If you have not yet returned your questionnaire, or your blood sample.

If you have not yet returned your questionnaire or blood sample but would still like to participate in the study, it is not too late to join.

If you have not replied because you have a specific query, please contact us with your question and we will try to help.

Telephone **0208 722 4469**
or write to:
Breakthrough Generations Study Team
FREEPOST NAT 21013
The Institute of Cancer Research
Sutton
SM2 5BR
(stamp not needed)

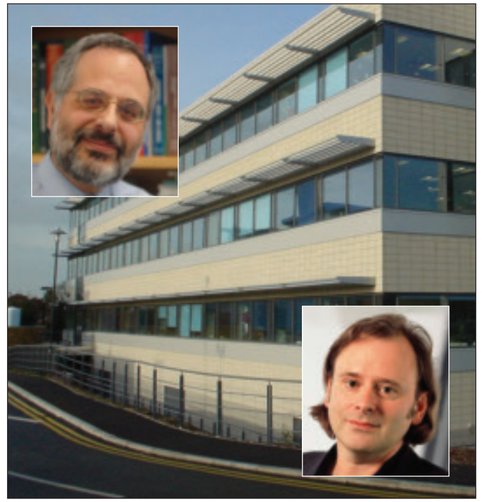
Similarly, if you have lost the questionnaire or blood pack and need another one, please get in touch and we will be happy to send you what you need.

About us, the study team

Some of you have asked about the team working on the study. The principal investigators, who designed and are leading the study, are Professor Alan Ashworth, who heads The Breakthrough Research Centre at The Institute of Cancer Research, and Professor Anthony Swerdlow, who heads the Epidemiology Section of The Institute.

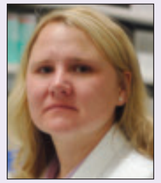
In the lead-up to the public launch, we recruited staff to the study teams, and more have joined since, so that more than 20 people now work on the study. At the Sutton branch of The Institute, there are several computing and scientific staff working under Dr Michael Jones, as well as a team led by Dawn Thomas who are carrying out the mailings and answering your telephone enquiries. Some of you may have met them when visiting to give a blood sample.

At the Breakthrough Research Centre at the Chelsea branch of The Institute, Jill Williamson and her team manage the processing of blood samples.



Professor Anthony Swerdlow ***Professor Alan Ashworth***

Jill Williamson heads the team processing the blood samples from the study volunteers …



"I manage the processing and storage of the blood samples that arrive at the Laboratory. I also take blood at the Chelsea site, so some of you may have met me already.

My science career started 16 years ago when I joined the Imperial Cancer Research Fund working with patients who had leukaemia and lymphoma. I then trained as a cytogeneticist (studying chromosomes) before moving to work in molecular biology in Professor Alan Ashworth's lab.

I love working on the Generations study because I feel it is a worthwhile project that will help people. We sometimes have visitors (some with breast cancer) who are shown around the Laboratory, and I enjoy meeting them and the other volunteers, and feel humble when I realise what they are doing by participating in the study. I feel fortunate that I have been involved at the very beginning of this unique study, which will run for many decades to come."

This study is supported by the commitment and funding provided by the sponsors of the study – Breakthrough Breast Cancer (www.breakthrough.org.uk) and The Institute of Cancer Research (www.icr.ac.uk).

Dawn Thomas heads the team communicating with the study participants, by mail and telephone …

"I joined The Institute of Cancer Research in May 2004 as Supervisor of the Communications Team for this new study into the causes of breast cancer. Having spent 9 years in retail staff management, although nervous, I was excited at the prospect of working in cancer research and looked forward to the challenges that lay ahead.

I have been married for 19 years and have two teenage children, Dean who is studying for his A-levels and Leanne who is 13. Being there to support and encourage them both is of course of great importance to me.

Two years on, I am really enjoying my work and the rewards it brings. I feel privileged to be associated with the study. I am extremely proud to lead the very hard working and dedicated group of people who carry out the mailings and communications for the Study."

