Official Title:

Comparison of the Effects of Extracorporeal Shockwave Therapy and Stretching Exercises on Pain, Flexibility, and Balance in Individuals with Low Back Pain Due to Hamstring Tightness

NCT Number:

Pending

Date of Document:

November 2024

Protocol ID: BAH-YLTez25

Principal Investigator: Mitra Valaei Bakhshayesh, MSc

Affiliation: Bahçesehir University

1 Study Identification

Unique Protocol ID: BAH-YLTez25

Brief Title: Comparison of ESWT and Exercise for Low Back Pain Due to Hamstring Tightness

Official Title: Comparison of the Effects of Extracorporeal Shock Wave Therapy (ESWT) and Exercise on Pain, Flexibility, and Balance in Individuals with Low Back Pain Associated with Hamstring Tightness

Secondary IDs: None

2 Study Status

Record Verification Date: November 2024

Overall Status: Active, not recruiting

Study Start Date: January 10, 2025

Primary Completion Date: May 20, 2025

Study Completion Date: August 20, 2025 (Anticipated)

3 Sponsor/Collaborators

Sponsor: None

Responsible Party: Principal Investigator

Investigator: Mitra Valaei Bakhshayesh, MSc, Physiotherapy and Rehabilitation, Bahçesehir University

Collaborators:

• Prof. Dr. Hasankerem Alptekin, Istanbul Bahçesehir University

• Assoc. Prof. Dr. Tugba Sahbaz, Istanbul Beykent Hospital

4 Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review:

• Board Status: Approved

• Approval Number: 61351342/020-631

• Board Name: Uskudar University Ethical Committee

• Board Affiliation: Bahçesehir University

• Contact:

– Phone: +902164002222

1– Email: bilgi@uskudar.edu.tr

– Address: Altunizade Mh. Universite sokagi No: 14, PK: 34662 Uskudar, Istanbul, Turkey

5 Study Description

5.1 Brief Summary

This randomized controlled trial aims to compare the short- and long-term effects of extracorporeal shock wave therapy (ESWT) and exercise therapy on pain, flexibility, and balance in individuals with low back pain associated with hamstring tightness. Thirty participants will be randomized into two groups (ESWT or exercise) and receive interventions twice weekly for four weeks. Outcomes include pain (Visual Analog Scale, VAS),
flexibility (Popliteal Angle and Fingertip-to-Floor tests), and balance (Y-Balance Test), assessed at baseline, post-intervention, and at a four-week follow-up.

5.2 Detailed Description

This study evaluates the efficacy of ESWT versus exercise therapy in managing low back pain due to hamstring tightness. Participants with diagnosed hamstring tightness and low back pain will be randomly assigned to receive either ESWT or an exercise program, each
administered twice weekly for four weeks. The ESWT group will receive standardized shock wave therapy targeting the hamstring muscles and related structures, alongside core exercises. The exercise group will perform a structured program including hamstring stretching and lumbar stabilization exercises, also with core exercises. Assessments will occur at baseline, immediately post-intervention, and four weeks post-treatment. Pain will be measured using the Visual Analog Scale (VAS), flexibility via Popliteal Angle

(PA) and Fingertip-to-Floor (FTF) tests, and balance using the Y-Balance Test (YBT). Data will be analyzed using SPSS 26.0, with a significance level of $p < 0.05$. The study hypothesizes that ESWT may provide faster pain relief and balance improvements, while exercise may offer more sustained flexibility gains.

6 Conditions

• Low Back Pain

• Hamstring Tightness

Keywords: Low back pain, Hamstring tightness, Flexibility, Balance, Exercise, Shock wave therapy, Extracorporeal Shock Wave Therapy (ESWT)

7 Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Not Applicable (Non-drug intervention)

2Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Outcomes Assessor)

Allocation: Randomized

Enrollment: 30 participants

8 Arms and Interventions

8.1 Arms

1. ESWT Group (n = 15):

• Receives extracorporeal shock wave therapy (ESWT) 2 times per week for 4 weeks, targeting hamstring muscles and related structures, plus core exercises.

