

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of peers support on the fear of hypoglycemia in patients with type I diabetes in Velayat Hospital of Qazvin University Medical Science

Protocol summary

Study aim

Determination of the effect of peer support on the fear of hypoglycemia

Design

Clinical trials with control group, and intervention, based on community with parallel, randomized groups

Settings and conduct

The place of the province is Vilayat Hospital. To select the peers, the researcher by referring to the clinic and the wards of the provincial hospital and referring to the list of patients who during the year received by their counterparts in the form of training classes for one month (weekly two two-hour sessions) They will get diabetes if they are suffering from diabetes.

Participants/Inclusion and exclusion criteria

Entry requirements: Passing for at least 6 months from a written diagnosis of type 1 diabetes by a specialist, non-use of antidepressants and anxiolytics, non-attendance in diabetes classes in the last 6 months Exit Conditions: Incorrect participation in training classes, history of participation in similar research, people with type 2 diabetes

Intervention groups

Intervention in this research is by counterparts, ie peer support is the group's training of peers to patients. Then, the patients in the intervention group, in addition to routine interventional protocols in the clinics or departments, receive interventions from their counterparts in the form of training classes for one month, but there is no intervention in the control group.

Main outcome variables

Fear of hypoglycemia

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20180623040197N1**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **prospective**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Leila Dehghankar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 8034

Email address

l.dehghankar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peers support on the fear of hypoglycemia in patients with type I diabetes in Velayat Hospital of Qazvin University Medical Science

Public title

The peers support on the fear of hypoglycemia in patients with type I diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Having informed consent to participate in the study • Passing for at least 6 months from a written diagnosis of type 1 diabetes by a specialist physician • Reading and writing skills • Lack of physical and psychological disabilities • Non-use of antidepressants and anxiolytics • Non-attendance classes About diabetes in the last 6 months • having enough time to attend group meetings • making direct telephone calls with the patient or active member of the family • the age group 16 to 40 • being able to speak in Farsi
Exclusion criteria:
 • History of the company in the same research • Disease that has type 2 diabetes. • Absence more than 2 sessions

Age
From **16 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate to the control and test groups, the random block method is used 3. By selecting 20 blocks of 3 randomly, from 6 blocks, we will reach the desired volume. The intervention group is randomly divided into 4 groups, and an equal person is assigned to each group randomly and by gender.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin Medical Ethics Committee

Street address

Qazvin, bahonar

City

Qazvin

Province
Qazvin

Postal code
43184-34197

Approval date
2018-05-16, 1397/02/26

Ethics committee reference number
IR.QUMS.REC.1397.032

Health conditions studied

1

Description of health condition studied

Diabet

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

reduction the fear of hypoglycemia

Timepoint

The beginning of the study and one month later intervention

Method of measurement

Hypoglycemia fears questionnaire

Secondary outcomes

1

Description

Glucose control

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Training through peers to patients in a month for 8 sessions in person, along with a training booklet.

Category

N/A

2

Description

Control group: Control group: Patients do not see any training but routine training in the department

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat

Full name of responsible person

leila dehghankar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

leila dehghankar

Position

instructor, Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

leili yekefallah

Position

Assistant Professor, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

After the article is published, it is possible to access data

To whom data/document is available

All interested

Under which criteria data/document could be used

To conduct research

From where data/document is obtainable

Email Researcher

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

Email researcher and send data

Comments