

# 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

##### 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 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

**City**

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**Province**

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**Postal code**

14395578

**Phone**

+98 21 8863 0227

**Email**

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

**City**

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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

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**Person responsible for scientific 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**

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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

**Other areas of specialty/work**

Sport Medicine

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ali\_ahmdzdh@yahoo.com

**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**

