TRUST LOGO

The SPELL Study
Children's Participant Information Sheet: 8 to 11 years old

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Research Ethics Committee: REC 23/EE/0153

A study about children with cerebral palsy and muscle stretching exercises

Hello. We would like to ask you and your family if you would like to take part in a study called The SPELL Study.

What is the SPELL study?

Children with cerebral palsy often have stiff legs. This makes it harder to walk and move about. Physiotherapy is trying to help.

We have made new exercises to stretch the leg muscles.
We want to find out if these new exercises are better than usual NHS physiotherapy.
This will help us find out the best ways to help other children with cerebral palsy.

We have tried to make the exercises fun and exciting!



Before you decide to join, it is important that you understand why we are doing this study and what it would involve for you.

Why are you asking me?

Because your doctor or physio believes the new exercises could help you and other children with cerebral palsy. This will help decide what exercises are best.

We are asking lots of children in the country with cerebral palsy if they will think about taking part in the SPELL study.

What kind of physio exercises will I get?

One of the two sets of exercises below:



SPELL exercises:
You will see a physiotherapist 6 times in 4 months to go through the new SPELL exercises.
You will do these exercises at home or school 4-5 times each week, with help if you need it.

Usual exercises:
You will see a physiotherapist once to go through your usual exercises.

The physiotherapist will help you choose which exercises to do.

We want to find out which exercises are best. We need your help to find this out.

Your treatment will be chosen fairly using a process called randomisation. This means you can't choose the treatment, and neither can the doctors or physios. Instead, a computer will decide.

Do I have to say yes?

No, not at all. It's up to you! If you don't want to, that's OK. Nothing will change.

What will happen if I say yes?

Your mum, dad or the person who looks after you will need to sign a consent form to say you can take part. We will also check you are happy to take part, and understand the study and what will happen.

In some places, the study is being run by a team that works with their local hospital. If that's the case for you, some of your visits might be at the hospital instead of at the community. The team will explain everything clearly and make sure you're happy with it before you join.

You will then see a physiotherapist to check how your legs move now. We will then ask you or your parent or the person who looks after you to answer some questions, with help if needed.

We will then tell you which treatment the computer has chosen for you.

You can then begin!

There will be another physiotherapy appointment 6 months later for the same checks. We will also ask you to answer the same questions at your first visit, 6 and possibly 12 months later. If you join our study less than 6 months before we stop inviting children to take part, we will not ask you to complete this last one.

Will it help if I take part?

What we learn from SPELL will help treat children with cerebral palsy in the future.

Who will know I am in this study?

You will be given a special SPELL number. All the information you give us will be linked to this number.

Your name and all other details will be kept safe with the research team. This means that only the people who are treating you, or who need to contact you, will know who you really are.

If you've said yes to visiting the local hospital, the hospital team and your local NHS team/Health Board will also know who you are.
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. Just tell your mum, dad or guardian to let us know.

Who is running this study?

This study is organised by a team at the University of Oxford and involves a big group of physiotherapists, doctors and researchers around the country.



An organisation called the National Institute for Health and Care Research have given them money to run the study.

They give money to lots of people to help them improve treatments for children in the UK.

What happens at the end of the study?

We will send you and/or your parent(s) or the person who looks after you, a summary of the study results.

We will also share the results with other physiotherapists and doctors.

This will help treat other children with cerebral palsy better.

Your name and personal details will <u>not</u> be included in the results.

What if I have questions?

If you have any questions or worries, please tell your mum, dad or the person who looks after you, and speak to the physiotherapist or doctor treating you.



THANK YOU FOR READING THIS LEAFLET AND THINKING ABOUT TAKING PART