

Participant Trial Number (TNO):

**1.1 SITE DETAILS**

Site:

**1.2 DETAILS OF PERSON COMPLETING THIS FORM**

Name:

Telephone:

Email:

**1.3 PARTICIPANT DETAILS**

1. Participant initials

2. Date of Birth

  -     -    

**1.4 CONSENT**

1. Date informed consent form received from participant   -     -

2. Was informed consent received in person or remotely?

In Person

Remotely

3. Name of person obtaining informed consent:

4. Which version of the PIS was used? Version: \_\_\_\_\_

5. Which version of the ICF was used? Version: \_\_\_\_\_

6. Has the participant consented to be contacted about an interview?

Yes

No

7. Has the participant consented to be contacted about future research?

Yes

No

8. What is the participants preference for completing questionnaires?

Paper

Electronic

*N.B. Questionnaires **must** be completed prior to randomisation.*

**TO BE COMPLETED AFTER REGISTRATION**

(please also record the participant trial number of the form header)

Participant Trial Number (TNO)

Form completed by

Printed name:

Signature:

Date signed:

  -     -

TNO:

Initials:

Please complete this form prior to randomisation

This form must be completed by a trial investigator who has been delegated the responsibility of confirming patient eligibility

## 2.1 PARTICIPANT ELIGIBILITY

### INCLUSION CRITERIA:

	Yes	No
1. Aged 18+	<input type="checkbox"/>	<input type="checkbox"/>
2. Female	<input type="checkbox"/>	<input type="checkbox"/>
3. Diagnosis of ER positive invasive breast cancer, stages 1-3 and treated with curative	<input type="checkbox"/>	<input type="checkbox"/>
4. Completed surgery for breast cancer	<input type="checkbox"/>	<input type="checkbox"/>
5. Within 14 weeks of first oral adjuvant endocrine therapy (AET) prescription (tamoxifen or aromatase inhibitor) post breast cancer completion surgery	<input type="checkbox"/>	<input type="checkbox"/>
6. Completed chemotherapy (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>		
7. Able to access the internet	<input type="checkbox"/>	<input type="checkbox"/>
8. Has access to an email address	<input type="checkbox"/>	<input type="checkbox"/>
9. Are willing to use a support package with a web-based component.	<input type="checkbox"/>	<input type="checkbox"/>

The following women will also be eligible providing they fulfil the above criteria:

*Women undergoing , or planned to receive radiotherapy,*

*Women receiving anti-HER2 therapies,*

*Women receiving ovarian suppression drugs,*

*Women receiving, or planned to receive an adjuvant CDK4/6i (i.e abemaciclib)*

### EXCLUSION CRITERIA:

	Yes	No
1. Male	<input type="checkbox"/>	<input type="checkbox"/>
2. Evidence of metastatic disease i.e. stage 4 disease (M1 regardless of T and N status)	<input type="checkbox"/>	<input type="checkbox"/>
3. Previous adjuvant endocrine therapy (AET) for another previous breast cancer	<input type="checkbox"/>	<input type="checkbox"/>
4. Have cognitive impairment sufficient to preclude participation, as judged by the clinical team	<input type="checkbox"/>	<input type="checkbox"/>
5. Are unable to read and understand English	<input type="checkbox"/>	<input type="checkbox"/>

TNO:

Initials:

**2.2 CONFIRMATION OF ELGIBILITY**

Is the participant eligible for randomisation?

Yes

No

**Form completed by**

Printed name:

Signature:

Date signed:

d	d	-	m	o	n	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---	---

*N.B. The individual named must be on the delegation log with the assigned responsibility for confirming eligibility .*

TNO:

Initials:

**Please complete this form prior to randomisation, and keep updated throughout the study**

**3.1 DEMOGRAPHICS**

1. Participant name *(in block capitals)*

2. Participant contact telephone number

3. Participant email address *(in block capitals)*

4. Participant identifier (NHS/CHI/HSCN number)

**3.2 GP SURGERY DETAILS**

1. Participant GP surgery name

2. Participant GP surgery address:


3. Participant GP surgery contact telephone number

**Form completed by**

Printed name:

Signature:

Date signed:

-    -

TNO:

Initials:

**4.1 ELIGIBILITY AND BASELINE ASSESSMENTS**

1. Has the participant completed the baseline questionnaire?

Yes  No

2. ELIGIBILITY <i>all answers must fall in unshaded boxes</i>	Yes	No
1. Has a designated individual completed and signed an Eligibility Form?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the participant meet all of the eligibility criteria?	<input type="checkbox"/>	<input type="checkbox"/>

3. If randomised to the intervention arm, would the participant prefer to receive the monthly brief notifications from the HT&Me website via email or text message?

Email  Text

**4.2 STRATIFICATION**

1. Age at trial entry *(defined by date of randomisation)*

<50years  ≥ 50 years

2. Current prescribed adjuvant endocrine therapy

Tamoxifen  Aromatase Inhibitor

3. Treatment complexity: Which of the following has the participant been prescribed, or is planned to receive as part of their breast cancer treatment?

- No chemotherapy, no anti- HER2, no CDK4/6i (i.e., abemaciclib)
- Chemotherapy, no anti-HER2, CDK4/6i (i.e., abemaciclib)
- Chemotherapy, anti-HER2, no CDK4/6i (i.e., abemaciclib)
- Chemotherapy, no anti-HER2, no CDK4/6i (i.e., abemaciclib)
- No chemotherapy, no anti-HER2, CDK4/6i (i.e., abemaciclib)

**TO BE COMPLETED AFTER RANDOMISATION**

**PLEASE TICK THE ARM THE PARTICIPANT HAS BEEN RANDOMISED TO**

HT&Me Intervention   
+usual care

Usual care alone

Form completed by

Printed name:

Signature:

Date signed:

-    -

N.B. The individual named must be on the delegation log with the assigned responsibility for CRF completion.

TNO:

Initials:

Please complete and enter this information post randomisation.

### 5.1 TUMOUR PATHOLOGY

1. Date of diagnosis (defined by date of first positive biopsy)

-    -

2. Date of surgery (date of main tumour excision)

-    -

3. Type of surgery (please tick all that apply)

- |   |   |
|---|---|
| <input type="checkbox"/> Local excision/ lumpectomy     | <input type="checkbox"/> Sentinel Node Biopsy |
| <input type="checkbox"/> Mastectomy                     | <input type="checkbox"/> Axillary sample      |
| <input type="checkbox"/> Mastectomy with Reconstruction | <input type="checkbox"/> Axillary clearance   |

4. Tumour ER status (Please complete at least one of these sections)

Please complete one section

<p><b>If <u>only</u> % staining was reported:</b></p> <p>% stained cells: <input type="text"/> <input type="text"/> <input type="text"/> (0–100)</p>
<p><b>If ER was reported as Allred score:</b></p> <p>Allred (Quick) Score: <input type="text"/> (0, 2 - 8)</p> <p><i>N.B. An Allred / quick score of 8 always equates to 67-100%</i></p> <p>% stained cells (tick one):</p> <p>&lt;1% <input type="checkbox"/> 1-10% <input type="checkbox"/> 11-33% <input type="checkbox"/> 34-66% <input type="checkbox"/> 67-100% <input type="checkbox"/></p>
<p><b>If ER was reported as H-score:</b></p> <p>H-score: <input type="text"/> <input type="text"/> <input type="text"/> (0–300)</p> <p>% stained cells: <input type="text"/> <input type="text"/> <input type="text"/> (0–100)</p>

5. Tumour grade

- Grade 1/ Low grade
- Grade 2/ Intermediate grade
- Grade 3/ High grade

6. Final TNM staging

T: 1, 2, 3 or 4

N: 0, 1, 2 or 3

M: 0 or x

(if T0 or Tx review eligibility)

(if M1 review eligibility)

### 5.2 BREAST CANCER TREATMENT

1. Did the participant receive neo-adjuvant chemotherapy?

- Yes
- No

2. Did the participant receive adjuvant chemotherapy?

- Yes
- No

3. Has the participant been prescribed anti-HER2 therapy?

- Yes → Date started:   -    -
- No

TNO:

Initials:

4. Has the participant been prescribed, or are they planned to receive a CDK4/6 inhibitor such as Abemaciclib or Ribociclib?

