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Bridging the age gap in breast cancer

Submission date 11/08/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/11/2016	**Overall study status** Ongoing	
Last Edited 11/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Current plain English summary as of 15/10/2018:
Background and study aims
Breast cancer is common in older women, affecting 13,000 women in the UK over the age of 70 every year. Despite this, 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. Surgery followed by a range of treatments is recommended and often tolerated well. However, for some older women, treatment may need to be changed to take into account other illnesses and frailty which may limit their ability to tolerate the full range of treatments. The problem is that there is little guidance available on this level of age, ill health and frailty, which makes the risks of some treatments (such as surgery and 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 in the UK. This study hopes to fill this gap in our knowledge by studying UK practice and treatment in older women.

Who can participate?
Women aged over 70 years with breast cancer

What does the study involve?
The study involves collecting detailed data about how fit older women are at the start of their treatment (other illnesses, level of independence, and quality of life), how they respond to their recommended treatment, and finally, how well their cancer is controlled in the long term. This study has a minimal impact on them and involves completing some questionnaires (some of which are optional). The study will then evaluate the use of decision support interventions (DESIs), which are given to 50% of sites and embedded as ‘standard of care.’ The DESIs comprise two patient-facing booklets and two web-based tools, which can be shared with individual patients. Women can take part in one of the following three ways. In its simplest form, the study only requires the participants’ permission to collect data about them, with no requirement to complete any questionnaires. The research staff 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 visit, but may not wish to fill in any further detailed quality-of-life questionnaires at follow-up visits. Some women may be happy to also fill in quality of life questionnaires at their first visit and when they attend follow-up visits.

What are the possible benefits and risks of participating?
This study will not directly benefit participants, but will give a much better understanding of the best ways to treat breast cancer in older women, and also help clinicians themselves to make better choices about treatment. The study is very low risk and involves no change of treatment. The study is designed to pose a minimal burden to participants, meaning that many parts are either optional or can be done later via telephone or postal return of quality of life questionnaires.

Where is the study run from?
Doncaster and Bassetlaw Hospitals NHS Foundation Trust and 48 other trusts in the UK

When is the study starting and how long is it expected to run for?
July 2012 to May 2016

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

Who is the main contact?
Ms Charlene Martin, agegap@sheffield.ac.uk

Previous plain English summary:
Background and study aims
Breast cancer is common in older women, affecting 13,000 women in the UK over the age of 70 every year. Despite this, 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. Surgery followed by a range of treatments is recommended and often tolerated well. However, for some older women, treatment may need to be changed to take into account other illnesses and frailty which may limit their ability to tolerate the full range of treatments. The problem is that there is little guidance available on this level of age, ill health and frailty, which makes the risks of some treatments (such as surgery and 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 in the UK. This study hopes to fill this gap in our knowledge by studying UK practice and treatment in older women.

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July 2012 to October 2017

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National Institute for Health Research (UK)

Who is the main contact?
Ms Charlene Martin

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-improving-outcomes-older-women-breast-cancer

Contact information

Type(s)
Public

Contact name
Ms Charlene Martin

Contact details
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University of Sheffield Medical School
Beech Hill Road
Sheffield
United Kingdom
S10 2RX

Additional identifiers

Clinical Trials Information System (CTIS)
2016-000779-25

Protocol serial number

DBH 0530/2013/NCT

Study information

Scientific Title
Bridging the age gap in breast cancer: improving outcomes for older women

Study objectives
Current hypothesis as of 15/10/2018:
The Age Gap study will use state of the art statistical and modelling techniques to determine the age, comorbidity, frailty and disease characteristics of women over 70 with early breast cancer to provide guidance on two primary questions:

1. What are the personal and cancer characteristics of women who can be safely advised that surgery is unlikely to confer any advantage for them?
2. What are the personal and cancer characteristics of women who should be advised to have adjuvant chemotherapy after surgery?
These data will be used to provide guidelines for clinicians to ensure that optimal individually tailored treatment is offered to all older women with breast cancer.

The data from the cohort study will then be used to develop two management algorithms for older women with breast cancer using a package of decision support interventions (DESIs) nested in the cohort study.

