**APPENDIX A**

**PARTICIPANT INFORMATION SHEET - PARENT/GUARDIAN**

**An Online CBT-based Self-Help Program For Eating Disorders: SkillED Pilot Evaluation**

## (1) What is this study about?

Your child has been invited to take part in a pilot study of an online self-help program based on cognitive behavioural therapy for the treatment of people with eating disorder symptoms. The program, named *SkillED,* is an interactive modularised program that has been developed by a group of subject matter experts at the InsideOut Institute for Eating Disorders, including eating disorder researchers, lived experience consultants, clinical psychologists, psychologists, and mental health clinicians.

The InsideOut Institute has developed *SkillED* to help address the barriers associated with treatment. We hope that by improving access to evidence-based skills, knowledge and resources, individuals with eating disorders will feel more equipped to improve their eating disorder symptoms.

*SkillED* is structured into 11 weekly learning modules organised into various topics, such as psycho-education about eating disorder symptoms, self-monitoring skills, practical skills for management of emotions and dietary intake. This study aims to evaluate how effective, acceptable, and useful *SkillED* is for individuals experiencing eating disorder symptoms by assessing how the program affects people's eating disorder symptoms. We would also like to use the feedback and information gained from your child's responses to inform ongoing development and improvement of the program's content and delivery.

Participation in this research study is voluntary. When your child participates in this study, they will be provided with access to *SkillED* free of cost.

This Participant Information Statement tells you about the evaluation study. Knowing what this is involved will help you decide if you agree for your child to take part in the research. Please read this sheet carefully and if you have any questions, the contact details of the research team are below.

By giving permission for your child to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree that your child will take part in the research study as outlined below.
- ✓ Agree to the use of your child's personal information as described.

You will be given a copy of this Participant Information Sheet to keep.

## (2) Who is running the study?

The study is being carried out by the following researchers:

- Dr Sarah Barakat, InsideOut Institute
- Prof Sarah Maguire, InsideOut Institute
- Dr Jane Miskovic-Wheatley, InsideOut Institute
- Dr Karen Spielman, Insideout Institute
- Dr Shu Hwa Ong, InsideOut Institute
- Daniel Rogers, InsideOut Institute
- Marcellinus Kim, Sydney Local Health District
- Melissa Pehlivan, Insideout Institute
- Peta Marks, InsideOut Institute
- Sally Corry, InsideOut Institute
- Stephanie Boulet, InsideOut Institute
- Patrick Eades, InsideOut Institute
- Steven Castle, InsideOut Institute
- Parthey Bhatt, InsideOut Institute
- Ashlea Hambleton, InsideOut Institute
- Cathy Anderson, InsideOut Institute
- Josephine Atwell, InsideOut Institute
- Ellen Ward, InsideOut Institute

There are no conflicts of interest to declare.

## (3) What will the study involve for your child?

Your child's eligibility to participate in the study will be determined based on their responses to a brief online screening questionnaire (approximately 5 minutes in length), in conjunction with a clinical assessment, where your child will be asked to complete a phone interview with the study's research assessing their eating behaviours, current and previous mental health experiences, and current risk. If your child shows active suicidality or plans to self-harm, or the interviewer perceives that your child is at high risk of self-harm, you will be encouraged to arrange face-to-face counselling for your child and they will not be invited to participate in the study. However, if the study is considered suitable for your child, you and your child will be provided with details to register and start the program. The phone interview may take approximately 30-60 minutes to complete.

Additionally, in order for your child to be eligible to enter the study, you will need to have a General Practitioner (GP) complete a full assessment of your child's physical and medical status. A form (written or online) signed by your child's GP must be returned to

the research staff which confirms that the GP has seen your child, considers your child as suitable to participate to the study and that they agree to medically monitor your child for the duration of the trial at intervals which they specify. You will also be required to provide the contact details of your nominated GP.

Once your child's eligibility has been confirmed, and you agree for your child to participate in this study, your child will be asked to complete a Participant Consent Form. Then, your child will be directed to a complete a set of online questionnaires before starting *SkillED*. The nature of these questionnaires and others that your child will be asked throughout the study are summarised further below.

Your child will be provided with two options for completing *SkillED*. SkillED is structured into 11 weekly learning modules organised into various topics, such as psycho-education about eating disorders symptoms, self-monitoring skills, practical skills for management of emotions and dietary intake. All participants are required to complete the first 5 core modules of the 11-module program, For the remaining 6 modules, they will be asked to choose between 2 options: (1) **full program**: complete all 6 modules in a pre-designed weekly order, or (2) **choose your own adventure**: complete as many of the 6 modules as they like, in whichever order they want.

