

Tommy's Qualitative (TQ) Participant Information Leaflet (PIL)

Men Living Through Multiple Miscarriages: Participant Information Leaflet Version 2.0

We are writing to invite you to participate in a study of the experiences of men who have lived through two or more pregnancies ending in miscarriage, with the most recent loss no more than 12 months ago. The study has two parts:

The first part will involve a one-to-one telephone interview to discuss your experiences of miscarriages. The second part will involve attendance at a focus group discussion with other men who have also experienced miscarriages. Participation in the second part is completely optional.

Before you decide whether or not to participate in any part of the study, it will be important for you to understand the research in more detail. Please take the time to read this leaflet carefully, and talk to others if you wish. Please also feel free to ask us about anything that is unclear, and let us know if you would like more information.

What is the purpose of the study?

This project aims to better understand the experiences and any support requirements of men living through multiple miscarriages. We want to understand what it was like for you.

The study is undertaken through Tommy's National Centre for Miscarriage Research at the University of Birmingham.

Why are you invited?

You are invited because you have experienced two or more clinically confirmed pregnancies that both ended spontaneously before 16 completed weeks of gestation, with the most recent loss no more than 12 months ago.

Do you have to take part?

It is up to you to decide whether or not to participate. If you do, you will be asked to complete a consent form. You will remain free to withdraw from the study at any time until two weeks after you contribute to the project, without giving a reason. More information about withdrawal after this time is available further below. Your withdrawal will not affect any of the miscarriage support available to you or your partner/s, nor your contribution to any other studies within Tommy's National Centre for Miscarriage Research.

What will happen if you take part?

If you decide to take part then we will contact you to arrange a convenient time for telephone interview with a trained member of our research team. With your consent, we will also collect some brief background details such as your age. Some of these details will be your personal data, and further below you can find out more about our management and protection of these data.

We expect the interview to last for up to 60 minutes. With your consent, the conversation will be audio-recorded and then transcribed for the purpose of analysis. You will be encouraged to talk freely about your personal experiences of miscarriages, and to tell us your thoughts and feelings in relation to repeated pregnancy loss. We hope to interview between 30 and 50 men who have experienced two or more miscarriages.

After the interview you will be invited to join a focus group discussion with a small number of other study participants. You can choose not to participate in the focus group discussion. It may be scheduled several months after your interview because it will be necessary for us to explore all the information collected in interviews first. We will contact you when we are ready to arrange a convenient time for the focus group discussion and you will be able to decide then whether or not you want to participate.

Are there any disadvantages or risks of taking part?

Although your appointment for interview will take some time out of your day, every effort will be made to suit your convenience. We will be happy to talk to you in the morning, afternoon or evening, and any day of the week. You will also receive a £20 honorarium (digital high street voucher) as a token of our appreciation for your contribution to the study.

Many people value the opportunity to talk about their experiences, but if you experience any distress then it will be possible for you to take a break, stop the audio-recording, or end the interview completely. If there is anything that upsets you during the interview or if you want to talk to someone beyond the research team then we will explain how to find support. We will be able to help with referral if required. The contact details of miscarriage support organisations are also listed at the end of this leaflet.

What are the benefits of taking part?

Although the findings of this study may not benefit you directly, participation will give you the opportunity to talk about your experiences, and express your views to an interested, non-judgemental listener. We will also publish our findings and we hope they will influence policy and practice in the management of multiple miscarriages.

What will happen if you decide not to carry on with the study?

We hope you will remain happy to participate in the study. You will be completely free to withdraw your consent at any time until two weeks after your telephone interview. Beyond this time, we will do our best to enable you to withdraw from the project, but we may not be able to completely eliminate the information that you contributed. If you participate in our focus group discussion and request withdrawal part-way through the event or afterwards, it may not be possible to exclude your contributions to that point, because they may have affected the contributions of others participating in the conversation. Therefore we request that you allow us to use the information already collected from you until the time of your withdrawal, but in order to safeguard your rights we will use the minimum personally identifiable information possible.

What if there is a problem?

We do not anticipate any problems to arise during this project. However if you have any concern about the research, please feel free to speak to any members of the study team (contact details at the end of this information leaflet). We will do our best to answer your questions. If you have any concern about the conduct of the study team, please contact the Chief Investigator, Professor Arri Coomarasamy (contact details at the end of this information leaflet).

What will happen to the results of the research study?

We expect the project to last for approximately three years from early 2019. The results will be written up to form the basis of a PhD thesis. The findings will also be submitted for publication, presented at conferences and disseminated via social media.

Who is organising and funding the research?

This study contributes to a PhD project funded jointly by the University of Birmingham and Tommy's, and sponsored by the University of Birmingham.

Who has reviewed the study?

This study has been reviewed to protect your safety, rights, well-being, and dignity. It has been given a favourable opinion by the West Midlands South Birmingham Research Ethics Committee of the Health Research Authority.

DATA MANAGEMENT AND PROTECTION

What will happen to the data collected from you?

Our study team will perform a qualitative analysis of the data collected from you. Under data protection law, our analysis of your personal data will be legally justified by your consent, and by the necessity of the data to achieve our research objectives in the public interest. The data will be used only for the purpose of academic research, and anonymised prior to sharing in any form.

Who will control the data?

