



Letter of Information and Consent

**Knee Kinematics and Kinetics During a Dynamic Balance Task and Gait in
Those With and Without Generalized Joint Hypermobility (GJH)**

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Introduction

What you should you know about this study?

- You are being asked to join a research study about people with “generalized joint hypermobility (GJH),” which describes very flexible joints.
- This informed consent form explains the research study and your part in the study. It also explains the risks of taking part.
- Please read it carefully. Take as much time as you need.
- Please ask the researcher or research assistants if about anything you do not understand.
- You can ask questions now or anytime during the study.
- If you join the study, you can change your mind at any time.
- You can leave the study at any time. If you decide to leave the study, there is no penalty.

We are asking you to provide information in the form of movement, body measurements and questionnaires. Your information would help us learn more about the joints of people with GJH. It will also help us compare the joints of those with GJH to joints that are considered normal. We hope this information will help identify those with GJH and identify situations that require treatment.

Purpose: Why Are We Doing this Study?

GJH affects 11-36% of people worldwide. It is a condition where joints can move more than typically expected. Some people with GJH have no problems related to their joints. Others with GJH may experience joint pain, tiredness, and difficulty with simple tasks. When GJH causes problems, it is called symptomatic GJH (S-GJH).

It is difficult to identify GJH and S-GJH. This study aims to investigate if a balance test can help identify GJH and to learn more about the angles and forces on knee joints in those with GJH.

We are asking participants to attend one session in a laboratory on the campus of the University of Waterloo to:

- Assess body weight and height. This will help us calculate how forces act on the knee joint.
- Assess range of motion in 9 joints. This will help us determine if your joints move beyond the expected range of motion.
- Analyze how your legs move and measure forces acting on the knee.
- Complete movement tests.

- Fill out questionnaires about you (age, sex, gender, race), your experience of pain, level of physical activity and how your general health affects your day-to-day life.

Thinking of Participating?

For this study, we are looking for people that do have GJH and do not have GJH:

- 18-38 years old.

To determine if you qualify for the GJH group:

- You will be asked 5 screening questions.
- If you do not qualify for the GJH group, you may still be able to participate in the non-GJH group.

People who cannot participate in this study include:

- Those who had surgery in the spine, knees, hips, ankles, elbows, or fingers.
- Those with a connective tissue disorder other than the hypermobile type of Ehlers-Danlos syndrome (hEDS).
- Those who have a diagnosis of patellofemoral pain syndrome.
- Those who had an ankle sprain that needed attention from a doctor, physiotherapist, or other health care worker.
- Athletes on teams that currently practice and compete regularly.
- Those who do more than 4 fitness activities per week. Fitness activities are structured exercise that last for at least 30 minutes. Activities can include strength training, cardio activities like fast walking, running, dancing, swimming, or any activity that makes you sweat, or balance training.
- Those who are pregnant or have been pregnant in the last 12 months.
- People with other conditions that may cause pain in a several joints, like fibromyalgia.
- Those who do not have GJH and experience current or chronic pain in their legs.
- Those who have brain, inner ear and/or eye conditions that may affect their balance.

Method – What Will We Ask Participants to Do?

If you meet the study requirements and want to participate, we welcome you to join!

We will ask you to:

- Provide us with your phone number and/or email address to contact you.
- Participate in **1 in-person visit** in Waterloo (University of Waterloo) lasting **approximately 3 hours**.

What Measurements Will We Ask to Make?

1. Informed consent (this form).
2. 3 questionnaires that describe you (sex, gender, race), your level of physical activity and how your general health affects your day-to-day life.
3. Measurements of body height and weight.
4. Assessment of range of motion in 9 joints.
5. Movement analysis during a balance task and during walking. We will ask you to wear markers that are fastened to your legs using medical tape. These surface markers will not be painful. You will be given directions on how to perform the balance task and given time to practice. You will then be asked to complete the same balance task in three conditions: on the floor and on a foam pad at your own speed and on the floor moving at specific speed. You will also be asked to complete multiple walking trials. During these movement tasks you will be asked to be in bare feet.
6. After the balance task you will be asked to rate your pain during the task.

What Are the Risks and Benefits of Participating?

Risks

- Fatigue. Feeling tired is not unusual during testing. You may take breaks as required.
- Skin allergy to the medical tape. However, such reactions are relatively rare.

Falling during balance tasks. A spotter will present.

If you experience any serious discomfort following the testing session, please contact our primary investigator, Monica Maly at mrmaly@uwaterloo.ca. The principal investigator must report all research-related injuries promptly to the University of Waterloo Research Ethics Boards. Any injury that requires health care will be reported to your family physician with your explicit permission.

Privacy breach is a risk with your participation in this study. We will make every effort to protect your privacy. We store all your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we label your information with a code number. The Master list that links your name to your code number will be stored as a secure file on a computer server at the University of Waterloo. Only the Principal Investigator (MM) and Student Investigator (DG) will have access to the Master list.

Benefits

There are no benefits to you. You will learn more about your knees during a balance task and walking. You will also learn more about your pain and physical activity. If you take part in this study, other people with GJH and S-GJH may be helped.

Confidentiality

Your confidentiality is one of our main concerns. We will not put your name on any research data. You will be identified in the study by a code only. Your name will not appear in any reports or presentations about this study. Outside of the study, nobody will know who you are based on the information we collect. We will store all your research records in locked cabinets and secure computer files in the Mobilize Laboratory at the University of Waterloo. This research space is also locked. When the study is finished, we will confidentially destroy your personal information.

Participation

Being in this study is your choice. You can say no now or leave the study at any time later. If you wish to stop being in this study, say to the researcher or one of the research assistants: "I no longer wish to participate in this study."

You can request that your data collected during a study visit is removed up to 30 calendar days after that visit. Unfortunately, it is not possible to withdraw your data after 30 days because the researchers will have processed the data for publication. Your data will be securely stored, without any connection to you or your name, for 7 years after the study is published.

Ethics Clearance or Concerns about Participation

The results of this study will be shared as summary information. We will not share any information that reveals your identity. The results will be shared in scientific publications and presentations for healthcare providers, scientists and people living with GJH. The summary information could also be shared in a safe place where others can access it.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB#45644). If you have questions for the Board contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440 or reb@uwaterloo.ca.

Questions

If you have any general questions, please call the Mobilize Research Laboratory at 519-888-4567 ext. 38786. If you have any questions about the study, you may contact the principal investigator Monica Maly, at mrmaly@uwaterloo.ca. This letter is yours to keep for future reference.

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Consent of Participant

- I understand that by signing this consent form, I am not waiving my legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.
 - I have read this form and the research study has been explained to me.
 - I have been given the chance to ask questions, and my questions have been answers. If I have more questions, I have been told to contact Monica Maly, at mrmaly@uwaterloo.ca.
 - I know I can leave this study at any time without penalty. I can leave the study by telling the researchers of my decision.
 - I agree to be in the research study described above.
- I agree to allow data collected, which does not capture my image, to be used in teaching, scientific presentations and/or publications. I understand that I will not be identified by name.

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For all other questions contact Monica Maly, at mrmaly@uwaterloo.ca.

Print Name of Participant

Print Name of Person Obtaining Consent

Signature of Participant

Signature of Person Obtaining Consent

Dated

Dated