The Linking Loss Study

Participant Information Sheet – Workshop

Short Study Title: Linking Loss Study
IRAS ID: 361211

We would like to invite you to take part in this research study. Before you decide whether you would like to do this, it is important for you to understand why the research is being done and what taking part will involve. Please read the following information carefully and take your time to decide whether you would like to take part.

If you have any questions about the study, need this information in an alternative format, or need support to read and understand the information, please contact the research team by email at linkingloss.study@annafreud.org.

1. Why are you doing this study?

The aim of this study is to better understand the mental health support needs of people who have experienced pregnancy loss before the 24th week of pregnancy and develop an intervention to support them. Many people are affected by pregnancy loss each year, and it is common to experience mental health difficulties after such loss. Currently, NHS mental health support after pregnancy loss in England is limited, which means many people do not receive the support which they need. The information that you share will be used to help adapt a programme of group support for people who experience mental health difficulties following a pregnancy loss before the 24th week of pregnancy. We want to make sure that this programme is inclusive and can be adapted to meet the needs of people who are Black, Asian, and LGBTQIA+.

2. Who can take part in the study?

You can take part in the workshop if you are:

- Aged 18-years or older
- Have personally experienced a pregnancy loss before the 24th week of pregnancy. This may include a miscarriage, molar pregnancy, or ectopic pregnancy. The experiences and support needs of people who have undergone a termination or termination for medical reasons (TfMR) can be different to those who have experienced other types of pregnancy loss. Because of this, you will not be invited to take part in this particular study if this type of termination is your only experience of pregnancy loss before 24-weeks'.
- Have experienced the pregnancy loss in the last 24-months.
- Live in England.

OR

- Working in a professional role which involves supporting people who have experienced pregnancy loss before the 24th week of pregnancy. This may include Obstetricians, Gynaecologists, Midwives, Nurses, Maternity Support Workers, Sonographers, or mental health professionals. Please note, this role ***does not*** need to be based within an NHS service.
- Working in England.

3. Do I have to take part?

No. Taking part in the workshop is completely voluntary, and this decision is entirely up to you. If you decide to take part, you can change your mind at any time without giving a reason. If you decide that you do not want to take part, that is fine.

4. What will happen if I choose to take part?

If you decide to take part in the study, a member of the research team will contact you with the details to join the coproduction workshops. The purpose of the workshops is to agree what components are needed for a peer-led, group intervention to support mental health difficulties following pregnancy loss before the 24th week of pregnancy. The workshops will also develop a guide to deliver this intervention to different communities. The workshops will be informed by existing literature on peer-led interventions and information about the support needs of people who have experienced pregnancy loss collected as part of this study (this will be provided to workshop attendees).

We will be delivering two types of workshop:

1. **Workshops with people who have experienced pregnancy loss before the 24th week of pregnancy**
   There will be four workshops, which are each approximately 3-hours long. The workshops will be facilitated by Experts by Experience who have lived experience of pregnancy loss. The workshops will take place in person at the Anna Freud Centre in London (address: 4-8 Rodney Street, London, N1 9JH). We will be able to reimburse reasonable travel expenses to attend these workshops, and childcare will be available on-site.

2. **Workshops with professionals who support people that have experienced pregnancy loss before the 24th week of pregnancy**
   There will be four workshops, which are each approximately 1-hour long. The workshops will be online and facilitated by two individuals with extensive experience of coproduction activities.

Before attending a workshop, you will be asked to complete a complete a Consent Form. This is to confirm that you understand what taking part in the workshop involves, and that you are happy to do this. You will also be asked to complete a short survey. The survey will ask you a few questions about yourself so that we can accurately report who has attended the workshops.

5. What will happen if I change my mind about taking part?

You can change your mind and decide to stop the study at any time without giving a reason. If you change your mind during the workshop, please let the researcher know and you can leave immediately. If you decide to withdraw from the study, all identifiable information (like your contact details) will be securely deleted. If you wish for information shared during the workshop to be deleted, you can request this up to one month after the workshop. After this point, it is possible that your views have been included within the analysis of the study, and it may not be possible to remove these. Please be aware that key points from the workshop discussions will be collated and so it may not be possible for all information which you share to be identified and removed.

6. What are the possible benefits of taking part?

Taking part in the study is unlikely to benefit you directly, however, you will be taking part in research which has the potential to help other people in the future. By taking part in the workshop, you will help us to adapt an intervention to support people who are experiencing mental health difficulties following pregnancy loss. Your contributions will help us to ensure that this intervention is suitable can be tailored to meet the needs of different communities.

7. What are the possible disadvantages of taking part?

We do not expect that taking part in the workshop will have any disadvantages. However, it is important to understand that the workshop will discuss pregnancy loss and mental health difficulties which may bring up difficult emotions or memories. Your safety and wellbeing are our priority. You can share as little or as much as you choose in the workshop, take breaks, and stop at any time.

8. How will we use information about you?

We will need to use information from you for this research project. This information will include your name, contact details, professional role, ethnicity, gender identity, and sexual orientation. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details.

Devon Partnership NHS Trust is the sponsor of this research. Anna Freud (a mental health charity) is running the research project and is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- All information that you share will be securely stored on an encrypted server. Your personal details (e.g., your name, contact details) will be stored separately from your survey response. All information can only be accessed by members of the research team involved in conducting this research, and is password protected.
- The Anna Freud Data Protection Officer will oversee the processing of personal data and can be contacted if you have any questions (dpo@annafreud.org)

Your data will not be shared outside the UK.

9. How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We may use anonymised quotes from the workshops in reports of the study findings, but we will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

10. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our

processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

11. Where can you find out more about how your information is used?

You can find out more about how we use your information by:

- Our leaflet (**www.hra.nhs.uk/patientdataandresearch**)
- By asking one of the research team
- By sending an email to linkingloss.study@annafreud.org, or
- By ringing us on 07977 948837
- By sending an email to the Sponsor's Data Protection Office [dpt.saferinformation@nhs.net]

12. What will happen to the results of the study?

When the study has been completed, all information will be analysed by the research team. We plan to publish the results of our findings in a scientific journal and may present these findings at scientific conferences. Your data will be always kept anonymous, and you will not be identifiable in any of the study findings. If you agree to take part in the study, you will have the option to receive a copy of the study findings.

13. Who is organising and funding this study?

The study has been funded by the National Institute for Health and Care Research (NIHR). The sponsor for the study (the organisation leading and organising the research) is Devon Partnership NHS Trust.

14. Who has approved the study?

The study has been reviewed by the HRA Research Ethics Committee and been approved (IRAS ID: 361211).

15. What will happen if something goes wrong or if there is anything which I am unhappy about?

If there is anything which you are unhappy about or would like to discuss with the research team, you can speak to the Study Co-ordinator, Hannah Hopson, by email (linkingloss.study@annafreud.org) or phone (07977948837).

16. What should I do if I'm interested in taking part?

If you are interested in taking part in the study, please get in touch with the study team by email at linkingloss.study@annafreud.org. We will be able to answer any questions that you may have about the study and share a link to the Consent Form.