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The SPELL Study – Parent/Guardian Information Sheet

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Research Ethics Committee: REC 23/EE/0153

We would like to invite your child to take part in the SPELL study

We would like to invite your child to take part in a research study called the SPELL study. The aim of the study is to find out whether a new exercise programme to stretch the muscles of children with cerebral palsy is better than their usual physiotherapy treatment.

Before you decide, it is important for you and your child 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 your child. This is to help you and your child decide whether they would like to take part.

SUMMARY INFORMATION

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

Why has my child been invited to take part?
Your child has been invited to take part because they are aged between 4 and 11 years, has CP causing spasticity (muscle tightness) and is able to walk with or without support (Gross Motor Function Classification System level I to III).

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

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

Your child's allocated physiotherapist will then perform some simple assessments to look at their range of movement in their legs and walking speed. Your child, with your support, will also be asked to complete a short questionnaire, which asks about their walking, ability to carry out activities, feelings and school attendance.

A researcher will then enter your child's details into a computer and the computer programme will then randomly select the treatment your child will receive.

Which physio exercises will my child receive?
Your child will be allocated to receive either:

- SPELL exercise programme, which includes 6 sessions with a physiotherapist over 16 weeks. The exercise programme includes specific dynamic muscle stretching exercises to stretch the muscles in your child's legs. These exercises need to be done at home 4 to 5 times per week for up to 30 minutes;
  or

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

What are the advantages and disadvantages of taking part?
Taking part in the study will allow researchers to understand if a stretching exercise programme is more beneficial, or not, compared to usual care. Understanding this could help other children with cerebral palsy in the future.

As with any form of exercise, your child 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 my child has attended for physio exercises?
If your child takes part in the study, we will ask you or your child, with your support, to complete 1 or 2 short questionnaires similar to the one they completed when they first entered the study. You or your child will receive the first questionnaire 6 months after they joined the study. Some participants will also receive a second questionnaire at 12 months. This depends on when you join the study. If you join within the final 6 months of the recruitment period, you will not be asked to complete the 12-month questionnaire.At 6 months, your child will also be invited to attend a 6 month follow up appointment with a physiotherapist. At this follow up appointment, the physiotherapist will perform some simple assessments to look at their range of movement in their legs and walking speed; the same as the ones they completed when they first entered the study.

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

DETAILED INFORMATION

What is the purpose of the SPELL study?

This study is looking at whether an exercise programme to stretch the muscles of children with cerebral palsy (CP) is better than their usual physiotherapy exercises.

As children with cerebral palsy grow, they develop stiff 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, stop them from becoming stiff and help children participate in activities.

It is possible that a programme of exercises to stretch their leg muscles could help children become less stiff and help them remain more active. We are not certain that children 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 stretch the muscles of children with cerebral palsy is better at improving walking and their ability to carry out daily activities, compared to usual physiotherapy treatment.



We have developed a new exercise programme to stretch the leg muscles in children with CP. We have tried to make the exercise programme interesting and fun so that children will be happy to follow it for a long time.

Who is taking part and why has my child been invited to take part?

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

Your child has been invited to take part because they have CP and are aged between 4 and 11 years and may therefore be eligible for the study.

We are recruiting children aged between 4 and 11 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. Children who are regularly performing a structured exercise programme, based on dynamic stretching exercises are not able to take part in this study.

Does my child have to take part in this study?

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

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

What will happen if my child takes part?

If you and your child are happy to take part in this study, a member of their clinical team will ask some simple questions to confirm that your child is eligible for the study.

In some areas, the study is being run by community teams working together with their local hospital. If this applies to you, the community team will make sure you're fully informed and happy to be referred to the local hospital, in line with the usual referral pathway, before any arrangements are made.

If your child is eligible and you still want to take part, you will be asked to complete a consent form and your child will be asked to complete an assent form. This shows that they also give their permission.

Your child's physiotherapist will then perform some simple assessments to look at their range of movement in their legs and walking speed. Your child, with your support, will be asked to complete a short questionnaire, which asks about their walking, ability to carry out activities, feelings and school attendance. This questionnaire should take no more than 10 minutes to complete and the whole appointment should last no longer than 40 minutes.

One of the trained team members will then enter your child's details into a computer and a computer program will make a decision about which group your child 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 your child into. This way of choosing is fair, as we don't really know if one treatment pathway is better than the other.

What treatment will my child receive?

You child will be allocated to receive either the:

SPELL exercise intervention: 6 sessions with a physiotherapist over 16 weeks. The first session will last around 90 minutes with 5 follow up sessions last around 60 minutes. Your child will set some exercise goals with the physiotherapist who will recommend specific stretching

exercises to help them achieve these. These exercises need to be done at home 4 to 5 times per week. Another person can help them with the exercises, if required. Your child 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. Your child will receive usual NHS physiotherapy treatment, which includes advice and guidance on their usual exercise and activity programme but does not include the specific muscle dynamic stretching exercises included in the SPELL programme.

The date, time, and location of study visits will be agreed with you and your child in advance; the study physiotherapist will provide options according to local arrangements.

