# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effects of Baduanjin Exercise Versus Instrument-Assisted Soft Tissue Mobilization on Erector Spinae Muscle Spasm in IT Workers: A Randomized Controlled Trial

## Protocol summary


**Study aim**

To compare the effectiveness of Baduanjin exercises versus Instrument Assisted Soft Tissue Mobilization (IASTM), both combined with hot packs, on reducing pain, muscle spasm, functional disability, and improving lumbar range of motion among IT workers in Gujranwala with erector spinae spasms.

**Design**

A two-arm, multi-center, parallel-group, single-blind, randomized clinical trial with 120 planned participants. Individuals were randomly allocated in a 1:1 ratio using a computerized sequence via an online randomizer with allocation concealment to maintain participant-level blinding.

**Settings and conduct**

This single-centered trial was conducted in Mega NADRA office in Gujranwala, Pakistan.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: IT workers (20–45 years) diagnosed with erector spinae spasms, localized tenderness, palpable trigger points, NPRS score :> 2/10, and ODI score between 0% and 40%. Exclusion Criteria: Spinal pathologies (tumors, infections, fractures), lumbar surgery within 6 months, severe cardiac conditions, active skin lesions, or pregnancy.

**Intervention groups**

Group A (Baduanjin): Received a 10-minute hot pack followed by 20–25 minutes of Baduanjin Qigong exercises (8 movements combining stretching, deep breathing, and focus). Conducted 3 times a week for 4 weeks. Group B (IASTM): Received a 10-minute hot pack followed by 20–25 minutes of Instrument-Assisted Soft Tissue Mobilization (scraping strokes using mechanical tools over the erector spinae muscles). Conducted 3 times a week for 4 weeks.

**Main outcome variables**

- Primary Outcome Measures: Pain intensity on the Numeric Pain Rating Scale (NPRS) and lumbar functional disability via the Oswestry Disability Index (ODI). - Secondary Outcome Measures: Active lumbar spine flexion and extension range of motion (ROM) measured by an inclinometer, and physical palpation findings for muscle spasm.


## General information

**Reason for update**

**Acronym**

BEST-IT Trial (Baduanjin vs Erector Spinae Treatment in IT workers)

**IRCT registration information**

IRCT registration number: **IRCT20260529069564N2**
Registration date: **2026-06-16, 1405/03/26**
Registration timing: **retrospective**

Last update: **2026-06-16, 1405/03/26**
Update count: **0**

**Registration date**

2026-06-16, 1405/03/26

**Registrant information**


**Name**

Sajjan Iqbal Memon

**Name of organization / entity**

Chiniot General Hospital, Korangi

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Pakistan

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-11-01, 1404/08/10
**Expected recruitment end date**
2026-04-30, 1405/02/10
**Actual recruitment start date**
2026-02-06, 1404/11/17
**Actual recruitment end date**
2026-05-30, 1405/03/09
**Trial completion date**
2026-05-30, 1405/03/09

**Scientific title**
Effects of Baduanjin Exercise Versus Instrument-Assisted Soft Tissue Mobilization on Erector Spinae Muscle Spasm in IT Workers: A Randomized Controlled Trial

