

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigation the effect of a program based on participatory ergonomics on musculo_skeletal disorders and general health of the operating room personnel

Protocol summary

Study aim

The purpose of this study is to determine the impact of a program based on collaborative ergonomics on musculoskeletal disorders and general health of operating room personnel in selected hospitals in Isfahan in 2023_2024

Design

A clinical trial with a control group, A parallel-group, single-blind, randomized, phase 2 study on 88 patients

Settings and conduct

The research environment will be the operating room of Al-Zahra, Kashani and Amin hospitals in Isfahan. Random allocation of samples, single blinded First, the variables are measured using the research tool, and then they are measured again 3 and 6 months later after the implementation of the best ideas.

Participants/Inclusion and exclusion criteria

Inclusion criteria Expression of willingness to participate in the study At least one year of experience in the operating room Lack of pregnancy Exclusion criteria Unwillingness to continue cooperation Lack of active participation and completing the questionnaire

Intervention groups

First a meeting is held with the hospital management and the operating room manager of the selected hospital, which is randomly selected as the intervention hospital, and the objectives of the study are explained in order to implement the necessary cooperation plan. Then the ergonomics team is formed and meetings related to collaborative ergonomics are held. It is taught to the ergonomics team by the researcher and with the personal supervision of an expert in ergonomics. After that, a brainstorming session is held and the solutions provided by the ergonomics team are documented. The most important problems and proposed actions are selected for implementation according to the interests of the personnel. No intervention performed in control group

Main outcome variables

Skeletal and muscular disorders, General health of personnel

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230730058980N1**

Registration date: **2023-08-07, 1402/05/16**

Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**

Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Mahshid Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4254 3971

Email address

mahshid.ahd74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-16, 1402/05/25

Expected recruitment end date

2024-02-14, 1402/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of a program based on participatory ergonomics on musculo_skeletal disorders and general health of the operating room personnel

Public title

Investigation the effect of a program based on participatory ergonomics on musculo_skeletal disorders and general health of the operating room personnel

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Expression of desire to participate in the study At least one year of work experience in the operating room
Absence of musculoskeletal disorders, in such a way that prevents ergonomic interventions
Absence to perform spine surgery
Not having a second job
Absence of pregnancy
Absence of cardiovascular and respiratory diseases based on self-report
No history of mental illnesses and taking psychiatric drugs based on self-report
Failure to participate in stress control classes based on self-report

Exclusion criteria:

Unwillingness to continue cooperation
Lack of active participation and completion of the questionnaire

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 88

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the nature of collaborative ergonomics that may be affected by the environment, it is not possible to select the test and control group from one hospital in order to carry out the study, therefore, for random allocation, one hospital will be randomly selected from among the selected hospitals through lottery. The intervention site and two other hospitals are selected as controls. In the next step, after determining the hospital where the intervention will take place, first, the people who meet the criteria to enter the study are selected using the available method, and then 44 personnel are placed in the test group by simple random allocation and using a table of random numbers. In the hospitals of the control group, after the identification of the hospitals, first, the people who meet the criteria for entering the study are selected using the available method, and then

by simple random allocation and using a table of random numbers, 22 personnel from each hospital will be in the control group. Placed. Finally, in order to compare the data, the number of selected people in each of the surgical fields in the test and control groups are selected in equal numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst has no knowledge of the intervention and control groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar jerib blv

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-07-28, 1402/05/06

Ethics committee reference number

IR.MUI.MED.REC.1402.168

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

Musculoskeletal disorders and general health

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

The score of Musculo_skeletal disorders based on the Cornell questionnaire

Timepoint

Before the intervention, 3 months and 6 months later

Method of measurement

Cornell Musculoskeletal Disorders Questionnaire

2

Description

General health based on the 28-item general health questionnaire

Timepoint

Before the intervention, 3 months and 6 months later

Method of measurement

28-item general health questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In order to conduct the research, all the subjects complete a written consent form. The studied units are free to refuse or accept participation in the research. At first, all the subjects in the control and test groups completed the questionnaires and the information obtained from the research tools was analyzed and the initial evaluation was done. Then the researcher uses a camera to take pictures of the personnel while doing the work. The purpose of doing this work is to evaluate the condition of the body parts of people during work using the quick assessment checklist of the whole body. In order to implement participatory ergonomics in the test group, first a meeting is held with the hospital management and the operating room manager of the selected hospital, which is randomly selected as the intervention hospital, and the objectives of the study are explained in order to implement the necessary cooperation plan. Have. Then the ergonomics team is formed and meetings related to collaborative ergonomics are held. It is taught to the ergonomics team by the researcher and with the personal supervision of an expert in ergonomics. After that, a brainstorming session is held and the solutions provided by the ergonomics team are documented. The most important problems and suggested measures are selected for implementation according to the interests of the personnel and officials.

Category

Prevention

2

Description

Control group: No intervention is performed in the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr soheila Bakhtiari

Street address

Alzahra hospital,Soffeh blvd,Isfahan town

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Dr soheila Bakhtiari

Street address

Kashani hospital, Ayatollah Kashani main street,Isfahan town

City

Isfahan

Province

Isfahan

Postal code

۸۳۴۳۴-۸۱۸۳۹

Phone

+98 31 3233 0091

Email

kashani@mui.ac.ir

3

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Dr Soheila bakhtiari

Street address

Amin hospital,Ibn Sina St,Isfahan town

City

Isfahan

Province

Isfahan

Postal code

81486-53141

Phone

+98 31 3445 5051

Email

amin@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr mansour siavash

Street address

Hezar jerib blvd

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 8134

Email

research@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mahshid Ahmadi

Position

Msd student

Latest degree

Bachelor

Other areas of specialty/work

Operating room

Street address

Isfahan university of medical science, Hezar jarib blvd, Isfahan town

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 71 4254 3971

Fax**Email**

mahshid.ahd74@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahshid Ahmadi

Position

Msd student

Latest degree

Bachelor

Other areas of specialty/work

Operating room

Street address

Isfahan university of medical science, Hezar jarib blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 71 4254 3971

Fax**Email**

mahshid.ahd74@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahshid Ahmadi

Position

Msd student

Latest degree

Bachelor

Other areas of specialty/work

Operating room

Street address

Isfahan university of medical science, Hezar jarib blvd, Isfahan town

City

Isfahan

Province

Isfahan

Postal code

81746-734618

Phone

+98 71 4254 3971

Fax**Email**

mahshid.ahd74@gmail.com

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 data is potentially shareable after de-identifying individuals

When the data will become available and for how

long

The access period starts 3 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used

The use of documents is allowed with reference to the source.

From where data/document is obtainable

Mahshid Ahmadi mahshid.ahd74@gmail.com

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

Send a request email and it takes about a week for a response.

Comments