Previous hypothesis:
The Age Gap study will use state of the art statistical and modelling techniques to determine the age, comorbidity, frailty and disease characteristics of women over 70 with early breast cancer to provide guidance on two primary questions:
1. What are the personal and cancer characteristics of women who can be safely advised that surgery is unlikely to confer any advantage for them?
2. What are the personal and cancer characteristics of women who should be advised to have adjuvant chemotherapy after surgery?
These data will be used to provide guidelines for clinicians to ensure that optimal individually tailored treatment is offered to all older women with breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London South East Research Ethics Committee, 30/11/2012 (revised 25/01/2013), ref: 12/LO/1808

Study design
Observational cohort study with nested cluster randomized controlled trial

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Current intervention as of 15/10/2018:
Phase One:
The first phase is to construct a preliminary disease outcome and health economic model of breast cancer in older women. This will be based on the rather limited published trial evidence in this age group and also retrospective data from the UK cancer registry and hospital episode statistics (HES data).

Once the participant has consented, the treatment they have decided to have will just proceed as normal, with no change. Information about how the participant is doing and the treatment they are receiving will be recorded by a member of study staff but the participant's hospital visit will not differ from normal with the exception of going through some questionnaires with a member of the study team about their health, fitness and independence. Health and fitness data will be collected using well validated tools widely used in the field of geriatric research (the IADL, ADL, MMSE, Charlson score etc). These questionnaires are only completed at the baseline visit and if the woman wishes, she may complete these at a later date via a telephone call to minimise the burden of the study at each visit. It is estimated that these baseline questionnaires will take 20 to 30 minutes.

The participant can opt to also take part in answering questionnaires about how they are feeling (quality of life validated questionnaires: the EORTC QLQ C30, BR23 and ELD 15) at baseline and when they attend for their follow up visits. These are all well validated, widely used instruments in health research and are easy to understand and administer. The participant can see the questionnaires before they decide whether they want to take part so they can see what sort of questions they are. If the participant agrees to this option, these questionnaires will be completed pre-treatment and at various follow-up visits. Again, these may be completed later either by the patient themselves (and posted back to the study centre) or via a telephone call.

The participant can also opt to agree to let the study team have potential future access to any biopsy samples of their breast cancer that may have already been taken as part of their normal care. No additional biopsies for the study will be taken. These samples will not be accessed as part of the present study but the consents may be used as the basis for a follow on biological markers study which will be the subject of further funding and ethics applications.

The participant also has the option of agreeing to let the research team follow their long-term progress, even after the clinic has discharged them by giving consent for the study team to have access to their cancer registry and HES data. Follow up by this means would be undertaken for 10 years.

The participant will be seen in the clinic 6 weeks after they started their treatment and then every 6 months after they entered the study for a minimum of 2 years and up to 5 years. At each visit their doctor will perform a routine physical examination to check that their disease is under control and that they are well, the participant will also be asked if they have had any treatment-related problems. If the participant has agreed to full participation, at some of these visits the participant will also be asked by their doctor/nurse to complete some questionnaires about their quality of life. Patients may complete these questionnaires at home after their clinic visit if they wish.

At follow-up visits, patients on Primary Endocrine Therapy will have the size of the primary tumour and the largest of the diseased axillary lymph nodes (if present) measured by the Consultant Breast Surgeon, Consultant Oncologist or an appropriate delegated individual. These assessments are all part of normal routine practice.

At follow-up visits all patients will have the following documented:
1. Treatment details will be recorded e.g. radiotherapy, surgery, chemotherapy, trastuzumab, endocrine therapy
2. Treatment-related adverse events
3. Management of local/regional recurrence, progressive disease, metastatic disease or new primary breast tumour (if applicable)

The data from the cohort study will then be used to modify and improve the preliminary model of cancer outcomes and enable us to develop two management algorithms for older women with breast cancer using a package of decision support interventions (DESIs).

