

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigating the effect of sports training on the quality and quantity of sleep in children aged 6 to 12 years with type 1 diabetes

Protocol summary

Study aim

Determining the effect of exercise training on sleep habits in children with type 1 diabetes

Design

This study includes 62 children with type 1 diabetes who are randomly divided into two control and intervention groups.

Settings and conduct

Children with type 1 diabetes who refer to hospitals affiliated to Kermanshah University of Medical Sciences during the study will be included in the study if they are eligible. Therefore, they will be randomly assigned to the intervention and control groups using the random block method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children who are in the age range of 6 to 12 years, Children who have a history of diabetes for one year, Children whose parents live in Kermanshah, Children who do not have a specific mental or cognitive illness, Children who do not have musculoskeletal diseases, Children who have not participated in another diabetes education program in the past month. Exclusion criteria: Children who have concurrent diseases such as kidney diseases, Children who use drugs that affect blood sugar, Children who are resistant to autoimmune diseases affecting insulin. Children who are active in a particular sport.

Intervention groups

Intervention group: The intervention includes the implementation of sports exercises based on sports instructions. The exercise training protocol (warming up, brisk walking, and cooling down) consists of eight weeks of training. There are 3 training sessions per week and each session includes 30 minutes of training. After the intervention, the sleep habits questionnaire will be completed by the parents. Control group: This group will have daily and routine walks.

Main outcome variables

Bedtime Resistance score; Sleep Onset Delay score;

Sleep Duration score; Sleep Anxiety score; Night Wakings score; Parasomnias score; Sleep Disordered Breathing score; Daytime Sleepiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221112056480N1**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **retrospective**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

Registration date

2023-10-29, 1402/08/07

Registrant information

Name

Nastaran Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 918 756 4498

Email address

nastaran.amiri.1982@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of sports training on the quality and quantity of sleep in children aged 6 to 12 years with type 1 diabetes

Public title
The effect of exercise training on the quality and quantity of sleep in children with diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Children who are in the age range of 6 to 12 years.
 Children who have a history of diabetes for one year.
 Children whose parents live in Kermanshah. Children who do not have a specific mental or cognitive illness.
 Children who do not have musculoskeletal diseases.
 Children who have not participated in another diabetes education program in the past month.
Exclusion criteria:
 Children who have concurrent diseases such as kidney diseases Children who use drugs that affect blood sugar, such as Corticosteroids Children who are resistant to autoimmune diseases affecting insulin. Children who are active in a particular sport

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: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are calculated using G*power sample size calculation software. Considering the effect size of 0.871, alpha value of 0.05, and test power of 0.90, 62 people are included in the study. The samples will be randomly divided into two control and intervention groups (blocks with a size of four). Random allocation software is used for randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study included two experimental and control groups. The intervention for the experimental group consisted of 8 weeks of regular exercise program. There is no intervention for the control group. The group will carry out its usual routine.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences., Anoshiravan Rezaei Square., Moalem Ave

City

Khorramabad

Province

Lorestan

Postal code

6183833946

Approval date

2022-10-19, 1401/07/27

Ethics committee reference number

IR.LUMS.REC.1401.174

Health conditions studied

1

Description of health condition studied

Type 1 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Sleep Habits Score

Timepoint

before the intervention and 8 weeks after the intervention

Method of measurement

Children's Sleep Habits Questionnaire (CSHQ)

2

Description

Bedtime Resistance score

Timepoint

before the intervention and 8 weeks after the intervention

Method of measurement

Children's Sleep Habits Questionnaire (CSHQ)

3

Description

Sleep Onset Delay score
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

4

Description
Sleep Duration score
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

5

Description
Sleep Anxiety score
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

6

Description
Night Wakings score
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

7

Description
Parasomnias score
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

8

Description
Sleep Disordered Breathing score
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

9

Description
Daytime Sleepiness score
Timepoint
before the intervention and 8 weeks after the

intervention
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention includes the implementation of sports exercises based on sports instructions. The video of these exercises will be sent to parents using virtual social networks (Eta, Rubika, Shad). The exercise training protocol (warming up, brisk walking, and cooling down) consists of eight weeks of training. There are 3 training sessions per week and each session includes 30 minutes of training. After the intervention, the sleep habits questionnaire will be completed by the parents.

Category
Lifestyle

2

Description
Control group: This group will have daily and routine walks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Kermanshahi Clinic
Full name of responsible person
Kimia Karami
Street address
Mohammad Kermanshahi Clinic., Red Crescent Square., Mosavari Ave
City
Kermanshah
Province
Kermanshah
Postal code
6713733135
Phone
+98 83 3721 8202
Email
MKH@kums.ac.ir

2

Recruitment center
Name of recruitment center
Taleghani educational and therapeutic center

Full name of responsible person

Kimia Karami

Street address

Taleghani educational and therapeutic center., Naft Square., Shahid Beheshti Ave

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Phone

+98 83 3836 7984

Fax

+98 83 3835 8754

Email

taleghani_hospital@yhoo.com

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Kimia Karami

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Lorestan University of Medical Sciences., Anoshiravan Rezaei Square., Moalem Ave

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Fax**Email**

pr@lums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Bahram Rasolian

Street address

Lorestan University of Medical Sciences., Anoshiravan Rezaei Square., Moalem Ave

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

Rasolian.Bahram@gmail.com

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

Yes

Title of funding source

Khoram-Abad 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Kimia Karami

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Lorestan University of Medical Sciences., Anoshiravan Rezaei Square., Moalem Ave

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

pr@lums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Kimia Karami

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Lorestan University of Medical Sciences., Anoshiravan
Rezaei Square., Moalem Ave

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

0986633300661

Email

pr@lums.ac.ir

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