A pilot study to compare Ankle Foot Orthosis (AFO) with Contracture Control Device (CCD) in the management of ankle contractures in ambulant boys with Duchenne Muscular Dystrophy (DMD).
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PATIENT INFORMATION SHEET FOR PARENTS AND GUARDIANS.

A pilot study to compare night time Ankle Foot Orthosis (AFOs) with Contracture Control Devices (CCDs) in the management of ankle contractures in ambulant boys with Duchenne Muscular Dystrophy (DMD

INVITATION

Your child has been invited to take part in a research project because they have Duchenne Muscular Dystrophy and have some stiffness in their ankles restricting their range of movement. Before you decide whether you want your son to take part, it is important to understand why the research is being done and what it will involve.

INTRODUCTION

Tight ankles are very common in boys with Duchenne Muscular Dystrophy (DMD). It can make walking, standing, jumping and going up and down stairs very difficult. A daily regime of stretches and wearing splints is important to keep their ankles flexible and maintain range of movement.

WHY ARE WE DOING THIS?

We know that stretching and wearing splints are the best way to look after tight ankles but at the moment we don't know which is the best type of splint. This is a small study which might lead to a bigger study where we learn more about the best splint. Therefore the results of this study will not tell us enough to change which splints are currently provided to the boys but will help decide what further research needs to be done in order to find out which is the most effective splint and which should be routinely provided to boys to help manage their tight ankles.

This study will look at 2 types of splints.

WHAT SPLINTS WILL BE USED?

Ankle Foot Orthosis (AFO)

Contracture Control Device (CCD)

A splint is made of hard plastic material and is designed to be applied to a joint to keep it in a certain position. To make them fit well, a cast is taken of the boys ankle. The AFO will not let them move their ankle at all and gives a steady amount of stretch which cannot be changed and will be worn every night. The CCD is very similar but has a joint at the ankle which means they can move their ankle a tiny bit but the amount of stretch can be changed and will be worn every evening for two hours.Your son's splint will be held in place by Velcro straps across the forefoot and across the shin.

WHO IS BEING ASKED TO TAKE PART?

We are asking 20 boys who receive their care from the Newcastle Neuromuscular Team or ~~,~~receive neuromuscular care in geographical areas that border us such as Leeds, Sheffield and Lincolnshire but still within a driveable distance who are willing to travel to Newcastle for study appointments to take part. Boys with genetically confirmed DMD, who are able to walk, who have never used splints or who have been provided with well fitting splints in the past 18 months, but whose~~'s~~ ankles are getting more stiff or not improving despite good compliance with their current regime and who can speak English, will be asked if they would like to take part.

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WHAT WILL HAPPEN IF MY SON TAKES PART?

If you would like your son to take part, you will be asked to read this information, given time to ask questions and if you are happy for him to participate, you will be asked to sign a form to give written consent. Your son will also be given some age appropriate information and you will be encouraged to discuss this with them and allow them opportunity to also ask questions. Your child may also be given an assent form and asked to sign /mark it if they are happy to participate.

WHAT HAPPENS DURING THE STUDY?

After giving consent for your son to participate, if all inclusion criteria are met and none of the exclusion criteria are met, your son will then be randomly allocated into a group and each group will test one of the splints. Following the end appointment for the study, your son will continue using the splint he was provided with for the study. If this is his locally provided AFO this will be monitored by his local team. If this was a Peacocks provided CCD this will be managed in conjunction with his local team by Peacocks and our team. ~~He will be advised and reviewed according to his clinical need which may mean a different splint is supplied.~~

Commented [MD1]: What happens to the out of area boys at the end of the study….will their orthotic care continue with local services? What is they are provided with CCD and local team not able/prepared to take this on?

Commented [AM2R1]: See my addition

INCLUSION CRITERIA	EXCLUSION CRITERIA

• Genetic diagnosis of DMD • Ankle ROM of between +10 degrees of dorsiflexion and -10 degrees of dorsiflexion. • On assessment ROM has either deteriorated or remained the same since prior appointment despite good adherence to current stretching regime • Have never used ankle splints before OR who have been provided with well fitting splints in the past 18 months • Aged between 4 and 10 years of age • From JWMDRC clinics or referred to us by a centre which borders us and willing to travel to Newcastle for appointment during the study. • Email or written evidence that the local specialist team are amenable to our oversight of orthotics for the duration of the study •	• Significant behavioural issues that would make adherence problematic • Previous or current lower limb fracture within the last year • Previous surgery or other interventions for managing ankle stiffness • Non-English speaking • Poorly fitting splints • Poor compliance with current regime.

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Deciding which splint your son will test will be done randomly by a computer programme.

All boys will be measured for and provided with the splint assigned to the group they are in and will be provided with instructions for how to wear the splint and also a daily stretching programme which they must do.

