



BASIS 2 Study

Information Sheet for young people aged 16 and over

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. We would now 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 would like to take part, we would like to explain why the study is important, and what we would be asking you to do that is extra to what you are already doing in BASIS.

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. You've already worn your brace for a number of months or years.

Up until now, it has been thought 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 you stop growing can reduce the chances of the curve getting bigger, compared to stopping the brace at the end of growth.

2. Why are you asking me?

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 are being asked because your doctor believes that either of these options would be suitable for you.

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 you will receive and ensures that the two groups are split equally, the same process that happened in BASIS. Neither you, nor your doctors would be able to change which group you go into.

The two groups are:

- Keep your brace and carry on wearing it for 6 months after you stop growing
- Stop wearing your brace straightaway when you stop growing

Doctors will tell you when your x-ray shows that you have stopped growing.

The sensor that is already in your brace, which detects when your brace is on and off, will stay in your 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 decide to say no, this is fine, and your doctor will discuss your ongoing treatment with you. If you say no to BASIS 2, you can still carry on with BASIS.

5. What will happen if I say yes?

Your doctor will ask you to fill in a consent form. This is a form to confirm you understand the study and what will happen, and that you agree to take part.

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

Everything else in BASIS 2 is exactly the same as in BASIS. You will have a visit to hospital one and two years after you have finished growing, which is normal clinical practice, and your doctor will tell you when these visits will be. They will contact you at the end of the 6 months if you have been asked to carry on wearing your brace, to tell you when you 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 you would have if you did not take part. These procedures use ionising radiation to form images of the body and provide your 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 you. The additional radiation dose is equivalent to about 4 hours of average natural background radiation in the UK.

7. Who will know I'm in this study?

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

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

The central team coordinating BASIS and BASIS 2 will have access to your 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 can change your mind about taking part in the study at any time, and you will still have access to hospital care and treatment.

If you 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 receive during or after the trial.

Any data collected from you 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 my data be kept confidential?

All information which is collected about you 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 medical records for this research project.

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

We will keep all information about you 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 you took part in the study.

Where can I find out more about how my 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 my choices about how my information is used?

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

We need to manage your 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 you.

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 you 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 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, or your local hospital's website.

Thank you for reading this information