

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Survey the effect of behavioral education to parents on sleep situation of school-age children.

Protocol summary

Summary

The purpose of this study is to determine the effect of behavioral education for parents on sleep situation in school-age children with attention deficit hyperactivity disorder who referred to pediatric psychiatric clinic in Rasht. Samples of this study contain 60 children between 6 to 12 years old with ADHD. Inclusion criteria: children who just suffer from ADHD or ADHD and ODD based on DSM IV criteria; taking Ritalin; having sleep problems; absence of other mental disorders; mental disabilities; blindness and deafness and so having IQ above 80 . Data collection instrument is Child Sleep Habits Questionnaire. First Questionnaires are completed by parents and then samples with sleep problems divided into control and test group(30) by Randomized Blocks method; then test group divided in two groups (15) for Behavioral training. Training sessions consisted of 5 sessions in 5 weeks: Three sessions are presence training and two sessions are telephone follow-up. Parents of test group can ask their questions with calling researcher. Immediately and two months after sessions Child Sleep Habits Questionnaire are completed by parents again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042112990N1**

Registration date: **2013-05-14, 1392/02/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-14, 1392/02/24

Registrant information

Name

Mino0 Mitra Cherhzad

Name of organization / entity

Guilan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 5056

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Recruitment status

Recruitment complete

Funding source

Department of Research and Technology, Guilan University of Medical Sciences

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2013-08-06, 1392/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of behavioral education to parents on sleep situation of school-age children.

Public title

Effect of behavioral education to parents on sleep situation of school-age children with attention deficit hyperactivity disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children who just suffer from ADHD or ADHD and ODD based on DSM IV criteria, taking Ritalin; having sleep problems; absence of other mental

disorders; mental disabilities; blindness and deafness and so having IQ above 80.

Age

From **6 years** old to **12 years** old

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

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences and Health Services

Street address

Guilan-Rasht, department of reaserch and technology of Guilan University of Medical Science

City

Rasht

Postal code

33967-41938

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

2920029703

Health conditions studied

1

Description of health condition studied

Attention Deficit and Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention-Attention deficit:

Primary outcomes

1

Description

Sleep position

Timepoint

Before the training, immediately after training, two months after the completion of the training

Method of measurement

Children sleep habits questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The control group wasn't be educated.

Category

Behavior

2

Description

Behavioral education sessions present for educational group in three presence and two telephone follow-up sessions once a week .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa educatinal & remedial center

Full name of responsible person

Minoos Mitra Chehrzad

Street address

Nursing And Midwifery Faculty of Shahid Beheshti of Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technolog of Guilan University Medical Sciences

Full name of responsible person

Sobhani Abdolrasool

Street address

Rasht - Blv of Imam Khomeini - the end of the flying bridge - top of Iran's Radiator Building of Deputy of

Research of University

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technolog of Guilan University 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

Guilan University of Medical Sciences

Full name of responsible person

Mahboobeh Mehri

Position

Bachelor degree in nursing - Nurse

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Bachelor degree in nursing - Nurse

Other areas of specialty/work

Street address

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Fax

Email

mah.mehri@ymail.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