**PATIENTS PARTICIPANT INFORMATION SHEET**

**Protocol Title: Exploring muscle structure, function and gait patterns in people with Distal Hereditary Motor Neuropathy: natural history and the effect of rehabilitation interventions, Student Study.**

Chief Investigator: Dr Gita Ramdharry

This research is being carried out as part of a PhD undertaken by researcher Aljwhara Alangary.

**We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.**

**Why is the research being done?**

Walking impairments are more common in people who have a particular type of nerve condition (dHMN) than in people without the condition. dHMN is a condition which affects the nerves causing a variety of symptoms including muscle weakness. Most often the impairments are most evident in the feet and legs. Research currently suggests that the reason for walking impairments in similar types of nerve conditions is due to muscle weakness.

The study will seek to explore how people with a particular type of nerve condition (dHMN) walk and how physical therapy can help. We aim to investigate this through a series of clinical examinations and rehabilitation treatments, such as ankle braces and exercises.

**Why have I been chosen?**

You have been asked to consider participating in this study because you have a neuropathy which affects strength in your feet and legs.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you choose not to, your care at the hospital or as part of any other research you are participating in will not be affected.

**What will happen if I do not want to continue with the study?**

Even if you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. Any data that has been collected prior to your decision to withdraw will still be used in the analysis unless you inform us otherwise.

**What is involved in the study?**

The study will involve three measurement sessions (0 months, 12 months, and 16 months), and a 4-month therapeutic exercise program for your legs.

**a. What will happen to me if I take part?**

We will plan a time to speak to you over the phone so that we can fully discuss the study and answer any questions that you may have. This can be done face to face if you prefer. If this is the case, we may ask you to sign the consent form at that point.

If you have agreed to participate over the phone, we will ask you to sign a consent form when you come in for the measures. The measurement session will take place at the Queen Square Centre for Neuromuscular Diseases, National Hospital for Neurology and Neurosurgery.in London.

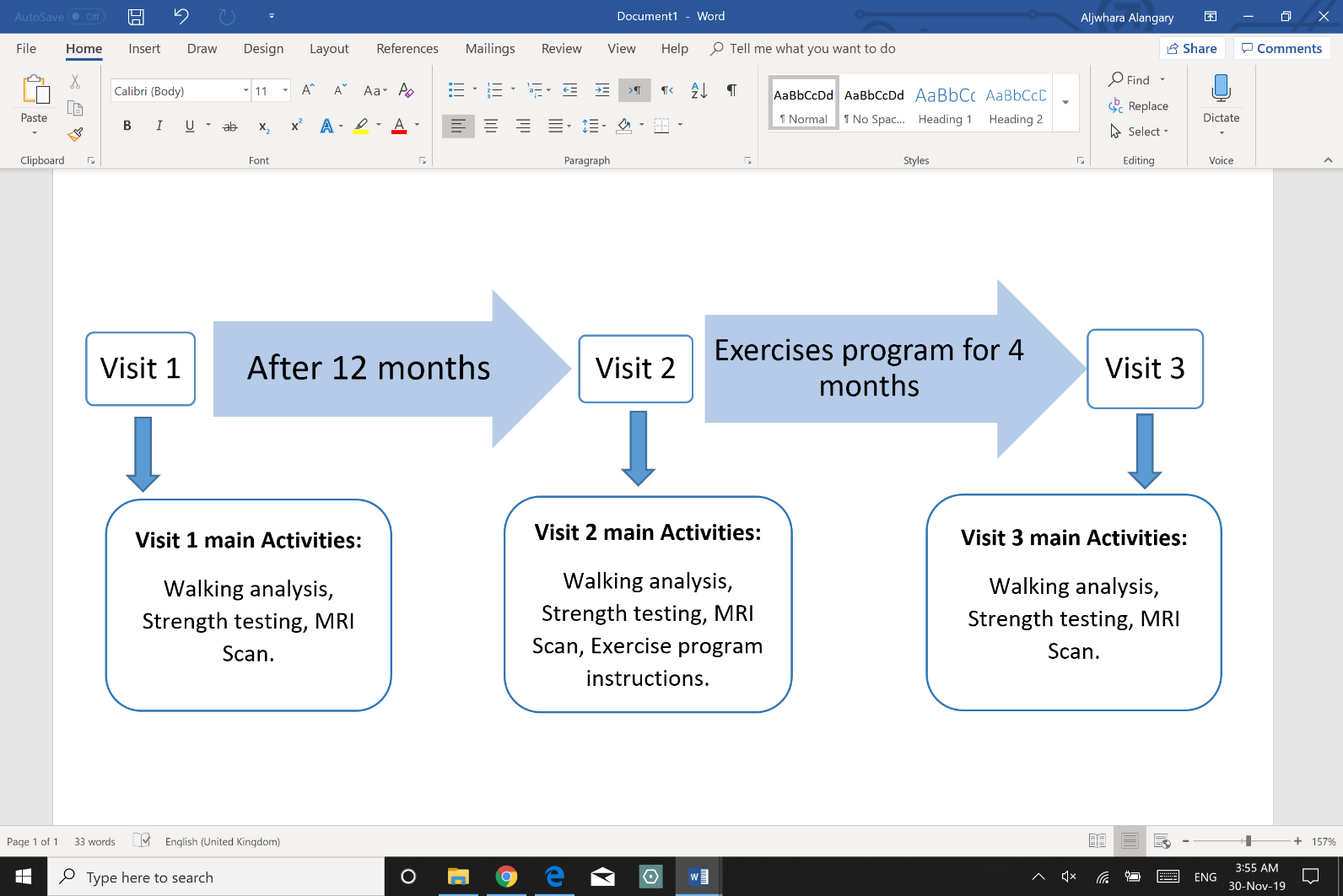
The measurement sessions will take approximately 2 to 3 hours each. The consent meeting will take place before the first measurements and will take approximately 30 minutes. If you would like us to inform your general practitioner or other health professionals about your participation in this study, we will be happy to inform them by post.

