

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Core Stability Exercises on sleep habits and quality of life in children with nocturnal enuresis

Protocol summary

Study aim

Determining The effect of Core Stability Exercises on sleep habits and quality of life in children with nocturnal enuresis

Design

Clinical trial with control group, with single, randomized groups, 70 patients

Settings and conduct

Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics checklist, Children's Sleep Habits Questionnaire and The Pediatric Quality of Life Inventory. In the intervention group, In eight weeks, the exercises will be done three sessions a week (the interval between the training sessions is one day) and each session will be 45 minutes as a group. 48 hours after completing the interventions, complete the Children's Sleep Habits Questionnaire and The Pediatric Quality of Life Inventory. The place of interventions is in one of the suitable sports halls in Yasuj city.

Participants/Inclusion and exclusion criteria

Admission requirements: Age range from 6 to 12 years.
Conditions of non-entry: Previous patient participation in studies similar to the current study

Intervention groups

Intervention group by core stability method: In eight weeks, the exercises will be done three sessions a week (the interval between the training sessions is one day) and each session will be 45 minutes as a group. Control group: non-intervention: this training group will not be given.

Main outcome variables

Sleep habits and Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055611N1**

Registration date: **2022-08-16, 1401/05/25**

Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**

Update count: **0**

Registration date

2022-08-16, 1401/05/25

Registrant information

Name

Nastaran Kheirandish

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3323 5138

Email address

nastaran.kherandish@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Core Stability Exercises on sleep habits and quality of life in children with nocturnal enuresis

Public title

The effect of Core Stability Exercises on sleep habits and

quality of life in children with nocturnal enuresis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range from 6 to 12 years Diagnosis of primary and secondary nocturnal enuresis by a specialist in children's kidney diseases Not doing sports professionally The quality of life of children with a cut-off point of less than 25 (low quality of life) based on the questionnaire of the quality of life of children Having the physical ability to participate in sports exercises according to the doctor's opinion Not suffering from concomitant diseases (cardiac, pulmonary and diabetes) Consent to participate in the study and sign the informed consent form by the parents and the child
Exclusion criteria:
 Previous patient participation in studies similar to the current study

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Block random allocation in such a way that first by multiplying the number of studied groups (two groups) by 2, the number of samples in each block is equal to 4, through factorial calculation, the number of samples in each block ($24=1 \times 2 \times 3 \times 4= 4$), the number of blocks resulting from all modes of arrangement of people will be calculated as 24 blocks. Then, since the number of people in each block will be 4 people and the estimated sample size is 60 people, therefore, by matching 20 random numbers generated by the Sample Randomizer software with the numbers of the aforementioned states, how to arrange 60 people in the research sample and assign each number from 1 Up to 60 will be assigned to one of the specified intervention and control groups and a block random allocation list will be compiled. After fully explaining and explaining the objectives of the study, eligible research samples will be selected and based on the time priority of referrals, a code will be assigned to each of them, and by matching that number with the random block allocation list, the patients participating in the research will be assigned to one of the intervention and control groups. This process will continue until the estimated sample size is completed.

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 of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

City

Yasuj

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Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2022-06-14, 1401/03/24

Ethics committee reference number

IR.YUMS.REC.1401.031

Health conditions studied

1

Description of health condition studied

Children with nocturnal enuresis

ICD-10 code

F98.0

ICD-10 code description

Nonorganic enuresis

Primary outcomes

1

Description

Outcome number 1: Sleep habits: Sleep habits means the score that a person gets from answering the questions of the children's sleep habits questionnaire.

Timepoint

The amount of sleeping habits of the patients at the beginning of the study (before the start of the intervention) and 48 hours after the completion of the interventions

Method of measurement

Children's Sleep Habits Questionnaire

2

Description

Outcome number 2: Quality of life: Quality of life means the score that a person answers to the questions of the Pediatric Quality of Life Inventory.

Timepoint

The level of quality of life of patients at the beginning of the study (before the start of the intervention) and 48 hours after the completion of the interventions

Method of measurement

The Pediatric Quality of Life Inventory

Secondary outcomes

empty

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

Intervention group: In eight weeks, the exercises will be done three sessions a week (the interval between the training sessions is one day) and each session will be 45 minutes as a group. The exercises will be as follows: The first session: 1- Raising the arms and legs in a round position 2- Bridging in such a way that the hips and waist rise from the ground. The number of performances of each two hands is 10. The second session: 1- Raising the arms and legs in a distant position 2- Bridging so that the hips and waist rise from the ground. The number of performances of each two hands is 15. The third session: - Raising the arms and legs in a round position 2- Bridging in such a way that the hips and waist rise from the ground. The number of performances of each two hands is 20. The fourth session: - Raising the arms and legs in a round position 2- Bridging in such a way that the hips and waist rise from the ground. The number of performances of each two hands is 25. Fifth session: 1- Lying down with rotation 2- Half lying down. The number of performances of each two hands is 10. Sixth session: 1- Lying down with rotation 2- Half lying down. The number of performances of each two hands is 15. Seventh session: 1- Semi-recumbent sitting 2- Recumbent sitting with rotation. The number of performances of each two hands is 20. Eighth session: 1- Semi-recumbent sitting 2- Recumbent sitting with rotation. The number of performances of each two hands is 25.

Category

Lifestyle

2**Description**

Control group: non-intervention: this training group will not be given.

Category

Lifestyle

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

Shahid Beheshti Hospital

Full name of responsible person

Nastaran Kheirandish

Street address

Shahid Beheshti Hospital, Shahid Montazeri Ave., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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2**Recruitment center****Name of recruitment center**

Martyr Dr. Jalil Hospital

Full name of responsible person

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3**Recruitment center****Name of recruitment center**

Imam Sajjad Hospital

Full name of responsible person

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Imam Sajjad Hospital, Next to Hotel Azadi, Yasuj, Kohgiluyeh and Boyerahmad, Islamic Republic of Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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nursing@yums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Nastaran Kheirandish

Position

Msc student in pediatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Msc student in pediatric nursing

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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Position

Msc student in pediatric nursing

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Email

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