

# Supporting women with adherence to hormone therapy following breast cancer

<b>Submission date</b> 27/07/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/08/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/02/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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 June 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>

**Study website**

<https://www.sweetstudy.co.uk>

## Contact information

**Type(s)**

Principal Investigator

**Contact name**

Prof Linda Sharp

**Contact details**

Newcastle University

Level 5

Sir James Spence Institute

Royal Victoria Infirmary

Queen Victoria Road  
Newcastle  
United Kingdom  
NE1 4LP  
+44 (0)1912086275  
SWEET@warwick.ac.uk

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

330129

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CPMS 57385, IRAS 330129

## 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

### Study design

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

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**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

### **Phase**

Not Specified

### **Primary outcome measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

31/05/2023

### **Completion date**

30/06/2027

## 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

### Age group

Adult

### Lower age limit

18 Years

### Sex

Female

### Target number of participants

Planned Sample Size: 1460; UK Sample Size: 1460

### 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

31/12/2025

## Locations

### Countries of recruitment

England

Scotland

United Kingdom

Wales

**Study participating centre**

**Royal Albert Edward Infirmary**

Wigan Lane

Wigan

United Kingdom

WN1 2NN

**Study participating centre**

**Poole Hospital**

Longfleet Road

Poole

United Kingdom

BH15 2JB

**Study participating centre**

**Musgrove Park Hospital (taunton)**

Musgrove Park Hospital

Taunton

United Kingdom

TA1 5DA

**Study participating centre**

**The Whittington Hospital**

Highgate Hill

London

United Kingdom

N19 5NF

**Study participating centre**

**St Albans City Hospital**

Waverley Road

St Albans

St. Albans

United Kingdom

AL3 5PN

**Study participating centre**

**Airedale General**

Airedale General Hospital  
Skipton Road, Steeton  
Keighley  
United Kingdom  
BD20 6TD

**Study participating centre**

**Glan Clwd Hospital**

Ysbyty Glan Clwydd  
Bodelwyddan  
Rhyl  
United Kingdom  
LL18 5UJ

**Study participating centre**

**Princess Alexandra Hospital**

Hamstel Road  
Harlow  
United Kingdom  
CM20 1QX

**Study participating centre**

**St Mary's Hospital**

St. Marys Hospital  
West Wing  
Milton Road  
Portsmouth  
United Kingdom  
PO3 6AD

**Study participating centre**

**Wrexham Maelor Hospital**

Croesnewydd Road  
Wrexham Technology Park  
Wrexham  
United Kingdom  
LL13 7TD



**Study participating centre**

**Singleton Hospital**

Sketty Lane  
Sketty  
Swansea  
United Kingdom  
SA2 8QA

**Study participating centre**

**Basingstoke and North Hants Hospital**

Aldermaston Road  
Basingstoke  
United Kingdom  
RG24 9NA

**Study participating centre**

**Royal Bournemouth General Hospital**

Castle Lane East  
Bournemouth  
United Kingdom  
BH7 7DW

**Study participating centre**

**Royal Hampshire County Hospital**

Romsey Road  
Winchester  
United Kingdom  
SO22 5DG

**Study participating centre**

**Bronglais General Hospital**

Bronglais Hospital  
Caradoc Road  
Aberystwyth  
United Kingdom  
SY23 1ER

**Study participating centre**

**James Cook University Hospital**

Marton Road  
Middlesbrough

United Kingdom  
TS4 3BW

**Study participating centre**  
**Milton Keynes University Hospital**  
Standing Way  
Eaglestone  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**  
**East Surrey Hospital**  
Canada Avenue  
Redhill  
United Kingdom  
RH1 5RH

**Study participating centre**  
**Darlington Memorial Hospital**  
Hollyhurst Road  
Darlington  
United Kingdom  
DL3 6HX

**Study participating centre**  
**Royal Liverpool University Hospital**  
Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

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

**Study participating centre**  
**West Suffolk Hospital**  
Hardwick Ln  
Bury Saint Edmunds  
United Kingdom  
IP33 2QZ

**Study participating centre**  
**Leighton Hospital**  
Leighton  
Crewe  
United Kingdom  
CW1 4QJ

**Study participating centre**  
**Lincoln County Hospital**  
Greetwell Road  
Lincoln  
United Kingdom  
LN2 5QY

**Study participating centre**  
**Pilgrim Hospital**  
Sibsey Road  
Boston  
United Kingdom  
PE21 9QS

**Study participating centre**  
**University Hospitals Coventry & Warwickshire**  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX

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

**Study participating centre**  
**Western General Hospital**  
Crewe Road South  
Edinburgh  
Lothian  
United Kingdom  
EH4 2XU

**Study participating centre**  
**St John's Hospital**  
Howden West  
Livingston  
Lothian  
United Kingdom  
EH54 6PP

**Study participating centre**  
**Forth Valley Royal Hospital**  
Stirling Road  
Larbert  
United Kingdom  
FK5 4WR

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

**Study participating centre**  
**Mount Vernon Cancer Centre**  
Rickmansworth Road  
Northwood  
United Kingdom  
HA6 2RN

**Study participating centre**

**George Eliot Hospital**

Lewes House  
College Street  
Nuneaton  
United Kingdom  
CV10 7DJ

**Study participating centre****Royal Sussex County Hospital**

Eastern Road  
Brighton  
United Kingdom  
BN2 5BE

**Study participating centre****Stoke Mandeville Hospital**

Mandeville Road  
Aylesbury  
United Kingdom  
HP21 8AL

**Study participating centre****Wythenshawe Hospital**

Southmoor Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9LT

**Study participating centre****Tameside General Hospital**

Fountain Street  
Ashton-under-lyne  
United Kingdom  
OL6 9RW

**Sponsor information****Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust

**Sponsor details**

Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle-Upon-Tyne  
England  
United Kingdom  
NE7 7DN  
+44 (0)191 2825959  
tnu-tr.sponsormanagement@nhs.net

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/>

**ROR**

<https://ror.org/05p40t847>

**Funder(s)****Funder type**

Government

**Funder Name**

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

**Results and Publications****Publication and dissemination plan**

The dissemination and publication plan includes conference presentations, scientific papers, regular social media and lay communications, and briefings (paper, digital and events) for clinical teams, patient groups and commissioners within 1 year of the overall study end date.

**Intention to publish date**

31/12/2026

**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?
<a href="#">Protocol file</a>	version 4.0	08/04/2024	08/07/2024	No	No