

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

compare the effect of custom made insole and training exercise on reduce post-work fatigue and discomfort of the lower extremities in assembly workers

Protocol summary

Study aim

The aim of this study is to investigate the effects of custom made insole and training exercise on post work fatigue and discomfort at low back and lower extremity in assembly line workers in DENA tire company

Design

in this research, 100 assembly line worker and with inclusion criteria and with block randomization divided into 4 group that are 3 intervention group and 1 control group.

Settings and conduct

this research will done in Dena rubber company on assembly line workers, insole and exercise training intervention will done, analyser and investigator are blind.

Participants/Inclusion and exclusion criteria

workers who have at least 1 year work record; stand at least for 3 hours a day; haven't any skeletal disorder in lower extremity.

Intervention groups

The first group will receive custom made insole, the second group will receive custom made insole with exercise, The third group will revive just exercise and the forth is control group

Main outcome variables

fatigue and discomfort in lower extremity discomfort and be any undesirable sensation such as pain, burn sensation and etc.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516033995N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Elahe Mousavi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 4440 2053

Email address

stud2411580177@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-10-26, 1396/08/04

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

2017-10-26, 1396/08/04

Actual recruitment end date

2017-12-20, 1396/09/29

Trial completion date

empty

Scientific title

compare the effect of custom made insole and training exercise on reduce post-work fatigue and discomfort of the lower extremities in assembly workers

Public title

Effect of custom made insole and training exercise on

post-work fatigue and discomfort of the lower extremities and low back after prolonged standing.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Assembly line workers of Dena rubber company
minimum work record 1 year minimum standing in day 3 hours

Exclusion criteria:

injury in lower extremity include fracture, dislocation or soft tissue injury in 6 month ago any surgery in lower extremity muscle, bone or joint muscle skeletal disorder such as RA, myopathy, neuropathy any deformity in lower extremity such as pes planus, pescavus, halux valgus vascular disorder in lower exterimity

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization, at first we choose 100 worker between who had inclusion criteria then allocated special number for everyone and blocks wrote base on 4 factorial and according to the list every one put in a special group.

Blinding (investigator's opinion)

Not blinded

Blinding description

investigator and data analyser are blind and don't know what intervention do for every group .

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, No. 3, Zand Ave., Namazi Blvd.

City

Shiraz

Province

Fars

Postal code

00987132357282

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.SUMS.REC.1395.190

Health conditions studied

1

Description of health condition studied

fatigue and discomfort in lower extremity and low back during prolonged standing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fatigue and Discomfort

Timepoint

before intervention and 8 week after intervention

Method of measurement

with questionnaire of body map and Rating on Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

first intervention group type of intervention : custom made insole. duration of intervention: 8 week

Category

Other

2

Description

the second intervention group type of intervention: custom made insole in their shoes and the exercise duration of intervention:8 week

Category

Other

3

Description

the third group intervention type of intervention:training

of the exercise duration of intervention:8 week

Category

Other

4

Description

The control group will not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

DenaTire Company

Full name of responsible person

Elahe Sadat Mousavi

Street address

Abbas Doran st., Modares blvd., Dena Rubber Company

City

Shiraz

Province

Fars

Postal code

1517973311

Phone

+98 71 3742 0030

Fax

+98 71 3742 0024

Email

Z.nikouei@yahoo.com

Web page address

<http://www.denatire.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Zahra Zamanian

Street address

Zand blv, front of palestin Ave

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Phone

+98 71 3230 5410

Fax

+98 71 3235 9317

Email

vcrdep@sums.ac.ir

Web page address

<http://www.sums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Elahe Sadat Mousavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Ergonomics

Street address

Behdasht College, Zahra Alley, Modares blvd.

City

Shiraz

Province

Fars

Postal code

7158863817

Phone

+98 71 3743 9199

Fax

Email

elahe.mousavi67@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Zamanian

Position

Assistant Professor, PhD

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Health

Street address

Behdasht College, Fatholmobin, Zahra Alley, Modares blvd.

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Phone

+98 71 3725 1003

Fax**Email**

zamaniaz@sums.ac.ir

Web page address

<http://www.sums.ac.ir>

Province

Fars

Postal code

7158863817

Phone

+98 71 3743 9199

Fax**Email**

elahe.mousavi67@gmail.com

Web page address

<http://www.sums.ac.ir>

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

Shiraz University of Medical Sciences

Full name of responsible person

Elahe Sadat Mousavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Ergonomics

Street address

Behdasht College, Fatholmobin alley, Zahra Alley, Modares blvd.

City

Shiraz

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