Sheffield Children's NHS
NHS Foundation Trust

THE BASIS STUDY

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

Information Sheet for young people aged 16 and over

1. Introduction

You have been taking part in the BASIS study for a while now, and before you turned 16 years old, we asked your parents for their permission for you to take part in BASIS. Now that you're 16 years old, we need to check that you are still happy to continue in the study.

2. What happens next?

If you have any questions about continuing in the study, please let the research team know.

If you are happy to continue with the study, nothing will change in relation to your treatment or follow up appointments, and you will continue to be in the study until approximately 2 years after you've finished bracing. We will ask you to sign a new consent form, which will confirm your agreement to continue.

If you decide that you no longer want to stay in the study, you will not need to sign the consent form, and we will not contact you about any more follow up appointments.

If you decide to continue, but change your mind later, please let the research team know. You don't have to give a reason for changing your mind, and your medical care will not be affected by your decision. Any data collected from you up to the point of withdrawal will be kept, and will be used in the results of the study.

If you agree to continue, information collected about you 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 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 clinical care or research will not be able to access any further details about you.

Your 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 have been created for you using your 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 you have finished growing.

You will also be asked whether you are happy for anonymised data collected about you 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 identifiable information to be stored in the British Spine Registry so that we can contact you in the future about long term follow up.

Your GP is already aware of your participation in this study.

3. What happens when the research study stops?

The study ends 2 years after you've finished bracing. It would be normal clinical practice to discharge you at this point although your spinal surgeon may choose to continue follow-up and will discuss this with you. You will be contacted about 8 years after this for a planned long-term follow-up.

At the end of the study, your ongoing care will return to the standard NHS care as it would be if you did not take part in the study.

4. 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.

5. 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 doctor or local research team. There are more details about the study available online at 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 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 2 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