School of Clinical Medicine, UNSW Medicine & Health

# PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

## The feasibility and acceptability of SIBS-ONLINE for siblings and parents of someone with a serious neurological condition: A pilot study

Parent and parent on child's behalf

### 1. What is the research study about?

You and your child are invited to take part in this research study. The research study aims to assess an online program to support siblings and parents of someone with a developmental and epileptic encephalopathy (DEE). A DEE is a condition which causes epileptic seizures, that are typically hard to treat and impacts on learning and/or development. As a parent, the program, SIBS-ONLINE, was developed with the aim to give you the skills to communicate effectively with your child, answer questions they may have about their sibling's condition and increase your confidence in communication. For your child, the aim of the program is to provide them with more knowledge about their sibling's condition, strengthen communication skills and improve their overall mental health and wellbeing.

There has been little research done on the wellbeing of siblings of people with a DEE, or chronic conditions in general. However, we know that living in a stressful environment, such as with a sibling who has a chronic or rare illness, can impact on their sibling's mental health and wellbeing, how well they are able to make and keep friends, and function at school. Some siblings also feel like they are left out of important conversations and are left with unanswered questions about their siblings' condition. Good communication and connection may have flow on beneficial effects for the family unit including empowering you as a parent.

This is the first study to assess SIBS-ONLINE for adolescent siblings and parents of patients with a DEE in Australia. SIBS-ONLINE is not yet offered in everyday care, but we hope that the results of this study will encourage this.

### 2. Who is conducting this research?

The study is being carried out by Maddison Smith as part of a PhD program with the School of Clinical Medicine at UNSW. The list of investigators are:

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| Maddison Smith | School of Paediatrics and Child Health, UNSW |
| Dr Elizabeth Emma Palmer | School of Paediatrics and Child Health, UNSW |
| Dr Lauren Kelada | School of Paediatrics and Child Health, UNSW |
| Professor Claire Wakefield | School of Paediatrics and Child Health, UNSW |
| Kris Pierce | Lived Experience Investigator, UNSW Director, Consumer Engagement and Advocacy |
| Kaitlyn Marsillo | Lived Experience Investigator |
| Jackson Horton | School of Paediatrics and Child Health, UNSW |

Maddison Smith's role as a PhD student is being funded by a National Health Medical Research Council grant in the Centre of Research Excellence.

### 3. Inclusion/Exclusion Criteria

Before you and your child decide to participate in this research study, we need to ensure that it is ok for you to take part. You would have spoken to a researcher prior to reading this information to confirm that your child's condition aligns with the current definition of a DEE. The research study is looking recruit people who meet the following criteria:

Siblings:

- Young people aged between 12 and 18 years old (inclusive)
- Currently living with a sibling who has been diagnosed with a developmental and epileptic encephalopathy (DEE) (e.g., Dravet Syndrome, Lennox-Gastaut Syndrome, West Syndrome, SCN1A, SCN2A and others) at least 6 months prior
- Able to give informed consent
- Able to speak and read conversational English
- Must have access to a computer/smartphone/tablet and Internet connection

Parents

- A parent/guardian of a participating sibling
- Must be parent/guardian to at least one child diagnosed with a developmental and epileptic encephalopathy (e.g., Dravet Syndrome, Lennox-Gastaut Syndrome, West Syndrome, SCN1A, SCN2A and others) at least 6 months prior who lives at home
- Able to give informed consent
- Able to speak/read conversational English
- Must have access to a computer/smartphone/tablet and Internet connection

Participants who meet the following criteria will be excluded from the study:

- They possess insufficient English language skills to complete and understand the core aims of the study, and to be able to participate in the group sessions
- Either a sibling or a parent from one family does not consent
- If the person with the DEE has died
- If they display significant distress including severe depression and/or suicidal ideation and/or suicidal intent

## 4. Do my child and I have to take part in this research study?

Participation in this research study is voluntary. If you and/or your child do not want to take part, you do not have to. If you and/or your child decide to take part and later change your mind, you are free to withdraw yourself and them from the study at any stage.

If you and your child decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

## 5. What does participation in this research require, and are there any risks involved?

If you agree to participate and for your child to participate, you will be asked to complete the following research procedures:

### SIBS-ONLINE

You and your child will participate in the SIBS-ONLINE program. It has been developed by a team of Norwegian researchers for siblings and parents of a child with chronic illness based on a Cognitive Behavioural Therapy (CBT) framework. The sessions will take place once per week over 6 weeks on your phone, laptop or other device. You and your child will complete the sessions on separate devices from a location that suits you best. In each session, you will be joined by 4-5 other siblings and parents and 2 group leaders.

SIBS-ONLINE involves:

1. **Session 1**: An introduction to the intervention and other participants (20 minutes).
2. **Session 2:** Siblings will learn how to ask questions about their siblings' illness, share challenges with their peers and write questions they have for you. You and the other parents will receive information about how to listen, explore, and validate child's thoughts about the disorder (60 minutes).
3. **Session 3:** A joint session with all the siblings and parents including time with just your child in a breakout room. Your child will present their questions and you will practise communication skills learned in session 2 (20-60 minutes).
4. **Session 4**: Siblings will focus on challenging emotions and feelings they have and write them down. You and the other parents will focus on listening, exploring, and validating emotional challenges (60 minutes).
5. **Session 5:** A second joint session where siblings present their challenges to you and further practise learned communication skills (20-60 minutes).
6. **Session 6**: Conclude the program with all the siblings and parents together. Siblings and parents will have the opportunity to ask questions and provide feedback about the program as well.

The online sessions will be recorded so that our team can analyse communication data and check the sessions for quality purposes.

## Surveys (yourself)

We will ask you to complete online surveys at three different time points:

| Time point | Content | Time |
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| Before SIBS-ONLINE | • Demographic questions about yourself, your child with a DEE and their sibling<br>• Three validated questionnaires:<br>○ One about your participating child's (sibling's) emotional and behavioural challenges, as well as their positive social traits.<br>○ Your current psychological health (i.e., feeling anxious, depressed or overwhelmed).<br>○ Your current communication with your child including how openly and effectively you speak with each other and areas of conflict. | 20 minutes |

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| After SIBS-ONLINE | • The same three validated questionnaires as above.<br>• Some questions about your experience with SIBS-ONLINE. | 25 minutes |
| 3-months later | • The same three validated questionnaires as above. | 20 minutes |

Your child (sibling) will also complete surveys at 3 different time points:

| Time point | Content | Time |
|---|---|---|
| Before SIBS-ONLINE | • Demographic questions about themselves (age, gender)<br>• Two validated questionnaires:<br>○ One about their emotional and behavioural challenges, as well as their positive social traits.<br>○ One about their communication with the participating parent including how openly and effectively you speak with each other and areas of conflict.<br>• Five questions to assess their knowledge of their sibling's condition | 20 minutes |
| After SIBS-ONLINE | • The same two validated questionnaires as above.<br>• Five questions to assess their knowledge of their sibling's condition<br>• Some questions about their experience with SIBS-ONLINE | 25 minutes |
| 3-months later | • The same two validated questionnaires as above.<br>• Five questions to assess their knowledge of their sibling's condition | 20 minutes |

## Interview

After completing SIBS-ONLINE, we will invite all siblings and parents who participated to discuss experiences with the program and provide the research team with more detailed feedback in an online interview. The discussion should take around 30-40 minutes. If you are happy for you and/or your child to be contacted about this, please tick the relevant box when filling out the consent form.

### 6. What are the possible benefits of my child and I taking part?

We hope that by participating in SIBS-ONLINE you will improve communication between yourself and your child and making a valuable contribution to a program that may benefit families of someone with a DEE in Australia. Access to SIBS-ONLINE is currently only available in Australia by participating in this study.

