Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison the effect of patient-led goal setting with pain neuroscience education and Manual therapy in Patients with chronic low back pain.

Protocol summary

Study aim

This study aims to compare the effectiveness of patient-led goal setting with pain neuroscience education and Manual therapy in patients suffering chronic low back pain.

Design

A sample population of 45 subjects was purposefully selected using G-power statistical software. The volunteers are then equally divided into 3 groups (control group, patient-led goal setting group with pain neuroscience education and patient-led goal setting group with manual therapy).

Settings and conduct

Targeted individuals are randomly assigned to 3 groups of 15 people. Initially, the Start Back questionnaire will be used to evaluate and classify patients suffering from nonspecific chronic low back pain. Additionally, appropriate questionnaires will be used to assess pain intensity, disability, quality of life, depression / anxiety and stress, kinesiophobia, pain self-efficacy, and catastrophic pain, neurophysiology of pain, beliefs about fear avoidance and the presence of central sensitivity. Accordingly, these variables will be measured 2, 4, and 12 months after the conclusion of the intervention.interventions will be performed in Kharazmi University Health Centre.

Participants/Inclusion and exclusion criteria

Inclusion criteria targets individuals aged 18 to 65 with a history of nonspecific low back pain. Exclusion criteria individuals who have had spinal surgery in the past 12 months or report serious pathological signs and symptoms are excluded from this study.

Intervention groups

This study consists of three groups, including the control group, the patient-led goal setting group with pain neuroscience education, and the patient-led goal setting group with Manual therapy.

Main outcome variables

There is a difference between a patient-led goal-setting approach with patient leadership combined with pain neuroscience education or manual therapy on pain intensity in people with chronic low back pain.

General information

Reason for update

It is respectfully requested that an update be made regarding the editing of the sample size due to the necessary corrections on the power values of the test and the effect size of the main research variables. The sample size was calculated based on the following process: Considering a repeated measure ANOVA test using effect size η=0.25, confidence level α=0.05, expected power 95%, number of groups 3, and by performing 4 measurement stages of the test Therefore, the total number of required samples was estimated to be 45 people (and in other words, 15 people in each group), the mentioned calculations were done using G*Power version 3.1.9.2 software (Faul, Erdfelder et al. 2007). Sincerely, Soheili

Acronym

IRCT registration information

IRCT registration number: **IRCT20210927052616N1**
Registration date: **2021-11-03, 1400/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-12, 1402/01/23**
Update count: **2**

Registration date

2021-11-03, 1400/08/12

Registrant information

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Sahar Soheili

Name of organization / entity

Kharazmi University of Tehran

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of patient-led goal setting with pain neuroscience education and Manual therapy in Patients with chronic low back pain.

Public title

Evaluation of the effect of patient-led goal-setting approach in combination with pain neuroscience training or manual therapy in patients with chronic low back pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a history of nonspecific low back pain Minimum duration of low back pain is 3 months They reported pain intensity with 4 out of 11 points in the NRS questionnaire and at least 20 points in the QBPDS.

Exclusion criteria:

Spinal surgery report in the last 12 months Severe osteoporosis Signs and symptoms reported from serious pathology Spondyloarthritis Spondylolisthesis Spinal canal stenosis Traumatic spinal cord injury such as a fracture or car accident Spinal dislocation Spinal cord metastasis Has symptoms of Cauda Equina syndrome Structural scoliosis Pregnancy History of seizures, epilepsy, stroke or head injuries Taking medications for patients with mental health problems

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Following the baseline examination, by using the method shown on the website http://randomizer.org/ (Social Psychology Network, Connecticut, USA), participants will be randomly assigned into the patient-led goal-setting approach group In combination with pain neuroscience education, the patient-led goal-setting approach group will be combined with manual therapy. Simple randomization will be used. Concealed allocation is performed using a computer-generated block randomized table of numbers (1 for patient-led goal-setting approach group In combination with pain neuroscience education and 2 for the patient-led goal-setting approach group will be combined with manual therapy) created before the start of data collection by a researcher who is not involved in the recruitment or treatment of patients. Then, the random numerical sequence is placed in sealed opaque envelopes. Another researcher, blind to the baseline examination, open an envelope and process with treatment according to the group assignment. An independent assessor who is not known about the study's hypothesis and methods and is blind to the treatment group, assess the outcome measures before the interventions, 2 months after treatment, and 4 and 12 months after the end of the intervention, each time measured.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor was blinded of the process of randomization and division of individuals into two experimental and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institute of Physical Education and Sports Sciences

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Saadat Abad, above Kaj Square, Ali Akbar St., No. 7

