

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of drawing and storytelling attachment and sleeping habits in children with autism

Protocol summary

Study aim

The effect of drawing and storytelling attachment and sleeping habits in children with autism

Design

A clinical trial with a control group, with parallel groups, randomized, on 42 patients. For randomization, a randomized triple block without permutation (21 blocks of 6 out of 126 cases) was used.

Settings and conduct

After receiving a referral letter from Iran University of Medical Sciences, researchers refer to rehabilitation centers under the supervision of the university and start sampling

Participants/Inclusion and exclusion criteria

Inclusion criteria Kid's age should be between 4 to 12 years Definitive diagnosis of autism in a child Family willingness to cooperate Exclusion criteria: The child has levels two and three with autism

Intervention groups

First, by obtaining the necessary permits, 42 people are randomly selected into three groups: painting intervention, storytelling and control intervention. Supervise the parent to start painting with the free subject. This intervention should be done at least 5 nights a week. In the storytelling group, the story was read to the child every night before bed and chosen by the parents. After one month, the questionnaire is filled out by the parents

Main outcome variables

Sleep habits Attachment

General information

Reason for update

Acronym

autism

IRCT registration information

IRCT registration number: **IRCT20141216020344N5**

Registration date: **2021-03-19, 1399/12/29**

Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**

Update count: **0**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of drawing and storytelling attachment and sleeping habits in children with autism

Public title

Effect of drawing and storytelling on autism

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:
Kid's age should be between 4 to 12 years Definitive diagnosis of autism in a child Family willingness to cooperate

Exclusion criteria:
The child suffers from levels two and three of autism

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
N/A

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
Ethics Committee of Iran University of Medical Sciences

Street address
Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

City
Tehran

Province
Tehran

Postal code
1919816766

Approval date
2020-11-30, 1399/09/10

Ethics committee reference number
IR.IUMS.REC.1399.940

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Attachment

Timepoint

Before and one month after the start of the intervention

Method of measurement

Kinship Center Attachment Questionnaire

2

Description

Sleep

Timepoint

Before and one month after the start of the intervention

Method of measurement

Children's Sleep Habits Questionnaire questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

After receiving a referral letter from Iran University of Medical Sciences, researchers refer to rehabilitation centers under the supervision of the university and start sampling. At the beginning the, the objectives of the study are explained to the parents whose children participating in the study. In addition, written consent is obtained from all individuals to participate in the study. The pre-test is then completed through the Child Sleep Habits and Attachment Questionnaire. The intervention group is asked about this process: every night, if the child and family wish to do so, after dinner and before sleep rituals such as brushing the child, Start painting with the subject alone under the supervision of a mother or father. Then paint and then take the sheet from the office and stick it on the wall of the child's room next to the bed, so that the child can see them. This intervention is performed at least for 5 nights a week for a month. Each week, the family takes paintings of the wall and sends it to the researcher so that the researcher can be sure of the intervention process.

Category

N/A

2

Description

First, after receiving a letter of introduction from Iran University of Medical Sciences, they refer to the rehabilitation centers under the supervision of the university and start sampling. At the beginning of the study, the objectives of the study are explained to the parents of the children participating in the study. In addition, written consent is obtained from all individuals to participate in the study. The pre-test is then completed through the Child Sleep Habits and Attachment Questionnaire. The intervention group is asked about this process: every night, if the child and family wish to do so, after dinner and before sleep rituals such as brushing the child. If the child and the family want to do this, the story will be read to the child before going to bed and chosen by the parents. After one month, the questionnaire is completed by the parents

Category

N/A

3

Description

In the control group: interventions are not performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Medical Sciences Rehabilitation Center

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

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khoshnezhad.hr@iums.acir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

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admins@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Emergency

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Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data is encrypted in order to make individuals'
identifiable and confidential

When the data will become available and for how long

From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr Hamidreza Khoshnezhad Ebrahimi

What processes are involved for a request to access data/document

After submitting the application via academic email, we
will provide the information files to the individuals within
a maximum of one week.

Comments