

INFORMATION and CONSENT to PARTICIPATE in RESEARCH

# TITLE

## Investigators

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## Introduction

You are being asked to participate in a research study conducted by the Department of Human Health & Nutritional Sciences at the University of Guelph.

## Background

[Explain in simple language why you are doing this project. What problem needs to be solved? What information needs to be obtained. Situate your project within your discipline in broad terms. Do NOT copy and paste from a grant application or a thesis proposal.]

The purpose of this study is to compare the effects of [A and B with C]

## Objectives

* State Objective 1 in clear simple language – one line.
* State Objective 2 in clear simple language – one line.

## Who can take part?

To participate in this study, **and to protect your safety,** you must meet the inclusion criteria:

* List inclusion/exclusion criteria

## What will be required of you?

* Your will be required to [state what they need to do, such as have blood sugar monitored; have a limb immobilized; have a muscle biopsy every day; participate in an exercise program] for two (2) weeks.
* You will [tell them what they will do] during those 2 weeks so that [tell them briefly why].
* You will return to the lab for **training sessions** lasting between 20 and 40 minutes. You will attend twice each weekday (Monday through Friday) 2 weeks (total 20) to undergo training in one of five randomly assigned training groups:
  + No training (Control)
  + Combo 1
  + Combo 2
  + Combo 3
  + Combo 4

**See Appendix 1 for Training Groups and Protocols**

* In addition, you will come to the lab for 2 **testing sessions** where we will test:
  + One thing
  + Another thing

## Procedures

**See Appendix 2 for Diagram of Study Timeline**

### How long will the study take?

The study will take 18 days from start to finish.

### Where will the study take place?

Human Health and Performance Lab (HHNS Annex Room 263) for testing

Neuromechanical Performance Research Lab (ANNU Room 276) for testing

Human Health and Performance Lab for training

Day 1 and Day 17: Testing [Thing A and Thing B] (Neuromechanical Performance Research Lab)

#### Procedure 1:

* Address the participant
* Tell them what will happen to them.
* Do not tell them the academic background of the test.
* Tell them what it will feel like. Will it hurt? What should they do if it does?
* Tell them how many times you plan to do it.

#### Procedure 2:

* Address the participant
* Tell them what will happen to them.
* Do not tell them the academic background of the test.
* Tell them what it will feel like. Will it hurt? What should they do if it does?
* Tell them how many times you plan to do it

Day 2 and Day 18: [Thing A and Thing B] (HHNS Annex Room 263)

**PLEASE NOTE: For 12 hours before you arrive for testing you must:**

* **fast overnight**
* **abstain from caffeine and alcohol**

#### Procedure 3:

* Address the participant
* Tell them what will happen to them.
* Do not tell them the academic background of the test.
* Tell them what it will feel like. Will it hurt? What should they do if it does?
* Tell them how many times you plan to do it

#### Procedure 4:

* Address the participant
* Tell them what will happen to them.
* Do not tell them the academic background of the test.
* Tell them what it will feel like. Will it hurt? What should they do if it does?
* Tell them how many times you plan to do it

#### Procedure 5:

* Address the participant
* Tell them what will happen to them.
* Do not tell them the academic background of the test.
* Tell them what it will feel like. Will it hurt? What should they do if it does?
* Tell them how many times you plan to do it

**PLEASE NOTE: Following Procedures on day 2, [tell them what will happen that they will need to know – use bolded red text to alert participants to crucially important information. Do not overuse this or it will become ineffective]**

### Day 3-16: Training

* Address the participant
* Tell them what kind of training they’ll take part in.
* They do NOT need to know the formal name of the equipment – just what it does
* Tell them what it will feel like. Will it hurt? What should they do if it does?
* Tell them how many times you plan to do it

## Potential Risks and Discomforts

**See Appendix 3 for Full Explanation of Risks**

There are a few risks involved with both the [state the parts] of the study. Please read the brief summary of the risks below and consult with the Appendices for extended discussions.

#### Procedure 1

**One or two sentences to describe risk to a maximum of one paragraph.**

#### Procedure 2

**One or two sentences to describe risk to a maximum of one paragraph.**

#### Procedure 3

**One or two sentences to describe risk to a maximum of one paragraph.**

#### Procedure 4

**One or two sentences to describe risk to a maximum of one paragraph.**

#### Procedure 5

**One or two sentences to describe risk to a maximum of one paragraph.**

PLEASE NOTE: You will be reminded throughout the study that at any time if you no longer feel comfortable with completing any of the tasks you can terminate the experimental trials without penalty.

## Potential Benefits

You will not experience any direct benefits from taking part.

You may benefit from taking part in a regular exercise program.

You may benefit from nutritional counselling.

Your data will contribute to the advancement knowledge on [what you are studying]. This will help practitioners gain a better understanding of [what they need to know], as well as close the knowledge gap on this novel area.

## Incentive

You will receive incentives based on the number of sessions you complete. Once your involvement in the study has finished, you will be paid as follows:

* $ for completing the pre-testing
* $ for each week of training completed
* $ for the post testing

The maximum incentive available is $ for full completion of the study.

SIN numbers must be provided.

## Confidentiality

Every effort will be made to ensure confidentiality of personal information that is obtained in connection with this study. Coded data will be kept on a password-protected computer and all written material secured in a locked cabinet on site. Personal identifiers including the master list will be kept on a encrypted laptop.

All personal identifiers will be destroyed following completion of the entire study, expected finish date of [DATE].

De-identified data will be retained for [time – or indefinitely], stored electronically in databases, with access granted to [investigators listed above, investigators in the lead advisor’s lab, anyone who requests access if they have REB approval]

[Explain if data may be used for future analysis and by whom. Explain what that future analysis might be studying]

[explain how participants receive feedback].

## Participation and Withdrawal

You may choose whether to be involved with this study or not.

You may withdraw at any time without consequence.

You may exercise the option of removing your data from the study up until [Date – should be consistent with when the master list is destroyed]

You may also refuse to answer any questions you don’t want to answer and remain in the study.

The investigator may withdraw you from this research if circumstances arise that warrant doing so.

**Modify the following** below to make it appropriate to your project:

The researchers wish to be inclusive in their recruitment process. This project requires:

* The placement of medical sensors on the head/body
* Interaction one on one with a male/female technician/researcher
* Removal of articles of clothing including headgear
* Viewing images which may trigger emotional responses

If for any reason you may feel uncomfortable taking part, please contact the researcher to discuss these requirements and possible modifications to the procedure to address your concerns.

## Rights of Research Participants

This project has been reviewed by the Research Ethics Board for compliance with federal guidelines for research involving human participants

If you have any further questions regarding your rights and welfare as a research participant in this study (REB#), please contact: Director, Research Ethics; University of Guelph; [reb@uoguelph.ca](mailto:reb@uoguelph.ca); 519-824-4120 ext. 56606.

You do not waive any legal rights by agreeing to take part in this study.

## SIGNATURE of RESEARCH PARTICIPANT

I have read the information provided for the study “The Use of Blood Flow Restriction Training Modalities on the Attenuation of Immobilization-induced Skeletal Muscle Atrophy” as described herein including the Appendices attached.

My questions have been answered to my satisfaction, and I agree to participate in this study.

I have been given a copy of this form.

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Name of Participant (please print)

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Signature of Participant Date