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Postal code

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Approval date

2021-08-21, 1400/05/30

Ethics committee reference number

IR.SSRC.REC.1400.084

Health conditions studied

1

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

Primary outcomes

1

Description
Pain intensity
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Numerical Rating Scale

2

Description
Kinesophobia
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Tampa Scale For Kinesiophobia

3

Description
Fear Avoidance Beliefs
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Fear Avoidance Beliefs Questionnare

4

Description
Disability
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Qubec Back Pain Disability Scale

5

Description
Quality Of Life
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
SF_36 Scale

6

Description
Anxiety
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Depression Anxiety Stress Scale

7

Description
Depression
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Depression Anxiety Stress Scale

8

Description
Stress
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Depression Anxiety Stress Scale

9

Description
Pain Self-efficacy
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Pain Self-Efficacy Questionnare

10

Description
Central Sensitivity Inventory
Timepoint
First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions
Method of measurement
Central Sensitization Inventory

11

Description
Catastrophic pain
Timepoint

First at the beginning of the work, 2 months after treatment, 4 and 12 months after the end of interventions

Method of measurement

Pain Catastrophizing Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patient-led goal setting group with Manual therapy. The goal-setting approach will be conducted over the course of 2 months through a one-hour face-to-face session followed by 4 sessions of 15 to 30 minutes over 2 weeks. Subsequently, two 30-minute sessions are performed with an interval of one month. Furthermore, twelve months after initiating the research the final session is performed and the results are collected. In this approach, the author has employed the SMART model which features measurable and achievable goal-setting processes that are specific to a time frame. In the aforementioned model, the researcher is trained in patient-led goal setting, takes the low back pain history of the patient into consideration, and engages in conversation regarding the consequences of their ailment. Moreover, the patient is asked to prioritize the problems based of their preferences. Afterward, strategies are considered based on evidence-based guidelines and the participant sets goals and chooses strategies to implement individually in between sessions. The participants will record their goals, progress, and obstacles and strategies to overcome the obstacles in their notebooks. If the target strategies include consultation with a healthcare professional, the participant is encouraged to pursue this independently. Manual therapy includes 18 sessions of 60 minutes over 6 weeks. For manual treatment, soft tissue mobilization techniques, muscle energy techniques, and joint mobilization are performed. Soft tissue mobilization includes myofascial stretching for superficial and deep muscles, transverse friction for intervertebral, and supraspinal ligaments. Muscle energy techniques include relaxation after isometric contraction for the quadratus lumbarum and piriformis muscles. The participant is asked to gently contract these muscles for 8 seconds with 30% of maximum contraction. This practice is repeated after each rest. The assessment of Joint mobilization is based on sacroiliac mobility test, sacroiliac mobility with standing flexion forward test, Gillet test, and Piedallu Sign.

Category

Other

2

Description

Intervention group: patient-led goal setting group with Manual therapy.The goal-setting approach will be done with patient leadership over 2 months, which includes 5 face-to-face sessions, with the first session lasting one hour and the other four sessions lasting 15 to 30 minutes over two weeks. After that, two follow-up sessions (duration 30 minutes) are performed with an interval of one month. Also, one session is performed after 12 months after the first session and finally the results are collected. To perform this approach, a model called SMART is used, which includes a special process for goal setting that is measurable, achievable and related to a specific time return. In this model, the researcher is trained in setting goals by the patient, history of low back pain Considers the participant and talks about the problems caused by low back pain. Ask the participant to prioritize these problems based on what they want to focus on. Strategies are then discussed based on evidence-based guidelines, and the participant sets specific goals and strategies for the participants to work independently between sessions. They record what they agree to achieve in their workbook. If the target strategies include consultation with a healthcare professional, the participant is encouraged to pursue this independently. Manual therapy includes 18 sessions of treatment for 6 weeks and three times a week, each session lasting 60 minutes. For manual treatment, soft tissue mobilization techniques, muscle energy techniques and joint mobilization are performed. Soft tissue mobilization includes myofascial stretching for superficial and deep muscles, transverse friction for intervertebral and supraspinal ligaments. Muscle energy techniques include relaxation after isometric contraction for the quadratus lumbarum and piriformis muscles. We ask the participant to gently contract these muscles for 8 seconds with 30% of maximum contraction. This movement is repeated after each rest. Joint mobilization is assessed based on sacroiliac mobility test, sacroiliac mobility with standing flexion forward test, Gillet test, Piedallu Sign.

Category

Other

3

Description

Control group: Without receiving any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi University Health Center

Full name of responsible person

Sahar Soheili

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
Amir Letafatkar
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, South Razan Street, Hesari Street, Keshvari Sport complex
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Grant name
Kharazmi University
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kharazmi University
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
Kharazmi University
Full name of responsible person
Sahar Soheili
Position
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Latest degree
Bachelor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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