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

Submission date
18/03/2021

Recruitment status
No longer recruiting

Registration date
25/03/2021

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 questionaries 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 Vallely 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?
Geovanna Nallely Quiñonez-Bastidas, PhD., Geovanna_quinonez@quimica.unam.mx

Contact information

Type(s)
Scientific

Contact name
Dr Geovanna Quiñonez-Bastidas

ORCID ID
http://orcid.org/0000-0002-8006-3022

Contact details
Ciudad Universitaria, Coyoacán
Ciudad de Mexico
Mexico
04360
+52 (0)5556225329
geovanna_quinonez@quimica.unam.mx

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures
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)

Overall study start date
08/07/2020

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

Age group
Adult

Sex
Both

Target number of participants
457

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

Sponsor details
Ciudad Universitaria
Coyoacán
Mexico City
Mexico
04510
+52 (0)5556225329
Omarf.carrasco@facmed.unam.mx

Sponsor type
University/education

Website
http://www.unam.mx

ROR
https://ror.org/01tmp8f25

Organisation
University of the Valley of Mexico

Sponsor details
Naranjos Punta Juriquilla 1000 Santa Rosa Jáuregui
Santiago Queretaro
Mexico
76230
+52 (0)800 000 0886
Diana.espinoma@my.uvm.edu.mx

Sponsor type
University/education

Website
https://uvm.mx/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2021

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