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Participant Information Sheet

Title	**Development of Depression Assist, a psychoeducation website for close family/ friends of adults with major depressive disorder**
Short Title	**Development of a website for family/friends of adults with depression**
Barwon Health ref. no	**17.192**
Project Sponsor	**Barwon Health**
Collaborating Institutions	**Deakin University, Australian Society for Bipolar & Depressive Disorders Ltd and Servier**
Principle Investigator	**Dr Lesley Berk**
Associate Investigators	**Professor Michael Berk, Dr Jerry Lai, Catherine Mazza, Sondita Mein, Anna Wrobel, Madeleine McCallum, Sarah Croce, Anthony Phillips, Lucy Saunders**
Location	**Geelong**

1. Introduction

We aim to develop a useful, easily accessible website resource, Depression Assist for family members, partners and close friends (family/friends) of adults with major depressive disorder. You are invited to help with this research by giving feedback about your views and experience of the site so we can make sure it is acceptable, useful, easy to use and engaging.

This Participant Information Sheet tells you more about this research and the processes involved in taking part. Knowing what is involved will help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with someone you trust. Participation in this research is voluntary. If you don't wish to take part, you don't have to.

You can contact the researchers via phone or email (contact details below), if you have any questions and/or decide you would like to participate. They will explain that you can go onto an Expression of Interest List until the study is ready to start. This means that they will contact you when the study starts and you can decide whether to consent to participate in it then. We expect to begin the study during 2021 as soon as the Depression Assist website is ready for participant feedback.

2. What is the purpose of this research?

Family and friends are often confronted with the major depression of someone they care for without having much information about helpful things they can do to provide support, and deal with the changes they see in the person and their relationship. They often report feeling distressed, worried and alone when the person is depressed. This project aims to evaluate, and if necessary improve, the Depression Assist website, which contains information, and training exercises specifically for family/friends of people diagnosed with major depressive disorder.

The aim is to provide family/friends of people with major depressive disorder with an easily accessible and useful online resource to assist them to:

- Be informed and better understand depression and how it is treated
- Recognise the signs and symptoms of depression and not lose sight of the person behind the condition.
- Find ways to be supportive in their particular situation
- Deal with the changes in their relationship with the person and maintain their own wellbeing
- Be aware of resources and support options for people with depression and their family/friends

To make sure the website is as useful, acceptable, engaging and easy to use as possible, we need your feedback. Your feedback will help to develop the final website, which will then be ready to be tested in a large rigorous trial to see if it is effective in assisting family/friends to carry out their supportive role, reduce their distress and maintain their wellbeing. If helpful, this online resource could be made publicly accessible and potentially make a difference to the lives of both family/fiends and the people with depression they support.

3. Who is conducting this research?

This research is being conducted by Dr Lesley Berk at the Impact SRC in the School of Medicine, Faculty of Health at Deakin University and University Hospital –Barwon, Professor Michael Berk, Dr Jerry Lai, Catherine Mazza, Anna Wrobel, Madeleine McCallum, Sarah Croce, Anthony Phillips, Lucy Saunders and Sondita Mein. It is funded by the Australian Society for Bipolar and Depressive Disorders - Servier Foundation Depression Grant and sponsored by Barwon Health.

4. Who can participate?

To participate you need to be:

- A key support person and relative, friend or partner of an adult with diagnosed major depressive disorder.
- 18 years or over and fluent in English
- Able to access the website and feedback surveys online and be contacted via email and

phone.

- Live in Australia, because some of the information and services are specific to Australia.
- Not too ill (e.g. with a memory problem like dementia) or so depressed that you will not be able to participate and give feedback. PLEASE NOTE: If when the study starts you are temporarily too ill or depressed to participate you are welcome to contact the researchers again when you are well enough to participate. Then, if the study has not closed recruitment you are welcome to contact the researchers again to express your interest in participating.

5. What is involved in participating in the study?

There is no face-to-face contact and the study is conducted online, and via email, phone or post, with the researchers. Participation is independent and private and you will have no contact with other participants.

a) Completing this screening survey

You will be asked to complete a brief screening survey to see if you are eligible to be accepted into this study. If you complete the screening survey, this will imply that you have consented to participate in the study. Thus, before you complete this survey we ask that you read the Plain Language Statement that is attached to the survey, which tells you about the study and participation and feel free to ask the researchers questions so you can make an informed decision about participating. If you complete the screening survey you will be telling us that you:

- Have read and understood the information in the Plain Language Statement, and what is involved in participating, study procedures, risks and benefits and what will happen to the information you provide.
- Freely consent to take part in this study as described in the Plain Language Statement and understand that you are free to withdraw from the project at any time without it affecting your relationship with the researchers, any future participation in research projects or care/treatment you may receive.

