*Thank you for participating in the **MUMentum Postnatal Study** last year!*

It has been about 12 months since you completed our research study and we were wondering how you were going since completing the course.

*These 12-month follow-up questions should only take about **5-10 minutes** to complete and will be very helpful for us in revising and improving the program for other mothers!*

We have provided the Participant Information Statement & Consent Form below again, in case you would like to read about the study again. You have already consented when you joined up last year. So we just need you to re-enter your Full Name and Email Address below to continue to the follow-up questions.

If you have any questions, please contact us at research@thiswayupclinic.org

St Vincent's Hospital

The Clinical Research Unit for Anxiety & Depression
Anxiety Disorders Clinic
Level 4, O'Brien Centre
T + 61 2 8382 1400
F + 61 2 8382 1402

www.crufad.org
www.virtualclinic.org.au

Participant Information Sheet/Consent Form

Title	A Randomised Controlled Trial (RCT) of an internet Cognitive Behavioural Therapy (iCBT) program for the treatment of perinatal anxiety and depression: The MUMentum Program – Study 2
Short Title	Perinatal MUMentum Program RCT – Study 2
Protocol Number	8
Project Sponsor	St Vincent's Hospital, Sydney
Coordinating Principal Investigator/ Principal Investigator	Dr Alison Mahoney
Associate Investigator(s)	Ms Siobhan Loughnan Dr Jill Newby
Location	St Vincent's Hospital, Sydney

Part 1 What does my participation involve?

1 Introduction

You are invited to participate in a research study evaluating the effectiveness of a new online program (The MUMentum Program) in reducing anxiety and depression in women during the postpartum period (i.e., up to 12 months after childbirth). In order to be eligible to participate in this study you need to be currently in the postpartum period (i.e., up to 12 months after childbirth) and experiencing elevated symptoms of anxiety and/or depression. Your anxiety and depression symptoms will be assessed during the online application.

This Participant Information Sheet tells you about the research project. It explains what the study involves, and will help you decide if you want to take part in the research before applying online

Please read this information carefully. You will be asked if you would like to ask questions about about the study before you consent to apply. Before deciding whether or not to take part, you might also want to talk about it with a relative, friend or your local doctor (GP).

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in this study, you will be asked to type in your full name and click the 'Yes, I consent' button to proceed with your application. By typing your full name you are telling us that you:

- Understand what you have read in this Participant Information Sheet
- Consent to take part in the application process, and if eligible, become a participant of the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

Remember to contact the research team before providing your consent, if you have any questions about the study. You can do this by emailing research@thiswayupclinic.org.au) or select the button at the bottom of the consent page to send VirtualClinic an email with your query. Once you have consented, you will be emailed a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

This research has been initiated by Professor Gavin Andrews, Ms Siobhan Loughnan, and Dr Jill Newby from the Clinical Research Unit for Anxiety and Depression (CRUfAD), Sydney and has been developed in collaboration with leading perinatal experts Professor Jeannette Milgrom from the Parent-Infant Research Institute (PIRI) in Melbourne, and Professor Marie-Paule Austin at the Royal Hospital for Women in Sydney. The study is being conducted at St Vincent's Hospital, Sydney and is funded by HCF Research Foundation.

Online treatment options for anxiety and depression during the postpartum period are an important area of investigation, as not everyone who experiences anxiety and/or depression wants to, or needs to, visit a mental health professional (e.g. psychologist) for face-to-face therapy. CRUfAD have demonstrated in over 25 research trials that online cognitive-behavioural therapy (iCBT) interventions are effective for mild to severe anxiety and depression in the general population. If effective, this program will increase the accessibility of evidence-based, perinatal-specific treatment for women experiencing anxiety and/or depression, particularly for those in rural and remote areas whose access to psychological treatments may be limited.

The purpose of this study is to assess whether our new online program is useful and helpful for people who are currently experiencing postpartum anxiety, depression, or both. Our new program is a self-management course teaching women the skills to manage their anxiety and depression, and how to incorporate these new skills in their daily life.

The results of this research will be used by the study researcher, Ms Siobhan Loughnan to obtain a Doctor of Philosophy (PhD) degree at the University of New South Wales (UNSW), Sydney under the supervision of Professor Gavin Andrews and Dr Jill Newby.

3 What does participation in this research involve?

If you agree to participate, you will be asked to provide online consent to participate in the application process and if eligible, the research study, by typing your full name and clicking the 'Yes, I consent' button at the bottom of the consent page that follows this section.

