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# What is the clinical effectiveness of hydrotherapy in maintaining physical function in people with Duchenne muscular dystrophy?

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|---|---|---|
| **Submission date**<br>12/06/2014 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>12/06/2014 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/03/2017 | **Condition category**<br>Nervous System Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
16831

# Study information

### Scientific Title
What is the clinical effectiveness of hydrotherapy in maintaining physical function in people with Duchenne muscular dystrophy?

### Acronym
Hydrotherapy for Duchenne Muscular Dystrophy (DMD)

### Study objectives
Duchenne muscular dystrophy (DMD) is a rare disease mainly affecting boys. DMD causes muscle cells to gradually break down so that with time, a patients muscles become weak to the point where they are unable to conduct many of the activities they used to. There is no cure for this disease, but doctors and physiotherapists try to slow down its progression and the development of complications by prescribing steroids and a physical management programme. Clinical experience shows that physical activity helps to maintain functional abilities. Mostly physical management programmes are done on dry land. However they can also be performed in warm water, under supervision by a physiotherapist; this is known as 'hydrotherapy' or 'aquatic therapy'. Hydrotherapy enables affected people to perform exercises which may not be possible on land due to the support provided by the water. Additionally the activity is seen as fun for them and their carers. Despite this, hydrotherapy is difficult to access in many places in the UK. Many NHS trusts do not fund it or have not got the facilities to offer it. While we know people with DMD value hydrotherapy, we are not sure whether it really adds anything to land-based exercises alone in terms of helping with walking and other daily activities. We are therefore undertaking a small scale pilot study to help decide if a larger scale trial would be feasible and if so, how we should best conduct it.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
14/EE/0204

### Study design
Randomised; Interventional; Design type: Treatment

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied
Topic: Children, Genetics; Subtopic: All Diagnoses, Genetics Research and Congenital Disorders (all subtopics); Disease: Genetics Research and Congenital Disorders, All Diseases

### Interventions
Participants will be allocated on a ratio of 1:1 using simple randomisation with permuted blinded block size to:
1. Control group to receive optimised land-based exercises (as defined by local community physiotherapy services and recorded by trial team) (n=20)
2. The intervention group will receive the same plus hydrotherapy (30 min, twice weekly, for 6 months: active assisted and/or passive stretching regime; simulated or real functional activities; sub-maximal exercise) (n=20)

Study participants will be assessed for key outcome measures at 3 time points: consent and screen 1 visit; baseline visit; 26 week visit. We will collect information on a number of outcomes relating to the feasibility of conducting the trial which will include interviews with participants.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
The feasibility of recruitment to the main trial

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/12/2014

### Completion date
30/05/2015

## Eligibility

### Key inclusion criteria
1. Genetically or biopsy confirmed DMD
2. Age 7-16 years
3. Established on glucocorticosteroids
4. North Star Ambulatory Assessment score 8-34 (stable over 4 weeks)
5. Able to complete 10 metre walk (6 minute walk test)

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
7 Years

### Upper age limit
16 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

### Key exclusion criteria
1.More than a 20% variation between baseline North Star Ambulatory Assessment scores
2.Unable to commit to the programme of twice weekly hydrotherapy for 6 months
3.Any absolute contraindications or precautions to hydrotherapy

### Date of first enrolment
01/12/2014

### Date of final enrolment
30/05/2015

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Health Services Research, School of Health & related Research (ScHARR) Regents Court**
Sheffield
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S1 4DA

## Sponsor information

### Organisation
Sheffield Children's Hospital (UK)

### Sponsor details

Western Bank
Sheffield
England
United Kingdom
S10 2TH

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05mshxb09

## Funder(s)

### Funder type
Government

### Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) (UK)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 27/03/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |