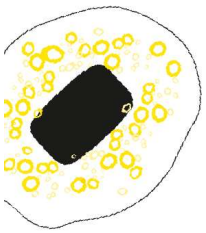
UNIVERSITY OF TWENTE.



This is an example information brochure and consent form for guidance. It is important to draft an information brochure and a consent form tailored to your research plan.

The aim of an Information Brochure and a Consent Form is to inform the potential subjects in such a way that they can make an informed choice whether or not to participate in the study. For this, the potential participant should be informed about the study goals, the actions to be performed for participating, project background (e.g. funders and collaboration partners), risks of participating, handling of collected data and envisioned impact (e.g. publications, talks, valorisation potential, reuse), all in plain language.

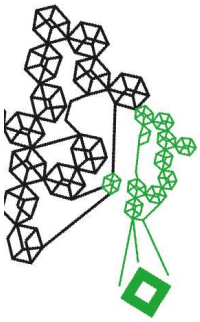
Context for this provided example Information Brochure and Consent Form: The research goal was to understand how humans walk at the full-body, joint and muscle level in response to very small perturbations.

Information Brochure

This letter elaborates on the study to provide you with the necessary information to choose whether to participate in the study. Even when deciding to participate you will be free to withdraw from the study at any time.

Purpose of the research
This research investigates how small and short torque pulses to the ankle affect biomechanics of walking. The research goal is to understand if we change how we walk or our muscle activity in response to very small perturbations. The finding of this research will inform future studies on using small perturbations to influence walking patterns.

Experiment description
The experiment has two sessions: a tuning and familiarization session, and a data collection session. In both sessions the participant walks on a treadmill with an ankle exoskeleton. The familiarization session lasts between [___ to __ minutes]. The data collection session lasts between [___ to __ minutes]. The break between the two sessions is [___ to __ minutes].
The exoskeleton used in this experiment is worn on the left and right lower-legs. The exoskeleton on the right-leg will apply short and small pulses of torque (rotational force) to the ankle at specific points in time – a pulse will typically happen once every 3-6 strides. The torque pulses are very small and, although they can be felt, they do not cause large changes in the ankle motion. The exoskeleton provides no assistance or resistance to the ankle movement when a pulse is not applied. This experiment will investigate different shapes of pulses at different instances in stride – each combination of shape and instance is referred to as a condition. A maximum of 45 discrete conditions will be considered in the experiment.



Tuning session
To begin, we (the researchers) will size and fit the exoskeleton to your (the participant's) lower leg. You will stand and/or sit during the fitting. You will then walk on the treadmill, and we will determine your preferred walking speed. We will tune the exoskeleton torque pulses for each condition over [number] strides. In certain circumstances, we may ask to continue tuning the exoskeleton for a greater number of strides (reaching a total maximum of [number] strides). You may take as many rest breaks as needed.

Data collection session
You will be equipped with sensors to measure the following biomechanical data:
- Electromyography (EMG) data (the electrical signals generated by the activation of muscles).
- Full body kinematics, with the use of passive reflective markers and motion capture cameras.
- Ground reaction forces, measured with force plates incorporated in the treadmill.

You wear the exoskeleton and are then invited to walk while pulse conditions are delivered in a random order. In between each condition, you will have 4-5 strides with no pulses delivered. Each condition will be repeated a maximum of 4 times for accuracy. The data collection will occur over 700 – 1000 strides. These strides are split into two walking bouts of about 15 minutes each with a 15-minute rest in-between.
Participant screening
To be admissible to the study participants need to comply with the following criteria:

- You should have no musculoskeletal injury to the legs in the past 6-months.
- You should have no neuromuscular disorder or condition affecting your walking.
- You should have sufficient fluency in English to be able and comfortable with understanding instructions given by researchers in English.
- You must be between 18 and 60 years old.
- Your shoe size should be between [number] to [number] EU size.

