Subject information for participation in scientific research

Unperturbed and perturbed gait variability and stability: healthy reference data

Official title: Unperturbed and perturbed gait variability and stability: healthy reference data

Introduction

Dear Sir/Madam,

You are kindly requested to take part in a scientific study.
Participation is voluntary. Participation requires your written consent.
Before you decide whether you want to participate, you will be given an explanation about what the study involves. Please read this information carefully and ask the investigator for an explanation if you have any questions. You may also discuss it with your partner, friends or family.
This study is being carried out by Maastricht University Medical Centre+.
53 study subjects will participate in the Netherlands.

1. Purpose of the study

In this study we will measure healthy people while they walk at different speeds, without and with some balance challenges. We will use this data to compare how healthy people walk under these circumstances with how patients with balance disorders walk with these circumstances. In this way, we will be able to identify how these patients differ to healthy people which will help us better understand these problems and potentially provide better interventions in the future.

2. What participation involves

Your participation will last about 1.5 hours.

Screening

Once you have given your written informed consent to participate in the study, we will evaluate whether you may participate based on some inclusion criteria.

Visit and tests

You will visit the Maastricht University Medical Center and the following will take place:

- We will confirm that you meet the inclusion criteria for the study
- We will enter the CAREN lab (motion capture movement laboratory)
- We will measure height and weight
- We will then attach some reflective markers and two accelerometers to the skin in order to measure your movement, and measure your leg length.

- You will walk on the treadmill for 2 minute bouts at 3 different speeds, in order to assess your walking pattern. This will be done an additional 3 times for 3 minute bouts, one is with no balance challenge and the other two are with balance challenges. Between each trial, you will have a short break.
- During all of these walking tests at the CAREN lab, you will be secured in a full body harness so that you cannot fall.
- We will then complete a dynamic visual acuity test on a regular treadmill which assesses visual acuity while walking at different speeds by asking you to read letters of different sizes from a screen. In total, this test takes about 10 minutes.

3. What is expected of you

In order to carry out the study properly, it is important that you follow the study instructions.

The study instructions require that you:

- Complete the tasks during the measurements as directed.
- keep appointments for visits.

It is important that you contact the investigator:

- if you are admitted to hospital or are going for treatment there.
- if you suddenly develop any health problems.
- if you no longer want to participate in the study.
- if your contact details change.

4. Possible undesirable effects

Tests

There is a small chance of experiencing some minor muscle soreness in the one or two days following the measurements due to the added perturbation during walking. There is also a small risk of ankle injury and therefore anyone with a recent history of foot/ankle problems cannot participate.

5. Possible advantages and disadvantages

You will not personally benefit from participation in this study. Your participation may contribute to increased knowledge about walking stability. This may be of great benefit for future studies aiming to reduce falls in the older adults and patients. A disadvantage is the time required for participation (about 1.5 hours).

6. If you do not want to participate or you want to stop participating in the study

It is up to you to decide whether or not to participate in the study. Participation is voluntary.
If you do participate in the study, you can always change your mind. You may stop participation at any time during the study. You do not have to say why you are stopping, but you do need to tell the investigator immediately.
The data collected until that time will still be used for the study.
If there is any new information about the study that is important for you, the investigator will let you know. You will then be asked whether you still want to continue your participation.

7. End of the study

Your participation in the study stops when

- you have completed all the tests
- you choose to stop

- the investigator considers it best for you to stop
- the ethics committee, government or Maastricht University Medical Centre+ decides to stop the study.

The study is concluded once all the participants have completed the study.

After processing the data, the investigator will inform you about the most important results of the study. This will happen about 1 to 2 years after your participation.
If you do not want this to happen, please tell the investigator. He/she will then not be permitted to tell you.

8. Usage and storage of your data

For this study, the collected data will be anonymised, meaning that no one can link the data to your name. Your name will be deleted.

Your data
All your data will remain confidential and will be stored in protected documents by the study investigators.

Groups who may access your data are the study team, the Healthcare Inspectorate, and the METC. They will keep your data a secret. If you sign the consent form, you consent to your data being collected, stored and accessed,used and shared as described here.

Once the study is completed, the anonymised data will be made publicly available. Any personal information that could reasonably identify you will be removed or changed before files are shared with other researchers or results are made public.