Yes → Date prescribed:   -    -

CDK4/6i planned but not yet received  
 No

5. Has the participant been prescribed bisphosphonates (oral or IV)?

Yes (Please detail below) →  
 No

*N.B. If the exact date is unknown because the prescription was started by the GP, please record the date the GP was first instructed to prescribe this from the hospital.*

Date prescribed (DD/MON/YYYY)	Drug name	Route
	<input type="checkbox"/> Zoledronic acid <input type="checkbox"/> Ibradronic acid <input type="checkbox"/> Other (please detail below) <input type="text"/>	<input type="checkbox"/> Oral <input type="checkbox"/> IV

6. Has the participant received ovarian suppression?

Yes (Please provide details) →  
 No

Date prescribed (DD/MON/YYYY)	Type of ovarian suppression
<input type="checkbox"/>	Surgical
<input type="checkbox"/>	Medical (i.e. GNRH agonist)

*N.B. If the exact date is unknown because the prescription was started by the GP, please record the date the GP was first instructed to prescribe this from the hospital.*

7. Has the participant received, or are they planned to receive radiotherapy?

Yes, radiotherapy received  
 Radiotherapy planned but not yet started  
 No

**5.3 ENDOCRINE THERAPY DETAILS**

*N.B. If the exact date is unknown because the prescription was started by the GP, please record the date the GP was first instructed to prescribe this from the hospital.*

1. Which adjuvant hormone therapy is the participant currently taking?

Date prescribed (DD/MON/YYYY)	Endocrine therapy	Who issued the prescription?	Total intended duration (years)
	<input type="checkbox"/> Tamoxifen <input type="checkbox"/> Letrozole <input type="checkbox"/> Anastrozole <input type="checkbox"/> Exemestane <input type="checkbox"/> Other (please detail) <input type="text"/>	<input type="checkbox"/> Consultant/ Hospital led <input type="checkbox"/> GP	

TNO:

Initials:

**2. Since adjuvant hormone therapy was first prescribed, have there been any changes to the prescription?**

- Yes (Please provide details below)
- No (Please skip to question 5.3.3)

Date prescribed (DD/MON/YYYY)	Date stopped (DD/MON/YYYY)	Previous endocrine therapy	Reason for drug change
		<input type="checkbox"/> Tamoxifen <input type="checkbox"/> Letrozole <input type="checkbox"/> Anastrozole <input type="checkbox"/> Exemestane <input type="checkbox"/> Other (please detail below) <input type="text"/>	<input type="checkbox"/> Toxicity <input type="checkbox"/> Other (please detail below) <input type="text"/>
		<input type="checkbox"/> Tamoxifen <input type="checkbox"/> Letrozole <input type="checkbox"/> Anastrozole <input type="checkbox"/> Exemestane <input type="checkbox"/> Other (please detail below) <input type="text"/>	<input type="checkbox"/> Toxicity <input type="checkbox"/> Other (please detail below) <input type="text"/>

**3. Did the participant receive neo-adjuvant endocrine therapy?**

- Yes (Please provide details below)
- No (Please skip to question 5.3.4)

Date prescribed (DD/MON/YYYY)	Date stopped (DD/MON/YYYY)	Neo-adjuvant endocrine therapy
		<input type="checkbox"/> Tamoxifen <input type="checkbox"/> Letrozole <input type="checkbox"/> Anastrozole <input type="checkbox"/> Exemestane <input type="checkbox"/> Other (please detail below) <input type="text"/>

