

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Incidence, prevalence, and degree of disability, treatment costs

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

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)

Phone

+98 21 8863 0227

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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 the 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

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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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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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

Tehran University of Medical Sciences

Full name of responsible person

Ali Ahmadzadeh Amiri

Position

Researcher

Latest degree

Medical doctor

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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

