Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Adding back package to the primary care service, a cluster randomized field trial study

Protocol summary

Study aim

Objective 1: To determine the effectiveness of adding a back package to primary care in reducing the incidence of back pain. Objective 2: To determine the effectiveness of adding back package to primary care in reducing the prevalence and disability in low back pain. Objective 3: To determine the effectiveness of adding back package to primary care in reducing back pain costs for the health system.

Design

The study includes a control group (without any intervention) and 3 intervention groups (including: exercise, exercise + back school, exercise + biopsychosocial). This Phase 3 double-blinded field trial study includes 9,440 participants using block and clustering methods for randomization.

Settings and conduct

The training will be provided by the Sports Medicine Specialist to health care providers, who will then provide the training with training pamphlets and explanations. The information required for the study will be obtained by the caregivers (with a questionnaire) after obtaining informed consent from the individuals and then presented to the researcher. Study and caregivers are blind to the type of package.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) People affiliated with medical centers in rural areas 2) People aged 18 to 60 years Exclusion criteria: 1) Diagnosed neoplasm 2) Significant psychiatric disorder 3) Cognitive disorder 4) Lack of willingness to participate

Intervention groups

Our intervention groups include: 1) Training in sports movements 2) Training in sports movements + Training of points related to low back pain with a back school approach 3) Training in sports movements + Training in points related to low back pain with a biopsychosocial approach

Main outcome variables

Incidence, prevalence, and degree of disability, treatment costs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048039N1**
Registration date: **2020-07-15, 1399/04/25**
Registration timing: **prospective**

Last update: **2020-07-15, 1399/04/25**
Update count: **0**

Registration date

2020-07-15, 1399/04/25

Registrant information

Name

Ali Ahmadzadeh Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8863 0227

Email address

ali_ahmdzdh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Adding back package to the primary care service, a cluster randomized field trial study

Public title
Effect of adding back package to he primary care
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
People affiliated with medical centers in rural areas
People aged between 18 to 60 years old
Exclusion criteria:
Diagnosed neoplasm Diagnosed significant psychiatric disorders Diagnosed Cognitive impairment Reluctance to participate
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **9440**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to prevent statistical contamination between individuals, randomization will be done in the cluster form at the level of health bases. 16 health bases with equal coverage population will enter the block randomization process in Excel software and will be blocked in four groups of control, Exercise Intervention, Exercise Intervention + Risk Factor Training, and Exercise Intervention + Fear-avoidance Training. The randomization method is block randomization, the unit is cluster randomization, and non-stratified randomization is used to better represent the reality of our target community. In this study, Excel statistical software will be used for randomization. The sequence construction is in the form of 4 blocks, each of which includes all 4 types of intervention (control and intervention). Finally, for allocation concealment, the subjects and health care providers do not know which group they belong to, but they do know that there are four groups in this study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, considering that each of the interventions is performed on separate bases, participants, health care providers (who are responsible for educating people and collecting data) were blinded to the type of low back pain package. The data analyst is also blinded to the type of training and back package.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Institute for Medical Research Development
Street address
No. 21, Besat St., West Fatemi St., Tehran, Iran
National Institute for the Development of Medical Research (NIMAD)
City
Tehran
Province
Tehran
Postal code
14196693111
Approval date
2019-06-16, 1398/03/26
Ethics committee reference number
IR.NIMAD.REC.1398.271

Health conditions studied

1

Description of health condition studied
Low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Low back pain incidence
Timepoint
After 12 months
Method of measurement
Based on the recorded information from the patient's referrals to the doctor and recording the diagnosis of low back pain in the patient's electronic file

Secondary outcomes

1

Description
Disability

Timepoint
After 12 months
Method of measurement
Roland Morris Disability Questionnaire

2

Description
Treatment costs
Timepoint
After 12 months
Method of measurement
Questionnaire

Intervention groups

1

Description
Control group: Without back package
Category
N/A

2

Description
Intervention group 1: A group of simple specific aerobic, strength and stretch exercises to strengthen the back muscles that are taught to people by a health care provider and pamphlet during a session and do not require special equipment
Category
Prevention

3

Description
Intervention group 2: A group of simple specific aerobic, strength and stretch exercises to strengthen the back muscles that are taught to people by a health care provider and pamphlet during a session and do not require special equipment + Teaching tips about the risk factors for low back pain and how to maintain a proper physical position that is taught to people during a session by a health care provider and pamphlet
Category
Prevention

4

Description
Intervention group 3: A group of simple aerobic, strength and stretch exercises to strengthen the back muscles that are taught to people during a session by a health care provider and pamphlets and do not require special equipment + educational tips on how to deal with fear and disability caused by low back pain that is taught to people during a session by a health care provider and pamphlet
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences Health Network
Full name of responsible person
Mohammad Hossein Pourgharib Shahi
Street address
Jalal Al-Ahmad Highway, in front of Dr. Shariati Hospital, Sports Medicine Research Center
City
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14395578
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pourgharib@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
National Institute For Medical Research Development
Proportion provided by this source
20
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Hossein Pourgharib Shahi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Jalal Al-Ahmad Highway, in front of Dr. Shariati Hospital, Sports Medicine Research Center
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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
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
The incidence rate of low back pain, the prevalence of low back pain, the low back pain disability, the costs of treatments
When the data will become available and for how long
Starting in January 2025 for 5 years
To whom data/document is available
Researchers in the field of public health, sports medicine, and health policymakers
Under which criteria data/document could be used
For systematic reviews and meta-analysis
From where data/document is obtainable
Sports Medicine Research Center, Tehran University of Medical Sciences
What processes are involved for a request to access data/document
Request from the Corresponding author with a well-explained reason
Comments