

Official Title of Study: Comparative effects of tissue flossing and proprioceptive neuromuscular facilitation on hamstring flexibility and knee joint range of motion among young female students

NCT Number: NCT07178132

Document Type:

- Study Protocol
- Statistical Analysis Plan (SAP)

Date: 19-09-2025

Principal Investigator:

- Sakshi Negi, MPT
- **Institution:** Guru Nanak Dev University
- **Email-** snegipt@gmail.com

Ethics Approval:

Approved by the Institutional Review Board of Guru Nanak Dev University, Amritsar

Approval Number: 2250/HG

Funding: None

STUDY PROTOCOL

AIMS AND OBJECTIVES OF THE STUDY

- To analyze the effect of PNF in increasing hamstring muscle flexibility
- To analyze the effect of kinetic tissue flossing in increasing hamstring muscle flexibility
- To increase the joint range of motion
- Reduce the risk of injury and enhance overall performance
- To prevent muscle imbalance and promote optimal musculoskeletal health

RESEARCH DESIGN

- **Study Design:** A crossover study
- **Source of Data:** Guru Nanak Dev University, Amritsar
- **Study population:** Young female students with hamstring tightness
- **Sample Size:** 60 subjects.
- **Selection of subjects:** Random sampling technique

SELECTION CRITERIA

Inclusion criteria:

1. Female subjects were included in the study
2. Subjects with hamstring muscle tightness were included
3. Subjects in the age group of 18-25 years were included

Exclusion criteria:

1. Male subjects
2. Subject who doesn't fulfill the age criteria
3. Subject with hamstring tear or other knee ligament injury
4. Any history of lower limb surgery dating back a year
5. Subjects with Lower back pain or any neurological compromise in the lower limb
6. Any acute injury like a sprain, strain, and open wound
7. Subjects who had latex allergies
8. Subjects with venous thrombotic disease, heart disease, respiratory illness, and dermatitis in their lower legs were excluded

STUDY DESIGN:

This study was designed as a randomized crossover trial. Participants were randomly assigned to one of two sequences:

1. Tissue Flossing followed by PNF hold–relax stretching, or
2. PNF hold–relax stretching followed by Tissue Flossing.

Each participant therefore received both interventions, with a minimum washout period of one week between sessions to reduce the risk of residual effects. Following the washout, participants crossed over to the alternate intervention. This design allowed each participant to serve as their own control, thereby reducing inter-individual variability.

INTERVENTION:

KINETIC TISSUE FLOSSING

- A floss band of 2.1 m in length, 5 cm in width, and 1.3 mm in thickness was used to conduct flossing.
- The participant assumed a standing position and placed their dominant leg forward.
- The floss band was wrapped around the thigh beginning at the superior pole of the patella progressing to the upper thigh.
- Compressive force on the hamstring muscle was produced through wrapping of the thigh with 50% overlap and stretch of about 50% of the band's maximum stretch
- Participants then performed one set of 20 active knee flexions, 10 standing knee hugs, and 10 lunges within 2-minutes
- The band was then subsequently removed and the procedure was repeated once more after a 2-minute break

PNF HOLD-RELAX

- The subject lay supine with both legs extended and the non-dominant leg was stabilized
- With no rotation at the hip, the therapist passively stretched the hamstring muscle until the subject felt a mild stretch sensation.
- The subjects were instructed to perform isometric contraction of the hamstring for 8 seconds followed by relaxation.

- Immediately following the muscle relaxation, the therapist further stretched the hamstring until a mild yet tolerable stretch was reported.
- The stretch was maintained for a further 30 seconds and the process was repeated three times.

PRIMARY OUTCOMES:

- Active Knee Extension Test (AKET, degrees)
- Passive Knee Extension Test (PKET, degrees)
- Straight-Leg Raise (SLR, degrees)
- Sit-and-Reach Test (cm)

STATISTICAL ANALYSIS PLAN (SAP)

General Principles:

- **Software:** analysed using SPSS (18) software
- **Statistical significance:** two-sided $p < 0.05$
- **Continuous variables:** mean \pm SD

Primary Outcomes:

- **Measures:** AKET, PKET, SLR, Sit-and-Reach
- **Analysis:**

Within-intervention analysis:

For each intervention (Tissue Flossing and PNF), paired-samples t-tests were used to compare pre- and post-intervention scores on the outcome measures (Active Knee Extension Test, Passive Knee Extension Test, Straight Leg Raise, and Sit-and-Reach).

Between-intervention comparison:

To compare the relative effectiveness of Tissue Flossing versus PNF, paired-samples t-tests were applied to the change scores from each intervention, since the same participants underwent both treatments.

