

Skills-Based Online Self-Help Program for Carers of People with an Eating Disorder:
SupportED Program Evaluation

PARTICIPANT INFORMATION STATEMENT

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(1) What is this study about?

You are invited to take part in an evaluation study about the InsideOut Institute SupportED eProgram for Carers of people with an Eating Disorder hosted by InsideOut. The InsideOut Institute is part of the Central Clinical School within the Faculty of Medicine and Health, the University of Sydney, and is a national institute for research and clinical excellence in eating disorders.

InsideOut has launched an online program for carers to address the lack of support and accessible resources afforded for carers of people with eating disorders. We hope by improving access to appropriate knowledge and resources, carers will feel more confident to care for their loved ones.

This study aims to evaluate how useful and practical the InsideOut SupportED eProgram is for Carers. We would like to see how the program supports carers in experiencing less burden and distress, and how it impacts carer's knowledge, willingness, confidence and skill-level in providing care to those they are supporting. We would also like to use the feedback and information gained to inform ongoing development and improvement of the program's content and delivery, and to provide some insight into how suitable online programs and resources for carers are more broadly.

Participation in this research study is voluntary and will provide you with access to SupportED for three months, free of cost, prior to release of SupportED to the public planned for late 2021.

This Participant Information Statement tells you about the evaluation study. Knowing what is involved will help you decide if you want 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.

(2) Who is running the study?

This study is being carried out by the following researchers:

- Dr Jane Miskovic-Wheatley, InsideOut Institute
- Jasmin Schlage, The University of Sydney
- Rachel Simeone, InsideOut Institute
- Dr Sarah Maguire, Sydney Local Health District and InsideOut Institute
- Dr Phillip Aouad, InsideOut Institute
- Eyza Koreshe, InsideOut Institute
- Daniel Rogers, InsideOut Institute
- Danielle Maloney, Sydney Local Health District
- Dr Genevieve Pepin, Deakin University
- Dr Caroline Hunt, The University of Sydney

(3) What will the study involve for me?

SupportED is structured into 5 program modules organised into various topics, such as information about eating disorders, communication skills, practical skills for facilitation recovery and management of emotions and burn out. Whilst the modules are ordered in a linear fashion, all the modules are optional, can be completed in any order, can be skipped if not relevant or repeated as often as desired within the 3-month access you have to the program.

For the evaluation, we will ask that you complete several questionnaires at different times:

SupportED eProgram

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Baseline – Presented at the start of SupportED, this questionnaire should take about 20 minutes to complete and include questions on your demographic and general information, your sense of wellbeing and burden and your general experiences, skill-level, willingness, confidence and knowledge. This questionnaire must be completed to gain access to the program.

Pre and post modules - Before (pre) and after (post) each module you will be asked a set of knowledge questions pertaining to the module, and module feedback, which should take approximately 2 minutes to complete per module.

Post-program – A questionnaire will be presented upon completion of SupportED, or after your 3-month access to the program has ended and ask about your sense of wellbeing and caregiving burden and your general experiences, skill-level, willingness, confidence and knowledge surrounding caregiving, as well as program feedback, and should take approximately 20 minutes to complete.

3-month follow up - You will be invited via email to complete a follow up questionnaire to evaluate the long-term impact of the program on carer's skill-level, wellbeing, confidence, willingness, knowledge and sense of burden. This questionnaire should take approximately 20 minutes to complete.

3-month follow up interview – You will also be invited to participate in a follow up interview which aim to gain in-depth feedback to provide us with a broader understanding of carer's experiences with the program and help to further identify barriers and issues carer's face with engaging in such a program. These interviews will be conducted via phone or via Zoom, with audio recorded, then transcribed verbatim by an external transcription service with identifying information removed. You can elect to be interviewed or not if you consent to this study. This interview will be semi-structured in nature and take no longer than 30 minutes to complete.

For the questionnaires, you will be emailed two reminders for the respective due dates for each questionnaire if questionnaires have not already been completed on invitation. For the interview, you will be emailed one invitation and two reminders pertaining to the interview.

To be eligible to undertake the SupportED eProgram at this point in time we require participants to be willing to partake in the evaluation study. The interview portion of the study, however, is an additional optional component. Alternatively, you can decline consent and you will be given the option to sign up for notifications on the public release of the program.

Program usage

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

(4) How much of my time will the study take?

Each questionnaire is anticipated to take around 20 minutes to complete, and the pre and post module questionnaires will take around 2 minutes per module. Therefore, the time taken to complete all program and module questionnaires over the six-month time period will be approximately 70 minutes. The interview is anticipated to take no longer than 30 minutes.

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(5) Who can take part in the study?

To take part in this study you need to be a carer for a person with an eating disorder, defined as an individual who provides ongoing personal care, support and assistance to someone else who needs it because that other individual is suffering from an eating disorder, and be at least 18 years of age.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary and you do not have to take part. Your responses, or your decision not to participate, will not impact your current or future relationship with the researchers or anyone else from the InsideOut Institute, NSW Health or the University of Sydney, or your access to the SupportED eProgram at the conclusion of the study.