The Plain Language Statement and Screening Survey will be available on the DepressionAssist.org homepage when the study starts. We estimate that the screening survey will not take more than **5-8 minutes** to complete and you can access it at the end of the Plain language statement.

The participants who meet the study criteria will be accepted into the study depending upon whether there is a two month window for them to receive the intervention. If you do not meet the study inclusion criteria, you are still welcome to receive a summary report of our findings once the study is over and can simply click “yes” when responding to this question on the screening survey. In addition all participants whether they are accepted into the study or not, can access a ***“resources leaflet”*** that includes contact details of suicide hotlines, and emergency and

community supports if they like.

b) Baseline assessment and website access

If you are accepted into the study you can proceed by clicking "Next" at the end of the screening survey and we will ask you to complete a brief baseline assessment that helps us to put the feedback you provide in context (e.g. demographic questions, how long you have supported the person, if you are their partner, friend or parent). There will also be questions from validated assessment measures about your quality of life, ways of coping, and any psychological distress you may be experiencing. This will help to see if the website brings about any changes in these areas. We do not expect that this baseline assessment will take more than **10 minutes**. Once complete you will be guided to develop your own secure user name and password to access the full Depression Assist website.

c) Interacting with Depression Assist

In order to be able to assess Depression Assist, you will be asked to access the website content when convenient as often as you can over a period of two month. The website includes 6 online modules or sections with information and training tools to help you apply the information to your situation.

The information included in the site was developed from the research and grey literature combined with a consensus study where we asked panels of experienced family/friends of people with major depressive disorder, people with lived experience of the condition and clinicians to rate what information was important to include, and to add comments and suggestions. This information has been adapted to the website by clinicians but we need input from family and friends to make sure it is acceptable, useful, easy to use and engaging.

Once you have completed the introductory session which explains how to use the website, you can access the other seven modules at your convenience. The modules include: 1) What is Depression 2) Causes and Triggers 3) Treatment and Management 4) Providing Support 5) Helping in a Crisis 6) Your Wellbeing 7) Relationships and Communication. You are welcome to contact the researchers if you have any questions or difficulties with the site.

Please note that Depression Assist is not meant to replace any psychological or medical treatment that you or the person with Major Depressive Disorder you care for is currently receiving or may need in the future. It is an online resource specifically aimed at assisting family/friends to be informed and cope effectively when supporting a person with major depression.

d) Giving your feedback

You will be asked to complete two **20-30 minute** online follow-up feedback surveys a month apart (**at 4 and 8 weeks**) while you have access to the site. The first part of each follow-up survey will include questions about your views of the site, whether you found it useful, acceptable (e.g. content is relevant and easy to understand, tone is appropriate and structure and design are acceptable), if it is easy to use and you find it engaging. Questions include a five point scale ranging from, for example, not useful at all to very useful and include the possibility of

rating “unsure” if useful /not. You will also have the option of adding comments and suggestions. You will also be asked what you liked and what you did not about Depression Assist, and any suggestions for improvement. The survey will also ask whether you think the program has helped you gain more knowledge or not, or changed the way you think about or deal with your situation, and whether you have used any of the information or suggestions and would refer the site to others. The second part of the survey will include the same validated measures of quality of life, coping, and psychological distress that you completed at baseline when you first started the study (see 5b) above) to see if there are any changes. You can complete the follow-up surveys at a time that is convenient for you and we will give you up to three reminder messages in case you forget. You can also request to access or change your responses prior to the researchers analyzing the results of the surveys. In order to assess the usability and popularity of the website, we also include objective information gathered from participant’s use of the website. Examples include what aspects of the website you access, when, and for how long.

e) Participant reimbursement
If you complete all the follow-up surveys (two), you will be offered a Coles/Myers voucher for AUD$40 as a gesture of our thanks at the end of the study.

6. Participation is entirely voluntary

Participation in this project is voluntary and if you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project. If you decide not to participate at all, or to withdraw from the project, this will not affect your relationship with any health professionals or researchers, nor any treatment you receive or research programs you join. We ask that if you do withdraw you discuss your reasons with the researchers over the phone and if possible complete a ‘withdrawal of consent form’ via email.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research study can be measured properly. You should be aware that data collected up to the time of withdrawal will form part of the research project results. If you do not want your data to be included, you must tell the researchers when withdrawing and they will ask you to sign a ‘study withdrawal form’. The researchers may end your participation in this research project for any reason that they may feel is appropriate and they will discuss this with you. These may include but are not limited to the very unlikely situation where your involvement in the study interferes with your welfare or if for any reason the study ends prematurely.

7. What are the possible benefits of taking part?

Feedback about Depression Assist from family and friends such as yourself will help to ensure that this online resource, which friends/family can access privately when convenient, is useful to those in similar situations. Helping to develop a program to benefit others in a similar situation can be empowering. You may experience a sense of achievement. In addition, you may find that participating in this project helps you to feel reassured about what you already do to cope. Also,

you may learn more about depression, how to deal with it, provide support, maintain relationships, and enhance your own wellbeing and quality of life.

