Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Designing and Evaluation of Theory based Intervention on Quality of life among parents of Autistic patients

Protocol summary

Study aim
Determination of the effect of educational intervention based on Social cognitive theory on Quality of life among parents of Autistic patients in Tehran Autism Centers

Design
Randomized control trial with control group, with parallel group, not blinded and randomized, sample size 74, pretest post test and follow up,1and 6 month follow up

Settings and conduct
This study was performed among the parents of autistic students of autism schools in Tehran. Thus, in the intervention group, self-care education was designed based on cognitive-social theory and implemented through telegram for three months. The control group did not receive any training. Data from both groups before, one month and 6 months after the intervention were collected using SF36 questionnaire and CarerQol questionnaire and analyzed by SPSS20 software.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Parents of autistic students under 13 years old in autism schools of Tehran Exceptional Education Organization.Having a smart phone and access to the Telegram application and the ability to use it and Willingness to participate in the study.

Intervention groups
The intervention group included the parents of autistic students of autism schools in Tehran, who received an educational intervention designed based on social cognitive theory via telegram. The control group included the parents of autistic students of autism schools in Tehran who did not receive educational intervention.

Main outcome variables
Quality of life among parents of Autistic patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200922048797N1**
Registration date: **2020-12-11, 1399/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-11, 1399/09/21**
Update count: **0**

Registration date
2020-12-11, 1399/09/21

Registrant information

Name
Samaneh Abolkheirian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-14, 1398/09/23

Expected recruitment end date
2020-12-13, 1399/09/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Designing and Evaluation of Theory based Intervention on Quality of life among parents of Autistic patients

Public title
The effect of educational intervention based on Social

Cognitive Theory on Quality of Life among parents of Autistic patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Parents of autistic students under 13 years old in autism schools of Tehran Exceptional Education Organization Having a smart phone and access to the Telegram application and the ability to use it Willingness to participate in the study

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, after preparing the list of autism centers of exceptional education in Tehran, first the names of all centers were written on balls and put in a bag. Then 6 centers were randomly selected. Among the above centers, three centers were randomly placed in the intervention group and three centers as the control group using the random draw method. In fact, the randomization unit in this study was clusters..

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 Tehran University OF Medical Science

Street address
School of health, Tehran University of Medical science, Pour Sina Ave,Keshavarz Blvd,

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2017-12-02, 1396/09/11

Ethics committee reference number
IR.TUMS.SPH.REC.1396.4130

Health conditions studied

1

Description of health condition studied
Autism spectrum disorder

ICD-10 code
F84.0

ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Quality of life Score in the Questionnaire

Timepoint
In this study, the quality of life of parents was measured before intervention and one month and six months after the intervention.

Method of measurement
SF36 questionnaire and CarerQol questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
the intervention group: In the intervention group, self-care training based on social cognitive theory was conducted using the Telegram group for three months. These tutorials included text messages, pictures, and short instructional videos, as well as podcasts that were sent to parents via the Telegram software.

Category
Behavior

2

Description
Control group: Control group: No action was taken in the control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Autism Schools in Tehran

Full name of responsible person
Samaneh Abolkheirian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahraian

Street address
Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St, Keshavarz Blvd

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Samaneh Abolkheirian

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Health Promotion

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people.
When the data will become available and for how long
Start the access period, 6 months after publishing the results
To whom data/document is available
Data will only be available to researchers in academia.
Under which criteria data/document could be used
It is permitted to use data for all scientific works within the framework of ethics in research.
From where data/document is obtainable
To receive the data, the official request of the applicant (via organizational email) should be sent to Samaneh Abolkheirian email and only through the address: samanehabolkherian@yahoo.com.
What processes are involved for a request to access data/document
The applicant application (via organizational email) should be sent to samanehabolkherian@yahoo.com and after confirmation, the data will be provided to the applicant within 14 days.
Comments