

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Improving sleep and psychological functioning in children and adolescents suffering from ADHD and their parents; an intervention study focusing on parent's and children's sleep patterns

Protocol summary

Summary

the purpose of this study is improving sleep and psychological functioning in children and adolescents suffering from ADHD and their parents. 60 ADHD children with their parents were selected in available method who having inclusion and exclusion criteria of this study. 3 groups were studied including 20 family for trial group, 20 family for control group and 20 intact family. firstly, participants complete the sleep questionnaires and then they were assigned in one of the both treatment or control groups. control group complete the daily log questionnaires for four consecutive weeks; every second week, and treatment group receives specific advice for parents' and children's sleep hygiene. At the end of the four-week period, participants again complete the identical series of questionnaires and the three groups were compared in sleep improvement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202259127N1**

Registration date: **2012-04-04, 1391/01/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-04, 1391/01/16

Registrant information

Name

Maryam Salmanian

Name of organization / entity

Tehran University of medical sciences, psychiatry and psychology research center

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 3540

Email address

marysal1981@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-03-10, 1390/12/20

Expected recruitment end date

2012-09-10, 1391/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Improving sleep and psychological functioning in children and adolescents suffering from ADHD and their parents; an intervention study focusing on parent's and children's sleep patterns

Public title

Improving sleep and psychological functioning in children and adolescents suffering from ADHD and their parents ; an intervention study focusing on parent's and children's sleep patterns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. age range 6 to18 years; 2- having ADHD symptoms based on DSM IV and 3-Pharmaceutical therapy under the supervision of a psychiatrist Exclusion

criterion: having comorbid disorders such as depression, Obsession and etc

Age
From **6 years** old to **18 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)
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

Street address
Teharan, Blvd Keshavarz, The Qods street

City
Tehran

Postal code

Approval date
2012-02-09, 1390/11/20

Ethics committee reference number
16524

Health conditions studied

1

Description of health condition studied
attention deficiency hyperactivity disorder

ICD-10 code
F90.0

ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description

Improving sleep

Timepoint

Baseline, 2 month after intervention

Method of measurement

Insomnia Severity Index, International physicalactivity questionnaire, Daily sleep, mood, and activity log, Children's sleep habits questionnaire – abbreviated form

Secondary outcomes

1

Description

Psychological functions

Timepoint

Baseline, 2 month after intervention

Method of measurement

Hypomania Check-List 32 , Strengths and Difficulties Questionnaire , Mood disorders questionnaire , Depression scale , Kid-screen; parent version

Intervention groups

1

Description

sleep hygiene intervention is just performed for trial group including 20 family with ADHD children; interventions for parents' and children's sleep hygiene is performed in two consecutive months; every month.

Category

Rehabilitation

2

Description

sleep hygiene intervention is not performed for intact group including 20 family with normal children. finally, this group is compared with trial and control groups.

Category

N/A

3

Description

sleep hygiene intervention is not performed for control group including 20 family with ADHD children. finally, trial, control and intact group are compared with each other.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry and Psychology Research Center, Roozbeh Hospital

Full name of responsible person

maryam salmanian

Street address

Psychiatry and Psychology Research Center, Roozbeh Hospital, South Kargar Avenue, after the Lashkar crossroads, Tehran, IRAN.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mrs karimi

Street address

fifth floor, The Qods street, Blvd Keshavarz, Tehran

City

Tehran

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

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, Psychiatry research center

Full name of responsible person

Zahra Keshavarzi

Position

MSc

Other areas of specialty/work

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Psychiatry and Psychology Research Center, Roozbeh Hospital, South Kargar Avenue, after the Lashkar crossroads, Tehran, IRAN

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pprct@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, Psychiatry and Psychology Research Center

Full name of responsible person

Mohammad Reza Mohammadi

Position

MD

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Psychiatry and Psychology Research Center

Full name of responsible person

Maryam Salmanian

Position

MS/Researcher

Other areas of specialty/work

Street address

City

Postal code

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Fax

Email

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

