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Supporting women with adherence to hormone therapy following breast cancer

Submission date 27/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/08/2023	**Overall study status** Ongoing	
Last Edited 26/05/2026	**Condition category** Cancer	

Plain English summary of protocol

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 5 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 the cancer returning and dying from cancer. At least 20% of women have poor adherence after 2 years and around 50% by 5 years. 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, supported by a Patient Advisory Group and Clinical Reference Group, will develop and test a support package to support women taking treatment as recommended. The aim of this study is to determine the clinical effectiveness of the trial intervention in reducing poor adherence to treatment and improving quality of life.

Who can participate?
Women recently diagnosed with ER-positive invasive breast cancer, stages 1- 3 and treated with curative intent, who have been prescribed oral adjuvant endocrine therapy (AET) within the past 3 months

What does the study involve?
Participants randomly allocated to Group A will receive access to the HT&Me Support Package which involves:
A consultation of around 30 minutes with a HT&Me study nurse (either based at your local hospital site, or via the charity Breast Cancer Now) to discuss hormone therapy, answer any questions you might have and introduce the HT&Me website. This appointment may be delivered in person, by video call or if required by telephone call, appointments with a Breast Cancer Now nurse will always be completed over video call.
Access to the HT&Me website which contains short videos, information, tips & tools to support you to take hormone therapy every day (e.g. set reminders to take hormone therapy or order repeat prescriptions), get tips for managing side effects, and information about how to get further support.

After 12 weeks, participants will have a follow-up consultation with the HT&Me study nurse to see how they are getting on with their hormone therapy and the HT&Me website. For a few women, the researchers might record their consultations; this is simply to check what information they have been given and that the consultations are going as planned. They may also be asked to provide feedback on the appointments by text message.
Participants will also be sent some messages by email or text, to remind them about the importance of taking hormone therapy and that the website may be a useful resource.
Participants randomly allocated to Group B will continue with their usual NHS care and hormone therapy as prescribed.

What are the possible benefits and risks of participating?
It is not known whether the HT&Me support package will be effective in helping women to continue taking their hormone therapy as prescribed or in improving quality-of-life, however, women in Group A who receive the intervention will receive more information and support whilst taking their hormone therapy and they may find this helpful. Participants may not directly benefit from taking part in this research, but your participation will help guide support for women with breast cancer taking hormone therapy in the future. There are no physical risks involved in taking part in the study, although being asked questions about cancer may be upsetting

Where is the study run from?
Warwick Clinical Trials Unit, University of Warwick (UK)

When is the study starting and how long is it expected to run for?
May 2023 to March 2027

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

Who is the main contact?
SWEET@warwick.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-helping-women-stay-on-hormone-therapy-after-breast-cancer-sweet

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
330129

Central Portfolio Management System (CPMS)
57385

Study information

Scientific Title
Supporting Women with adhErence to hormonE Therapy following breast cancer (SWEET)

Acronym
SWEET

Study objectives
Provision of a tailored support package for women with breast cancer (at moderate or high risk of recurrence) who are prescribed adjuvant hormone therapy reduces poor adherence and improves quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/08/2023, South Central – Hampshire B (2 Redman Place, Stratford, Health Research Authority, E20 1JQ, UK; +44 (0)207 104 8088; hampshireb.rec@hra.nhs.uk), ref: 23/SC/0254

Primary study design
Interventional

Study design
Randomized; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Management of Care, Other, Qualitative

Study type(s)
Treatment

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

Interventions
SWEET is a multi-centre, unblinded, pragmatic randomised controlled trial (RCT) of HT&Me intervention + usual care vs usual care alone. The aim is to determine the clinical effectiveness of the trial intervention in reducing poor adherence to AET and improving cancer-specific HRQoL.

