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

Submission date 27/05/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/06/2021	**Overall study status** Completed	
Last Edited 18/10/2022	**Condition category** 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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Study website
https://agegap.shef.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293691

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 293691, 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

Study design
Multicentre mixed method study

Primary study design
Observational

Secondary study design
Mixed method design

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information available

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 measure
Patient and consultant feedback on the usability of the online web tool collected using a quantitative questionnaire at baseline

Secondary outcome measures
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

Overall study start date
01/11/2020

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

Age group
Senior

Sex
Both

Target number of participants
234 in total. Interviews (30 in Phase 1, 60 in Phase 4); Decision Tool Review with patients and clinicians (120 participants in Phase 4); Focus groups (24 participants in Phase 1)

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
England

United Kingdom

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
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DN2 5LT

Sponsor information

Organisation
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

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+44 (0)1302644069
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Sponsor type
Hospital/treatment centre

Website
https://www.dbth.nhs.uk/

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

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals. The study protocol has not been published and the researchers do not have plans as yet to make it available online.

Intention to publish date

30/04/2024

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