

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### Effect of family Centered\_Education on Treatment Adherence and Glycosylated Hemoglobin in Patients with Type 1 Diabetes

#### Protocol summary

##### Study aim

The effect of family-centered education on treatment adherence and glycosylated hemoglobin in patients with type 1 diabetes

##### Design

In a quasi-experimental clinical trial with pretest-posttest design, 60 patients with type 1 diabetes who met the inclusion criteria will be allocated into intervention and control groups using random allocation software.

##### Settings and conduct

This study will be conducted in Urmia Diabetes Association. The researcher will meet the patients in an introductory session. After sufficient explanations about the study, patients and active family members who sign the consent form will enter the study and receive family-centered education for 12 sessions. The intervention group (active family member) will be divided into three small groups of 10 patients, and according to their educational needs, four sessions will be performed for each group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were: 1. Diagnosis of type 1 diabetes, 2. Not having mental illness, 3. Age between 15 and 30 years, 4. Willingness to participate in the study, 5. Lack of early and late complications, 6. Living with family, 7. Not having a private nurse. Exclusion criteria included: 1. Unwillingness to participate in the study, 2. Having family member as a medical staff, 3. Having physical disability, 4. Inability to read and write of patient or family member.

##### Intervention groups

Receiving family-centered education by 30 patients in the intervention group and receiving the routine care of the Urmia Diabetes Association by the control group

##### Main outcome variables

Treatment adherence (Primary outcome), glycosylated hemoglobin and fasting blood sugar (Secondary outcomes)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131112015390N4**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

##### Registration date

2020-08-21, 1399/05/31

##### Registrant information

##### Name

Naser Parizad

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 1348 7649

##### Email address

parizad.n@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-04-18, 1399/01/30

##### Actual recruitment start date

2020-01-21, 1398/11/01

##### Actual recruitment end date

2020-04-18, 1399/01/30

##### Trial completion date

2020-04-18, 1399/01/30

**Scientific title**

Effect of family Centered\_Education on Treatment Adherence and Glycosylated Hemoglobin in Patients with Type 1 Diabetes

**Public title**

The effect of family-centered education on treatment adherence and glycosylated hemoglobin

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of type 1 diabetes for at least one year by a specialist Lack of mental illness with the approval of a specialist Age between 15-30 years Willingness to participate in the study Not having early or late side effects Living with family Not having a private nurse

**Exclusion criteria:**

Unwillingness to participate to the study Having an active family member as a medical staff Having a physical disability Inability to read and write of a patient or active family member

**Age**

From **15 years** old to **30 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants were randomly divided into two intervention (n=30) and control (n=30) groups through simple random allocation. Randomization was performed according to the numbers randomly selected by Random Allocation Software ( Version 1.0.0) in the computer, and participants were divided into intervention or control groups based on pre-designated numbers.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

**Street address**

Urmia University of Medical Sciences Headquarters, Emergency Alley, Resalat Street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Approval date**

2020-01-18, 1398/10/28

**Ethics committee reference number**

IR.UMSU.REC.1398.408

**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**

Mean scores of adherence to treatment

**Timepoint**

Before intervention and 4 months after intervention

**Method of measurement**

Modanloo Adherence to Treatment Questionnaire (MATQ)

