PARTICIPANT INFORMATION SHEET

Study title: ADAP-NMD Study

Chief Investigator: Dr Gita Ramdharry

This research is being carried out as part of a PhD (a course of studies leading to a doctorate degree) undertaken by research fellow Louie Lee. The PhD is sponsored by University College London and funded by Muscular Dystrophy UK.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Purpose of the study

Supported self-management is part of the 'NHS Long-term Plan's' commitment to make personalised care 'business as usual' across the health and care system. It proactively identifies the knowledge, skills and confidence people have to manage their own health and care. Research has shown that self-management programmes can support people with long-term conditions to problem solve, set goals, and take action. The focus is on living well with a condition, not just the medical needs. Self-management support has been shown to be effective in other neurological diseases, but there is very little research into specific programmes for people living with a neuromuscular condition.

Bridges is a social enterprise that exists to make a difference to the lives of people who live with acute and long-term conditions, by working with teams from health, social care and the third sector, to define and deliver best practice in self-management support. Bridges have recently worked with people with neuromuscular conditions to produce a support programme that is tailored specifically to their needs. This new programme needs to be evaluated, which is why this study is taking place. We will also be investigating how the Bridges programme can be effectively introduced into the clinical service at the Queen Square Centre for Neuromuscular diseases.

Why have I been chosen?

You have been asked to consider participating in this study because you have a diagnosis of neuromuscular disease and you are a patient at the Queen Square Centre for Neuromuscular Diseases.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to, you will be invited to attend a consent meeting where we will go over what participating involves with you and ask you to sign a consent form. If you have any queries about the study, we are happy to discuss them with you, without any commitment to taking part. You can take as long as you need to consider being involved, and you can discuss this with others before making a decision. If you do decide to take part you will be involved in the trial for a total of 3 months.

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?

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

1. If you consent to take part, you will be asked to fill in a selection of questionnaires asking you about your experience of living with a neuromuscular condition. This will either be done remotely or face-to-face depending on your preference.
2. Fairly soon after this, you will attend a routine appointment with one of the health care professionals that you are working with at Queen Square (this could be a nurse, a physiotherapist or an occupational therapist). This professional will have been trained in the 'Bridges self-management approach' and will work with you to find new ways to build on your knowledge, skills and confidence. Hopefully this will help you to manage the condition you have effectively in the context of your everyday life.
3. Directly after the session you will be asked to complete some more questionnaires.
4. Three months later, you will be asked to complete the questionnaires one final time.

b. What happens during the main therapy/nursing appointment?

If you consent to take part in the study, you will attend one of your usual appointments with either a physiotherapist, occupational therapist or specialist nurse who has been trained by Bridges. During the session they will work with you to find ways that you can approach problem-solving, setting goals and doing the things that are important to you. Some of the sessions will be video recorded so that we can make sure that the way that we are working with people is consistent. However, we will only do this if you provide consent to be video recorded.

c. Optional interview

You may be asked if you would like to take part in an interview to discuss your experience of being involved in the study. If you decide that you would like to do this, the interview will take place at some point in the three months after the therapy/nursing appointment. The interviews will take up to one hour and will be held in a location that suits you. This could be a private room at the hospital, in your own home, or via video-link or telephone. They will be audio-recorded using a small voice recorder so that we can accurately record what was talked about. The audio recordings of the interviews will be transcribed by an external service. Your details will be coded to ensure that all your data remains anonymous before the recordings are sent for transcription.

What are the possible benefits of taking part?

Bridges training helps health professionals to adapt their approaches to working with people, and work in a personalised way based on 'what matters' to the person. It enables them to use techniques to support people to build knowledge, skills and confidence. People with other neurological conditions have found this to be very helpful, and you may too. This study may help us improve the advice and treatment given to patients with neuromuscular diseases in the future and help us with future research. Some people may enjoy the opportunity to share from their experience and take part in a research project.

What are the possible risks?

It is very unlikely that taking part will cause harm, but some people might find it upsetting to talk about their experiences of living with the condition that they have. If this happens, we will offer to refer to counselling services if you feel it would be helpful.

Taking part in the study will require some of your time in order to complete the questionnaires and the interview if you decide to take part. If you need to travel, we will reimburse you for any reasonable travel expenses.

The information held about the research participant

How will we use information about you?

All of your data will be handled in line with GDPR regulations. GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

We will need to use information from you from your medical records for this research project. This information will include your:

- Initials
- NHS number
- Name
- Contact details.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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 we won't be able to let you see or change the data we hold about you.
- The data custodian for this study is Dr Gita Ramdharry, whose contact details are as follows: **Email: g.ramdharry@ucl.ac.uk Telephone: 020 3448 2455**

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/
- by asking one of the research team
- by sending an email to louie.lee@ucl.ac.uk or
- by ringing us on 02031086301
- contacting the Data Protection Team at UCL- data-protection@ucl.ac.uk

Will I be recorded and how will the recorded media be used?

The video recording of your therapy/nursing appointment, and audio recording of your interview made during this research, will be used only for analysis, so we can see if the intervention is effective and if it is being carried out properly by the clinical team. An anonymised version of the audio recording of your interview (if you have one) will be sent to an external transcription service who will transcribe it. The transcription service is bound by a confidentiality agreement to protect your data. No other use will be made of it without your written permission, and no one else outside the project will be allowed access to the original recordings.

What if something goes wrong?

Every care will be taken in the course of this study. However, 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.

If you remain unhappy and wish to complain formally, you can do this from the NHS Complaints Procedure. Details can be obtained from the (NHS site), Patient advice and liaison service (PALS). PALS can be contacted on line (https://www.royalfree.nhs.uk/contact-us/patient-advice-and-liaison-service-pals/contact-pals-online-form/) or by telephone (020 7472 6446 or 020 7472 6447).

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. Articles outlining the results may also be published in the Muscular Dystrophy UK newsletters and websites. Please note that no identifiable data will be included in the publication. We may use direct quotes from participants, but the quotes will be anonymous, and care will be taken to ensure that no information is included that could identify participants. If you would like to be sent the results of this study, we would be delighted to share them with you, just request this from a member of the research team.

Who is organising and funding the research?

This study is part of a PhD funded entirely by the charity Muscular Dystrophy UK (more information on the PhD is available on the MDUK website) and is sponsored by University College London.

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 ……..

Contact the research team for further information:

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Dr Gita Ramdharry (Chief Investigator) g.ramdharry@ucl.ac.uk **020 3448 2455**

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.