

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 2026

### Effects of guided imagery on anxiety, muscle pain and vital signs in patients with COVID-19 hospitalized in Taleghani Hospital and temporary housing in Urmia, 2020

#### Protocol summary

##### Study aim

Determining the effect of guided mental imagery on anxiety, muscle pain and vital signs in patients with Covid-19

##### Design

The selected samples will be divided into two groups of intervention and control by simple random sampling. The Envelope cards method will be used to win 110 cards, and the letter G (intervention group with guided mental imagery) and 55 letters C (control group) will be written on 55 cards. The cards will be then mixed together and one of the cards will be randomly selected by the patient and according to the writing on the cards, will be placed in one of two groups. Baseline data including demographic characteristics, vital signs and SPO2% of patients will be obtained in the first session and questionnaires of anxiety and severity and quality of pain in both intervention and control groups will be filled by patients.

##### Settings and conduct

This study is a clinical trial and research environment is Taleghani hospital in Urmia.

##### Participants/Inclusion and exclusion criteria

Should be positive for covid-19 with PCR test;  
Satisfaction to participate in the study; Age: between 18 and 60 years; SPO2% > 93%.

##### Intervention groups

Intervention group: a guided mental imaging protocol will be performed under the supervision of a psychiatrist.  
Control group: routine care in the ward.

##### Main outcome variables

Level of anxiety; Quality and severity of pain

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20131112015390N5**

Registration date: **2020-09-26, 1399/07/05**

Registration timing: **retrospective**

Last update: **2020-09-26, 1399/07/05**

Update count: **0**

#### Registration date

2020-09-26, 1399/07/05

#### Registrant information

##### Name

Naser Parizad

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 1348 7649

##### Email address

parizad.n@umsu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-05-21, 1399/03/01

