Participant Information Sheet & Consent Form

Project: Online Health Monitoring: A large prospective study of major depression in Australia

Researchers:

1) Professor Julio Licinio, South Australian Health and Medical Research Institute (SAHMRI)/ Flinders University
2) Professor Ma-Li Wong, South Australian Health and Medical Research Institute (SAHMRI)/ Flinders University
3) Associate Professor Niranjan Bidargaddi, Flinders University and SA Health, Director goAct.
4) Dr Michael Musker, South Australian Health and Medical Research Institute (SAHMRI)
5) Dr Geoffrey Schrader, Flinders University
6) Mrs Megan Winsall, Flinders University
7) Mr Yang Yang, Flinders University
8) Mr Ville-Petteri Makinen, South Australian Health and Medical Research Institute (SAHMRI)

Brief Summary:
You have been contacted because of your enrolment in the '***Genetics of Risk and Response to Treatment of Depression***' study (APP1086683). You must be aged 18 years and up to 65 years.

We invite you to participate in an online health monitoring study using the goAct application. goAct helps us gather information from you to assist in our research, whilst giving you direct feedback on your health and mood. You can learn more about goAct by visiting this website: http://b-bright.org

We will be gathering information through online surveys and monitoring activity, sleep and other physiological measures using commercially available apps and wearable devices. We will do a combined analysis of this data to find out how depressive disorders start, how symptoms progress over time, and how response to treatments varies in individuals. We hope this research will lead to more personalised and effective treatments in the future.

This project is carried out under the guidelines set out by the National Statement on Ethical Conduct in Human Research and there is certain information we are required to give you. *If you don't understand this explanation, please talk to the research staff.* You may want to discuss this information and your involvement with family, friends or your usual doctor. Once you understand the research and agree to take part, you will need to sign a Consent Form.

PURPOSE OF STUDY

The primary objective of this study is to understand how an individual's past history of mental health and overall brain function (such as memory, logic, and ability to solve puzzles) affect their success in using internet based apps to track and improve health. We will evaluate adults who have registered for the study '***Genetics of Risk and Response to Treatment of Depression***' study (APP1086683) and our research will regularly measure mood, sleep, quality of life and overall brain function using online applications. This will be achieved by asking the participants to join our health tracking software called 'goAct'. By doing this study, we might be able to shape treatment for depression and lifestyle modification programs for individuals who have indicated they have depression.

STUDY PROCEDURE

1. You will be invited to our web page www.B-Bright-org where you will be provided with more information about the work we are doing on depression and mental health. You will be offered the opportunity to join our goAct programme and will be asked to provide us with your email and mobile contact details. To take part in the programme you will join the goAct website and you will initially be asked some basic questions about your physical and mental health. Before you agree to sign up for the website and are given access to the software applications, you will be shown a copy of the consent form. You should read the consent form carefully before proceeding further. Once you have read the consent form press the agree button which indicates that you are consenting to take part in the study and that you understand the information that has been provided to you. You should also note that at any time you want to withdraw from the study, you can email us, or use the online chat facility to indicate your wish to withdraw. Any data that you have provided up until that date will be used unless you indicate that you do not wish the information to be used.

2. Once you have provided your consent to proceed with the online enrolment into the programme, we will then ask you to complete some questionnaires. These include questions regarding your medical history (past and present), use of medication, alcohol and tobacco consumption, and family history of disease. Part of the study involves the completion of a cognitive functioning test called Webneuro, which is a web based neurocognitive test that lasts approximately 45 minutes. This is completed via the internet and involves some questionnaires and puzzles. During the study, this test will be taken at three times across the two years. Most questionnaires will be repeated at 3 monthly intervals i.e. 8 times across the length of the 2 years, allowing us to compare how you have been feeling at different times across the project. The total time for questionnaires will be approximately 30 minutes, and the total time for the web based neurocognitive functioning test will take approximately 45 minutes.

