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Issue 1

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286 patients from
across Europe

€3million
awarded from the
European Commission

Munich,
Newcastle,
Paris and
Nijmegen

First European trial for
myotonic dystrophy

Welcome to the first OPTIMISTIC newsletter. You are receiving this newsletter as we think you might find it interesting. To continue to receive updates about this project then please sign up for the newsletter at www.optimistic-dm.eu or contact Libby Wood elizabeth.wood2@ncl.ac.uk.

There are many different aspects to OPTIMISTIC and throughout the course of the project we will try and introduce you to them all. As this is the first edition, it contains a general overview and explanation of what OPTIMISTIC is doing and who is involved. Each newsletter we will focus on a different element of the study. This time we will provide some additional detail about cognitive behavioural therapy.

Thank you for your interest in OPTIMISTIC!

What is OPTIMISTIC?

OPTIMISTIC is a 4 year EU-funded research project focusing on myotonic dystrophy type 1 (DM1). The project will form a trial testing a new non-pharmacological treatment for the condition. A combination of cognitive behavioural therapy and exercise will be assessed to see if it can reduce fatigue, and improve quality of life.

The trial will be carried out in four cities across Europe, Newcastle; United Kingdom, Nijmegen; Netherlands, Munich; Germany and Paris; France. Recruitment will soon be opening in all sites.

As well as the trial itself we will be trying to find out as much as possible about myotonic dystrophy and how it affects people in different ways. Researchers across Europe will be looking at a number of different aspects of the condition such as biomarkers, genetics and outcome measures.

In future newsletters we will give you more information about these different areas. Some more information is also available on the study website www.OPTIMISTIC-dm.eu



Baziel Van Engelen is coordinating the project from Nijmegen in the Netherlands.

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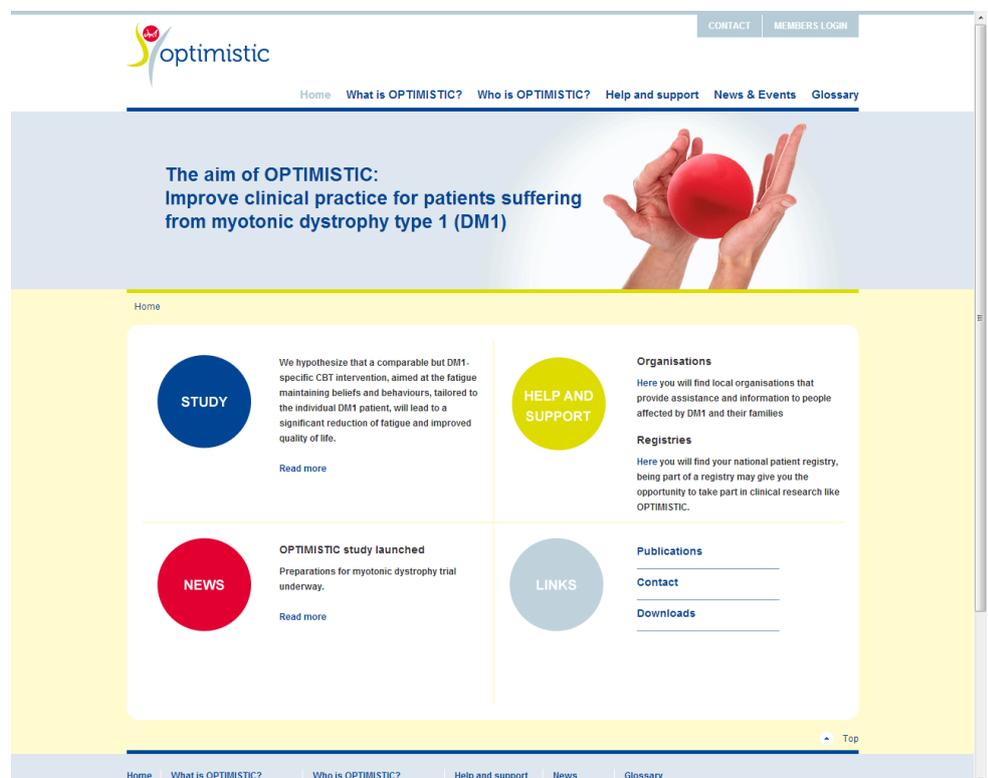
Who is involved in OPTIMISTIC?

For projects like this to be successful, the collaboration of many professionals with different skills is required. There are nine European partners involved in OPTIMISTIC coordinated by Professor Baziel Van Engelen at Radboud University in Nijmegen, Netherlands.