If you consent, you will be asked to provide your personal contact details (e.g. name, address, phone number) and answer a few initial questions to see if you are suitable to apply for this study (e.g. 18 years of age or older). You will then be asked to provide your GP contact details. As your safety is very important to us, your GP contact details are required in order to proceed with the online application. We will only contact your GP in writing (via letter) if we are concerned about your safety. We will also contact your GP if you are accepted into the study as

a participant, just to let them know that you are participating in our trial and to provide some general information about the MUMentum program and if you have not accessed the program within 14 days of being enrolled in the study. Once you have provided your GP information, you will proceed to the online questionnaire which will enquire about your current and past mental health, and your obstetric history.

If you do not meet our criteria during the online application, you will be notified on-screen and provided with information on where you might be able to seek further support. Some applications will require more information to determine your suitability for this study, and you will be notified of this at the end of your application on-screen and via email. If more information is required a VirtualClinic staff member will contact you via telephone to ask a few more questions. After this telephone interview, the VirtualClinic staff member will accept you into the study or redirect you to more appropriate care.

At the end of the online application (or telephone interview), if you are eligible to participate, you will be accepted into the study as a participant. As this is a "randomised controlled" project, you will then be randomly allocated to a study group. This is a very important part of the study. Randomised controlled projects are conducted in order to find out if one treatment option is better than another treatment option. To do this fairly, people are randomly put into groups to receive a different treatment and the results are compared to see if one is better. In this research study, we are comparing participants who complete an online treatment program to those who just access their usual care. If you agree to participate, you will be randomly allocated to either Group 1, who will receive the online treatment program immediately; or to Group 2, who will wait 11 weeks before accessing the treatment program. To ensure the groups are similar, a computer will randomly allocate each person into a group, like the flip of a coin. There is a 1 in 2 chance you will be allocated to Group 1, who receives the treatment program immediately. Neither the researcher nor the participant can decide which group you will be placed into.

Group 1 – The MUMentum Program: Postpartum

CRUfAD at St Vincent's Hospital, Sydney has developed an online program for adult women in the postpartum period (i.e., up to 12 months after childbirth) who are experiencing anxiety and/or depression. If you are allocated to this group, you will complete the postpartum MUMentum program, which is based on traditional cognitive behaviour therapy (or CBT), known to be helpful in treating both anxiety and depression.

C	=	Cognitive	=	Thoughts or ways of thinking
B	=	Behavioural	=	How we act or respond
T	=	Therapy	=	A way of helping someone

If you are allocated to this group, you will complete the MUMentum Postpartum Program over 6 weeks via our secure website, www.virtualclinic.org.au. A username (your email address) and password is required for you to access the online program, and you will be emailed details about how to do this. Participation does not require high levels of computer training but does require basic computer skills in order to access the lessons and activities. Each time you log on to the website to complete a lesson, we will take that as a sign of your continued consent to participate

The MUMentum Postpartum program is a 3-lesson illustrated story of two women, who learn how to manage their symptoms of anxiety and depression during the postpartum period. Each lesson includes lesson slides which introduce you to the key concepts and skills, and a lesson summary which provides more detailed information about the lesson and activities for you to complete. We recommend you spend approximately 3-4 hours per week reading the lesson slides and completing the lesson summary activities from your home, or wherever you prefer. We've found that people who get the most out of our programs spend about 3-4 hours a week reading and completing the exercises and activities, and applying the new skills they're learning on a daily basis. Below is an outline of The MUMentum Postpartum program:

Lesson 1: Learning About Postpartum Anxiety & Depression
Lesson 2: Identifying & Tackling Thoughts, and Unhelpful Thinking Patterns
Lesson 3: Tackling Unhelpful Behaviours & Building Confidence

As part of the MUMentum Program, you will also complete three sets of key questionnaires (which will take about 10 minutes to complete). This is a very important part of the study as it allows us to assess if the treatment program is effective. These questionnaires will need to be completed at Week 1, Week 7, and Week 11. For example, in Week 1 you will log on to www.virtualclinic.org.au and complete your first set of online questionnaires before starting Lesson 1. You will then have 6 weeks to complete the 3 lessons, with one lesson becoming available every two weeks (i.e., Lesson 1 available in Week 1; Lesson 2 available in Week 3; Lesson 3 available in Week 5. When you access Lesson 2 and 3, you will only be asked to answer a few questions (will take about 5 minutes to complete) before starting the lesson.

