

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The study of group parental training about autism and behavioral management of children on mental health of parent and behavioral problems of their children

Protocol summary

Summary

This study evaluates the effect of parental training group on autistic children and their parents. Inclusion criteria are having a child affected by autistic disorder in preschool or school age and no participation in other parent training groups. The parents of 30 autistic children are selected by in convenience method, and then they will be divided in 2 groups randomly. Their parents of the intervention group will participate in 10 weeks of parent training program according to Taung (2006). Each session lasts 90 minutes. The parents and their children of both groups will be assessed before and after intervention in 2 extra weeks. For assessing the maintaining effect of intervention, they will be assessed 3 months later. The parents will be assessed by Family Assessment Device, The Billings and Moos coping checklist (1981) and General Health Questionnaire of Goldberg and their children with Childhood Autism Rating Scale and social communication questionnaire. These questionnaires have been normalized in Iranian population. It is difficult for the researchers to design a sham intervention for control group to reduce placebo effect.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010812053N1**
Registration date: **2013-03-16, 1391/12/26**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name

Mitra Hakim Shooshtari

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9024

Email address

hakim.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Mental Health Research Center of Tehran Psychiatric Institute

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2013-12-29, 1392/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of group parental training about autism and behavioral management of children on mental health of parent and behavioral problems of their children

Public title

declining the problems of autistic children and their parents with parent psychoeducation

Purpose

Other

Inclusion/Exclusion criteria

inclusion criteria: the parents with a child affected by autistic disorder in preschool or school age; no participation in other parent training group

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences, Mental Health Research Center of tehran psychitric institute

Street address

Tehran, Islamic Revolution, Ghods Street, Tehran University of Medical Sciences and Health Services, Postal Code: 1417614411

City

Tehran

Postal code

1417614411

Approval date

2012-12-15, 1391/09/25

Ethics committee reference number

17571

Health conditions studied

1

Description of health condition studied

autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

family assessment

Timepoint

pre and post intervention and 3 months later

Method of measurement

Family Assessment Device

2

Description

coping mechanism

Timepoint

pre and post intervention and 3 months later

Method of measurement

The Billings and Moos coping checklist (1981)

3

Description

general health

Timepoint

pre and post intervention and 3 months later

Method of measurement

General Health Questionnaire of Goldberg

Secondary outcomes

1

Description

social communication

Timepoint

pre and post intervention and 3 months later

Method of measurement

social communication questionnaire

2

Description

childhood autism

Timepoint

pre and post intervention and 3 months later

Method of measurement

childhood autism rating scale

Intervention groups

1

Description

parents of intervention group should participate in 10 sessions of parental training according to Taung(2006). it appears that participation of control group in 10 weeks without any clear content is not etical, so they will be seen in 3 sessions (before and after and 3 months later) to fill questionnaire. . Each session lasts 90 minutes. Content of sessions are: Session 1: introduction Goals of the intervention; group rules; talking about autism

Session 2: problems of parents after diagnosis Reaction to diagnosis; stress and dealing with it Session 3: identifying and management of behavioral problems What is behavioral management? How do the parents start it? Session 4: how can we change inappropriate behavior with modifying the consequences? Positive rewards, extinction, punishment Session 5: how do we reinforce new behavior? Giving feedback; shaping new behavior Session 6: communication problems in autistic children that can talk How these problems do affect on their behavior? Session 7: communication problems in autistic children that cannot talk How do these problems affect on their behavior? Improving nonverbal communication; how can we reinforce communication? How can we start communication? (Some ideas to start interaction with young children) Session 8: social problems in autistic children Therapeutic approach for young children; Therapeutic approach for older children and adolescent Session 9: playing and working with others The importance of playing; how do you attract your child's attention? Increasing eye contact, paying and sustaining attention on a task, recalling Session 10: evaluating and criticizing all previous sessions

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Psychiatric Institute and Mental Health Research Center

Full name of responsible person

zarafshan Hadi

Street address

Tehran, Sattar, Worship St., Shahid Mansouri, Tehran Psychiatric Institute and Mental Health Research Center, Mail Code: 1443813444

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Psychiatric Institute, Mental Health Research Center, Tehran University of Medical Sciences

Full name of responsible person

Eftekhar Mehrdad

Street address

Tehran, Sattar khan Avenue, Shahid Mansouri Street, Tehran Psychiatric Institute and Mental Health Research Center, Mail Code: 1443813444

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Tehran Psychiatric Institute, Mental Health Research Center, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, Mental Health Research Center

Full name of responsible person

Hakim Shooshtari Mitra

Position

associate professor of child and adolescent psychiatrist

Other areas of specialty/work

Street address

Shahid Mansouri street, Niayesh street, Sattar khan Avenue, Tehran psychiatric Institute and Mental Health Research Center, Mail Code: 1443813444

City

Tehran

Postal code

Phone

+98 21 6650 9024

Fax

Email

mitra.hakim@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hakim Shooshtari mitra

Position

associate professor of child and adolescent psychiatrist

Other areas of specialty/work

Street address

Shahid Mansouri street, Niayesh street, sattar khan Avenue, Tehran Psychiatric Institute and Mental Health Research Center, Mail Code: 1443813444

City

Tehran

Postal code

1443813444

Phone

+98 21 6650 9024

Fax

Email

mitra.hakim@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hakim Shooshtrai Mitra

Position

associate professor of child and adolescent
psychiatrist

Other areas of specialty/work

Street address

Shahid Mansouri street, Niayesh street, sattar khan
Avenue, Tehran Psychiatric institute amd Mental
Health Research Center

City

Tehran

Postal code

1443813444

Phone

+98 21 6650 9024

Fax

+98 21 6650 6853

Email

mitra.hakim@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty