



## **BASIS 2 Study**

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

Hello! We would like to ask you and your family if you would like to take part in another part of the BASIS research study, BASIS2. 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 children and 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 children finish growing, the spine curve will not get any bigger. But 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 children to wear their brace for a little bit longer.

BASIS 2 is trying to find out whether wearing the brace for six months after children have stopped 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. 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 and your parents. 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 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 group you've been put into, 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 stop growing, which is normal clinical care, 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 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](http://www.basisstudy.org).

Thank you for reading this information