



Strength Training for Adolescents with ceRebral palsy

PARTICIPANT INFORMATION SHEET FOR YOUNG ADULTS (16-19 years)

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 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 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 you if you take part.

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

Part 1 – Overview of the Study

Why is this project being done?

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



seat. In this study we are aiming to strengthen the calf muscles as we think this will result in the most improvements in walking.

Why have I been chosen?

You have been chosen because you are a teenager with cerebral palsy. You will help us to improve the physiotherapy we give to teenagers with cerebral palsy in order to make it easier for them to walk. We are asking 60 teenagers all together.

Do I have to take part?

No. It is up to you. We would like you to read this information sheet. If you agree to take part, we would like you to provide consent by signing two forms. You will give one form to us. You can change your mind at any time during the study. If you don't want to take part, just say no! If you decide you don't want to take part in the study the care you receive, either now or at any time in the future, will not be affected.



What will happen if I decide to take part?

We will ask you to come to Brunel University London three times to take part in a number of assessments. After you come the first time you will be randomly chosen to take part in a resistance training programme or to continue with your usual physiotherapy (we understand that at the moment you might not be doing any physiotherapy). We use a computer to randomly decide whether you receive resistance training or not and we do not have a say in this. It is really important that even if you do not do the resistance training that you 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. Taking **body measurements** (height, weight and leg length)
2. **Walking on a treadmill** while we record how you move using motion cameras like the ones used in animation films
3. We will measure how much energy you use while you sit down for 10 minutes and while you **walk around a room for 6 minutes**.
4. We will ask you to complete 5 questionnaires. Two questionnaires will help us to see how active you are in everyday life. Once we know this we can see if resistance training changes the amount of activity you



We measure your movement

Available online at: <http://corner.duke4.net/the-idea-of-capturing-motion/>

can perform in everyday life. Two questionnaires will ask about your general health (e.g. how you are feeling today, if you have any pain) and one will ask about how much you've seen your doctor, physiotherapist and other health professionals in the past 3 months.

5. We will measure your calf muscle strength. To do this we will ask you to sit on a special chair called a dynamometer. One foot will be strapped onto a foot plate connected to a machine. The machine will **slowly move your foot backwards and forwards.** This will feel like your muscles are being fully stretched but should not cause any pain.



6. While your foot is moving we will take pictures of the muscles inside your leg using ultrasound. To do this we will rub a little gel over your lower leg. The gel may be cold but it will not cause any pain. You do not have to do anything. We will ask you to keep your leg relaxed during the testing and not to squeeze your muscles.



The dynamometer



The machine that measures how much energy you use
We take pictures of your muscles

7. We will measure if your ability to walk, run, jump and stand has improved by asking you to do a number of activities like running and jumping. We will videotape you doing this and will measure how good your quality of movement is from the video. You 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 you can still take part in the study. We will also time you walking over 10 m.

8. Before you leave we will ask you to take home an activity monitor to wear for 7 days. This is a small device that you wear around your waist. We will ask you to post this back to us after you've worn it in a stamped addressed envelope that we will provide.



Activity monitor

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 face is blurred before using it so that no one can recognise you. You 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 you can still take part in the study.

Resistance Training Programme

If you are randomly assigned to the resistance training programme you will be asked to:

1. Do exercises 3 times a week for 10 weeks. You will do exercises once a week for an hour in a local gym with a group of other teenagers taking part in the study. You will 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 recording your exercise – this should not take in excess of 5 minutes per entry.

2. Your physiotherapist will give you exercises for your calf muscles. The exercises you do will depend on what you're able to do at the start of the programme and will be changed as you get stronger. Examples of exercises include sitting with your legs in front of you and 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 with Theraband

3. We will ask you to take part in an interview with a researcher when you finish the programme. During the interview you will be asked if you liked the programme, if you found it difficult to do and other thoughts you have about it. You will have the choice of doing this this interview in Brunel University London or at home. You can ask your parent/guardian to take part in the interview with you if you want them to. This interview will be recorded and we may use quotes from you when we write up the study. However we will use a made up name so that no one knows the quotes are from you.

4. A researcher will also visit you at home and in the class four times to see how well you are doing the exercises.



Exercise: Going up and down on your toes



Exercise: Pointing your toes against a weights machine

In exchange for your time and effort we will be offering 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. Your travel costs to get to Brunel University London for the assessments will also be reimbursed.

What are the potential benefits and possible risks of taking part?

The benefits you might get from the study are to increase your muscle strength. The information we get might also help physiotherapists to provide better treatment to children with cerebral palsy in the future.

The possible risks are that your muscles may be sore after the assessments and/or after you do the exercises. This is completely normal and is a sign that your 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. You will also be asked about any side effects by your physiotherapist when you attend the group exercise session. If you find that the resistance training is too painful you can withdraw from the study at any time.

It may also be painful when we remove the sticky tape that we use to attach sensors to your legs and feet to record your movement, video your muscles and measure how much your muscles are working (like taking off a plaster). We will do our best to minimise any pain.

Part 2 – Further Information

This section details the organisation of the study and complaint procedures if you are not happy with the conduct of the study.

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

We will collect all the information together. This includes bringing information collected while you do the programme in your physiotherapy department or gym to Brunel University London. None of this information will include your 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 you were 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.

What if I want to withdraw from the study?

If you wish to withdraw from the study please contact your physiotherapist or Jennifer Ryan at the contact details below. If you want to withdraw or you lose the capacity to consent to participating in the study, data collected with consent will be retained and used. However no further data will be collected.

What if I wish to complain about the study?

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. You can also contact your local Patient Advice and Liaison Service (PALS) on X

Will my taking part in this study be kept confidential?

Your identity will remain confidential. Your name will not be published on any material and will not be disclosed to anyone outside of the study group. You will be assigned an ID code that will be used on all of the information collected from you. When we collect your 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.

There is one important exception to the guarantee of confidentiality. If you tell us something during the interview that suggests that you 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.

Who is funding the research?

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

Did anyone else check the study is OK to do?

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.

Contact details

You can get more information or answers to your questions about the study, your participation in the study, and your rights from a member of the STAR trial who can be telephoned or texted on [0785 066001](tel:0785066001) or emailed at Starstudy@brunel.ac.uk.

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