

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effectiveness of spiritual self-care training on sleep quality and insomnia severity in adolescents with diabetes and its comparison with the control group

Protocol summary

Study aim

Determining the effect of spiritual self-care training on sleep quality and severity of insomnia in diabetic adolescents

Design

Experimental study with test and control group, By available sampling method, Then randomization, on 66 diabetic adolescents aged 12 to 20 years, Sealed envelopes were used for randomization.

Settings and conduct

Experimental study on diabetic adolescents aged 12 to 20 years referred to Health and treatment centers of Qaemshahr city. First, by available sampling method, the Insomnia Intensity Questionnaire and the Peter Borg Sleep Quality Questionnaire were completed by qualified adolescents. Then divided into two groups of test and control by sealed envelopes. The test group will be trained in spiritual self-care.

Participants/Inclusion and exclusion criteria

Included criteria: Diabetes, Age range between 12 to 20 years, Family satisfaction with the continuous participation of subjects in training sessions, No history of neurological and psychological diseases, No drug abuse, insomnia; Criteria for non inclusion: Suffering from various underlying diseases, Mental disability

Intervention groups

Test group and control group. The test group is trained in spiritual self-care. The control group received routine care.

Main outcome variables

Program independent variable: spiritual self-care training and dependent variable: sleep quality and insomnia severity of diabetic adolescents and disturbing variable: age, gender, weight and average blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220327054359N1**

Registration date: **2022-09-04, 1401/06/13**

Registration timing: **retrospective**

Last update: **2024-02-12, 1402/11/23**

Update count: **1**

Registration date

2022-09-04, 1401/06/13

Registrant information

Name

Elham Valipour Eskandarkolaii

Name of organization / entity

Islamic Azad University of Aliabad Katool

Country

Iran (Islamic Republic of)

Phone

+98 11 4227 6928

Email address

valipoureahme@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of spiritual self-care training on sleep quality and insomnia severity in adolescents with diabetes and its comparison with the control group

Public title

The effect of spiritual self-care training on the severity of insomnia and sleep quality of diabetic adolescents

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having diabetes Age range between 20 to 12 years
Family satisfaction with the continuous participation of the subjects in the training sessions
No history of neurological and psychological diseases
No drug abuse
insomnia

Exclusion criteria:

The presence of various underlying diseases
Mental disability

Age

From **12 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, the samples will be selected by available sampling method as follows: After obtaining consent and stating the targets and providing the necessary information, the questionnaire severity insomnia and the Petersburg Quality of Sleep Questionnaire will be completed by diabetic patients with the help of a researcher. Then by using a secret envelope, will be selected for randomization into two groups of test and control. For randomization, the secret letters which previously prepared that containing numbers 1 (control group) and numbers 2 (test group) are given to individuals.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Dezful Branch

Street address

University Blvd, Azadegan Street, Dezful

City

Dezful

Province

Khuzestan

Postal code

۶۴۶۱۶۴۵۱۶۹

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.IAU.D.REC.1401.004

Health conditions studied

1

Description of health condition studied

Insomnia and decreased sleep quality in diabetic adolescents

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Earning score of 15 to 21 has meaning of moderate and 22 to 28 has meaning of severe insomnia in Insomnia Intensity questionnaire and earning score of 6 and more than 6 has meaning of unpleasant of sleep quality in Petersburg Sleep Quality Inventory.

Timepoint

30 DAYS

Method of measurement

Petersburg Sleep Quality Questionnaire and Insomnia Intensity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Test group is diabetic adolescents 12 to 20 years that educated in White's spiritual self care training. White's spiritual self-care training is held in 6 sessions of 30 to 45 minutes. This training is in 5 areas: Self control,

Performing religious duties, Personal activities, Getting close to God, Asking God for help

Category

Behavior

2

Description

Control group: This group are not trained and receives routine care. After completing the research educational materials will be provided to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers of Qaemshahr city

Full name of responsible person

Elham Valipour Eskandarkolaii

Street address

University blvd

City

Aliabad katul

Province

Golestan

Postal code

4941793451

Phone

+98 17 3422 2300

Email

valipoureelham@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Aliabad Katoul Branch

Full name of responsible person

dr. Nafise Hekmatipour

Street address

University Blvd

City

Aliabad Katul

Province

Golestan

Postal code

49417-93451

Phone

+98 17 3422 2300

Fax

+98 17 3422 5673

Email

info@aliabadiu.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, Aliabad Katoul Branch

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, Aliabad Katoul Branch

Full name of responsible person

Elham Valipour Eskandarkolaii

Position

Master of science student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

University blvd

City

Aliabad katul

Province

Golestan

Postal code

4941793451

Phone

+98 17 3422 2300

Email

valipoureelham@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Ali Abad katol Branch

Full name of responsible person

Nafise Hekmatipour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Islamic Azad University, Ali Abad katol Branch

Street address

University Blvd

City

Ali Abad katol

Province

Golestan

Postal code
93451-49417
Phone
+98 911 279 9047
Fax
+98 17 3422 5673
Email
n_hekmati68@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Aliabad Katoul Branch
Full name of responsible person
Elham Valipour Eskandarkolaii
Position
Masters of science student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
University blvd
City
Aliabad Katoul
Province
Golestan
Postal code
4941793451
Phone
+98 17 3422 2300
Email
valipoureahme@gmail.com

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

There is no more information

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some personal data, such as information about the main outcome, can be shared.

When the data will become available and for how long

The access period starts from 2022

To whom data/document is available

Researchers

Under which criteria data/document could be used

Researchers if they want to use the available data with the permission of the original researchers.

From where data/document is obtainable

Islamic Azad University, Aliabad Katoul Branch, Nafiseh Hekmatipour, 01734237933

What processes are involved for a request to access data/document

Approval of the Vice Chancellor for Research, Islamic Azad University, Aliabad Katoul Branch

Comments

2 articles will be extracted from this proposal.