

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison of the effect of touch by nurse with touch by the patient himself on vital signs and level of consciousness of patients admitted to intensive care units

#### Protocol summary

Vital signs, level of consciousness

##### Study aim

The effect of touching the patient's hand on their level of consciousness and vital signs

##### Design

This study is a randomized clinical trial with 48 patients in two groups. The touch group by the patient's own hand (first group) and the touch group by the nurse (second group). After the available selection of hospitalized and purpose-based patients, in terms of admission criteria, they are randomly assigned to two groups in equal numbers using quadruple permutation blocks. Blindness for patients due to their lack of consciousness has been investigated and due to the lack of knowledge of the registrar of consciousness and vital signs of the subject in the groups and also a statistical analyst, in fact, this study was designed with two parallel groups, random and double-blind.

##### Settings and conduct

This randomized clinical trial is performed on patients with impaired level of consciousness (GCS below 8) admitted to intensive care units of Khorasan Razavi (in two groups). In the first group, touch therapy of the face and torso is performed by the patient's own hand, but with the help of a nurse, for six consecutive days and each time for 10 minutes. It takes time. Blinding for patients due to lack of consciousness is practically achieved and does not require special action.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 15-60 years, absence of tactile disorders in different parts of the patient, GCS below 8 Exclusion criteria: dissatisfaction of companions

##### Intervention groups

The intervention group includes patients who receive sensory stimulation with their own hands. The control group includes patients who receive sensory stimulation through the nurse.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210327050780N1**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

##### Registration date

2021-12-06, 1400/09/15

##### Registrant information

##### Name

Khadijeh Sadeghiyan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5232 9110

##### Email address

info@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-22, 1400/07/30

##### Expected recruitment end date

2022-01-20, 1400/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of touch by nurse with touch by the patient himself on vital signs and level of consciousness of patients admitted to intensive care units

**Public title**

The effect of touch on vital signs and level of consciousness

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Effect by reducing the level of consciousness with the inclusion criteria of age between 15 to 60 Patients with decreased level of consciousness with GCS inclusion criteria below 8 Patients with decreased level of consciousness with the criterion of the absence of various sensory disorders

**Exclusion criteria:**

Transfer the patient to other medical centers Having sensory problems

**Age**

From **15 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, the research units are selected according to the estimated number of available patients admitted to intensive care units according to the inclusion criteria and in a purposful method. Then, using the quadruple block method, they are randomly assigned to two groups of two touch therapy groups (one group by the patient's own hand with help and the other by the nurse, 24 people in each group). In this way, for the group to be touched by the patient's own hand) with the help of the letter A and for the group to be touched by the nurse's hand, the letter B is considered. Possible modes in the four blocks of six modes include AABB, BBAA, ABAB, BABA, ABBA, BAAB, each mode is written on a card and the cards are assigned the number one to six. Then, using a dice, one of the six possible modes is selected and based on that, the selected patients are assigned to two relevant groups. This process continues until the sample size is completed.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Are sensory stimuli performed by patients themselves more effective than sensory stimuli performed by the nurse on the patient? In addition, at present, the policy of meeting in the private sector in the country has many restrictions. In most medical centers, sensory stimulation is performed by nurses and also the role of the patient himself in comparison with nurses in performing sensory stimulation has not been measured in a separate study in Iran. Vital signs and level of consciousness of patients admitted to special wards are not mentioned and this indicates the research gap and knowledge in this regard.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Gonabad University of Medical Sciences

**Street address**

Khordad St. 6, No. 2, Unit 2

**City**

Torbat Heydariye

**Province**

Razavi Khorasan

**Postal code**

9518951607

**Approval date**

2021-03-14, 1399/12/24

**Ethics committee reference number**

IR.GMU.REC.1399.135

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

Loss of consciousness

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

Level of conciosness

**Timepoint**

Touch for six consecutive days, each time for 10 minutes in the morning and evening shifts.

**Method of measurement**

Glasgow Coma Scale

**Secondary outcomes**

## 1

### Description

Vital Signs

### Timepoint

Control vital signs before and after the intervention on 6 consecutive days in the morning and evening

### Method of measurement

Respiratory rate by counting the number of ups and downs of the chest, checking systolic and diastolic blood pressure, heart rate with the vital signs monitoring device Saadat brand model S1600 and oral thermometer is used for temperature.

## Intervention groups

### 1

#### Description

Intervention group 1: the group that is touched by a nurse.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: A group that is touched by the patient herself and with the help of a nurse.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Torbat heydariye Razi and 9-day hospital

##### Full name of responsible person

Khadijeh Sadeghiyan

##### Street address

Khordad St., Khordad 6, No. 2, Unit 2

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##### Province

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##### Email

kh.sadeghiyan59@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Meysam Dastani

#### Street address

Khorasan Razavi, Gonabad, Imam Khomeini St.,  
Gonabad University of Medical Sciences

#### City

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#### Province

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#### Fax

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#### Email

info@gmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

##### Full name of responsible person

Khadijeh Sadeghiyan

##### Position

Senior Nursing 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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**Full name of responsible person**

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**Position**

Senior Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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