DO I HAVE TO TAKE PART IN THE TRIAL?
Participation in the trial is completely voluntary and you can refuse to take part or withdraw at any time from the trial without having to give a reason and without this effecting your future medical care or relationship with medical staff involved in your care.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?
Yes, your personal details and information we record will be kept strictly confidential. You will not be identified in any future publications or reports related to the study. We will ask your permission to tell your GP that you are taking part in the study.

WHO IS CARRYING OUT THIS TRIAL?
The trial is a European collaboration and is a multi-centred randomised control trial. Collaborating centres are within the United Kingdom (UK), France, Germany and The Netherlands. The study is funded by the European Union Seventh Framework Programme.

IF YOU ARE INTERESTED IN TAKING PART:
Please complete the enclosed reply slip and return it to us using the stamped addressed envelope provided. We will then contact you with the full details about the trial. Alternatively you can also telephone us on one of the numbers provided above.

IF YOU ARE NOT INTERESTED IN TAKING PART:
Please complete the enclosed reply slip and return it to us using the stamped address envelope provided. If we do not hear from you, a member of the study team will contact you by mail or telephone to ask if you are interested in taking part in the study.

If you would like more information on this study you can contact the Trial Manager or your Myotonic Dystrophy Clinic Research Nurse.

Contact Details:

Dr Grainne Gorman

UK Clinical Research Facility,

Level 6, Leazes Wing,

Royal Victoria Infirmary

Newcastle Upon Tyne, NE1 4LP

Email: grainne.gorman@ncl.ac.uk

Jan Gebbie (Research Nurse)

Contact Number: 0191 2820070

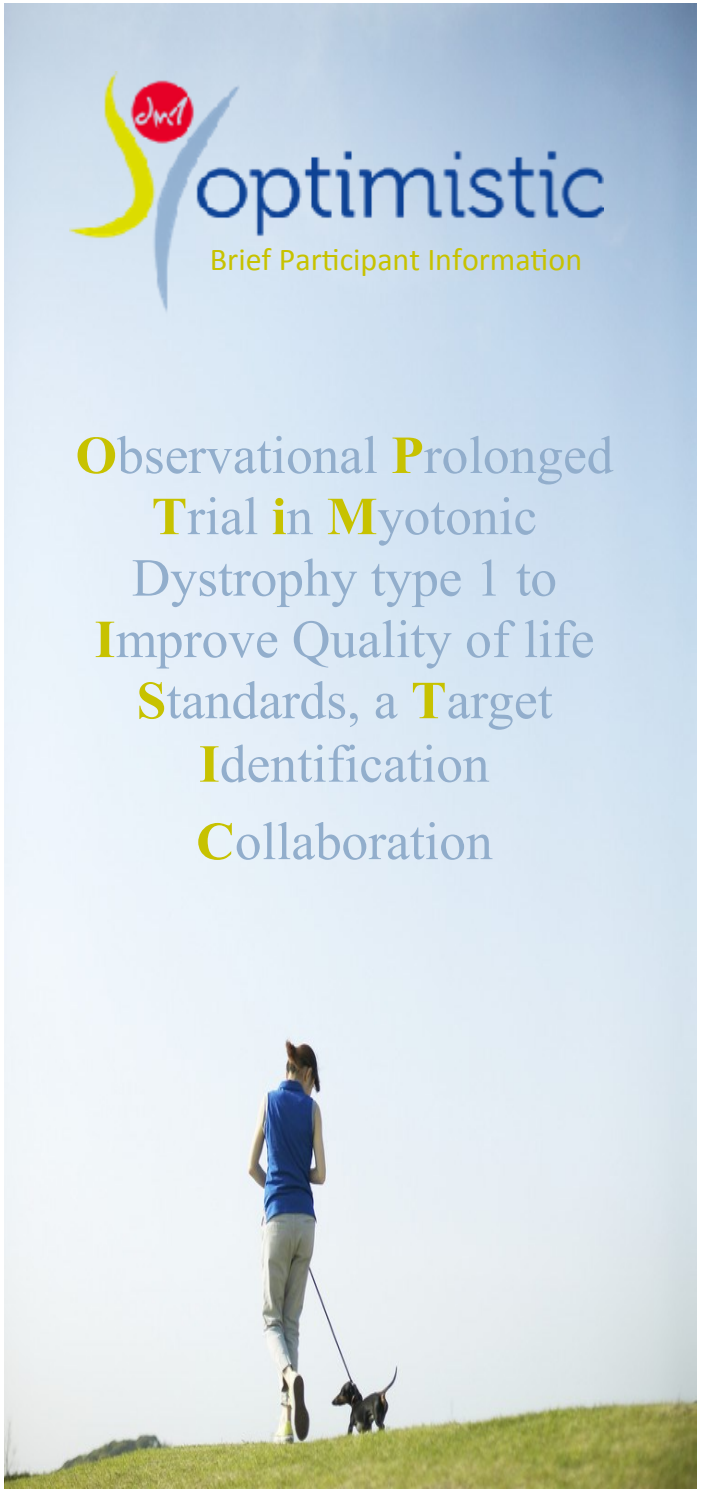
Further Information can be found on the website address below.