**Public title**
Relieving Back Muscle Spasms in IT Workers: Comparing Baduanjin Exercises and Instrument-Assisted Soft Tissue Therapy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Demographics: Male and female IT-workers aged between 20 to 45 years. Clinical Presentation: Formally diagnosed with erector spinae muscle spasm, tenderness, and visible or palpable trigger points upon clinical palpation. Pain Level: A baseline pain intensity score of $\ge$ 2/10 recorded on the Numeric Pain Rating Scale (NPRS). Disability Score: Baseline Oswestry Disability Index (ODI) scores indicating an impairment range between 0% and 40%.
**Exclusion criteria:**
Red Flags: Presentation of spinal pathology "red flags", including cauda equina syndrome, active infections, tumors, structural spondylolisthesis, severe spondylosis, or a recent spinal fracture. Surgical History: Any recent history of lumbar spine surgery performed within the past 6 months. Pregnancy & Systemic Conditions: Patients who are pregnant or present with severe cardiac diseases and other contraindications to manual or exercise therapy. Skin & Integumentary Conditions: Active skin infections, lesions, or open wounds over the localized treatment area.
**Age**
From **20 years** old to **45 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **124**
Actual sample size reached: **120**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Method of Randomization: Simple Randomization was used to distribute the study participants. The distribution of assignments followed a fixed 1:1 allocation ratio, ensuring that participants had an equal probability of being assigned to either treatment arm. Unit of Randomization: The unit of randomization was the individual participant (adult IT professionals formally diagnosed with erector spinae muscle spasm). Cluster or group-based randomization was not utilized. Randomization Strata: Stratified randomization was not applicable (N/A) for this study, as no pre-enrollment stratification or subgroup blocking (e.g., separating by gender or specific age bands) was carried out prior to assignment. Tools Used in Randomization: The primary tool used to generate the random assignments was an automated computer program, specifically the Online Research Randomizer tool. How the Random Sequence was Built: A random sequence was electronically built and generated by the software program. This computerized sequence dictated whether an enrolling individual would enter Group A (Baduanjin Exercise program) or Group B (Instrument-Assisted Soft Tissue Mobilization). Allocation Concealment:Yes, allocation concealment was carried out. To safeguard against selection bias, the generated random allocation sequence was concealed from the study participants. Participants were kept fully blinded to their specific group allocation; only specific research team members handling data logistics held access to the generated sequence.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
To ensure transparency and minimize potential bias, the blinding procedures used in this randomized controlled trial are described below. Participants: Participants were blinded to group allocation. They were not informed whether they were assigned to the Baduanjin exercise group or the Instrument-Assisted Soft Tissue Mobilization (IASTM) group. Allocation details and the randomization sequence were concealed from participants throughout the study period. Treating Physiotherapists: Blinding of the physiotherapists delivering the interventions was not feasible due to the nature of the treatments. The physiotherapists were required to know whether participants were receiving supervised Baduanjin exercises or IASTM in order to administer the interventions appropriately. Principal Investigators and Data Collectors: The principal investigators and data collectors responsible for coordinating treatment sessions, monitoring adherence, and maintaining study records were not blinded to group allocation. Outcome Assessors and Data Analysts: Outcome assessment and statistical analysis were conducted by members of the research team who had access to the allocation information. Therefore, outcome assessors and data analysts were not blinded. Data Safety Monitoring Board (DSMB) and Manuscript Preparation: No independent Data Safety Monitoring Board was established for this institutional study. Manuscript preparation was undertaken by members of the research team who had access to the unblinded study data during data interpretation and reporting.
**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Number of Groups (Arms): 2 groups.Allocation Ratio: 1:1 (Participants were distributed equally into two arms).Sampling / Recruitment Technique: Non-probability convenience sampling.Study Setting: Multi-center workplace recruitment across Gujranwala (including Brackets Software House, Faisal Bank, and NADRA offices). Intervention Duration: 4 weeks total, with a frequency of 3 sessions per week. Each individual treatment session lasted 20–25 minutes.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethical Committee of Gujranwala Institute of Medical and Emerging Sciences (GIMES)

**Street address**

Main Campus: Ali Pur Chattha Road (near Gujranwala Medical College)

**City**

Gujranwala

**Postal code**

52250

**Approval date**

2026-02-04, 1404/11/15

**Ethics committee reference number**

(Ref: GIMES/RA/26-00091)

## Health conditions studied

### 1

**Description of health condition studied**

Erector spinae muscle spasm, characterized by localized tenderness, myofascial trigger points, mechanical back pain, and functional spine disability due to prolonged static postures, repetitive strain, and ergonomic stressors among information technology (IT) workers and computer professionals.

**ICD-10 code**

M62.830

**ICD-10 code description**

Muscle spasm of back

## Primary outcomes

### 1

**Description**

Pain Intensity

**Timepoint**

Measured at Baseline (Week 0) and Post-Intervention (Week 4).

**Method of measurement**

Numeric Pain Rating Scale (NPRS)

### 2

**Description**

Lumbar Functional Disability

**Timepoint**

Measured at Baseline (Week 0) and Post-Intervention (Week 4).

**Method of measurement**

Oswestry Disability Index (ODI)

## Secondary outcomes

### 1

**Description**

Lumbar Range of Motion (ROM)

**Timepoint**

Measured at Baseline (Week 0) and Post-Intervention (Week 4).

**Method of measurement**

Spinal Inclinometer (measuring active flexion and extension in degrees).

