



Study Title: ALOE: Acknowledging Pregnancy Loss Outcomes and Experiences

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Introduction

We invite you to take part in this study examining how pregnancy loss may affect couples' sexual, relationship, and psychological experiences. The information below tells you what you will be asked to do throughout the study and about any potential benefits and risks of participating. Participation in this study is voluntary, which means you are not required to participate and can withdraw from the study at any point.

Study Purpose

The purpose of this research is to better understand how experiences with pregnancy loss relate to sexual, relationship, and psychological wellbeing and how it might differ among couples who have experienced pregnancy loss and those who have not. Results of this study will enhance knowledge of the sexual, relationship, and psychological well-being of couples after pregnancy loss, which may help us or others develop interventions to improve couples' coping in similar situations in the future.

Outline of Study Procedure

This study is being conducted by the Couples and Sexual Health Laboratory at Dalhousie University and the IWK Health Centre. We will collect data from couples who have experienced a pregnancy loss in the past 3 months. This study aims to be inclusive of all individuals and their partners regardless of gender identity, biological sex, and sexual orientation.

Participation in this research study involves completion of a one-time online survey and includes answering both multiple choice and open-ended questions about background demographics, experiences with pregnancy loss, sexuality, relationship with your partner, and psychological well-being. The survey will take between 40 and 55 minutes to complete.

Participants will complete the survey separately from their partner and responses will be kept completely confidential.

Compensation

You can receive \$20 CAD (or USD equivalency) per person in the form of a gift card for completing the survey.

Canadian participants will also have the choice of receiving an e-transfer for this compensation. You will be asked to indicate your preferred method of compensation at the end of the survey. If you select e-transfer (available for those with Canadian bank accounts), your email address will be temporarily entered into the e-transfer contact list of a secure Canadian bank account, accessed only by authorized personnel from the Couples and Sexual Health Laboratory at Dalhousie University and the IWK Health Centre. Your email address will be deleted upon study completion.

The surveys include clearly marked attention check questions. These questions are designed to ensure that participants are reading and understanding each question carefully. Participants who fail to answer attention questions correctly may be withdrawn from the study and/or be ineligible for the compensation.

Risks and Discomforts

You may find some of the topics discussed during the study to be intimate as we are asking you to share about your pregnancy loss as well as sexual, relationship, and psychological experiences. If a survey question makes you uncomfortable, please feel free to skip it.

If you still feel uncomfortable, please let our research team know and we'd be happy to provide you with resources to find the appropriate health care professional to help (Couples and Sexual Health Laboratory at rosenlab@dal.ca or David Allsop at David.Allsop@dal.ca)

Some survey questions will ask about symptoms of depression, anxiety, and grief. A research assistant will examine these scores and contact you by email to provide you with resources if your scores suggest that you may be experiencing high levels of distress.

Possible Benefits

Participation may be of no benefit to you. It is possible that as a participant, you may find that completing these surveys helps you to reflect on your experiences, or to learn more about yourself and your relationship, which some people find beneficial. You and your partner's feedback about your experiences with pregnancy loss will help our team grow the literature on the well-being of couples after pregnancy loss, which may help us or others develop interventions to improve couples' coping in similar situations in the future.

How your information will be protected

All information collected will be kept confidential. Both during and after survey completion, none of your data are stored on your personal device. To maintain confidentiality while completing the survey, we recommend finding a quiet, private room in your home away from distraction.

Survey data will be kept on an online password-protected server for Dr. Rosen's secure laboratory at Dalhousie University. Qualtrics Research Suite was selected for survey data collection, and these data are stored on protected servers, which are located in Canada and are certified by the Statement on Standards for Attestation Engagements (SSAE – 16 SOC II). Information that you provide to us will be kept private. Only the research team will have access to this information, and it will not be shared outside of the research team. We will describe and share our findings in many ways, including journal articles, Ph.D. theses, conference and public presentations, and public media. Results will be de-identified (e.g., results averaged across all persons; quotes from open-ended responses will be reported with pseudonyms). This means that you will not be identified in any way in our reports. The people who work with us have a strict obligation to keep all research information private and confidential.

