JENNY LIND
CHILDREN'S HOSPITAL

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

BENDY

'The efficacy and cost effectiveness of a multidisciplinary intervention strategy for the treatment of benign joint hypermobility syndrome in childhood study'

Research Information Sheet for Parents & Carers

We would like to invite you and your child to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you and your child wish to take part.

What is the study and why is it being done?

In recent years it has been increasingly recognised that children with Benign Hypermobility Joint Syndrome (those with a greater than normal range of motion) are more prone to joint and muscle symptoms including growing pains and exercise-related pain that can have an impact on the child's family and social life and schooling.

At present not enough is known about the best way to treat BJHS as few good quality research studies have been done.

This research study will compare two different treatments, one will be the standard treatment currently offered by your child's paediatrician, the other will be a structured treatment programme involving physiotherapy and occupational therapy in addition to care from your child's paediatrician.

Why has my child been invited?

We are inviting all 5 – 16 yr old children attending the Norfolk and Norwich University Hospital who are diagnosed with BJHS.

Does my child have to take part?

It is up to you and your child to decide if you would like to take part. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care your child receives.

What will happen if I agree to my child taking part?

If you agree to your child taking part, your child will be randomly put in one of the two study treatment groups; **'standard treatment'** or **'structured treatment'**. Please note that this will be decided by chance – you cannot chose which treatment group your child is put in.

After this, your child will be invited to attend an initial study appointment (study appointment 1) with a Physiotherapist at the hospital who will do a physical assessment of your child and complete some questionnaires with you both. This appointment will take around 1 hour.

Two more study appointments (study appointments 2 and 3) with the Physiotherapist will take place, approximately three months after the first one and one year after the first one, to repeat the physical assessment and questionnaires. These appointments will also take around 1 hour each time.

At the end of study appointment 2 we may ask some parents, children and young people whether they would like to take part in a further study asking about their experiences of this research.

If your child is in the **'standard treatment'** group:

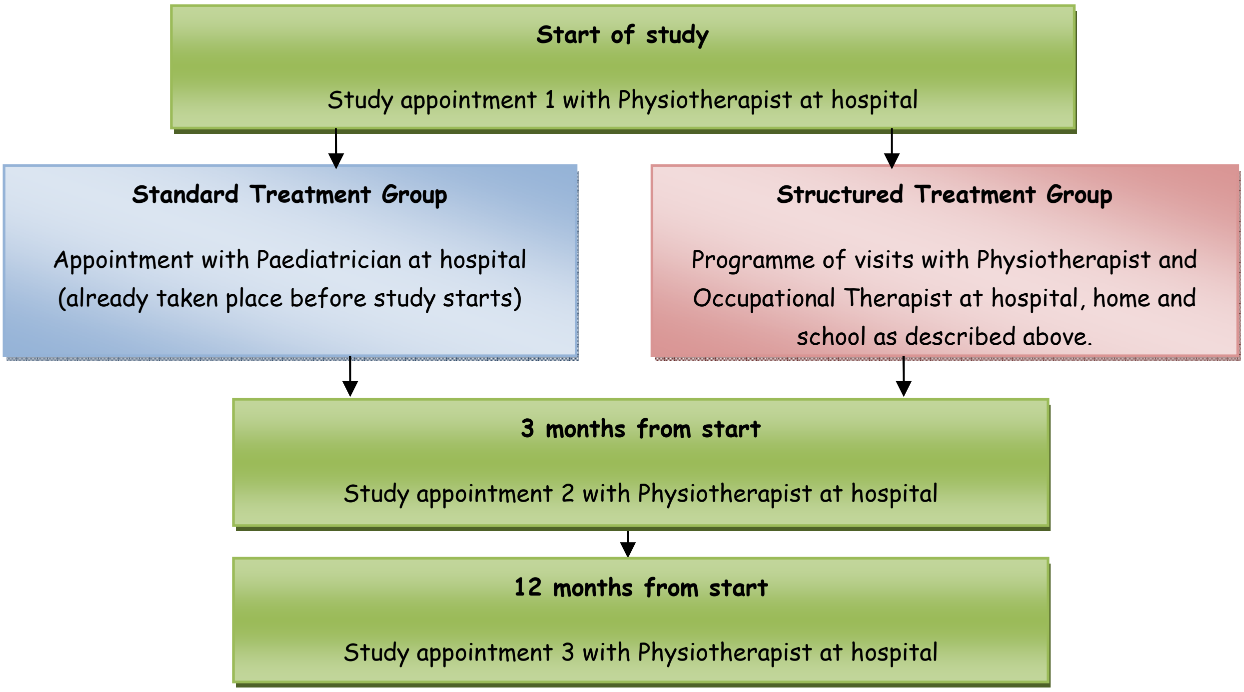
After study appointment 1 your child will not receive any further treatment and will not be seen again until study appointments 2 and 3 take place. He/she will already have had an appointment with the Paediatrician and will have been given information and advice about BJHS and referred for orthotic support if necessary, however if your child has any problems and needs to see the doctor again, this will be arranged. This is what would usually happen with children diagnosed with BJHS.

If your child is in the **'structured treatment'** group:

A structured treatment programme for your child will take place between study appointment 1 and the study appointments 2 and 3. Each treatment visit will be based on individual exercises and advice and will take around 30 to 60 minutes.

> **Treatment visit 1 -** Appointment at hospital with physiotherapist and occupational therapist to receive information packs and discuss an individual treatment and exercise programme.
>
> **Treatment visit 2 -** Appointment at your home with occupational therapist.
>
> Between treatment visits 2 and 3 a physiotherapist and occupational therapist will visit your child's school to offer advice.
>
> **Treatment visit 3 -** Appointment at hospital with physiotherapist to review progress with exercises.
>
> **Treatment visit 4 -** Appointment at hospital with physiotherapist to review progress with exercises.

Diagram of study visits:



Who is organising and funding the research?

The research is being organised by a team of health care professionals and research staff at the Norfolk and Norwich University Hospital and University of East Anglia led by Professor MacGregor, Consultant Rheumatologist. The study is being funded by an NHS Research grant.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the East Norfolk and Waveney Research Ethics Consortium.

What are the possible disadvantages and risks of taking part?

We do not feel that there are any disadvantages or risks involved with this study.

What are the possible benefits of taking part?

We cannot promise the study will help your child but the information we get from this study may help improve the treatment offered to children with BJHS.

What happens when the research study stops?

Your child's involvement in the study will last for one year. After this time, your child will continue to receive care from his/her paediatrician as required.

What will happen to the results of the research study?

The results of the study will be publicised within in the hospital, through professional conferences and publications and a summary report will be sent to all families involved.

Will my child's involvement in the study be confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. With your permission we will inform your child's GP about his/her involvement in the study but will not pass on any personal details.

Some parts of your child's medical records and the data collected for the study will be stored securely and only looked at by authorised persons from the team organising the research and possibly by representatives of regulatory authorities and authorised people to check that the study is being carried out correctly, for example, members of a Research Ethics committee.

Any information which leaves the hospital will have names and addresses removed so that no-one can be recognised.

What will happen if we don't want to carry on with the study?

You may withdraw from the study at any time and do not have to give a reason for doing so. If you decide to withdraw from the study we will ask for your permission to use the information collected up to the point of withdrawal.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this with the NHS Complaints Procedure through the Patient Advise & Liaison service. The telephone number is: **01603 289036**

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

For further information about this research please contact:

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