**4. Has the participant had a previous breast cancer?**

- Yes
- No

**Form completed by**

Printed name:

Signature:

Date signed:

-    -

TNO:     Initials:

**TIMEPOINT:**  Month 6  Month 12  Month 18

**6.1 PARTICIPANT STATUS**

**1. Is the participant alive?**

Yes → Date last known to be alive:   -    -

No → If no, please complete a death form

Unknown →

**2. Has the participant been diagnosed with an invasive breast cancer recurrence?**

Yes → If yes, please complete an event form

No

**3. Has the participant been diagnosed with a new primary malignancy?**

Yes → If yes, please complete an event form

No

**6.2 FOLLOW UP ASSESSMENTS**

**1. Has the participant completed the follow up questionnaire?**

Yes

No →

Form completed by

Printed name:

Signature:

Date signed:

-    -



**SWEET**  
SUPPORTING WOMEN WITH ADHERENCE TO ADJUVANT  
ENDOCRINE THERAPY FOLLOWING BREAST CANCER

## HT&Me Consultation tracking form

Participant ID: \_\_\_\_\_ Date of signed consent: \_\_\_\_\_

**Please book Consultation 1 for within 4 weeks of the date of randomisation**

**Booking of Consultation 1:** Please log how many times you attempted to make contact – note: if they do not answer, try at different times of day. Please provide other information eg. did you leave a voice message or send a text message? *'for example, answered and booked on first attempt OR phoned 3 times at 9.30am, 1pm and 4.30pm, left a voice message and woman phoned back and booked consultation'*

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**Date of Consultation 1:** \_\_\_\_\_ **Did they attend Consultation 1: Y / N**

If they did not attend – what was the reason given?

Please note if the consultation was stopped partway through, and the reason for this

If you rebook Consultation 1, please update the database and let the SWEET trial office know: SWEET@warwick.ac.uk

**Date of rebooked Consultation 1:** \_\_\_\_\_ **Did they attend rebooked Consultation 1: Y / N**

**Please book Consultation 2, 12 weeks after consultation 1**

**Date of Consultation 2:** \_\_\_\_\_ **Did they attend Consultation 2: Y / N**

If they did not attend – what was the reason given?

Please note if the consultation was stopped partway through, and the reason for this

**Date of rebooked Consultation 2:** \_\_\_\_\_ **Did they attend rebooked Consultation 2: Y / N**

Other comments:

**SWEET study practitioner: Consultation 1 Checklist  
(Initial consultation) v1.0 15.09.2023**

To be completed by the SWEET study practitioner following the initial consultation

<b>TNO:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<b>Initials:</b> <input type="text"/> <input type="text"/> <input type="text"/>	
<b><u>1.0 Introduction</u></b>			
1.1 Did the appointment take place? Yes <input type="checkbox"/> No <input type="checkbox"/>			
1.1.1 If yes, please provide the date of session:		<input type="text"/> <i>d</i> <input type="text"/> <i>d</i> - <input type="text"/> <i>m</i> <input type="text"/> <i>o</i> <input type="text"/> <i>n</i> - <input type="text"/> <i>y</i> <input type="text"/> <i>y</i> <input type="text"/> <i>y</i>	
1.1.2 If no, why not?*			
<i>*Form now complete</i>			
1.2 Session duration: <input type="text"/> <input type="text"/> minutes		1.3 Mode of consultation delivery:	
		<input type="checkbox"/> Video <input type="checkbox"/> Phone <input type="checkbox"/> Face to Face	
1.4 Has the participant started taking their hormone therapy (HT)? Yes <input type="checkbox"/> No <input type="checkbox"/>			
1.4.1 If no, why not?			
<b><u>2.0 Content covered – animation &amp; website</u></b>			
2.1 Had the participant watched the animation before the appointment? Yes <input type="checkbox"/> No <input type="checkbox"/>			
2.1.1 If no, why not?			
2.2 Did you demonstrate the website with the participant? Yes <input type="checkbox"/> No <input type="checkbox"/>			
2.2.1 If no, why not?			

