Therapist language versus dry needling effects on hip strength and time to stabilisation

Submission date	Recruitment status	Prospectively registered
08/11/2019	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/12/2019	Completed	Results
Last Edited	Condition category	Individual participant data
19/08/2021	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

Trigger points are more generally referred to as muscular "knots" which can often be found in both sporting and general populations. Dry needling is among the most common treatment techniques used by allied health professionals to treat trigger points. Dry needling consists of inserting an acupuncture type needle directly into the trigger point in order to cause the muscle fiber to loosen its low-level contraction. With dry needling's widespread use, researchers are unsure as to the bext timing of its use before performance or function and also, how its effects are perceived by patients. Gluteus medius is just one muscle in which trigger points frequently are found. It contributes to the strength of the hip and also plays an important role in maintaining stability during single-leg standing, moving and indeed sporting activities. By treating gluteus medius trigger points, there may be some temporary decreases in hip strength and stability, but it is not known if this weakness stems from an inability of the muscle to perform, or the patients' reluctance to exert themselves in response to having been treated. Therefore, this study aims to assess both the treatment effect of dry needling vs placebo dry needling, and also the contextual influence of the message given by the therapist just before applying the treatment. One message will warn of possible adverse effects that are typically felt after receiving dry needling, the other will focus on the beneficial performance effects typically reported after dry needling. It is hoped to investigate the close interaction of the treatment effect and the context in which the treatment is applied, and that overall effect on both objective and subjective treatment outcomes.

Who can participate?

Third-level students of the Institute of Technology Carlow, aged 18 to 40, participating in a multidirectional jump-sport (e.g. Gaelic football, hurling, soccer, volleyball, basketball or handball) for more than 3 hours per week, who have two or more latent trigger points present in the gluteus medius muscle of their preferred jumping leg

What does the study involve?

Participants are randomly allocated to one of four treatments:

- 1. Dry needling with a positive message
- 2. Dry needling with a neutral message
- 3. Placebo dry needling with a positive message

4. Placebo dry needling with a neutral message

Participants receive a single treatment to between 2 and 5 trigger points with a pre-scripted message given to the participant immediately before the administration of the intervention. Hip strength and time to stabilisation are measured before and immediately after and 24 and 48 hours after the treatment. At each follow-up participants also complete a short questionnaire in which they are asked to rate and describe the sensations and effects felt after dry needling and how this affected their daily activities or sporting participation.

What are the possible benefits and risks of participating?

There may be immediate or direct benefits such as 'loosening' of the muscle. Participation will help to determine which treatment should be used in the treatment of athletes in the future and would be extremely useful to athletes, coaches and therapists. Participants may experience minor pain or discomfort in the area where the dry needling or manual pressure release is applied. This pain or discomfort is commonly associated with myofascial trigger point treatment. This pain or discomfort will last for a short period of time.

Where is the study run from?
Institute of Technology Carlow (Ireland)

When is the study starting and how long is it expected to run for? May 2019 to December 2021 (updated 19/08/2021, previously: December 2020)

Who is funding the study?
Institute of Technology Carlow (Ireland)

Who is the main contact? Mr Aaron Byrne Aaron.Byrne@itcarlow.ie

Contact information

Type(s)

Scientific

Contact name

Mr Aaron Byrne

ORCID ID

http://orcid.org/0000-0001-6466-8147

Contact details

K221, Dargan Centre
Institute of Technology Carlow
Kilkenny Road
Carlow
Ireland
0000
+353 (0)862331849
Aaron.Byrne@itcarlow.ie

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

238

Study information

Scientific Title

Positive message versus neutral message with dry needling to gluteus medius and its effect on single leg stability and hip strength. A randomised placebo-controlled trial

Study objectives

- 1. Dry needling will cause a short-term decrease in hip strength
- 2. The positive message will attentuate the initially negative effect of dry needling on strength

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/07/2019, Ethics in Research Committee in the Department of Science and Health of Institute of Technology Carlow (Sandra Kirwin, Academic Administration Officer; Tel: +353 (0) 59-9175707; Email: ethicscommittee@itcarlow.ie), ref: 238

Study design

Randomized placebo-controlled intervention study

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 contact details to request participant information sheet

Health condition(s) or problem(s) studied

Latent myofascial trigger points in gluteus medius muscle

Interventions

All participants will randomly be assigned one of four treatment arms, via random number sequence, without knowing which arm they have been assigned (single-blinded).

