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The ROBUST Study
16-18 Year Olds Participant Information Leaflet

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Research Ethics Committee: REC 23/SC/0231

We would like to invite you to take part in the ROBUST study

We would like to invite you to take part in a research study called the ROBUST study. The aim of the study is to find out whether a new exercise programme to strengthen the muscles of young people with cerebral palsy is better than their usual physiotherapy treatment.

Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. If anything is unclear, or if you would like more information, please ask a member of the team who approached you about this study.

This leaflet explains why we are doing this research, what the study will involve and exactly what being in the study would mean for you. This is to help you decide whether you would like to take part.

SUMMARY INFORMATION

What is the ROBUST study?
The ROBUST study is looking at whether a new exercise programme to strengthen the muscles of young people with cerebral palsy (CP) is better at improving walking and ability to carry out daily activities, compared to usual NHS physiotherapy treatment.

Why have I been invited to take part?
You have been invited to take part because you are aged between 12 and 18 years, have CP causing spasticity (muscle tightness) and are able to walk with or without support (Gross Motor Function Classification System level I to III).

Do I have to take part?
No. You should decide whether or not to take part in this study. Should you choose not to participate you will continue to be treated under the NHS as before, without a change to your management.

What happens if I take part?
If you are happy to take part in this study, a member of your clinical team will ask some simple questions to confirm you are eligible. If you are eligible and you still want to take part, you will be asked to complete a consent form.

One of the trained staff members, who is helping us with the study, will then perform some simple assessments to look at your muscle strength and walking speed. You will also be asked to complete a short questionnaire, which asks about your walking, ability to carry out activities, feelings and school attendance (if relevant).

A researcher will then enter your details into a computer and the computer programme will then randomly select the type of exercises you will receive.

What type of exercises will I receive?
You will be allocated to receive either:

- ROBUST exercise programme, which includes 6 sessions with a physiotherapist over 16 weeks. The exercise programme includes specific muscle strengthening exercises to strengthen leg muscles. These exercises need to be done at home 3 times per week for approximately 30-40 minutes each time; or

- Usual NHS physiotherapy, which includes 1 session with a physiotherapist with advice and guidance on your usual exercise and activity programme. It does not include the specific muscle strengthening exercises included in the ROBUST programme.

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.

As with any form of exercise, you may experience delayed muscle soreness on movement or when walking and/or mild altered walking (limping) for a few days after completing some of the exercises suggested by the physiotherapist.

What happens after I have attended for the exercise programme?
If you take part in the study, we will ask you to complete 2 short questionnaires similar to the one you completed when you first entered the study. You will receive the first questionnaire 6 months after you've joined the study and the second questionnaire 12 months after joining the study.

At 6 months, you will also be invited to attend a 6 month follow up appointment. At this follow up appointment, a trained staff member will perform some simple assessments to look at your muscle strength and walking speed; the same as the ones you completed when you first entered the study.

You can find more detailed information about the ROBUST study and what's involved by reading the rest of this information leaflet.

DETAILED INFORMATION

What is the purpose of the ROBUST study?

This study is looking at whether an exercise programme to strengthen the muscles of young people with cerebral palsy (CP) is better than their usual physiotherapy treatment.

As children with cerebral palsy grow, they develop stiff and weak muscles. They often have difficulty walking and moving and that makes it difficult for them to join in different activities. Physiotherapy becomes a big part of their lives as it tries to train their muscles and help them participate in activities. When children reach their adolescent years, and their body grows bigger, the weakness of muscles in the legs becomes more of a challenge.

It is possible that a programme of exercises to strengthen their leg muscles could help young people remain more active. We are not certain that young people with CP truly benefit from the time and effort they dedicate to doing these exercises. We are also not sure if this exercise might cause them too much discomfort and muscle soreness to be able to carry it out long-term.

The aim of this study is to assess if a specific exercise programme to strengthen the muscles of young people with cerebral palsy is better at improving walking and their ability to carry out daily activities, compared to usual physiotherapy exercises.

We have developed a new exercise programme, using resistance exercises, to strengthen the leg muscles in young people with CP. We have also tried to make the exercise programme interesting and fun so that young people will be happy to follow it for a long time.

Who is taking part and why have I been invited to take part?

We plan to recruit 334 young people from at least 12 NHS hospitals in the UK who monitor and treat children and young people with CP.

You have been invited to take part because you have CP and are aged between 12 and 18 years and may therefore be eligible for the study.

We are recruiting young people aged between 12 and 18 years with CP causing spasticity (muscle tightness), who are able to walk with or without support (Gross Motor Function Classification System level I to III) and who are able to comply with an exercise programme with or without the support of a parent/guardian/other relative or friend. Young people who

are regularly performing a structured exercise programme, based on resistance exercises, to strengthen their muscles are not able to take part in this study.

Do I have to take part in this study?

No. You should decide whether or not to take part in this study. Please keep this leaflet and use it to help make your decision. You are free to leave the study at any time without giving a reason. We will collect data from you up until this point.

