

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of life skills-based interventions on stress, anxiety and depression in patients with type 1 diabetes

Protocol summary

Summary

(1) The main purpose of this project was to determine the effect of life skills-based interventions on stress disorders, anxiety and depression in type 1 diabetic patients referred to the Urmia Diabetes Association in 96 (2). This study was a clinical trial study with "pretest and Post-test with control group ". (3) A final sample of 80 patients with type 1 diabetes was selected by available sampling method and assigned to two groups of intervention (n = 40) and control group (n = 40) by random allocation method. The data are The study will be compiled by demographic questionnaire and DASS-21 questionnaire. (4) Entry criteria for participants including: Type 1 diabetes mellitus, age range of 12-40 cases at the Diabetes Association, in terms of physical and mental health, ability to answer questions, have reading and writing skills, addiction to non-narcotics Not attending 6 months in the life skills workshop, according to a patient's opinion. (5) Interventions: At first, both groups undergo a pretest, and then the intervention group participates in 9 sessions of one-fifth-hour lifestyle education that is conducted in collaboration with a psychologist. The control group does not receive any intervention. Finally, the post-test will be applied to both groups after the intervention and 2 months later. The results of the two groups will be compared. (6) The main outcome variable is stress, anxiety and depression.

General information

Acronym

Life Skills Training(LST)

IRCT registration information

IRCT registration number: **IRCT2017082326347N6**

Registration date: **2017-11-07, 1396/08/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-07, 1396/08/16

Registrant information

Name

Soheyla Ahangarzade Rezaei

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

rezaei.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Urmia University Of Medical Scinces

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of life skills-based interventions on stress, anxiety and depression in patients with type 1 diabetes

Public title

The effect of life skills-based interventions on stress, anxiety and depression in patients with type 1 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Entry criteria: Type 1 diabetes; Age range of 40-40; Case records in the Diabetes Association; Physical and mental health; Ability to answer questions; Have a reading and writing literacy; Drug addiction; Do not attend. 6 months ago at the store of life skills according to the patient's opinion

Age

From **84 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The randomized assignment of the groups into two groups is as follows: on the sheets of numbers 1 to 80 will be written and, after being placed in a container, will be asked from patients, each of which will be one In the end, individuals with paired numbers in the intervention group and individuals with numbers in the control group will be placed at random.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Central Headquarters of Urmia University of Medical Sciences,Organs Quarter,Resalat Boulevard,Urmia

City

Urmia

Postal code

5714783734

Approval date

2017-07-16, 1396/04/25

Ethics committee reference number

IR.umsu.rec.1396.101

Health conditions studied

1

Description of health condition studied

Diabets

ICD-10 code

E10.0,E10.

ICD-10 code description

With coma,With ketoacidosis ,With renal complications,With ophthalmic complications ,With neurological complications ,With peripheral circulatory complications ,With other specified complications ,With multiple complications ,With unspecified complication

Primary outcomes

1

Description

Stress

Timepoint

Before intervention - after intervention - two months after intervention

Method of measurement

Dass-21 questionnaire

2

Description

Anxiety

Timepoint

Before intervention - after intervention - two months after intervention

Method of measurement

Dass-21 questionnaire

3

Description

Depression

Timepoint

Before intervention - after intervention - two months after intervention

Method of measurement

Dass-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group was first measured by the DASS-21 questionnaire. The mean of depression, anxiety and stress was measured and then the intervention group in 9 sessions of life skills training included self-awareness, stress management, problem-solving and effective communication skills, which was conducted by

a psychologist Runs, participate. Then, the mean of depression, anxiety and stress after the completion of the intervention and two months after the intervention measure and the results are compared

Category

Other

2

Description

Control group: This group does not receive any intervention. The mean of stress, anxiety and depression was compared by using the DASS-21 questionnaire in the pre-intervention, post-intervention, and 2-month intervals after intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Diabetes Association

Full name of responsible person

Mr. Enari

Street address

Urmia Diabetes Association, Municipality Health Building, Corner of Vesal Street, Mehrab Ave, Facing Mosalli, Resalat Boulevard, Orumieh

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research Of Urmia University Of Medical Scinces

Full name of responsible person

Ms. Ghaffarzadeh

Street address

Central Headquarters of Urmia University of Medical Sciences,Organs Quarter,Resalat Boulevard,Urmia

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor For Research Of Urmia University Of Medical Scinces

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Urmia Nursing and Midwifery Faculty

Full name of responsible person

Soheila Ahangarzadeh Rezaei

Position

PHD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Pardis Nazlou, 11 km Road sero

City

Urmia

Postal code

Phone

+98 443275496361

Fax

Email

nursing-college@umsu.ac.ir

Web page address

http://www.nm.umsu.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia Nursing and Midwifery Faculty

Full name of responsible person

Sayedeh Farideh Hashemi

Position

Student of Master of Psychiatric Nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Pardis Nazlou, 11 km Road sero

City

Urmia

Postal code

5551338335

Phone

+98 44 3275 4961

Fax

Email

f.hashemi9062@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Alzahra Hospital Tabriz University of Medical Sciences

Full name of responsible person

Sayedeh Farideh Hashemi

Position

Master's student of psychiatric nursing

Other areas of specialty/work**Street address**

AlZahra Educational Center, Baghshomal Cross
road, South artesh Street, Tabriz City, East Azarbaijan

City

Tabriz

Postal code

5138665793

Phone

+98 413553916163

Fax

Email

alzahrahospital@tbzmed.ac.ir

Web page address

alzahrahosp.tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty