Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 28 3252 3405

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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

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Qazvin

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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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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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Position
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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