TRUST LOGO

The ROBUST Study
12-15 Year Olds Participant Information Leaflet

Version 5.0_09Jun2025
Research Ethics Committee: REC 23/SC/0231

A study about young people with cerebral palsy and strengthening exercises

Hello. We would like to ask you if you would like to take part in a study called The ROBUST Study. Please read this information carefully and talk to your mum, dad or guardian about the study. Ask us if there is anything that is not clear or if you want to know more. Take time to decide if you want to take part. It is up to you if you want to do this. If you don't then that's fine, you'll be looked after just the same.

What is the ROBUST study?

The ROBUST study is finding out whether a new exercise programme to strengthen the muscles of young people with cerebral palsy is better than usual NHS physiotherapy exercises. We want to find out if this new exercise programme makes it easier for young people with cerebral palsy to walk and carry out different activities. We have tried to make the exercises interesting and fun so that young people will be happy to carry on doing them.

As children with cerebral palsy get older, their bodies get bigger and the muscles in their legs get weaker. This can make it more challenging to do things like walking, climbing stairs or participating in hobbies and sports. Doctors and physiotherapists think that specific exercises to strengthen the muscles in the legs could help young people with cerebral palsy stay more active as they get older.

Why are you asking me?

You are being asked to take part because your doctor or physiotherapist believes that either treatment (ROBUST exercises or usual physiotherapy) would be suitable for you. We are asking lots of young people, from around the country, with cerebral palsy (aged between 12 and 18 years) if they will think about taking part in the ROBUST study.

What kind of exercises will I get?

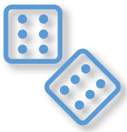
You will receive either:

ROBUST exercise programme: You will have 6 sessions with a physiotherapist over 16 weeks. The exercise programme includes specific muscle strengthening exercises to strengthen the muscles in your legs. The physiotherapist will show you how to do the exercises during your study visit. You will then need to do these exercises at home, without the physiotherapist 3 times a week, for approximately 30-40 minutes each time. You can ask someone to help you do this. You can check how to do them by watching the exercise videos we will provide. We can support families who do not have access to the internet.

Usual NHS physiotherapy: You will have 1 session with a physiotherapist. The physiotherapist will give you advice about your cerebral palsy and how to continue your usual exercise and activity programme. It does not include the specific muscle strengthening exercises included in the ROBUST programme.

There are good points, and bad points with the ROBUST and with the Usual exercises, which are discussed in detail in the parent version of the information leaflet given to your parent/guardian. You may like to read this too. This information is also available online at The ROBUST Study (robust-study.org)

The way we compare the two kinds of exercises fairly is to split the young people into two groups who are the same, by a process called randomisation. You can't choose the exercises, and neither can the doctors or physiotherapist, it is done by a computer. When we have groups of people who are as similar as possible, we can then compare them in the best possible way.



Do I have to say yes?

No you don't. If you decide to say no, nobody will mind!

You will just have the care as planned by you and your physiotherapists and doctors and we won't ask you for any further information.

What will happen if I say yes?

You will be asked to sign a form called an "Assent Form" online (or on paper, if preferred). This says that you understand the study and what will happen. You will be given a copy of the form to keep, as well as this information leaflet. Your parent or guardian will need to sign a consent form to agree to you taking part as well. Your parent or guardian will be listed as the primary contact for any correspondence we would like to send you about the study.

In some places, the study is being run by community teams working with their local hospital. If that's the case for you, a few of your study visits might happen at the local hospital instead of at the community. The team will explain it all clearly and make sure you're happy with it before you decide to take part.

A trained team member will then carry out some simple tests to look at the strength of the muscles in your legs and how fast you can walk. They will also ask you to complete a short questionnaire. You can ask your parent or guardian to help you do this. The questionnaire will ask about your walking, ability to carry out activities, feelings and school/college attendance. You will then learn which exercise group you have been put in, by the process of randomisation, and you can then start exercising!

At 6 and 12 months, we will send you the same short questionnaire to complete as before. This will be sent to the e-mail address that your family tells us to, or by post if they prefer. At 6 months, we will also ask you to attend an appointment with the trained staff member at the hospital. They will carry out the same simple tests to look at your muscle strength and how fast you can walk.

