



Information for participants



Breakthrough Generations: the UK study of the causes of Breast Cancer

Information for Participants

Introduction

You are invited to take part in the Breakthrough Generations study of the causes of breast cancer. This booklet explains why the research is being done and what would be involved if you chose to take part. Please feel free to discuss it with your friends, relatives and anyone else you wish, and to take your time to decide whether or not you wish to take part. Please ask us if there is anything that is not clear or if you need any further information.

Summary of the study

If breast cancer is to be prevented its causes must be found. In order to try to find these causes, and particularly to find causes that might be preventable, we have decided to undertake, with Breakthrough Breast Cancer, a very large national study of the causes of breast cancer. The study will include over 100,000 women in the UK; it will be the largest, longest running scientific study that Breakthrough Breast Cancer has yet undertaken, and we hope will play a major part in its research for the future. It will have a unique focus and will continue to give information for the next 40 years and longer, although the first results on breast cancer causes will be ready much sooner than that, in a few years from now. Supporters of Breakthrough and other women with an interest in helping to find the causes of breast cancer are being approached for the study.

Each woman is being asked to complete a questionnaire, which asks about factors that might affect the risk of breast cancer. The participants are also asked if they would be willing to give a blood sample, which will be analysed for

hormonal and familial (genetic) factors that may affect breast cancer risk. Further similar information will be collected from the women in the study every five years, and also information will continue to be collected on whether any of the women have developed breast cancer. Over time it will therefore be possible to compare the risk factors in the women who develop breast cancer with those who do not, to find out which factors are predictive of breast cancer occurrence, and which lead to reduced risk.

Why is the study needed?

Scientific evidence indicates that the causation of breast cancer involves a complex mixture of factors – some to do with behaviour, some to do with environment and some genetic (inherited). These factors act at many different stages of life, probably starting before birth, and continuing to the menopause and beyond. To find out what these factors are, and how they combine with each other to cause breast cancer, a study is needed in which information about the factors, and how they change through life, is collected from women who are then followed over time to determine their risks of breast cancer in relation to these factors; in medical terminology the study is called a “cohort study”. Cohort studies need to include a very large number of people, and to continue for a long time, but in the long-run they are the most powerful method available to science to find out the causes of cancer in people. They are for instance, the method by which it was shown most clearly that cigarettes cause lung cancer and that asbestos causes cancer of the lining of the lung (pleural cancer).

In a cohort study, each woman in the study contributes valuable information to the whole, but it is the collective information from over 100,000 women that will be crucial. We believe that with the participation of the supporters of Breakthrough and of other women who wish to help, we can create a study with unique scientific potential to unravel the factors that cause breast cancer, and hence to find out how it can be prevented. This is a venture we are all very excited about, and hope you will be too.

Recruitment of study members

You are invited to join the study, as a woman aged 18 years or older.

We do not know what your personal risks of breast cancer are, and the study is not designed to find this out. Instead it is intended to discover collectively about risk factors, which may be of interest and relevance to you and your family as well as to women in general. If you have any questions about your personal cancer risks or those of your family, you should consult your GP as you would for any other question about your health.

You should note that the study is not an experiment and we would not wish to do anything to any of the people in the study, but simply to gain questionnaire information and take blood samples from them over time. Taking part in the study would not in any way affect your personal risks of breast cancer or indeed of any other illness, and nor would it affect your medical care.

Do I have to take part?

No, of course you do not have to take part. It is your choice. Participation is entirely voluntary and whether you participate or not will not affect your medical care. If you decide to take part you will be asked to sign an informed consent form and you will be given a copy to keep. You will still be free to withdraw at any time, without giving any reason.

I have had breast cancer, am I eligible to take part?

Yes, we would welcome the participation of women who have had breast cancer. Although the prime focus of this study is to examine breast cancer occurrence in women who at the start of the study have not had this disease, nevertheless, there are very valuable aspects of the study, investigating the causes of breast cancer, to which women who have had breast cancer can contribute.

What would I need to do to take part?

We would send you a questionnaire to complete, asking about various factors in your life that might be connected with risk of breast cancer – for instance asking about how many children you have had and what age you were at their births, whether and when you have taken the oral contraceptive pill, whether you have had breast disease, height, waist/hip measurements and so on. The questionnaire will take about 45-60 minutes to complete.

We would also wish to obtain a blood sample from you. To obtain the blood sample, we would send you a package with the necessary equipment for you to take to your general practice, in order that your GP or practice nurse could take the blood sample at the practice. We would analyse the blood sample for hormonal, family (genetic) and other blood factors that might influence the risk of breast cancer. The blood would be used solely for research purposes, and it would not provide information that can be used for your health care or the health care of your family. As a consequence, the particular findings in your personal blood samples would not be notified to you or to your doctor. The overall collective results of the study will, however, be available to you. If you are apprehensive about having a blood sample taken, you would be welcome to phone and discuss it with a nurse at our research centre before deciding whether or not to give such a sample.