Phase Two:
The DESIs will be embedded in half of Age Gap recruiting sites as part of standard care, with completion of two additional questionnaires focusing on pre-treatment counselling and decision-making, and the ability to use the decision aids if they wish to help patients decide on treatment. The aim of the intervention is to improve the quality of life, decision quality, decision regret, satisfaction and treatment understanding of older women entering the Age Gap study. These DESIs will be aimed at women facing a choice of surgery or primary endocrine therapy (PET) or, following surgery, for those with higher risk cancer facing a choice of chemotherapy or no chemotherapy. These are the two areas where clinical practice in older women differs most markedly from that in younger women and where there are high levels of variation between breast units.
The DESIs comprise of two patient facing booklets designed especially for older women facing these choices and two web based algorithms, which may be used by the clinical team to predict individual risk and benefit information that can be shared with patients. These resources have been carefully developed using the best available evidence and have undergone extensive user testing. Sites will be allocated access to use the decision tools as part of routine care or simply continue with normal best practice pre-treatment counselling. Randomisation of sites will be stratified according to PET and chemotherapy rate.
1. Control – Usual standard practice for older women (>70 years) diagnosed with breast cancer with no change to normal counselling and decision-making practice.
2. Intervention – Usual standard practice for older women (>70 years) diagnosed with breast cancer plus optional clinician and patient access to the DESIs (option grid, detailed information booklet and clinical algorithm), which will have been made available to these units to adopt as their standard of care.

Previous intervention:
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Once the participant has consented, the treatment they have decided to have will just proceed as normal, with no change. Information about how the participant is doing and the treatment they are receiving will be recorded by a member of study staff but the participant's hospital visit will not differ from normal with the exception of going through some questionnaires with a member of the study team about their health, fitness and independence. Health and fitness data

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2. Treatment-related adverse events
3. Management of local/regional recurrence, progressive disease, metastatic disease or new primary breast tumour (if applicable)

The data from the cohort study will then be used to modify and improve the preliminary model of cancer outcomes and enable us to develop two management algorithms for older women with breast cancer. These will be made freely available as web-based tools to help to guide clinicians in optimising the management of older women.

Intervention Type
Other

Primary outcome(s)
Global health status/quality of life, measured using questions 29+30 of The European Organization for Research and Treatment of Cancer QLQ-C30 (EORTC QLQ-C30) at 6 weeks and 6 months post-intervention

Key secondary outcome(s))
Current secondary outcome measures as of 15/10/2018:
Measured at the time of diagnosis:
1. Comorbidity, measured using the Charlson comorbidity index
2. Frailty, measured using the Barthel Index (ADL) and instrumental activities of daily living scores (IADL)
3. Cognitive status, measured using the mini-mental state examination MMSE)
4. Quality of life, measured using the EORTC QLQ C30, EORTC breast cancer-specific quality-of-life questionnaire (BR23), EORTC quality of life questionnaire module for older people with cancer (EORTC ELD 15, EuroQol Group EQ-5D)
5. Tumour stage, grade and receptor status
6. Decision regret, measured using the Decision Regret Scale
7. Shared decision making using the CollaboRATE score
8. Patient anxiety levels using the Speilberger short-form State Anxiety Score
9. Knowledge and treatment preference, measured using a non-validated questionnaire
10. Illness perceptions after the relevant treatment decision using the Brief Illness Perceptions Questionnaire
11. Coping after the relevant treatment decision, using the Brief COPE

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Measured at the time of diagnosis:
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5. Tumour stage, grade and receptor status

Completion date
30/05/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/10/2018:
1. Female
2. Aged over 70 years of age at the time of diagnosis of cancer
3. Primary operable (TNM categories: T1 (Tumour 2 cm or less in greatest dimension), T2 (Tumour more than 2 cm but not more than 5 cm in greatest dimension), T3 (Tumour more than 5 cm in greatest dimension), N0 (No regional lymph node metastasis), N1 (Metastasis in movable ipsilateral axillary lymph node(s), M0 (No distant metastasis)) invasive breast cancer (core biopsy

or diagnostic incision biopsy)
4. Tumour ER and Her-2 status will be available and categorised according to accepted scoring systems e.g. H score 6 or Allred score 57 for ER and for Her-2, IHC score 1-3 plus FISH testing if IHC equivocal
5. Ability to give informed consent if considering full or partial trial participation (see below)
6. Willing to complete the questionnaires for the additional trial evaluations if considering full trial participation
7. If suitable for data collection only, the patient does not need to give consent but participation in the data collection exercise should be agreed and assented to by their next of kin, friend or carer
8. Willing to complete the additional questionnaires for the additional trial evaluations relating to decision-making quality, regret and knowledge. All women in the study who are offered a choice of treatments will have the decision quality forms sent to them in both intervention and control sites at baseline, 6 week and 6 month after their treatment decision. The PET versus surgery DESI may be used for any women who are considering this treatment choice. The chemotherapy versus no chemotherapy DESI may be used for any women who are considering this treatment choice. For women who are not offered either choice, the DESI will not be used.
9. Relating only to women entered into the study by a proxy decision maker because they lack cognitive capacity: the proxy decision maker will be offered access to the DESIs as part of the normal counselling process in intervention sites (and normal counselling in control sites). These proxy decision makers will be invited to complete optional questionnaires and take part in an interview about the counselling process.