Benefits and risks

There are no personal benefits to participating in this study. There are small risks associated with the study.
- The placement and removal of stickers for the reflective markers and electrodes could cause skin irritation. The preparation of shaving leg hair for the EMG electrodes may also cause skin irritation. To minimize the risk of skin irritation, we use only biocompatible stickers and skin preparation materials. Furthermore, any irritation of the skin will be temporary.
- The weight and fit of the ankle exoskeleton has the potential to cause physical discomfort. We ask you to request breaks whenever needed to prevent physical discomfort or tiredness from walking with the device. We will also adjust fit of the exoskeleton should you experience any discomfort.
- Walking on the treadmill is associated with possibility of tripping over (similar to normal risk of walking on a gym treadmill), however fall risk is mitigated as you will wear a safety harness which will catch you and minimize injury risk should you fall.
- The exoskeleton has multiple safety measures to prevent the device from delivering large forces or moving the ankle outside the comfortable range of motion. The exoskeleton has safety measures implemented in the hardware and software. To further minimize risk, there are two large safety buttons that will immediately turn off the exoskeleton. One safety button is always within arm's reach of yourself, and the other is next to the researcher during the experiment.

Research/personal data collection

During this research we collect data via force plates, electromyography, motion capture, questionnaires and this consent form. All data collected during the experiment will only be used for scientific purposes. Your information collected on the consent form (name, age, sex, height and weight) will not be disclosed to any third party other than you and the experimenter and will be stored securely in accordance with data protection regulations. All other data is transformed in a pseudonymized dataset containing the: participants' pseudonym, height and weight, electromyography, ground reaction forces, and motion capture data.
Publication of your information will only be done using group averages/totals of all participants in the study. We will process the pseudonymized dataset to obtain the scientific results of the study and the pseudonymized dataset will be available together with possible future publication of the research. Moreover, after 6 months the pseudonymized dataset can be used for future research and learning, that may be similar or completely different to this study and, with this goal in mind, the dataset can also be shared with other researchers.
We will safely store your information form (in non-digital form) at the University of Twente, Department of Biomechanical Engineering for a period of 2 years. We will securely store the pseudonymized dataset on servers of the University of Twente or a recognised repository (e.g. DANS or 4TU) for an indefinite period. We might use the pseudonym key for the sole reason of contacting you to invite you for a follow up study, which you can accept or reject. Up to 2 years after the experiment you have the right to access and withdraw all collected data. Afterwards, the informed consent including pseudonym key will be destroyed rendering data access or withdrawal impossible. All collected data will be destroyed and removed from the dataset as soon as possible in case of a withdrawal request within 2 years.

Contact information for questions about your rights as a participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the executing researcher(s), please contact one of the following:
ethicscommittee-nes@utwente.nl
Ethics Committee Natural Sciences and Engineering Sciences
University of Twente

PO box 217, 7500AE Enschede, The Netherlands

Project Leader
_____ (supervisor name)
University of Twente
Engineering Technology, De Horst
7522LW Enschede, The Netherlands
Tel: +31_____
_____@utwente.nl

Data Protection Office
dpo@utwente.nl
University of Twente
PO box 217, 7500AE Enschede, The Netherlands

Consent Form

Please tick the appropriate boxes					**Yes**	**No**
Taking part in the study						
I have read and understood the study information dated dd/mm/yy, or it has been read to me.					☐	☐
I have been able to ask questions about the study and my questions have been answered to my satisfaction.					☐	☐
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.					☐	☐
I understand that taking part in the study involves walking on a treadmill with an ankle exoskeleton.					☐	☐
Risks associated with participating in the study						
I understand that taking part in the study involves the following risks: small discomfort due to the placement and removal of markers and electrodes. Small discomfort would be possible due to weight of the ankle exoskeleton and how it fit into each leg.					☐	☐
Use of the information in the study						
I agree that information I provide will be used for possible scientific publication and a PhD thesis. Scientific publications will be supported with a pseudonymized dataset containing: biomechanical, electromyography and motion capture data.					☐	☐
I understand that the participant information collected on this form, i.e. name, age, sex, height and weight, will not be shared beyond the study team. Scientific publications will be supported by group averages/totals of the participant information.					☐	☐
I agree to be video recorded, and the researchers might watch them to help them in the data analysis.					☐	☐
I agree that my recorded video and anonymized footage is used to support possible scientific presentations and reports (optional).					☐	☐
Future use and reuse of the information by others						
I understand that the dataset can be used for future research and learning, that may be similar or completely different to this study. Moreover, with this goal in mind the dataset can also be shared with other researchers.					☐	☐
I understand that I might be contacted to be asked to participate in a follow up study, which I can accept or reject.					☐	☐
Participant Information						
Pseudonym	Age [y]	Sex	Height [m]	Weight [kg]		

Signatures

Participant name Signature Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Researcher name Signature Date