Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of applying virtual yoga technique on depression amongst female adolescents with type 1 diabetes

Protocol summary

Study aim

Determining the effect of using virtual yoga technique on depression in female adolescents with type 1 diabetes referred to Imam Reza (AS) clinic in Shiraz in 1398

Design

A clinical trial with a control group, community-based and pragmatic, with parallel, randomized, random allocation of study samples in the intervention and control groups using simple random sampling

Settings and conduct

Refer to Diabetes Clinic of Imam Reza Clinic of Shiraz, Easy-Targeted Sampling from Adolescents with Type 1 Diabetes Eligible

Participants/Inclusion and exclusion criteria

Inclusion criteria:1-Girl gender2-The age range of adolescents is between 12 and17 years3-No other chronic illness4-Adolescent able to perform yoga exercises as per physician's diagnosis. Exclusion criteria:1-Adolescents and parents unwilling to pursue research cooperation. 2-Unable to continue the exercise on the basis of patient's consent and physician's approval. 3-Missing 2 training sessions4-Incidence of illness and accidents.

Intervention groups

8 sessions of yoga classes for 8 weeks are held virtually for the experimental group under the supervision of an instructor and researcher. The first session of the yoga class is held online using the adobe connect application. The rest of the sessions are in the form of sending short videos virtually. Yoga training CDs and report forms will be provided to the test group. In the control group, routine clinic care is performed.

Main outcome variables

Average Depression

General information

Reason for update

Due to the prevalence of Covid-19 disease and the lack of referral of adolescents with diabetes to Imam Reza (AS) clinic, yoga technique sessions are held virtually. For this purpose, adolescents with type 1 diabetes are randomly divided into control and intervention groups and are asked to complete a depression questionnaire before and 2 months after the start of the study. In the control group, routine clinic care is provided, and in the intervention group, 8 sessions of yoga classes are held virtually for 8 weeks (one session per week) under the supervision of an instructor and a researcher. The first session of the yoga class is held online. The rest of the sessions are in the form of short videos.The duration of these videos is 15 to 20 minutes for each session, and a 30-minute video that includes repetitive movements and each session must be done is sent to the teens in the first session. At the end of the control group, a yoga training session will be sent virtually in the form of a short video.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191203045590N1**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **prospective**

Last update: **2020-08-12, 1399/05/22**
Update count: **1**

Registration date

2019-12-26, 1398/10/05

Registrant information

Name

Sedighe Sedigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3363 6307

Email address

sedigh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-09-11, 1399/06/21

Expected recruitment end date
2020-11-11, 1399/08/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of applying virtual yoga technique on depression amongst female adolescents with type 1 diabetes

Public title
The effect of applying virtual yoga technique on depression amongst female adolescents with type 1 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Girl gender. The age range of adolescents is between 12 and 17 years. No other chronic illness. Adolescent able to perform yoga exercises as per physician's diagnosis.

Exclusion criteria:
Any changes in body posture during exercise Unwillingness to perform regular exercises throughout the study Unwilling to continue to participate in research Severe decrease in blood sugar and death of the patient

Age
From **12 years** old to **17 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Examples are simple random sampling with two testing and control groups . they will be divided . First , all qualified people are given a number . then The numbers are registered on a card . all the numbers in the box were arranged in a ballot box People are selected . The selected people will enter the group A and the rest are in Group B .The two groups A and B are one by the accident group and one control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The study participants were divided into two experimental and control groups. The participants in the study group received one type of intervention and at the end of the study they were compared with the control group who did not receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical al Sciences

Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
713451978

Approval date
2019-09-15, 1398/06/24

Ethics committee reference number
IR.SUMS.REC.1398.839

Health conditions studied

1

Description of health condition studied
Diabet

ICD-10 code
E10

ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Depression

Timepoint
Before intervention, 8 weeks after intervention

Method of measurement
Childrens Depression Inventory (CDI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before the intervention, the Depression Questionnaire is completed by the adolescents in the test groups. 8 sessions of yoga classes for 8 weeks (one session per week) are held virtually for the test group under the supervision of an instructor and researcher. The first session of the yoga class is held online using the adobe connect application. The rest of the sessions are in the form of sending short videos virtually. The duration of these videos is 15 to 20 minutes for each session, and a 30-minute video that includes repetitive movements and each session must be done is sent to the teens in the first session. Yoga training CDs and reporting forms (self-report checklist: to control and track diabetic adolescents from exercise) are provided to the test group and they are asked to complete a daily report form. These sessions will include teaching the principles and goals of yoga and performing posture, breathing, relaxation and meditation exercises (meditation from the third session) under the supervision of a yoga instructor. The researcher makes the necessary follow-ups regarding the performance of exercises by adolescents by telephone. Teenagers also make videos of their practice, and the instructor provides observation and feedback. After the intervention, the depression questionnaire is completed again by the adolescents in the test groups.

Category
Treatment - Other

2

Description
Control group: Before starting the study, the depression questionnaire is completed by the adolescents in the control group and the adolescents in this group receive their routine treatments without any intervention. In order to observe the ethical principles, after the study, a yoga training session in the form of a short video will be sent to the control group. An educational CD will also be reproduced and made available to them. The depression questionnaire is completed again by the adolescents in the control group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Clinic of Imam Reza Clinic

Full name of responsible person
Razie Attar

Street address
Imam Reza Clinic Next to Namazi Hospital, Namazi Square, Shiraz

City
Shiraz

Province
Fars

Postal code
714737-71348

Phone
+98 71 3212 7605

Fax
+98 71 3647 4673

Email
bonyaddiabet.az13@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Younes Qasemi

Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
713451978

Phone
+98 71 3235 7282

Fax
+98 71 3230 7594

Email
vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person

Zahra Hadian Shirazi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Shiraz University of Medical Sciences, Namazi Square, Zand Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7193613119

Phone
+98 71 3647 4254

Email
zhadian@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Zahra Hadian Shirazi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Shiraz University of Medical Sciences, Namazi Square, Zand Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7193613119

Phone
+98 71 3647 4254

Email
zhadian@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Sedighe Sedigh

Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Shiraz University of Medical Sciences, Namazi Square, Zand Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7193613119

Phone
+98 71 3647 4254

Fax

Email
sedigh@sums.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