

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of Ergon Technique with Neuromuscular Electrical Stimulation in Addition to Routine Physical Therapy on Pain and Functional Mobility in Patients with Non Specific Chronic Low Back Pain

Protocol summary

Study aim

Purpose of this study was to investigate the effectiveness of Ergon technique with neuromuscular electrical stimulation (NMES) on pain and functional mobility in patients with chronic low back pain (CLBP).

Design

Two-center, parallel group, concealed, double blind, randomized controlled trial of 50 participants.

Settings and conduct

1) Physical Therapy Department, University of Lahore Teaching Hospital. 2) University Physical Therapy and Rehabilitation Clinic, University of Lahore. Participant, and outcome assessor blinded.

Participants/Inclusion and exclusion criteria

Both adult males and females; 18 - 60 years of age diagnosed with chronic low back pain (CLBP) duration 3 months or greater and BMI less than 30 were included. Participants were excluded if they have positive nerve root tension signs or neurological deficit. Suffered from any spinal tumor or infection, spinal fracture. Contraindications to Ergon technique and NMES (e.g. skin allergy/wound). Previous experience with myofascial therapy or a history of rehabilitation treatment for back pain within the preceding 1 month.

Intervention groups

In group 1 Progression of Ergon Technique from basic to advance using multiple strokes on lower back especially paraspinal muscles, multifidus and transverse abdominis(TrA) for a duration of minimum 10 mins as per patient requirement. The NMES electrodes were placed on multifidus and TrA for 20 mins. Same protocol of physical therapy as in group 2 except for TENS because of NMES protocol. In group 2 Lumbar mobility, stabilisation and strengthening exercises, aerobic exercises, hams stretching, Hot pack, TENS (20 mins) (Continuous mode) The treatment was provided for 1 hour, 3 days per week on alternate basis, for 4 weeks (12

sessions).

Main outcome variables

Modified oswestry disability questionnaire was used to assess functional mobility. Numeric pain rating scale was used for pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201101049222N1**

Registration date: **2020-11-27, 1399/09/07**

Registration timing: **retrospective**

Last update: **2020-11-27, 1399/09/07**

Update count: **0**

Registration date

2020-11-27, 1399/09/07

Registrant information

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Name of organization / entity

The University of Lahore

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-09, 1398/12/19

Expected recruitment end date

2020-09-10, 1399/06/20
Actual recruitment start date
 2020-03-09, 1398/12/19
Actual recruitment end date
 2020-09-15, 1399/06/25
Trial completion date
 2020-10-16, 1399/07/25

Scientific title
 Effectiveness of Ergon Technique with Neuromuscular Electrical Stimulation in Addition to Routine Physical Therapy on Pain and Functional Mobility in Patients with Non Specific Chronic Low Back Pain

Public title
 Effect of Ergon IASTM technique in treatment of chronic low back pain

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosed patients of chronic low back pain (CLBP) duration 3 months or greater Both adult males and females; 18 - 60 years of age Body mass index (BMI) less than 30
Exclusion criteria:
 Positive nerve root tension signs, signs of progressive or persistent neurological deficit. Suffered from any spinal tumor or infection, spinal fracture Contraindications to Ergon Technique and neuromuscular electrical stimulation (NMES) (e.g. skin allergy/wound). Have severe cardiovascular or pulmonary problems Fibromyalgia, cauda equina syndrome, previous spine surgery or musculoskeletal injuries of the lower limbs, pregnancy or plans to become pregnant. Systemic disease (autoimmune, infectious, vascular, endocrine, metabolic or neoplastic disease) Previous experience with myofascial therapy or a history of rehabilitation treatment for back pain within the preceding 1 month.

Age
 From **18 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **50**
 Actual sample size reached: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The study was designed to be a parallel group randomized controlled trial. After baseline assessment, eligible patients were randomly assigned (in a 1:1 ratio) Ergon + NMES + routine physical therapy (ERGON intervention group) or routine physical therapy (control group). Computer generated randomization assignments designed by an independent statistician and

randomization was done by one of the research team member who was not involved in patient recruitment or assessment or data analysis. Randomization is without stratification, with the use of permuted-block randomization; the randomization assignments were kept in opaque, sealed envelopes and unsealed by a researcher after baseline testing.