All anonymised data collected during this study may be reused for future studies.

The investigator will store your data for 15 years.

9. Study subject insurance

Insurance has been taken out for everyone participating in this study. This insurance covers damage caused by the study. The insurance does not cover all damages. **Appendix B** contains more information about the insurance. It also tells you who to report damage to.

10. Compensation for participation

We will provide reimbursement for travel expenses based on the participants' distance to MUMC+, when arriving by private car or public transport with a rate of 19 cents per kilometer travelled.

11. Future research

You will be asked to state whether you are willing to be contacted for future research. You can indicate your preference on the consent form.

12. Any questions?

If you have any questions, please contact the investigators.

Thank you for your attention.

13. Appendices to this information

A. Contact details
B. Insurance information
C. Informed Consent Form

Appendix A: contact details for Maastricht University Medical Centre

Investigators:

Meichan Zhu

PhD candidate

Dept. of Human Movement Science, Maastricht University

Dept.of Otorhinolaryngology and Head and Neck Surgery, Division of Balance Disorders, Maastricht University Medical Center(MUMC+)

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Investigators:

Christopher McCrum, PhD

Assistant Professor

Dept. of Human Movement Science, Maastricht University

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Email: chris.mccrum@maastrichtuniversity.nl

Appendix B: Insurance Information

Insurance has been taken out by Maastricht University for everyone participating in this study. The insurance covers damage due to participation in the study. This applies to damage manifesting during the study or within four years of the end of the study. You must notify the insurance company about the damage within those four years.

The insurance does not cover all damages. The damages that are not covered are listed briefly at the end of this text.
This is set out in the Medical Research (Human Subjects) Compulsory Insurance Decree. This decree is listed on the website of the Central Committee on Research Involving Human Subjects www.ccmo.nl (see “Library” and then “Legislation and regulations”).

In the event of damage please contact the insurance company [or claims adjustor] directly.

The insurance company for the study is:	
Name:	CNA Insurance Company Ltd.
Address:	World Trade Centre, Strawinskylaan 703, 1077 XX Amsterdam
Telephone:	020-5737272
E-mail:	Esther.VanHerk@cnaeurope.com
(Policy number:	10193666)
(Contact person:	Esther van Herk, Snr Claims Examiner)

The claims adjustor for the study is:	
Name:	Anissa El-Kaddouri, relatiebeheerder Meeùs
Address:	Meeùs, Paasheuvelweg 9C, 1105 BE Amsterdam
E-mail:	anissa.elkaddouri@meeus.com
Telephone:	020-3011810

The contact person in Maastricht University is:
Name: afdeling Treasury, Stefan Groenveld
Address: Maastricht University, Postbus 616 6200 MD MAASTRICHT
E-mail: um-verzekeringen@maastrichtuniversity.nl
Telephoner: 043-3882047

The insurance offers a cover of €650,000 per study subject and €5,000,000 for the entire study (and €7,500,000 annually for all studies at Maastricht University).

The insurance policy does **not** cover the following damage:

- damage as a result of a risk that you were informed about in the written information. This does not apply if the risk occurs in a more severe form than envisaged, or if the risk was very unlikely to occur;

- damage to your health that would also have occurred if you had not participated in the study;
- damage resulting from not or not entirely following directions or instructions;
- damage to descendants as a result of a negative effect of the study on you or your descendants;
- damage as a result of an existing treatment method for research into existing methods of treatment.

Appendix C: Subject Consent Form

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- I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
- I know that some people can access my data. These people are listed in this information sheet.
- I consent to my data being used and shared in the way and for the purpose stated in the information sheet.
- I consent to my data being stored for another 15 years after this study.
- I □ **do**
  □ **do not** consent to being contacted again after this study for other related studies.
- I want to participate in this study.

Name of study subject:
Signature: Date: __ / __ / __

I hereby declare that I have fully informed this study subject about this study.

If information comes to light during the course of the study that could affect the study subject's consent, I will inform him/her of this in a timely fashion.

Name of investigator (or his/her representative):
Signature: Date:__ / __ / __

The study subject will receive the full information sheet, together with a copy of the signed consent form.