Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 Firouzabadi 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 committe 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

Street address
Tehran_Rey_ Fadaeianeslam St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
Shahriar Bijani

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

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Web page address
http://shahed.ac.ir

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

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Nursery

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1331853859

Phone

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Fax

Email

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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