

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the effect of using the Patient Communication software on the ease of communication and satisfaction of conscious patients under mechanical ventilation admitted to the ICU

Protocol summary

Study aim

Determining the effect of the use of patient communication software on the ease of communication and satisfaction with the quality of care of conscious patients under mechanical ventilation in ICU

Design

Semi-experimental intervention with a control group, with parallel groups, two-way blind, randomized, on 60 patients, spss software was used for randomization

Settings and conduct

After preparing the software and obtaining the consent of the patients hospitalized in the ICU, the selected statistical population is divided into two control and intervention groups by random allocation method. At first, the researcher is not aware of the allocation of people to two groups. The statistical analyst will also be unaware of the groups.

Participants/Inclusion and exclusion criteria

Patients hospitalized in special care departments of Mashhad public hospitals
Inclusion: having an artificial airway, mastering the Persian language, an acceptable level of consciousness, minimum literacy, having the ability to see and hear, at least 24 hours of stay in the intensive care unit and attending the unit for a full day.
Exclusion: history of mental problems, having an underlying disease affecting the level of consciousness, hospitalization of the patient due to head injuries, change in the patient's state of consciousness

Intervention groups

In the control group, communicating with the patient through common methods including lip-reading, sign language, etc., and in the intervention group, communicating with the use of designed software, each of the main needs of the patients is visualized on the pages. Digital has brought that these images themselves can be enlarged and sound, and by using it, it will be possible to communicate between the research nurse

and the conscious patient without the ability to speak

Main outcome variables

Ease of communication, Satisfaction of conscious

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054293N1**

Registration date: **2022-11-29, 1401/09/08**

Registration timing: **prospective**

Last update: **2022-11-29, 1401/09/08**

Update count: **0**

Registration date

2022-11-29, 1401/09/08

Registrant information

Name

Zahra Poursadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3607 7453

Email address

z_psg@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using the Patient Communication software on the ease of communication and satisfaction of conscious patients under mechanical ventilation admitted to the ICU

Public title

Application of patient communication software in conscious patients under mechanical ventilation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having an artificial tracheal airway or tracheostomy
Proficiency in Persian language
Acceptable level of consciousness
Minimum literacy
Having the power of sight and hearing
At least 24 hours of stay in the intensive care unit and one full day in the unit

Exclusion criteria:

Having a history of mental problems according to the patient's family
Having an underlying disease affecting the level of consciousness
Hospitalization of the patient due to head injuries
Changing the patient's state of consciousness so that he is unable to communicate

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The selected statistical population is divided into two intervention and control groups by the randomization method with a random sequence generated through the Randomization site. After the random allocation, the allocations will be taken in the envelopes, and after selecting the research sample, it will be removed from the envelope in the allocation package, and the person will be placed in the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluator and statistical analyst are unaware of the placement of the samples in the intervention or control group. In the data analysis stage, the groups will be entered into the software as A and B, and the statistical analyst will not be aware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mashhad University of Medical Science

Street address

Ibn Sina Street, doctora intersection

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.MUMS.REC.1401.074

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

Conscious patients under mechanical ventilation

ICD-10 code

QF22

ICD-10 code description

Difficulty or need for assistance with communication

Primary outcomes**1****Description**

Ease of communication

Timepoint

Before and after the intervention, 12 hours after the end of the intervention

Method of measurement

ECS Questionnaire

2**Description**

Satisfaction with the quality of patient care

Timepoint

Before and after the intervention, 12 hours after the end of the intervention

Method of measurement

PSI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, communication with the patient is through common methods to identify the needs of the patients. These methods are different according to the patient's condition and include lip reading, sign language, using pen and paper, and whiteboard, and the patient can express his feelings, needs and problems through them.

Category

N/A

2

Description

Intervention group: In this group, communication will be done using the software designed under the Android system. The communication software with the patient will have the facilities of playing audio, displaying schematic images, and the possibility of typing, and it has visual appeal, flexibility, beauty, and quality, so that, for example, each of the main needs of patients can be visualized in There are digital pages that can be enlarged and have audio. This software can be installed on the researcher's phone as a user of the software, and by using it, it will be possible to establish communication between the research nurse and the conscious patient without the ability to speak.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mahmoud Mohammadzadeh Shabestri

Street address

Imam Reza Hospital Square, Ibn Sina Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

shabestarim@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Gholam Ali Mamouri

Street address

Ahmedabad St

City

Mashhad

Province

Razavi Khorasan

Postal code

9919991766

Phone

+98 51 3840 0001

Email

MaamouriGh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayor Mobarhan

Street address

Qurashi Building, next to Hoizeh Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Poursadeghi

Position

Master's student in intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No 6, Resalat St, 25th Ally, Faramarz Abbasi Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3607 7453

Fax**Email**

z_psg@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Poursadeghi

Position

Master's student in intensive care nursing

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z_psg@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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Zahra Poursadeghi

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Phone

+98 51 3607 7453

Fax**Email**

z_psg@yahoo.com

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