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3. Primary operable (TNM categories: T1 (Tumour 2 cm or less in greatest dimension), T2 (Tumour more than 2 cm but not more than 5 cm in greatest dimension), T3 (Tumour more than 5 cm in greatest dimension), N0 (No regional lymph node metastasis), N1 (Metastasis in movable ipsilateral axillary lymph node(s), M0 (No distant metastasis)) invasive breast cancer (core biopsy or diagnostic incision biopsy)
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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit

70 years

Sex
Female

Total final enrolment
3416

Key exclusion criteria
1. Disease unsuitable for surgery e.g. inoperable or metastatic disease
2. Previous invasive breast cancer (within past 5 years)
3. There is no restriction for people who are unable to speak English. Translation of study documents and translators will be undertaken by recruiting centres if required
4. For patients considered for the PET versus surgery comparison, use of concurrent Hormone Replacement Therapy (HRT) or therapy with any other oestrogen-containing preparation is an exclusion criteria, unless treatment is discontinued for 4 weeks before the study starts
5. There is no restriction for any co-morbidity or frailty as the study aims to capture data on management and outcomes in these cases
6. Patient without capacity being considered for the data collection only arm of the study but for whom there is no consultee available

Date of first enrolment
01/04/2013

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Doncaster and Bassetlaw Hospitals NHS Trust
Doncaster Royal Infirmary
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Sheffield Teaching Hospitals
Royal Hallamshire Hospital
Sheffield

United Kingdom
S10 2JF

Study participating centre
Barnsley Hospital NHS Trust
Barnsley Hospital
Barnsley
United Kingdom
S75 2EP

Study participating centre
Milton Keynes Hospital NHS Trust
Milton Keynes Hospital
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
North Lincolnshire & Goole NHS Trust
Diana, Princess of Wales Hospital
Scunthorpe General Hospital
United Kingdom
DN33 2BA

Study participating centre
University Hospitals of Leicester
Glenfield Hospital
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
East Lancashire Teaching Hospitals
Burnley General Hospital
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Harrogate & District Foundation Trust
Harrogate District Hospital
Harrogate
United Kingdom
HG2 7SX

Study participating centre
St Helens & Knowsley Teaching Hospitals NHS Trust
Whiston Hospital
Prescot
United Kingdom
L35 5DR

Study participating centre
York Teaching Hospital NHS Foundation Trust
The York Hospital
Scarborough Hospital
York
United Kingdom
YO31 8HE

Study participating centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Royal Liverpool University Hospital
Liverpool
United Kingdom
L7 8XP

Study participating centre
Airedale NHS Foundation Trust
Airedale General Hospital
Keighley
United Kingdom
BD20 6TD

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James's University Hospital

Leeds
United Kingdom
LS9 7TF

Study participating centre
Bradford Teaching Hospitals NHS Trust
St Luke's Hospital
Bradford
United Kingdom
BD5 0NA

Study participating centre
Cardiff and Vale University Health Board
University Hospital Llandough
Llandough
United Kingdom
CF64 2XX

Study participating centre
Aneurin Bevan Health Board
Royal Gwent Hospital, Newport
Nevill Hall Hospital, Abergavenny
Newport
United Kingdom
NP18 3XQ

Study participating centre
University Hospitals of Morecambe Bay NHS Trust
Royal Lancaster Infirmary
Furness General Hospital
Lancaster
United Kingdom
LA1 4RP

Study participating centre
University Hospitals Coventry & Warwickshire NHS Trust
University Hospital
Coventry
United Kingdom
CV2 2DX

Study participating centre
United Lincolnshire Hospitals NHS Trust
Lincoln County Hospital
Grantham and District Hospital
Pilgrim Hospital Boston
Lincolnshire
United Kingdom
LN2 5QY

Study participating centre
Hull and East Yorkshire Hospitals NHS Trust
Castle Hill Hospital
Hull
United Kingdom
HU16 5JQ

