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HREC Ref: *[Provided by HREC when study approved]*

"Ultrasound Imaging of Myofascial Trigger Points: Characterisation and Response to Conservative Interventions "
Information Sheet for participants

Kia ora,
You are invited to take part in a research study being conducted by Donald Derrick and Sibi Walter from the University of Canterbury (UC).

What is the purpose of this research?
This study aims to investigate whether ultrasound can be used to identify and measure muscle knots (also known as myofascial trigger points).

We are interested in:
How muscle knots appear on ultrasound images.
Their size, depth, and location within muscle tissue.
Whether dry needling changes the appearance of muscle knots on ultrasound.

The information collected may help improve understanding of muscle knots and assist clinicians in locating and treating them in the future.

Why have you received this invitation?
You have been invited because:
You are 18 years of age or older.
You have a muscle knot
(To take part in phase 2, your muscle knot must be scheduled for dry needling by your own clinician.)
You have expressed interest in participating in this research.

Taking part is entirely voluntary. If you choose not to participate, your treatment and relationship with your clinician will not be affected in any way.

What is involved in participating?
If you agree to participate:

You will be asked to complete a short screening questionnaire and consent form. An ultrasound scan will be performed over the area containing your muscle knot by Donald Derrick, Sibi Walter, or a PhD student who has been trained in musculoskeletal ultrasound by the research team. The appointment is expected to take approximately 30 to 60 minutes.
If your scheduled treatment is dry needling, you may choose to return to the UC Sports Science Lab for a second session after your treatment. A follow-up ultrasound scan will be taken to see whether the appearance of the muscle knot has changed.
You will receive a $30 Prezzee digital gift card for each session (maximum two sessions)

Are there any potential benefits from taking part in this research?
You may not receive any direct health benefit from participating. However, you may request a copy of your ultrasound images and findings, which can also be shared with your treating clinician if you wish. Your participation will help researchers learn more about muscle knots and how ultrasound may be used to assess treatment outcomes.

One of the researchers, Donald Derrick, invented the ultrasound post-processing technique used in this study, it is the subject of patent filings, and he could benefit if it leads to clinical tools in future. He has declared this conflict of interest to the University of Canterbury Human Research Ethics Committee. To keep the research transparent, the de-identified data and analysis methods will be made publicly available so that other researchers can independently check the results.

At the conclusion of the study, we will provide you with a $30 Prezzee digital gift card per session (maximum 2 sessions). You will get this inducement even if you withdraw from the study.

Are there any potential risks involved in this research?

Treatment: The research team does not provide dry needling or any other treatment. Any treatment you receive is provided by your own clinician as part of your usual care, whether or not you take part in this study. Your clinician will discuss the risks of that treatment with you.

Ultrasound Imaging: Ultrasound is a safe, non-invasive imaging method that does not use radiation.
The scan involves placing a small handheld probe and water-based gel on the skin. Some people may feel mild discomfort if pressure is applied over a tender area. The gel is hypoallergenic and will be removed after the scan. We will not scan over broken skin, a wound, or a skin infection. If you return after treatment, we will use the same gentle technique and avoid any area that is bleeding or bruised.

What if you change your mind during or after the study?
Yes. Participation is voluntary, and you may withdraw at any time without giving a reason. If you withdraw within two weeks after your last session, all of your information, including your ultrasound recordings, will be deleted. We will not upload any de-identified recordings to the public research archive until at least two weeks after your last session. Once they have been uploaded, they can no longer be withdrawn.

What will happen to the information you provide?
Your privacy is important to us. Your name and contact details will appear only on your consent form and, for the gift card, on a separate register (see below). Your questionnaire and ultrasound recordings are labelled with a participant code, not your name. If you would like a follow-up session, you will write your name, email address, and referring clinic on your consent form so that we can contact you.
Consent forms will be stored separately from the research data. Ultrasound recordings will not contain any information that identifies you. Only authorised members of the research team will have access to identifiable information. All data will be stored securely on password-protected University of Canterbury computers and servers.

Will my ultrasound images be shared?
Yes. De-identified ultrasound images and videos will be stored in an online research archive and may be used by other researchers and clinicians for future research and educational purposes. These recordings contain only ultrasound images of muscle tissue and cannot be used to identify you. We will store all study data in password-protected files on the University of Canterbury computer network or in lockable cabinets in lockable offices.

To provide you with the $30 Prezzee digital gift card, the person recording your data must keep a register of your participation for 7 years in case IRD (Inland Revenue) wish to audit the University. The register will need to include your name and email address; but an email address alone is acceptable to maximise confidentiality.
The register will not be linked to any other aspect of this study – you cannot be identified through it.

Donald Derrick will be responsible for making sure that only members of the research team use your data for the purposes mentioned in this information sheet.

How long will your information be kept?
Consent forms and paper questionnaires are kept separately in locked cabinets in a locked office at UC. They, and any research data not placed in the public archive, will be securely destroyed 10 years after the project ends. Your contact details for a follow-up session are used only to arrange that session. The gift card register is kept for 7 years and then destroyed. De-identified ultrasound recordings placed in the public archive will be kept indefinitely.

Will the results of the study be published?
Results may be published in peer-reviewed, academic journals. Results will also be presented during conferences or seminars to wider professional and academic communities. You will not be identifiable in any publication. A summary of results will be sent to all participants who request a copy of these.

Who can you contact if you have any questions or concerns?
If you have any questions about the research, please contact: Donald Derrick (donald.derrick@canterbury.ac.nz), or Sibi Walter (sibiboycott.noelwalter@canterbury.ac.nz).

This study has been reviewed and approved by the University of Canterbury Human Research Ethics Committee (HREC). If you have concerns or complaints about this research, please contact the Chair of the HREC at human-ethics@canterbury.ac.nz).

What happens next?
Please review the consent form. If you would like to participate, please sign, scan/take a photo of, and return the consent form to Donald Derrick (donald.derrick@canterbury.ac.nz), or Sibi Walter (sibiboycott.noelwalter@canterbury.ac.nz).