Long term follow up

We would also like to retain your identifiable information (i.e name and NHS number) for up to five years to enable long term follow up using routinely collected NHS data (i.e. if you have been admitted to hospital for surgery). This will allow us to see if the physiotherapy treatment has helped prevent you from needing surgery. Collection of this data will be subject to further funding being secured. If you give your permission, then only authorised individuals from the research team will access this information for up to 5 years after your entered into the study. However, it is not essential that you agree to long-term follow-up, to take part in the ROBUST study.

What are the advantages and disadvantages of taking part?

Taking part in the study may help improve the strength of your leg muscles for walking and taking part in activities. If the ROBUST exercise programme is found to be beneficial, it may become widely used in the NHS in the future to help other young people with cerebral palsy. Strengthening exercises can cause some discomfort. The physiotherapist will show you how to do these safely and tell you how to recognise any problems.

Who will know I am in this study?

You will be given a special identification number and any information that you give us will be linked only to this number. This means that only the people who are treating you, or who need to contact you, will know who you really are. Your name, phone number and your NHS number will be kept safe and secure so no one else can see information about you.

If you are being asked to go to the local hospital, and have agreed, both the hospital team and your local NHS Trust/Health Board will also know.

You can tell people you are taking part in this study, if you would like to.

What happens if I change my mind?

You can change your mind at any time and we will stop contacting you. If you do change your mind please ask your parents or guardian to let your physiotherapist or one of the research team members know.

If your treating clinician believes it is necessary for you to be withdrawn from the study, you will no longer continue to receive the exercise programme (depending on which group you have been allocated to). However, we would still like you to attend the 6 month follow up appointment with the physiotherapist and complete the 6 and 12 month questionnaires, if you are still happy to do so.

Who is running this study?

Physiotherapists, doctors and researchers are helping to run this study. It is sponsored by the University of Oxford and an organisation called the National Institute for Health and Care Research (NIHR) have given the money to run the study. The NIHR give money to lots of people to help them improve treatments for children and adults in the UK.

What will happen to my data?

We will be using information from your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

We will ask you if we can keep identifiable information about you and your parent/guardian for up to 12 months after the study has finished so that we can send you a summary of the results (or five years after you've entered the study, if you and your parent/guardian agree to the long term follow up). If you do not wish for your details to be retained for either of the above then *personally identifiable* information will be deleted after your last research appointment. We will store the *anonymised* research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for a maximum of 5 years after you've entered into the study as part of the research record.

Your local NHS Trust/Health Board will use your NHS number and your/your parent or guardian's contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

If your community team refers you to your local hospital for the study, they'll need to share some details with the hospital - like your name, phone number, email address, and study ID. This only happens if you agree, and it helps the hospital contact you.

They will keep identifiable information about you from this study until the study visits are completed. Study documents, including those with personal information such as consent forms, held at your local NHS Trust/Health Board (and the hospital, if discussed) will be archived in accordance with their local procedures.

For those who claim reasonable travel expenses their financial information will be held in accordance with the University of Oxford financial policy for 7 Years.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research (eg, sending automated emails for logging into our study app) and as explained in this information sheet. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

United Kingdom data protection regulation provides you and your parent/guardian with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the ROBUST study team: robust@ndorms.ox.ac.uk.

What happens at the end of the study?

We will send you a summary of the study results. When you join the study we will ask if you would like to see the results, and how you and your family would like to receive these (either by post or email).

The results will be shared with other physiotherapists and doctors to help with exercise advice for other young people with cerebral palsy more effectively. Any data that could identify you will not be included in the results.

What if I have questions or there is a problem?

If you have any questions or worries about the information in this leaflet or anything else related to the study please speak to one of your physiotherapists or doctors. Further details of the study can be found in the parent version of the information leaflet given to your parent/guardian, and available online at the following address The ROBUST Study (robust-study.org) or by scanning this QR code:

Alternatively, you can also ask for a paper copy.

THANK YOU FOR READING THIS INFORMATION LEAFLET AND CONSIDERING TAKING PART