SWEET plans to recruit 1460 women, across up to 80 sites. Patients who are confirmed to be eligible will be invited to take part in the study and if, following review of the patient information sheet, they decide to participate, written, or remote verbal informed consent will be obtained. The target population will be women with invasive ER+ve breast cancer, stages 1 – 3 treated with curative intent, who have been prescribed adjuvant endocrine therapy (AET) within the past 3 months.

Baseline: Prior to randomisation, participants will be issued with a baseline questionnaire and health resource use questionnaire, as well as providing clinical information. Personal information (name, contact details and NHS number) will be collected for the purpose of creating HT&Me accounts where required, and for data linkage.

Participants will be randomised on a 1:1 basis to receive either:
HT&Me intervention, which includes:
1. Initial consultation with a SWEET nurse/practitioner (either at site, or remotely via Breast Cancer Now) to introduce the HT&Me intervention, discuss the patient's beliefs and concerns about AET, and experiences of AET.
2. Access to the HT&Me web app which contains a short animation, information, tips & tools to support adherence including optional daily reminders to take AET or order repeat prescriptions, strategies for managing side effects, and signposting to further support
3. Follow-up consultation with a SWEET nurse/ practitioner (either at site, or remotely via Breast Cancer Now) to discuss any new concerns and review the use of the HT&Me web app. Participants will also be asked to complete a feedback questionnaire on their experience of the HT&Me support package
4. Regular motivational messages delivered by email or text, promoting adherence and encouraging the use of the web app.

Usual care: Participants randomised to usual care alone will continue to access AET as per institutional guidelines and will continue to be followed up (either at site or through their GP) as per institutional guidelines and follow-up processes.

Follow-up: Patients will be followed up by a questionnaire at 6 months, 12 months and 18 months for adherence and HRQoL. Sites will be responsible for the distribution of questionnaires to participants. Participants may be followed up for up to 15 years longer-term data linkage (subject to additional funding).
Process evaluation: A parallel process evaluation will be undertaken, using a mixture of qualitative and quantitative methods. The aims of the process evaluation are to:
1. Explore fidelity of the intervention as delivered, received and enacted
2. Assess whether the intervention worked as hypothesized by the logic model
3. To identify any moderating contextual factors and/or unintended consequences of the intervention.

Semi-structured telephone interviews will be conducted throughout the trial with participants (Arm A- HT&Me intervention, n=25-30; Arm B (control), n=10-15) to discuss their experience of the study. Interviews with SWEET study practitioners (n=20-25) will also take place. These interviews will explore:
1. Views and experiences of the trial, intervention and Behaviour Change Techniques (BCTs) (as appropriate)
2. Intervention fidelity and quality
3. Potential contamination
4. Contextual factors

Intervention Type
Other

Primary outcome(s)
AET adherence using combined self-report (Medical Adherence Report Scale (MARS-5) and prescription encashment records (e.g. Medication Possession Ratio (MPR); Timepoint(s): Baseline, 6 months, 12 months and 18 months

Key secondary outcome(s)
1. Cancer-specific HR-QOL using Functional Assessment of Cancer Therapy scale- General (FACT-G); Timepoint(s): Baseline, 6 months, 12 months and 18 months
2. AET-specific HRQoL using Breast Cancer Trialist Prevention Checklist (BCPT; Timepoint(s): Baseline, 6 months, 12 months and 18 months
3. Cost-effectiveness using within-trial cost per quality-adjusted life year (QALY); QALYs; resource use and cost to NHS, patients and society, and EQ-5D-5L; Timepoint(s): Baseline, 6 months, 12 months and 18 months
4. Extent of adherence using MPR (continuous); encashment records and/or GP prescribing records throughout the study
5. Suboptimal implementation self-reported using MARS-5; Timepoint(s): Baseline, 6 months, 12 months and 18 months
6. Non-persistence, self-reported using >180 days gap in AET prescriptions; Timepoint(s): Baseline, 6 months, 12 months and 18 months

