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Supporting Women with adhErence to hormonE Therapy following breast cancer (SWEET): the feasibility study

Submission date
13/07/2022

Recruitment status
No longer recruiting

Registration date
12/08/2022

Overall study status
Completed

Last Edited
22/04/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-support-women-to-take-their-hormone-therapy-following-breast-cancer-sweet

Background and study aims
In 2016, 11,563 women died from breast cancer in the UK. Most would have been prescribed hormone therapy (HT); sometimes known as endocrine therapy, which blocks the effect of oestrogen on breast cancer cells. HT is prescribed as a daily tablet, usually for at least five years and often up to 10 years. When women stop taking HT prematurely or don't take it as prescribed (known as "poor adherence"), they have up to a three times higher chance of cancer returning and dying from cancer. At least 20% of women have poor adherence after two years and around 50% by five years. Our previous research has identified reasons for poor adherence, including feeling negative or concerned about HT, not fully understanding its importance, side effects, feeling unsupported, and forgetfulness. SWEET is an NIHR-funded research programme, which is supported by a Patient Advisory Group and Clinical Reference Group, which will develop and test a support package to support women taking ET as recommended. The feasibility study will run at up to five NHS clinical sites and use mixed methods to inform the potential for a larger randomised controlled trial (RCT), answering the following key questions:
1. Can we identify and recruit potentially eligible patients?
2. Is it feasible to deliver the initial face-to-face intervention consultation within 8 weeks of recruitment?
3. Are the baseline and follow-up questionnaires acceptable?
4. Do women find the different components of the intervention acceptable and useful?
5. What is the timeliness and quality of primary care prescription encashment data, and is it possible to use this to compute an objective measure of adherence to adjuvant endocrine therapy (AET)?

Who can participate?
Sub-study 1: Women recently diagnosed with early-stage ER-positive invasive breast cancer and prescribed oral AET (in the past 3 months), who have a medium or high risk of recurrence.

Sub-study 2: Women diagnosed with early-stage ER-positive invasive breast cancer and prescribed oral AET in the previous 9-36 months.

What does the study involve?
Sub-study 1: Participants will receive the intervention (HT&Me support package) and will be followed for 7-9 weeks. As part of the HT&Me support package, participants will be offered an initial appointment with a study nurse who will ask women about their experiences of hormone therapy so far and will show them the HT&Me website and how it works. Some consultations may be recorded so that the research team can review how they went. Participants will also have access to a follow-up consultation to check how they are getting on with their hormone therapy and ask about their experiences with the website. Participants will then be asked to complete a follow-up questionnaire, and a sub-sample will undergo interviews. Interviews will also be conducted with a sample of health professionals involved in the study.

Sub-study 2: The AET prescribing history for each individual recruited woman will be obtained through linkage of the cohort to the National Cancer Registration Database (NCRD) and the NHS Business Services Authority (BSA) Primary Care Prescribing Database (PCPD). This will provide information on timeliness and completeness. If this information cannot be collected via NHS digital we will seek to obtain this information through GP records.

What are the possible benefits and risks of participating?
Participants may find taking part in this research helpful as you will be provided with additional information and support in relation to taking hormone therapy. Participants will also be contributing to research which could help women with breast cancer who are taking hormone therapy in the future. As a thank you to women that take part in additional interviews at the end of the study, we will be offering a £30 high street voucher.

Participating in qualitative research and completing questionnaires may have emotional consequences for the participant and may involve them considering and discussing potentially upsetting issues related to their own experiences. Participants do not have to answer any questions they do not feel comfortable answering and they can take a break during consultations or interviews if they wish.

Where is the study run from?
Newcastle NHS Foundation Trust, Imperial College Healthcare Trust, Oxford University Hospitals, (with the potential addition of Great Western Hospital) (United Kingdom)

When is the study starting and how long is it expected to run for?
March 2022 to November 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) Programme Grant for Applied Research (PGfAR) (United Kingdom)

Who is the main contact?
SWEETStudy@ncl.ac.uk (United Kingdom)

Contact information

Type(s)
Principal investigator

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
307011

Central Portfolio Management System (CPMS)
52782

Study information

Scientific Title
Improving outcomes for women diagnosed with early breast cancer through adherence to adjuvant endocrine therapy: the feasibility study

Acronym
SWEET

Study objectives

The provision of a tailored support package for women with breast cancer (at moderate or high risk of recurrence) is feasible and acceptable

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2022, South Central – Hampshire A - Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8196; hampshirea.rec@hra.nhs.uk), ref: 22/SC/0150

Primary study design
Interventional

Study design
Non-randomized single-arm interventional study

Study type(s)
Treatment

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

Interventions
Sub-study 1 is a single-arm, non-randomised feasibility study to explore the acceptability and feasibility of delivering the SWEET intervention (HT&Me support package). Recruited women (n=45) will receive the intervention and will be followed for 7-9 weeks, at which point they will complete a follow-up questionnaire, and a sub-sample will undergo interviews. Interviews will also be conducted with a sample of health professionals involved in the study (n=15-18).

