Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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Pakistan

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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 neoplasic 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 Bhobatian Chowk, Lahore

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54000

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 μs, 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 3reps * 3 sets), Hot pack 10 mins, Lumbar mobility exercises (10 reps * 2 sets), Aerobic exercises (Cycle ergometer 10 mins), Lumbar Stabilisation exercises (5reps * 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
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Full name of responsible person
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2

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
Physiotherapy

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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