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optimistic

CARERS INFORMATION SHEET: OPTIMISTIC Trial

***O**bservational **P**rolonged **T**rial **i**n **M**yotonic Dystrophy type 1 to **I**mprove Quality of Life **S**tandards, a **T**arget **I**dentification **C**ollaboration*

We would like to invite you to participate in a research project called OPTIMISTIC which is collaboration between [local PI] and doctors and researchers in the UK, the Netherlands, Germany and France. Before you decide whether or not to participate, we need to be sure that you understand why we are doing the study, and what it would involve if you agreed to take part. Please take time to read this information carefully. On the last page of this leaflet you will find a space for 'My Questions' please use this space to write down any questions you may wish to ask your partner/relative's doctor, research nurse or GP. We will do our best to explain and provide any further information you may ask for now or later. You do not have to make an immediate decision to participate if you are not ready.

Why have I been invited to participate in the OPTIMISTIC Trial?

You have been contacted because you provide care for a person with the rare neuromuscular disease, myotonic dystrophy type 1 and we want to know how you feel and cope by providing essential care and support.

What is the purpose of this study?

Myotonic dystrophy type 1 is a progressive disease with typical symptoms which include progressive muscle weakness, daytime sleepiness and fatigue. There are no known medicines to treat the major symptoms of myotonic dystrophy type 1 with the exception of the drug Modafinil, which is sometimes used to help control excessive daytime sleepiness.

Our research group is a Europe-wide collaboration of myotonic dystrophy type 1 specialists including doctors, therapists and researchers. The OPTIMISTIC study is a randomised controlled trial that will use a unique personalised therapy attempting to reduce fatigue (this therapy will be called the "intervention"). We will compare the outcome of the group that received the intervention with those who did not. This is called the comparison or control group. The groups will be decided in a random way (a bit like tossing a coin, but done by a computer.) The person will have a 50:50 chance of being part of the group receiving cognitive behavioural therapy (CBT) the intervention or the comparison group

The intervention will use cognitive behavioural therapy (CBT) to try to reduce levels of fatigue and improve quality of life. This will be done using a range of different techniques, depending on your partner/relative's specific situation. The main focus will be to gradually increase their day to day activities. During the therapy sessions the aim will be to support caregivers and guide the carer in ways to help their partner/relative achieve their goals.

If this study shows that the therapy benefits people with myotonic dystrophy, we hope to change clinical guidelines and practice so that care and management may be improved for people with myotonic dystrophy type 1, their carers and families.

Do I have to take part?

No. It is entirely up to you whether or not to take part. Participation in this study is entirely voluntary and you are free to withdraw from the study at any time without having to give a reason.

If you do not wish to participate the person you help to care for can still take part in the main study and in no way will your non-participation affect their future care or treatment.

If your partner/relative wishes to withdraw from the study or is withdrawn by one of the study doctors or researchers we would like your permission to keep and analyse the data already collected. In this circumstance we would like to invite you both to attend a withdrawal visit. If you attend the withdrawal visit we would like to perform the measurements and activities scheduled for Visit 5. These will be prioritised incorporating you and your partner/relative's preferences.

What will happen to me if I take part?

At the first visit you will attend with the person you care for. You will both have the opportunity to discuss the study in more detail and ask the study team any questions you have. If you agree to take part you will be asked to sign a consent form explaining your participation. You will be given a copy of this along with this Participant Information Sheet for your records.

Depending on which group your partner/relative is allocated to you will either be invited to:

- Complete 3 brief questionnaires at 5 visits over 17 months. Each visit takes approximately an hour.

Or

- Complete 3 brief questionnaires at 5 visits over 17 months and if your partner/relative is allocated to the intervention group, invited to attend all/some of the therapy sessions.

The visits schedule diagram at the end of the information sheet summaries the study visits.

Please note that although your visits will only take about an hour, if you chose to stay with your partner/relative or they are allocated to the intervention group, then these visits may take about 4 hours as they perform their study activities.

Expenses and payments

You will not be paid to take part in this study but we will be able to reimburse for your travel expenses for coming to study visits.

