

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of diabetic rehabilitation on happiness and resilience of type 2 diabetic patients and their family caregivers, referring to diabetes clinics affiliated to Shiraz Medical Science University, in 1998-99

Protocol summary

Study aim

Diabetic rehabilitation effect on type 2 diabetic patients and their family caregivers

Design

A random clinical trial with two groups of intervention and control, based on the story of the central limit in statistics, sample size in the control and intervention groups of 70 and including a 10% drop in Each group consists of 39 people, The samples will be selected first using the available sampling method using a table of random numbers and according to the entry criteria, and then and by completing the questionnaires, random allocation with block randomization list with size 4 blocks of 17 and 2 blocks of 5, a total of 6 blocks, will be in the two groups of control and intervention

Settings and conduct

Shiraz Medical Sciences University-affiliated Clinics, The intervention group will receive diabetic rehabilitation during 8 session of face-to-face visits and 8 phone calls between face -to-face sessions; The control group will receive routine clinical care, training on diet and medication

Participants/Inclusion and exclusion criteria

Inclusion criteria, Diagnosis of diabetes by a specialist, literacy, Patients and their family caregivers willingness and satisfaction with to participate in the study, Physical ability to travel to the clinic; Exclusion criteria, Failure to attend the training session for two consecutive sessions, Mental retardation and mental disorders, Unpleasant events for the samples during the study, The incidence of sickness in the samples

Intervention groups

Intervention Group will receive the Diabetes Rehabilitation Program including diabetes introduction and its complications, treatment and self-control of blood sugar, foot care, nutrition, exercise, happiness and

resilience training and self-management; control group will receive routine clinical care, diet and medication

Main outcome variables

Happiness and Resilience Score with OHQ and CD-RISC scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200313046758N1**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Sepide Sheikh Hasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 8562

Email address

sepideshh112233@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-19, 1399/01/31

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of diabetic rehabilitation on happiness and resilience of type 2 diabetic patients and their family caregivers, referring to diabetes clinics affiliated to Shiraz Medical Science University, in 1998-99

Public title

Diabetic rehabilitation effect on type 2 diabetic patients and their family caregivers

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of diabetes by a specialist literacy Patients and their family caregivers willingness and satisfaction with to participate in the study Physical ability to travel to the clinic

Exclusion criteria:

Failure to attend the training session for two consecutive sessions Mental retardation and mental disorders Unpleasant events for the samples during the study (such as losses and calamities that can aggravate distress or prevent participation in the intervention and continue cooperation in the study) The incidence of sickness in the samples that causes them to be hospitalized and prevents them from participating in the intervention and continuing to work with the researcher

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **156**

More than 1 sample in each individual

Number of samples in each individual: **2**

Since no similar study was found on these patients, which was consistent with the present study objectives, according to the central limit theorem in statistics, the sample size in each group was 35, minimum sample for normal data distribution and Parametric statistical tests usage, and a total of 70 people, including family caregivers, 140 people are considered, and after collecting data and obtaining results by analyzing the power, the power of this sample volume in showing significant differences is calculated and Reported. Taking into account the 10% drop in sample size in each group, 39 people were obtained; 78 people in the intervention

group, 39 patients plus 39 family caregivers, and 78 people in the control group, 39 patients plus 39 family caregivers, a total of 156 participants will become participants.

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are first selected using the available sampling method using a random number table and according to the input criteria, then complete the questionnaires and random allocation using Random allocation software to generate a block randomization list, With the size of 4 blocks of 17 and 2 blocks of 5, a total of 6 blocks will be in two groups of intervention and control, which will be a total of 78 people, 39 people in the intervention group and 39 people in the control group, It should be noted that since the present study will be performed on the patient and his family caregiver, the patient's family caregiver will also be subject to intervention, taking into account the intervention group of 78 people, 39 patients plus 39 family caregivers, and the control group 78 A total of 156 people, 39 patients plus 39 family caregivers, will be included.

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that the questionnaires are distributed at all stages by the researcher and also the data analyzer will be unaware of the random allocation of groups to the intervention and control group, then the outcome assessor and data analyzer from the intervention and control groups they will not be aware.

Placebo

Not used

Assignment

Parallel

Other design features

The present study will be performed on type 2 diabetic patients and their family caregivers, Taking into account the drop of 10%, 39 patients and 39 family caregivers will be included in a total of 78 people in each of the intervention and control groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Fatemeh Nursing and Midwifery Faculty, Namazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code
7936-13119
Approval date
2020-02-16, 1398/11/27
Ethics committee reference number
IR.SUMS.REC.1398.1330

Health conditions studied

1

Description of health condition studied

Type 2 diabetic patients

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Family caregivers of type 2 diabetic patients

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Happiness score

Timepoint

First time, before beginning the intervention, second time, at the end of the 8th session, third time, 5 weeks after the second time

Method of measurement

Oxford Happiness Questionnaire

2

Description

Resiliency score

Timepoint

First time, before beginning the intervention, second time, at the end of the 8th session, third time, 5 weeks after the second time

Method of measurement

Conner and Davidson Resiliency scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group, during 8 weeks and 8 face-to-face sessions will receive the rehabilitation program for

diabetes, including introduction of diabetes education, treatment and its complications, foot care and self-control of blood sugar, nutrition and diet, exercise and amount of daily activity Individual, happiness training that includes, motivation and purpose, communicating with others and receiving support from them, being active, achieving, feeling positive and resilience training that includes, gaining self-awareness skills, positive thinking and optimism, problem-solving skills and anger management, crisis management and coping strategies, and the eighth session of diabetes management itself, which includes a summary of what has been said in previous sessions; And 8 times by phone, every 8 weeks after each training session Present and before the next meeting, based on the rehabilitation program and with the objectives of teaching, and if necessary, re-teaching the topics discussed in the face-to-face meetings, removing ambiguities and answering sample questions and remembering the time and place of the meeting The future will be and at the end of each session, educational pamphlets will be distributed

Category

Rehabilitation

2

Description

Control group, will receive no intervention and will only receive the clinical care routine, training on diet and medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dr. Faghihi Specialty and Specialty Hospital

Full name of responsible person

Sepideh Sheikh Hasani

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Rakhshan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Phone

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Rakhshan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Sepideh Sheikh Hasani

Position

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Other areas of specialty/work

Nursery

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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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Obtaining a license to implement the project from the School of Midwifery Nursing officials, Obtaining a license from the research environment officials, Provide basic and necessary information about research goals to all study people, Collecting data, Educate and provide a summary of training to the control group, The confidentiality of the collected information

When the data will become available and for how long

After completing the study and publishing the results

To whom data/document is available

Private and public centers and Educational centers, where the researcher has taken samples

Under which criteria data/document could be used

Obtaining permission from the faculty and center officials where the sampling was performed and keeping the information confidential

From where data/document is obtainable

Mr. Qasemi Library, Shiraz School of Nursing and Midwifery Library, Zand Street, Shiraz, phone: 00987136474254

What processes are involved for a request to access data/document

Requests for the results will be sent to the Shiraz School of Nursing and Midwifery library, They will be provided with the arrangements made

Comments