The University of Birmingham will take responsibility for management and protection of the data that we collect from you. Thus our arrangements to control the data will comply with relevant policies and procedures of the University of Birmingham, in addition to the requirements of the EU General Data Protection Regulation 2016/679 and Data Protection Act 2018.

Will the data be stored securely?

The University of Birmingham takes great care to ensure that any personal data are stored and disposed confidentially and securely. All University employees receive regular data protection and security training to adopt the appropriate organisational and technical measures to manage personal data in compliance with data protection law. The University is accredited under the NHS Information Governance Toolkit and the Payment Card Industry Data Security Standard, and we are in the process of gaining Cyber Essentials Plus accreditation for defined services.

All the written data generated by this project will be held securely, in a locked room or locked cabinet that is accessible only to the research team and relevant regulatory authorities. All our study data in electronic form will be held securely on encrypted and password-protected computers at the University of Birmingham, where our electronic information security management system is based on ISO27001.

Will the data remain confidential?

All the information collected about you during the course of the research will be kept strictly confidential, and anonymised. However, in reporting the findings of the project we request your consent to use anonymous verbatim quotations, and to refer to the number of miscarriages you have experienced, and to mention whether or not you identify yourself as a parent of any other children. We also request your consent to share the anonymised data with other miscarriage researchers, in order to advance our knowledge of the effects of miscarriages on the lives of individuals and families. We will make every effort to ensure that all appropriate legal, ethical and other approvals are in place to perform any additional analyses. For practical reasons once you have taken part in the study and the results are published then your consent to re-use the anonymised data will not be sought again.

Meanwhile, in order to verify that our research is carried out in line with the law and good practice, data collected during the study may occasionally be audited by independent authorised individuals and/or representatives of regulatory bodies. All these individuals will maintain a duty of confidentiality to you as a participant in our project.

Sometimes external organisations may assist us to manage the information we collect from you. For example, we may engage a trusted external supplier to transcribe audio-recordings. We instruct these external organisations to act on our behalf with explicit agreement from them to manage your data in absolute compliance with our study protocol and relevant policies and procedures of the University of Birmingham, in addition to the requirements of the EU General Data Protection Regulation 2016/679 and Data Protection Act 2018. Any other use of the information is strictly prohibited by contractual agreement to protect and safeguard your data.

Please be aware that in certain exceptional circumstances where you or others may be at significant risk of harm, it may be necessary for us to report information to an appropriate authority.

How long will your personal data be retained?

Your data will be securely retained for 10 years after the study findings are first published.

Where can you find out more about data management and protection?

You can find out more about data management and protection at the University of Birmingham via the University website: <https://www.birmingham.ac.uk/privacy/index.aspx>.

Your rights in relation to your data

You may have the following rights to your personal data:

- The right to access to your data, sometimes known as a Subject Access Request
- The right to rectification of inaccuracies in your data
- The right to erasure of your data in certain circumstances
- The right to restrict processing of your data in certain circumstances
- The right to object to the processing of your data in certain circumstances
- The right to ask for your personal data to be transferred electronically to a third party
- The right to withdraw consent

However these rights may be limited by the necessity for us to manage the data effectively in order to ensure that our study findings are reliable and accurate.

If you would like to exercise any rights to your personal data, or if you have any queries about data management and protection at the University of Birmingham, please contact our Information Compliance Manager via email dataprotection@contacts.bham.ac.uk or telephone: +44 (0)121 414 3916.

If you would like to make a complaint about data management and protection at the University of Birmingham, please contact our Data Protection Officer, Mrs Carolyn Pike OBE, via email dataprotection@contacts.bham.ac.uk or telephone: +44 (0)121 414 3916. You will also be entitled to complain to the Information Commissioner's Office (ICO). You can register a complaint via the ICO website.

Where can you find out more about research?

More general information about public engagement in research is available from INVOLVE: www.invo.org.uk.

Thank you for taking the time to read this information sheet. If you have any queries then please contact us.

Contact Details of the Research Team

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Further Support

Beyond the scope of this study, support after miscarriage is offered by the charities listed below:

<p>Miscarriage Association <i>Support and information for anyone affected by miscarriage, ectopic pregnancy or molar pregnancy</i> Email: info@miscarriageassociation.org.uk Online: www.miscarriageassociation.org.uk</p>
<p>Tommy's <i>Information for parents-to-be, to help them have a healthy pregnancy and baby</i> Email: mailbox@tommys.org Online: www.tommys.org</p>
<p>4Louis <i>Support for anyone affected by miscarriage, the death of a baby or child</i> Email: mail@4louis.co.uk Online: www.4louis.co.uk</p>
<p>Life After Loss <i>Help for anyone affected by the death of a baby at any stage of pregnancy or early in life, for any reason</i> Email: helen@lifeafterloss.org.uk Online: www.lifeafterloss.org.uk</p>
<p>Petals <i>Specialist counselling for women and partners who suffer psychological distress from trauma and grief related to pregnancy loss</i> Email: contact@petalscharity.org Online: www.petalscharity.org</p>
<p>Sophia Pregnancy Loss Support <i>Support for anyone who has experienced the loss of a baby through miscarriage, termination for medical reasons, stillbirth and neonatal death</i> Email: Sophiagroup16@gmail.com Online: www.sophiapregnancylosssupport.com</p>