Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of corona personal protective equipment (PPE) on physiological indicators and Fatigue of nursing Intern students after cardiopulmonary resuscitation(CPCR)

Protocol summary

Study aim

Determining the effect of using corona personal protective equipment on physiological indicators and fatigue index of nursing students after cardiopulmonary resuscitation

Design

A clinical trial with a control group, double-blind, randomized, was conducted on 40 nursing intern students, and Randomizer 2016.6.0.56 software was used for randomization.

Settings and conduct

The double-blind study will be done only with the information of the statistical consultant. Intervention people wearing personal protective equipment and control people will perform 12 minutes of resuscitation in the clinical skills center of the nursing school.

Participants/Inclusion and exclusion criteria

Entry requirements : 1. Age 21 to 30 years. 2. No history of respiratory diseases and heart disorders. 3. Body mass index 18 to 30. 4. The resting heart rate is more than 50 or less than 120 beats per minute. 5. At rest, the oxygen saturation should be more than 95%. 6. Breathing rate at rest is more than 10 or less than 20 beats per minute. 7. At the time of conducting the study, they should not be infected with Covid-19 or during the recovery period. 8. Not participating in regular and professional sports activities. Exit conditions: 1- Withdrawal from further study. 2- Inability to continue working until the end

Intervention groups

In the intervention group, 20 nursing intern students in groups of two wearing personal protective equipment and 20 people in the control group without wearing this equipment perform cardiopulmonary resuscitation for 12 minutes. Immediately after that, the physiological indicators and fatigue index of both groups are recorded.

Main outcome variables

Physiological indicators included heart rate, systolic blood pressure, diastolic blood pressure, arterial blood oxygen, oral temperature and Cr10 Borg fatigue index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220131053897N1**
Registration date: **2022-08-29, 1401/06/07**
Registration timing: **prospective**

Last update: **2022-08-29, 1401/06/07**
Update count: **0**

Registration date

2022-08-29, 1401/06/07

Registrant information

Name

Sahar Tavan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of corona personal protective equipment (PPE) on physiological indicators and Fatigue of nursing Intern students after cardiopulmonary resuscitation(CPCR)

Public title

The effect of personal protective equipment on physiological indicators and fatigue

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

No history of respiratory diseases and heart disorders Body mass index 18 to 30 Not participating in regular and professional sports activities Passing the theoretical and practical unit of cardiopulmonary resuscitation in accordance with the educational curriculum of the field of nursing Resting heart rate greater than 50 beats per minute or less than 120 beats per minute At rest, oxygen saturation is more than 95% Resting breathing rate should be more than 10 or less than 20 beats per minute Do not have Covid 19 disease or have no symptoms at the time of the study Do not recover from Covid 19 Absence of pregnancy or menstruation in women at the time of the study Age 21 to 30 years

Exclusion criteria:

Students who did not pass the 7th nursing semester. Lack of access to participant prior to randomization

Age

From **21 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling of nursing students in the 8th semester will be done by census method. The list of students was prepared from the nursing faculty education unit, according to the conditions of entry into the study and based on the announcement of students' readiness to participate in the study, which was made after the call. Each student was assigned a code that These numbers were randomly selected using Excel software and random data generation, and by entering these codes in the random allocation software, they will be assigned to the intervention (20 people) and control (20 people) groups by the statistical consultant.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, due to the nature of the study, it is not possible to blind the participants, but the data collector and data analyst will be blinded and will not know how to allocate people to two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee ofJahrom University of Medical Sciences

Street address

Pardis site- Jahrom University of Medical Sciences -- after the Nursing Faculty-- Ostad Motahari St-Jahrom

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74148-46199

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.JUMS.REC.1400.117

Health conditions studied

1

Description of health condition studied

Comparison of physiological indices and students' fatigue index after cardiopulmonary resuscitation with and without personal protective equipment.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fatigue score in Borg cr10 questionnaire

Timepoint

At the beginning of the study (before the start of cardiopulmonary resuscitation) and 12 minutes after the start of resuscitation in both intervention and control groups.

Method of measurement

Pressure Borg CR10 Perception Scale Questionnaire

2

Description
Blood pressure score in mm Hg
Timepoint
At the beginning of the study (before the start of cardiopulmonary resuscitation) and 12 minutes after the start of resuscitation in both intervention and control groups.
Method of measurement
Tensval digital blood pressure checker comfort model

3

Description
Arterial blood oxygen saturation percentage
Timepoint
At the beginning of the study (before the start of cardiopulmonary resuscitation) and 12 minutes after the start of resuscitation in both intervention and control groups.
Method of measurement
New model blood oxygen check machine (onix Vantage)

4

Description
The number of heartbeats per minute
Timepoint
At the beginning of the study (before the start of cardiopulmonary resuscitation) and 12 minutes after the start of resuscitation in both intervention and control groups.
Method of measurement
Tensval digital blood pressure checker comfort model

5

Description
Degree of oral fever
Timepoint
At the beginning of the study (before the start of cardiopulmonary resuscitation) and 12 minutes after the start of resuscitation in both intervention and control groups.
Method of measurement
Imperial digital thermometer model 301

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:" In this group, 20 nursing intern students enter the clinical skills center of the nursing faculty in the form of groups of two. In the beginning, physiological indicators, including systolic and diaphragmatic blood pressure, heart rate, arterial blood saturation, and Borg's fatigue score are expressed by the group members. He performs basic cardiopulmonary resuscitation for 12 minutes, changing the position of two people every 2 minutes. After the recovery, the physiological indicators and the specified number are measured and recorded by the researchers.
Category
Diagnosis

2

Description
Control group: "Control group:" In this group, 20 nursing intern students enter the clinical skills center of the nursing faculty in the form of groups of two. At first, physiological indicators including systolic and diastolic blood pressure, heart rate, arterial blood oxygen saturation and oral temperature are taken by the researcher, and the Borg fatigue score is expressed by the group members. They perform cardiopulmonary resuscitation exactly like the intervention group. Immediately after recovery, the physiological indicators and the fatigue index score are measured and recorded again by the researcher.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Jahrom University of Medical Science
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Sponsors / Funding sources

1

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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
Jahrom 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
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Full name of responsible person
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Position
Internal Masters Student in Nursing Surgery

Latest degree
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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the individual data of the participants in the intervention groups and the control group, including demographic, biometric, and anthropometric information, after making the individuals unidentifiable by the researcher, can be published in the form of a thesis, printed article, and full and detailed information by accessing the researcher's email can be received.

When the data will become available and for how long

The access period starts 3 months after the results are published in the form of theses and articles.

To whom data/document is available

The data of this study will be available for researchers working in academic and scientific institutions and people working in the field of nursing.

Under which criteria data/document could be used

Applicants use this data after coordination with the researcher and for the purpose of use in the fields of medicine, nursing, sports physiology and with the consent for any analysis on the data required by the applicant.

From where data/document is obtainable

In order to receive the desired documents and data, the applicant can refer to the website of Jahrom University of Medical Sciences at the address /www.jums.ac.ir and enter the title of the thesis and the name of the researcher or via the e-mail of the researcher academy at the address S.Tavan@jums. ac.ir can access the information by contacting the researcher.

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

The applicant can access the researcher's email three months after the publication of the article by visiting the website of Jahrom University of Medical Sciences and searching for the name of the researcher and the article, or send an email directly to the researcher's email address that is registered on the article, and if the researcher approves, it is complete. The information will be made available to him after making it unidentifiable.

Comments