Please note that regardless of which group your child is joining, the next module will only be unlocked on a weekly basis given after your child has completed the previous selected module in regardless of which group your child is joining.

Once your child has selected their preferred option, they will then be randomly assigned to one of two engagement-based conditions: (1) **engagement intervention**, where a clinician will contact your child if we detect signs of potential disengagement and (2) **no engagement intervention,** where we will not monitor disengagement risk, and no action will be taken.

Please note, the engagement intervention will be administered **before** your child disengages from the program and is distinct from follow-up procedures that will be used should a participant actually disengage. All participants, regardless of assignment, will be contacted by research staff after two to three consecutive weeks of inactivity on the program.

To evaluate how people interact with the SkillED program, we will ask you and your child complete questions at different times during the study:

*Screening* – Before your child enrol into the program, we will ask your child some screening questions to make sure that the program is safe for them to join.

*Baseline* – Before your child starts *SkillED,* these questionnaires should take about 20 minutes to complete and includes questions regarding their demographic and general information. Your child will also be asked to complete the Eating Disorder Diagnosis

Scale (EDDS), Eating Disorder Examination-Questionnaire (EDE-Q), 4 Key Motivational questions, Readiness and Motivational Questionnaire (RMQ), Depression Anxiety Stress Scale (DASS-21), Eating Disorder Inventory (EDI-3) Drive for Thinness subscale, Self-harm and Suicidality Risk Assessment, adapted Help Seeking Behaviour, EQ-5D-Y-5L Health questionnaire, Clinical Impairment Assessment (CIA) and credibility/expectancy questionnaires. As their parent/ guardian, you will be invited to complete the Parent Eating Disorder Examination-Questionnaire (PEDE-Q), which will take an approximately 10 minutes of your time. These questionnaires must be completed to gain access to the program.

*Weekly* – Your child will be invited to complete a short version of both the Self-harm and Suicidality Risk Assessment and Eating Disorder Examination-Questionnaire when they begin each module during the program to monitoring their safety and eating disorder symptoms. They will also need to complete Kessler Psychological Distress Scale (K-10) and Therapeutic Mechanism questionnaire. These questionnaires should take approximately 5 – 10 minutes to complete.

*Mid-treatment* – When your child finishes the first 5 modules, your child will be asked to complete questionnaires include EDE-Q, EDI-3 Drive for Thinness subscale, 4 Key Motivational questions, RMQ, DASS-21, Self-harm and suicidality risk assessment, adapted help seeking behaviour questionnaire, EQ-5D-Y-5L Health questionnaire, CIA, Credibility/Expectancy questionnaire and their history of visiting health care professionals. You will be invited to complete the PEDE-Q.

*Post-program* – Upon completion of core modules and also upon completion of optional modules of *SkillED*, your child will be asked to complete the Eating Disorder Diagnosis Scale (EDDS), EDE-Q, 4 Key Motivational questions, DASS-21, EDI-3 Drive for Thinness subscale, Self-harm and Suicidality Risk Assessment, adapted help seeking behaviour, EQ-5D-Y-5L Health questionnaire, CIA, Credibility/Expectancy questionnaire, Negative effects/events questionnaire and program feedback. Together these will take approximately 20 minutes to complete. As their parent/guardian, you will be invited to complete the PEDE-Q. Your child will also be invited to participate in an optional interview (approximately 45 minutes in length) to help us identify areas for further improvement of *SkillED.*

*3-month, 6-month & 12-month follow up* – Your child will be invited via email to complete a follow-up questionnaire to evaluate the long-term impact of the program on their eating disorder symptoms, psychological distress and quality of life. These questionnaires will take approximately 20 minutes to complete. You will also be invited to complete PEDE-Q.

For the questionnaires you and your child will be sent two email reminders for each questionnaire.

*Program usage*

Throughout the study we will also collect analytic information regarding your child's usage of the program, including how much of the program your child completes, time taken, and completion pattern. This information will allow us to understand whether completing more of the course and/or parts of the course results in better outcomes from the program. By consenting to the study, you agree for us to use this deidentified information of your child in the current evaluation study.

**(4) How much of my child's time will the study take?**

Baseline, post-treatment, and follow-up questionnaires will each take approximately 20 minutes to complete, and the weekly questionnaires will take around 5-10 minutes. Therefore, the time taken to complete all program and module questionnaires per the 12-month period will be approximately 6.5 hours.

