

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluate the effect of peer digital storytelling on depression, emotional distress and burnout of patients with type 1 diabetes referring to selected health centers in Isfahan in 2023

#### Protocol summary

##### Study aim

Determining the effect of peer digital storytelling on depression, emotional distress and burnout in patients with type 1 diabetes

##### Design

This is a single-blind randomized clinical trial study using software on 60 patients with type 1 diabetes.

##### Settings and conduct

This study will be conducted in the health centers of Isfahan city and the collected data will be analyzed after coding by a researcher who is not aware of the control and intervention groups.

##### Participants/Inclusion and exclusion criteria

1. Adults with type 1 diabetes for at least 6 months
2. Lack of physical disability such as blindness or deafness
3. Not taking psychiatric drugs
4. Minimum reading and writing literacy
5. Access to social media and access to the Internet
6. No addiction to drugs, psychedelics and alcohol
7. No disease besides diabetes as approved by the attending physician and according to the contents of the medical file

##### Intervention groups

The study is two groups. In the intervention group, people with type 1 diabetes participate in peer digital storytelling sessions. In the control group, they receive routine services from the centers.

##### Main outcome variables

Diabetes burnout, Diabetes emotional distress and Depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170625034743N2**  
Registration date: **2023-07-05, 1402/04/14**

Registration timing: **prospective**

Last update: **2023-07-05, 1402/04/14**

Update count: **0**

##### Registration date

2023-07-05, 1402/04/14

##### Registrant information

###### Name

Leila Mardanian Dehkordi

###### Name of organization / entity

Isfahan University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7541

###### Email address

mardanian@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-10-23, 1402/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluate the effect of peer digital storytelling on depression, emotional distress and burnout of patients with type 1 diabetes referring to selected health centers in Isfahan in 2023

## Public title

Evaluate the effect of peer digital storytelling on depression, emotional distress and burnout of patients with type 1 diabetes

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

1. Adults with type 1 diabetes for at least 6 months 2. Willingness to participate in research 3. Persian-speaking 4. Lack of physical disability such as blindness or deafness 5. Not taking psychiatric drugs 6. Minimum reading and writing literacy 7. Access to social media and access to the Internet 8. No addiction to drugs, psychedelics and alcohol 9. No disease besides diabetes as approved by the attending physician and according to the contents of the medical file

### Exclusion criteria:

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is done in two steps. First, as a cluster of centers covered by comprehensive health service centers in the city of Isfahan, according to the equality of the covered centers, 5 centers are randomly selected (lottery) and if no sample is provided, one center is randomly added. Then, from each center according to the proportional allocation method (based on the ratio of type 1 diabetic patients covered by that center to the total number of diabetic patients in the selected centers, this ratio is observed in the sampling) through the Sib system and from Al Ibrahim's specialized clinic. Through the existing list, eligible patients are selected to enter the study and are randomly placed into two experimental and control groups through the software.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The researcher who conducts the data analysis will be unaware of the control and intervention groups and will analyze the data that has been coded.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Hezarjarib Street, Isfahan University of Medical Sciences, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2023-06-25, 1402/04/04

#### Ethics committee reference number

IR.MUI.NUREMA.REC.1402.043

## Health conditions studied

### 1

#### Description of health condition studied

Type 1 diabetes

#### ICD-10 code

E10

#### ICD-10 code description

Type 1 diabetes mellitus

## Primary outcomes

### 1

#### Description

Diabetes burnout

#### Timepoint

Before intervention and quickly and one month after intervention

#### Method of measurement

Diabetes burnout questionnaire

### 2

#### Description

Diabetes emotional distress

#### Timepoint

Before intervention and quickly and one month after intervention

#### Method of measurement

Diabetes distress questionnaire

### 3

#### Description

Depression

#### Timepoint

Before intervention and quickly and one month after intervention

#### Method of measurement

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, the participants complete demographic, depression, emotional distress, and diabetes burnout questionnaires before starting the study, and then receive peer digital stories during 4 weekly sessions. Immediately and one month after the end of the intervention, the questionnaires are filled out again by the participants.

#### Category

Treatment - Other

### 2

#### Description

Control group: In the control group, demographic, depression, emotional distress, and diabetes burnout questionnaires are completed before the start of the study, and the participants receive the usual care and counseling provided by health centers and clinics. At the end (immediately and one month after the end of the intervention) depression, emotional distress and diabetes burnout questionnaires are completed again by the participants. At the end of the study, digital stories will be provided to the control group.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan comprehensive health service centers

##### Full name of responsible person

Leila Mardanian Dehkordi

##### Street address

Deputy of health district, next to Amin Hospital, Ibn Sina St., Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8148653374

##### Phone

+98 31 3447 6060

##### Email

health@mui.ac.ir

##### Web page address

<https://phc.mui.ac.ir>

### 2

#### Recruitment center

##### Name of recruitment center

Al Ibrahim Diabetes Clinic

##### Full name of responsible person

Leila Mardanian Dehkordi

##### Street address

East Balal St., Lahore St., Isfahan, Iran

##### City

Isfahan

##### Province

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##### Postal code

8154645731

##### Phone

+98 31 3225 8444

##### Email

diabets\_ngo@yahoo.com

##### Web page address

<http://www.diabet-charity.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Gholamreza Asgari

##### Street address

Deputy of Research and Technology, Building No.4, Isfahan University of Medical Sciences and Health Services, Hazarjarib St., Isfahan

##### City

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##### Phone

+98 31 3668 7898

##### Email

askari@mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Sheyda Zamani

**Position**

Nursing student in Master Science

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezarjarib St., Isfahan, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The collected data will be published in a paper.

**When the data will become available and for how long**

1 year after study

**To whom data/document is available**

Reviewers and authors of the article

**Under which criteria data/document could be used**

Data are available from the authors upon reasonable request with the permission of [name of third party].

**From where data/document is obtainable**

corresponding author

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

Request from corresponding author through an email.

**Comments**