Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Street address
Ferdosi

City
Zabol
Province
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
City
Tehran
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
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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