If you are willing, we might want to look at your past medical notes and, if we can locate them, medical notes relating both to your own birth and to any pregnancies that you may have had. With your consent we might also ask your doctor for detailed and technical information, for instance, about any x-ray exposure to the breast you have had.

Will you be contacting me in the future?

Because the purpose of the study is to assess breast cancer risks over the long-term, we would plan to keep in touch with you every couple of years, to ask very

briefly about your current health, and every five years we would send you another questionnaire and ask if you would provide a blood sample. It would of course be entirely up to you whether you gave further information or a blood sample at these future contacts. We would also send you information to let you know how the study is progressing, and what has been found about the causes and prevention of breast cancer. In case we should be unable to contact you in the future, for example if you have moved house, we would like your consent for us to be able to check your details against NHS records and records maintained by the General Register Office, to help us to maintain contact, and also to use these sources, if necessary, to find out if you have died or have been diagnosed with cancer.

What are the benefits of the study?

By participating you would help in the search for factors that cause breast cancer and hence for ways in which the disease can be prevented. Finding out about such factors is important both for the care and counselling of the families of breast cancer patients, and also for women in general, to understand their risks and to find ways in which they can be reduced. The results of the study will be available to you if you want to know them, but as noted above the study will not provide results about individuals and we are not in a position to give you personal counselling about your particular risks. If you need advice or you have concerns about this, you should consult your GP.

How will the questionnaires and blood samples be used in the future?

Because the Generations study is so large and is seen as so important by both Breakthrough Breast Cancer and The Institute of Cancer Research, we have drawn up a detailed plan for the next 40 years, to ensure that the questionnaires and blood samples are used to maximum advantage to find the causes of breast cancer. Supervisory committees have been established, including senior individuals from Breakthrough and The Institute of Cancer Research, as well as independent scientists, and women taking part in the study, to oversee the

scientific conduct of the study and to consider also the views of participants. The questionnaire information and blood samples will be stored under the custodianship of The Institute of Cancer Research, for as long as is needed to enable the research to be done. The research is likely to call on the expertise and input of many scientists within The Institute of Cancer Research, not just the study team who have written to you now. However, scientists who are outside the study team will not be given identifiable information about you. If the Oversight Committee consider that it will benefit the objectives of the study, the research may also involve input by scientists outside the Institute including, if it helps in the search for the causes of breast cancer, scientists working in industry as well as in Universities and other Research Institutes; they too will not be told your identity.

It is not the purpose of this study to develop commercial applications. If the research does lead to a new medical test, or preventive measure or treatment that results in financial gain to The Institute of Cancer Research or Breakthrough, the Oversight Committee would ensure that these proceeds would be used for the benefit of cancer patients and for cancer prevention. Neither the study scientists nor you would personally benefit financially.

Although the research has been designed specifically to maximise the knowledge that can be gained about the causes and prevention of breast cancer, it is of course inevitable that some women in the study will develop other diseases over the next 40 years, and therefore that the study will eventually contain valuable information on the causes of other diseases. This especially applies to ovarian cancer because its risk factors are similar to those for breast cancer, but it is also true for other cancers and causes of death. Because the primary objective of the study is to find the causes of breast cancer, the material collected will not be used to investigate the causes of other diseases if such an investigation reduces the ability to find the causes of breast cancer. If, however, there are circumstances where the causes of other cancers or diseases can be investigated, to the benefit of women's health, without reducing the ability to find the causes of breast cancer, then the Oversight Committee will be able to consider and authorize such uses.

Will the information collected about me be kept confidential?

Yes, of course. All information collected about you during the course of the research will be treated in the strictest confidence and kept under the supervision of Professor Swerdlow, who is a medical doctor. We will not pass on personal information to anyone outside the study, and no individually-identifiable information will be published. All individually-identifiable data will be destroyed at the end of the study. The Institute of Cancer Research is registered under the Data Protection Act and data will be stored in compliance with the Act. The blood sample will be kept under the custodianship of The Institute of Cancer Research, labelled with a code not your name. The personal results of the blood sample will never be available to any agency and will never be used for any purpose other than the research described in this booklet. We will not pass any information about you on to your doctor. The results of the study will only be published as overall statistics for all people in the study, not as results for particular individuals.

What next?

Please would you complete and return to us the form attached to the invitation letter, in order to let us know whether you are interested in taking part in the study. We hope that you will join this research study; we believe that with your help we can make great advances in knowledge of why breast cancer occurs and how it can be prevented.


Contact for further information

If there is anything that is not clear, or if you would like more information, please contact a research nurse in the Generations Study Team, The Institute of Cancer Research, Brookes Lawley Building, 15 Cotswold Road, Sutton, Surrey SM2 5NG. Telephone: 020 8722 4469 (answerphone outside office hours).

Thank you for reading this







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