

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of educational intervention based on social support theory on the reduction of stress related to COVID-19 in diabetic patients

Protocol summary

Study aim

Determining the effect of educational intervention based on social support theory in reducing stress caused by COVID-19 disease epidemic in people with diabetes

Design

Samples are 212 people. They will be randomly assigned to the intervention and control groups. The study will be parallel groups and single blind. 106 people in the intervention group will be sampled randomly and 106 people in the control group will be randomly selected through multi-stage cluster sampling

Settings and conduct

The participants in the intervention group will be chose from Bandar Abbas Diabetes Clinic and the control group from the comprehensive health service centers of Rudan city. In this study, people do not know their allocation to the the control and intervention groups but the researcher is aware of the allocation so the study is single blind. The groups are also selected from two different cities so that people are least likely to meet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People over 18 years old with a definite diagnosis of diabetes; informed consent; Ability to use cyberspace; Ability to read and write. Non-inclusion criteria: Dissatisfaction with participating in the study; Occurrence of a specific disease; having a serious problem in mental and physical health ; suffering from COVID-19

Intervention groups

In this study, there will be two groups of intervention and control. In the control group, only pre-test and post-test will be done. In the intervention group, after the pre-test, educational intervention will be done according to the structures of the social support model. Telephone conversations and educational content in cyberspace After three months, the effects of the educational intervention will be examined by conducting a post-test.

Main outcome variables

Emotional support; informational support; instrumental

support; appraisal support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049693N1**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

Registration date

2021-02-13, 1399/11/25

Registrant information

Name

Laleh Hassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 6202

Email address

laleh_hassani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-29, 1399/10/09

Expected recruitment end date

2021-02-16, 1399/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of educational intervention based on social support theory on the reduction of stress related to COVID-19 in diabetic patients

Public title
The effect of educational intervention based on social support theory on the reduction of Stress related Covid-19 in Diabetic Patients in Bandar Abbas

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
People over 18 years old with a definite diagnosis of diabetes Satisfaction to enter the study in writing and consciously Ability to use cyberspace Ability to read and write
Exclusion criteria:
Reluctance to enter the study Occurrence of a specific disease in during the study Without having a serious problem in mental and physical health With Covid-19 infection

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **212**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The sampling location of the intervention and control groups is selected in such a way that the least contact between the samples of the two groups is likely. The intervention group will be selected from the patients referred to Bandar Abbas Diabetes Clinic and the control group from the Health Service Centers of Rudan city.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences

Street address
Jomhoori-e-Eslami street

City
Bandarabbas

Province
Hormozgan

Postal code
7919915519

Approval date
2020-10-19, 1399/07/28

Ethics committee reference number
IR.HUMS.REC.1399.370

Health conditions studied

1

Description of health condition studied

Stress caused by Covid 19 in Diabetic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Emotional support

Timepoint

Before the intervention and three months after the intervention

Method of measurement

researcher-made questionnaire

2

Description

Information support

Timepoint

Before the intervention and three months after the intervention

Method of measurement

researcher-made questionnaire

3

Description

Instrumental support

Timepoint

Before the intervention and three months after the intervention

Method of measurement

researcher-made questionnaire

4

Description

Appraisal support

Timepoint

Before the intervention and three months after the intervention

Method of measurement

researcher-made questionnaire

5

Description

Perceived stress caused by COVID-19

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Questionnaire to assess the perceived stress caused by COVID-19

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, educational classes, telephone conversations, sending educational content based on the structures of the social support model in order to reduce the stress caused by COVID-19 in diabetic patients will be done. The type of intervention, types of intervention target groups, educational content, educational methods, number and timing of educational classes will be determined according to the analysis of pre-test

Category

Behavior

2

Description

Control group: No intervention will be performed in the control group, and the control group will receive the usual training of the Health Service Centers. Including: visit by a doctor, follow-up and training by health care providers

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Diabetes clinic

Full name of responsible person

Dr Ahmad Behzad

Street address

Payambar Aazam Medical Educational Complex;
Jomhory Eslami Blvd.

City

Bandar-e Abbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3334 7000

Email

shmh@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr.Teamur Aghamolaei

Street address

Payambar Aazam Medical Educational Complex;
Jomhory Eslami Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3333 7192

Email

taghamolaei@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Laleh Hassani

Position

Science Committee

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Jomhory Eslami Blvd.

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79119916753

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Person responsible for scientific inquiries

Contact

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Bandare-abbas University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data is confidential.

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available