### 2

**Description**

Clinical Muscle Spasm Status

**Timepoint**

Measured at Baseline (Week 0) and Post-Intervention (Week 4).

**Method of measurement**

Physical palpation (assessing localized tenderness, tightness, and myofascial trigger points).

## Intervention groups

### 1

**Description**

Group A (BDJ): Participants performed Baduanjin exercises under supervision, following a standardized protocol throughout the intervention period.

**Category**

Treatment - Other

### 2

**Description**

Group B (IASTM): Participants received Instrument-Assisted Soft Tissue Mobilization using standardized techniques applied to the erector spinae muscles throughout the intervention period

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
National Database and Registration Authority (NADRA), Gujranwala

**Full name of responsible person**
Dr. Noha Arshad

**Street address**
NADRA Mega Center (Main City): Main Grand Trunk (G.T.) Road, near Bajwa Road, Khalid Colony

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## Sponsors / Funding sources

**1**

**Sponsor**

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**Full name of responsible person**
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**Grant name**
Thesis Project

**Grant code / Reference number**
Ref: GIMES/RA/26-00091

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Gujranwala Institute of Medical and Emerging Sciences (GIMES)

**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**
Chiniot General Hospital, Korangi

**Full name of responsible person**
Dr. Sajjan Iqbal Memon

**Position**
Quality & Patient Safety Officer

**Latest degree**
Master

**Other areas of specialty/work**
Quality Improvement & Patient Safety

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## Person responsible for updating data

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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**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
The study will share a de-identified dataset containing demographic information and outcome measures (NPRS, ODI, and lumbar ROM). The study protocol detailing methodology, interventions, and analysis procedures will also be available. Blank informed consent forms and assessment tools used in the study will be shared upon request. Statistical analysis outputs may be provided for verification purposes. All shared data will be anonymized to protect participant confidentiality. Documents will be made available electronically upon reasonable request to the research team.

**When the data will become available and for how long**
The Individual Participant Data (IPD) dataset, Study Protocol, and Statistical Analysis Plan (SAP) will become available to qualified researchers beginning six months after the official publication of the final summary data results. This data will remain accessible for a period of up to three years from the initial start date of availability.

**To whom data/document is available**
The de-identified Individual Participant Data (IPD) and supporting clinical trial documents will be made available strictly to qualified academic researchers, physical therapy clinicians, and medical investigators affiliated with recognized academic institutions, universities, or healthcare organizations. Access will not be extended to commercial businesses, industry corporations, or entities seeking the data for commercial profit. All applicants must submit a methodologically sound research proposal demonstrating that the dataset will be utilized solely to achieve the scientific objectives specified in their approved study protocol.

**Under which criteria data/document could be used**
he de-identified Individual Participant Data (IPD) and clinical trial documents will be shared strictly for academic research, scientific verification, or secondary meta-analyses. Data will be securely transmitted electronically in spreadsheet formats once the applicant signs a formal Data Use Agreement prohibiting any participant re-identification. Requests will be evaluated by an internal Scientific Review Committee based on the methodological soundness and scientific validity of the proposed research protocol.

**From where data/document is obtainable**
The Individual Participant Data (IPD) dataset, clinical trial protocol, and Statistical Analysis Plan (SAP) are obtainable directly from the clinical trial's supervisor and principal investigators at the executing academic institution. The preferred mode of communication for data requests is via formal electronic mail. Clear Contact Information: Contact Person / Supervisor:** Dr. Noha Arshad, Dr.Minahil Zahir, and Dr. Samia Nawaz Affiliated Department:** Department of Physical Therapy Institutional Mailing Address:** Gujranwala Institute of Medical and Emerging Sciences (GIMES), Ali Pur Chatha Road, Near Gujranwala Medical College, Gujranwala, Punjab, Pakistan Primary Email Address:** info@gimes.com.pk Telephone / Contact Number:** +92 321 111 9104 (Alternate: +92 321 111 9105)

**What processes are involved for a request to access data/document**
Interested researchers should submit a written request describing the study objectives, methodology, and intended use of the data. Requests will be reviewed by the principal investigator and research team within approximately 2–4 weeks. Upon approval and completion of any required data-sharing agreement, the requested documents and de-identified dataset will be provided electronically.

**Comments**
No personally identifiable participant information will be shared. Data will be provided in accordance with ethical approval requirements, participant confidentiality protections, and applicable institutional policies.