

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of supportive role of nurse on stress, anxiety and depression in the hospitalized elderly with COVID-19 in Firoozabadi hospital at Rey city

Protocol summary

Study aim

Determining and comparing the effect of nurse supportive role on stress, anxiety and depression in the elderly with COVID-19 admitted to Firoozabadi Hospital in Rey

Design

Non-randomized controlled trials was conducted with 78 subjects (39 in each group) .

Settings and conduct

In this study, 78 eligible elderly persons hospitalized in Firoozabadi Hospital were divided into group of experimental and control group (39 in each group). The control group received routine general patient education. The experimental group, in addition to routine general patient education, received informational, emotional-spiritual and social support implementations by the researcher from 2nd to 5th day of hospitalization, daily, 8 - 10 AM (for one hour). Before the intervention and after the intervention, on the fifth day of hospitalization , Depression Anxiety and Stress Scale 21 (DASS-21) was completed in both experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Age over 60 years based on patient record , patient with COVID-19 on first day of hospitalization ,ability to dialect and understanding of Persian language score 7 or higher on abbreviated mental test (AMT). non- inclusion criteria include: history of depression and psychological problems under medication according to information ,previous history of hospitalization due to COVID-19 disease, use of barbiturates and anti-anxiety drugs during hospitalization

Intervention groups

Implementation of support in informational, spiritual, emotional and social fields daily and during the five days of hospitalization of the elderly patients 8 - 10 am (for one hour).

Main outcome variables

Stress, Anxiety and Depression

General information

Reason for update

The address and information I have entered has changed

Acronym

IRCT registration information

IRCT registration number: **IRCT20220609055119N1**

Registration date: **2022-08-12, 1401/05/21**

Registration timing: **retrospective**

Last update: **2022-11-27, 1401/09/06**

Update count: **1**

Registration date

2022-08-12, 1401/05/21

Registrant information

Name

Hanie Sayadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 918 691 4710

Email address

zasa70901@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-16, 1400/12/25

Expected recruitment end date

2022-04-17, 1401/01/28

Actual recruitment start date

2022-03-16, 1400/12/25

Actual recruitment end date

2022-04-17, 1401/01/28

Trial completion date

2022-04-17, 1401/01/28

Scientific title

The effect of supportive role of nurse on stress, anxiety and depression in the hospitalized elderly with COVID-19 in Firoozabadi hospital at Rey city

Public title

The effect of supportive role of nurse on stress, anxiety and depression in the hospitalized elderly with COVID-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Being infected with COVID-19 Patient consent for participating in the study Getting 7 score or higher at abbreviated mental test(AMT) First time hospitalized due to COVID-19 disease Dialect and understanding of Persian language The first day of hospitalization

Exclusion criteria:

Taking barbiturates and anti-anxiety or psychoactive drugs History of depression and psychological problems under treatment

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahed university

Street address

Shahed University, Opposite Holy Shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2022-03-05, 1400/12/14

Ethics committee reference number

IR.SHAHED.REC.1400.172

Health conditions studied

1

Description of health condition studied

Depression,Anxiety,Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress

Timepoint

The first day (before intervention) and the fifth day of hospitalization (after intervention).

Method of measurement

Questionnaire 21 questions of stress, anxiety and depression

2

Description

Anxiety

Timepoint

The first day (before intervention) and the fifth day of hospitalization (after intervention).

Method of measurement

Questionnaire 21 questions of stress, anxiety and depression

3

Description

Depression

Timepoint

The first day (before intervention) and the fifth day of hospitalization (after intervention).

Method of measurement

Questionnaire 21 questions of stress, anxiety and depression

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The patients received routine general

education.

Category

Other

2**Description**

Intervention group: In addition to receiving general routine training , the subjects received informational, spiritual, emotional and social support from 2nd day to 5th day of hospitalization during one hour, 8 - 10 AM, daily.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firoozabadi hospital at Rey city

Full name of responsible person

Dr. Soheila Mahdavinia

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Tehran_Rey_ Fadaeianeslam St.

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

Shahed University

Full name of responsible person

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Research Vice Presidency Office, Central Building, Shahed University, Opposite Holy Shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran.

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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

Shahed University

Proportion provided by this source

20

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**

Shahed University

Full name of responsible person

Hanie Sayadian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Latest degree

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Latest degree

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Other areas of specialty/work

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Fax

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The form of personal information including age, sex,
marriage, number of children, level of education, income
level, cohabitation status, underlying diseases and drugs
used and percentage of lung involvement is available
without mentioning patients' names and logos. A
summary of how the research was conducted and its
duration is available. results of 21-item questionnaire on
depression, anxiety; stress is available.

**When the data will become available and for how
long**

After defending the thesis

To whom data/document is available

Students and researchers

Under which criteria data/document could be used

Research in a field similar to current research

From where data/document is obtainable

Visit the website of Shahed University or send a message
to researcher's email. Zasa7090@yahoo.com

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

It can be downloaded from the library of university .

Comments