**b. What happens during the measurement sessions?**

First: We will be analysing your walking, using specialist movement analysis equipment. We will do this in a few conditions: 1) wearing simple shoes, 2) wearing your own prescribed ankle brace (where appropriate), and 3) wearing carbon fibre AFO’s.

Second: we will be measuring your legs muscles strength using specialist measuring device.

Third: we will be taking images of the muscles of your legs using MRI scans. Prior to each MRI scan, female participants of childbearing potential who are sexually active will be asked if they are or may be pregnant. The confidentiality of potential participants will be respected. If a participant becomes pregnant after enrolment in the trial, they will be withdrawn from the trial immediately and not be subjected to any further assessments and scans.

After the second measurement session, you will be given instructions about the exercise program.

**c. How long will I be involved in the study?**

Your involvement in this study will last for the three measurement sessions only (0 months, 12 months, and 16 months). After these measures have been completed, you will have finished your time on this study. Travel expenses by train, car, and public transportation will be reimbursed from the study funder.

**d. What will the research participant be required to do?**

We will ask you to wear shorts and a vest for the measurement sessions.

The measurement session will take place at Queen Square Centre for Neuromuscular Diseasesin the National Hospital for Neurology and Neurosurgery (NHNN).

**What are the known risks of the study or the side effects of training?**

All the measures and rehabilitation treatments will be done by a trained physiotherapist. MRI scans will be performed by a trained radiographer. However, an MRI safety check questionnaire will be completed prior to the scan to ensure participants safety.

There are no known health risks and we are not expecting any adverse events from the measures and treatments used in this study.

You may find the measurement sessions tiring, to minimise this, we will offer you breaks during the session.

If participants have any concerns regarding injury or risk following or during the measurements, they should contact the research team immediately. Dr. Gita Ramdharry can be contact by email [g.ramdharry@ucl.ac.uk](mailto:g.ramdharry@ucl.ac.uk) or telephone: 020 3108 7517.

**What if new information about risks or side effects becomes available during the study?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens your research physiotherapist will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research physiotherapist will make arrangements for your care to continue.

Also, on receiving new information your research physiotherapist might consider it to be in your best interest to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

**What are the possible benefits of taking part?**

Participants will have the chance to get an exercise program taught by a qualified physiotherapist. They will also have the chance to be referred to specialist clinic to get ankle braces.

**How will my information be kept confidential?**

In this research study we will use information from measurement sessions. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

You will be given the option to your GP/family doctor being informed about your participation in this research study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

At the end of the study we will save some of the data in case we need to check it and for future research in dHMN and may be shared anonymously with commercial companies and other researchers.   
We will make sure no-one can work out who you are from the reports we write.

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to UCL Data Controller: [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

**What if something goes wrong?**

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor’s (University College London) or the hospital's negligence, then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr. Gita Ramhrarry who is the Chief Investigator for the research and is based at the Queen Square Centre for Neuromuscular Diseases. The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, contact details are at the end of the document. If you remain unhappy and wish to complain formally, you can do this via the hospital’s Patient Advisory Liaison Service (PALS).

Site: University College London Hospitals NHS Foundation Trust

Address: Ground Floor Atrium, University College Hospital, 235 Euston Road, London NW1 2BU

Tel: 020 3448 323

Email: uclh.pals@nhs.net

When contacting them, please quote the study number that can be found on the first page of this information sheet.

**What will happen to the results of the research study?**

The detailed results of the study will be published in a peer reviewed medical journal and will be used by the student researcher for their PhD thesis

**Who is organising and funding the research?**

This study has been organised by University College London and is part of a PhD funded by the Royal Embassy of Saudi Arabia Cultural Bureau in the UK & Ireland.

**Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Cambridge Central NRES Committee Research Ethics Committee and the Health Research Authority (HRA).

**How have patients and the public been involved in this study?**

Design of the research and patient information sheet (PIS) are going to be discussed in a meeting with 3 to 4 patients.

**Contact for further information**

Aljwhara Alangary (Doctoral Student, UCL)  [a.alangary@ucl.ac.uk](mailto:a.alangary@ucl.ac.uk) 02031089899  
  
Dr Gita Ramdharry (Chief Investigator)  [g.ramdharry@ucl.ac.uk](mailto:g.ramdharry@ucl.ac.uk)  02034482455

Thank you very much for taking the time to consider your involvement in our study. Please keep this copy of the information sheet and do not hesitate to contact us if you have further questions.