The study lasts for 12 weeks and during that time, your son will attend Peacocks (orthotics clinic) for four~~five~~ visits (normal provision needs at least 2-3 visits) and there will also be an extra telephone call at week 2. This means there will be a total of 2-3~~3-4~~ extra appointments, 1 of which will be a telephone call to reduce the number of times you need to attend clinic. At these visits, you will both be asked about the splint and a physiotherapist will measure his ankles and ask him to

complete some assessments. You will also be asked to complete a daily diary giving information about splint use and satisfaction and the daily stretching programme.

The person taking the measurements will NOT know which group you are in. It is very important that you DO NOT tell them. You will be reminded of this.

Schedule of appointments

Physiotherapist	Visit Number	Timeline	Research Physiotherapist (does not know which splint your son is using)
Information given about trial	Clinic visit or trial appointment. Boy is suitable for this trial	Before we start	
Consent **Randomisation** **Cast for orthotics**	Visit 1 At Orthotics clinic	Before we start	*Assessments for study

Supply and fit of orthotic **Shown standard stretching regime**	Visit 2 At Orthotics clinic	Start of clock – Baseline Week 0	*Assessments for study
Telephone Review	Visit 3 -	Week 2	Questionnaire only
~~**Appointment**~~	~~Visit 4~~	~~Week 4~~	~~*Assessments for study~~
Appointment	Visit 4	Week 6	*Assessments for study
~~**Appointment**~~	~~Visit 5~~	~~Week 8~~	~~*Assessments for study~~
Appointment	Visit 5~~6~~	Week 12 End of study	*Assessments for study
		Return to regular clinic visits	

DOES MY SON HAVE TO TAKE PART?

No, it is up to you and your son to decide if he wants take part. You do not have to take part and if you chose not to, this will not affect the care provided to your son.

WHAT ARE THE BENEFITS OF TAKING PART?

We cannot guarantee that participating will offer any direct benefit to your son but it will help us improve how we look after boys with DMD in the future. The information collected from this study will contribute to the development of larger studies. Larger studies, studying larger numbers of boys are needed before any conclusions that may change which splints are provided can be made.

WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY?

This is a low risk trial. Both types of orthotics have been previously used in patients with DMD in Newcastle and also in patients with other conditions. Both splints have been reported as being safe and well tolerated.

There is a small chance of discomfort or skin irritation if the splint is not fitted well or applied correctly. If this occurs, it will be assessed and managed during the appointments.There is also a small chance of discomfort from stretching the tight muscles either from the stretch applied by the splint or during the stretches being performed. This should only last for the duration of the stretch or for the duration the splint is worn and often improves as the boys become used to wearing the splints and performing the stretches. Our clinical experience is that given the necessary instruction, providing a good fitting splint and verbal support, the majority of families have very few issues with using either splint.

WILL THIS PREVENT MY SON FROM TAKING PART IN OTHER TRIALS?

There are some studies that do not allow changes in contracture management during the study however orthotic provision and contracture management are recommended as part of standards of care. The doctor can discuss this on a case by case basis if required but this should not prevent your son from participating in other trials however he may have to wait until this study has finished prior to starting the other trial.

WHAT HAPPENS TO MY SON'S INFORMATION?

We will need to use information from you and from your son's medical records for this research project.

This information will include your son's initials, NHS number, name, contact details and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly. Any information that could show who you are will be held safely with strict limits on who can access it.

People who do not need to know who you are will not be able to see your son's name or contact details. His data will have a code number instead.

We will keep all personal information safe and secure. We need to manage records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your son.

Once the study is completed, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes personal details, and how long they will keep it.

Usually your hospital or GP will keep a copy of the research data along with your son's name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to [**email**], or
- by ringing us on 0191 2418756.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Once the study has finishes, the research team will write reports about the study presenting the results. The results will be shared in a variety of ways. Results will be anonymised and will be shared with other professionals at conferences both nationally and internationally. Findings will also be published in peer reviewed journals. Participants will receive feedback regarding their management from the research team and will also receive a summary of the overall results.

Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study and therefore all personal information will be kept confidential.

Once your details like your name or NHS number have been removed, other researchers won't be able to contact you to ask you about future research.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

WILL MY GP INFORMED?

If you agree, a letter will be sent to your GP informing them of your son's participation in this study.

WHAT IF I DO NOT WANT MY SON TO CARRY ON WITH THE STUDY?

You may withdraw from the study at any time, without giving a reason and this will not affect the care your son will receive.We will keep information about you that we already have.

WHO IS FUNDING THE STUDY

Duchenne UK is funding the study in collaboration with Newcastle University and Newcastle Upon Tyne Hospitals Foundation Trust. All research in the UK is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by the < insert name of committee> Research Ethics Committee.\

HOW CAN I FIND OUT MORE

You can ask a member of the research team if you have any questions.

Dionne Moat / Dr Anna Mayhew
Neuromuscular Physiotherapy Team
International Centre for Life
Central Parkway
Newcastle
NE1 3BZ
0191 2818756

WHO CAN I SPEAK TO IF I WOULD LIKE TO MAKE A COMPLAINT?

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone:0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: 0191 223 1382 or 0191 223 1454
Email: nuth.patient.relations@nhs.net
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust The Freeman Hospital
Newcastle upon Tyne
NE7 7DN