A study to help ensure older women get the best treatment when they have breast cancer
Why is this study needed?

Breast cancer is a very common problem in older women, affecting 13,000 UK women over the age of 70 every year. Despite this, very little has been done to study breast cancer in older women to find out the best way to treat this disease and what types of treatment older women prefer.

For many older women, treatment is identical to that of younger women as they have comparable levels of health and fitness as their younger counterparts. Surgery followed by a range of adjuvant treatments are recommended and often tolerated very well.

However, for some older women treatment may need to be modified to take into account other illnesses and frailty which may limit their ability to tolerate the full range of treatments.

The problem we have is that there is little guidance available on the level of age, ill health and frailty which makes the risks of surgery or chemotherapy outweigh the benefits. At present these decisions are based on the personal expertise of the treating team with no research to guide them to best practice. This has resulted in a high level of variation in practice across the UK. The Age Gap study hopes to fill this gap in our knowledge by studying UK practice and treatment outcomes in older women.

Who is eligible to take part?

Any woman over the age of 70, who has operable breast cancer, can take part, regardless of their health and fitness or the type of cancer treatment proposed. Even women who lack cognitive capacity are eligible if their relatives and carers agree on their behalf.

What does taking part involve for my patients?

The study does not alter the treatment of older women in any way. It simply wants to observe current, normal UK practice, with detailed collection of data about how fit the older women are at the start of treatment (other illnesses, level of independence, quality of life), how they respond to their recommended treatment and finally how well their cancer is controlled in the long term.

We therefore wish to recruit older women at the start of their cancer journey for a very simple study which will have minimal impact on them (completing a few questionnaires, some of which are optional).

The study needs to find over 3000 older women with breast cancer from all across the UK who are willing to help us answer these questions.

When should eligible women be approached?

We are aware that recruiting women soon after a diagnosis of cancer needs to be handled with great sensitivity. We are also aware that older women may be less able to tolerate lengthy additional hospital visits purely for the purpose of a research study. We have therefore designed the study to pose a minimal burden to them. We want to avoid them having extra visits to hospital purely for the study and many of the study interventions are either optional or can be done later via a telephone call or postal return of quality of life questionnaires.

For many older women they will have several visits to hospital whilst they decide on what treatment to have and in preparation for surgery. These women may be approached to take part at any pre-operative visit.
What Questionnaires will women have to complete?

Women can chose to take part in 3 different ways.

In its simplest form the study only requires their permission to allow the study to collect data about them with no requirement for any questionnaires: the research staff will just need permission to access the notes to obtain as much data as they can or ask carers for information if they have cognitive decline.

Some women may be happy to spend a little time going through some initial questions about their health, fitness and independence on their first and follow up visit but not want to fill in any detailed quality of life questionnaires at any visits.

Some women may be happy to also fill in quality of life questionnaires at their first visit and when they come to follow up.

Women can chose to take part in any of the ways detailed above.

All women are asked for us to have permission to obtain long term follow up from cancer registries and also for us to have future access to any samples of their cancer taken during their normal care for use in future research.

Thank You for helping with this study.

The full protocol contains more detailed information and is available from Mrs Rosie Cooper, (rosie.cooper@sheffield.ac.uk), the Age Gap Study Manager, or from your local Principle Investigator.

However, frailer women who may only be suitable for primary endocrine therapy may be started on this treatment at their first visit, shortly after being given their diagnosis.

For this reason we have asked that the initial approach is made on the first visit for these women so we can get baseline data before they start treatment. This will avoid them having to re-attend for an extra visit which may be more stressful and tiring.

We know that many older women have already got a good idea that they may have cancer before they get their result. They have often been pre warned by their GP or on the previous visit to clinic.

We therefore feel that for many, asking them if they would like to be part of the study will be feasible and not cause undue distress. However we also want staff to use their discretion and if they feel that a woman needs more time to accept the diagnosis, this approach may be made when they re-attend to discuss their care with their breast care nurse.

Because of our wish to avoid burdensome extra visits purely for the study the protocol only mandates that women have as little as 15 minutes to consider if they wish to take part, perhaps having a cup of tea in a quiet room where they can discuss the study with their friends, relatives or carers. Of course they can have as long as they need or want.

Once they have agreed to take part, after the consent form is signed, they may be happy to spend a little time with the doctor or research staff completing some baseline questionnaires, but some of these may be completed later over the phone if the patient wishes, or self completed and posted back to the Unit.
Thank you.