Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Soheyla Ahangarzade Rezaei
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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

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Person responsible for scientific inquiries

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Student of Master of Psychiatric Nursing

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Person responsible for updating data

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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