Please remember, it is your decision to take part, either now or if you change your mind during the study, this will not change the standard of the care you receive. Should you choose not to participate you will continue to be treated under the NHS as before, without a change to your management.

What will happen if I take part?

If you are happy to take part in this study, a member of your clinical team will ask some simple questions to confirm that you are eligible for the study. If you are eligible and you still want to take part, you will be asked to complete a consent form. This shows that you have given your permission.

In some places, the study is being run by community teams working with their local hospital. If this applies to you, a few of your study visits might happen at the local hospital instead of at the community. The team will make sure you're fully informed and happy with this arrangement before you decide to take part.

A trained staff member will then perform some simple assessments to look at your muscle strength and walking speed. You will be asked to complete a short questionnaire, which asks about your walking, ability to carry out activities, feelings and school attendance (if applicable). This questionnaire should take no more than 10 minutes to complete and the whole appointment should last no longer than 40 minutes.

A trained staff member will then enter your details into a computer and a computer program will make a decision about which group you will be in while in the study. This allocation (50/50) is made by chance, rather like the toss of a coin, this is important because it ensures that the different treatment pathways are tested fairly, no one can influence the group the computer puts you into. This way of choosing is fair, as we don't really know if one treatment pathway is better than the other.

What kind of exercises will I receive?

You will be allocated to receive either the:

ROBUST exercises: 6 sessions with a physiotherapist over 16 weeks. The first session will last around 90 minutes with 5 follow up sessions lasting around 60 minutes. You will set some

exercise goals with the physiotherapist who will recommend specific strengthening exercises to help you achieve these. These exercises need to be done without the supervision of the physiotherapist 3 times per week for approximately 30-40 minutes each time. Another person can help you with the exercises, if required. 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.

Or

Usual NHS physiotherapy: 1 session with a physiotherapist lasting around 90 minutes. You will receive usual NHS physiotherapy treatment, which includes advice and guidance on your usual exercise and activity programme but does not include the specific muscle strengthening exercises included in the ROBUST programme.

Remember, a computer will randomly select the treatment you will receive. Your usual healthcare professional, the researcher or physiotherapist will not be able to affect which treatment is selected and you will not be able to choose which treatment you will receive if you take part in the study. The ROBUST exercise programme is currently available only through taking part in the ROBUST study.

You will be told which treatment you will receive at your clinic appointment. Your treatment will be provided by fully trained NHS physiotherapists in your local area.

What are the risks for me doing these exercises?

As with any form of exercise, you may experience delayed muscle soreness on movement or when walking and/or mild altered walking (limping) for a few days after completing some of the exercises suggested by the physiotherapist.

Other side effects from the treatment are very rare and are highly unlikely to occur, but may include:

- Muscle soreness lasting more than 7 days
- Acute pain when performing the exercises
- Altered walking (limping) for more than 7 days
- Bone fracture, minor joint injury or inflammation
- Significant joint injury requiring hospital admission and/or surgery
- Fainting during the intervention exercises

You will be told what to do if you have any problems after doing any exercises that the physiotherapist asks you to do at home.

A researcher may visit while you are having your physiotherapy session so that we can check how the treatments are being delivered. We will always check you are happy for this to happen. At the end of the study, we will report how well the treatments were delivered as it is important we fully understand this process. Please note no-one can ever be identified in any report about the study, data is always anonymised.

What happens after I have attended for the exercise programme?

If you take part in the study, we will ask you to complete 2 short questionnaires similar to the one you completed when you first entered the study. You will receive the first questionnaire 6 months after you've joined the study and the second questionnaire 12 months after joining the study.

You can decide if you would like to complete the questionnaire electronically (if so, we will send an email with a link to the questionnaire to complete online) or as a paper questionnaire in the post for you to complete and return it to the research team using the stamped addressed envelope provided. If we do not receive the completed questionnaire, we will send you at least one letter or email to remind you after two weeks and we may call you (after another two weeks) to ask about the key questions that are in the questionnaire. You will be able to indicate on the consent form who you would prefer to act as the primary contact for all study related correspondence (either your parent/guardian or yourself).

At 6 months, you will also be invited to attend a 6 month follow up appointment with a trained staff member. At this follow up appointment, the trained staff member will perform some simple assessments to look at your muscle strength and walking speed; the same as the ones you completed when you first entered the study. If you have not yet completed the 6 month questionnaire, you will be asked to complete this as part of this clinic appointment.

People sometimes feel uncomfortable answering certain questions about their health. If the researcher, health professional, or follow-up questionnaire asks questions that you are uncomfortable with, then you do not have to answer them.

As part of this research, we may want to look at information held by the NHS and by sources maintained by NHS Digital and other central UK NHS bodies. To enable this, we will collect your NHS number. We will only look at information that is relevant to this research. We will request your permission to access this information.

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 benefits of taking part in this study?

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.

Will I be reimbursed for taking part?