• Standardized ESWT protocol for frequency, intensity, and session duration.

2. Exercise Group (n = 15):

• Receives a structured exercise program 3 times per week for 3 weeks, including hamstring stretching, lumbar stabilization, and core exercises.

• Each session lasts 30-45 minutes.

8.2 Interventions

• Device: Extracorporeal Shock Wave Therapy (ESWT): Non-invasive therapy delivering high-energy shock waves to stimulate healing in musculoskeletal tissues.

• Behavioral: Exercise Program: Structured exercises focusing on hamstring flexibility and lumbar stabilization, supplemented with core exercises.

9 Outcome Measures

9.1 Primary Outcome Measures

1. Pain Intensity

• Time Frame: Pre-treatment (Baseline), Post-treatment (Week 4), Follow-up (Week 8)

• Measured using the Visual Analog Scale (VAS), a 0-10 scale where 0 indicates no pain and 10 indicates the worst possible pain.

2. Hamstring Flexibility

• Time Frame: Pre-treatment (Baseline), Post-treatment (Week 4), Follow-up (Week 8)

3• Assessed using the Popliteal Angle (PA) test (degrees) and the Fingertip-to-Floor (FTF) test (cm).

3. Dynamic Balance

• Time Frame: Pre-treatment (Baseline), Post-treatment (Week 4), Follow-up (Week 8)

• Measured using the Y-Balance Test (YBT) in the anterior, posteromedial, and posterolateral directions (cm).

9.2 Secondary Outcome Measures

1. Patient Satisfaction

• Time Frame: Post-treatment (Week 4)

• Assessed via a questionnaire with response options: Very Satisfied, Satisfied, Not Satisfied.

2. Functional Improvement

• Time Frame: Post-treatment (Week 4), Follow-up (Week 8)

• Evaluated based on participants' subjective reports regarding pain, mobility, and balance (Improved, Same, Worsened).

10 Eligibility Criteria

Ages Eligible for Study: 18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Inclusion Criteria:

• Diagnosed with low back pain due to hamstring tightness.

• Aged 18-65 years.

• Male or female.

• Medically cleared for ESWT or exercise therapy.

• Experienced low back pain in the past 6 months without serious spinal pathology (e.g., herniated disc, fracture).

Exclusion Criteria:

• Other musculoskeletal conditions causing low back pain (e.g., disc herniation, spinal stenosis).

4• Outside the specified age range.

• Serious health conditions that may affect study outcomes.

• Pregnant or breastfeeding women.

• Surgical intervention in the back or hamstring region within the past 6 months.

11 Contacts and Locations

11.1 Contacts

• Primary Contact: Mitra Valaei Bakhshayesh, MSc

– Phone: +90 541862 1639

– Email: mitravalaei2965@gmail.com

• Secondary Contact: Hasankerem Alptekin, Prof. Dr.

– Phone: +90 5062392426

– Email: hasankerem.alptekin@bau.edu.tr

11.2 Locations

• Bahçesehir University, Physiotherapy and Rehabilitation, Istanbul, Turkey, 34353

– Status: Not yet recruiting

– Contact: Mitra Valaei Bakhshayesh (details above)

12 Results

Results Submission: Not applicable (study not yet finished).

Results Point of Contact: Mitra Valaei Bakhshayesh, MSc

Phone: +90 541862 1639

Email: mitravalaei2965@gmail.com

5**Study Protocol with Statistical Analysis Plan**

STATISTICAL ANALYSIS PLAN (SAP)

Title: Comparison of the Effects of Extracorporeal Shock Wave Therapy and Stretching Exercises on Pain,

Flexibility, and Balance in Individuals with Low Back Pain Due to Hamstring Tightness

Principal Investigator: Mitra Valaei Bakhshayesh, MSc in Physiotherapy and Rehabilitation

Institution: Bahcesehir University, Istanbul, Turkey

Date: July 2025

1. Objectives of Statistical Analysis

This SAP outlines the statistical methodology for evaluating the effects of ESWT and stretching exercises on

pain, hamstring flexibility, and dynamic balance in adults with low back pain due to hamstring tightness.

