

Evaluation of Sleep in SYNGAP1-related Intellectual Disability

Research Study Information Sheet

INTRODUCTION:

Parents and/or carers are asked to go through this information sheet with their child. Please ask study staff if you or your child have any questions.

You are being invited to take part in a research study. It is important that you know what it is about before you decide whether to take part. Please read this information carefully and talk to us if you have questions. Talk to your family or friends about it if you want to.

What are we trying to find out?

- We are trying to find out how changes in a gene called SYNGAP1 affect your sleep. Your genes are part of your DNA like a codebook inside you for building your brain and your body.
- Children or young people with changes in SYNGAP1 can find it hard to learn and remember things, they can be poorly and most of them have problems with their sleep.
- We want to know what sleep is like in children or young people who have changes in SYNGAP1.

Why am I being asked to join in?

We are asking you because you have a change in the gene SYNGAP1 or know someone else who does.

Do I have to join in?

No. It is up to you and it is ok to say no. If you do take part then you can still change your mind at any time, without telling us why.

What will happen if I join in?

- We will meet you and your parent or carer by video-link and ask you questions to see if you understand the study well enough to choose to take part for yourself. Choosing to take part is called 'giving consent'. If we don't think you can choose for yourself then the law says we need to ask your parent or Guardian instead. We will still ask you what you think too though.
- The person who gives consent can sign a paper form and post it to us or sign it electronically on a computer or tablet. We will tell you how to do this.
- If you have SYNGAP1, we will ask you for proof of this from something like a doctor's letter or test report.
- The video-link we use will always be one that the University of Edinburgh says is safe and secure.
- We will ask someone who knows you well to answer questions about things like your health, quality of life and your sleep. You may be able to help them with some of them. Filling in the questionnaires will probably take around 90 minutes (1.5 hours), but they don't have to do them all in one go. We will also ask them to keep a diary of your sleep. This will take 5 or 10 minutes each morning, every day for a week.

- We will come to your house to record your sleep for 2 nights using a video camera and special equipment like in Picture 1.
- We will use protective equipment, clean our reusable equipment and keep socially distanced as much as possible to try to make sure we don't spread COVID-19 (Coronavirus) or any other infection. We will follow the Government and our University rules about what sort of equipment to wear. It is very likely this will include face masks. We will also study your circadian rhythm which is your daily body clock that links to when you're asleep and when you're awake. To do this we will ask you to wear something like a watch for a week (Picture 2). It will measure your activity levels.



Picture 1



Picture 2

Will the study be helpful for me?

If you take part we will be able to tell you more about your sleep patterns and circadian rhythm. We will also be able to tell you if there are problems with your sleep that you should talk to your doctor about in case they can help. You might also help us find sleep patterns that are only seen in people with SYNGAP1 gene changes.

Are there any downsides to taking part?

None of the things we do with you are known to be bad for your health and they won't hurt. Some people find it a bit strange or frightening to meet new people and do new things like wear the recording equipment. We will make it as easy as we can for you and will also send photos of us before we come. If there is anything you don't want to do then you can stop at any time. We will show you how to take off the equipment if you can't sleep with it. It would be good if you can still wear some of it, but it is ok if you want to take it all off.

What do you do with my information?

We store it in locked filing cabinets and on secure computers and laptops at the University of Edinburgh where we work. The data on the sleep recording equipment in Pictures 1 and 2 is encrypted which is a way of coding it so only people who have the right computer programme can read it. We will download the video from the camera to a university laptop that has a password to access it and delete the video on the camera so no one else can see it. We don't keep things that could identify you (like your name or address) with your other information. This means that anyone who saw the other information wouldn't know it was you. If we use a video-link to contact you about the study, this will not be recorded. We will follow strict privacy laws during the study to keep your data safe.

If you agree, we will let your doctor know as soon as possible about any problems that we find with your sleep.

If you agree to take part, the information about your health and care may be shared with researchers running other studies in the University of Edinburgh and in places like other

universities, the National Health Service (NHS) or companies involved in health and care research in this country or abroad. There are laws to make sure information shared is only used for this kind of research and we will not share anything that would mean people could recognise that the information is about you. This means we won't share things like your name, date of birth, address, email address and phone number.

There aren't that many people in the world who have SYNGAP1 and so there is a small chance that if you have SYNGAP1, someone could work out who you are if they look at our study and already know some things about you. We think this is really unlikely though.

We might want to use the videos of you sleeping in talks or reports to other people interested in SYNGAP1. We will disguise your face and take out any sounds that might mean people could tell it is you in the video. We will show you the video first and ask you if you are happy for us to use it like this.

We will keep all the information from this study including the video recordings for 20 years and then we will destroy it.

If you have any worries about how we will use your information, you can contact:

- Send an email to Dr Mizen who is running the study: lmizen@ed.ac.uk
- Telephone Dr Mizen: 0131 537 6263
- Email The University of Edinburgh Data Protection Officer: dpo@ed.ac.uk Their job is to help keep your information safe

What if something goes wrong?

The study shouldn't cause any health problems, but if it did, the University's insurance would pay you compensation. You would not have to prove it was anyone's fault. If you were unhappy about anything to do with the study then you could talk to the head researcher, Dr Lindsay Mizen. Her details are below.

What will happen if I leave the study?

You can leave the study at any time and without telling us why. This will not change any medical care you get or stop you speaking to someone like a lawyer if you are unhappy about the study. If you leave we will keep the information about you that we already have, but will remove as much information that could identify you (such as name and address) as possible. This will mean that it is much harder for anyone to link the rest of your information back to you.

Will I be paid for taking part?

If you show us the receipts we will refund you for anything you had to pay for because you were in the study.

Do the researchers make money for signing people up for the study?

The study team are not paid anything for including you in the study, other than their ordinary salary.

What will happen after the study has finished?

- At the end of the research study we will write to you to tell you what we have learnt.
- We will also write reports for specialist scientific magazines and the funders who paid for the study.
- We give talks at meetings with different groups like doctors and other researchers. Your personal details will never appear in any report or talk unless we ask you for permission first.
- After the end of the study we will keep your information for 20 years. This is so we can study it in more detail if we have other research questions linked to it.
- We would also like permission to contact you in the future to let you know about other studies that you might be interested in.

Who is running and paying for this research?

It has been organised by researchers who work at the University of Edinburgh. The money to fund the study comes from charities called the Simons Foundation and The Patrick Wild Centre.

Has anyone else checked it is ok to do the study?

The study plan has been reviewed by the funders and a group of people called a 'Research Ethics Committee' at the University of Edinburgh to check they think it is safe and going to help answer important research questions about sleep in SYNGAP1.

If you have any questions or want to make a complaint you can contact



Dr Lindsay Mizen
She is running the study

Email: lmizen@ed.ac.uk
Telephone: 0131 537 6263

If you would like impartial information about the study from someone who is not directly involved in it you can contact

Professor Stephen Lawrie **Email:** s.lawrie@ed.ac.uk **Telephone:** 0131 537 6771

If you don't feel you can talk to Dr Mizen about any worries you have about the study or about any complaint you want to make, you can email researchgovernance@ed.ac.uk

Thank you for reading this sheet!