3. You have already provided information and biological samples during your enrolment in the '***Genetics of Risk and Response to Treatment of Depression***' study (APP1086683) and your consent to this study will include allowing us to access this information and samples. You must register with above the study first.

More about your participation:

4. As part of the sign up process we will ask if you would like to provide us with a 'second contact' person. This is optional, but will enable us to get in touch with this second person when you appear to be in some distress.
5. We will ask you to respond to questionnaires to evaluate: i) whether you meet the research criteria for major depression or any other important psychiatric conditions, and ii) my medical history, such as the PHQ9 – a depression questionnaire. This initial questionnaire consists of 9 brief questions about your mood, which enables us to score your overall mood against a scale. This questionnaire is a good indicator of the level of depression that someone has and will enable us to consider what part of the study is best suited to you.
6. The second part of the mental health questions will ask you to complete more detailed questionnaires that will assess i) your mood and anxiety levels, Becks Depression Inventory, the Hamilton Depression Rating Scale and the Hamilton Anxiety Rating Scale and WebNeuro (an online computer test for neurological functioning). All questionnaires will be online. This will take approximately 1 hour and 15 minutes.
7. To enable us to match your health data with your genes, we will need to use the information generated from your biological sample and related information provided in the QIMR Study entitled 'Genetics of Risk and Response to Treatment of Depression' study (APP1086683) and we ask that you enable them to share this information with the SAHMRI Mind & Brain Theme for identification of genes related to the biological pathway of major depressive disorder and related physiological conditions such as obesity, diabetes, and Coronary Heart Disease. All of your information will be kept confidential, and only ever used for research that has been approved by an ethics committee.
8. To enable us to match your past treatment data with your genes, we will need to use the medicare information obtained in the QIMR Study entitled 'Genetics of Risk and Response to Treatment of Depression' study

(APP1086683) and we ask that you enable them to share this information with the SAHMRI Mind & Brain Theme for identification of genes related to the biological pathway of major depressive disorder and related physiological conditions such as obesity, diabetes, and Coronary Heart Disease. Your medicare data will also be requested from medicare at the end of the project to be used to compare any treatments or medications used across the study period. All of your information will be kept confidential, and only ever used for research that has been approved by an ethics committee.

9. As part of this research programme we are asking you to participate in online interactive health programs including the B-Bright and goAct software - Online Depression Intervention and Online Physical activity and exercise Interventions. This involves providing us with snapshots of information about how you are feeling, about your diet, and about your physical activity. This has been simplified by using sliding scales so you can easily provide feedback about your mood and activities.

10. If required, wear and use a health and fitness tracking device which will record my activity, sleep pattern and diet (a Fitbit or common wearable activity tracker, which are widely available to the public). This is not essential to the research, but will help us get a clearer picture of your overall health and activity. Part of depression includes symptoms like not being able to sleep, too little activity, and a tendency to over or under eat. The more information we can collect about your health, the clearer the diagnostic accuracy of our research.

11. We will ask you whether you would be happy to be contacted by the research coordinator throughout the project period to discuss participation requirements, and general queries on health and wellbeing relative to the study. This will also enable us to provide you with prompts and support throughout the programme. You can asked not to be contacted at any point in the research.

12. Depression affects people in different ways, and for some there will be period of remission, or recurrence of symptoms. A key part of our research is to track how it effect participants over time – that time period being 2 years. As part of our time sampling, we will ask you to participate in the 3 monthly data collection periods (8 times throughout the 2 years). This will involve repeating a number of the questionnaires again, and to complete the separate Webneuro test, which will occur 3 times in total across the 2 years. Essentially taking less than 1 hour every 3 months completing the online questionnaires. As part of the 3 monthly assessment, we will ask you to provide a daily snapshot each day for 2 weeks. This snapshot will take no more than 3 minutes per day.