2. Outcome Variables

Primary Outcomes:

- Pain intensity measured by Visual Analog Scale (VAS)

- Hamstring flexibility assessed using Popliteal Angle (PA) and Fingertip-to-Floor (FTF) tests

- Dynamic balance assessed using the Y-Balance Test (YBT)

Secondary Outcomes:

- Patient satisfaction

- Subjective functional improvement

3. Study Design Overview

This is a two-arm parallel randomized controlled trial with repeated measures at baseline, week 4, and week

8. Participants (n = 30) are randomly allocated into two equal groups.

4. Sample Size Determination

Sample size (n = 30) was determined via a priori power analysis using G*Power software. Effect size: f =

0.336, = 0.05, power = 0.95, 3 measurement points.

5. Statistical Methods

- Descriptive statistics (mean SD) will summarize all outcomes.
- Normality will be assessed via the Shapiro-Wilk test.
- Between-group differences: Independent samples t-test for normally distributed data; Mann-Whitney U test

for non-normal distributions.

- Within-group changes over time: Repeated Measures ANOVA; if assumptions violated, the Friedman test

will be used.

- Interaction effects (Group Time) will be analyzed using Mixed ANOVA.
- Post-hoc pairwise comparisons will be corrected with Bonferroni adjustment.
- Categorical data (e.g., satisfaction levels) will be analyzed using chi-square tests or Fishers exact test.

6. Handling of Missing Data

Missing data will be managed using the Last Observation Carried Forward (LOCF) method. Sensitivity

analyses will be conducted if >10% data are missing.

7. Statistical Software

All analyses will be conducted using IBM SPSS Statistics version 26.0 (Armonk, NY, USA).

8. Significance Level

Statistical significance will be set at $p < 0.05$ for all analyses.

9. Ethical Considerations

This analysis plan is part of an ethically approved protocol (Approval No: 61351342/020-631).

10. Amendments

Any deviations from this plan will be documented and justified in the final report.

STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN (SAP)

Title: Comparison of the Effects of Extracorporeal Shock Wave Therapy and Stretching Exercises on Pain,
Flexibility, and Balance in Individuals with Low Back Pain Due to Hamstring Tightness

Principal Investigator: Mitra Valaei Bakhshayesh, MSc in Physiotherapy and Rehabilitation
Institution: Bahcesehir University, Istanbul, Turkey

Date: July 2025

Protocol ID: BAH-YLTez25

1. Background and Rationale

Low back pain (LBP) is a global health concern, with hamstring tightness identified as a contributing
biomechanical factor. ESWT and stretching exercises are common non-invasive treatments, yet their
comparative efficacy in managing LBP associated with hamstring tightness is unclear. This study aims to
address that gap.

2. Study Objectives

To compare the short- and long-term effects of ESWT and stretching exercises on pain intensity, hamstring
flexibility, and dynamic balance.

3. Study Design

- Randomized controlled trial (parallel-arm)

- 30 participants, randomly assigned (15 per group)
- Three assessment time points: baseline, post-treatment (week 4), follow-up (week 8)
4. Participants