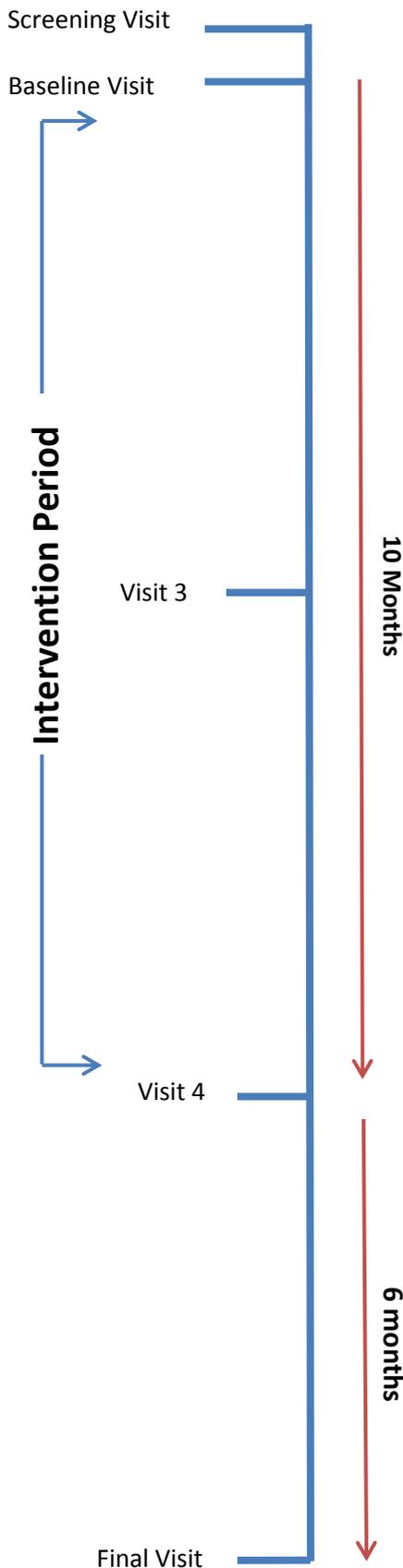
There is also an External Advisory Board made up of experts from around the world available to provide advice and expertise. A patient panel has been involved in setting up of the trial and we hope to continue working with them and patient organisations across Europe to make sure your interests are represented. The project website has full details about all partners involved (www.optimistic-dm.eu)

The OPTIMISTIC website

OPTIMISTIC has its own website (www.optimistic-dm.eu) which has full details of the project, progress updates and information about who is involved. Parts of the website will soon be translated into French, German and Dutch. Check back often to see when updates are made.



The screenshot shows the homepage of the OPTIMISTIC website. At the top, there is a navigation bar with the logo and links for CONTACT, MEMBERS LOGIN, Home, What is OPTIMISTIC?, Who is OPTIMISTIC?, Help and support, News & Events, and Glossary. The main heading reads: "The aim of OPTIMISTIC: Improve clinical practice for patients suffering from myotonic dystrophy type 1 (DM1)". Below this, there are four main content areas: STUDY, HELP AND SUPPORT, NEWS, and LINKS. The STUDY section describes a hypothesis about a CBT intervention. The NEWS section mentions the launch of the OPTIMISTIC study. The HELP AND SUPPORT section lists local organizations and registries. The LINKS section provides links to publications, contact, and downloads. A "Top" button is visible at the bottom right of the content area.



The Trial

This is a brief overview of what is involved in the trial. A full information sheet and study leaflet is also available to download on the website which provides detailed information. You can contact any of the sites listed on page 2 for more information.

Who can take part?

There are certain criteria to taking part. You must be:

- Genetically confirmed myotonic dystrophy type 1 (DM1)
- Over 18 years old
- Experience severe fatigue (so that it has a negative impact on daily life)
- Able to walk independently (use of cane allowed)

Other criteria also apply and these would be discussed with you fully before starting the trial.

What is involved?

The diagram to the left is a time line of events, anyone taking part will be involved for about 16 months. Half of the participants will continue to receive their normal care but will also visit the trial site 5 times for a number of tests. These tests include

- Provide blood and urine samples
- Complete a number of questionnaires about your condition and how it affects you
- Complete the 6 minute walk test

The other half of the participants will also make these visits but in addition they will take part in **the intervention** this will involve a number of extra visits to the trial site to undergo the unique therapy, a combination of cognitive behavioural therapy (CBT) and exercise.

Wherever possible the researchers would like someone close to you for example your significant other or parent to take part in the study with you. This person would have to attend the trial site with you and will be asked to complete some questionnaires.

Diary Dates

28th February 2014

Rare Disease Day,
Worldwide

3rd-5th April 2014

OPTIMISTIC steering
committee meeting, Paris,
France

8th - 10th May 2014

European Conference on
Rare Diseases, Berlin,
Germany

5th-10th July 2014

International Congress on
Neuromuscular Diseases
(ICNMD) Nice, France 7th-11th

October

World Muscle Society,
Berlin, Germany

Spotlight on Cognitive Behavioural Therapy: The Intervention

Half of the people involved in the study will receive the intervention. Intervention is a term used to describe the treatment or therapy being tested in a trial e.g. a drug. In this case the intervention is a unique combination of cognitive behavioural therapy (CBT) and exercise. Here we provide some more information about cognitive behavioural therapy, what it is and why researchers think it might be helpful in myotonic dystrophy.

CBT is a type of psychotherapy. The therapy aims to find practical ways to deal with symptoms and problems.

CBT emphasises how a person responds to problems both through the way they think and act. In order to change thoughts and behaviour a person must be actively involved in the therapy and practise new ways of coping with daily life. Involving a significant other or carer can help to achieve this. CBT is aimed at the present and tries to find practical ways to deal with symptoms and problems rather than focussing on past issues. Specific goals are set as part of the therapy; the participant and therapist work together in reaching these goals.

In OPTIMISTIC Cognitive Behavioural Therapy aims to:

- Reduce fatigue by changing the thoughts and behaviour that can unintentionally maintain fatigue. This might include changing sleeping patterns or trying to increase the level of physical activity.
- Teach people how to compensate for problems in taking initiative or starting an activity, e.g. by learning to schedule your activities.
- Work together with significant others to discover how to best manage the impact DM1 has on daily life.

Hans Knoop who is designing the intervention has lots of experience with CBT and has shown that it can help in other conditions like chronic fatigue syndrome and post-cancer fatigue.

Thank you for reading our first Newsletter. Any comments or feedback you have about this newsletter would be most appreciated – please let us know what is useful, what is not and what you feel is missing so that we can improve the next edition