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 serious neurological condition: specifically developmental and epileptic encephalopathy (DEE), childhood dementia or Angelman Syndrome. 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.

There has been little research done on the wellbeing of siblings of people with serious 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:

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

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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 serious neurological condition. 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 (e.g., Dravet Syndrome, Lennox-Gastaut Syndrome, West Syndrome, SCN1A, SCN2A and others), childhood dementia or Angelman syndrome 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), childhood dementia or Angelman syndrome 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 serious neurological condition 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 practice 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
Before SIBS-ONLINE	• Demographic questions about yourself, your child with a DEE and their sibling • Three validated questionnaires: o One about your participating child's (sibling's) emotional and behavioural challenges, as well as their positive social traits. o Your current psychological health (i.e., feeling anxious, depressed or overwhelmed). o Your current communication with your child including how openly and effectively you speak with each other and areas of	20 minutes

	conflict.	
After SIBS-ONLINE	• The same three validated questionnaires as above. • 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)
	• Two validated questionnaires
	  o One about their emotional and behavioural challenges, as well as their positive social traits.
	  o One about their communication with the participating parent including how openly and effectively you speak with each other and areas of conflict.
	• Five questions to assess their knowledge of their sibling's condition
		20 minutes

After SIBS-ONLINE	• The same two validated questionnaires as above. • Five questions to assess their knowledge of their sibling's condition • Some questions about their experience with SIBS-ONLINE	25 minutes
3-months later	• The same two validated questionnaires as above. • 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 and New Zealand 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 is 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 additionally 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:

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

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

Chief Investigator

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:

Name/ Organisation	Beyond Blue
Telephone	1300 224 636

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

Name/ Organisation	Kids Helpline
Telephone	1800 55 1800

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

Consent Form – Parent participant providing own consent

Please read: It is important for us to collect data from the surveys to ensure this program does work and is acceptable for parents and siblings. However, if you wish to only participate in the SIBS-ONLINE program without completing the surveys, please complete Declaration 2.

Declaration 1 by the participant

- I understand I am being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of the research described in the study;
- Recordings: I understand that the research team will audio/video record the SIBS-ONLINE program; I agree to be recorded for this purpose.
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- I understand that I will be given a signed copy of this document to keep.
- I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.
- I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future.
- I provide consent to be contacted about participating in a 30-minute interview after SIBS-ONLINE to provide feedback.

Declaration 2 by the participant (ONLY SIBS-ONLINE)

- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of completing the SIBS-ONLINE program;
- Recordings: I understand that the research team will audio/video record the SIBS-ONLINE program; I agree to be recorded for this purpose.
- I provide my consent for video recordings of me to be used for the purpose of this research study only.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- I understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- I understand that I will be given a signed copy of this document to keep.

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- I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.

Name: _____

Address or email address: _____

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

Consent Form – Parent participant providing consent for child

Please read: If you completed Declaration 2 for your own consent, please do the same for your child.

Declaration 1 by the parent

- I understand my child is being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of the research described in the study;
- Recordings: I understand that the research team will audio/video record the SIBS-ONLINE program; I agree for my child to be recorded for this purpose.
- I provide my consent for the information collected about my child to be used for the purpose of this research study only.
- My child has had an opportunity to ask questions and they are satisfied with the answers they have received;
- I freely agree for my child to participate in this research study as described and they understand that they are free to withdraw at any time during the study and withdrawal will not affect their relationship with any of the named organisations and/or research team members;
- My child would like to receive a copy of the study results via email or post, I have provided their details below and ask that they be used for this purpose only;
- I understand that I will be given a signed copy of this document to keep.
- I provide my consent for my child's name and contact details to be retained in a register so they can be contacted about other research projects in the future.
- I provide consent for my child to be contacted about participating in a 30-minute interview after SIBS-ONLINE to provide feedback.

Declaration 2 by the participant (ONLY SIBS-ONLINE)

- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of completing the SIBS-ONLINE program;
- Recordings: I understand that the research team will audio/video record the SIBS-ONLINE program; I agree for my child to be recorded for this purpose.
- I provide my consent for video recordings of my child to be used for the purpose of this research study only.

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- My child has had an opportunity to ask questions and they are satisfied with the answers they have received;
- My child understands that they are free to withdraw at any time during the study and withdrawal will not affect their relationship with any of the named organisations and/or research team members;
- My child would like to receive a copy of the study results via email or post, I have provided their details below and ask that they be used for this purpose only;
- My child understands that they will be given a signed copy of this document to keep.

Name: _____

Address or email address: _____

Parent participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Child participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my and my child's consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales or any member of the research team.

- I am withdrawing my and my child's consent and I would like any identifiable information collected about me and my child which I have provided for the purpose of this research study withdrawn. I understand that recordings of SIBS-ONLINE sessions will be retained and de-identified.

- I am withdrawing my and my child's consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me and my child which I have provided for the purpose of this research.

Parent participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Child participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Maddison Smith
Email:	maddison.c.smith@unsw.edu.au