Sheffield Children's NHS
NHS Foundation Trust

THE BASIS STUDY

BASIS 2 Study

Parent/Guardian Information Sheet

You and your child have been involved in the BASIS study for a while now, and we would like to ask you if you would like to take part in another part of the BASIS research study, BASIS 2. Before you decide if you and your child would like to take part, it is important for you to understand why the research is being done and what it will involve that is additional to the current BASIS study. Please take time to read the following information carefully and discuss it with a member of the study team if you wish. Please 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.

1. What is the BASIS 2 study?

As you know, the BASIS study is looking at night-time braces compared to full-time braces for young people with scoliosis. Your child will have already worn their brace for a number of months or years.

Up until now, research has suggested that when young people stop growing, the spine curve will not worsen. However, we now know that in some patients, the curve does get bigger in the few months after the brace is removed. So some doctors now ask young people to wear their brace for a little bit longer.

BASIS 2 is trying to find out whether wearing the brace for six months after your child stops growing can reduce the chances of their curve getting bigger, compared to stopping the brace at the end of growth.

2. Why are you asking my child?

We are asking people who have been wearing a brace in the BASIS study if they would like to take part in this next study. You and your child are being asked because your doctor believes that either of these options would be suitable for your child.

3. What treatment will I get?

In BASIS 2, patients are split into two groups, through a process called randomisation. This means that a computer randomly decides which option your child will receive and ensures that

the two groups are split equally, the same process that happened in BASIS. You, your child, nor your doctors would be able to change which group your child goes into.
The two groups are:

- Your child will keep their brace and carry on wearing it for 6 months after they stop growing
- Your child will stop wearing their brace straightaway when they stop growing

Doctors will tell you when your child's x-ray shows that they have stopped growing.

The sensor that is already in your child's brace, which detects when their brace is on and off, will stay in their brace so that we can see how often you have worn your brace. As with BASIS, these sensors are commonly used in braces and are safe. They don't send or receive any signals so all the data about brace wearing is on the sensor. The sensor stores the data which will then be downloaded and sent to the research team. We cannot share this data with you as it may influence the study.

4. Do I have to say yes?

No. If you or your child decide to say no, this is fine, and your child's doctor will discuss their ongoing treatment with you. If you say no to BASIS 2, you and your child can still carry on with BASIS.

5. What will happen if I say yes?

Your child's doctor will ask you to fill in a consent form, and your child to fill in an assent form. This confirms you understand the study and what will happen, and that you and your child agree to take part.

Your child's doctor will then check which group they've been randomised to, and they will tell you what happens next and what your child needs to do with their brace. They will be asked to answer one more set of questions about wearing their brace, and they will have an x-ray of their left hand and wrist.

Everything else in BASIS 2 is exactly the same as in BASIS. Your child will have a visit to hospital one and two years after you have finished growing which is normal clinical practice, and their doctor will tell you when these visits will be. They will contact you at the end of the 6 months if your child has been asked to carry on wearing their brace, to tell you when they can stop. You will also be sent an envelope to post back the sensor from the brace.

6. What are the potential risks of taking part?

Participation in this study requires a left hand and wrist x-ray for bone age assessment. This will be extra to those that your child would have if they did not take part. These procedures use ionising radiation to form images of the body and provide your child's doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening to your child. The additional radiation dose is equivalent to about 4 hours of average natural background radiation in the UK.

7. Who will know my child is in this study?

Your child will keep the same special identification number for BASIS 2 as the one they have for BASIS, and all information collected about your child for the study will be linked to that number. That means only the people treating your child, or who need to contact you or your child, will have access to their personal information. It is normal in medical databases for other doctors and medical staff to be able to see your child's name and date of birth. But only the staff involved with BASIS and BASIS 2 will be able to see further information about your child.

Information collected about your child for the BASIS 2 study may also be used for other research, but this will not include their name.

The central team coordinating BASIS and BASIS 2 will have access to your child's data that is collected for the purposes of the research. At the end of the 6 month period of BASIS 2, you will be posted a padded envelope to send back the sensor that is in the brace. This may be sent to you by your local BASIS research team, or by the central coordinating team.

8. What happens if I change my mind?

You or your child can change your mind about taking part in the study at any time, and they will still have access to hospital care and treatment.

If you or your child decide that you no longer wish to take part in the study, please let the research team know. You do not have to give a reason, and this will not impact on the medical care you or your child receive during or after the trial.

Any data collected from you or your child up to the point of withdrawal will be retained and used in the trial results.

There are more details about the study available online at www.basisstudy.org.

9. Will our data be kept confidential?

All information which is collected about your child during the course of the research will be kept strictly confidential.

Once the study is complete, all information will be kept securely for 15 years after the end of the project, or kept in confidential notes.

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 2018.

10. What if there is a problem?

If you have a concern about any aspect of the study, you should ask to speak to the study team, who will do their best to answer any questions you may have. You will have been provided with their contact details. If you remain unhappy and wish to make a complaint, you can do this through the NHS Complaints Procedure.

If you wish to make a report of a concern or incident relating to potential exploitation, abuse or harm resulting from your involvement in this project, please contact the project's Designated Safeguarding Contact, through your local PALS team. If the concern or incident relates to the Designated Safeguarding Contact, or if you feel a report you have made to this Contact has not been handled in a satisfactory way, please contact the Sponsor safeguarding team at Sheffield Children's Hospital on 0114 226 7803.

11. Who is organising and funding the study?

The study has been designed by paediatric and adult orthopaedic and spinal surgeons, along with patient representatives and researchers. The research is organised by the University of Sheffield Clinical Trials Research Unit on behalf of Sheffield Children's NHS Foundation Trust (the Sponsor). This project is funded by the NIHR Health Technology Assessment (HTA) Programme (project number NIHR131081).

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your rights, wellbeing and dignity. This study has been reviewed and approved by a Research Ethics Committee. It has also been given approval by the Research Department to run at the hospital you are being treated at

12. How will our information be used?

We will need to use information from your child's medical records for this research project.

This information will include your child's NHS (or CHI) number, name, age and information about their scoliosis. People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

We will keep all information about your child safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

Where can I find out more about how my child's information is used

You can find out more about how we use your information at:www.hra.nhs.uk/information-about-patients/

- by asking one of the research team
- by sending an email to the central research team using the contacts on the BASIS website
- by ringing us on 0114 222 4023

13. What are our choices about how our information is used?

Your child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.

14. What will happen to the results of this research study?

When the study has finished we will present our findings to other researchers, and we will put the results in medical journals and websites that researchers read. We would also like to put a brief summary on the research websites of the hospitals who took part so that you will be able to read about our results too. This will be available at the end of the study, and will also be available on the BASIS study website – www.basisstudy.org. They will be anonymous, which means that your child will not be able to be identified from them.

Your information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

15. Contact details

If you have any questions about the information in this leaflet, or anything else to do with this study, please speak to your child's doctor or local research team, or contact the BASIS central study team through the BASIS website.

16. Who can I contact if I have a complaint?

Complaints about Data Handling

If you are not happy, you can contact the Data Protection Officer for Sheffield Children's Hospital.

Name: Mark Talbot

Contact: scn-tr.dataprotection@nhs.net

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Complaints about your treatment on the research study:

If you have a concern about your participation on 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 by contacting your local PALS team using the contact details available through the BASIS website, your local hospital's website, or PASS Scotland.

Thank you for reading this information