<insert trust logo>

The University Of Sheffield.

Clinical Trials Research Unit.

HydroDMD

Participant Information Sheet for Children (11-16)

To be shown and read by parent/carer if required

HydroDMD

Study title: Hydrotherapy vs land based therapy **for Duchenne muscular dystrophy**

1. Invitation

We are asking if you would join in our research project. Before you decide if you want to join in, it's important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk to your mum, dad, doctor or nurse if you want to.

2. What is research? Why is this project being done?

Research is a careful experiment to find out the answer to an important question. This project is to see if hydrotherapy (exercises in water) could help people with Duchenne.

3. Why me?

You have been invited as you have Duchenne and can do the walking tests in the study.

4. Do I have to take part?

No. It is entirely up to you. If you do not want to, you don't have to. If you would like to take part:

- you will be asked to write your name on a form to say that you agree to take part (an assent form)

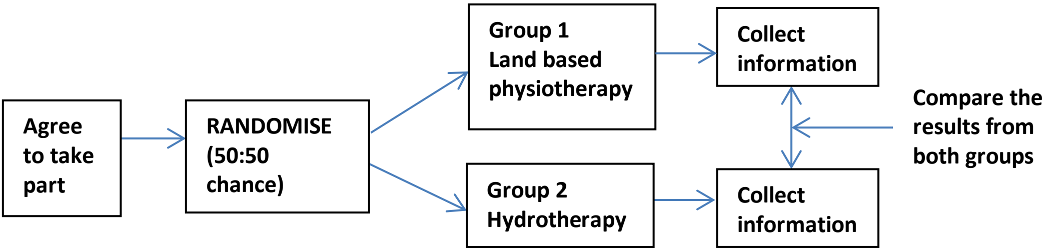
- you will be given this information sheet and a copy of your form with your name on to keep.

5. What will happen?

If you agree to take part, you will be asked to do the same tests as when you go to clinic, like measuring your height and weight, how well you can blow and how well you stand up, walk and get up and down stairs. You will also be asked to walk up and down a corridor for six minutes or for as long as you can manage if this is too long.

These tests will be repeated after a month. If there is no big change, your physiotherapist will look at the results of these tests to see if you are able to take part in this research. If there is a big change, you will not be able to take part.

If your tests show you can take part, some of you will be offered hydrotherapy and some will not. Who does and who doesn't is decided by a computer. This process is called "randomisation" and is shown in this diagram:



You will then be asked to do your normal exercises. You may also be asked to do special exercises in a warm water pool, which is like a special swimming pool. A therapist will be with you in the water to help and to make sure that you are OK. After being in the pool you will be asked how tiring it was, if it was at all uncomfortable and to provide a sample of urine. This will go on twice a week for six months. After the six months you will be asked to do the same tests as the first time.

You will also be invited to take part in an optional interview to tell us about your experiences of taking part in the research project. We will let your usual doctor (GP) know you are taking part in this research.

6. Will joining in help me?

No. It is unlikely to help you but the information we get will help in deciding if hydrotherapy might help treat other boys with Duchenne.

7. What else might happen?

We do not expect there to be any risks or disadvantages to you. Your name and address will be given to researchers if you are interested in taking part in the interview and some of these forms (which include your) name will be sent by post to them.

8. What happens when the research stops?

We will collect all the information together and we will decide if it is useful in telling us if other children at hospital have problems with the strength of their muscles. There won't necessarily be any further hydrotherapy classes after the research finishes.

9. What if something goes wrong?

We do not expect anything to go wrong. If something goes wrong your mum, dad or carer will be able to talk to someone who will be able to tell them what they need to do about it.

10. What if I don't want to do the research anymore?

If at any time you don't want to do the research anymore, just tell your teacher or your mum or dad. We will not be cross with you. No more will be said about it.

11. What if I wish to complain about the study?

If you want to complain you or your mum, dad or carer can talk to <insert local PI name, contact details>

12. Will anyone else know I'm doing this?

No. While the doctors who look after you will know you are taking part, no one else will need to.

13. What happens to what the researchers find out?

When we collect your information we will make sure it is stored in a safe place and only the people doing the research study can look at it. The information will show what we need to do next to find out if hydrotherapy is helpful to people with Duchenne. Your parent/guardian can request the results .

14. Did anyone else check the study is OK to do?

This study has been checked by several people, to make sure it is alright.
Before any research is allowed to happen it has to be checked by a group of people called an Ethics Committee. They make sure the research is OK to do. Your project has been checked by the Cambridge South Research Ethics Committee.

15. How can I find out more about this study?

Your mum, dad or other grown up you trust may be able to answer your questions. -

Thank you for taking the time to read this – please ask any questions if you need to.