Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Public title
Investigation the effect of a program based on participatory ergonomics on musculo_skletal 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
Isfehan
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
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Isfehan
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2

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Dr soheila Bakhtiari
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Kashani hospital, Ayatollah Kashani main street,Isfahan town
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3

Recruitment center
Name of recruitment center
Amin hospital
Full name of responsible person
Dr Soheila bakhtiari
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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81746-73461
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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
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Person responsible for scientific inquiries

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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 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