www.optimistic-dm.eu

Optimistic

Brief Participant Information

Observational **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



WHY ARE WE DOING THIS STUDY?

Evidence shows that patients diagnosed with myotonic dystrophy type 1 experience fatigue and difficulty with cognitive function. ***There are no known medicines to treat the core symptoms of myotonic dystrophy type 1*** with the exception of the drug Modafinil which is used to control excessive daytime sleepiness.

The aim of the OPTIMISTIC study is to compare how effective sessions of personally tailored cognitive behavioural therapy are on patients' levels of fatigue and physical activity compared to standard patient care (no behavioural therapy).

WHAT IS COGNITIVE BEHAVIOURAL THERAPY?

Cognitive Behavioural Therapy (CBT) is a type of psychological therapy. According to CBT how a person thinks and what they do in response to problems is important. CBT is a coaching process that can help an individual to change unhelpful thoughts and behaviour. ***During CBT sessions you will be given advice on how to change your behaviour to help you cope with daily living.*** This will include setting personal goals which your therapist will help you meet.

OPTIMISTIC will test if CBT can:

- **Reduce fatigue**
- **Help you learn to compensate for problems taking imitative or starting an activity**
- **Improve relationships with significant others**

If you are allocated to receive CBT you, will have 10 months of therapy delivered over 10-14 sessions. The sessions may be face to face, over the telephone or using the internet.

WHY AM I BEING INVITED TO TAKE PART IN THE STUDY?

You are being invited to take part in this research trial because you have myotonic dystrophy type 1.

If you are interested in taking part in OPTIMISTIC we will arrange an appointment for you at your local myotonic dystrophy clinic. A member of the research team will discuss the study and answer any questions you may have. If you decide that you would like to take part, you be will asked to sign a consent form.

You will then be randomly allocated to either receiving CBT (the intervention group) or not (comparison group).

To make sure you are eligible to take part in the study, you will be asked some questions about your medical history, current health and asked to complete a few questionnaires. You will also be asked to complete a 6 minute walk test to see how far you can walk at your own pace in 6 minutes and how many times you need to rest. If you have not had a genetic diagnosis of Myotonic Dystrophy type 1 you will be referred to your clinic for a blood test.

The next 4 visits will each involve questionnaires about your physical status, quality of life and activity levels, a 6 minute walk test.

We will also take a sample of blood and urine at 3 of the 4 visits. Your blood and urine samples will be stored and analysed at the end of the trial by members of the trial team. We will be looking at DNA and protein (biomarkers).

Your physical activity you will be assessed using an actometer. This is a watch like device worn on your ankle which measures how active you are on a normal day. You will be asked to wear an actometer for 14 days after each study visit.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

People taking part in the study will be asked to attend their myotonic dystrophy clinics for 5 to 12 visits over 17 months depending on which group they are allocated to. All your travel expenses will be reimbursed.

CAN I INVOLVE MY PARTNER OR CARER?

Your partner, carer, family or other people close to you often provide essential care and support. We would like, with your agreement, to invite someone who helps you deal with your myotonic dystrophy to take part in the study.

We will give them more information and if they wish to take part, they will be asked to sign a consent form. We will ask them to complete 3 questionnaires at each study visit.

If you are allocated to the intervention group, the therapist will try and teach them how to support and encourage you to meet your goals. If you or your partner/carer does not wish to take part in this study, you can still take part in the main study and this will not affect your future care or treatment.

Should you be not eligible to take part in the trial a member of the trial team will explain why, this will mean you do not have to attend for further visits.