

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of White Voice on the Quality of Sleeping Children in One to Three Years

Protocol summary

Study aim

Overall Objective: Determine the effect of white noise on the sleep quality of children aged one to three years
Special Purpose: 1. Determine the quality of sleep in children 1 to 3 years before intervention in the intervention group 2. Determine the quality of sleep in children aged 1 to 3 years after intervention in the intervention group

Design

Quasi-experimental clinical trial with intervention group without control group, randomized, lottery type

Settings and conduct

The intervention method is to refer to the kindergarten and the importance of sleep and quality of sleep and its effective factors are explained in person. If they wish to enter the Sleep quality questionnaire before the intervention, they are given to complete and then to The intervention group delivers audio files, which for 10 nights the white noise is distributed to the child while the baby is sleeping for the child and after the intervention the questionnaire is returned to complete again.

Participants/Inclusion and exclusion criteria

Criteria for entering the study 1. The age of the child is one to three years 2. Pass at least three months from the time you arrive at the kindergarten 3. At least 5 days per week in kindergarten 4. The child will live with his real mother 5. Ability to listen to the medical records in kindergarten 6. The absence of psychiatric and neurological disorders according to the medical records in kindergarten 7. Do not use drugs that affect sleep, including hypnotics and psychosocial drugs 8. Not having breathing problems and allergies 9. The existence of informed consent
Exit criteria 1. Unwilling to continue the scheme 2. Occurrence of a medical disorder or trauma at the time of study

Intervention groups

All 1-3 year old children are kept in kindergartens in Zabul city, including 24 kindergartens, 136 children from 1 to 3 years of age

Main outcome variables

sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190704044096N1**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **prospective**

Last update: **2019-07-16, 1398/04/25**

Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

Zahra Mosalman Kahkha Jaleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6690 2184

Email address

zahra.mosalman2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of White Voice on the Quality of Sleeping Children in One to Three Years

Public title

Effect of White Voice on the Quality of Sleeping Children in One to Three Years

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of a child is one to three years
Passing for at least three months after admission to kindergarten
At least 5 days a week in kindergarten
The child lives with his real mother
Listening ability according to the medical records in kindergarten
Not having psychiatric and neurological disorders according to the medical records in kindergarten
Not using sleep medications, including hypnotics and psychosocial drugs
Not having breathing problems and allergies
Conscious Consciousness

Exclusion criteria:

Unwilling to continue the scheme
Occurrence of a medical disorder or trauma at the time of study

Age

From **1 year** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the samples will be chosen randomly based on the criteria for entering the study. For grouping, random sampling will be done by lottery method that will be selected in the intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics Committee on Biological Research, Islamic Azad University, Tehran, Iran

Street address

Islamic Azad University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1234567890

Approval date

2018-09-03, 1397/06/12

Ethics committee reference number

IR.IAU.TMU.REC.1397.102

Health conditions studied**1****Description of health condition studied**

Sleep Quality

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sleep Quality

Timepoint

Before the intervention and 7 days after the intervention began

Method of measurement

The Children's Sleep Habits Questionnaire Abbreviated

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Children one to three years old

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kindergartens in Zabol city

Full name of responsible person

Zahra Mosalman

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Ferdosi

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Sistan-va-Balouchestan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Hejazi
Street address
Sohanak
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Province
Tehran
Postal code
1234567890
Phone
+98 21 2200 6660
Email
info@nursing.iautmu.ac.ir
Web page address
<http://nursing.iautmu.ac.ir/>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Zahra Mosalman
Position
Student

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Not having enough free time

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable