

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of online group support on psychological distress and self-care behaviors of the elderly with type 2 diabetes during the COVID-19 pandemic: a parallel randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of online group support on psychological distress and self-care behaviors of the elderly with type 2 diabetes during the Covid-19 pandemic

Design

Parallel randomized superiority controlled trial, using a random blocking allocation that cannot be blinded and sample size will 90.

Settings and conduct

The research will be performed in Imam Hossein Clinic in Shahroud. Standard questionnaires of diabetes self-efficacy scale and stress, anxiety and depression at the beginning and 7 days after intervention will be completed.

Participants/Inclusion and exclusion criteria

The patient's age is over 60 years; a definitive diagnosis of diabetes by a physician; the ability to access the Internet and online mass communication; has the minimum ability to use smartphones and social networks; absence of psychological disorders; Not participating in other supportive interventions.

Intervention groups

Intervention group: The intervention group received 6 sessions over 3 weeks are held in the form of participation in a group video call (webinar) in the form of lectures, group discussions, questions and answers, slide shows and clips. The outlines of the sessions include (diabetes education, diet, physical activity and medication in diabetes, stress education and its influencing factors, supporting older adults in identifying ineffective and stressful thoughts, providing solutions (problem-oriented and emotion-oriented) in dealing with stress, providing support in the application of the support provided in daily life.

Main outcome variables

Self-care; stress; anxiety; depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180728040617N4**

Registration date: **2022-12-12, 1401/09/21**

Registration timing: **prospective**

Last update: **2022-12-12, 1401/09/21**

Update count: **0**

Registration date

2022-12-12, 1401/09/21

Registrant information

Name

Syedmohammad Mirhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 3811

Email address

mirhoseinim@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of online group support on psychological distress and self-care behaviors of the elderly with type 2 diabetes during the COVID-19 pandemic: a parallel randomized clinical trial

Public title

The effect of online group support on psychological distress and self-care behaviors of the elderly with type 2 diabetes during the COVID-19 pandemic: a parallel randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age at least 15 years The definitive diagnosis of diabetes has been made by a doctor Smartphone access Having minimum media literacy Ability to access the Internet and online mass communication software. No psychological disorders Non-participation in other supportive interventions.

Exclusion criteria:

Do not participate in the post-test Absence from more than two sessions in support sessions Patient death during the study Occurrence of stressful events (except for the usual treatment process) for the patient

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into intervention and control groups by random block allocation using quadruple blocks created by SPSS software version 22. According to the sample size of 90 in the present study, 23 quadruple blocks will be considered. Each patient will be randomly assigned to Group A (intervention) or B (control group) in the order determined by the software, and the sampling process will be performed sequentially until sampling is completed. Individuals are assigned to the target group in order of their entry into the study and randomly through randomized blocks.

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

IR.SHMU.REC.1401.165

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Psychological distress

Timepoint

At the beginning of the study (before the intervention) and 7 days after intervention.

Method of measurement

Lovibond Depression, Anxiety and Stress Scale (DASS-21)

2

Description

Self care behaviors

Timepoint

At the beginning of the study (before the intervention) and 7 days after intervention.

Method of measurement

Toobert & Glasgow diabetes self care scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, 6 sessions will be held in 3 weeks for a duration of 60 minutes in the form of participation in a group video call (webinar) in the form of lectures, group discussions, questions and answers, slide shows and clips. Supportive content in the educational field: (diabetes education, diet, physical activity and medication in diabetes) and in the psychological field of the stress management program according to the theoretical model of stress management by Lazarus and Folkman (1- stress education and factors affecting it 2- support older adults in identifying ineffective and stressful thoughts 3- Providing solutions (problem-oriented and emotion-oriented) in dealing with stress 4- Providing support in applying the support provided in daily life. Data collection tools include demographic information form, Lavibond anxiety and depression scale (DASS-21) and Tobert and Glasgow diabetes self-care which were administered by all patients before the intervention before the first session. (Intervention and Control Group), will be completed online. After 7 days from the end of the intervention sessions, the mentioned questionnaires will be completed to assess the effect of the intervention.

Category

Other

2

Description

Control group: They will receive routine support from the treatment centre. Supporting contents will be provided to the control group after the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Clinic

Full name of responsible person

Fateme Ebrahimiyan

Street address

Imam Hossein Hospital, Emam St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

ebrahimiyani.fateme@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Fateme Ebrahimiyan

Position

Bachelor in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Bahar Hospital, 22th Bahman St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone
+98 23 3239 5054
Email
ebrahimian.fateme@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Hossein Ebrahimi
Position
Professor of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shahroud University of Medical Sciences, Tehran St.,
Shahroud, Iran.
City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3239 3811
Email
ebrahimi@shmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Seyedmohammad Mirhosseini
Position
Instructor of Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Shahroud University of Medical Sciences, Tehran St.,

Shahroud, Iran.

City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3239 3811
Email
mirhoseinim@shmu.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some of the patient's demographic information can be shared after unidentifying individuals. All of the patients' psychological distress and self care behaviors assessment information can be shared with caregivers after unidentified individuals.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Project partners

Under which criteria data/document could be used

People who do similar research

From where data/document is obtainable

It will be done by email with the person in charge of the project.

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

Data is made available to individuals via email.

Comments