

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The Effect of Recreational Physical Activity Combined with Routine Physical Therapy in Comparison with Routine Physical Therapy Alone on Functional Ability and Quality of Life in Patients with Chronic Non-Specific Low Back Pain

Protocol summary

Study aim

Investigating the Effect of Recreational activities along with Routine Physical therapy in Comparison with Conventional Physical therapy alone on Functional tests and Quality of life in Chronic Non-specific low back pain in Patients. Referring to the Physiotherapy Clinic of the Faculty of Rehabilitation Sciences of Iran University of Medical Sciences in 1397

Design

Randomized Single-Blind Controlled Parallel Clinical trial

Settings and conduct

In this study, people with Chronic Non-Specific Low Back Pain Participated. After the Initial Evaluation and Filling out Questionnaires by Participants of the Project, Individuals are Randomly Assigned to Two Treatment Groups. The Treatment Lasts for 4 Weeks. Before and After Treatment, the pain and Function Variables of the Individuals are Evaluated. People in the Usual Treatment Group, 10 Sessions of "Tens" and Exercises are Performed. For the Physical Activity Group, the Actions Taken in the Usual Treatment Group are the Same, and after that, 30 Minutes of Constant Moderate Cycling is Added to the Program. The sessions are held Every Other Day at the Physiotherapy Clinic of the Faculty of Rehabilitation, University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Entry Requirements: Age 20-55 Causing Chronic Non-specific Low Back Pain Pain Intensity 30-60 at Rest Based on Pain Score Normal Body Mass Index Non-Entry Conditions: Severe Heart Disease Bone Abnormality in the Lumbar and Pelvic Region Systemic and Autoimmune Diseases Lumbar Discopathy and Radicular Pain to the Lower Extremity Trauma that has Recently Entered the Spinal Column

Intervention groups

Routine Physiotherapy Group Routine Physiotherapy

Combine with Recreational Activity Group

Main outcome variables

Reduce Pain Return to Normal Life Improve the Person's Performance and Ability to Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180728040618N2**

Registration date: **2019-09-18, 1398/06/27**

Registration timing: **retrospective**

Last update: **2019-09-18, 1398/06/27**

Update count: **0**

Registration date

2019-09-18, 1398/06/27

Registrant information

Name

Holakoo Mohsenifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 6933

Email address

mohsenifar.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2018-12-21, 1397/09/30
Actual recruitment start date
 2019-07-03, 1398/04/12
Actual recruitment end date
 2019-09-03, 1398/06/12
Trial completion date
 2019-09-09, 1398/06/18

Scientific title
 The Effect of Recreational Physical Activity Combined with Routine Physical Therapy in Comparison with Routine Physical Therapy Alone on Functional Ability and Quality of Life in Patients with Chronic Non-Specific Low Back Pain

Public title
 The Effect of Recreational Physical Activity On Functional Ability and Quality of Life in Patient with Chronic Non-Specific Low Back Pain

Purpose
 Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient Without any Precaution or Contraindication to Do Exercise Therapy Pain Between Twelfth Rib and Inferior Gluteal Fold in More Than Three Months and Without any Specific Reason Pain Intensity Between 30-60 in Rest Position for the 0-100 Pain Scale Normal Body Mass Index
Exclusion criteria:
 Acute Low Back Pain (Less Than 3 Months) Bone Anomalies in Lumbar and Hip Region (Such as Scoliosis Pregnancy Central or Peripheral Nerve Diseases Self Immune and Systemic Diseases Lumbar Discopathy with Radicular Pain in Lower Limb New Trum

Age
 From **20 years** old to **55 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **34**
 Actual sample size reached: **34**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization method is "Balanced Block Randomization" which include 4 letters and made from letter A and B. Then, randomization list in the shape of A and B are placed in numbered pockets. "A" is for the control treatment (routine physiotherapy) and "B" is for the subject treatment (routine physiotherapy combined with recreational activities). The randomization process is done before starting the study and by someone who is not in the research team. After the primitive assessment by the researcher, the numbered pockets are given to the subjects with the match numbers. Finally, after entering to the treatment sections the researcher choose

the treatment plane due to the numbers in the pockets.
Blinding (investigator's opinion)
 Single blinded
Blinding description
 Each patient does not know anything the other patient's type of treatment.

Placebo
 Not used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee for Biomedical Research

Street address

Thirteenth floor, block A, Central Headquarters of the Ministry of Health and Medical Education, Between South Falamak and Zarafshan ,Simaye Iran Street, Ghods(West) Town,Tehran , Iran

City

Tehran

Province

Tehran

Postal code

1916813797

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.IUMS.REC.1398.338

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Functional Ability

Timepoint

Before the Start of the Treatment Period and After it is Completed (Within 4 Weeks)

Method of measurement

Roland Morris Questionnaire Star Excursion Test Side hop test Single hop test

2

Description

Pain

Timepoint

Before the Start of the Treatment Period and After it is Completed (Within 4 Weeks)

Method of measurement

Linear Pain Measurement Score

Secondary outcomes

empty

Intervention groups

1

Description

Control group: For people in this group, the "TENS" treatment is done using the Germany-based 5820SL BTL device and exercise therapy. The sessions are held every other day between 13 and 17 . in each session, Therapy is used for 30 minutes of TENS (fifteen minutes of current with {high frequency; 100 Hz and pulse duration of 40 μ s}, and fifteen minutes of low frequency{ 5 Hz and pulse duration of 300 μ s }). There is no specific sequencing for the use of high and low frequencies for patients. The device used is the same for all people and uses a 60x80mm electrodes in this study. The location of the electrodes for patients can be variable, but their best position is on the site of pain. Therapeutic exercises in this study includes stretching exercises and core stability exercises. Stretching exercises include stretching of the lower limbs hamstrings, stretching of the quadratus lumbar muscle in both sides, knee extension to the chest with one leg and two legs. Each tensile exercise is repeated 10 times and kept for 10 seconds. The number of stretching training sets is set to 3. The core stability exercises include posterior hip tilt in supine position, cat and camel training in quadriceps and hands and feet lifting exercises in the four-legged position. The parameters of core stability exercises are the same with stretching exercises. People are also asked to repeat the exercises 2 or 3 times a day at intervals between therapeutic sessions.

Category

Rehabilitation

2

Description

Intervention group: For groups of recreational activities, previous interventions are exactly the same as the routine treatment group, and after that, 30 minutes of fixed cycling activity is added to the program. Tolerable intensity cycling is done in the way that the patient will perform 50 to 80 cycles per minute on the bike. The fixed bike seat is adjusted so that the knee joint does not reach its full extension and remains at 10 ° F. The fixed bike used in this study was manufactured by Horizon USA.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic, Faculty of Rehabilitation, Iran University of Medical Sciences

Full name of responsible person

Mahan Shahrooie

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Holako Mohsenifar

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Rehabilitation Faculty of Iran University of Medical Science, Madadkaran alley, Shahnazari street, Madar Square , Mirdamad Boulevard

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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
Iran University of Medical Sciences
Full name of responsible person
Mahan Shahrooie
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified individual participant data collected for the
primary and secondary outcome measures will be shared
if necessary.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

The data will be available for physical therapists working
in academic institutions and also clinicians working in the
field of musculoskeletal disorders

Under which criteria data/document could be used

The raw data and results of this study can be used in
future relevant systematic reviews. Thus, the raw data
and results of this study will be available for researchers
working in the field of low back pain.

From where data/document is obtainable

Applicants can contact the researcher of this study
Mahan Sahahrooie by email. Email address:
mahansh70@yahoo.com

What processes are involved for a request to access data/document

Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.

Comments