**(5) Who can take part in the study?**

To take part in this study your child will need to exhibit a clinically significant level of eating disorder symptoms. These symptoms will be determined by our research staff team, who will carry out a clinical assessment with your child over the phone, as part of the screening process. Participants will also need to have access to a computer or digital device with internet connection; not pregnant; living in Australia; not currently suicidal or engaging in self-harm, medically stable; not have experienced rapid changes in weight (loss or gain) and/or are very underweight; not actively engaged in any psychological treatment for eating disorder or disordered eating, and at least 12 years of age.

**(6) Does my child have to be in the study? Can they withdraw from the study once they've started?**

Being in this study is completely voluntary and your child does not have to take part. Your consent or your child's consent will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, Sydney Local Health District or InsideOut Institute for Eating Disorders. You and/or your child can decline consent and your child will be given the option to sign up to be notified upon public release of the program.

Submitting a completed questionnaire is an indication of consent to participate in the study. If your child decides to take part in their study and changes their mind later, they are free to withdraw their responses any time before they have submitted the questionnaire within the three-month course access period. Your child can withdraw their questionnaire data up to the point of submitting their responses. If your child takes part in the follow-up interview, you or your child can contact us at any time up till one month after they complete the interview, and their data will be withdrawn. After this period, their data will be used for analyses.

Your child can withdraw their data by contacting us on 02 8627 5690, or by email at skilledstudy@sydney.edu.au.

If it is noted that your child has not engaged with the program for two or three consecutive weeks, the research staff will contact your child via telephone/email to prompt re-engagement with the study. Following a consecutive period of absence of contact and participation in the study, your child will be considered disengaged. Alternatively, if it becomes apparent during the trial that your child is at risk of severe medical or psychiatric instability, we will advise you and your child to speak to your GP and seek face-to-face counselling and/or medical monitoring. In this case, you may no longer be allowed to participate in the study as other more intensive treatment options are evidenced to be more effective in such situations.

**(7) Are there any risks or costs associated with being in the study?**

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. As a standard GP medical examination is required, we anticipate very little to no physical discomfort and undue stress for your child. However, it is possible that as a result of doing the questionnaires your child may feel some emotional distress. Your child's nominated GP will serve as an appropriate support person who will monitor their risk as frequently as clinically indicated and can be contacted should your child become distressed or upset after or during the questionnaires, or at any time during the program. If at any time your child feels distressed, you or your child can also call the Butterfly Foundation at 1800 33 4673 to get support from an eating disorder specialist, the Mental Health Access Line for NSW at 1800 011 511, or LifeLine at 13 11 14 for crisis support, or by contacting your regular healthcare professional (GP, Psychologist, Psychiatrist).

Although there are no known risks for participating in the study, if your child encounters any difficulties or complications, we recommend that you contact your child's GP who can arrange appropriate help. Your child's GP will be sent a monthly report of your child's medical and psychiatric status to assist with their monitoring of their condition for the duration of the study. If it is indicated through your child's weekly questionnaires that they are at increasing risk of medical and/or psychiatric instability, your child's GP will also be informed. The research staff may contact your child to prompt reengagement with their GP and may also contact your child's GP to ensure that your child is being monitored appropriately. If there are any concerns about your child's safety or well-being, we will contact also you so that you are able to support your child in receiving the care they need. If it is indicated that emergency intervention is required, the research team will contact the appropriate crisis teams.

**Please note: SkillED is an online, self-help program and is not in lieu of medical or mental health treatment. If your child is experiencing significant serious medical and/or psychological symptoms, please speak to a medical practitioner or other health professional to discuss whether SkillED is right for your child.** Whilst your

child is in the study, they will be required to follow their nominated GP's advice regarding ongoing input and/or monitoring they will need from them for the duration of your child's involvement. The responsibility for your child's psychiatric and physical care is between you, your child, and your medical health professional.

Participating in this study will not cost you or your child anything, nor will you or your child be paid.

**(8) Are there any benefits associated with my child being in the study?**

We cannot guarantee that your child will receive any direct benefits from being in the study, however, we hope your child will gain benefits from *SkillED*. We hope this study will provide evidence supporting the effectiveness of *SkillED* and provide directions for ongoing development and improvement of the program's content and delivery.