13. Time commitment:

Initial assess	3month	6month	9month	1 year	3month	6month	9month	2 year
Web neuro				Web neuro				Web neuro
PHQ9 Becks, HAM A HAM D	PHQ 9	PHQ 9	PHQ 9	PHQ9 Becks, HAM A HAM D	PHQ 9	PHQ 9	PHQ 9	PHQ9 Becks, HAM A HAM D
subtotal = 1hr 15m	Subtotal = 5 min	Subtotal = 5 min	Subtotal = 5 min	subtotal = 1hr 15m	Subtotal = 5 min	Subtotal = 5 min	Subtotal = 5 min	subtotal = 1hr 15m
Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min	Plus 2 weeks at 3 min per day = 42 min
Total = 1hr 57m	Total = 47 min	Total = 47 min	Total = 47 min	Total = 1hr 57m	Total = 47 min	Total = 47 min	Total = 47 min	Total = 1hr 57m

Feedback

We will not provide any individual results from the overall study to you nor family members. There will be graphs that you can follow as part of the goAct application that will assist you in tracking your health. We recommend that your first course of action would be to contact your general practitioner (G.P). If you have concerns about your health here is a website that will provide you with information about some useful services http://b-bright.org/support-services/.

To take part in this study, it is essential that you have access to a device capable of accessing the internet.

We will keep you informed, if you would like us to do so, should we have any news regarding the overall results of the study.

14. POTENTIAL RISKS AND DISCOMFORT

Although very uncommon, there is a risk that you may become distressed if asked to recall particular experiences. If that happens, you may wish to access Lifeline (Tel. 13 11 14 or http://www.lifeline.org.au/) for counselling, without needing to contact us. At any time during the study you can ask to stop or to withdraw completely.

Your general practitioner (G.P) is able to help and can make referrals to specialist mental health services. There is also assistance you can obtain in a mental health emergency, contact the mental health triage service - telephone 13 14 65 available 24 hours, seven days a week. These are some of the highly specialised services in mental health:

Counselling and other useful support services:

- beyondblue - telephone 1300 224 636 http://www.beyondblue.org.au/
- Salvo Care Line: 1300 36 36 22 http://salvos.org.au/salvocareline/
- Crisis Support Services - on line help http://www.ontheline.org.au/
- Kids Help Line - telephone 1800 55 1800 http://www.kidshelp.com.au/
- Lifeline - telephone 13 11 14 https://www.lifeline.org.au/
- Mensline - telephone 1300 789 978 http://www.menslineaus.org.au/
- Relationships Australia - telephone 1300 364 277 http://www.relationships.org.au/
- Sane Australia - telephone 1800 187 263 http://www.sane.org/
- Veterans and Veterans Families Counselling Service - telephone 1800 011 046 http://www.dva.gov.au/health_and_wellbeing/health_programs/vvcs/Pages/index.aspx
- Suicide Call Back Service - telephone 1300 659 467 https://www.suicidecallbackservice.org.au/

Other Useful Links:

- Headspace http://www.headspace.org.au/
- Blue Pages http://www.bluepages.anu.edu.au/help_and_resources/state_by_state/sa/
- Health Consumers Alliance http://www.hcasa.asn.au/
- KidsMatter http://www.kidsmatter.edu.au/
- The Mental Health Coalition of SA http://mhcsa.org.au/
- Mental Illness Fellowship of SA http://www.mifellowship.org/
- Mind Matters http://www.mindmatters.edu.au/

- Multicultural Mental Health Australia http://www.mhima.org.au/
- One Voice Network http://www.onevoicenetwork.websyte.com.au/

15. ANTICIPATED BENEFITS

This research may or may not benefit society; we will be able to identify changes in mood, quality of life and brain function according to your performance and feedback on the online applications. These applications give you direct feedback, but also a cumulative picture of your health status. We will use the data provided to link with your genes, and whilst this will not benefit you directly, it will help us work toward identifying individual genetic factors that affect depression.

16. FINANCIAL OBLIGATION

The study doctor, Dr. Licinio, and SAHMRI have no financial responsibility for additional treatments that you may need that is not directly involved with this study.

