

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of peer coaches education on self care activities and its related confidence in adolescents with type 1 diabetes mellitus: a randomized controlled trial

Protocol summary

Summary

(1) Objectives: The effect of peer coaches education on self care activities and its related confidence in adolescents with type 1 diabetes mellitus. (2) Design: This study is a randomized clinical trial with two groups (intervention and control). Because of lack of similar studies, the sample size will be measure by pilot studies. The participants will collect with inclusion and exclusion criteria and assign randomly to experimental and control groups. (3) Setting and conduct: four session educational intervention in 2 hours for 4 day with group discussion, question and answer For adolescents who have been selected as coach of the Iranian Diabetes Association will be in Tehran. Then three sessions a week part provide will by the same instructor in the adolescents to other adolescents center. (4) Participants: adolescents with type 1 diabetes mellitus that have Inclusion and exclusion. (5) Intervention: These interventions designed for adolescents by the questions in scale. Before and one month after the last training session, the Summary of Diabetes Self-Care Activities Questionnaire and The Confidence in Diabetes Self-Care Scale will be completed by the all adolescents (intervention and control group). (6) Main outcome measures variables: self care activities and its related confidence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060912264N2**
Registration date: **2014-08-01, 1393/05/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-01, 1393/05/10

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences (Seyed kazem Shakori)

Expected recruitment start date

2013-08-24, 1392/06/02

Expected recruitment end date

2013-10-05, 1392/07/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peer coaches education on self care activities and its related confidence in adolescents with type 1 diabetes mellitus: a randomized controlled trial

Public title

The effect of peer coaches education on self care activities and its related confidence in adolescents with type 1 diabetes mellitus: a randomized controlled trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion of and adolescents with peer educators to study: ● A diagnosis of diabetes: ● Being aware of the diagnosis of type I diabetes: ● Having medical records in Iranian Diabetes Society: ● Having age between 13 to 18 years: ● They should last at least 15 months after the diagnosis of type 1 diabetes: ● The ability to read and write: ● Access to telephone: ● No other pathological or chronic illness: Adolescents with Specific inclusion of for study entry: ● Diabetes and endocrinology specialist, medical records and confirmed that they were not able to control the disease: Specific entry inclusion of to the study of peer educators: ● Diabetes and endocrinology specialist in their medical records confirmed that they were able to control the disease: ● Sufficient information regarding a diabetes self-care in adolescents and its control method: ● Ability to communicate with peers: Adolescents with peers and exclusion of the study: ● Failure at any stage of the study questionnaire: ● Not participate in training sessions: ● Participation in another study:

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Not

Secondary trial Id

Not

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of medical sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Postal code

5138947977

Approval date

2013-08-08, 1392/05/17

Ethics committee reference number

9270

Health conditions studied

1

Description of health condition studied

Type 1 diabetes mellitus

ICD-10 code

E10,E11,E1

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Self-care education to adolescents with type I diabetes

Timepoint

Before and one month after intervention

Method of measurement

Summary of Diabetes Self-Care Activities Questionnaire

Secondary outcomes

1

Description

Confidence in Diabetes Self-Care

Timepoint

Before and one month after intervention

Method of measurement

The Confidence in Diabetes Self-Care Scale

Intervention groups

1

Description

The intervention group trained will be provided by the researcher in adolescents with type I diabetes as peer educators 4 training sessions this week will be a 2-hour intervals. Also, a clinical psychologist in a 2-hour training sessions will for peer educators to provide young people with communication. Then the peer educators will train other young people with diabetes 3 sessions of 2 hours of physical education a week and will be held one week

apart, will be used the content of the training sessions and pamphlets, lectures and practical exercises and questions and answers.

Category

N/A

2

Description

And usual care control group by the third meeting held on 3 consecutive days and 4 hours will receive. The teaching methods and the use of the booklet.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetic department of Iran

Full name of responsible person

Dr. Asadolah Rajab

Street address

Diabetic department of Iran, Patris lomombar Street, Satarkhan Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research Deputy in Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Shakouri

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Tabriz University of Medical Sciences, Golgasht Street, Azadi Street.

City

Tabriz

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 Deputy in Tabriz University of Medical Sciences

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

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences.

Full name of responsible person

Elham Nasiri

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Masters of Sciences student

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty