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A study investigating the effects of an adapted Qigong exercise programme in patients suffering from chronic low back pain

Submission date
18/06/2024

Recruitment status
No longer recruiting

Registration date
02/07/2024

Overall study status
Ongoing

Last Edited
02/07/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-specific chronic low back pain is a common musculoskeletal condition with very high direct and indirect costs in health systems globally. Furthermore, it is linked with several comorbidities such as depression, anxiety, sleep disorders, and kinesiophobia and has been linked with considerable functional disability. Evidence suggests that Qigong exercise plays a beneficial role in the treatment of chronic low back pain. However, there is still a limited number of studies investigating the effects of Qigong on parameters and comorbidities that exist in this population and comparing Qigong with other treatment methods. The main hypothesis of this study is that the addition of a Qigong exercise routine will be superior to the addition of stretching exercises or no exercises on standardised acupuncture treatment.

Who can participate?
Adults aged between 18 and 65 years old with pain in their lower back for more than three months and have been previously diagnosed with non-specific chronic lower back pain

What does the study involve?
Participants will be randomly allocated to three groups. In all the groups, participants will receive acupuncture as a baseline treatment and either receive no other treatment, supervised and home-based stretching exercises or supervised and home-based Qigong exercises.

What are the possible benefits and risks of participating?
The benefits of participating in this study are pain reduction, improvement in functionality, and psychosocial factors commonly linked with the disease. Acupuncture and exercise techniques have a very good safety record and adverse events are extremely rare.

Where is the study run from?
University of West Attica, Greece

When is the study starting and how long is it expected to run for?
January 2020 to December 2025

Who is funding the study?
1. Investigator initiated and funded
2. University of West Attica, Greece

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomised control trial comparing the effects of acupuncture combined with an add on Qigong programme, to acupuncture as a stand alone treatment and acupuncture combined with stretching exercises, in terms of pain, proprioception, functionality and psychosocial comorbidities.

Study objectives
Participants allocated in the group receiving the add-on program of adapted Qigong exercises will show statistically significant differences compared to the group who will follow usual exercises with stretching and in the acupuncture group, regarding pain, functionality and psychosocial factors.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 15/11/2021, Aretaieio Hospital (EKPA / Medical School), Research Ethics Committee (76 Vas. Sofias Str., Athens, 11528, Greece; +302107286128; bxeir@aretaieio.uoa.gr), ref: 377/15-11-2021

2. Approved 21/06/2023, Research Ethics Committee University of West Attica (Agiou Spyridonos 28, Aigaleo, 12243, Greece; +302105387294; ethics@uniwa.gr), ref: 52120/30-05-2023

Study design
Interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, University/medical school/dental school

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
Chronic low back pain

Interventions
Participants will be randomly allocated into three treatment Groups. All treatment groups will receive two treatments in the first four weeks and one treatment in the following four weeks.

Group A (Acupuncture): Sixteen standardised acupuncture points will be used. Needling placement will follow the WHO (2008) guidelines on acupuncture point locations. The acupoints chosen are: Large Intestine 4 (LI4), Stomach 36 (ST36), Spleen 6 (Sp 6), Gallbladder 30 (GB30) and Bladder 23, 24, 25, 26 (Bl23, Bl24, Bl25, &Bl26). All acupoints will be used bilaterally and electroacupuncture will be used in the following parts: LI4- LI4, ST36 - ST36, BL23(R)- BL26(R) and BL23(L) - BL23(L). The electroacupuncture will be delivered with a Frequency of 2 Hz. Each treatment session will have a duration of 25 minutes

Group B (Acupuncture and stretching). In this group, all participants will receive the same acupuncture treatment as described in Group A and additionally, they will receive a stretching exercise programme. Stretching will involve the hamstrings, the quadriceps, the tensor fascia latte, the gastrocnemius, the piriformis, and the core flexor and extensor muscles. Specifically, the following stretching exercises will be used bilaterally when needed: double knee to chest, hamstring muscle stretching, piriformis muscle stretching, tensor fasciae latae stretching, cat-camel stretching, and calf stretching. All stretches will be performed under the supervision of a researcher (blinded to the experiment and any other treatments either offered in other groups or in this group) following the acupuncture treatment. All stretches will be performed three times, the duration of each stretch will be 30 seconds followed by a 30-second interval. Participants will be given a handout and will be asked to perform them once daily at their house.

