



## **Bracing Adolescent Idiopathic Scoliosis – night-time versus full-time bracing in adolescent idiopathic scoliosis**

### **Parent/Guardian Information Sheet**

You and your child are being invited to take part in a research study. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. 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 purpose of the BASIS study?**

At the moment, children and young people diagnosed with adolescent idiopathic scoliosis often need to wear a full-time brace to try and treat the curve to the spine, which means wearing the brace for most of the day. This study is looking at a different type of back brace to that used in the UK, a brace worn only at night time. This is currently used in other countries in the world, though before we use it routinely in the UK, we need to ensure it is as good as the standard brace that is worn for most of the day. The night time brace might be easier to wear than the usual care full-time brace, but we do not know whether it is as effective.

#### **2. What is being tested?**

The BASIS study is comparing the following two braces for patients with adolescent idiopathic scoliosis.

- Full-time brace – this is worn for at least 20 hours per day, and is currently the routine brace type used in the NHS for adolescent idiopathic scoliosis.
- Night-time brace – this is worn only at night, whilst in bed (8-12 hours). The night-time brace is not currently routine and is only available as part of this trial in the UK.

At the moment, we do not know whether the night-time brace is more beneficial than the full-time brace.

#### **3. Why has my child been asked to take part?**

Your child has been invited to take part in the BASIS study because they have been diagnosed with adolescent idiopathic scoliosis. The likely standard treatment would be a full-time brace

until they finish growing. The brace reduces the chance the scoliosis curve(s) will get bigger. If the scoliosis does get bigger, an operation may be required.

#### 4. Does my child have to take part?

No. It is up to you and your child to decide whether or not you want to take part in the study. You will be given time to consider the study information, discuss it with family or friends, and ask questions to the research team before making your decision. You'll be asked for your permission to keep hold of your child's name, NHS (or CHI) number and date of birth, as well as your contact details, so that you can be contacted to see whether you would like to take part.

If you do decide to take part, you will be asked to complete a consent form, and your child will be asked to complete an assent form, to confirm that they also understand what will happen. This will be an online form that you will be sent a link to during a phone call with a member of the research team, or possibly in person at the hospital if appropriate. This is the informed consent procedure for the study, and there is no hand-written consent being obtained. This has no effect on the standard consenting practices/withdrawal from research, and you and your child are free to withdraw from the study at any time should you wish to.

If you decide that you do not wish to take part, the identifiable details that have been held for your child for the study, will be removed.

Whether or not you decide to take part in the study, your child's doctor will discuss standard treatment options with you which will not be influenced by your decision whether to take part in the study or not.

Your child will be in the BASIS study until around 2 years after they've finished their bracing treatment. We anticipate that young people will be in brace for between 2-4 years, but this depends on their growth.

#### 5. What should my child and I expect if we agree to take part?

If you and your child agree to take part, we will need to make sure the study is right for your child. It is likely that your doctor has already confirmed this from a recent x-ray but this will be confirmed. Your child will be asked to complete some questions on their health, back symptoms, feelings about the brace, pain levels, and their quality of life. These will be sent as a link via email or text, to be completed online. This should take no more than around 20 minutes to complete.

Following this, your child will be fairly allocated to one of the two different braces through a process called randomisation. This randomisation process is done by a computer, and you, your child and their medical team will not be able to influence or change the brace type. Once this has been done, you and your child will be informed of the outcome and will be given information on when you will need to attend hospital for measurements to be taken for the brace.

Your child's brace will be fitted with a small sensor placed in the lining of the brace to detect when the brace is on and off. 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 or your child as it may influence the study. These sensors are very small, and whilst it is very uncommon for them to fall out of the brace lining, please take care especially around younger children when removing/fitting the brace to avoid any risk of choking.

Your child will have an x-ray within around 6 weeks of brace fitting, as a routine check.

Roughly every 6 months, your child will be asked to complete the same questions as at the beginning, as well as having an x-ray which is part of normal care for patients being treated in a scoliosis brace. The study timepoints have been designed to try and match with the timing of usual care visits to the hospital, which reduces the number of times you'll be asked to come into hospital. You will be asked for a mobile phone number and email address that the questionnaires can be sent to at these timepoints. The questionnaire can be completed using a mobile phone, tablet or computer.

If your child takes part in this study they will have a series of spine x-rays. Some of these may be extra to those that they 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 increase the chances of this happening to your child from 50% to 50.03%.

When your child attends the hospital for an x-ray, which will usually be done every 6 months, often at a clinic appointment, you should remove your brace first thing on a morning and not wear it until after the x-ray. Please bring your brace with you to each appointment.

In addition to the main BASIS study, we would also like to talk to parents/guardians and children and young people about their experiences of the study. This is so we can learn how to improve the ways that we communicate with families about studies in future and improve support for families during the study. It's important for us to speak to people who agree to take part in the main study and people who decide not to. We may ask if a researcher from the University of Liverpool who are running the BASIS Communication Study can contact you over the coming months to talk to you about your experience of the BASIS study. You can decline the interview from the start, or change your mind about this part later, and still take part in the main study. Please just let any member of the research team know if you change your mind.

## 6. What are the potential risks in taking part?

If your child was not taking part in the study, they would be treated using a full-time brace which can be uncomfortable to wear and cause skin irritation especially in the first few months. This may also occur with the night-time brace, but this has no additional risks.

## 7. What are the potential benefits to taking part?

If your child takes part in this study, they (and you) will be contributing to important research that will inform treatment choices for patients in the future. You will also be under the close follow-up which is normal for those taking part in research.

The night-time brace is currently only available through this study, but only to those allocated to this at the start.

As a thank you for completing the patient and parent questionnaires in this study, your child will be entered into a prize draw to potentially win a shopping voucher. These prize draws will take place at least 4 times a year during the study, and all patients will be entered providing the required questionnaires have been completed.

## 8. Will our data be kept confidential?

If you decide to take part, we will inform your child's GP. The outcomes of this study may be published in journals, on websites or at conferences; however, your child will not be identifiable from the published results, and your personal details will be kept strictly confidential.

If you agree to take part in the interviews that run alongside this study, we may ask your permission to use anonymised quotes in the published study materials.

If you agree to take part, information collected about you and your child will be stored on the British Spine Registry who are providing the database for this study. Information collected as part of the study will only be accessible by those involved in the running of the BASIS study, including your local hospital, Sheffield Children's Hospital as Sponsor for the study, researchers at the University of Liverpool who are co-ordinating the interview study, and researchers at the University of Sheffield who are managing the study and analysing the data. All of these staff are trained in GDPR. As with any clinical system, your child's name and date of birth may come up on a search by other clinical staff with access to the British Spine Registry, who are not involved in BASIS. However staff not involved in your child's clinical care or research will not be able to access any further details about your child.

Your child's x-rays will be transferred to Sheffield Children's Hospital (SCH) using the same secure system used to transfer clinical images between hospitals every day in the NHS. So that they can be stored in the secure SCH system until the end of the study, a record will be created for your child using their name, NHS (or CHI) number and date of birth. At the end of the study any identifiable data will be removed from the SCH systems. X-rays may be anonymised and uploaded to a secure cloud-based x-ray analysis system called Surgimap. This will allow an adjudication committee to review the x-rays and make a group decision on curve size and when your child has finished growing.

If your child was to be prescribed a back brace outside of the trial, the company who make that brace must be provided with your child's name to ensure that your child receives the correct brace, once manufactured. This process will be the same for the BASIS study.

You will also be asked whether you are happy for anonymised data collected about you/your child to be used in future research, but you will not be told what this research is.

We would also like to look at the long-term follow up of young people treated with a back brace. We will ask your permission for your child's identifiable information to be stored in the British Spine Registry so that we can contact them in the future about long term follow up. Once your child reaches the age of 16, they will be asked for their own consent to this.

## 9. What will happen if we decide we no longer want to take part?

If you or your child decide that you no longer wish to take part in the study, please let your child's hospital doctor or 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. You will also be asked whether you consent to your child's routinely collected information can be used for the study. This means that we will not ask anything of you or your child after your withdrawal, but we may be able to use some of the x-ray measurements taken as part of your child's usual care to help with the trial results.

## 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, and the details for your local PALS team are available on the study website.

In the event that something does go wrong, and this is due to someone's negligence then you may have grounds for legal action for compensation against your treating hospital, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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 (details on the study website). 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 and/or the University of Sheffield's Research Ethics & Integrity Manager (Lindsay Unwin; l.v.unwin@sheffield.ac.uk).

## 11. What happens when the research study stops?

Your child will be in the study until approximately 2 years after they've finished bracing which is stopped at the end of growth. It would be normal clinical practice to discharge them at this point, although their spinal surgeon may choose to continue follow-up and will discuss this with you and your child. You/your child will be contacted about 8 years after this for a planned long-term follow-up. At the end of the study, your child's ongoing care will return to the standard NHS care as it would be if they did not take part in the study.

## 12. 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.

## 13. 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. There are more details about the study available online at [www.basisstudy.org](http://www.basisstudy.org).

### **General Data Protection Regulation Information**

Sheffield Children's NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Your local hospital will keep identifiable information about you for 15 years after the study has finished, in some instances personal data maybe kept for longer where there is explicit consent in place.

You can find out more about how we use your information at the following link: <https://www.sheffieldchildrens.nhs.uk/your-information/>

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your local hospital will use your name, hospital number and other identifiers 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. The only people who will have access to information that identifies you will be people who need to contact you regarding your participation in the study, or audit the data collection process, with the exception of other British Spine Registry users as outlined in section 8 above. The people who analyse the

information will not be able to identify you and will not be able to find out your name, NHS number, or contact details.

The following website provides information about how your information is used in research:  
<https://www.hra.nhs.uk/information-about-patients/>

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.

**Thank you for reading this information**