Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ccale 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
Seyedmohammad Mirhosseini

Name of organization / entity

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Iran (Islamic Republic of)

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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Position
Bachelor in Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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