

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Effect of coping skills training on diabetic adolescences self-efficacy, depression, anxiety, stress and quality of life

Protocol summary

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Summary

The aim of this study was to evaluate the effect of coping skills training on self-efficacy, depression, anxiety, stress and quality of life of adolescents with diabetes type 1. A randomized controlled trial was carried out in the diabetic clinic in Emam Reaz Institute affiliated to Shiraz University of Medical Sciences. The adolescents with diabetes type 1 (n = 100) were included in two groups: a coping skills training group (n = 50) and a control group (n = 50). Coping skills training was done in intervention groups for eight sessions, twice a week for 4 weeks. Self-efficacy, depression, anxiety, stress and quality of life were assessed in both groups at baseline and 8 weeks after intervention.

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2015-05-01, 1394/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050113690N4**

Registration date: **2015-05-16, 1394/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Masoume Rambod

Name of organization / entity

Shiraz University of Medical Science

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Iran (Islamic Republic of)

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Email address

Scientific title

Effect of coping skills training on diabetic adolescences self-efficacy, depression, anxiety, stress and quality of life

Public title

Effect of coping skills training on diabetic

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria of this study will be having diabetes type I, being 12-18 years old, having been diagnosed of diabetes for at least the previous 3 months, and being oriented and alert. The exclusion criteria of this study would be included training in six months ago or current participation in any coping skills training.

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shiraz University of Medical Sciences

Street address

71345-1978, 7th floor, shiraz university of medical sciences, beside the Red-Crescent building, Zand Street, Shiraz

City

Shiraz

Postal code

Approval date

2014-05-23, 1393/03/02

Ethics committee reference number

93-01-86-7217

Health conditions studied

1

Description of health condition studied

diabetes type 1

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Self-efficacy

Timepoint

First day of study and 8th week

Method of measurement

General self-efficacy

Secondary outcomes

1

Description

Depression, anxiety, and stress

Timepoint

First day and 8th week

Method of measurement

Depression, Anxiety, and Stress Scales (DASS)

2

Description

Quality of life

Timepoint

First day of study and 8th week

Method of measurement

War & Sherbon SF- 36

Intervention groups

1

Description

Intervention: Coping skills training (CST) was performed by lecture, question and discussion, and role playing. In the lecturer, power points were prepared. The intervention was performed by a MS of pediatric nursing who has been experiencing in the field of diabetes for 15 years. The contents CST were as follow: Session 1, "Introduction": at the first session, the interventionist introduces herself to the participants and then subjects introduce themselves. Then the content of the CST was given to them. Session 2, "Recognizing the disease": In this session, information about diabetes disease, etiology, symptom, and treatment were given to the adolescents. Session 3, "Principles of self-care": In this session, teaching about effect of disease on adolescents, and self-care (nutrition, physical activity, prevention of infection, vaccination, drug, and . . .) were given. Session 4, "Stress management": In this session, the subjects expressed their feelings about diabetes, symptoms, complication, and their fear and anxiety. Moreover, information about stress' psych-somatic symptoms, factors which increasing stress, and strategies to decrease it and methods of increasing self-esteem were described for subjects. Session 5, "Coping strategies": in this session, interventionist described about coping and effective and ineffective coping strategies. Session 6: "Relaxation Techniques": in this session the importance of relaxation techniques in decreasing stress and improving coping were discussed. Interventionist trained the subjects to do breathing exercises and muscle relaxation, two times a day (9AM and 5 PM). Session 7, "Problem Solving": In this session, the interventionist explained the concept of problem, problem solving, problem-solving stages and the significance of problem solving in managing and coping with stress. Session 8, "Assessment" In this session, the CST and the interventionist are evaluated. Moreover, answers to adolescents' questions were given.

Category
Behavior

2

Description

control: The participant in control group received the routine care of clinic without any interventions.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetic clinic in Emam Reaz Institute affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Skandari

Street address

71345-1978,7th floor, Shiraz University of Medical Sciences, beside the Red-Crescent building, Zand Ave, Shiraz.

City

Shiraz

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 of Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person

Masoume Rambod

Position

MS and PhD Candidate

Other areas of specialty/work

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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