You may experience positive effects on your own wellbeing and quality of life, coping skills or a reduction in psychological distress (e.g. mild anxiety or depressive symptoms or stress), but as Depression Assist is still under development, we cannot ensure that you will experience any of these benefits. Even if you do not experience any clear benefit from participating in this research, you will still be contributing to the development of the final Depression Assist website. Furthermore, your input will help to improve our knowledge about the needs of family/friends of people with major depressive disorder and what they find helpful when it comes to online programs.

8. What are the possible risks and disadvantages of taking part?

Participation in the project where people are approached as experts to give feedback is likely to be empowering and the website focuses on enhancing wellbeing, but sometimes people may initially experience a little distress or discomfort when they become aware of their problems or difficulties and start to address them, and you may experience this. If you experience any distress feel free to contact the researcher at the contact details above to discuss this and your support options such as community supports, friends or if necessary professional health providers.

Keep in mind that you are welcome to refuse to answer a question/survey and not to participate in anything that makes you feel discomfort or distress. In addition, at the end of the online feedback surveys there is a question that asks whether you feel distressed or upset and whether you would like to be contacted by the researchers to discuss support options.

9. If you are depressed

This feedback study and the Depression Assist website are not designed to treat clinically severe depression or suicidality that may accompany it. Therefore, if a participant (or their relative/friend) becomes very depressed or suicidal, they will need to contact a clinician (e.g. a GP, registered psychologist or your treating doctor), and/or if necessary, emergency services. Nevertheless, as statistics show that some family/friends tend to become depressed themselves, if the researchers become aware that you have become depressed (e.g., from your contact with them, or your responses to the monthly feedback surveys), they will discuss this with you and offer to assist you to get help from a health professional, if you have not already done so. If in this discussion with you the researchers become aware that you are at high or immediate risk of suicide they will act in accordance with their duty of care and contact a treating health professional and/or if necessary triage or emergency services. For this reason all participants are required to give a contact address. In this circumstance they will exchange information with the treating health professional/emergency services regarding their concerns. In these circumstances they will only provide whatever information is essential for your welfare and inform you about this as far as possible. Furthermore, if you are very depressed or suicidal you will be encouraged to take time off from the feedback study to focus on your own health. The researchers will try to

stay in contact with you and you are welcome to return when you feel better, provided the study is still in progress.

10. What will happen to the information you provide?

The information we collect from the assessments and our contact with you (see section 5 above) will be used for the purposes of this research. To safeguard your privacy and confidentiality, details that identify you are removed from the information we collect about you and marked with a code instead of your name. Identifying information is stored separately from all your other information. Your information is stored in secure cabinets under lock and key or password protected files on our secure database. Only named researchers and Barwon Health Human Research Ethics Committee (HREC) will have access to this information, including your identifiable data, in order to run this intervention study and for regulation purposes. Thus, it is possible for the researchers to link the code back to you if necessary (e.g. if we need to contact you during the study). Information gathered from your use of the website will also be securely encrypted and stored. Information that can identify you will remain confidential and only be disclosed with your permission, except as required by law.

Once the study is over, we will analyze the results and prepare a feedback summary that will be sent to you. In this feedback summary and any publications and/or presentations of the results of this project, information will be provided in such a way that you cannot be identified. All names, places, dates or any other identifying information provided by you will be excluded. If we would like to use extended quotes from the feedback you provide in any results, you will first be asked for permission.

Only the data that does not identify you will be used in the future by the researchers on this study in order to conduct further analyses towards better understanding and developing programs for family/friends of people with mental health conditions and online/app programs. Other researchers will need to be approved by the Principle Investigator and the Barwon Health Research Ethics Committee (HREC) in order to gain access to this de-identified data. After the study has been completed, all study-related documents will be stored securely for 5 years in line with national research guidelines, and then destroyed. By completing the study screening survey (see section 5a above) you will be consenting to the research team using the information you provide as described above.

11. Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people, called a Human Research Ethics Committee (HREC). This research study has been reviewed and given approval by Barwon Health Human Research Ethics Committee. This project will be carried out in accordance with the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia.

How do I get more information and/ or put my name down on the Expression of Interest List?

The outline of the research study has been described to you. If you would like more information about the study, have any questions or if there is any matter about it that concerns you, either now or in the future, do not hesitate to contact the research team.

If you have any questions about the study at any time, feel free to contact the researchers:
Dr Lesley Berk: 03 42153324 or Madeleine McCallum: (03) 522 73923.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about rights as a research participant, then you may contact:
Dr Giuliana Fuscaldo
Manager, Office for Research Ph: (03) 4215 3372 Email: gfusca@barwonhealth.org.au