



## ODD SOCKS STUDY

### Patient Information Sheet for Children & Young people

#### A study about children with leg injuries

**Chief Investigator: Mr Nicholas Peterson**

Hello. We would like to ask you and your family if you would take part in an important study called the ODD SOCKS Study.

We will compare two different types of treatment for your ankle injury.

Before you decide to join in, it is important that you understand why we are doing this study and what it would involve for you.

If there is anything that you are not sure about, or if you would like more information, please ask your mum or dad (or guardian), or one of the doctors or nurses looking after you.

Further details of the study can be found in the parent version of the information leaflet given to your parent/guardian, and also online at

**Alder Hey Children's**  
NHS Foundation Trust

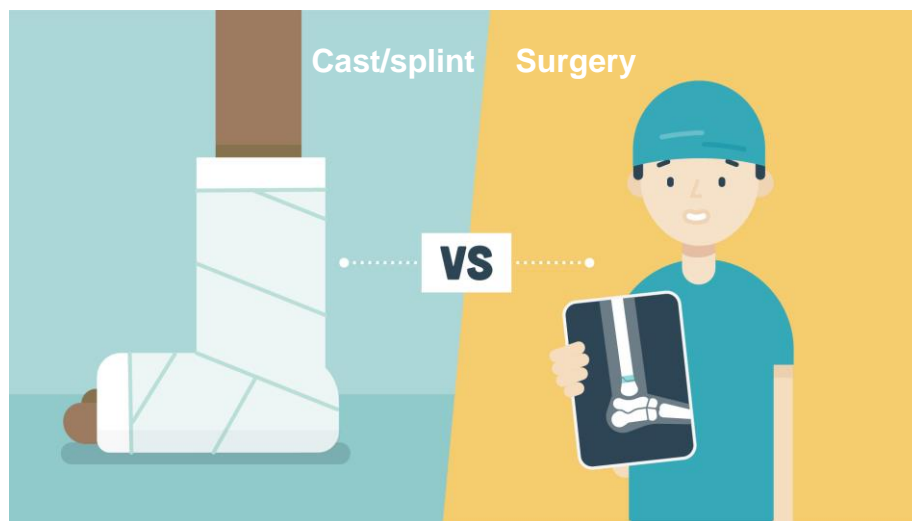


**NIHR** | National Institute for  
Health and Care Research

[www.ODDSocks.org](http://www.ODDSocks.org)

## 1) WHAT IS THE ODD SOCKS STUDY?

The ODD SOCKS Study is trying to find out the best way to treat an injury like yours. Your leg has a broken bone near the ankle. This is called a 'growth plate fracture'. Hundreds of children have this injury each year in the UK. Doctors can treat this injury in two different ways. They can rest the leg in a cast or splint and allow it to heal, or they can do surgery to fix the bones back together in their natural position.



The doctors at this hospital are taking part in the study because we do not know the best way to treat these injuries and would like to find out.

## 2) WHY ARE YOU ASKING ME?

You have been given this information sheet because your doctors believe that either treatment would be suitable for you. We are asking lots of children in the country who have the same injury as you if they will think about taking part in the ODD SOCKS Study.

## 3) WHAT TREATMENT WILL I GET?

The treatments are:

- Resting the leg in plaster cast for up to 6 weeks, to allow it to heal by itself.
- Surgery to fix the bones back into their natural position, usually with screws, and then resting the leg in a splint or cast for up to 6 weeks.

The way we compare the treatments fairly is to split the children into two groups who are the same. Please (see "What is a Trial" video at <https://oddssocks-study.digitrial.com/taking-part/> or further information). You can't choose the treatment, and neither can the doctors. When we have groups of patients who

are as similar as possible, we can then compare them in the fairest way possible.

#### 4) DO I HAVE TO SAY YES?

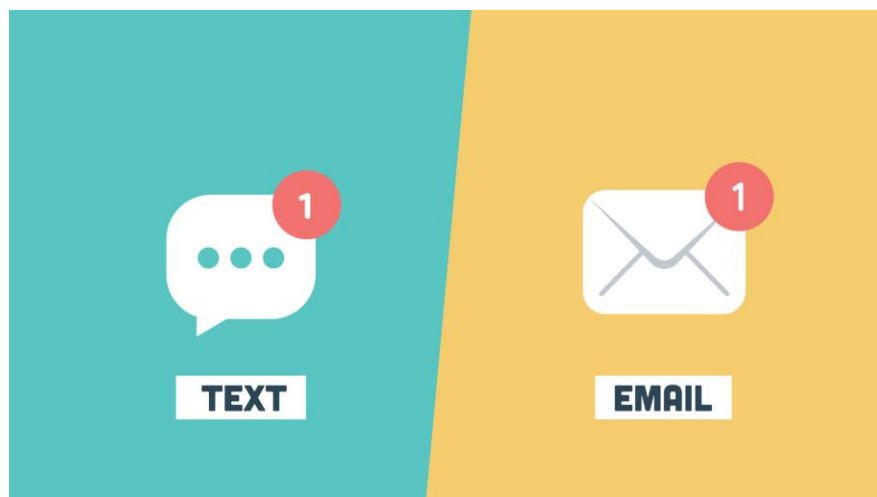
No, you don't. If you decide to say no, your care will not be affected, and nobody will mind. You and your parents/guardians, doctors and nurses can talk about what treatment you will have. We don't know which treatment is best, that's why we are doing this study!

#### 5) WHAT WILL HAPPEN IF I SAY YES?

Your parent or guardian will need to sign a consent form to agree to you taking part, and then one of your doctors or nurses will ask if you would like to sign a form called an "Assent Form". This is just to say that you understand the study and what will happen. You will be sent an electronic copy of the form to keep, as well as this information leaflet.

We will then learn which treatment group you have been fairly put in, by a study process called randomisation. Doctors and nurses can then begin your treatment.

We will ask you to answer some questions about how well you can use your leg. We'll send these questions four times over the next year, and then once more in the second year. These will be sent to the mobile phone or e-mail address that your family gives us.



If you turn 16 years of age during the study, we will ask you to sign your own consent form to agree to you continuing to take part.

The care from your doctors will be the same as if you did not take part in the study, including having x-ray pictures taken of your ankle. Some of these x-rays may be extra to those that you would have if you did not take part.

#### **6) WHO WILL KNOW I'M IN THIS STUDY?**

You will be given a special identification number and any information that you give us will be linked only to this number. This means that only the people who are treating you, or who need to contact you, will know who you really are.

#### **7) WHAT HAPPENS IF I CHANGE MY MIND?**

You can change your mind at any time and we will stop contacting you. If you do change your mind, please ask your parents to let your doctor or one of the research team members know.