#### Expected recruitment end date

2020-06-09, 1399/03/20

#### Actual recruitment start date

2020-06-15, 1399/03/26

#### Actual recruitment end date

2020-07-08, 1399/04/18

#### Trial completion date

2020-08-10, 1399/05/20

#### Scientific title

Effects of guided imagery on anxiety, muscle pain and

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                                                 |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| vial signs in patients with COVID-19 hospitalized in Taleghani Hospital and temporary housing in Urmia, 2020                                                                                                                                                                                                                                                                                                                                                                                                                            |  | Ethics committee of Urmia University of Medical Sciences                                                                                                        |  |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Street address</b>                                                                                                                                           |  |
| Effects of guided imagery on anxiety, muscle pain and vial signs in patients with COVID-19                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | Resalet Boulevard, Emergency kooy                                                                                                                               |  |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | <b>City</b>                                                                                                                                                     |  |
| Education/Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | Urmia                                                                                                                                                           |  |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Province</b>                                                                                                                                                 |  |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | West Azarbaijan                                                                                                                                                 |  |
| The sample should be positive for covid-19 with PCR test. Be between 18 and 60 years old. Allow the treating physician to intervene. The sample must be alert and oriented. Be able to speak Persian. Willingness to participate in the study with complete satisfaction.                                                                                                                                                                                                                                                               |  | <b>Postal code</b>                                                                                                                                              |  |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | 5714783734                                                                                                                                                      |  |
| The sample have a history of mental illness and a previous history of Covid-19. SPO2% < 93%                                                                                                                                                                                                                                                                                                                                                                                                                                             |  | <b>Approval date</b>                                                                                                                                            |  |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | 2020-06-02, 1399/03/13                                                                                                                                          |  |
| From <b>18 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Ethics committee reference number</b>                                                                                                                        |  |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | IR.UMSU.REC.1399.102                                                                                                                                            |  |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | <b>Health conditions studied</b>                                                                                                                                |  |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  | <b>1</b>                                                                                                                                                        |  |
| N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Description of health condition studied</b>                                                                                                                  |  |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | COVID-19                                                                                                                                                        |  |
| No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | <b>ICD-10 code</b>                                                                                                                                              |  |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | U07.1                                                                                                                                                           |  |
| Target sample size: <b>110</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | <b>ICD-10 code description</b>                                                                                                                                  |  |
| Actual sample size reached: <b>96</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | COVID-19, virus identified                                                                                                                                      |  |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | <b>Primary outcomes</b>                                                                                                                                         |  |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <b>1</b>                                                                                                                                                        |  |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | <b>Description</b>                                                                                                                                              |  |
| The selected samples will be divided into two groups of intervention and control by simple random sampling with random allocation. The Envelope cards method will be used to win 110 cards and write the letter G (55 on the intervention group with guided mental imagery) and the other 55 on the letter C (control group). Then the cards are mixed together and at the patient's bedside, one of the cards is randomly selected by the patient and according to the writing on the cards, they will be placed in one of two groups. |  | Anxiety Scale in Spielberger's Hidden and Obvious Anxiety Scale Questionnaire                                                                                   |  |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | <b>Timepoint</b>                                                                                                                                                |  |
| Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  | Measuring anxiety in the first session (before the intervention) and then After completing the guided mental imagery training sessions on the fifth day         |  |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  | <b>Method of measurement</b>                                                                                                                                    |  |
| <b>Placebo</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | Spielberger's Hidden and Obvious Anxiety Scale Questionnaire                                                                                                    |  |
| Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | <b>2</b>                                                                                                                                                        |  |
| <b>Assignment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  | <b>Description</b>                                                                                                                                              |  |
| Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | Pain Quality Score on the McGill Pain Questionnaire                                                                                                             |  |
| <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  | <b>Timepoint</b>                                                                                                                                                |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | Measuring quality of pain in the first session (before the intervention) and then After completing the guided mental imagery training sessions on the fifth day |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Method of measurement</b>                                                                                                                                    |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | McGill Pain Questionnaire                                                                                                                                       |  |
| <b>Secondary Ids</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | <b>3</b>                                                                                                                                                        |  |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>Description</b>                                                                                                                                              |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | Pain intensity score on the Visual Analog Scale                                                                                                                 |  |
| <b>Ethics committees</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | <b>Timepoint</b>                                                                                                                                                |  |
| <b>1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | Measuring pain intensity in the first session (before the intervention) and then After completing the guided mental imagery training sessions on the fifth day  |  |
| <b>Ethics committee</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  | <b>Method of measurement</b>                                                                                                                                    |  |
| <b>Name of ethics committee</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | Visual Analog Scale                                                                                                                                             |  |

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, a guided mental imaging protocol will be performed under the supervision of a psychiatrist. In the intervention group, in parallel with routine care, for each sample, 10 sessions of guided mental imaging methods were performed for five consecutive days, twice a day; It will be performed once in the morning from 9:00 to 9:30 and once in the evening from 18:00 to 18:30 in the patient's room. During each session, the patient listens for about 25 minutes to the headphone-guided mental imagery training mp3 file, and according to the sentences that will be played, closes his eyes, takes a deep breath, and relaxes his muscles to relax completely. It is then directed to the relevant imagery using the power of the mind and imagination.

#### Category

Behavior

### 2

#### Description

Control group: There is no intervention in the control group and they will continue the treatment process based on routine care in the ward.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Taleghani Educational and Medical Center in Urmia

##### Full name of responsible person

Naser Parizad

##### Street address

Kashani St., in front of Takhti Sports Complex, Ayatollah Taleghani Hospital, Urmia

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5915931637

##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Naser Parizad

##### Street address

Resalet Boulevard, Emergency Cui

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

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##### Phone

+98 44 3223 4897

##### Email

parizad.n@umsu.ac.ir

#### Grant name

School of Nursing and Midwifery, Urmia University of Medical Sciences

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

##### Full name of responsible person

Naser Parizad

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Nazloo Pardis, 11th Km of the Seroo road, Urmia

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##### Province

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##### Postal code

5756115111

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Naser Parizad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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

Yes - There is a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Data related to the main outcome of the study will be shared.

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

Data access will begin three months after the results are published.

### To whom data/document is available

All researchers and practitioners in the field can access the results.

### Under which criteria data/document could be used

Anyone can access the results by pointing to the source used.

### From where data/document is obtainable

People can access data from reputable databases that publish results.

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

Searching for the main outcome of the research or the researchers conducting the research after publishing the results in valid databases

### Comments