PARTICIPANT INFORMATION SHEET

Preferences and acceptability of chemoprevention trials to reduce the risk of breast cancer

Before deciding whether to take part in this study, it is important for you to understand the purpose of the project and what it will involve. Please take time to read the following information carefully and ask if anything is unclear.

The study aims to explore the views of **women who do not have breast cancer** about a potential new treatment for people who have a family history of breast, ovarian, prostate or pancreatic cancer. Women who have changes to certain genes (referred to as BRCA 1 or BRCA 2 positive) are more at risk of developing breast and/or ovarian cancer.

We are hoping that a total of 30 women (who **do not have breast or ovarian cancer** and **are not BRCA 1 or BRCA 2 positive**) will take part in a group discussion known as a focus group (with 6 to 10 women per group). We want to try and recruit younger and older women and will check potential participants' age group at screening (18-35yrs, 36-55yrs, 56-65yrs, 66yrs+).

1. Do I have to take part?

No, participation is voluntary and if you take part, you can change your mind at any time without giving a reason.

2. What will happen to me if I take part?

A member of our research team will ask you some screening questions to see if the study is suitable. Then you will be invited to attend a focus group discussion at the Sussex Health Outcomes Research and Education Centre (SHORE-C), located on the University of Sussex Falmer campus. Refreshments will be provided, and free parking can be arranged. You will be asked to complete 5 questionnaires before the focus group and 1 afterwards.

3. What happens at the focus group?

Before the focus group starts, the researcher will receive your consent to participate before asking you to complete 5 questionnaires (either online or on paper). The questionnaires relate to your beliefs and understanding about medical treatments and how you cope with stress. These will take approximately 10-15 minutes.

A 15-minute group presentation will follow to explain simply what BRCA 1 and BRCA 2 genes are, and the treatments currently offered to women who are BRCA 1 and BRCA 2 positive. The researchers will also outline a potential new risk reducing clinical treatment trial for BRCA 1 and BRCA 2 positive women.

Following the presentation, we will invite you to share your thoughts in a group discussion with 6 – 10 women. We expect sessions to last between 30 and 45 minutes. We will audio record these to help with our note taking. At the end we will ask you to complete 1 questionnaire concerning different clinical trial designs to test the new prevention treatment.

4. What are the possible benefits of taking part?

There are no direct benefits for you in taking part in this study, but you may gain some knowledge about BRCA 1 and BRCA 2 positive breast cancer. We will give you a £25 voucher for your time and offer a maximum of £20 to cover public transport / mileage costs.

5. Are there any disadvantages or risks of taking part?

The main disadvantage of joining the study is that we will use up some of your time attending the focus group and completing questionnaires. In total it could take up to 1.5 hours.

We are asking you to complete the questionnaires for research purposes, not for any kind of psychological assessment. If completing the questionnaires highlights any emotional or personal concerns, we suggest you contact general mental health support services such as the MIND charity (via https://www.mind.org.uk/ or telephone 0300 123 3393) or contact your GP.

There is also a possibility that recalling personal experiences or hearing the experiences of others in the group may cause some distress or upset. Should this occur, we would again recommend contacting MIND. If you have any concerns about hereditary cancer risk, we suggest you contact BRCA Chat for further support (https://brcachat.com/ or info@brcachat.com).

6. What about confidentiality?

Everyone involved in this study will keep your data safe and secure. We will not disclose your name, contact details, or any other information to third parties. Personal identifying information (name, email etc.) will be stored in a password protected database separate from your research data and will be destroyed at the end of the study.

You will be given a study identification (ID) number which will be used on all questionnaires. All questionnaire data will be stored securely at the University of Sussex and will be accessible only to the SHORE-C team. We will audio record the focus group discussion to ensure accuracy when checked against the discussion notes. The recordings will then be destroyed. The final versions of the focus group discussion notes will be stored securely at the University of Sussex for 5 years after the end of the study and will then be destroyed. Only members of the SHORE-C research team will be able to access them.

Any published papers may also include results from the questionnaire data and anonymised quotes. It will not be possible to identify any individuals. The data are stored and processed according to the UK Data Protection Act (2018). The SHORE-C data privacy policy is available at: https://shore-c.sussex.ac.uk/dp.php.

7. What will happen if I do not want to carry on with the study?

Taking part is voluntary and you are free to withdraw your consent at any time without giving a reason. All data you have provided before withdrawing (including questionnaire responses and focus group contributions) will still be included in the analysis, as it is not possible to remove individual comments from a group discussion.

8. What will happen to the results of the research study?

The findings from our study will be published in reports and scientific journals. The results will also help inform the design of a large UK preference and acceptability study of a new chemoprevention drug in people who have inherited a faulty BRCA 1 or BRCA 2 gene. If you would like a summary of the study findings, please indicate this on the consent form by providing your email address or postal address.

9. Who is organising and funding the research?

A charity, the Breast Cancer Research Foundation, has funded the study. The research is organised by SHORE-C.

10. Who has approved this study?

The Science, Engineering and Medicine Faculty Research Ethics Committee: Brighton & Sussex Medical School (BSMS) has reviewed and approved this study (Ref: --).

11. What if there is a problem?

If you have any concerns or complaints about the conduct of the study or about the way you have been approached or treated during the study, or if you wish to speak to someone outside of the research team, please contact the University of Sussex Research Governance Office via rgoffice@sussex.ac.uk.

12. Contact for further information and to register your interest?

If you would like further information and/or want to register your interest in joining the study, please contact the Chief Investigators Professor Dame Lesley Fallowfield on 01273 873 019 or Professor Valerie Jenkins on 01273 873 016 or Niomie Wogan at adminshore-c@sussex.ac.uk.

13. Insurance

The Universities of Brighton and Sussex have insurance in place to cover their legal liabilities in respect of this study.

Thank you for taking the time to read this information sheet