

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Designing and evaluation of a theory-based educational intervention to change damaging behaviors to vertebra among staff who transferring patients in hospital

Protocol summary

Summary

Objectives: This study aims to evaluate the designed educational program based on social cognitive theory to change damaging behaviors to vertebra of nurses caring/transferring patients working in Qom hospitals of Iran.

Design: This program will be tested in a clinical trial in which 120 eligible staff who transferring patients in two groups of intervention and control will participate

Setting and conduct: To select participants, firstly from all hospitals located in Qom city, two hospitals affiliated to Qom University of Medical Sciences in city of Qom will be selected randomly and then randomly will be divided into either to control or intervention hospital. Participants including major eligibility criteria: having been care workers for at least one year, being aged 18-60 years, and suffering from chronic low back pain (CLBP) due to mechanical forces for more than 90 days. However patient-care workers who reported suffering from infection in their vertebra, having myofascial back pain, spinal stenosis or recent vertebral fracture, or a history of surgery on the vertebra during the past two years of the study initiation will not enter into the study. From intervention hospital 63 eligible nurses' aides and from other hospital 62 eligible nurses' aides who will be satisfied to enter into the study were selected

Intervention: The participants in intervention hospital will be received four 2-hour multidisciplinary educational intervention consisted of social cognitive theory based educational program and ergonomic posture training in two working days

main outcome measures: Low back pain (LBP) intensity and disability reduction are the outcomes and will measure through Visual Analogue Scale (VAS), and Quebec Disability Scale (QDS) in three times of before intervention and immediately after and 6 months after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090618022N2**

Registration date: **2016-12-21, 1395/10/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-21, 1395/10/01

Registrant information

Name

Sarallah Shojaei

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Chancellor for research of Tarbiat Modares University

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2017-03-01, 1395/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluation of a theory-based educational intervention to change damaging behaviors to vertebra among staff who transferring patients in hospital

Public title

Designing and evaluation of a theory-based educational intervention to change damaging behaviors to vertebra among staff who transferring patients in hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion:having been care workers for at least one year, being aged 18-60 years, and suffering from chronic low back pain (CLBP) due to mechanical forces for more than 90 days Exclusion: who reported suffering from infection in their vertebra, having myofascial back pain, spinal stenosis or recent vertebral fracture, or a history of surgery on the vertebra, participate in exercise programs and nutritional and other physical therapy at the same time

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **125**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in Tarbiat Modares University

Street address

gisha paul

City

Tehran

Postal code

Approval date

2015-04-28, 1394/02/08

Ethics committee reference number

IR.TMU.REC.1394.15

Health conditions studied

1

Description of health condition studied

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Acute or chronic pain in the lumbar or sacral that may strain or sprain a muscle or movement Ligament- spine and other related conditions

Primary outcomes

1

Description

Chronic low back pain

Timepoint

6 month following end of intervention

Method of measurement

visual analog scale

Secondary outcomes

1

Description

Chronic Low Back Pain Preventive Behaviors

Timepoint

6 month following end of intervention

Method of measurement

low back pain preventive behaviors questionnaire

Intervention groups

1

Description

educational program included four 2-hour education/practice sessions as follows: Promoting self-efficacy of the participants in complying with ergonomic posture Promoting self-regulation of the participants regarding complying with ergonomic posture Highlighting outcome expectations of maintain ergonomic posture of vertebra Focusing on emotional coping with maintaining ergonomic posture of vertebra in workplace

Category

Prevention

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals nekoei and shahid beheshti dependent Qom university of medical sciences

Full name of responsible person

mahdi safa

Street address

taleghani street

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor for research of tarbiat modares university

Full name of responsible person

Dr movahedin

Street address

gisha paul

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chancellor for research of tarbiat modares university

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Health Education & Health Promotion, Faculty of Medical Sciences, Tarbiat Modares Univ

Full name of responsible person

Sarallah Shojaei

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty