



**Strength Training for Adolescents with ceRebral palsy**

**PARTICIPANT INFORMATION SHEET FOR PARENTS/LEGAL GUARDIANS**

We are a team of physiotherapists and researchers who are conducting a study to find out if resistance training, a.k.a. strength training, can make movements such as walking easier for young people with cerebral palsy.

We would like to invite you and your child to take part in this study. Before you decide we would like you to understand why the research is being done and what it will involve.

One of our team or your child's physiotherapist can go through this information with you and answer any questions you have. You may also talk to others about the study if you wish.

**Part 1** of this leaflet tells you the purpose of this study and what will happen to your child if you take part.

**Part 2** gives you more detailed information about the conduct of the study.

**Part 1: Overview of the Study**

**What is the purpose of the study?**

We want to try and answer a number of questions:

1. Do teenagers with cerebral palsy find a resistance training programme acceptable? Does it fit well into day-to-day life?
2. Does resistance training make walking easier, reducing the effort required? Does it increase teenagers' physical activity levels and help them participate more fully in everyday life?
3. How does resistance training improve walking? What effects does it have on the different muscles and tendons in the leg?

**What is resistance training?**

Resistance training is designed to make muscles stronger. When you lift a weight over and over again your muscles will gradually become stronger. It has been shown that people with cerebral palsy have weak calf muscles, which may make it more difficult for them to carry out activities such as walking, running or standing up from a seated position. In this study we are aiming to strengthen the calf muscles as we think this will result in the most improvements in walking.

## Why has my child been chosen?

Your child has been chosen because he/she is a teenager with cerebral palsy. We are asking 60 teenagers to take part.

## Does my child have to take part?

No. It is up to you and your child to decide to join the study. Your physiotherapist will explain the study and go through this information sheet with you. After reading the information sheet, if you have any questions you can contact the research team and the contact details provided below. If you agree for your child to take part, we will ask you to sign a consent form. If your child is happy to take part they will be asked to sign an assent form with you.

You will be given a copy of the information sheet and the signed consent/assent forms to keep for your records. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care your child receives.

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

We will ask you and your child to come to Brunel University London three times to take part in a number of assessments. After you come the first time your child will be randomly chosen to take part in a resistance training programme or to continue with his/her usual physiotherapy (we understand that at the moment your child might not be receiving any physiotherapy). We use a computer to randomly decide whether your child receives resistance training or not, and we do not have a say in this. It is really important that even if your child does not do the resistance training that you and your child come back to Brunel University London for the assessments. Otherwise we won't know if resistance training is any better than usual physiotherapy.

In order to investigate if resistance training makes walking easier and increases participation in physical activity, and what effect it has on muscles and tendons we will do the following **assessments** in Brunel University London:

1. We will start by taking **body measurements** (height, weight and leg length)
2. We will ask your child to **walk on a treadmill** while we record how they move using motion cameras
3. We will measure how much energy your child uses while they sit down for 10 minutes and while they **walk around a room for 6 minute**
4. We will ask you and your child to complete 5 questionnaires. Two questionnaires will help us to see how active your child is in everyday life so that we can decide if the training we suggest helps improve the amount of activity they can perform in everyday life. Two questionnaires will ask about your child's general health (e.g. how you are feeling today, if you have any pain), and one will ask about how much your child has seen his/her doctor, physiotherapist and other health professionals in the past 3 months.
5. We will measure your child's **calf muscle strength**. To do this we will ask them to sit on a dynamometer. One foot will be strapped onto a foot plate connected to a machine.



The machine that measures how much energy your child uses

The machine will **slowly move your child's foot backwards and forwards**. This will feel like their muscles are being fully stretched but should not cause any pain.

**6. While your child's foot is moving we will take pictures of the muscles inside their leg** using ultrasound.



The dynamometer



We take pictures of your child's muscles with ultrasound

**7. We will measure if your child's ability to walk, run, jump and stand** has improved by asking them to do a number of activities like running and jumping. We will videotape your child doing these activities and will measure how good his/her quality of movement is from the video. You and your child will be asked if you are happy to have a photograph or video taken before you take part. If you don't want to have a photograph or video taken we won't take one and your child can still take part in the study. We will also time how long it takes your child to walk 10 metres.

**8. Before you leave we will ask your child to take home an activity monitor to wear for 7 days.** This is a small device that they can wear around their waist.

Sometimes we take photographs and videos during the assessment to use for conferences and educational purposes. If we take a video or a photograph we will make sure your child's face is blurred before using it so that no one can recognise him/her. You will be asked if you are happy to have a photograph or video taken of your child



Activity monitor

before he/she takes part. If you don't want to have a photograph or video taken of your child we won't take one and your child can still take part in the study.

### **Resistance Training Programme**

If your child is randomly assigned to the resistance training programme he/she will be asked to do exercises 3 times a week for 10 weeks. He/she will do exercises once a week for an hour in a local gym with a group of other teenagers who are taking part in the study. He/she will be asked to do exercises on two other days a week (for about 20 minutes) in your home. Participation in this study will involve the completion of an exercise diary twice a week by your child recording his/her exercise – this should not take in excess of 5 minutes per entry. Your child's physiotherapist will give your child exercises for his/her calf muscles. The exercises your child does

will depend on what he/she is able to do at the start of the programme and will be changed as your child gets stronger. Details of the exercises can be found in part 2.