Although your information will be kept private and confidential, you will not be completely anonymous to the research staff who are authorized to work on the study. We will need to collect your contact information in order to send you the survey, make reminder and check-in calls, and to send you compensation. Your personal information will be kept separate from your data at all times.

In order to promote research transparency (i.e., being explicit and clear about our research methods) and replicability (i.e., sharing details so that others can conduct similar study designs), with your consent, upon completion of the study researchers outside of our research team may access the data we collect in this study via Open Science Framework (OSF) software. That is, we will deposit deidentified data (i.e., no names or personally identifying information such as demographics) into our OSF webpage. The data may be inspected and analyzed by other researchers for the purposes of replication and/or collaboration. All data shared via OSF will be deidentified and password protected.

I have read and understand the information about data-sharing via Open Science Framework and **I agree to include my deidentified data in the OSF.**

I have read and understand the information about data-sharing via Open Science Framework

and **I would like to opt out of including my deidentified data in the OSF.**

If You Decide to Stop Participating

Your participation in this study is voluntary, and you are free to withdraw your consent and discontinue participation at any time. Your healthcare (e.g., at the IWK Health Centre) will not be impacted in any way if you choose not to participate in this research. If you wish to withdraw your responses once they have been submitted, please contact the research team noted below. You are able to withdraw your data until data collection ends for this study (approximately November 2022), when all participant contact information will be deleted. At this point it will be impossible to identify your data, and therefore we cannot remove it. If you do not make this request, then the researchers will use the anonymous data that you provided up until that point, as it will still be helpful for the goals of the project.

For any questions about this study, or to withdraw from the research project, please contact us at aloe@dal.ca.

How to Obtain Results

We will send out a summary of group results when the study is finished, about 3-5 years after all data are collected and published. Would you like to receive a summary of the results?

Yes No

Knowledge Translation

We are interested in including participants in our efforts to promote the sharing of our research findings. Interested participants would be invited, for example, to provide the research team with feedback regarding the research results and how best to use these results to improve sexual well-being for other couples. Would you be interested and willing to work with the research team on these types of activities? Indicating “yes” to being contacted in the future in no way obligates you to participate in these initiatives. You will be able to decline when we contact you if you no longer wish to participate.

Yes No

Future Research

It is possible that we will conduct further research about relationships and sexuality. Do you consent to be contacted for future research? Indicating “yes” to being contacted in the future in no way obligates you to participate in future studies.

Yes No

Questions?

If you have any ethical concerns about your participation in this research, you may also contact

- **Research Ethics Office**, IWK Health Centre. Contact: Joanne Street, Ethics Coordinator, Phone: (902) 470-8520, E-mail: joanne.street@iwk.nshealth.ca (and reference REB file #TBD). Monday to Friday between 9:00 a.m. and 4:00 p.m. (Atlantic Daylight Time).
- **Research Ethics Office**, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca Monday to Friday between 8:00 a.m. and 4:00 p.m. (Atlantic Daylight Time).
- **ALOE Research Team Contacts**
 - **General enquires:** aloe@dal.ca
 - **David Allsop**, Principal Investigator, Ph.D. Student, Dalhousie University, E-mail: David.Allsop@dal.ca
 - **Natalie Rosen**, Ph.D., R. Psych. Department of Psychology and Neuroscience, Dalhousie University, Phone: (902) 494-4044, E-mail: natalie.rosen@dal.ca

*If you have any questions at all, please email us **before** you give your informed consent electronically in the survey. It is an important part of your research rights that you have all of your questions answered before consenting to participate.*

Research Rights

Your signature on the form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. “If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.

If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 476-3523, Monday to Friday between 8:00a.m. and 4:00p.m.

By clicking ‘I Agree’, I am agreeing that:

- I have read, reviewed and understand the details of the consent form.
- I have no remaining questions.
- I am providing my informed consent to participate in this study.

I understand that I can choose to withdraw consent and my data from the study at any time by contacting aloe@dal.ca.