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# Integration of quality of life outcomes into the decision making of older women with early breast cancer

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| **Submission date**<br>27/05/2021 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>01/06/2021 | **Overall study status**<br>Completed | |
| **Last Edited**<br>18/10/2022 | **Condition category**<br>Cancer | |

## Plain English summary of protocol

Background and study aims
Breast cancer is a very common disease in older women, and over one third of cases are seen in women over the age of 70 years. A great deal of scientific research has been done to ensure that every woman with breast cancer receives the best treatment for her cancer. As women get older they value quality of life and independence as much as life expectancy, but at present there are no decision tools that provide enough information to help them weigh this up. A new online decision tool has been developed to meet the needs and wishes of older women, whose life priorities may differ from younger women. The aim of this study is to evaluate our new online decision tool, which can be used to support shared treatment decision making in older women with early breast cancer.

Who can participate?
Older women (aged over 70 years) who have been seen in breast clinic within the last 2 years, and healthcare professionals (oncologists, breast surgeons, consultants and breast nurses)

What does the study involve?
The researchers will be carrying out interviews and focus groups to discuss the importance of quality of life, physical activities and preferences for receiving treatment information. They may also ask participants to use the new online web tool and complete a questionnaire giving feedback on the decision tool.

What are the possible benefits and risks of participating?
There are no specific risks associated with taking part in the study, but participants may be inconvenienced in terms of the time taken to complete a questionnaire and take part in an interview or a focus group. In terms of benefits, the study result should help provide better support for people involved in making decisions about breast cancer treatments in the future.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
November 2020 to April 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Jenna Morgan
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# Contact information

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Public

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# Additional identifiers

### Integrated Research Application System (IRAS)
293691

### Central Portfolio Management System (CPMS)
48717

# Study information

### Scientific Title
Bridging the age gap: Integration of quality of life outcomes into the decision making of older women with early breast cancer

### Study objectives
As women get older, they value quality of life (QoL), physical function and independence as much as life expectancy. At present, no decision tools provide enough information to help them weigh this up. An online tool (Age Gap Decision Tool, https://agegap.shef.ac.uk/) has already been developed for older women with breast cancer, and this can calculate survival outcomes for women who have non-standard treatment. This study will explore what older women think about adding QoL and adverse event outcomes to the tool, explore how they feel QoL data should be best displayed to be understandable, add QoL outcomes into the tool and obtain feedback about whether older women feel this is useful in the clinical setting.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 14/05/2021, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048285; tyneandwearsouth.rec@hra.nhs.uk), REC ref: 21/NE/0072

### Primary study design
Observational

### Study design
Multicentre mixed method study

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Quality of life in older women with breast cancer

### Interventions
Semi-structured interviews, questionnaire completion and focus groups with older women (aged >70 years, seen in the breast clinic within the last 2 years); and health care professionals (breast clinic team, oncologists).

### Intervention Type

Mixed

### Primary outcome(s)
Patient and consultant feedback on the usability of the online web tool collected using a quantitative questionnaire at baseline

### Key secondary outcome(s)
1. Patients' and healthcare professionals' views on the importance of quality of life (QoL), adverse events (AE) and functional outcomes collected using semi-structured interviews at baseline
2. Patients' and healthcare professionals' preferences for visual display of QoL, physical function and AE outcomes collected using focus groups at baseline

### Completion date
30/04/2023

## Eligibility

### Key inclusion criteria
1. Older women (aged <70 years) diagnosed with early breast cancer within 2 years and documented to have discussed treatment options (surgery versus PET, types of surgery (mastectomy versus lumpectomy, axillary clearance or sentinel node biopsy) or chemotherapy or not)
2. Able to speak and read English
3. Able to give informed consent, and has capacity to take part in research
4. Older women (aged >70 years) attending breast clinic with benign pathology (such as breast pain, benign lumps) to reduce bias due to treatment experiences
5. Health care professionals (breast surgeons, oncologists, breast nurse specialists)

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### Key exclusion criteria
1. Individuals who are unable to give informed consent to take part in the study
2. Individuals who cannot speak and read English

### Date of first enrolment
07/06/2021

### Date of final enrolment
30/04/2023

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Doncaster Royal Infirmary**
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

# Sponsor information

**Organisation**
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

**ROR**
https://ror.org/01yc93g67

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**

United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 26/07/2023 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |