbaba@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peimani

Street address

Dept of research Qazvin University of Medical
Sciences Shahid Beheshti,

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Qazvin

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Qazvin

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13911/34156

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nursingpublicaffairs@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Marzieh Haji Karim Baba

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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