

Participant Information Sheet – General (Unspecified)

Project Title: Mixed-methods single-arm repeated measures study evaluating the feasibility of massage as an adjunct approach to care for pregnant women who have experienced a stillbirth

Project Summary: You are invited to participate in a research study being conducted by Dr Sarah Fogarty, School of Medicine, Western Sydney University, Professor Phillipa Hay, School of Medicine, Western Sydney University, Professor Alexander Heazell, Maternal and Fetal Health Research Centre in the School of Medical Sciences, University of Manchester and Associate Professor Munk, Acting Chair School of Health and Human Sciences, Department of Health Sciences, Indiana University. Research shows that women experiencing pregnancy after stillbirth experience anxiety, fear, and depression. There is a limited evidence of adjunct emotional care approaches for women to utilise to help manage pregnancy after a stillbirth. Massage may assist women who are pregnant after a stillbirth via decreasing anxiety, worry and stress. The study aims to measure the feasibility of massage as an adjunct approach to care for pregnant women who have experienced a stillbirth.

How is the study being paid for? The study is being funded by a Research Support Grant from The Massage Therapy Foundation.

What will I be asked to do?

You will be asked to attend between four and five massage appointments in a four-month period. The massage treatments, as part of the study, are provided to you at no cost. Prior to your first appointment and after your last appointment you will complete questionnaires on worry (Cambridge Worry Score), anxiety (Generalized Anxiety Disorder Assessment (GAD-7)), coping (Revised Prenatal Coping Inventory), self-efficacy (Strategies Used by People to Promote Health measure) and stress (Perceived Stress Scale). You will also be asked to complete an online questionnaire on empathy (Consultation and Relational Empathy (CARE) measure) and a post intervention questionnaire after the last massage treatment.

Some individuals will be asked to participate in an in-depth interview about your experiences about the massage treatment you received as part of the study. The interview will be recorded and transcribed. The interview will take place at a time that is convenient to you and will be conducted over the phone/online meeting. You will be given a false name (pseudonym) for the data that is reported, so that your data can't be identified from your information.

How much of my time will I need to give?

The total time for the project is estimated to be 5 hours plus travel time to the appointment. This includes 4 x 60-minute treatments plus approximately 30 minutes to complete the questionnaires prior to treatment starting and once all the treatments have finished and approximately 30 minutes for screening prior to consenting to the study. It is estimated the in-depth interview will take between 30-60 minutes.

What benefits will I, and/or the broader community, receive for participating?

Possible potential benefits include decreased pain, increased function, feeling supported, and mental health benefits, however, these are not guaranteed. A feasibility study provides information for a larger study, which aims to provide information about the role of massage as an adjunct approach to care for pregnant women who have experienced a stillbirth that can be used to inform women about their treatment options.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

Potential risks include post massage/exercise soreness, tiredness, and exacerbation of symptoms. These symptoms are related to the massage treatments and are not able to be rectified other than with time. Care will be taken with the depth of massage treatment, specifically noting for fatigue and pain during the treatments to try to limit any post treatment soreness.

Pregnancy after stillbirth is a time of anxiety, fear, and worry. Massage is a non-medical support and at times you might need more support. The below services offer additional support:

- Red Nose/SANDS – 24/7 Bereavement Support Line 1300 308 307
- PANDA – 1300 726 306
- Lifeline – 13 11 14
- Beyond Blue – 1300 224 636

How do you intend to publish or disseminate the results?

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 the participant cannot be identified, except with your permission. Confidentiality will be maintained by using de-identified data and pseudonyms.

Will the data and information that I have provided be disposed of?

No. Your data will be used as per Western Sydney University's Open Access Policy. This means that data collected from this study can be made available online and world-wide in perpetuity. The stored data available for re-use **will not** have information in it that makes you identifiable.

Can I withdraw from the study?

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason. If you do choose to withdraw, any information that you have supplied can either be withdrawn or you can allow any information collected up to that point to be included in the study findings.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with Dr Sarah Fogarty's details. They can contact Dr Fogarty to discuss their participation in the research project and obtain a copy of the information sheet.

What if I require further information?

Please contact Dr Sarah Fogarty at s.fogarty@westernsydney.edu.au or pregnancyafterstillbirth@gmail.com should you wish to discuss the research further before deciding whether or not to participate.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H15261.

What will happen with my information if I agree to it being used in projects other than this one?

Thank you for considering being a participant in a University research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Unspecified consent

Unspecified consent

When you agree to unspecified consent it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in any future research.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use **will not** have information in it that makes you identifiable.

The researchers who are managing the data under this Plan will decide what types of future projects are suitable for this data to be used in. The projects may mean that the dataset is given to other researchers outside of the current research team. The researchers could also be from anywhere in the world and may, or may not, have affiliations with a University. The data will be held for a significant period of time – until it is felt that it is no longer needed for research. After this time the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the [National Statement on Ethical Conduct in Human Research](#) – see Sections 2.2.14 - 2.2.18.

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

