

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

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Shiraz

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714737-71348

#### Phone

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#### 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

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##### Province

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##### 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**

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## Person responsible for scientific inquiries

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## 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

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## 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