

Physical therapy for non-specific chronic low back pain derived from occupational risk

Submission date 18/03/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 25/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/03/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aim

Non-specific chronic low back pain (NSCLBP) is one of the most prevalent musculoskeletal disorder (13-15%) in the Mexican working population. This affection produces disability and impairs the quality of life of patients who suffer from this condition. Recently, the international guidelines for the management and treatment of low back pain suggest that physical therapy, as a non-pharmacologic treatment, is an effective therapeutic option for patients with NSCLBP. On the other hand, non-treated NSCLBP in the working population produces a high economic impact for the company and the public and private health systems. Hence, the early detection of occupation risk and concomitantly, the diagnoses and treatment of affected workers with back pain, is one of the gold objectives in the field of occupational health. The aim of this study was to determinate the effects of physical therapy as a treatment approach in NSCLBP derived from occupational risk. Also, this physical intervention tries to impact the overall quality of life in the workers.

Who can participate?

Patients in a range of age between 18 - 55 years of both genders, who presented chronic low back pain condition during the last 12 months.

What does the study involve?

The included participants undergo a physical therapy rehabilitation intervention which includes: 1) Core exercises 2) manual therapy and 3) pain neurological education, applied for 4 weeks. Participants complete questionnaires and assessments at the beginning of physical therapy and at the end.

What are the possible benefits and risks of participating?

The benefits of this physical therapy intervention are directly measured as a improvement in pain and quality of life in patients. It is important to highlight that this alternative treatment doesn't represent a risk for enrolling patients. The main risk of manual therapy is a musculoskeletal lesion; however, this therapy involves a light manipulation free of pain or damage. The intensity of core exercise is increased gradually each week. Participants will be able to abandon the study if they consider that have not improved after the first week, or if the painful condition gets worse.

Where is the study run from?

The study is being run by National Autonomous University of Mexico, including Medicine School and Chemistry School, and the University of the Valley of Mexico and takes place Queretaro bottling industry IEQSA, whom we acknowledgment for allowing the development of this protocol in their facilities.

When is the study starting and how long is it expected to run for?

July 2020 to December 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CSUVM042020

Study information

Scientific Title

Pre-clinical and post-clinical evaluation of physical therapy rehabilitation on non-specific chronic low back pain derived from occupational risk: a pilot study with an intervention of 4-week follow-up

Study objectives

The physical therapy rehabilitation intervention decreases non-specific chronic low back pain derived from occupational risk.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/09/2020, University of the Valley of México Research and Ethics Committee (Naranjos Punta Juriquilla 1000, 76230 Santiago de Querétaro, México; +52 (0)442 2111900; belzabeth.tovar@uvmnet.edu), ref: CSUVM042020

Study design

Clinical interventional longitudinal and prospective pilot trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-specific chronic low back pain derived from occupational risk

Interventions

Participants are recruited by an internal call for low back pain during the last 12 months. All participants were diagnosed with non-specific chronic low back pain derived from occupational risk. The participants undergo a physical therapy rehabilitation intervention which includes core exercises (basic, intermediate and advanced), manual therapy (myofascial release, McKenzie exercises and diaphragmatic breathing) and pain re-education, in a scheme of 30 minutes per session, two times a week, for 4 weeks.

Intervention Type

Behavioural

Primary outcome(s)

Pain measured using a visual analogue scale (VAS) at baseline (pre-treatment) and after 4 weeks (post-treatment)

Key secondary outcome(s)

1. Kinesophobia measured using the Tampa scale of Kinesophobia at baseline (pre-treatment) and after 4 weeks (post-treatment)
2. Disability measured using the Oswestry Questionnaire at baseline (pre-treatment) and after 4 weeks (post-treatment)
3. Sleep quality measured using the Pittsburgh Questionnaire at baseline (pre-treatment) and after 4 weeks (post-treatment)

4. Quality of life measured using the short form 36 questionnaire (SF-36) at baseline (pre-treatment) and after 4 weeks (post-treatment)

Completion date

08/12/2020

Eligibility

Key inclusion criteria

1. Worker with localized chronic low back pain (≥ 6 months) presenting mild, mild-moderate and /or moderate pain, according to the VAS scale
2. Pain associated with an occupational risk
3. Constant and collaborative patient
4. Not receiving pharmacological treatment
5. Without aggravating family history
6. Aged 20 to 55 years
7. Actively working in the company

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

14

Key exclusion criteria

1. Workers who are receiving pharmacological treatment prior to or during the study
2. Non-cooperative worker
3. Neoplastic process
4. Neurological disorders
5. Pregnancy
6. Previous or current trauma
7. Obesity

Date of first enrolment

08/10/2020

Date of final enrolment

01/11/2020

Locations

Countries of recruitment

Mexico

Study participating centre

IEQSA bottling industry

Av. 5 de Febrero 1323, Benito Juárez

Santiago de Querétaro

Mexico

76130

Sponsor information

Organisation

National Autonomous University of Mexico

ROR

<https://ror.org/01tmp8f25>

Organisation

University of the Valley of Mexico

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			26/03/2021	No	No