Inclusion Criteria:
- Aged 1865 years
- LBP with clinically confirmed hamstring tightness
- VAS 4, PA < 120, FTF > 10 cm
Exclusion Criteria:
- Spinal surgery, systemic disease, pregnancy, neurological or inflammatory conditions, ESWT
contraindications
5. Interventions
Group 1: ESWT (2x/week for 4 weeks, 2000 pulses/session, 3.0 bar, 0.5 Hz) + core exercises
Group 2: Supervised static stretching protocol (3x/week for 3 weeks) + home program during follow-up
6. Outcome Measures
- Pain: VAS (cm, 010)
- Flexibility: Popliteal Angle (degrees), Fingertip-to-Floor (cm)
- Balance: Y-Balance Test (normalized % reach and composite score)
7. Assessment Schedule
All measures taken at Baseline, Week 4, and Week 8.
8. Statistical Analysis Plan (SAP)
- SPSS v26.0 used for all analysis
- Normality: Shapiro-Wilk
- Between-groups: Independent t-test / Mann-Whitney U test
- Within-groups: Repeated Measures ANOVA / Friedman test

- Post-hoc: Bonferroni correction
- Significance: $p < 0.05$

- Handling missing data: LOCF (Last Observation Carried Forward)

9. Ethical Considerations

Approved by Uskudar University Ethics Committee (No: 61351342/020-631). All participants provided
informed consent.

10. Facilities and Oversight

Study conducted at Bahcesehir University, Istanbul. PI: Mitra Valaei Bakhshayesh. Oversight provided by
institutional supervisors and ethics committee.

*Page 3*INFORMED CONSENT FORM

STUDY TITLE:

Comparison of the Effects of Extracorporeal Shock Wave Therapy (ESWT) and Exercise on
Pain and Balance in Individuals with Low Back Pain Due to Hamstring Tightness

Dear Participant,

You are invited to participate in a clinical research study. Participation is entirely voluntary.
Before deciding, it is important that you understand the purpose of the study, how your data will
be used, what the study involves, and any potential risks or benefits.
Please take your time to read the following information carefully. If you agree to participate,
please sign the consent section at the end of this form. You may withdraw from the study at any
time without any negative consequences. No payment or material contribution will be requested
from you.

PURPOSE OF THE STUDY:

This study aims to compare the effects of extracorporeal shock wave therapy (ESWT) and

exercise therapy on pain and balance in individuals with low back pain caused by hamstring
tightness. The goal is to determine the most effective approach for managing this condition.

METHODS AND PROCEDURES:

Participants will be randomly assigned into one of two groups:

- ESWT Group: Participants will receive ESWT once or twice per week for 4 weeks, along
with core stabilization exercises.
- Exercise Group: Participants will follow a stretching and lumbar stabilization program,
performed 1–2 times per week for 3 weeks, with core exercises included.

ASSESSMENT SCHEDULE:

All participants will be evaluated at the following times:

- Before treatment (Baseline)
- After 4 weeks of treatment
- At 8 weeks (1-month follow-up)

MEASUREMENTS:

- Pain: Visual Analog Scale (VAS, 0–10 scale)
- Flexibility: Popliteal Angle Test and Fingertip-to-Floor Test
- Balance: Y-Balance Test

RISKS AND DISCOMFORTS:

Participants may experience mild pain, muscle soreness, or fatigue during or after treatment. All
procedures will be conducted under professional supervision.

BENEFITS:

Participants may experience:

- Reduced pain
- Improved flexibility and balance

The study may also contribute to scientific knowledge and benefit future patients.CONFIDENTIALITY:

All personal data will be kept strictly confidential and used only for scientific purposes. You will
not be identified in any reports or publications.

VOLUNTARY PARTICIPATION:

Your participation is voluntary. You may withdraw at any point without providing a reason and
without affecting your rights or access to services.

CONTACT INFORMATION:

Principal Investigator: Mitra Valaei Bakhshayesh

Phone: +90 541 862 1639

Email: mitravalaei2965@gmail.com

CONSENT STATEMENT:

I have read and understood the above information. I had the opportunity to ask questions and all
of them have been answered. I voluntarily agree to participate in this study.

Participant Name: _____

Signature: _____

Date: _____

Investigator Name: _____

Signature: _____

Date: _____