17. POSSIBLE COMMERCIAL PRODUCTS

If a commercial product is developed from this research study, SAHMRI or its designee intends to claim ownership of the commercial product. There are no plans for you to profit financially from such a product.

18. EMERGENCY CARE AND COMPENSATION FOR INJURY

If, as a result of your participation in this study, you become ill or are injured, immediately advise your study contact of your condition. In the first instance your study contact will evaluate your condition and then discuss treatment with both you and your regular treating doctor. Since you are participating in a non-sponsored study/investigation any question about compensation must initially be directed to your study contact who should advise their insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.

19. PRIVACY AND CONFIDENTIALITY

Participating in this study involves using third party web applications goAct. goAct is a third-party software that collects health data from you. Some of our research team members might also interact with you using the chat and reminder functionalities of goAct application. You should read and familiarise yourself with its policies (http://goact.co/privacy.php, http://goact.co/terms.php) before you activate the goAct account, as by participating in this study means you accept the policies of goAct application. You might also choose to use other optional third party applications linked to the goAct applications such as Fitbit. Here is a complete list of those applications - http://b-bright.org/personal-apps/.

Each of these applications also have their own policies and if you wish to use any of them, you should familiarise yourself with their policies by visiting their websites.

Our research team will download your information from goAct application and remove your identifiable details before making it available for analysis purposes. The methods by which SAHMRI researchers access and use this information are outlined here: https://test.goact.co/mint/register-sahmri.seam

All identifiable data will be kept in locked files, and subjects will be identified only by codes when the data gathered in this procedure is presented or published. Only the Principal Investigator, Professor Julio Licinio, will have access

to a password-protected file linking the codes to your identifiable personal information. Data will be stored for at least 5 years after the study is completed.

Only Professor Licinio will be able to re-identify your information by accessing a password-protected file linking the code to your personal information.

20. PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty or loss of benefits to which you are entitled.

If you decide to withdraw from the study, you should understand that all information already collected from you would not be cancelled or deleted. If you desire, you may also withdraw your data, which will then be deleted.

The researchers may withdraw you from participating in this research study at any time, without your consent, if circumstances arise which warrant doing so.

21. NEW FINDINGS

During the course of the study, if you choose to, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might change your decision to be in the study. If new information is provided to you, your consent to continue participating in this study will be re obtained.

Your treating Doctor/s will be notified of your participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

22. QUESTIONS

Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone from the study team or with family, friends or your personal physician or other healthcare professionals. Some people have personal, religious or ethical beliefs that may limit the kinds of medical or research studies they would want to be involved with. If you have such beliefs, please discuss them with your study doctors or members of the research team before you agree to the study. You should read all the information above, and ask questions about anything you do not understand, before deciding whether or not to participate.

In the event of a research-related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact:

Michael Musker, Ph.D.
SAHMRI, North Terrace
Adelaide, SA 5000.
Phone: +61 8 8128 4714 or a member of the Mind & Brain Team on 8128 4000

A list of counselling services and other supports have been listed above.

Do not sign the consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to enrol in this study, you will be given a signed and dated copy of this consent form.

23. **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study.

24. **FUTURE CONTACT**

By signing the consent form, you agree to participate only in the study described here. After this study is completed, we may recontact you to participate in other future studies. At the bottom of this consent, are asking your permission to contact you at any time for follow-up reasons, and you may choose not to give us permission. This will not compromise the present study.

If in the course of those future contacts we discuss the possibility of participation in a new research study, we would provide you with a new consent form.

25. **Re-imbursement**

There will be no payment for participation in the study. An incentive of $50 Coles / Myer Voucher will be provided upon the completion of the 2 year study for participants who have participated for the full course of the study.

You can read more about the facility at our website: www.Sahmri.com

If you would like more information about this study, now or later, you can contact Dr Michael Musker on (08) 8128 4714 / or 8128 4000 or email michael.musker@sahmri.com

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

26. Terms of Consent

I acknowledge that the nature, purpose and risks of the research project and alternatives to participation have been provided in the participation information sheet.

