Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The impact of the continuous care model on self-care behaviors related to the psychological symptoms of older adults to prevention of long-covid-19 complications

Protocol summary

Study aim
The impact of the continuous care model on self-care behaviors related to the psychological symptoms of older adults to prevention of long-covid-19 complications

Design
Clinical trial with two test and control groups, with parallel groups, single-blind, randomized study, sample size 142 patients

Settings and conduct
The present study is a before-and-after trial that will be conducted in Isfahan Health Centers 1 and 2, randomly in 4 centers, on 142 elderly people who have previously contracted COVID.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. History of infection with covid 2. Age over 60 years 3- Consent to participate in the study 4- Having reading and writing literacy 5- Internet access Not inclusion criteria: 1. Prohibition of physical activity as determined by the physician 2. Suffering from specific mental illnesses including paranoid, schizophrenia, bipolar

Intervention groups
ntervention group: The duration of the follow-up care model is 12 weeks, which is held during a familiarization phase and 4 sessions of 30 to 45 minutes according to the level of tolerance and acceptance of the elderly for the sensitization phase. Two control and evaluation phases are carried out using a questionnaire. Control group: In this group only familiarization and evaluation phase will be done.

Main outcome variables
Measuring anxiety, depression, and fatigue in elderly people with a history of COVID

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230219057454N2**
Registration date: **2025-02-09, 1403/11/21**
Registration timing: **prospective**

Last update: **2025-02-09, 1403/11/21**
Update count: **0**

Registration date
2025-02-09, 1403/11/21

Registrant information

Name
Hossein Shahnazi

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
2025-02-19, 1403/12/01

Expected recruitment end date
2025-09-23, 1404/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of the continuous care model on self-care

behaviors related to the psychological symptoms of older adults to prevention of long-covid-19 complications

Public title
The effect of follow-up care on the psychological consequences of prolonged Covid in the elderly
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
History of infection with covid Age over 60 years Consent to participate in the study
Exclusion criteria:
Suffering from specific mental illnesses including paranoid, schizophrenia, bipolar
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
Choosing one of the two health centers No. 1 and 2 in Isfahan by simple random draw, then choosing 4 comprehensive health centers covered by the previously selected center by simple random draw, then from these four centers, using the method A simple random draw of two centers to select control groups and two centers to select intervention groups will be considered.Then, from among the people covered by the centers selected for the control group, 72 people eligible to enter the study (36 people in each center) are placed in the control group using a random number table, And among the people covered by the centers selected for the intervention group, 72 people qualified to enter the study (36 people in each center) were placed in the intervention group using a table of random numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
All the participants of the control and intervention groups in the study do not know which of the control and intervention groups they belong to.
Placebo
Not used
Assignment
Other
Other design features
Allocation to the study groups is such that one group is considered as an intervention and receives the intervention of the continuous care model, and one group is considered as a control and does not receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hazar Jarib Street, Isfahan city
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2025-01-18, 1403/10/29
Ethics committee reference number
1403.189.IR.MUI.DHMT.REC

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F33.8
ICD-10 code description
Other recurrent depressive disorders

2

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

3

Description of health condition studied
Fatigue Syndrom
ICD-10 code
G93.3
ICD-10 code description
Postviral fatigue syndrome

Primary outcomes

1

Description
Geriatric Depression Scale scores
Timepoint

Before the intervention, immediately after the intervention, three months after the intervention

Method of measurement

Geriatric Depression Scale

2

Description

Scores of Chalder Fatigue Questionnaire

Timepoint

Before the intervention, immediately after the intervention, three months after the intervention

Method of measurement

Chalder Fatigue Questionnaire

3

Description

Geriatric Anxiety Scale scores

Timepoint

Before the intervention, immediately after the intervention, three months after the intervention