We will ask your child to take part in an interview with a researcher when he/she finishes the programme. You may take part in this interview also if you and your child wish. During the interview your child will be asked if he/she liked the programme, if he/she found it difficult to do and other thoughts you or your child has about the programme. You will have the choice of doing this this interview in Brunel University London or at home. The interview will be recorded to allow the research team to review the interview and identify common themes. A researcher will also visit your child at home and in the class four times to see how well he/she is doing the exercises.

*In exchange for you and your child's time and effort we will be offering all participants a £20 Love2shop voucher on completion of the study. All teenagers who take part in the study will receive a voucher at their final assessment. We will also reimburse any travel expenses incurred with travelling to Brunel University London.*

### **What are the possible benefits of taking part?**

The information we collect may help us to decide on the best treatment to provide teenagers with cerebral palsy better. If your child is in the resistance training group their muscles may get stronger and they may find it easier to walk. If your child is in the usual care group they will not receive direct benefits. However, they may be offered the resistance training programme if it proves beneficial.

### **What are the possible disadvantages and risks of taking part?**

Your child's muscles may be sore after the assessments and/or after he/she does the exercises. This is completely normal and is a sign that his/her muscles are working hard. If you are concerned about any side effects to the treatment or assessments please report them to a member of the research team or your physiotherapist as soon as possible. Your child will also be asked about any side effects by his/her physiotherapist when he/she attends the group exercise session. If your child finds that the resistance training is too painful he/she can withdraw from the study at any time.

We use sticky tape to attach sensors to your child's legs and feet to record his/her movement, video his/her muscles and measure how much his/her muscles are working. This can be painful when we remove it (like taking off a plaster). We will do our best to minimise any pain.

***If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.***

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## **Part 2: Detailed information about the study**

This section details the organisation of the study, the procedures involved and complaint procedures if you are not happy with the conduct of the study. If you decide you wish your child to take part after reading this section, you will be asked to sign a consent form (Copies of consent form and this information sheet will be

provided for you to keep).

### **Who is funding the research?**

The work is being funded by two different charities: Action Medical Research ([www.action.org.uk](http://www.action.org.uk)) and The Chartered Society of Physiotherapy Charitable Trust.

### **Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable ethical opinion for conduct in the NHS by Surrey Borders NRES Committee. It has also been approved by the Research Ethics Committee in Brunel University London and by the Research Department at this hospital.

### **What are the indemnity arrangements?**

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

### **Details of Resistance Training Programme**

Examples of exercises include pointing your toes against Theraband, going up and down on your toes, going up and down on your toes with a weight added to your shoulders to make it harder, and pointing your toes against a weights machine.



**Exercise: Going up and down on toes**



**Exercise: Pointing toes against a weights machine**

### **What will happen if we don't want to carry on with the research?**

If you wish to withdraw from the study please contact your physiotherapist or Jennifer Ryan at the contact details below. If you withdraw from the study unidentifiable data collected up to that point will be retained and used.



**Exercise: Pointing toes against Theraband**

## **What if there is a problem?**

If you have any concerns or complaints about the conduct of the researchers or the study please contact Professor Christina Victor (Chair of the Research Ethics Committee, College of Health and Life Sciences) [christina.victor@brunel.ac.uk](mailto:christina.victor@brunel.ac.uk). You can also contact your local Patient Advice and Liaison Service (PALS) on X

## **What will happen with the information you collect during the study?**

We will collect all the information together. This includes bringing information collected while your child does the programme in his/her physiotherapy department or gym to Brunel University London. None of this information will include your child's name. After analysing the information we will decide if resistance training might be useful for changing how teenagers with cerebral palsy's muscles work, if it improves their walking and everyday activity, and if teenagers find it easy to do. We will show physiotherapists and doctors the results of the study by publishing it in scientific journals and presenting it at conferences. A short summary will also be on the study's website. No-one will know your child was in the study. If you would like to receive a copy of the results please contact Jennifer Ryan at the contact details below.

During the study individuals from the research team at Brunel University London, regulatory authorities or your NHS trust may look at your medical notes or the information collected during the study.

## **Will my child's taking part in this study be kept confidential?**

Your child's identity will remain confidential. Your child's name will not be published on any material and will not be disclosed to anyone outside of the study group. Your child will be assigned an ID code that will be used on all of the information collected from your child. When we collect your child's information we will make sure it is stored in a safe place and only the people doing the research study can look at it. This information will be stored for 10 years after the study is completed. We may use quotes from the interview with you and your child when writing up the study. However, you and your child will be given pseudonyms so that the quotes aren't attributed to you.

There is one important exception to the guarantee of confidentiality. If you or your child tells us something during the interview that suggests that your child or others are being placed at risk of significant harm we are obliged to pass this information on to the manager of the therapy team involved. We will talk to you about the procedures involved before the information is shared.

## **Contact details**

You can get more information or answers to your questions about the study, your participation in the study, and your rights from Jennifer Ryan who can be telephoned or texted at [0785 4066001](tel:07854066001) or emailed at [starstudy@brunel.ac.uk](mailto:starstudy@brunel.ac.uk)

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