

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A Clinical trial for evaluation of the efficacy of parenting skills group training to the mothers of children with Attention Deficit Hyperactivity Disorder (ADHD) on the quality of life of the children

Protocol summary

Summary

This study will be designed, as a clinical trial with pre- and post- tests, aiming to evaluate the impact of the parenting skills group training to the mothers of children with Attention Deficit Hyperactivity Disorder (ADHD) on the quality of life of the children. The study population will include 60 cases of the children with Attention Deficit Hyperactivity Disorder (ADHD) 8 to 12 years referring to the psychiatric center of Guil of Rasht. After attendance at the psychiatric center of Guil of Rasht, the patients are selected by a psychiatrist based on a clinical interview according to diagnostic criteria of Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The mothers of patients with Attention Deficit Hyperactivity Disorder meet the inclusion and exclusion criteria; will be entered in the study after obtaining informed consent. Using convenient sampling, the samples will be divided randomly into two groups of the intervention and the control. The training process will be continued for eight sessions of 90 minutes and using Positive Parenting Program (Triple P), by a child and adolescent psychiatrist in the psychiatric clinic of Guil of Rasht. The efficacy of the training will be evaluated last session and then three months after based on the scores obtained from the Pediatric Quality of Life Questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701297237N2**
Registration date: **2017-04-14, 1396/01/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

Maryam Kousha

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 1163

Email address

m-kousha@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial for evaluation of the efficacy of parenting skills group training to the mothers of children with Attention Deficit Hyperactivity Disorder (ADHD) on the quality of life of the children

Public title

A Clinical trial for evaluation of the efficacy of parenting skills group training to the mothers of children with Attention Deficit Hyperactivity Disorder (ADHD) on the

quality of life of the children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Children 8 to 12 years with a diagnosis of Attention Deficit Disorder / Hyperactivity Disorder and Oppositional Defiant Disorder (ODD), children who receive medical treatment and will respond with optimal dosage, mother cooperation with the researcher and her regular attendance training sessions, minimum qualification of the mother is third grade of middle school, lack of acute and severe psychiatric illness in the mother, at the same time there are no psychiatric disorders in children with attention deficit disorder / hyperactivity disorder other than ODD, lack of diseases such as epilepsy, mental retardation and Pervasive Developmental Disorders in the child; Exclusion criteria: The reluctance of the mother to continue for cooperation in research

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The random numbers table will be used for random selection

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical

Sciences

Street address
Shahid Beheshti Blvd, Opposite to the Sepah bank, Above Iran Radiator Representation. Building Of Assistance Research and Technology, Rasht, Iran

City
Rasht

Postal code
4193893345

Approval date
2015-09-22, 1394/06/31

Ethics committee reference number
IR.GUMS.REC.1394.245

Health conditions studied

1

Description of health condition studied
Attention Deficit Disorder / Hyperactivity Disorder

ICD-10 code
F90.0

ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
Pediatric Quality of Life

Timepoint
Before the start of the first session, at the end of the eighth session and three months after the end of the eighth session

Method of measurement
Pediatric Quality of Life Inventory PedsQL Parent-Proxy Report (ages 8-12)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: For 30 others, mothers of the control group, will be conducted only conventional therapy and routine monthly visits for their sick children

Category
Treatment - Other

2

Description
Intervention group: will be trained about parenting skills during 8 sessions of 90 minutes. The training sessions will be held on a weekly basis and based on common educational content, using Positive Parenting Program (Triple P), by a child and adolescent psychiatrist in the

psychiatric clinic of Guil of Rasht.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Psychiatric Clinic Gil, Rasht

Full name of responsible person

Dr Maryam Kousha

Street address

Poursina Avenue, Children's Psychiatric Clinic Gil ,
Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr Maryam Kousha

Street address

15 khordad avenue, Shafa Hospital, Rasht, Iran Rasht
Guilan

City

Rasht

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Investigator

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

Guilan University Of Medical Sciences

Full name of responsible person

Dr Maryam kousha

Position

Associate Professor

Other areas of specialty/work

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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