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham City Hospital
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Southport & Ormskirk Hospital NHS Trust
Southport & Formby District General Hospital
Southport
United Kingdom
PR8 6PN

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Crewe
United Kingdom
CW1 4QJ

Study participating centre

Royal Marsden NHS Foundation Trust
The Royal Marsden, Chelsea, London
The Royal Marsden, Sutton Surrey
London
United Kingdom
SW3 6JJ

Study participating centre
Gloucestershire Hospitals NHS Trust
Gloucestershire Royal Hospital
Cheltenham General Hospital
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Guys and St Thomas' NHS Foundation Trust
Guy's Hospital
London
United Kingdom
SE1 9RT

Study participating centre
Dorset County Hospitals NHS Foundation Trust
Dorset County Hospital
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Mid Essex Hospital Services Trust
Broomfield Hospital
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Pinderfields General Hospital

Wakefield
United Kingdom
WF1 4DG

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Hospital
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Rotherham NHS Foundation Trust
Rotherham General Hospital
Rotherham
United Kingdom
S60 2UD

Study participating centre
Dartford and Gravesham Trust
Darent Valley Hospital
Dartford
United Kingdom
DA2 8DA

Study participating centre
Kingston Hospital NHS Foundation Trust
Kingston Hospital
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Colchester Hospital University NHS Foundation Trust
Essex County Hospital
Colchester
United Kingdom
CO3 3NB

Study participating centre
Yeovil District Hospital Foundation Trust
Yeovil District Hospital
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Croydon Health Services NHS Trust
Croydon University Hospital
Croydon
United Kingdom
CR9 2RS

Study participating centre
North Tees and Hartlepool NHS Trust
University Hospital of North Tees
Stockton on Tees
United Kingdom
TS19 8PE

Study participating centre
South Tees NHS Foundation Trust
The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Luton and Dunstable University Hospital NHS Foundation Trust
Luton and Dunstable Hospital
Luton
United Kingdom
LU4 0DZ

Study participating centre
Weston Area Health NHS Trust
Weston General Hospital
Weston-super-Mare
United Kingdom
BS23 4TQ

Study participating centre
Tameside Hospital NHS Foundation Trust
Tameside General Hospital
Ashton-under-Lyne
United Kingdom
OL6 9RW

Study participating centre
East Cheshire NHS Trust
Macclesfield District General Hospital
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Wrightington, Wigan and Leigh NHS Trust
Royal Albert Edward Infirmary
Wigan
United Kingdom
WN1 2NN

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
King's Mill Hospital
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Wythenshawe Hospital

Manchester
United Kingdom
M23 9LT

Study participating centre
Aintree University Hospital NHS Foundation Trust
Aintree University Hospital
Liverpool
United Kingdom
L9 7AL

Study participating centre
Sandwell and West Birmingham Hospitals NHS Foundation Trust
Birmingham City Hospital
Birmingham
United Kingdom
B18 7QH

Study participating centre
Brighton and Sussex University Hospitals NHS Foundation Trust
The Park Centre for Breast Care
Brighton
United Kingdom
BN1 6AG

Study participating centre
St Margaret's Hospital
The Princess Alexandra Hospital NHS Trust
The Plain
Epping
United Kingdom
CM16 6TN

Study participating centre
St Mary's Hospital
Isle of Wight NHS Trust
Parkhurst Road
Newport
United Kingdom
PO30 5TG

Study participating centre
Churchill Hospital
Oxford University Hospitals NHS Foundation Trust
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Frimley Park Hospital
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Sponsor information

Organisation
Doncaster and Bassetlaw 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 datasets generated and/or analysed during the current study are available from Ms Lynda Wyld (l.wyld@sheffield.ac.uk) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No
Results article	results	10/06/2015		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/01/2021	23/11/2020	Yes	No
Results article	results on quality of life in patients undergoing chemotherapy	01/02/2021	30/12/2020	Yes	No
Results article		01/07/2021	12/05/2021	Yes	No
Results article		27/05/2021	30/11/2022	Yes	No
Results article		01/06/2022	30/11/2022	Yes	No
Other publications	Intervention development and usability testing	14/01/2019	30/11/2022	Yes	No
Other publications	Process evaluation	13/07/2021	30/11/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			14/03/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes