Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Investigating the effect of ergonomic intervention based on social cognitive theory in comparison with the control group on the preventive behaviors of musculoskeletal disorders in Women working on the assembly line

Protocol summary

Study aim
Determining the effect of theory-based ergonomic intervention on preventive behaviors of musculoskeletal disorders in female assembly workers

Design
The clinical trial has a control group with parallel, two-blind, randomized groups; two industrial units for the test group and the control group are selected by lottery, and the selection of workers in each group will be based on a table of random numbers. The sample size in each group will be 80 people.

Settings and conduct
The study will be done in the assembly sector of electronics industries in Neyshabur city. Using a random sampling method, 160 workers in two separate industries will be assigned to control and intervention groups. The educational content of the intervention will be determined based on the most important predictive structures obtained from the descriptive phase of the study. The participant, the outcome assessor, and the data analyst do not know about the allocation of control and intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being employed in the assembly line; having literacy; ability to participate in the program for at least six months; age 20 years and older; having consent to participate in the study. Exclusion criteria: Having any disease that barred women from stretching; pregnancy

Intervention groups
The educational intervention in the intervention group will use the learning-by-doing approach in the form of social cognitive theory structures that the workers will correct their physical condition and practice to continue using it at the same time as work activities, and during daily rest times during work intervals. Stretching movements will be taught to them, and the control group will not have the intervention related to the purpose of the research.

Main outcome variables
Correct posture; doing stretching; Predictive constructs of social cognitive theory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220825055792N1**
Registration date: **2022-09-23, 1401/07/01**
Registration timing: **prospective**

Last update: **2022-09-23, 1401/07/01**
Update count: **0**

Registration date
2022-09-23, 1401/07/01

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-17, 1401/07/25
Expected recruitment end date
2022-11-16, 1401/08/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of ergonomic intervention based on social cognitive theory in comparison with the control group on the preventive behaviors of musculoskeletal disorders in Women working on the assembly line

Public title
Examining the effect of ergonomic intervention on preventive behaviors of musculoskeletal disorders
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being employed in the assembly line having literacy ability to participate in the program for at least six months age 20 years and older having consent to participate in the study
Exclusion criteria:
Having any disease that barred women from stretching pregnancy
Age
From **20 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be cluster sampling method. First, two electronics industries will be randomly selected from among the electronics industries of Neyshabur city, and the allocation of industries to the control and intervention groups will be done randomly based on the throwing of dice, then from among the line workers. Assembling in each industrial unit, the workers have specified criteria for entering the study, and 80 participants from each industry are selected by simple random (a list of workers is prepared and based on a table of random numbers). The randomization unit is the industrial unit.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants in the control group will also be provided with training unrelated to the main purpose of the research. Since the control and intervention groups are in two separate industries, the workers will not know how they will be assigned to the control or intervention group. Considering that the participants in the study will be identified based on the code, the people analyzing the data and results will be unaware of the names of the participants and the control and intervention groups.
Placebo
Not used
Assignment
Parallel
Other design features
This study considers the limitations related to training in medium industries, such as the lack of separate training space and the lack of time allocation during working hours for the training of workers, and the design of the training intervention is based on the training theory and structured in the form of learning by doing approach in the environment. Work will be provided. Considering the role of several factors in the occurrence of musculoskeletal disorders related to work, in this research, social cognitive theory that considers the role of individual, environmental and behavioral factors in the form of theoretical constructs will be used. In this study, the scoring system based on the Bayesian network and fuzzy sets will be used, which is a more accurate evaluation method to provide the effectiveness of ergonomic interventions, in addition to the fact that the assessment of musculoskeletal disorders will be completed by self-reporting through the participants. The physical condition of the workers in each of the work stations will be evaluated using the advanced method of rapid assessment of the upper limbs through direct observation of the individual's tasks, during several work cycles and in all the work stations of the assembly line. Data will be collected within and between groups three weeks, 12 weeks, and 24 weeks after the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
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Approval date

2022-08-27, 1401/06/05

Ethics committee reference number

IR.MODARES.REC.1401.110

Health conditions studied

1

Description of health condition studied

preventive behaviors of musculoskeletal disorders

ICD-10 code

M95.8

ICD-10 code description

Other specified acquired deformities of musculoskeletal system

Primary outcomes

1

Description

Body posture score during work from checklist of fuzzified Rapid Upper Limb Assessment

Timepoint

Before the intervention, 3, 12, 24 weeks after the educational intervention

Method of measurement

checklist of fuzzified Rapid Upper Limb Assessment

2

Description

The score of stretching during work

Timepoint

Before the intervention, 3, 12, 24 weeks after the educational intervention

Method of measurement

Researcher-made questionnaire

3

Description

Scores of constructs predicting social cognitive theory

Timepoint

Before the intervention, 3, 12, 24 weeks after the educational intervention

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The educational intervention will take advantage of the learning-by-doing approach in the form of social cognitive theory structures. The workers will correct their physical posture and exercise to continue using it simultaneously as their work activities. During daily rest periods, they will also do stretching exercises. Based on the most important predictor structures of the theory obtained from the first stage of the study, they will be taught that the main content of the training and the number of days the trainer should be present in the workplace will be adjusted. During the training program to improve the self-efficacy of women, with step-by-step training, an attempt will be made to facilitate the implementation of ergonomic behavior and to improve women's belief in their ability to apply behavior, as well as behaviors related to the correct body position in each of the work stations, as well as how to perform movements. Stretching will be shown practically and step-by-step in the work environment. Based on the obstacles and facilitators related to ergonomic behavior in the work environment, the researcher will try to provide suitable solutions to overcome each of the barriers as much as possible for each of the workers and also teach women to regularly monitor the recommended ergonomic behaviors at the end of each work shift. It will be possible, regarding the structure of social support, it is tried to accompany and support the trainer towards correcting inappropriate ergonomic behaviors in the workplace and encouraging women who are careful in applying the recommended behaviors. Educational posters will be installed in the work environment during the training and illustrated training booklets will be given to the workers.

Category

Prevention

2

Description

Control group: This group will not receive the educational intervention and the follow-up of this group will be to complete the questionnaires in specific time intervals.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Electronics Industries

Full name of responsible person

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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
Tarbiat Modares University
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

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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

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

Yes - There is 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

Title and more details about the data/document

Part of the data, such as the information related to the main and secondary outcomes, can be shared.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will be sent by official request through academic or organizational e-mail of researchers after confirming and identifying the identity of the sender.

From where data/document is obtainable

Data can be obtained via email at hossini88ho@gmail.com.

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

Applicants can apply for correspondence through email or postal address 6 months after printing the results, and a response will be given one week after sending the email.

Comments