

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Investigating the effect of education on social stigma, body image and body image coping strategies of diabetic patients

Protocol summary

Study aim

The investigation of the effects of education on social stigma, body image and body image coping strategies in diabetes patients

Design

Two arm parallel group, randomised, clinical trial design of 102 patients with blindness for the statistician. By random allocation software the random blocked of 2 are made.

Settings and conduct

All patients presented to diabetes care delivery centers of Kerman university of medical sciences.

Participants/Inclusion and exclusion criteria

All diabetic patients referred to medical centers of Kerman university of medical sciences with diagnosis of diabetes and having a medical record in these centers; suffering from diabetes for at least three months; lack of self-reported mental illnesses; Age 18-40 years.

Intervention groups

In this study, education is provided to the intervention group by the researcher in four 90-minute sessions during four weeks with the number of 5-15 people. And the researcher follows up people through the available social media. The control group received only the usual care provided by their physician.

Main outcome variables

social stigma, body image, Body image coping strategies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200421047161N2**

Registration date: **2023-01-20, 1401/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-20, 1401/10/30**

Update count: **0**

Registration date

2023-01-20, 1401/10/30

Registrant information

Name

Omsalimeh Roudi Rashtabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

fatroody@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of education on social stigma, body image and body image coping strategies of diabetic patients

Public title

The effectiveness of education on social stigma, body image and coping strategies of diabetic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of diabetes by a specialist doctor Having diabetes for at least three months Age between 18-40 years

Exclusion criteria:
Mental illness and depression diagnosed by a doctor Participation in classes or educational interventions with a similar topic

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, random blocks of 2 are used to assign people to intervention and control groups. A total of 51 binary blocks will be used based on the specified arrangement obtained from the online randomization software
"https://www.sealedenvelope.com/simple-randomiser/v1/lists". In each binary block, one person will be randomly assigned to the control group and one person to the intervention group(Allocation is determined by the software). In the begining, patients assigned to groups based on the allocation determined by software. Each group has 51 member and in total 102 people will enter the study.

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

Ethics Committee of Kerman University of Medical Sciences

Street address

No.2, Ibn Sina Street, Deputy of research and technology Bldg

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-11-13, 1401/08/22

Ethics committee reference number

IR.KMU.REC.1401.361

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E08.0

ICD-10 code description

Diabetes mellitus due to underlying condition with hyperosmolarity

Primary outcomes

1

Description

social stigma

Timepoint

Before entering the study, immediately and one month after the intervention

Method of measurement

diabetes stigma assessment scale

2

Description

body image

Timepoint

Before entering the study, immediately and one month after the intervention

Method of measurement

body image scale

3

Description

Body image coping strategies inventory

Timepoint

Before entering the study, immediately and one month after the intervention

Method of measurement

body image coping strategies inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention protocol is a course that includes four 90-minute weekly training sessions, in

which: the prevalence of diabetes, its types, causative factors, pharmacological and non-pharmacological control methods, lifestyle changes that must be made by the individual for better control of the disease, practical training on how to inject insulin to reduce the development of lipodystrophy and atrophy, familiarization with the concept of stigma and its manifestations, identifying the presence of stigma and its effect on body image, talking about the fears and concerns of patients, familiarizing participants with the concept of body image, Familiarity with adaptive mechanisms in dealing with stress is to identify effective and ineffective adaptive mechanisms in diabetes.

Category

N/A

2

Description

Control group: In this study, the control group receives only the routine care provided to diabetic patients by their physician.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical Centers affiliated to Kerman University of Medical Sciences

Full name of responsible person

Negin Jamshidi

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Omsalimeh Roudi rashtabadi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Omsalimeh Roudi rashtabadi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

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