The four treatment arms are as follows:

- 1. Dry needling with positive message
- 2. Dry needling with neutral message
- 3. Placebo dry needling with positive message
- 4. Placebo dry needling with neutral message

Participants will receive a single treatment to between 2 and 5 trigger points with a pre-scripted message given to the participant immediately before the administration of the intervention.

Hip strength and single leg stability will be measured immediately prior to and immediately post intervention as well as 24, 48 hours post intervention.

Intervention Type

Other

Primary outcome measure

Measured immediately before the intervention, immediately after and 24 and 48 hours after the intervention:

- 1. Hip abduction strength (maximal voluntary isometric contraction), measured using a portable strain gauge (hand-held dynamometer)
- 2. Hip internal rotation strength (maximal voluntary isometric contraction), measured using a portable strain gauge (hand-held dynamometer)
- 3. Hip external rotation strength (maximal voluntary isometric contraction), measured using a portable strain gauge (hand-held dynamometer)

Secondary outcome measures

- 1. Single-leg vertical time to stabilisation following a 20 cm drop landing onto a forceplate, measured immediately before the intervention, immediately after and 24 and 48 hours after the intervention
- 2. Objective feedback will be attained from all participants at the end of each testing session in the form of a web-based (Microsoft forms) questionnaire focusing on sensations felt, perceived effect of treatment on performance in strength tests, single-leg time to stabilisation, perceived effect of treatment on performance if a hypothetical competition was imminent and if any effect was felt on physical activity between follow-up days

Overall study start date

01/05/2019

Completion date

31/12/2021

Eligibility

Kev inclusion criteria

- 1. Third-level students of IT Carlow
- 2. Aged between 18 and 40 years of age
- 3. At the time of testing, are participating in a multi-directional jump-sport including but not

limited to; gaelic football, hurling, soccer, volleyball, basketball, handball more than 3 hours per week

4. Have 2 or more Latent Trigger Points present in the gluteus medius muscle of their "self-selected preferred jumping leg" - identified by physical palpation examination conducted by the researcher

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

n = 40

Key exclusion criteria

- 1. Have, at the time of testing, any injury to the lower limb or low back. Injury is defined as "any injury that prevents a player from taking a full part in all training and match play activities" (Brooks et al. 2005)
- 2. Present with signs of or report during screening process, any neurological or bleeding disorders
- 3. Have a needle phobia or aicmophobia

Date of first enrolment

18/11/2019

Date of final enrolment

20/09/2020

Locations

Countries of recruitment

Ireland

Study participating centre Institute of Technology Carlow

Department of Science and Health Kilkenny Road Carlow Ireland

Sponsor information

Organisation

Institute of Technology Carlow

Sponsor details

Kilkenny Road Carlow Ireland 0000 +353 (0)59 91 75000 info@itcarlow.ie

Sponsor type

University/education

Website

https://www.itcarlow.ie/

Funder(s)

Funder type

University/education

Funder Name

Institute of Technology Carlow

Results and Publications

Publication and dissemination plan

This study will form part of the completion of PhD in Rehabilitative Science through Institute of Technology Carlow and as such, the total study, protocols used, data analysis undertaken will all be represented in the submission.

Intention to publish date

01/05/2022

Individual participant data (IPD) sharing plan

All statistical analyses and anonymised participant-level data-sets will be made available upon completion of the trial and can be requested from the lead researcher Aaron Byrne (aaron. byrne@itcarlow.ie).

IPD sharing plan summary

Available on request