Investigation of the effect of soft tissue movement using a tool in comparison to manual stretching on hip range of motion, and muscle power in people with hamstring tightness

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/03/2021		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/03/2021	Completed	[X] Results		
Last Edited 06/04/2021	Condition category Musculoskeletal Diseases	[] Individual participant data		

Plain English summary of protocol

Background and study aims

People may develop hamstring tightness due to multiple reasons, being seated for a long period of time is one of the factors that can contribute to hamstring tightness development. Having hamstring tightness can affect the way we stand and the way we walk. The common treatment to release the tightness in the hamstring is by self-stretching or manual stretching, which is mainly performed by physiotherapists. Physiotherapists recently have been using an instrument that can reduce muscle tightness. This device has been used in many muscles and less investigated in hamstring muscles. Therefore, the aim of the study is to compare the effect of the use of this instrument in comparison to manual stretching in range of motion of the hip and hamstring muscle's power.

Who can participate?

People aged between 18 - 30 years old with hamstring tightness and has no history of back, neurological related problem are invited to participate.

What does the study involve?

The study involves measuring the range of motion of the hip via a goniometer, measuring hamstring muscle power via sitting on a chair while moving leg forward and backward against resistance. These measurements will be taken again after either receiving treatment with the instrument applied to the hamstring muscles, or after receiving manual stretching.

What are the possible benefits and risks of participating?

The benefits of the study that you will gain relief from the tight hamstring, and you will be provided with information about the strength of the hamstrings muscles. The risk associated with the study is minimal, it may include some sensation of fatigue in the muscle after measuring the muscle power. However, this will be minimized with proper warming up for a minimum of 5 minutes before the testing.

Where is the study run from?
Prince Sattam bin Abdulaziz University (Saudi Arabia)

When is the study starting and how long is it expected to run for? April 2020 to August 2020

Who is funding the study? Investigator initiated and funded

Who is the main contact?

Dr Ahmad Osailan, Ahmad.osailan@gmail.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

020047

Study information

Scientific Title

Instrument assisted soft tissue mobilization (IASTM) versus stretching: a comparison in effectiveness on hip ROM, muscle torque and power in people with hamstring tightness

Acronym

IVS-HIPROM-POWER

Study objectives

IASTM will positively impact hip flexion active ROM, HMC torque, and HMC power similar to manual stretching

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/03/2020, Ethical Committee at Prince Sattam bin Abdulaziz University (Riyadh region, Alkharj, 16273, Saudi Arabia; +966 115888888; IRB-sciences@psau.edu.sa), ref: RHPT/020/047

Study design

A single-centre interventional single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Instrument assisted soft tissue mobilization and manual stretching in improving hip active range of motion and muscle power in people with hamstring tightness

Interventions

We will recruit non-athletic people with hamstring tightness. The hamstring tightness will be identified via a straight leg raise (SLR) test. SLR test is a reliable measure to examine the flexibility of the hamstrings (Neto et al. 2015). The investigator aims to recruit young male students from the campus.

There will be two groups, one receiving IASTM, and another receiving only manual stretching. Randomization of the participant will be performed by putting two covered forms of assessments (one for IASTM, and the other for manual stretching). Both forms share the same first page, which will include the information sheet about the study. The eligible participant hand in the form after signing the informed consent to the examiner. The second page of the form will indicate whether the eligible participant would be assigned to group 1 (receiving IASTM) or group 2 (manual stretching). The participants will be blinded to the intervention they

received, and only the team members will be aware of the intervention that the participant will receive. Both groups will be measured for baseline data for hip active range of motion, hamstring muscle power, and muscle torque using an isokinetic dynamometer. Then each group will be re-assessed post the treatment.

Both groups will receive one session of either IASTM or manual stretching, there is no follow up. The approximate total duration of treatment is less than 30 minutes. The total duration for the treatment as well as the testing is 45 - 50 minutes.

Intervention Type

Mixed

Primary outcome measure

Measured at baseline and post-treatment:

- 1. Hip Active Range of motion measured using goniometer
- 2. Hamstrings muscle power measured using human Isokinetic dynamometer
- 3. Muscle torque measured using human Isokinetic dynamometer

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

05/04/2020

Completion date

10/08/2020

Eligibility

Key inclusion criteria

- 1. 18 30 years old
- 2. Positive straight leg raising (SLR) test <65 degrees without neurological manifestation, indicating short hamstrings
- 3. No history of injury to the hamstring or surgical history of the lower extremity

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Total final enrolment

23

Key exclusion criteria

- 1. Reporting vigorous physical activity in the last 24 hours
- 2. Fracture in the lower extremity
- 3. Unilateral or bilateral radiating symptoms from the back or sciatic nerve damage
- 4. Complaining of neurological symptoms during SLR test
- 5. Hematoma
- 6. Varicose vein
- 7. Skin infection

Date of first enrolment

10/05/2020

Date of final enrolment

10/08/2020

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Prince Sattam bin Abdulaziz University

College of Applied medical sciences Alkharj Saudi Arabia 16273

Sponsor information

Organisation

Prince Sattam Bin Abdulaziz University

Sponsor details

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Sponsor type

University/education

Website

https://www.psau.edu.sa/en/

ROR

https://ror.org/04jt46d36

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in high-impact peer-reviewed journal.

Intention to publish date

20/04/2021

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	06/04/2021	Yes	No