

Parents / Guardian Information Sheet

HydroDMD

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

Part 1

Invitation

This is to ask if you would be willing for your child to participate in a research project. The project has been set up by medical and physiotherapy colleagues from several UK centres and is being administered by Sheffield Children's Hospital.

What is the purpose of the research project?

Hydrotherapy, also called aquatic therapy, is a set of exercises carried out under the supervision of a physiotherapist in a warm water pool. In boys with Duchenne there is no data showing if hydrotherapy has any benefit, which is one reason why it is not generally available throughout the UK. To obtain data of high enough quality to justify hydrotherapy will require a formal trial. The UK National Institute of Health Research (NIHR) has asked for an initial study to decide what would be needed for a formal trial and if it is possible to set one up in the UK. Our study aims to provide this information. Your child has been invited as he has Duchenne muscular dystrophy..

Does my child have to take part?

No. It is up to you and your child to decide whether or not to take part. You are both free to withdraw from the research at any time and without giving a reason. Your decisions about this will not affect your child in any way.

What will happen to my child if we agree to take part?

Your child can only take part if you agree that they may do so and sign the consent form attached. We will also ask your child for assent. If they do not wish to take part they will not be asked to do anything further.

What does my child have to do if we agree to take part? The study would mean extra time commitments for you both. Additionally, children who are allocated to the hydrotherapy group may need to miss some school time if they need to travel to a hydrotherapy pool for their sessions.

The first step would be to attend your local centre for a baseline assessment. This involves the same tests as at a clinic visit (measurement of height and weight; a blowing test; the North Star score of abilities such as time to walk 10 metres, the ability to rise from a chair etc). In addition there will be another test of mobility, where your son walks up and down a corridor for 6 minutes (or less if that is too much) and the distance they walk is measured. You would be asked to complete a questionnaire about independence in day to day life activities. The research project will be able to reimburse your travel expenses for this visit.

The test of mobility and the North Star score would be re-checked a month later, if possible during a routine clinic appointment. If there has been no major change in the results your child will then be randomly allocated to receive **either** standard physiotherapy treatment **or** standard physiotherapy treatment together with hydrotherapy as well. If you agreed to take part there would be a 50:50 chance of your son being in either group. Within this trial, the research physiotherapist will prescribe the land based physiotherapy prescription for the boys on the land based therapy (LBT) physiotherapy proforma and inform the community physiotherapists the combination of exercises prescribed.

If your son is in the group receiving hydrotherapy, this would then mean going twice a week for 6 months to a local hydrotherapy pool for a 20-30 minute exercise session in the pool with a physiotherapist. After the session your child would be asked if the session caused any fatigue or pain and would be asked to provide a urine sample for chemical analysis. After the 6 months boys in both groups would have another extra local centre visit where there would be a repeat of the tests performed at the first visit. The research project is not permitted to reimburse you for any hydrotherapy or land based physiotherapy visits, but you may be entitled to claim travel costs from your local NHS Trust.

If you give your consent, you may be interviewed to tell us about your experiences of taking part in the research project. With your consent, we will make an audio-recording of each interview to make sure everyone receives the same information. The recordings from these interviews will be transcribed and then destroyed; any direct quotations appearing in publications will be anonymous. We will let your child's usual doctor (GP) know you are taking part in this research.

During the trial your child will be able to continue with their normal activities such as walking or swimming. We would need to keep a record of these as well.

What are the possible disadvantages and risks of taking part?

The main disadvantage would be the extra time and travel for the hydrotherapy sessions. In our experience no harm has ever come to a child from hydrotherapy. However, if your child becomes anxious during a session, we would not expect them to continue. If you or they are at all concerned about any aspect of the study, please do not hesitate to tell the researcher.

One of the study outcomes is a short questionnaire about your feelings. Sometimes it is possible that putting these down on paper can be upsetting. You do not have to complete the questionnaire but if doing so is upsetting, please feel free to contact us (see details below) or discuss it with your GP who is aware of this study

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What are the possible benefits from taking part?

There are no likely benefits for you or your child. However, we hope it will help decide if a formal trial of hydrotherapy is possible in boys with Duchenne.

What happens when the research stops?

There will be no further contact and there will be no ongoing provision of hydrotherapy from the study. However, if you would like to hear the outcome of the research once the results have been analysed, we would be happy to let you know.

What if there is a problem?

Any complaint about the way you or your child have been dealt with during the study, or any possible harm your child might suffer will be addressed. For any complaints please contact <insert local PI name>

Will my child taking part in the research project be kept confidential?

We will inform your GP that you have taken part in this study. All information that is collected about you during the study will be kept strictly confidential. The information will be stored in a secure area of the hospital which can only be accessed by the research team and regulatory authorities. Information will be entered onto a secure database which is managed by the University of Sheffield. We will destroy all identifiable information five years after the end of the study. An anonymised copy of the computer file (with any details that might identify you or your child removed) will be kept and made available to other researchers for future ethically approved studies. Your name and address will be given to authorised members of the research team at the University of Sheffield if you are interested in taking part in the interview. Some of these forms (which include your name) will be sent to these team members by post.

Contact details

If you need to contact us about this research please initially contact

<insert local PI name>

<insert local PI hospital name>

<insert local PI telephone number>

If the information above is interesting to you and you are considering participation, please continue to read the additional information in part 2 before making any decisions.

Part 2

What if relevant new information becomes available?

If we discover during the study that other researches elsewhere have carried out the same study, we would discontinue ours as there would no point in duplicating their work.

What will happen if my child or I don't want to carry on with the research?

Both you and your child would be free to withdraw at any time. Any data collected up to this point will be used in the study.

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What if there is a problem?

We do not anticipate any problems. If your child was to encounter any problems, they will be managed by their physiotherapist.

Complaints

If you have any cause to complain about any aspect of the way in which you or your child has been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study. If you have any complaints or concerns please contact the your local investigator: [<insert local PI name here>](#)

Alternatively you can use the normal hospital complaints procedure and contact the following person:

[< insert local PALS or other complaints procedure details for NHS site>](#)

Harm

If your child is harmed by taking part in this research project, there are no special compensation arrangements. If your child is harmed due to someone else's fault, then you may have grounds for a legal action – but you may have to pay for it.

Will my child taking part in this study be kept confidential?

Yes. Your doctor and your consultant will be informed, but nobody else.

Involvement of the General Practitioner / Family Doctor (GP)

We are not intending to involve your own doctor. We will inform your GP of your involvement in the trial as long as you are happy for us to do so.

What will happen to the results of the research study?

We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You will not be personally identified in any report or publication we produce. Please contact us using the details below if you would like to see a summary of the results when the trial is completed appropriate to your child's age.

Who is organising and funding the research?

The research is being organised by Dr Baxter and is funded by the NIHR.

Who has reviewed the study?

This study has been reviewed by the [Cambridge South Research Ethics Committee](#).

If you and your child decide to take part in this study, you will be given this information sheet and a signed consent/assent form to keep.

Thank you for taking the time to read this information sheet.