What are the possible disadvantages and risks in taking part?

The additional visits to the muscular dystrophy centre or research facility may be inconvenient.

You will be asked to complete questionnaires relating to how you feel generally and specifically about proving care and support for your partner/relative. The research nurse or therapist will be able to assist you to complete the questionnaires.

What are the possible benefits of taking part in the study?

The study may not immediately benefit you, but if the intervention is effective then this may improve the quality of care and management for people with myotonic dystrophy type 1 in the future. Further information and study progress will be available on the study's webpage; *www.optimistic-dm.eu*.

What will happen to the results at the end of the study?

The results will be published in scientific journals, presented at conferences and may be used in guidelines to help doctors provide care to patients with myotonic dystrophy type 1. Some results will also be made available to you, patients and patient organisations to publish in their newsletters and on their websites. You will not be identified in any publication of results.

In addition, we will also ask your permission for the research team to contact you in relation to future research you may be interested in. By giving permission to contact you, you are not giving consent to participate merely to be informed of other research projects.

What will happen if I don't want to carry on in the study?

Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your partner/relatives future medical care or your relationship with medical or nursing staff looking after your partner/relative. If you decide to withdraw from the study, we would like your permission to retain and analyse the data already collected.

Will my participation in the study be kept confidential?

Yes. All the information that is collected about you during the course of this study will be kept strictly confidential.

With your permission, the sessions you have with the therapist as part of the intervention may be taped (audio only, not video). The recording will be typed up verbatim and your name will not be used on the tape or transcript. The tapes and transcripts will be kept in a locked cabinet and tapes will be destroyed 1 year after the study is completed.

At the end of the study the confidential records will be kept for 5 years and then destroyed.

The confidential handling, processing, storage and disposal of data are in accordance with the Data Protection Act 1998.

What happens if something goes wrong?

If you have a complaint about your participation in the study you should first talk to a researcher involved in your care. You can ask to speak to a senior member of the research team or the Complaints Officer for Newcastle upon Tyne Hospitals NHS Foundation Trust at the Patient Relations Department on 0191 223 1382. In the event that something goes wrong and you are harmed during the study there are no special compensation arrangements**.** If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle upon Tyne Hospital NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate.)

If you feel that you have been treated unfairly throughout the research, or would like to comment on the conduct of any aspect of this research, please contact the Patient Advice and Liaison Service (PALS) 0800 0320202

Who is managing and funding this research?

The study has been organised by Dr. Grainne Gorman and her colleague Professor Hanns Lochmuller at University of Newcastle and Newcastle upon Tyne Hospital NHS Foundation Trust. The study is funded by European Union Seventh Framework Programme.

Who has reviewed the study?

The North East England (Sunderland) Ethics Committee which has responsibility for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics.

Contact Details.

For additional information contact:

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There is also more information on the OPTIMISTIC website: http://optimistic-dm.eu.

If during the study you become unwell or are concerned, contact NHS Direct. You can also contact the study team from 9am to 5pm on 0191 282 0070. If you are unwell and need urgent advice or assistance do not delay in seeking further advice or treatment as usual through the NHS services.

Thank you for reading this information sheet and considering taking part in this study.

OPTIMISTIC STUDY - VISIT SCHEDULE

VISIT 1
Screening Visit
1 hr
Questionnaires

Randomisation of Partner/Realtive

Comparator (No intervention)

Intervention

Baseline Approx. 60mins	Questionnaires	Baseline Approx. 60mins *therapy	Intervention (Baseline and 10 months) Delivered over 10-14 sessions for 10 months, face to face, telephone call or computer Interviews) You will be invited to attend and participate in some of these sessions.
Visit 3 (month 5) Approx 60mins	Questionnaires	Visit 3 (month 5) Approx. 60mins *therapy	
Visit 4 (month 10) Approx. 60ms	Questionnaires	Visit 4 (month 10) Approx. 60mins *therapy	
Visit 5 (month 16) Approx. 60 mins	Questionnaires	Visit 5 (month 16) Approx. 60mins *therapy	

My Questions