Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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
Self-efficacy , Adherence to treatment, Self-care

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 (Sorush, 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
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

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