2.2.2 If yes, which sections did you focus on most?

Taking HT  Help & Support  Setting a plan for taking HT

Side effects  Healthy Living, Healthy Mind

Goal setting for exercise/diet  Side effects diary  Setting reminders

### **3.0 Content covered – practical barriers**

**3.1 Did you cover practical barriers or issues around actually taking HT everyday (e.g. forgetting)?** Yes  No

3.1.1 If yes, was this initiated by you or did the participant raise this spontaneously?

Explicitly asked by nurse  Raised by participant

3.1.2 If, yes was there anything you found challenging to address in this section?

Yes  No

Please provide any details:

### **4.0 Content covered – beliefs about hormone therapy**

**4.1 Did you cover beliefs about the importance of taking HT everyday?**

Yes  No

4.1.1 If yes, was this initiated by you or did the participant raise this spontaneously?

Explicitly asked by nurse  Raised by participant

4.1.2 If yes, was there anything you found challenging to address in this section?

Yes  No

Please provide any details:

**5.0 Content covered – concerns**

**5.1 Did you cover concerns about HT (e.g. side effects)?**

Yes  No

*5.1.1. If yes, was this initiated by you or did the participant raise this spontaneously?*

Explicitly asked by nurse  Raised by participant

*5.1.2 If yes, was there anything you found challenging to address in this section?*

Yes  No

*Please provide any details:*

**6.0 Overall**

**6.1 How engaged do you think the participant was during the consultation?**

*Very engaged*

*Fairly engaged*

*Not sure*

*Not really engaged*

*Not at all engaged*






*6.1.1 If you have any comments about the participant's engagement, please provide details here:*

**6.2 Were there any specific questions raised by the participant that weren't covered by the guide? Yes  No**

*6.2.1 If yes, please provide details:*

Please use this space for anything else you want to note about the consultation:

**Form completed by**

Printed name:

Signature:

Date signed:

d	d	-	m	o	n	-	y	y	y	y
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**3.0 Content covered – beliefs about hormone therapy**

**3.1 Did you cover beliefs about the importance of taking HT everyday?**

Yes  No

*3.1.1 If yes, was this initiated by you or did the woman raise this spontaneously?*

Explicitly asked by nurse  Raised by participant

*3.1.2 If yes, was there anything you found challenging to address? Yes  No*

*Please provide any details*

**4.0 Content covered – concerns**

**4.1 Did you cover concerns about HT (e.g. side effects)?**

Yes  No

*4.1.1 If yes, was this initiated by you or did the women raise this spontaneously?*

Explicitly asked by nurse  Raised by participant

*4.1.2 If yes, was there anything you found challenging to address? Yes  No*

*Please provide any details*

**6.0 Overall comments**

**6.1 How engaged do you think the participant was during the consultation?**

Very engaged  Fairly engaged  Not sure  Not really engaged  Not at all engaged

*6.1.1 If you have any comments about the participant's engagement, please provide details here:*

**6.2 Were there any specific questions raised by the participant that weren't covered by the guide?**

Yes  No

*6.2.1 If yes, please provide details:*

**6.3 Is there anything else you would like to add about the consultation?** *For example any positives or negatives from your or the patient's point of view?*

**Form completed by**

Printed name:

Signature:

Date signed:

d	d	-	m	o	n	-	y	y	y	y
---	---	---	---	---	---	---	---	---	---	---

TNO:     Initials:

**Please complete this form if a participant has any cancer event.**  
It may be necessary to complete this form more than once per participant

## 7.1 BREAST CANCER RECURRENCE

**1. Has the participant been diagnosed with an invasive breast cancer recurrence OR a new breast malignancy?**

Yes  → Skip to question 7.1.2

No  → Skip to Section 7.2

**2. Which of the following has the participant been diagnosed with?**

- Breast cancer recurrence (continue to question 7.1.3)  
 New breast cancer malignancy (skip to question 7.1.4)