We value the time you and your child take out of your busy lives to participate in this research. To show our appreciation for your time, we will provide yourself and your child with remuneration for completing the additional surveys and interview. Remuneration for each survey will be $20 and for the interview will be $30

### 7. Are there any risks?

We do not anticipate you or your child will experience significant distress from participating in this research. There have been no harms reported from trials done for SIBS-ONLINE in Norway. But there is a chance that you and/or your child may find the content in SIBS-ONLINE or the surveys stressful or upsetting. If you or your child does not wish to answer a question, you can skip it, or stop immediately.

The research team has a distress management protocol in place if you or your child feels significant distress during a SIBS-ONLINE session. In this case, a designated group leader will speak to you or your child in the moment, provide resources such as support hotlines and follow-up with a call the next day. To protect your child's right to privacy, we will only contact you if we feel they are at significant risk for harming themselves or others. A clinician on the research team can make referrals to a mental health professional if necessary. If you and your child decide you no longer want to participate, we can help you withdraw. This study is monitored by a trial management group, to make sure that everyone involved is safe.

### 8. What will happen to information about me and my child?

By signing the consent form, you consent to the research team collecting and using information about you and your child for the research study. The research team will store the data collected from you and your child for this research project for a minimum of 15 years after the completion of the research.

The information about you and your child will be stored in a:

- Re-identifiable format where any identifiers such as you and your child's name will be replaced with a unique code.
- Information collected from you and your child in an electronic format will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators.

- Information collected from you and your child using paper-based measures will be stored in the secure office of Primary Investigator Dr Elizabeth Palmer at UNSW, and only the approved research investigators will have access to this information.
- Audio recordings will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators. Recordings will only be made available after a confidentiality agreement has been signed.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the UNSW Privacy Management Plan.

## 9. How and when will I find out what the results of the research study are?

The research team intend to publish the results of the research and report findings at conferences. The results will also be used in Maddison Smith's final PhD dissertation. All Information will be published in a way that will not identify you or your child. If you or your child would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

## 10. What if my child and I want to withdraw from the research study

If you consent to participate and consent for your child to participate, you both may withdraw at any time. You can do so for yourself and your child by completing the 'Withdrawal of Consent Form' which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney, any researchers on the investigator team, or the care you receive for your affected child. If you and your child decide to leave the research study, the researchers will not collect additional information from you.

You can request that any identifiable information about you and your child be withdrawn from the research project. If you and your child have participated in any SIBS-ONLINE sessions at the time of withdrawal, the recordings will be retained however, all personal and identifiable information will be de-identified.

## 11. What if my child or I have a complaint or any concerns about the research study?

This study has been approved by the University of New South Wales Human Research Ethics Committee (iRECS8910). If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

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| **Position** | UNSW Human Research Ethics Coordinator |
| **Telephone** | + 61 2 9385 6222 |

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| **Email** | humanethics@unsw.edu.au |
| **HC Reference Number** | iRECS8910 |

## 12. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

### Research Team Contact Details

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| **Name** | Maddison Smith |
| **Position** | Principal Investigator – PhD Student |
| **Email** | maddison.c.smith@unsw.edu.au |

### Chief Investigator

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| **Name** | Dr Lauren Kelada |
| **Position** | Coordinating Principal Investigator |
| **Telephone** | +61 2 9065 2902 |
| **Email** | l.kelada@unsw.edu.au |

### Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

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| **Name/Organisation** | Beyond Blue |
| **Telephone** | 1300 224 636 |

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| **Name/Organisation** | People with Disability Australia |
| **Telephone** | (02) 9370 3100. |

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| **Name/Organisation** | Kids Helpline |
| **Telephone** | 1800 55 1800 |

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| **Name/Organisation** | 13Yarn (Aboriginal or Torres Strait Islander Crisis Support Line) |
| **Telephone** | 139276 |