

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effectiveness of methylphenidate with and without massage therapy on Attention Deficit-Hyperactivity Disorder among the Students of Primary Schools of Qom

Protocol summary

Summary

The purpose of present study is to determine the effect of massage therapy on ADHD students(attention deficit and hyperactivity disorder) . 30 students with pure ADHD diagnosed by a children psychiatrics that have taken methylphenidate more than 2 months include the study and researcher allocates them to control and intervention groups randomly. Control group take only methylphenidate and intervention group take methylphenidate and 10 minutes massage at bed time by mother for 30 days. Teachers complete the teacher conners questionnaire and mothers complete the parent conners questionnaire as well as mother-child relationship inventory and questionnaire of sleep pattern before and after intervention. Then the results are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305142531N2**

Registration date: **2013-11-11, 1392/08/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-11, 1392/08/20

Registrant information

Name

Tahmineh Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7596

Email address

dadkhahtehrani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of methylphenidate with and without massage therapy on Attention Deficit-Hyperactivity Disorder among the Students of Primary Schools of Qom

Public title

Effects of massage on students with ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obtaining score 20 or more in teacher conners questionnaire; more than two months after beginning methylphenidate with a stable situation; having age 7-12 years old; having no other psychological disorders; absence of mental retardation; having no history of convulsion; having no contraindication for massage. Exclusion criteria: irregular performing of massage program due to any causes; stopping the massage or methylphenidate; applying any other

interventions to treat ADHD during study.

Age

From **7 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Shahid Lavasani street, Qom, iran

City

Qom

Postal code

371364967

Approval date

2013-04-24, 1392/02/04

Ethics committee reference number

muq.rec.1392.7

Health conditions studied

1

Description of health condition studied

Attention Deficit/ Hyperactivity Disorders

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Symptoms of ADHD

Timepoint

Before intervention and just after 30 nights intervention

Method of measurement

Conners questionnaire of teacher and parents

Secondary outcomes

1

Description

Changes in pattern of sleep

Timepoint

2 times:1-just before intervention 2- just after 30 nights intervention

Method of measurement

with a valid and reliable questionnaire called BEARS

2

Description

weight changes

Timepoint

two times 1- before intervention 2- just after 30 nights intervention

Method of measurement

by a standard scale

3

Description

mother-child relationship

Timepoint

two times :1- befor intervention 2- just after 30 nights intervention

Method of measurement

ROBERT M Ross scale

Intervention groups

1

Description

in intervention group, in addition to taking methylphenidate tablets as before, subjects will be massaged by parent 10 minutes at bed time for 30 nights

Category

Other

2

Description

in control group ,subjects only take methylphenidate tablets as before

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric psychiatric office

Full name of responsible person

Dr. Shirin Moallemi

Street address

Amin building - alley 5- Amin boulevard-Qom- Iran

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Dr. Alireza Kouhpaei

Street address

Qom University of Medical Sciences, shahid Lavasani street, Qom, Iran

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Qom

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qom 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**

Qom University of Medical Sciences

Full name of responsible person

Tahmineh Dadakhah Tehrani

Position

MSc degree/ academic member

Other areas of specialty/work**Street address**

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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