If you decide to take part in the study and then change your mind later, you are free to withdraw your baseline, module and post-course questionnaire data anytime within the three-month course access period. You can withdraw your three-month follow up questionnaire data up until the point of submitting the responses. If you do take part in the follow-up interview, you can contact us any time up until one month after completing the interview and your data will be withdrawn. After this period, all data will be locked for analysis. You can withdraw by contacting Jasmin Schlage on 02 8627 5690 or by email at insideout.research@sydney.edu.au.

(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. If at any time you feel distressed, you can 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, the Carer Gateway at 1800 422 737 for carer specific support or LifeLine at 13 11 14 for crisis support.

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

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

We cannot guarantee that you will receive any direct benefits from being in the study, however, we hope you will gain benefits from SupportED. We hope this study will confirm the effectiveness and sustainability of the InsideOut SupportED eProgram and to provide directions for ongoing development and improvement of the final program content and delivery.

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

Your analytic data and module questionnaire data will be collected via LITMOS, a Learning Management System (LMS) 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.

Your information in the baseline questionnaire, post program questionnaire and 3-month follow up questionnaire will be stored securely in a secure network data management system (REDCap) compliant with the University of Sydney Research Data Management Policy for 7 years and then all files will be permanently destroyed in accordance with University policy. REDCap (Research Electronic Data Capture) is an online data capture tool that will be used to manage the collection and storage of research data for this project. 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,

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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.

Zoom interviews will be secured by creating individual scheduled Zoom Meetings for each participant. Zoom meeting will require a password for entry that will only be provided to the respective participant and researcher with the waiting room function enabled. Audio recordings of the phone/Zoom interviews will be transcribed and deidentified, stored in the University of Sydney's Research Data Store (RDS) in password protected files during the project. Audio recordings of interviews will be sent securely in a zipped password protected folder to a third-party transcription service and the external providers will email back the deidentified transcript project as a Microsoft word document. The identifiable nature of the qualitative follow-up interview will be managed by having an external provider transcribe the interviews whilst removing identifiers (including names) and the interviews will be analysed via the deidentified transcripts only. The deidentified grouped data gathered from the interviews will be analysed by the Eating Disorders Research Team via thematic analysis and reported in presentations and publications.

All electronic data and study materials will be stored on the University's Research Data Store (RDS) during the project. 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 7 years and then all files will be permanently destroyed in accordance with the University policy.

Your 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 will be given an ID code. The data will then be entered in the main data set identified by the ID code. For the follow-up interviews identifiable information (such as names) from the interview will be removed from the audio files prior to being sent to an external party for transcription. The interviews will be analysed via the deidentified transcript.

(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, Jasmin Schlage will be available to discuss it with you further and answer any questions you may have. Jasmin Schlage is a provisional psychologist and study investigator who is undertaking the current evaluation study as part of her Masters project in Clinical Psychology at the University of Sydney. If you would like to know more at any stage during the study, please contact Jasmin on 02 8627 5690 or by email at insideout.research@sydney.edu.au.

(12) Will I be told the results of the 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 via the InsideOut website. In any publication and/or presentation, information will be provided in such a way that you cannot be identified as we will not use any of your personal information as part of this research study. Participants will not be given their individual results but will be send a copy of all academic publications pertaining to this study.

(13) How is this study funded?

Dr Miskovic-Wheatley, Ms Simeone, Dr Maguire, Dr Aouad, Ms Koreshe and Mr Rogers are paid employees of InsideOut Institute, Central Clinical School, Faculty of Medicine and Health, University of Sydney. InsideOut receives financial benefit from those who pay to complete an e-learning course for course administration costs and to fund the future development of e-learning courses.

The evaluation study is not funded and will be conducted by the staff at InsideOut and by Masters of Clinical Psychology candidate Jasmin Schlage, as part of her higher degree at the University of Sydney, supervised by investigators Dr Jane Miskovic-Wheatley and Dr Caroline Hunt.

The development of the SupportED program was funded by a philanthropic donation from the MAST foundation, which is a family organisation which seeks to help the less fortunate and give back to the community through health programs that provide outreach, support or advocacy for sufferers of chronic disease and their carers, medical research that aims to enhance human health and wellbeing, and education, training and employment initiatives assisting children and young people (aged 0-25) in disadvantaged areas of Australia and southeast Asia. The MAST foundation will receive updates around the number of people completing the SupportED eProgram and will be provided with an executive summary of key findings that will be available for publication but will not be provided with any data from the study.

Study researcher A/Prof Pepin is affiliated with Deakin University and has been asked to consult on this study given her strong research experience involving carers of people with mental health disorders. However, there are no other affiliations or conflicts with Deakin University and no data will be sent to Deakin University.

(14) 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). This study has been approved by the Human Research Ethics Committee - CRGH of the Sydney Local Health District. 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 have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee, on (02) 9767 5622 and quote protocol

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number 2020/ETH01779. The conduct of this study at the InsideOut Institute has been authorised by the University of Sydney. Any person with concerns or complaints about the conduct of this study may contact the study coordinator on (02) 8627 5690 and quote the protocol number 2020/ETH01779.

This information sheet is for you to keep