… And finally,

May we finish by thanking you again for your contribution to the study. We have been enormously encouraged by the response that we have received, and by the time and effort given by you, the study members. Without your help the study would be impossible.
Thank you for your support.

The Breakthrough Generations Study Team

GENERATIONS

Newsletter No.1
SPRING 2006

THE NEWSLETTER OF THE BREAKTHROUGH GENERATIONS STUDY

WELCOME

Dear study member,

It is over a year since the public launch of the Breakthrough Generations Study investigating the causes of breast cancer, and we thought that the women who have joined the study, or who have written to say that they are interested in joining, might like to hear about its progress.

In brief, the study has been progressing extremely well, and we have been encouraged and delighted with the support we have received from tens of thousands of women from every part of the UK. We have now received questionnaires and blood samples from over 42,000 women, and many hundreds more are arriving every week, as well as comments and messages of encouragement. Recruiting to such an ambitious project inevitably takes time, but we are pleased to say that we are well on schedule to reach our target of more than 100,000 women within the study.

This newsletter explains the background to the study, how it works, and progress to date, as well as information about you, the participants, and us, the study team. We have also tried to answer some of the questions that participants have asked us over the past year. We will send you further newsletters in future, to keep you up to date with progress and developments.

Thank you for your participation in the study. Without your help, and the help of tens of thousands of other women like you, this study would not be possible.

With best wishes,

Professor Anthony Swerdlow

Professor Alan Ashworth

How the study started, and how it has progressed

The Beginnings

The Breakthrough Generations Study was set up because of a stark fact – that breast cancer is now the most common cancer in women in the UK, with over 40,000 new cases each year – and from a firm determination that the best way to defeat this disease would be to prevent it from occurring in the first place. Our aim, therefore, was to design a study specifically dedicated to finding the causes of breast cancer. Because the causation involves a complex interplay of lifestyle, environmental, genetic and hormonal factors acting throughout a woman's life, we knew that the study would need to be conducted over decades, would need to include both questionnaires and blood samples, and would need to include a very large number of women. In June 2003 we started a "pilot study", and following this Breakthrough Breast Cancer and The Institute of Cancer Research agreed to provide the support needed for the full study to proceed. The women who participated in the pilot study provided valuable feedback as well as taking part in the study like everyone else; we are very grateful to them for the effort they made to enable the study to start successfully.

BREAST CANCER: JOIN IN THE DEFINITIVE STUDY

SIR RICHARD DOLL, still working at Oxford in his nineties, made his international reputation by starting a nationwide study into the effect of smoking. He chose doctors as his subjects as they could always be contacted, provided they stayed on the medical register. The results of his study proved conclusively that there was a direct relationship between cigarette smoking and lung cancer as well as cardiovascular disease – information that has saved tens of thousands of lives and revolutionised chest and cardiovascular medicine.

Dr Thomas Stuttaford
The Times, 6th September 2004

The Launch

The study was launched publicly on 2nd September 2004, and received extensive television and newspaper coverage.

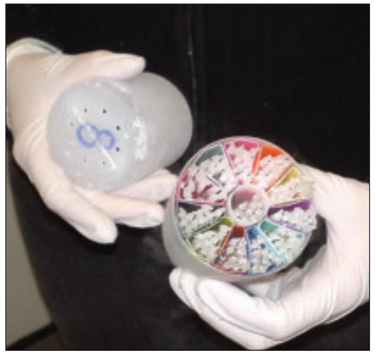
The response we received was rapid and beyond anyone's expectations. Within 24 hours, almost 15,000 women had registered an interest to join the study via the website or telephone, and the study team had a massive task to deal with the incoming wave of requests. Enquiries to join the study have kept arriving ever since, and the scale of the initial response has meant that even with a large team working on the study, it has taken many months to work through the tens of thousands of requests we have received. We apologise to those women who had to wait patiently before we could write to them.