Group C (Acupuncture and Qigong)
In this group, all participants will receive the same acupuncture treatment as described in Group A and additionally, they will receive a Qigong exercise programme. Specifically, a standardised version of the Baduanjin - Eight pieces of Brocade - Qigong routine will be used. The participants will have an exercise session under the supervision of a researcher (blinded to the experiment and any other treatments either offered in other groups or this group) following the acupuncture treatment. The duration of this exercise routine will be approximately 10 - 15 minutes. Participants will be given a handout and will be asked to perform them once daily at their house.

Intervention Type
Mixed

Primary outcome measure
Pain measured through the sensitivity to pressure stimuli using a digital algometer calculating pressure pain thresholds at baseline, and 8 and 22 weeks

Secondary outcome measures
The following Secondary outcome measures are assessed at baseline, 8 weeks and 22 weeks, unless stated:
1. Functional impairment measured using the five-repetition sit-to-stand test
2. Pain in conjunction with its psychosocial properties measured using the Short Form McGill Pain Questionnaire
3. Patients subjective measurement of their condition measured using the Global Perceived Effect scale at 8 weeks and 22 weeks
4. Disability measured using the Roland Morris Disability Questionnaire
5. Kinesiophobia measured using the Fear-Avoidance Beliefs Questionnaire (FABQ)

6. Depression and anxiety measured using the Hospital Anxiety and Depression Scale (HADS)
7. Catastrophising measured using the Pain Catastrophising Scale (PCS)
8. Quality of life measured using the 12-item Short Form Survey (SF-12) questionnaire
9. Compliance measured using a log that the participants complete at 8 weeks and 22 weeks
10. Medications measured using data recorded in a log

Overall study start date
01/01/2020

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Aged between 18-65 years old
2. Ability to provide consent, good knowledge of Greek
3. Low back pain lasting more than three months
4. Diagnosis of nonspecific chronic low back pain
5. Pain sensation on the VAS scale >5

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Participation in an exercise program in the previous three months
2. Participation in a physiotherapy program in the previous three months
3. Pain due to malignancy
4. Spondyloarthritis
5. Rheumatoid arthritis
6. Pregnancy
7. Postpartum (Up to six months from birth)
8. Knee osteoarthritis

9. Cognitive disability
10. Red Flags (e.g. suspicion of fracture, malignancy, cauda equina syndrome, rapid decrease in muscle strength, etc.)

Date of first enrolment
03/03/2023

Date of final enrolment
15/01/2025

Locations

Countries of recruitment
Greece

Study participating centre
University of West Attica
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Study participating centre
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Sponsor information

Organisation
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Sponsor type

University/education

Website
https://physiolab.uniwa.gr/

ROR
https://ror.org/00r2r5k05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
University of West Attica

Results and Publications

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

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan
Individual participant data collected during the trial will be available after de-identification (text, tables, figures, and appendices), until the 31st of December 2027. Access will be granted to researchers who provide a methodologically sound proposal to achieve the aims of the approved proposal. Proposals should be directed to Mr. Spyridon Sotiropoulos (spiros_sotiropoylos@hotmail.com). Data requestors must sign a data access agreement to gain access. After this date, the data will not be applicable. During recruitment, patients are informed of the purposes of our study.
Upon acceptance and before baseline measurements, participants give their written informed consent (document in Greek). The ethics committee of the University of West Attica will have to co-sign the release of the data.

IPD sharing plan summary
Available on request