One week after your program has finished (Week 7), you will be asked to complete your second set of questionnaires (which will take about 10 minutes to complete). Access to the program via www.virtualclinic.org.au will finish at Week 7. If you complete all three lessons within the six-week time period and your post-treatment questionnaires (in Week 7), you will be provided an additional 4 weeks access to the program via the VirtualClinic. You will then be asked to complete a third set of online questionnaires in Week 11. To help you complete the lessons within this timeframe, we will monitor your progress throughout the program and will contact you by e-mail or phone if we notice you haven't accessed the lessons in more than 7 days. There will be an additional follow-up questionnaire emailed to participants12 months after completion of the program.

Completing questionnaires is an important aspect of participating in a research study. They help us monitor your progress through treatment, make informed decisions about your treatment, and they provide us with valuable information necessary to evaluate and improve the treatments we offer. If you decide to apply for this study, we kindly ask that you are willing and committed to completing these questionnaires. If you are not willing to complete the study questionnaires you may withdraw your consent to participate in this study by emailing research@thiswayupclinic.org.au. **The total time commitment for participants in Group 1 is 11 weeks.**

At conclusion of the research study, if you have completed all 3 lessons within the six-week period, and you have completed all 3 sets of questionnaires at Week 1, Week 7, and Week 11 (excluding 12 month follow-up questionnaire), you will be provided with login details to the Perinatal MUMentum website, where both the pregnancy and postnatal course content and resources will be available for you to access.

Group 2 – Control Group
If you are allocated to this group, you will be the part of the control group for the study. This is an important aspect of the study as it allows us to determine whether the treatment program is more effective at managing anxiety and depression than your usual postpartum care. You will be provided with login details to the VirtualClinic where you will complete three sets of questionnaires (which will take around 10 minutes to complete) at three time points: Week 1, Week 7, and Week 11.

Completing questionnaires is an important aspect of participating in a research study. If you are not willing to complete the study questionnaires you may withdraw your consent to participate in this study. **The total time commitment for participants in Group 2 is 11 weeks.** As soon as a questionnaire is available on VirtualClinic, we will email you to ask you to complete this questionnaire as soon as possible (with a reminder email being sent one week later, if you have not completed them). It is important that each set of questionnaires is completed within two weeks as this is a short research trial. At the end of the 11-week waiting period if all 3 sets of questionnaires have been completed, you will be provided with login details to the Perinatal

MUMentum website, where both the pregnancy and postnatal course content and resources will be available for you to access.

Note: This study aims to further medical knowledge and we anticipate that most people who complete the program will benefit, however it may or may not directly benefit you. Participation in this study will not cost you anything other than costs associated with using your computer or accessing the internet. You will not be paid.

4 What do I have to do?

For this research study you are required to access and complete the treatment program and questionnaires online. In order to participate, you will need to have regular access to a desktop computer (the program is not compatible with tablets or smartphones), reliable internet connection, and printer. Participants allocated to Group 1 (treatment program) will be required to spend 3-4 hours per week reviewing the lesson content and practising the skills.

Any medications and treatment that you are already receiving for your anxiety and depression can continue during the course of the research trial. All participants will have full access to their general practitioner and perinatal care team throughout the course of the study.

5 Other relevant information about the research project

For this research study, we will recruit approximately 80 people who will be randomly placed into Group 1 or Group 2. The study will be conducted by the study researchers at St Vincent's Hospital, Sydney.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. 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 at any stage. If you do decide to withdraw, you need to let us know via e-mail that you do not wish to continue participating in this study.

If you do decide to apply for this study, you will need to provide consent before proceeding to the online application. You will be emailed a copy of this information sheet for your records once you consent. You can also download or print this information sheet from the online application page.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with St Vincent's Hospital or the UNSW.

7 What are the alternatives to participation?

Participation in this study is not intended to replace your standard assessment or treatment. Participation in this study is not your only option. You should discuss standard care options available to you, with your GP and/or perinatal care team. Please note that you can withdraw from this study at any time without prejudicing your relationship with St Vincent's Hospital, Sydney.

8 What are the possible benefits of taking part?

This study aims to further medical knowledge and may improve future treatment of anxiety and depression during the perinatal period. However it may or may not directly benefit you.

9 What are the possible risks and disadvantages of taking part?

There are no known risks associated with taking part in this study. If you have concerns during or following participation in this study, you may direct them to a member of the research team who will arrange appropriate assistance.

10 What will happen to my results?

We plan to publish the results in peer-reviewed journals, at presentations and conferences, or in other professional forums. Individual results will not be analysed. In any publication, information will be provided in such a way that you cannot be identified as a participant. Please let the researchers know if you would like to be personally informed of the research results. Results may also be discussed with the Human Ethics Research Committee (HREC) for monitoring purposes.