Blinding (investigator's opinion)

Double blinded

Blinding description

After randomisation, study participants were only informed about the content of their allocated programme by their therapist, remaining unaware of the intervention in the other group. Patient information stated that the study purpose was to evaluate the effects of exercise and physical therapy interventions on chronic low back pain, without specifying that one of the programmes was considered a control intervention. Information about the details of both programmes was not provided except for similarities across both groups (exercise regime). Both programmes were personalised to the patient's abilities to ensure all eligible patients could complete the programme. Outcome assessors were masked to group allocation. Patients were instructed not to talk about the content of their exercise programme during the post intervention visit and could contact their therapist in case of any problems during trial participation. Moreover, if two or more study participants were in the clinic/hospital at the same time, they were assign to different treatment areas without any opportunity to observe each other or their treatment times were rearranged to prevent unintended crossover.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of The University of Lahore

Street address

1-KM Defence Road, Off Bhubatian Chowk, Lahore

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Approval date

2020-03-06, 1398/12/16

Ethics committee reference number

IRB-UOL-FAHS/718-V/2020

Health conditions studied

1

Description of health condition studied

Non Specific Chronic Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain

Timepoint

At baseline (before intervention), and at end of treatment (4 weeks)

Method of measurement

Numeric pain rating scale (NPRS). The NPRS measures pain intensity on an 11-point scale from 0 (no pain) to 10 (maximum pain). We used the "triple NPRS" in which the subject is asked to respond to three questions: (1) the intensity of current pain; (2) the best pain intensity in the past 24 h; and (3) the worst pain intensity in the past 24 h. The mean of these sub-scores was reported as the subject's NPRS score.

2

Description

Functional mobility

Timepoint

At baseline (before intervention), and at end of treatment (4 weeks)

Method of measurement

Modified Oswestry disability questionnaire (MODQ). The MODQ is a self-reported measure of functional disability consisting of 10 questions about various activities related to back pain. Each question has 6 possible responses ranging from 0 to 5, with a total possible maximum score of 50. The total MODQ score is multiplied by 2 to get a percentage score, with higher percentages indicating greater levels of self-reported disability.

Secondary outcomes

1

Description

Fear Avoidance

Timepoint

At baseline (before intervention) and at end of treatment (4 weeks)

Method of measurement

The Fear Avoidance-Behavior Questionnaire (FABQ) is a self-reported questionnaire consisting of a total of 16 items, divided into two subscales: physical activity (5 items) and work (11 items). Not all items are calculated toward the final score (i.e. item 1 in the physical activity

scale, and items 8, 12, 14 and 16 in the work scale do not count). The total possible maximum FABQ score is 66, with higher scores indicating greater levels of fear avoidance.

Intervention groups

1

Description

Intervention group: ERGON + EMS +RPT. Progression of ERGON Technique from basic to advance using multiple strokes on lower back especially paraspinal muscles, multifidus and transverse abdominis (TrA) for a duration of minimum 20 mins as per patient requirement. The NMES electrodes were placed on multifidus and TrA and parameters were set to produce a pulse frequency of 75 pulses per second, a pulse duration of 250 μ s, with a 4-s ramp up and ramp down time, and a 6-s stimulation period at the maximum amplitude, followed by a 50 s rest period to minimize fatigue. Same protocol of exercise and routine physical therapy as in control group except for TENS because of NMES protocol in this group.

Category

Rehabilitation

2

Description

Control group: Routine physical therapy. Strengthening exercises of lumbar extensors (10 reps * 2 sets), Stretching Hams (5 sec hold 3 reps * 3 sets), Hot pack 10 mins, Lumbar mobility exercises (10 reps * 2 sets), Aerobic exercises (Cycle ergometer 10 mins), Lumbar Stabilisation exercises (5 reps * 3 sets), TENS (20 mins) (Continuous mode). The treatment was provided at hospital/rehabilitation clinic during the 1 hour therapy session, 3 days per week on alternate basis, for 4 weeks (12 sessions).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Department, University of Lahore Teaching Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

The University of Lahore

Proportion provided by this source

100

Public or private sector

Private

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**

The University of Lahore

Full name of responsible person

Muhammad Haider Ullah Khan

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

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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

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

Title and more details about the data/document

IPD, study protocol, statistical analysis plan, informed consent form and clinical study report will be shared for primary and secondary outcome measure with interested research after considering the ethics and confidentiality.

When the data will become available and for how long

Data will be available after 6 months of publication for 3 consecutive years.

To whom data/document is available

Data will only be shared with individual researcher and academic researchers working in movement disorders. Data will not be shared for any commercial purposes/businesses for any reasons.

Under which criteria data/document could be used

Data can be used under confidentiality and ethics.

From where data/document is obtainable

Data can be obtained by emailing at haiderullah@live.com. Mobile number 0092 331 4127210

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

Simple email can do this. But this can take up to 4 weeks.

Comments