

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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, 1 and 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)

Phone

+98 21 3318 0272

Email address

sabolkherian@razi.tums.ac.ir

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
Street address
school of health, Pour Sina Ave, Keshavarz Blvd
City
Tehran
Province
Tehran
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1417613151
Phone
+98 21 4293 3210
Email
samanehabolkherian@yahoo.com

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
City
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Tehran
Postal code
1417613151
Phone
+98 21 8163 3698
Email
msahrai@sina.tums.ac.ir
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