PARTICIPANT INFORMATION SHEET
Version 4.0, 11/05/2021

A Randomised Controlled Trial of Specialist Physiotherapy for Functional Motor Disorder (Physio4FMD)

We are inviting you to take part in a research study. 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. Please ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

Thank you for taking the time to read this information sheet

What is the purpose of the study?

Physiotherapy is often recommended for people with functional motor disorder (symptoms such as weakness, tremor or muscle spasms where there is no damage to the nervous system) but there is little scientific evidence to show whether or not it is helpful.

In this study, we will compare two types of physiotherapy to see if one is more effective than the other for people with functional motor disorder.

Do I have to take part?

No. It is up to you to decide whether or not to take part and you are free to withdraw at any time. If you decide to take part we will ask you to sign a consent form indicating your willingness to participate in the study. A decision to withdraw, or a decision not to take part, will not affect the standard of care you receive. If you choose not to take part or to withdraw from this study your neurologist can refer you to your local physiotherapy service.

If you withdraw from the study, we will continue to use any information we have collected about you, unless you ask us not to.

What will I have to do if I take part?

If you choose to take part you will be asked to complete a questionnaire booklet to give us more information about your health – we can help you complete this if need be. This will take between 30 and 60 minutes in total.

The information you provide will remain strictly confidential, will be stored securely and will only be seen by the research team.

Treatment groups
You will then be allocated by chance to one of two treatment groups.

Group 1
Participants in this group will be referred to their local physiotherapy service for standard physiotherapy treatment. If you are currently receiving physiotherapy or have recently been discharged, a letter summarising your consultation with your neurologist will be sent to your local physiotherapy team. You will receive a copy of this letter.

Group 2
Participants in this group will receive the research physiotherapy programme at a physiotherapy department near where you saw your neurologist. The physiotherapy will involve between 6 and 9 physiotherapy sessions, which will be scheduled over three weeks. The physiotherapist will then follow you up after three months, in person or over the telephone, to see how you are going.

Both Groups
We will ask you to complete the questionnaire booklet again six months after you have signed up to the study and again after 12 months. Repeat questionnaire booklets will be sent to you by post with a return-paid envelope. You will also be given the option of completing the questionnaires by telephone, or a secure online (internet) form. We will remind you by telephone or email if you forget to fill in the booklet.

You will also be contacted by telephone after you have completed your physiotherapy treatment. We will ask you to describe the treatment you received and rate your satisfaction with this treatment. We will not share this information with your physiotherapist.

How do you decide which group I am in?
You will be assigned to one of the two groups by chance.

At the moment we do not know if one type of physiotherapy is better than another. We will compare two different physiotherapy approaches by selecting the group you are assigned to by chance, using a computer programme. You will have a 50:50 chance of being in either group.

How long will I be in the study?
If you agree to take part you will be in the study for 12 months. After this you will return to standard NHS care.

We will also ask for your permission to contact you to find out about your health after you complete the study. We would like to find out how your health changes after two years, five years and ten years. You may choose to opt out of this part of the study. Also, at any time you may ask for your contact details to be removed from this list and you will no longer be contacted.

Expenses and Payments
We will reimburse your travel costs to your physiotherapy appointments up to the value of £25 per visit.

What are the benefits of taking part?
We cannot promise that the study will help you, but the information from this study may help improve future physiotherapy treatment of functional motor disorder. We also hope to increase awareness of functional motor disorders amongst physiotherapists and other health care professionals.

What are the possible risks?
Physiotherapy is considered a standard and safe treatment for people with functional motor disorder. We believe there are no additional risks in taking part in this research study.

What about COVID-19?
As you are likely aware, due to the outbreak of COVID-19 (Coronavirus), NHS Trusts are taking extra steps to ensure both staff and patients are kept safe at all times and to prevent any further spread.

As part of this you will be asked to follow our Hospital policies on social distancing and Personal and Protective Equipment (PPE) whilst you attend on-site.

Staff will be adhering to strict cleanliness guidelines and, in some cases, this may mean wearing PPE, such as a face mask, a plastic gown and/or gloves.