Sub-study 2 is a retrospective cohort study which will test the processes for obtaining prescription encashment data for a small cohort of women (n=45) with breast cancer initially prescribed adjuvant endocrine therapy (AET) at the hospital (thereby testing, on a small scale, the processes that will require to be followed in the subsequent RCT). The AET prescribing history for each individual recruited woman will be obtained through linkage of the cohort to the National Cancer Registration Database (NCRD) and the NHS Business Services Authority (BSA) Primary Care Prescribing Database (PCPD). This will provide information on timeliness and completeness.

Intervention Type
Other

Primary outcome(s)
Sub-study 1:
1. Optimal patient recruitment pathways measured using patient and health care provider (HCP) interviews at around 8-9 weeks post initial consultation and by review of patient screening logs recorded at time of assessment of eligibility
2. Feasibility of recruiting women to receive the intervention measured using patient and HCP interviews at around 8-9 weeks post initial consultation and by review of:
2.1. Patient screening logs recorded at the time of assessment of eligibility

2.2. Information recorded on reasons why women declined to take part (decliner log), recorded at the time of recruitment
3. Feasibility of delivering the intervention measured as percentages of recruited women who:
3.1. Received the initial nurse consultation within 8 weeks of recruitment
3.2. Accessed the web app during their time in the study, determined from the questionnaire and analytic data at 8-9 weeks post initial consultation and from HCP interviews at 8-9 weeks post initial consultation
4. Acceptability and usefulness of the HT&Me intervention to patients measured using patient and HCP interviews at around 8-9 weeks post initial consultation
5. Barriers to, and facilitators of, trial implementation, including:
5.1. Willingness of staff to recruit women to a randomised controlled trial (RCT) measured using HCP interviews at around 8-9 weeks post initial consultation
5.2. Willingness of women to be recruited and randomised to an RCT measured using patient interviews and follow-up questionnaire at around 8-9 weeks post initial consultation
6. Test processes for collecting self-reported outcome data measured using patient questionnaires at baseline and at 8 weeks after the initial consultation

Sub-study 2:
7. Test processes for obtaining prescription encashment data for a small cohort of women with breast cancer initially prescribed adjuvant endocrine therapy some months previously measured retrospectively using prescription data from NHS digital or GP records, collected prior to the end of a feasibility study (June 2022)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/11/2023

Eligibility

Key inclusion criteria
Sub-study 1 Inclusion criteria:
The following patients will be eligible:
1. Aged 18 years old and over
2. Female
3. Diagnosis of ER-positive invasive breast cancer
4. Medium or high risk of recurrence, defined as one of the following:
4.1. T2 and N0
4.2. T2 and N>0
4.3. T1 and N>0
4.4. T1 and N0 and grade 3
5. Within 3 months of first oral adjuvant endocrine therapy (AET) prescription (tamoxifen or aromatase inhibitor)
6. Completed surgery
7. Completed chemotherapy (if applicable)
8. Can access the internet and have an email address
9. Are willing to use a support package with a web-based component

Sub-study 2 Inclusion criteria:
The following patients will be eligible:

1. Aged 18 years old and over
2. Female
3. Diagnosis of ER-positive invasive breast cancer
4. Medium or high risk of recurrence, defined as one of the following:
4.1. T2 and N0
4.2. T2 and N>0
4.3. T1 and N>0
4.4. T1 and N0 and grade 3
5. Were first prescribed oral AET (tamoxifen or aromatase inhibitor) within the past 9-36 months
6. Have completed surgery
7. Have completed chemotherapy (if applicable)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment
115

Key exclusion criteria
Sub-study 1 and 2 exclusion criteria:
The following patients with early-stage ER+ve invasive breast cancer will be ineligible:
1. Male
2. Have been prescribed adjuvant CDK4/6i (abemaciclib)
3. Have cognitive impairment sufficient to preclude participation, as judged by the clinical team
4. Are unable to read and understand English
5. Had previous AET (for another breast cancer)
6. Have not had surgery for breast cancer

Date of first enrolment
01/09/2022

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
St Marys Hospital
South Wharf Road
London
England
W2 1BL

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Central Commissioning Facility (CCF); Grant Codes: NIHR200098

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 during and/or analysed during the current study will be stored in a publicly available repository.

Added 22/04/2026:
The name of the repository: Open Science Framework (https://doi.org/10.17605/OSF.IO/ZP7US).
The type of data stored: participant-level datasets, data dictionary and questionnaire packs used in the Feasibility Study of the HT&Me intervention.
Dates of availability: 20/11/2025 onwards.
Consent for data sharing was obtained from participants.
Comments on data anonymization: Identifiable data was removed, including any location data. Participant IDs were changed to remove location data. The diagnosis date was changed to the year.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2025	22/12/2025	Yes	No
Results article		01/11/2025	19/02/2026	Yes	No
Dataset		20/11/2025	22/04/2026	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	21/07/2022	08/08/2022	No	Yes