

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of family education in improving the sleep function of children 3 to 6 years old with sleep problems

Protocol summary

Study aim

Evaluation of the effectiveness of family education in improving the sleep function of children 3 to 6 years old with sleep problems

Design

Randomized, single-blinded parallel group trial with on 52 children.

Settings and conduct

Children with sleep problems who refer to the rehabilitation centers of Tehran University of Rehabilitation Sciences and Social Health, if they are eligible, will be included in the study and will be randomly assigned to the intervention and control groups. The study will be conducted in a blinded manner. The evaluator does not know about the allocation of people.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Child with sleep problems from ages 3 to 6 years. Parent must participate in all workshop sessions. Parental consent for their children's participation. Exclusion criteria: Existence of obvious physical, sensory, cognitive and motor disorders including cerebral-palsy, ADHD, autism spectrum, developmental delay which is checked through interviewing parents, taking history and CPRS-48 questionnaire. The child use medications that may affect sleep.

Intervention groups

The control group will not receive any intervention. The intervention-group receives a 4-week educational program during the first, second and fourth weeks (2 hours each session) in the form of a family education workshop under the following headings: an introduction to sleep, providing good sleep exercises, teaching behavioral and environmental strategies, Scoreboard training. For deep interaction, 8 families are present. For continuous interaction with parents, creating a group in virtual space consisting of researcher and families and telephone calls are used.

Main outcome variables

Resistance during sleep: Sleep delay: Sleep duration: Anxiety at bedtime: Quality of life of the child: Quality of life of parents: Parental stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220705055381N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

Fatemeh Hemmati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4497 8349

Email address

fatemehhemmati529@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2022-12-31, 1401/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of family education in improving the sleep function of children 3 to 6 years old with sleep problems

Public title
The effect of family education in improving the sleep performance of children with sleep problems

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The age of children should be between 3 and 6 years
Children who only have sleep problems
Participation in all training workshop sessions
Parents' consent for children's participation in the study
Exclusion criteria:
Existence of obvious physical, sensory, cognitive and motor disorders including cerebral palsy, ADHD, autism spectrum, developmental delay which is checked through interviewing parents, taking history and CPRS-48 questionnaire. Child use medications that may affect sleep.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate the samples, random block allocation method is used and it is done in several steps. First, a random sequence with blocks of 4 is created and Random Allocation software is used. Then, to hide the random allocation, sealed opaque envelopes are used in a random sequence. Based on the sample size of the research, a number of envelopes with aluminum foil (for lack of clarity of the contents of the envelopes), will be prepared and each of the created random sequences are recorded on a card and the cards are placed inside the envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed inside the boxes in order. At the time of registration of the participants, according to the order of entry of the eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. In this method, the people who check the Inclusion and Exclusion criteria and the person who performs the allocation process are independent.

Blinding (investigator's opinion)
Single blinded

Blinding description
The researcher of the study is aware of the allocation of children's parents to the control and intervention groups. Measurements are conducted by an evaluator (occupational therapist) masked to study design and group allocation. Also in order to maintain blinding, the questionnaires were completed in one session with the presence of all participants (control and intervention group) and evaluator (occupational therapist).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the University of Rehabilitation Sciences and Social Health
Street address
Koudackyar Ave., Daneshjo Blvd., Evin
City
Tehran
Province
Tehran
Postal code
1985713834

Approval date
2022-09-21, 1401/06/30

Ethics committee reference number
IR.USWR.REC.1401.114

Health conditions studied

1

Description of health condition studied
sleep problems

ICD-10 code
Z72.82

ICD-10 code description
Problems related to sleep

Primary outcomes

1

Description
Resistance during sleep

Timepoint
Before the intervention, immediately after the end of the intervention and one month after the end of the

intervention	
Method of measurement	The Children's Sleep Habits Questionnaire
2	
Description	Sleep delay
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	The Children's Sleep Habits Questionnaire
3	
Description	Sleep duration
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	The Children's Sleep Habits Questionnaire
4	
Description	Anxiety at bedtime
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	The Children's Sleep Habits Questionnaire
5	
Description	night walk
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	The Children's Sleep Habits Questionnaire
6	
Description	parasomnia
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	The Children's Sleep Habits Questionnaire
7	
Description	Sleep-disordered breathing

Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	The Children's Sleep Habits Questionnaire
8	
Description	Quality of life of the child
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	Pediatric Quality of Life Inventory
9	
Description	Quality of life of parents
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	the Canadian Occupational Performance Measure
10	
Description	Parental stress
Timepoint	Before the intervention, immediately after the end of the intervention and one month after the end of the intervention
Method of measurement	Parenting Stress Index Short Form (PSI-SF)

Secondary outcomes

empty

Intervention groups

1	
Description	The intervention group will receive a 4-week educational program during the first, second and fourth weeks (2 hours each session) in the form of a family education workshop under the following headings: an introduction to sleep, providing good sleep exercises, teaching behavioral strategies, teaching Environmental strategies, scoreboard training. For deep interaction, 8 families are present. Also, for continuous interaction with parents, the creation of a group in the virtual space consisting of the researcher and families and telephone calls will be used.
Category	Rehabilitation

2

Description

Control group: will not receive any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeide Rehabilitation Hospital

Full name of responsible person

Fatemeh Hemmati

Street address

Rofeideh Rehabilitation Hospital, Shahid Nemati Alley,
South Salimi St., Anderzgo Blvd., Qaitarieh

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rofeideh.hospital@uswr.ac.ir

2

Recruitment center

Name of recruitment center

Nizam Mafi specialized treatment and rehabilitation
clinic

Full name of responsible person

Fatemeh Hemmati

Street address

Next to Nizam Mafi Mosque., Ayat Allah Kashani Blvd.

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3

Recruitment center

Name of recruitment center

Asma Rehabilitation Center

Full name of responsible person

Fatemeh Hemmati

Street address

Next to 20th Street., Seyyed Jamaluddin Asadabadi
Street., Youssef Abad.

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asma@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Masoud Fallahi Khoshknab

Street address

University of Rehabilitation and Social Health
Sciences., Koudakyar Ave., Daneshjo Blvd., Evin

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1985713871

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webmaster@uswr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Fatemeh Hemmati

Position

Masters student of Occupational Therapy

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Fatemeh Hemmati

Position

Masters student of Occupational Therapy

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Masters student of Occupational Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available