Remember, a computer will randomly select the treatment your child will receive. Your child's 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 your child will receive if they take part in the study. The SPELL exercise programme is currently available only through the SPELL study.



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

What are the risks of my child doing these exercises?

As with any form of exercise, your child 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 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 your child has any problems after doing any exercises that the physiotherapist asks them to do at home.

A researcher may visit while your child is having their physiotherapy session so that we can check how the treatments are being delivered. We will always check you and your child 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 my child has attended for the exercise programme?

If you take part in the study, we will ask you or your child, with your support, to complete 1 or 2 short questionnaires similar to the one they completed when they first entered the study. You will receive the first questionnaire 6 months after they joined the study. Some participants will also receive a second questionnaire at 12 months. This depends on when you join the study. If you join within the final 6 months of the recruitment period, you will only be asked to complete the 6-month questionnaire.

You can choose how you would like to complete the questionnaire. You can complete it online using a link sent by email, or you can complete a paper version sent to you by post and return it using the stamped addressed envelope provided.

If we do not receive your completed questionnaire, we will send you a reminder by email or post after two weeks. If we still do not receive it, we may send you a final paper copy after a further two weeks. We may also contact you by phone to ask about the key questions from the questionnaire.

At 6 months, your child will also be invited to attend a 6 month follow up appointment with a physiotherapist. At this follow up appointment, the physiotherapist will perform some simple assessments to look at your child's range of movement in their legs and walking speed; the same as the ones they completed when they first entered the study. If you have not yet completed the 6 month questionnaire, your child, with your support, 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 or your child 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 England and other central UK NHS bodies. To enable this, we will collect your child's NHS/CHI 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 child's identifiable information (i.e. name and NHS/CHI number) for up to five years, or until your child's 16th birthday, if sooner, 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 your child 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, or until your child's 16th birthday, if sooner, after your child has entered into the study. However, it is not essential that you agree to long-term follow-up, to take part in the SPELL study.

What are the benefits of taking part in this study?

If the SPELL exercise programme is found to be beneficial, taking part in the study may make the muscles in your child's legs less stiff and help with walking and taking part in activities. If the programme is proven to be overall beneficial it may become widely used in the NHS in the future to help other children 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 child's 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 your child is taking part in this study are members of the research team and the healthcare professionals involved in their care. Representatives from the sponsor (University of Oxford) and << Insert local Trust/NHS Health Board name here >>, may also require access to your data to monitor or audit the study.

If your child is under the care of a community team and are referred to your local hospital for the study, both the hospital team and your local NHS Trust/Health Board will also be aware as part of the referral process.

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

Will my child's details be kept confidential?

The research team will keep all of the information collected strictly confidential. Your child 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 and your child 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 data.

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 your child told a health professional or research team member about something that could result in harm to yourself, your child or others.

Responsible members of the University of Oxford [insert relevant NHS Trust(s) /NHS Health Board name here] 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 child's data?

We will be using information from your child's medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, based in the United Kingdom as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your child's 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 your child for up to 12 months after the study has finished so that we can send you a summary of the results (or five years or until your child's 16th birthday if sooner, 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 your child enters the study or until your child's 16th birthday if sooner, as part of the research record.

The [insert local NHS Trust/NHS Health Board name here] will use your child's 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 child's care, and to oversee the quality of the study.

If your child is 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 child's 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 your child from this study until the study visits are completed. Study documents, including those with personal information such as consent

forms, held at [insert local NHS Trust/NHS Health Board name here] 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 child's 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 child's personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your child's personal data for their own purposes, but rather to only process your child's personal data for specified purposes and in accordance with our instructions.

UK Data protection regulation provides you with control over your child's personal data and how it is used. When you agree to your child's 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 SPELL study team: spell@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 your child 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 my child decides to withdraw from the study?

Your child can withdraw from the study at any time. You do not need to give a reason and their medical care or legal rights will not be affected. If you decide to withdraw 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. Your treating clinician might also believe it is necessary for your child to be withdrawn from the study, and this will be communicated effectively to you.

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 Tim Theologis 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 children 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 [INSERT] 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 and your child 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 and your child will be asked to sign an assent form. This shows that they also give their 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 child's 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 child's 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 your child suffers any harm as a direct consequence of their participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you or your child 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 <insert name of investigator><contact details> (phone number & email)here> 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.complaints@admin.ox.ac.uk

If you would prefer to speak with someone who is not involved in the research and are outside of Scotland, 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>

For support in Scotland, then please contact the Patient Advice & Support Service (PASS). PASS can advise those who wish to raise concerns, give feedback or comments, or make a complaint regarding the NHS care in Scotland.

PASS national helpline phone number: 0800 917 2127
PASS website (webchat): www.patientadvicescotland.org.uk

Contact details

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

Email: spell@ndorms.ox.ac.uk
Website: <INSERT WEBSITE>
Telephone: <INSERT SITE Tel NO>



Further details, including a study explainer video animation, can be accessed via the following web address [insert website] or by scanning the study website QR code [insert QR code].

THANK YOU FOR READING THIS INFORMATION LEAFLET AND CONSIDERING TAKING PART