What has happened since then?

Since the launch, we have been steadily contacting women who expressed an interest in joining the study, and processing their questionnaires and blood samples. So far, more than 42,000 women have returned a completed questionnaire and provided a blood sample. They have also sent a wide range of comments, encouraging messages, questions and suggestions. We are grateful to you all: we are aware that the questionnaire takes time and quite an amount of detective work to complete, and that obtaining a blood sample has also taken time and effort. We had to decide at the outset of the study whether to try to obtain detailed information, even if this required a long questionnaire. We came to the conclusion that the study should be done to the highest standards, to maximise the information gained about breast cancer causation. It has been extremely encouraging that so many women have been willing to give their time and effort to make it successful.

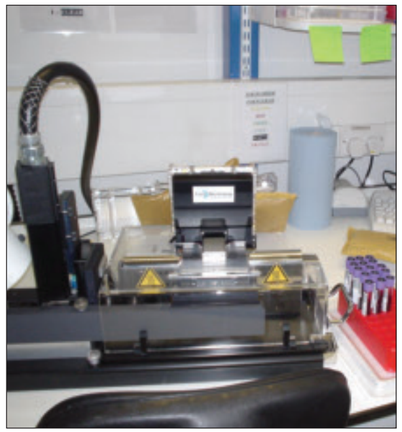
What happens to your blood sample?

The blood samples you send are processed by Jill Williamson and her team in a special laboratory at the Breakthrough Toby Robins Breast Cancer Research Centre at The Institute of Cancer Research in Chelsea. Blood samples from many hundreds of study members arrive in the post every week and each must be processed immediately. Initially, the samples are spun at high speed in a machine called a centrifuge, to separate the blood into its constituent parts. Then, in order to ensure that the blood samples can be used for as many tests as possible in the future, we divide the samples into very small volumes and store them in "straws", as shown to the right.



Blood storage "straws"

Each of these straws is barcoded and stored securely in large tanks cooled to -180°C by liquid nitrogen for long-term preservation. A computer system keeps track of precisely where in the liquid nitrogen tanks each sample is stored: in the first round of data collection we will generate about 3½ million straws. Because the blood samples are so precious and are a limited resource, the future use of the samples will be approved by a Scientific Advisory Committee, comprised of scientific experts and participant representatives who provide independent advice, to ensure that the greatest possible benefit to breast cancer research is achieved.



The "MAPI" machine that divides the samples into straws.

The plasma (liquid) from the blood will be used, for instance, to investigate how sex hormone levels influence breast cancer risk. A woman's blood contains both female hormones (oestrogens) and male hormones (androgens). There is evidence that each can affect the risk of breast cancer, but considerably more needs to be found out about this, and the study samples will be invaluable for investigating these crucial factors.

Cells from the blood will be processed to extract DNA, the genetic code, which will be used to look for genetic changes that affect a woman's risk of breast cancer. Each person's DNA includes about 30,000 genes, which affect every aspect of the structure, growth and function of our bodies, so the work to find out which genes matter will be complicated and painstaking. The technology to do this is improving rapidly, however, so there should be substantial progress over the next few years. Comparisons will be made between the genes of women who develop breast cancer and those who do not, to look for genetic differences that may explain why some women develop breast cancer and others do not. We will then examine how particular environments and lifestyle factors affect the risk of breast cancer in women with different genetic profiles, and therefore whether women with a particular genetic profile could reduce their risk of breast cancer by avoiding particular exposures or adopting particular behaviours.

The next steps

For a study that will continue for 40 years or more, we are still in the very early stages. For the next 2 years or so we will need to concentrate all our efforts on the work needed for recruitment, until we have over 100,000 women enrolled in the study. However, we also need to plan ahead. As we mentioned when we first approached you, we plan that in about two years' time we will send the study members a very short questionnaire, for you to update us on your health and any changes in your address or other contact details. In the meanwhile, we will send you a newsletter like this one about once a year. Looking further ahead, we plan to contact you again about 5 years after you joined the study, to ask for more detailed update information. This is important because one of the main purposes of the study is to try to find out how changes in behaviours and hormone levels throughout a woman's life affect her future risk of breast cancer. As you have already sent so much information when you joined the study, the subsequent questionnaires will not need to be as long as the initial one, so the hardest part is now behind you!

