

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of education on self-efficacy and diabetes-related outcomes in patients with type 1 diabetes: A follow-up care model based on online messaging service

Protocol summary

Self-efficacy , Adherence to treatment, Self-care

Study aim

Determining the impact of continuous care model based on online messaging service on self-efficacy and diabetes-related outcomes in patients with type 1 diabetes

Design

A single-center, single-blinded, parallel-group, randomized controlled trial with balanced randomization (1:1) will be conducted over three months.

Settings and conduct

Patients with Type 1 diabetes who are admitted to the internal ward of Shahid Mustafa Khomeini Hospital, Ilam, Iran will be invited to participate in this study. Eligible participants will be randomized using permuted block randomization with allocation concealment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being clinically diagnosed with type 1 diabetes Mellitus at least 6 months. The age range of 18-65 years. Willingness to participate in the research. No medical history of having cognitive deficits or mental illness. No acute medical condition in the last 6 months. Having the ability to read and write Persian. Have a mobile phone and be able to use it. Exclusion criteria: Type 1 diabetes combined with severe complications which would interfere with self-care such as DKA, heart attack, and angina. Have hemolytic anemias, and hemoglobinopathies. Known hearing impairment. Known vision impairment. Unable to participate in the education program (for example are housebound or are participating in another research study).

Intervention groups

Intervention group: The duration of training based on the online messenger service is 3 months (12 weeks) which will be sent to patients 3 times a week in the form of text and videos related to type 1 diabetes. The control group will receive routine and usual care related to diabetes

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221029056335N1**

Registration date: **2023-06-17, 1402/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-17, 1402/03/27**

Update count: **0**

Registration date

2023-06-17, 1402/03/27

Registrant information

Name

Mohammad amir Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3222 5234

Email address

mamirsadeghi96@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education on self-efficacy and diabetes-related outcomes in patients with type 1 diabetes: A follow-up care model based on online messaging service

Public title

Investigating the effect of education on the self-efficacy of patients with diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being clinically diagnosed with type 1 diabetes Mellitus at least 6 months, Age range 18-65 years, Willingness to participate in the research, No medical history of having cognitive deficits or mental illness, No acute medical condition in the last 6 months, Having the ability to read and write Persian, Have a mobile phone and be able to use it

Exclusion criteria:

Have type 1 diabetes combined with severe complications which would interfere with self-care such as DKA, heart attack, and angina, Have hemolytic anemias, hemoglobinopathies, Known hearing impairment, Known vision impairment, Unable to participate in the education program (for example are housebound or are participating in another research study).

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

After baseline assessment eligible patients will randomly be assigned to one of two treatment groups using permuted block randomization with allocation concealment. Block randomization will be conducted by Random Allocation Software 2.0, with a block size of four, and an allocation ratio of 1:1. The main use of Random Allocation Software is to produce simple or block randomized sequences for parallel group trials. Participants will be sequentially allocated to the treatments in the order in which they were recruited. Intervention assignment will be ascertained using sealed, opaque envelopes with consecutive numbering. The investigator who opens the envelopes and implements assignments will not be involved in the generation and allocation concealment. Due to the nature of the intervention, patients and the study researchers will be

aware of the allocated treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, neither participants nor researchers can be blinded. This is a single-blinded study. The assessor (who will assess the outcome measures) and the data analyzer will be blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ilam University of Medical Sciences

Street address

Pazhohesh Blvd, Ilam University of Medical Sciences, Ilam

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2022-10-24, 1401/08/02

Ethics committee reference number

IR.MEDILAM.REC.1401.134

Health conditions studied**1****Description of health condition studied**

Type 1 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

self-efficacy

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Sharr General Self-Efficacy Questionnaire

2

Description

Adherence to treatment

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

medanlo Questionnaire of adherence to treatment

3

Description

self care

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Tobert self-care questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The education intervention package consisted of text, educational illustrations, and movie clips. The intervention content is based on the Iranian Ministry of Health Guideline on the management of type 1 diabetes which involves education on self-care management, lifestyle modification (including diet, physical activity, monitoring), and medications. This education will be provided on an individual basis using online messaging applications (Soroush, Gap, Ita, Baleh, WhatsApp, and Telegram). The intervention group will receive 36 sessions of type 1 diabetes education within 12 weeks, three times per week. Each education session will last 10 minutes. In addition, the researcher will provide one follow-up call every two weeks to participants in the experimental group. The length of each call will be varies depending on the participant. All telephone calls will be arranged at the participants` convenience times. The purpose of calling is to foster continued performance accomplishment via verbal persuasion and answering participants' questions (if any). In addition, Telephone follow-up will provide continuous enhancement skills fostering, goal-setting sharing, and mental support for diabetics.

Category

Lifestyle

2

Description

Control group: They will receive routine care related to type 1 diabetes and no additional education will be delivered to this group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital

Full name of responsible person

Mohammad Amir Sadeghi

Street address

Mostafa Khomeini Hospital, Shahid Keshvari Square, Ilam, Iran

City

Ilam

Province

Ilam

Postal code

6931934833

Phone

+98 84 3333 8228

Email

mamirsadeghi96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Abbas Maleki

Street address

Ilam University of Medical Sciences , Pazhohesh Blvd , Ilam, Iran

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3223 5724

Email

maleki-a@medilam.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Amir Sadeghi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 4, Zakaria Steet., Sanaye Blvd

City

Ilam

Province

Ilam

Postal code

6931345715

Phone

+98 84 3222 5234

Fax**Email**

Mamirsadeghi96@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Amir Sadeghi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 4, Zakaria Steet., Sanaye Blvd

City

Ilam

Province

Ilam

Postal code

6931345715

Phone

+98 84 3222 5234

Fax**Email**

Mamirsadeghi96@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Amir Sadeghi

Position

Nurse

Latest degree

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Nursery

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No 4, Zakaria Steet., Sanaye Blvd

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6931345715

Phone

+98 84 3222 5234

Fax**Email**

Mamirsadeghi96@gmail.com

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