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Aged 18+ years
2. Female
3. Diagnosis of ER-positive invasive breast cancer, stages 1-3 and treated with curative intent
4. Completed surgery for breast cancer
5. Within 3 months of first oral AET prescription (tamoxifen or aromatase inhibitor) post breast cancer completion surgery
6. Completed chemotherapy (if applicable)
7. Able to access the internet
8. Has an email address
9. Are willing to use a support package with a web-based component

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Male
2. Evidence of metastatic disease i.e. stage 4 disease (M1 regardless of T and N status)
3. Have cognitive impairment sufficient to preclude participation, as judged by the clinical team
4. Had previous AET (for another breast cancer)
5. Are unable to read and understand English

Date of first enrolment
26/03/2024

Date of final enrolment
26/09/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
England
WN1 2NN

Study participating centre
Poole Hospital
Longfleet Road

Poole
England
BH15 2JB

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
England
TA1 5DA

Study participating centre
The Whittington Hospital
Highgate Hill
London
England
N19 5NF

Study participating centre
St Albans City Hospital
Waverley Road
St Albans
St. Albans
England
AL3 5PN

Study participating centre
Airedale General
Airedale General Hospital
Skipton Road, Steeton
Keighley
England
BD20 6TD

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
Wales
LL18 5UJ

Study participating centre
Princess Alexandra Hospital
Hamstel Road
Harlow
England
CM20 1QX

Study participating centre
St Mary's Hospital
St. Marys Hospital
West Wing
Milton Road
Portsmouth
England
PO3 6AD

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
Wales
LL13 7TD

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
Wales
SA2 8QA

Study participating centre
Basingstoke and North Hants Hospital
Aldermaston Road
Basingstoke
England
RG24 9NA

Study participating centre
Royal Bournemouth General Hospital
Castle Lane East
Bournemouth
England
BH7 7DW

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
England
SO22 5DG

Study participating centre
Bronglais General Hospital
Bronglais Hospital
Caradoc Road
Aberystwyth
Wales
SY23 1ER

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5LD

Study participating centre
East Surrey Hospital
Canada Avenue

Redhill
England
RH1 5RH

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
Scotland
G12 0YN

Study participating centre
West Suffolk Hospital
Hardwick Ln
Bury Saint Edmunds
England
IP33 2QZ

Study participating centre
Leighton Hospital
Leighton
Crewe
England
CW1 4QJ

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre
Pilgrim Hospital
Sibsey Road
Boston
England
PE21 9QS

Study participating centre
University Hospitals Coventry & Warwickshire
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
University Hospital of North Tees
Hardwick Road
Stockton-on-tees
England
TS19 8PE

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Study participating centre
St John's Hospital
Howden West
Livingston
Lothian

Scotland
EH54 6PP

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
Scotland
FK5 4WR

Study participating centre
Conquest Hospital
The Ridge
St. Leonards-on-sea
England
TN37 7RD

Study participating centre
Mount Vernon Cancer Centre
Rickmansworth Road
Northwood
England
HA6 2RN

Study participating centre
George Eliot Hospital
Lewes House
College Street
Nuneaton
England
CV10 7DJ

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
England
BN2 5BE

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
England
HP21 8AL

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
Tameside General Hospital
Fountain Street
Ashton-under-lyne
England
OL6 9RW

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200098

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request through the CI (SWEET@warwick.ac.uk) after trial publication. A proposal describing the purpose, scope, data items requested, and analysis plan and including appropriate acknowledgement of the SWEET trial management group) should be provided for approval from the SWEET TMG. Any data transfer would be in accordance with the University of Warwick SOPs and require data sharing /processing agreements to be in place. Participant Consent for future research is requested.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/11/2025	28/11/2025	Yes	No
Other files	Feasibility study plain English results		26/05/2026	No	No
Protocol file	version 4.0	08/04/2024	08/07/2024	No	No
Study website		11/11/2025	11/11/2025	No	Yes