Participants who have completed and returned their 3-month follow-up questionnaires will gain a chance to win one of the 10 visa gift cards valued at $100 each. Each participant will be assigned with a participant code number. The lucky draw will be conducted using the "Wheel of Names" online platform for a random pick number assigned to each participant. A total of 10 spins will be conducted. The selected number will be removed from the subsequent spin for a fair distribution chance to all participants. Participants will be eligible for the lucky draw if they complete and return all questionnaires at both baseline and follow-up. Participants will still be eligible for the lucky draw prize even if they dropout during the study but return to complete the follow up assessment.

**(9) What will happen to information about my child that is collected during the study?**

The responses to the screening, baseline, mid-treatment, end of treatment and follow-up analytic data and module questionnaires data will be collected via REDCap (Research Electronic Data Capture), a secure web application that ensures all data is encrypted and stored behind a hardware firewall, all accounts are password protected and data is transferred over a secure SSL (HTTPS) secure connection and keyed with a private certificate to ensure all information is fully protected and GDPR compliant. The weekly questionnaire will be collected via the online eClinic platform.

**Confidentiality**

All information that we collect from you and your child during the study will be confidential, and only the researchers that are involved will have access to it. Unique identification codes will be used to protect your child's identity when storing data. Only de-identified health information is given to researchers for healthcare research. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation. Please be assured that your child's and your

identity will not be revealed at any time and that details of individual participants will not be identifiable if data is pooled with other institutions.

**Storage of Data**

Weekly questionnaires and program usage data will be collected via the eClinic platform where *SkillED* is hosted. This data will be stored on the InsideOut-Eating Disorder Research Database (IOI-EDRD) which is a secure, firewall protected web platform that meets all SLHD requirements for online privacy and confidentiality of data. All personal information (i.e., name, date of birth, email address) will be stored in a separate location to participants' responses, which can only be re-identified by a unique identification code to link baseline and future data.

While the study is still active, the information your child and you provide will be stored in a secure network data management system (REDCap) compliant with the University of Sydney Research Data Management Policy for 15 years and then all files will be permanently destroyed in accordance with University policy. The University of Sydney licence for REDCap is hosted on secure and encrypted University-licensed servers within NSW and they meet University standards for security, data ownership and privacy. REDCap projects are backed up automatically on the University of Sydney's servers on a regularly scheduled basis. The backup data files are kept in a secure environment and are available for recovery. REDCap has been approved by ICT as suitable for data classified as "highly protected" under the University's data classifications.

Upon completion of the study, all electronic data and study materials will be downloaded from REDCap and stored on the University's Research Data Store (RDS). The RDS is a secure, enterprise-grade Network Attached Storage Device located within NSW. The RDMP on DashR associated with this project will provide the network path to the RDS folder for this project. All electronic data and study materials will be stored for 15 years and then all files will be permanently destroyed in accordance with the University policy.

Your child's information will be kept strictly confidential, except as required by law. The data will be identifiable only during the data linkage action to link pre and post measures. As part of our data management plan, the identity of each participant (including their registration email address) is maintained in one password protected spreadsheet, with each participant given a unique ID code. The data will then be entered in the main data set identified by the ID code. The questionnaires will be analysed via the deidentified data set in a group format.

To ensure appropriate management of your child's safety, the GP will be sent a monthly report of your child's medical and psychiatric status according to the most recent questionnaires they have completed. The GP may also contact the research staff or be contacted by the research staff and/or send reports of your child's questionnaire scores if there are any concerns regarding their safety. Note that we will always endeavour to speak with you and your child first if we are concerned about your child's safety.

**(10) Can I tell other people about the study?**

Yes, you are welcome to tell other people about the study.

**(11) What if I would like further information about the study?**

When you have read this information, one of our research team members will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please contact us by email at skilledstudy@sydney.edu.au.

**(12) Will we be told the results of the study?**

You and your child have a right to receive feedback about the overall results of this study. It is anticipated that the results of this research study will be published in academic journals and policy documents and be presented at local and international scientific conferences. Results will also be communicated to the wider community through public talks, social media networks and print media, as well as the InsideOut website. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, as we will not use any of your child's personal information as part of this research study. Participants will not be given their individual results but if requested, we will send a copy of the academic publications that emerge from the results of this study.

The development of *SkillED* was funded by the NSW Federal Government, Department of Health.

**(13) What if I have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the approved by the Human Research Ethics Committee - RPAH of the Sydney Local Health District ([X22-0396]). As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, you may contact the Executive Officer of the Ethics Committee, on (02) 9515 6766 and quote protocol X22-0396.

*This information sheet is for you to keep.*