Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

Objectives: This study aime 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 transfering 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 reporte 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

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Sarallah Shojaei
Name of organization / entity
Qom University of Medical Sciences
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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 transfering patients in hospital

Public title
Designing and evaluation of a theory-based educational intervention to change damaging behaviors to vertebra among staff who transfering 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
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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