



BASIS Study

Young People Information Sheet, for those 10-15 years old.

Hello! We would like to ask you and your family if you would like to take part in the BASIS research study. 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.

1. What is the BASIS study?

The BASIS study is the Bracing in Scoliosis Study. At the moment, children and young people diagnosed with scoliosis often need to wear a brace most of the day to treat the curve to the spine. The 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 that it is as good as the standard brace that is worn for most of the day.

2. Why are you asking me?

We are asking lots of young people aged 10-15 years old who have been diagnosed with scoliosis if they would like to take part. You are being asked because your doctor believes that either treatment would be suitable for you.

3. What treatment will I get?

Braces for scoliosis reduce the risk of the curve getting bigger and have been shown to reduce the need for surgery. We try to avoid surgery as much as possible because of the risks.

The treatments the BASIS study is looking at are:

- A 'standard' full time brace, which is the same as you may be offered if you weren't taking part in the study. This should be worn for at least 20 hours each day.
- A night-time only brace, which is currently only available in this study. It should be worn whilst you are in bed at night (around 8-12 hours).

There are positives and negatives for each type of brace and, at the moment, we don't know which one is best.

To make things fair we will split those people taking part into two groups, through a process called randomisation. This means that a computer randomly decides which brace you will receive and ensures that half of the people are treated with one brace, and the remainder with the other brace. Neither you, nor your doctors would be able to change which group you go into.

Your 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 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 and your parents. At the moment, the night-time brace is only available as part of the BASIS study.

As part of BASIS, we are also asking some young people and their parents to talk to us about their thoughts on brace treatment. We'd like to talk to people who don't take part in the study, as well as some who do. Your parents will be asked for their permission for us to pass your name and contact details to researchers in Liverpool who are running this part of the study.

5. What will happen if I say yes?

Your doctor will ask you to fill in a form called an "assent form". This is a form to confirm you understand the study and what will happen. Your parent or guardian will also sign a consent form to confirm that they are also happy for you to take part.

Your doctor will then check which treatment group you've been put into, and you will receive information on which brace you will have fitted. Your doctor will then tell you what happens next and when you will need to come back to the hospital. This will usually be in an email, or a letter through the post.

You will be asked to answer some questions about your back, and how you feel. These same questions will be sent to you twice a year while you are taking part in the study. A link to these will be sent to the mobile phone or email address that you or your family has given us. We expect that you'll be in the study for around 4 years, but this depends on your growth, and how long you need to wear a brace for.

You will also have some spine x-rays. Some of these may be extra to those that you would have if you didn't take part.

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

You will be given a special identification number for the study, 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. Your GP will also be told that you are taking part. You will have regular x-rays, as you would if you weren't in the study, and these will be measured by a few doctors but your name will be removed and replaced by your study number before they see them. 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 will be able to see further information about you.

It is also normal for the company who makes your back brace to know who you are. This is so that they can make sure you receive the correct brace. This will also happen in the BASIS study.

Information collected about you for the BASIS study will be kept on a database, and when you turn 16 years old, you'll be asked for your permission for us to keep that information so we can contact you in the future to see how you are.

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

7. 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 do change your mind, please ask your parents to let your doctor or one of the research team members know.

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 one of the research team. There are more details about the study available online at www.basisstudy.org.

Thank you for reading this information