Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mental imagery on anxiety and sleep quality in patients with COVID-19

Protocol summary

Study aim
Determining the effect of mental imagery on anxiety and sleep quality in patients with Covid 19

Design
The clinical trial has a control and intervention group that is collected in two stages by referring to two groups of patients. Variables are examined before and after the intervention. 70 patients are purposefully divided into two groups based on a table of random numbers.

Settings and conduct
Data collection in this study is done by completing a questionnaire of demographic characteristics, Beck anxiety and sleep quality in Pittsburgh by the researcher in both groups, in the inpatient wards of patients in COVID-19.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients admitted to infectious wards due to Covid-19, without hearing, vision or speech impairment, non-use of drugs and alcohol and self-expression of participants in relation to: no depression, no use of antipsychotic drugs, Having a mobile phone. Exclusion criteria: unwillingness to continue attending meetings, occurrence of stressful events such as: death of loved ones, accidents, deterioration of the patient and the need for hospitalization in the ICU

Intervention groups
Hospitalized patients with COVID-19

Main outcome variables
Helps to reduce anxiety, increase the quality of sleep in patients with COVID-19

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180608040007N3**
Registration date: **2022-01-08, 1400/10/18**
Registration timing: **retrospective**
Last update: **2022-01-08, 1400/10/18**
Update count: **0**

Registration date
2022-01-08, 1400/10/18

Registrant information

Name
Maryam Mohammadi
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
2020-07-22, 1399/05/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
2020-10-22, 1399/08/01

Actual recruitment end date
2021-04-04, 1400/01/15

Trial completion date
empty

Scientific title
The effect of mental imagery on anxiety and sleep quality in patients with COVID-19

Public title
the effect of mental imagery on COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients admitted to infectious wards due to Covid 19 No

hearing, vision or speech impairment Do not use drugs and alcohol Participants' self-declaration for: no depression, no use of antipsychotic drugs Having a mobile phone

Exclusion criteria:

Occurrence of stressful events such as: death of loved ones, tragic events Tendency to end treatment Deterioration of the patient and the need for hospitalization in the ICU

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of intervention and control by census method with simple random assignment. Based on the time of filing in the admission unit, the patients who meet the inclusion criteria are selected from the infectious wards. Then, individual patients will be in the intervention group and paired patients will be in the control group, respectively. Sampling will continue until the total number of patients reaches 70 (35 patients in the intervention group and 35 patients in the control group).

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

Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Central Administration, Bahonar Sq., Shahid Sadoughi University of Medical Sciences, Yazd Iran

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-06-09, 1399/03/20

Ethics committee reference number

IR.SSU.REC.1399.058

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Anxiety reduction based on Beck questionnaire

Timepoint

Measurement of anxiety, before intervention and one month after intervention

Method of measurement

Beck Anxiety Questionnaire

2

Description

Increase sleep quality

Timepoint

Measurement of sleep quality, before intervention and one month after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 15 minutes are explained about mental imagery, and then in a 45-minute session, first muscle relaxation is performed and then mental imagery is performed under the guidance of the researcher. Perform the mental imagery steps and the content expressed by the patient's mobile phone and the participant is asked to listen to this recorded sound every day for three weeks and do mental imagery. In addition, perform tasks related to mental imagery identified by the researcher. Post-test in both groups will be completed by telephone by the researcher and research colleague by phone within 15 to 20 minutes four weeks after the intervention.

Category

Other

2

Description
Control group: .Control group: Due to the critical conditions and the possibility of rapid disease transmission, all safety conditions are observed to prevent the transmission of infection among patients and the researcher. In the control group, after completing the consent form, the pre-test is completed in a quiet and private environment, which is intended for all patients (intervention and control). The pre-test is answered by the patient in 15 to 20 minutes. Routine Covid-19 treatments continue in both groups according to the hospital infectious disease specialist. In the control group, only routine procedures are performed according to the doctor's instructions. The post-test is completed three weeks later by the researcher and research partner over a period of 15 to 20 minutes by telephone.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Yazd Hospital
Full name of responsible person
Maryam Mohammadi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Central Administration Shahid Sadoughi University ofMedical Sciences, Bahonar Sq., Yazd Iran
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dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
50
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
Yazd University of Medical Sciences
Full name of responsible person
Maryam Mohammadi
Position
Faculty
Latest degree
Master
Other areas of specialty/work
Midwifery
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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
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main consequences will be shared upon formal request.
When the data will become available and for how long
6 months after the article is published, it will be shared upon official request.
To whom data/document is available
Researchers working in academic and scientific institutions will be shared upon formal request.
Under which criteria data/document could be used
It will be shared upon formal request and use cases after review.
From where data/document is obtainable
ba_zendegy@yahoo.com
What processes are involved for a request to access data/document
After the official request, the determination of the uses will be provided after at least one month after the review and approval of the applicant.
Comments