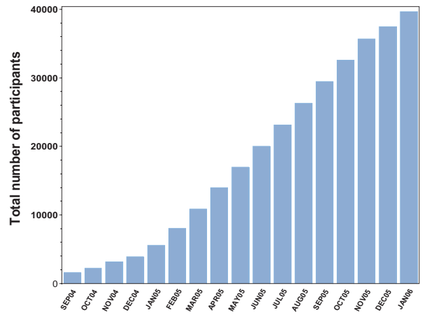
We are also starting to plan what analyses can usefully be done early on. Within a few years we should be able to produce results that will contribute to our understanding of the causes of breast cancer, although the major results of the study, as you know, will take longer. As we obtain results, we will let you know about them through the newsletter and the study website (www.breakthroughgenerations.org.uk).

About you, the study members

Although we are still in the early stages of the study, we thought you might like to know a little about the women who have joined so far.

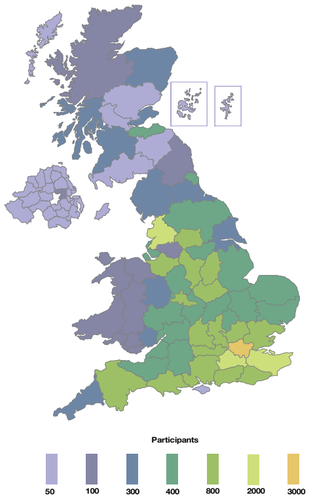
Numbers of study members joining since the launch

The figure below shows how the current study members have joined since the launch.



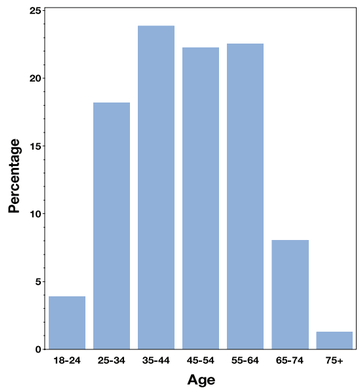
Where the study members live

The members of the study come from all social groups and all areas of the country.



Ages of study members

The study members are of a wide range of ages, with most between ages 25 and 64. We continue to wish to include women of all adult ages.



Brigitte Allen is one of the women who have joined the Study

"I got involved when I saw a small article in a national newspaper explaining the study and asking for volunteers. I registered on the website and was sent a questionnaire and the forms for the blood test – that was it! It has not taken a great deal of my time but the implications of the study for the future are enormous.

I am a full time mother and I have been married for 9 years and have 5 children – 2 girls and 3 boys. The oldest is 8 and the youngest is 1 month, and I don't plan to have any more! My life is very hectic, what with the school run, homework and various out of school activities such as swimming and Brownies.

I feel honoured to be able to help with something that may help to save lives in the future."

Has your name or address changed?

If your name or address is different from that on the newsletter envelope, please detach and return this reply slip in an envelope addressed to:

Breakthrough Generations Study Team
FREEPOST NAT 21013
The Institute of Cancer Research
Sutton
SM2 5BR
(stamp not needed).

Please enter your study number (which you will find next to your address on the envelope containing this newsletter), and your date of birth, so that we can be absolutely sure that we are updating details for the right person.

If the details on the newsletter envelope are satisfactory to reach you, there is no need to return this slip.

BLOCK CAPITALS PLEASE

First Name(s) _____

Surname(s) _____

Address _____

_____

_____

_____

Postcode _____

Telephone no. _____

Date of birth

Day Month Year _____

Study number _____
(the 6 digit number next to your address on the envelope containing this newsletter)