Reasonable travel expenses that are in line with the University of Oxford travel policy of reimbursement for travel to and from your study appointment will be paid, if requested and receipts provided.

Who will know that I am taking part?

The only people who will know that you are taking part in this study are members of the research team and the healthcare professionals involved in your care. Representatives from the sponsor (University of Oxford) and your local NHS Trust/Health Board may also require access to your data to monitor or audit the study.

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

You can tell anyone you would like to that you are taking part. We will send a letter to your GP and community physiotherapist to inform them you are taking part in this study.

Will my details be kept confidential?

The research team will keep all of the information collected strictly confidential. You will be allocated a unique study ID number. Any data collected will either be stored in a locked cupboard within the study office or on a secure server within the University of Oxford. Personal details will be used to contact you throughout the study and to send you a summary of the results, if you so desire.

If you do not agree to the five year long term follow up or do not want to receive a summary of the results your contact details can be destroyed earlier than the end of the study. If you agree to the receiving of a summary of results only, your contact details will be stored for up to 12 months after the end of the study and will then be destroyed unless you have consented to collection of long term follow up.

Only authorised members of the study team will access this information. This information will only be used for the purpose of health and care research.

In line with what happens in the NHS, the only situation that confidentiality would need to be broken would be if you told a health professional or research team member about something that could result in harm to yourself or others.

Responsible members of the University of Oxford and relevant NHS Trust(s)/Health Board may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

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 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 entry into the study, if you 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 entry into the study as part of the research record.

Your local NHS Trust/Health Board will use your NHS number and your 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 you are under the care of a community team and referred to your local hospital for the study, with your consent, the community team will share necessary details such as your name, phone number, email address, and study ID with the hospital. This allows the hospital team to contact you as part of the referral process.

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 you've been referred too (if applicable) 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.

Data protection regulation provides you 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?

With your agreement, we will send you a summary of the study results at the end of the study. When you join the study we will ask if you would like to have a copy of the results, and how you would like to receive these (either by post or email). The study results will also be made available on the study website.

The results will be shared with other healthcare researchers and professionals to improve future patient care. The results will also be published in an anonymised form, and presented in research reports, at scientific conferences, and in scientific journals. Any data that could identify you will not be included in the results. After the end of the study an anonymised study dataset will be created and stored for as long as it is useful, and may be shared with other researchers upon request.

What if I decide to withdraw from the study?

You can withdraw from the study at any time. You do not need to give a reason and your medical care or legal rights will not be affected. If you decide to withdraw all information collected up to the date of withdrawal will still be used but no further data will be collected. 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 organising and funding the research?

The study is sponsored by the University of Oxford and conducted by a research team led by Professor Sally Hopewell who is known as the Chief Investigator for this study. The study is funded by the National Institute for Health and Care Research.

How have patients and the public been involved in this study?

Young people with CP and their parents are part of the study team. Young people and their parents are involved in the design of the study, the study materials, and how we make the exercises fun and engaging for young people with CP. They have also helped us with the wording of this information leaflet.

Who has approved this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central – Hampshire A Research Ethics Committee.

What to expect during the consent process

If, having read this leaflet and you have had opportunity to ask questions about the study, you are satisfied that you understand what the research study involves and you wish to take part, you will be asked to give your consent to join. You will be asked to sign a consent form. This shows that you give your permission.

You will be asked to sign a form via an electronic link (a handwritten signature using a finger or a stylus or eSignatures) showing you have understood the reasons and requirements for this study and agree to join the research study. You will be sent a copy of this signed form by email. The research team will download a copy which will be kept securely in our research records and a copy will be kept in your medical notes. If you are unable to sign the consent form via the electronic link a paper copy can be supplied. You will be asked to sign and date the paper copy, you will be given a copy, the site will keep the original and a copy will be placed into your medical notes.

What if I have concerns?

The University of Oxford, as the study sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you have any concerns or wish to complain about any aspect of the way in which they have been approached or treated, or how their information is handled during the course of this study, you should contact <name of investigator><contact details> (phone number & email)> or you may contact the University of Oxford Research Governance, Ethics and Assurance

Team (RGEA) office on 01865 616480, or the head of RGEA, email RGEA.Sponsor@admin.ox.ac.uk.

If you would prefer to speak with someone who is not involved in the research, then please contact the Patient Advice and Liaison Service (PALS). PALS is a confidential NHS service that can provide you with support for any complaints or queries you have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research study.

PALS phone number: <Insert local PALS phone number>
PALS email: <insert local PALS email address>

Contact details

If you have any questions about the study, please contact the research team using the details below.

Email: robust@ndorms.ox.ac.uk
Telephone: <INSERT SITE Tel NO>

Further details, including a study explainer video animation, can be accessed via the following web address The ROBUST Study (robust-study.org) or by scanning the study website QR code:

THANK YOU FOR READING THIS INFORMATION LEAFLET AND CONSIDERING TAKING PART