

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of The Effect of Telephone Consultation on The Syndrome of The Patients Family In Thy Intensive Care Unit With Covid 19

Protocol summary

Study aim

Determining the effect of nurse telephone counseling on the syndrome of patients with covid19

Design

The present study will be a simple randomized clinical trial in the control and intervention groups, which will be performed in the intensive care unit (ICU) of selected military hospitals in Tehran on the families of patients admitted with Quid 19 who are spontaneously breathing and not connected to the ventilator. The sample size is 40 people who will be placed in each group of 20 people according to the method of availability and having the conditions for entering the study. The first starting group for sampling the study is identified randomly by tossing a coin. Routine communication method is performed in the control group and in the intervention group is examined by telephone consultation.

Settings and conduct

This project is a clinical trial that is randomly divided into two groups of control and intervention. Samples will be from the special ward of Tehran Army Hospitals.

Participants/Inclusion and exclusion criteria

Families of patents with covid 19 patients admitted to thy intnseive care unit

Intervention groups

Families of patients with Covid 19 admitted to the intensive care unit of selected military hospitals who are eligible for inclusion in the study.

Main outcome variables

Family syndrome is a set of psychological and non-psychological symptoms (physical, social and spiritual) including: fear, sadness, fatigue, depressive symptoms and anxiety. this research To determine the effect of telephone counseling, the nurse will examine the family syndrome of patients with coronavirus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210809052125N1**
Registration date: **2021-10-26, 1400/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

2021-10-26, 1400/08/04

Registrant information

Name

Mehdi Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6696 0000

Email address

akbarinurse97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-19, 1400/07/27

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Effect of Telephone Consultation on The Syndrome of The Patients Family In Thy Intensive Care Unit With Covid 19

Public title

Evaluation of The Effect of Telephone Consultation on The Syndrome of The Patients Family In Thy Intensive Care Unit With Covid 19

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to enter the Plan Do not use Anti_Anxiety Drugs and Sedatives No Auditory or Visual Impairment The Patient was Hospitalized for more 5 days in the Intensive Care Unit

Exclusion criteria:

Reluctance to continue cooperation Occurrence of a critical event for a family member Less than 72 hours in the intensive care unit

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by Tossing Coins The sample size is 40 people who will be placed in each group of 20 people according to the method of availability and having the conditions for entering the study. The first starting group for sampling the study is identified randomly by tossing a coin. Routine communication method is performed in the control group and in the control group, the intervention is examined by telephone counseling method.

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 Aja University of Medical Sciences

Street address

No. 105, Kashan St.

City

Tehran

Province

Tehran

Postal code

1318918664

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.AJAUMS.REC.1400.066

Health conditions studied**1****Description of health condition studied**

Family syndrome

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Family syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Family syndrome

Timepoint

Before the intervention begins _Fifth day _Day of discharge

Method of measurement

Lesk Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: First in the experimental group, before the intervention and after the patient enters the ward of a form of personal information that includes age, sex, marital status, number of children, level of education, economic level, history of smoking, history of psychiatric drugs And the address of the residence is the history of hospitalization. We will complete it in five minutes. Counseling is provided by a researcher who has about ten years of experience in the intensive care unit, four years in the emergency department and six years in the psychiatric ward. The content of the training includes familiarity with covid disease and methods of treatment and familiarity with the environment and care in the special ward. Family questions are then answered. Counseling is done on the first day for a maximum of one hour and then 5 minutes a day by phone in the morning

by the researcher and if necessary, the patient's family can call the researcher's mobile phone number. To take. Due to the visit ban, no visits are made by the family in order to prevent the spread of infection. In this study, for each patient, only one of the family members who is most involved in the patient care process is studied.

Category

Behavior

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

بیمارستان 501، 503، خانواده

Full name of responsible person

مهدی اکبری

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Imam Reza Hospital (501).Sarhang Etemadza .Fatemi
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akbari_nurse97@yahoo.com

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

Artesh University of Medical Sciences

Full name of responsible person

Dr. Azam Sajjadi

Street address

Shariati St., next to Aja Nursing School Family
Hospital

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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

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Mehdi Akbari

Position

Nurse

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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Full name of responsible person

mehdi akbari

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

mehdi Akbari

Position

MSc student

Latest degree

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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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Only the results of the research will be made available to the public and no information will be made public

When the data will become available and for how long

6 months after printing

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Aja School of Nursing

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

Use the request announcement email.

Comments