**Secondary outcomes****1****Description**

Fasting blood sugar

**Timepoint**

Before intervention and four months of intervention

**Method of measurement**

Laboratory blood samples

**2****Description**

Glycosylated hemoglobin

**Timepoint**

Before intervention and four months after intervention

**Method of measurement**

Laboratory blood samples

**Intervention groups**

## 1

### Description

The patients in the intervention group will be asked to introduce an immediate family member (spouse, parents, child, or sibling) with whom they have the most interaction. Then their educational needs will be assessed and determined using a checklist prepared in advance. The needs assessment will be performed to design and implement the best intervention method and ensure the intervention's effectiveness in achieving the study's objectives. After the needs assessment, the educational program's content will be prepared using a literature review and valid books and articles according to the educational needs of patients and family members and the approval of an endocrinologist. The educational sessions will be held based on need assessment checklists and the needs of patients and their active family members in each group. The intervention group (with active family members) will be divided into three small sub-groups with ten patients each. Four educational sessions will be held for each sub-group. Then, 12 training sessions will be held to empower patients and their active family members in the intervention group. Thus, one session per week will be held for groups one, two, and three on Saturdays, Mondays, and Wednesdays, respectively. Training sessions will be ended in four weeks. The first session topics will be included endocrine physiology, diabetes, types of diabetes, and its symptoms and treatment. In the second session, the importance of adherence to treatment, the reasons for not accepting treatment, and the symptoms and complications of the lack of adherence to treatment procedure will be discussed. The third session will be about diabetes care such as diet, tips to take medications, preventing complications, blood sugar self-monitoring, and foot care. In the fourth session, "Question and Answer Session," the questions and concerns of patients and their active family members will be addressed. The content of each session will be given to the patients' family members to review with their patients and write down what they will learn or the questions they might have to discuss them at the beginning of the following session. It is noteworthy that the two researchers will be presented in all 12 sessions of group discussions and will make the discussion more effective with their guidance when appropriate. After the intervention is over, the patients and family members will be given three months to take care of themselves and keep their illness under control based on the skills they will gain during educational sessions. The pre-designed care checklist will be given to the active members of the patients to fill in based on the care provided for patients and to give it to the researcher at a certain time at the beginning of each week in Urmia Diabetes Association. After four months of the family-centered empowerment education course, all patients will be called to refer to the Urmia Diabetes Association. After taking blood samples from all patients, Modanloo adherence to the treatment questionnaire will be completed again by patients in both groups. Educational packages, including booklets, DVDs, and pamphlets, will also be provided to patients in the control group at the

end of the study.

### Category

Other

## 2

### Description

Control group: They will receive routine education from the Urmia Diabetes Association. Three educational sessions (one and a half hours each) per week are the routine education in the Urmia Diabetes Association. Classes on diabetes, symptoms, and treatment by an endocrinologist on Saturday, nutrition education on diabetes by a nutritionist on Monday, and anxiety reduction classes by a psychiatrist on Wednesday.

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Urmia Diabetes Association

#### Full name of responsible person

Mahsa Mansour

#### Street address

Urmia Diabetes Associationin , in front of the municipal building , corner of Vesal St., Mehrab St., Resalat St.,

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

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#### Phone

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#### Email

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Oroumia University of Medical Sciences

#### Full name of responsible person

Dr Iraj Mohebbi

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Sata Urmia University of Medical Sciences, Emergency Alley, Resalat Street

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parizad.n@umsu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
No

**Title of funding source**  
Mahsa Mansour

**Proportion provided by this source**  
100

**Public or private sector**  
Private

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
Persons

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Oroumia University of Medical Sciences

**Full name of responsible person**  
Mahsa Mansour

**Position**  
Student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

**Street address**  
Unit 44, 4th floor, Shahid Danaeifar block, The third town of Khordad, West Yasemi Street, North Kurdistan Street

**City**  
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**Province**  
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**Phone**  
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parizad.n@umsu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Oroumia University of Medical Sciences

**Full name of responsible person**  
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**Position**  
University Student

**Latest degree**

Bachelor

**Other areas of specialty/work**  
Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Oroumia University of Medical Sciences

**Full name of responsible person**  
Mahsa Mansour

**Position**  
University Student

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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**

Laboratory data on fasting blood sugar and glycosylated hemoglobin and treatment adherence scores

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

۲۰۲۰/۰۷/۲۰

**To whom data/document is available**

University of Medical Sciences Professors

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

Statistical analysis

**From where data/document is obtainable**

parizad.n@umsu.ac.ir

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

by Email

**Comments**