

# 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

Farahnaz Abdollahzadeh

###### Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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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

**Street address**

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

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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

**Position**

Masters of Sciences student

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*