

# 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

#### City

Tehran

#### Province

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#### Postal code

1919816766

#### Phone

+98 21 2222 2045

#### Email

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

### City

Tehran

### Province

Tehran

### Postal code

۱۴۴۹۶۱۴۵۳۵

### Phone

+98 21 86701

### Email

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

#### Street address

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

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Hamidreza Khoshnezhad Ebrahimi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Hamidreza Khoshnezhad Ebrahimi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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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**