

PATIENT INFORMATION SHEET FOR CHILDREN AGE 6-10

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

Please read this with your parent or guardian.

INVITATION

You are being invited to take part in a research project as you have Duchenne Muscular Dystrophy and have some tightness in your ankles. Research is a way we try to find out the answers to questions. Before you decide whether you want 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. Wearing splints and doing stretches every day are important to keep your ankles as bendy as possible.



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 study will look at 2 types of splints.

WHAT SPLINTS WILL BE USED?



OR



Ankle foot orthosis (AFO)

Contracture control device (CCD)

Splints are made of hard plastic and you wear them like a boot on your foot. They are used to help stretch your ankle. The 2 splints are very similar but have a few differences. One splint (AFO) does not allow you to move your ankle at all and the other one (CCD) allows for a little bit of movement and can be changed to give more or less of a stretch.

WHO IS BEING ASKED TO TAKE PART?

We are asking 20 boys who attend Newcastle for their appointments or who live close enough to Newcastle to travel to come and see us to take part. Boys with DMD, who are able to walk, who have never used splints or already have AFO splints, but whose ~~se's~~ ankles are getting stiffer er or not improving will be asked if they would like to take part.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you would like to take part, you and your parents will be asked to sign some forms.

There are 2 groups: the AFO group and the CCD group. You will be put into one of these groups by chance (you cannot choose which splint) and that is the splint that you will be given to wear for the study.

You will come to clinic regularly over 12 weeks. At these visits, you will be asked about the splint and a physiotherapist will measure your ankles and ask you to do some activities.

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

DO I HAVE TO TAKE PART?

No, it is up to you to decide if you want take part. We will still look after you even if you say no.

WHAT ARE THE BENEFITS OF TAKING PART?

We always look after boys who are given splints and if you take part in this study we may see you a little more frequently than usual. Taking part may not have added benefit for you, but will help us improve how we look after other boys who have DMD.

WHAT HAPPENS TO MY INFORMATION?

We will only share the information with other people in the study and your name will not be made available either.

HOW CAN I FIND OUT MORE?

You can ask your parents or carers if you have any questions and if they don't know the answer, you can ask the physiotherapist or your parents can ask them for you.



Dionne Moat / Dr Anna Mayhew

**Neuromuscular Physiotherapy Team
International Centre for Life
Central Parkway
Newcastle
NE1 3BZ
0191 2418756**