Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of using the Patient Communication software on the ease of communication andsatisfaction 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)

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+98 51 3607 7453

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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 andsatisfaction 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
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2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Gholam Ali Mamouri
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Ahmedabad St
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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
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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
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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
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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