Please note, all applicants and participants that report that they have been referred to this study by Geelong Hospital (last question of application) will have their application and trial outcome data included in the non-identifiable dataset that will be provided to the Geelong Hospital Obstetric Unit at conclusion of the trial. No identifying information will be included (e.g. name, phone, address etc.). If you do not wish to have your data included in this file, please do not select 'referred by Geelong Hospital' during your application.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the researchers will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the researchers will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study clinician might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important during the application process, to tell the research team about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also contact the research team and supervising clinician about any changes to other treatments you are receiving during your participation in the research project.

13 What if I withdraw from this research project?

Participation in this study is voluntary. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason by contacting the research team via email (research@thiswayupclinic.org) or phone (02 8382 1400).

If you do withdraw your consent during 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 and comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research study results.

14 Could this research project be stopped unexpectedly?

We cannot think of any reason why this research project will need to be stopped before completion. If it does need to be stopped we will contact you via email or phone. We will also provide information on where to seek further help with your mental health such as your local GP, or perinatal care team.

15 What happens when the research project ends?

At the end of the research study, the effectiveness of the treatment program in reducing anxiety and depression will be evaluated. The program will not be available for public use until results have been finalised. At the end of the treatment program, clinicians in CRUfAD can direct you to alternative resources should additional assistance for managing your anxiety and/or depression be required. Please let the researchers know if you would like to be personally informed of the research results.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By consenting, you agree for the researchers to collect and use personal information about you for the research project. Any identifiable information that is collected about you (i.e., an email address, phone number) in connection with this study will remain confidential. All data will be lodged in our secure electronic database and in your research trial medical record which is maintained by St Vincent's Hospital as a confidential document. Only the researchers will have access to your details which will be held securely at St. Vincent's Hospital for 15 years before being permanently destroyed. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Individual participant results will not be analysed, only group data.

17 Complaints and compensation

There are no known risks for participating in this study. If there are difficulties or complications you should contact the study clinician or your GP who will arrange appropriate help. To ensure your safety, we are asking all participants to provide us with the contact details of their GP. This is so we can contact them if we have any concerns for your safety. We will not contact them under any other circumstances and will always endeavour to speak with you first.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

This study has been approved by St Vincent's Hospital HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 8382 2075 and quote (HREC/16/SVH/63).

18 Who is organising and funding the research?

The study is paid for by a HCF Research Foundation Grant awarded to the Clinical Research Unit for Anxiety and Depression, UNSW at St Vincent's Hospital. No money is paid directly to individual researchers.

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital, Sydney.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

When you have read this information, you are welcome to contact the researchers, Dr Jill Newby or Ms Siobhan Loughnan. If you would like to know more at any stage, please do not hesitate to contact the researchers.

Clinical contact person

Name	Dr Alison Mahoney
Position	CRUfAD Director
Telephone	02 8382 1400
Email	alison.mahoney@svha.org.au

Clinical contact person

Name	Dr Jill Newby
Position	Clinical Research Director
Telephone	02 8382 1400
Email	j.newby@unsw.edu.au

Research Study contact person

Name	Ms Siobhan Loughnan
Position	Researcher
Telephone	02 8382 1400
Email	Siobhan.Loughnan@svha.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Local HREC Office contact (Single Site - Research Governance Officer)

Position	Research Governance Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Thank you for taking the time to consider this study.

If you wish to take part in this study, please continue to the consent form on-screen.
After you consent, you will be emailed a copy of this information sheet to keep for your records.

Consent Form - *Adult providing own consent*

Title	A Randomised Controlled Trial (RCT) of an internet Cognitive Behavioural Therapy (iCBT) program for the treatment of perinatal anxiety and depression: The MUMentum Program – Study 2
Short Title	Perinatal MUMentum Program RCT – Study 2
Protocol Number	8
Project Sponsor	St Vincent's Hospital, Sydney
Coordinating Principal Investigator/ Principal Investigator	Dr Alison Mahoney
Associate Investigator(s)	Ms Siobhan Loughnan Dr Jill Newby
Location	St Vincent's Hospital, Sydney

Declaration by Participant

1. I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
2. I understand the purpose and aim of the research study, why I have been selected, the nature of my participation, and the possible risks and benefits.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
5. I freely agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Alison Mahoney, Dr Jill Newbyor Ms Siobhan Loughnan on (02) 8382 1400, and complaints may be directed to the St Vincent's Hospital Research Office on (02) 8382 2075.
7. I understand that I will be emailed a copy of this document to keep.

Yes, I consent

I do not consent

Name of Participant:_____