Method of measurement

Geriatric Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention of this study is based on the follow-up care model and during face-to-face training classes for the test group. The stages of this model include familiarization, sensitization, control, and evaluation. The first step in the follow-up care model is familiarization, which aims to get to know each other (elderly, family, and educator) and explain the steps of the model. The steps of this stage include introducing the educator to the elderly and family, clarifying the educator's expectations in the study stages, specifying the expectations of the elderly and their family, completing ethical consideration forms, agreeing on the time of training sessions, and conducting a pre-test by filling out the elderly depression, elderly anxiety, and Chalder's fatigue questionnaires by the elderly. The sensitization phase aims to involve the elderly and their families in implementing the follow-up care model in the test group in 4 sessions of 30 to 45 minutes, depending on the level of tolerance and acceptance of the elderly. In the first session, anxiety and depression after Covid in the elderly are discussed with the aim of familiarizing the elderly with these diseases and ways to reduce and control them, and teaching self-care exercises related to them, and appropriate educational videos in this regard will be sent to the elderly via a virtual channel. In the second session, information will be provided to the elderly about weakness and fatigue after Covid and muscle breakdown, its complications and consequences, and ways to reduce and deal with it. In the third and fourth sessions, training will be provided on appropriate physical activity and types of appropriate exercises to strengthen muscles, and educational videos suitable for the elderly to increase physical strength and strengthen muscles, including aerobic, strength, and resistance exercises, will be presented and sent to the elderly. In this stage, the questionnaires for elderly depression, elderly anxiety, and Chalder's fatigue will be completed again by the elderly in the test group. In the control phase, telephone calls will be made in accordance with the care needs of the test group, and the information that has been taught to the elderly in the form of lectures and educational videos during the training sessions will be repeated to them every week in retraining sessions, by telephone or through virtual channels. In the evaluation phase, the evaluation of the desired variables will be carried out using questionnaires. Finally, this phase will end with the completion of the questionnaire at the end of the third month after the intervention, in the test and control groups. The content of the training sessions will also be made available to the elderly in the control group after the completion of the project.

Category

Prevention

2

Description

For the control group, the first and last step in the follow-up care model is the familiarization and evaluation problem, which aims to familiarize mutual understanding (elderly, family, and educator) and explain the steps of the model. The steps in this step include introducing the educator to the elderly and family, clarifying the educator's expectations in the study stages, specifying the expectations of the elderly and their family, completing ethical consideration forms, agreeing on the time of the educational sessions, and conducting a pre-test by filling out the questionnaires on elderly depression, elderly anxiety, and Chalder's fatigue by the elderly. In the final step, or evaluation, the steps include evaluating the desired variables using questionnaires. The content of the educational sessions will be made available to the elderly in the control group after the plan is completed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Hamzeh Health Center, Isfahan

Full name of responsible person

Maedeh kholafaie

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Hezarjarib Ave, School of health, Isfahan University of Medical Sciences, Isfahan

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Web page address
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Recruitment center
Name of recruitment center
Shahid Fadaei Health Center, Isfahan
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Shahnazi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access begins after results are printed.

To whom data/document is available

All people working in academic, scientific, and industrial sectors are able to receive data.

Under which criteria data/document could be used

1- Using information to conduct scientific and research studies 2- Not changing information and observing ethical standards

From where data/document is obtainable

Research project implementers and authors 2- Research assistant of the relevant university and educational institution (Isfahan University of Medical Sciences).

Contact information for research project implementers: 1- Ms. Maedeh Khalafai, Address: Isfahan, Third Abshar, 4th Alley of Shahid Tabaeiyan, Prince Park Building, Contact number: 09132748272, Email address: maedeh.kholafai.kh@gmail.com. Mr. Dr. Hossein Shahnazi, Address: Isfahan, Hezar Jerib Street, Isfahan University of Medical Sciences, School of Public Health, Department of Public Health Education, Contact number: 09133360148, Email address: h_shahnazi@yahoo.com.

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

After contacting the project implementers and reviewing the applicant's scientific and ethical qualifications, the information will be provided to him/her as soon as possible.

Comments