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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, Servier and GMHBA**
Principle Investigator	**Dr Lesley Berk**
Associate Investigators	**Professor Michael Berk, Dr Jerry Lai, Sondita Mein, Anna Wrobel, Madeleine McCallum, Lucy Saunders, Josie O'Donohue, Claire Young, , Beth O'Gorman,** Rose Georgiou, and Kate McSweeney.
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 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.

In addition to the main DA study which involves no more than 30 participants, we are also conducting two small sub-studies:

- A rural sub-study to find out a bit more from family and friends in rural areas who care for people with depression. This sub-study will involve a maximum of 12 participants. Their experience and what they need from Depression Assist may be slightly different from friends and families located in other areas of Australia.
- A sub-study of men, which will involve a maximum of 15 male participants who are key supports for a person with depression. We are interested to learn more about men's experiences with supporting a person with depression and get feedback on how DepressionASSIST meets their needs.

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, Anna Wrobel, Madeleine McCallum , Claire Young, Sondita Mein,

Josie O'Donohue, Beth O'Gorman, ,Rose Georgiou, and Kate McSweeney . The DepressionASSIST study is funded by the Australian Society for Bipolar and Depressive Disorders - Servier Foundation Depression Grant, GMHBA partnership funding 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 providing care for someone who experiences depression in the context of bipolar disorder. PLEASE NOTE: If the person you support has experienced depression in the context of bipolar disorder, the current study may not suit your situation. It is specifically for those who support a person with major depressive disorder. Another of our research studies BipolarASSIST focuses on those who care for a person with bipolar disorder. If you would like more information on BipolarASSIST please contact us by email at bipolarwise@deakin.edu.au or phone 0459 965 545
- 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.

If you would like to also be part of the rural sub-study, in addition to the above criteria to participate you need to live in a medium or small rural town or remote community. For more about the Modified Monash Model classification of rural or remote we use please see the https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm. To check the classification of your or the person you support's address, follow this link https://depressionassist.org/static/MMMsearch.html. Feel free to contact the researchers if you have trouble identifying what we mean by a small rural town or remote community.

If you would like to take part in the male sub-study, in addition to the above inclusion criteria you must identify as male. If live in a rural area and identify as male you are welcome to participate in both sub-studies and you will only need to attend one follow-up interview.

Recruitment will close when we have a maximum of 30 *eligible* and *enrolled* participants who have started the main study including a maximum of 15 men, and 12 *eligible* and *enrolled* participants in the rural sub-study.

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, except for through an optional moderated discussion board.

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 Participant Information Sheet 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 Participant Information Sheet, 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 Participant Information Sheet 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.

When the study starts, the Participant Information Sheet and link to the Screening Survey will be emailed to those who have submitted an expression of interest. 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 Participant Information Sheet.

The participants who meet the study criteria will be accepted into the study depending upon whether there is a three 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, and whether they live in a rural area). There will also be questions from validated assessment measures about your quality of life, ways of coping, wellbeing 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 username and password to access the full Depression Assist website. Then you will be able to start the online DepressionASSIST program once you have read and accepted the Terms of Use and Privacy Statement for using the website. If you are unsure or have difficulty accessing the website or have questions about the Terms of Use and Privacy Statement, you are welcome to contact the researchers.

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 three months. The website includes 7 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.

When you first log in to the Depression Assist program, you will be able to access the Welcome Module which explains how to use and get the most from Depression Assist. You can also discuss this with the facilitator. You will also be able to access the following Modules: 1) Managing Your Wellbeing 2) What is Depression 3) Causes and Triggers 4) Treatment and Management 5) Providing Support, 6) Helping in a Crisis and 7) Relationships and Communication.

You will also have the opportunity to participate in monthly telehealth individual coaching sessions with the facilitators to provide your feedback on the Depression Assist program, assist with any questions you may have about the information and discuss ways it may apply to your situation. In line with good practice, we need to confirm your identity at these telehealth sessions throughout the program, and this will be done privately by the research facilitator. These sessions should not take more than half an hour and can be conducted over Zoom or telephone, depending on your preference. Facilitators are trained and supervised by an experienced clinical psychologist. You are also 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

i) Main study

You will be asked to complete three **20-30 minute** follow-up feedback surveys a month apart (**at 4, 8 and 12 weeks**) while you have access to the site. One part of each follow-up survey will be completed during the facilitation sessions, where you will be asked 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 be asked what you liked and what you did not about Depression Assist, and any suggestions for improvement. The facilitator 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. You will be invited to complete the other part of the survey online and this part includes the same validated measures of quality of life, coping, wellbeing 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 to complete each survey. 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.

ii. Rural sub-study

In addition to the above online feedback surveys, at the end of the three month program, participants in the rural sub-study will be asked to complete a telehealth interview with the researcher to clarify and discuss their feedback with regard to any specific challenges they may encounter in rural areas . The aim of this semi-structured interview is to enrich the survey results and gain a deeper understanding of your views. You can select whether to be interviewed over the phone or via zoom as part of your final facilitation session.

iii. Male sub-study

In addition to the above online feedback surveys, at the end of the three month program, participants in the male sub-study will be asked to complete a telehealth interview. In this interview, participants will be asked about their experiences supporting a person with depression, whether current carer support services address their needs, and their thoughts on whether the DepressionASSIST website addressed their needs (including positive elements of the program as well as what could be improved).

Please note, if you participate in both the rural sub-study and the male sub-study, you will attend one interview where we will ask you questions relating to both sub-studies.

iv. *Interview transcription (Rural and male sub-studies)*
To help the researchers to remember what you have said, we plan to record the final additional rural feedback interview digitally and then transcribe it excluding any identifying information that you may have provided. Both the recording and transcription will be stored securely online in locked files with password protection. The digital recording will be destroyed once it has been transcribed. In the week following your interview you are welcome to ask to review our record of what you said and free to make any changes you like before we conduct our final analysis to see how participants evaluated the program.

e) Participant reimbursement
If you are in the main study and complete all the follow-up surveys (three), you will be offered an online gift voucher for AUD$40 as a gesture of our thanks at the end of the study. Participants in the rural sub-study or male sub-study will also be offered an online gift voucher for $100 for the final additional follow-up interview. Please note, if you are accepted as a participant into both rural and male sub-studies, as you will complete one follow up interview you will be offered an online gift voucher for $100.

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 'revocation of consent 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 and the name of their GP or other health professional and to confirm their (the participant's) location at the start of their telehealth sessions with the facilitator. Only 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, the rural sub-study interview and our contact with you (see section 5 above) will be used for the purposes of this research. To safeguard your privacy and confidentiality, telehealth invitations will be issued via secure Deakin email and include a password that will have to be entered to log into the session and the facilitator will discuss tips for enhancing privacy at the start of each session. The facilitation sessions will not be recorded.

Any details that identify you are removed from the information we collect about you for analysis and marked with a code instead of your name. Identifying information is stored securely using the Health Insurance Portability and Accountability Act (HIPAA)–compliant software, Research Electronic Data Capture (REDCap). If you are in the rural study, transcripts of your final feedback interview that we record will not only use a code for the name of the participant but also delete other names, places, dates, organisations and wording that could reveal any unique identifying characteristic of yourself, or any other person mentioned in your interview. The same will apply to any notes made about you (e.g. by the research facilitator as part of the intervention).

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 on the dedicated study phone line: 0456 755 552

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 the Consumer Liaison Officer, P.O. Box 281, University Hospital Geelong, Bellerine Street, Geelong VIC 3220, (03) 4215 1251, Consumer.LiaisonOfficer@barwonhealth.org.au