

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of Quality of Life Education on Self-concept in patients with type 2 diabees

Protocol summary

Summary

Type 2 diabetes mellitus is a chronic disease with severe late complications and high mortality. The prevalence of type 2 diabetes in Iran is 4-4.5% and in population aged above 30 years is greater than 14%. Further, although glycemic control, the development of complications and mortality represent critical outcomes in people with type 2 diabetes, quality of life (QOL) outcomes are also important. Quality of life represents a broad, multi-dimensional concept that reflects an individual's sense of well-being or satisfaction with life circumstances, and self concept is one's image of oneself. Individuals with a positive self concept are better able to develop and maintain inter personal relationship and resist psychological and physical illness. The aim o f this study is determine the effect of quality of life education on self concept of patients with type 2 diabetes. This investigation is a clinical trial study on 123 patients with type 2 diabetes that referred to clinic of diabetes in Emam Khomeini hospital of Ardebil. These participants were known or newly diagnosed type 2 diabetes with range age 30-70, and divided randomly in two groups :case (61 persons) and control group(62 persons). The information was gathered using 4 questionnaires. The first one was socio-demographics , second one was Beck's self concept questionnaire, third one Rosenberg's self esteem questionnaire, and the last one was body image questionnaire. The quality of life education as intervention factor was performed using face-to-face , group teaching methods, and handout to case group. The quality of life education program consist of one weekly group session of 45 minutes for 6 weeks, limited to 8 patients per group. A nurse, a physiotherapist, a dietician, and a psychologist run the sessions. Then, the patients will be evaluated 1 month after the final intervention program by filling the same questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904084256N2**

Registration date: **2010-06-29, 1389/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-29, 1389/04/08

Registrant information

Name

Nasrin Samadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 3057

Email address

na.samadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2010-01-20, 1388/10/30

Expected recruitment end date

2010-06-20, 1389/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Quality of Life Education on Self-concept in patients with type 2 diabetes

Public title

Effect of Quality of Life Education on Self-concept in patients with type 2 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria were: • being 30 years of age or older • having cognitive ability to answer the questions in the research instruments and agreement to take part in the study • Known or newly diagnosed type 2 diabetes • Both genders The exclusion criteria were: • Prior quality of life intervention during the last year • Severe heart, liver, or kidney disease or any incurable cancer • Chronic mental disease history

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **123**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran's Azad university of medical science

Street address

Tehran,shariati street,gholhak

City

Tehran

Postal code

Approval date

2009-04-03, 1388/01/14

Ethics committee reference number

88/3898

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

non-insullin-dependent diabetes mellitus

Primary outcomes

1

Description

self concept

Timepoint

3monthes

Method of measurement

Beck's self-concept test

Secondary outcomes

1

Description

self steem

Timepoint

3monthes

Method of measurement

Rosenberg's questionnaire

2

Description

Body image

Timepoint

3 months

Method of measurement

Body image questionnaire

Intervention groups

1

Description

Case group: The quality of life education programme (physical , Social and Emotional/Spiritual dimation) consist of one weekly group session of 45 minutes for 6 weeks, limited to 8 patients per group by lecture, face to face and handout.

Category

Prevention

2

Description

Control group: Routine care and educational hand outs after the time of intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Emem Khomeini Hospital in Ardebil

Full name of responsible person

Nasrin Samadi

Street address

Ardebil university of medical sciences

City

Ardebil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Nasrin Samadi

Street address

Ardebil university of Medical Science

City

Ardebil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Azad University of Medical Sciences, Tehran's branch

Full name of responsible person

Nasrin Samadi

Position

MSc

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