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been provided to me.

I freely agree to participate in this research project according to the conditions in the Participant information Sheet which I confirm has been provided to me.

I understand that my involvement in this study may not be of any direct benefit to me.

I have been given the opportunity to discuss this with a member of my family or another person.

I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.

I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed, unless I state otherwise.

I am 18 years of age or over and under 65 years of age.

I consent to participating in the following procedures:

1. To respond to questionnaires to evaluate: i) whether I may meet research criteria for major depression or any other important psychiatric conditions, and ii) my medical history, such as the PHQ9 – a depression questionnaire.
2. To complete more detailed questionnaires that will assess i) my mood and anxiety levels, Becks Depression Inventory, the Hamilton Depression Rating Scale and the Hamilton Anxiety Rating Scale and WebNeuro (an online computer test for neurological functioning). All questionnaires will be online.
3. To allow my biological sample and related information provided in the QIMR Study entitled 'Genetics of Risk and Response to Treatment of Depression' study (APP1086683) to be shared with the SAHMRI Mind & Brain Theme for identification of genes related to the biological pathway of major depressive disorder and related physiological conditions such as obesity, diabetes, and Coronary Heart Disease.
4. To participate in online interactive health programs including the B-Bright and goAct software - Online Depression Intervention and Online Physical activity and exercise Interventions.
5. If required, wear and use a health and fitness tracking device which will record my activity, sleep pattern and diet (a Fitbit or common wearable activity tracker, which are widely available to the public).
6. If required, be contacted by the research coordinator throughout the project period to discuss participation requirements, and general queries on health and wellbeing relative to the study.
7. To participate in the 3 monthly data collection periods (8 times throughout the 2 years). This will involve repeating a number of the questionnaires again, and to complete the separate Webneuro test, which will occur 3 times in total across the 2 years.
8. To use the medicare information obtained in the QIMR Study entitled 'Genetics of Risk and Response to Treatment of Depression' study (APP1086683) and it may be shared with the SAHMRI Mind & Brain Theme for identification of genes related to the biological pathway of major depressive disorder and related physiological conditions such as obesity, diabetes, and Coronary Heart Disease. My medicare data will also be requested from medicare at the end of the project to be used to compare any treatments or medications used across the study period.

I do understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage before the "code key" link between my personal information and my research data is removed, and if I withdraw my consent it will not affect my rights or the responsibilities of the researchers in any respect. There will be a temporary link between my personal data and my research data after which that link will be removed and data stored in a key-coded format; which means that following the research my identity will no longer be linked to my research data. So the research data will effectively be anonymous.

I do understand that whilst the online applications will give me feedback, I will not be able to receive my individual results in relation to the research findings.

I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

I do understand that this study has been reviewed and approved by Bellberry Ltd Human Research Ethics Committee (HREC) and it is my right as a participant, to contact Bellberry Ltd HHREC on (08) 8361 3222/ email: bellberry@bellberry.com.au if I have concerns, complaints or queries about the conduct of this study I wish to discuss with someone not directly involved in the study.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

I declare that all my questions have been answered to my satisfaction.

I have read and I understand the Participant Information Sheet & Consent Form, v1 19-6-15.

You will be asked to accept that you have read and understand this participant information sheet and consent form as part of the online enrolment to the goAct software.

From time to time, other researchers at the SAHMRI conduct online studies on other health related topics. Participation in any of these studies would be completely voluntary, and you may choose not to participate in any or all of these studies. Would you like to be contacted about participating in other studies in the future?

NB: This information will be provided online and an electronic agreement will be obtained to accept that the information and consent has been provided. It will also require registration with the QIMR for participants are eligible to this study. More information can be found at the following websites:

www.B-Bright.org.

http://www.qimrberghofer.edu.au/page/Our_Research/Research_Programs/Mental_health_complex_disorders/Depression/