You may bring a support person or carer to appointments if you need to, but where possible, please attend on your own.

Please don't attend hospital if you:

1) Are under current instruction from your doctor that you should be isolating and avoiding social contact.
2) Have a household member, or are yourself, currently experiencing any COVID-19 symptoms, in which case you must stay at home and please contact us so we can postpone any appointments.

Depending on the hospital policy at the time of your appointment, you may be contacted by a member of the research or treatment team prior to appointments to check for COVID-19 symptoms.

If you do not feel comfortable attending the hospital for treatment due to COVID-19, you are under no obligation to participate in the research. If this is the case or you have any additional concerns or questions regarding COVID-19, please use the contact details of the local hospital team, provided in the following section of this Information Sheet.

What if there is a problem?
We do not anticipate anybody to come to any harm by taking part in this study. If you have a concern about any aspect of this study, you should ask to speak to the person in charge of this study at your hospital/neurology department. Their contact details are:
Dr Glenn Nielsen (Principal Investigator), telephone number: 020 8266 6858.

If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure. The Patient Advice and Liaison Service (PALS) can support you through this process. Contact PALS via your hospital switchboard.

Will my taking part be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. You will be allocated a unique study code in order to keep any information stored about you confidential. All research staff not directly involved with you will only know you by this code. Information will be stored on a secure password protected computer database and will only be accessible to the research team and potentially by regulatory authorities for auditing and monitoring purposes. When the results of the study are reported, individuals who will have taken part will not be identified in any way.

St Georges, University of London is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. St Georges, University of London may keep information collected for the purpose of the study up to 10 years after the study has finished. This is to ensure integrity of the results. All data will be stored in a secure manner.

St Georges University Hospital will collect information from you and/or your medical records for this research study in accordance with our instructions.

St Georges University Hospital will use your name, contact details and other identifiers to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from St Georges, University of London, St Georges University Hospital and regulatory organisations may look at your medical and research records to check the accuracy of the research study. St Georges University Hospital will pass these details to St Georges, University of London along with the information collected from you and/or your medical records. The only people in St Georges, University of London who will have access to information that identifies you will be people who need to contact you to as part of the research study you are involved in, and or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

St Georges University Hospital will keep identifiable information about you from this study for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage the data in specific ways to ensure the research we conduct is reliable and accurate. If you withdraw your consent to participate in a research project, this will not mean we will have to remove all data as well. We will keep the information about you that we have already obtained to ensure research integrity is maintained in the public's interest. To safeguard your rights, we will strive to use the minimum personally-identifiable information possible.

You can find out more about how we use your information https://www.stgeorges.nhs.uk/education-and-research/research/research-privacy-notice/

For general information on how the NHS uses research data please visit https://www.hra.nhs.uk/information-about-patients/

Will my GP be informed about my participation?
Yes, we will send a letter to your GP informing them of your participation. Any medical or physiotherapy letters or reports from the study will be copied to you and your GP.

How will the information be used?
The findings of this research will be published in scientific journals and presented at conferences. You will be informed about the results by the researchers, who will provide you with a study newsletter informing you of the progress of the trial and a plain English summary of the results when the trial is completed. We will also let you know how to access the scientific publications.

The plain English summary will also be sent to online patient support organisations, such as www.FNDHope.org and www.FNDAction.org.

Who is funding this research?
Funding for this research is provided by the National Institute for Health Research (NIHR).

Who has reviewed this study?
This study has been reviewed and approved by the National Institute for Health Research (NIHR) and the Health Research Authority (HRA).

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 approved by the London – Surrey Borders Research Ethics Committee.

Contact details

If you have any questions or concerns, please contact –

The Trial Manager, Hayley Noble
Tel: 020 8266 6468
Email: hnoble@sgul.ac.uk

For further information, please visit our website: www.Physio4FMD.org

This research project is registered on the following database –
ISRCTN registry [https://www.isrctn.com/ISRCTN56136713
Registration Number: ISRCTN56136713