**3. Please select the site of recurrence (please select all that apply)**

- Local recurrence (breast or chest wall)  
 Regional nodal Recurrence (i.e. Axilla, supraclavicular nodes)  
 Distant recurrence

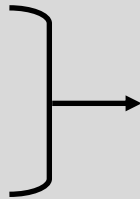
**4. Date recurrence, OR new breast malignancy was confirmed**

-    -

**5. What treatment is planned for the recurrence OR new breast malignancy?**

(Please select all that apply and always provide additional details of the treatment).

- Chemotherapy  
 Surgery  
 Radiotherapy  
 Hormone therapy  
 Other



**ADDITIONAL DETAILS**

## 7.2 NEW NON-BREAST MALIGNANCY

**1. Has the participant been diagnosed with a new non-breast malignancy**

Yes  → Continue to Q7.2.2

No  → Form complete

**2. Date of diagnosis of new non-breast malignancy:**

-    -

**Form completed by**

Printed name:

Signature:

Date signed:

-    -

TNO:

Initials:

**Please complete this form in the event of participant withdrawal**

**8.1 SITE DETAILS**

Site:  Principal investigator:

**8.2 DETAILS OF WITHDRAWAL: *\*Please consider that it may not be necessary to withdraw the participant from all aspects of the trial. Please discuss with SWEET@warwick.ac.uk***

**1. Has the participant been withdrawn from the HT&Me intervention?**

*Participant will continue to complete questionnaires and will continue to be followed up per the protocol schedule.*

Yes\*  No

*\*If yes, provide date and reason for withdrawal*

Date of withdrawal:   -    -

Reason for withdrawal:

Participant Choice  Medical Reason

Other, please specify:

**2. Has participant withdrawn their consent to be contacted for follow-up information?**

*(follow-up information should still be reported from hospital records, where possible, using CRF 6. This can continue without further contact with the patient)*

Yes\*  No

*\*If yes, provide date and reason for withdrawal*

Date of withdrawal:   -    -

Reason for withdrawal:

Participant Choice  Medical Reason

Other, please specify:

TNO:

Initials:

**3. Has the participant withdrawn from questionnaire completion?**

*Participant will no longer complete questionnaires, but will continue to be followed up per the protocol.*

Yes\*  No

*\*If yes, provide date and reason for withdrawal*

Date of withdrawal:  -  -

Reason for withdrawal:

Participant Choice  Medical Reason

Other, please specify:

**4. Has the participant withdrawn completely from the study?**

*Encompasses all previous options. No further data will be collected, all data collected to date will be retained and analysed.*

Yes\*  No

*\*If yes, provide date and reason for withdrawal*

Date of withdrawal:  -  -

Reason for withdrawal:

Participant Choice  Medical Reason

Other, please specify:

**5. If required, please provide further details of reason for patient withdrawal**

**Form completed by**

Printed name:

Signature:

Date signed:

 -  - 

*N.B. The individual named must be on the delegation log with the assigned responsibility for CRF completion.*

TNO:

Initials:

## 9.2 DETAILS OF DEATH

1. Date of death

-    -

2. Primary cause of death

*(Please select one option only)*

Breast cancer

Other cancer

Other known cause

Unknown cause

3. Please provide further details

**N.B. Please complete an *Event Form* if this participant had a known cancer event before their death.**

**Form completed by**

Printed name:

Signature:

Date signed:

-    -

TNO:

Initials:

**10.1 SITE DETAILS**

Site:  Principal investigator:

**10.2 DETAILS OF PROTOCOL DEVIATION**

1. Date of protocol deviation

-    -

2. Date site became aware of the protocol deviation

-    -

3. Reason for protocol deviation  
(Please select only one option)

- 1. Non-compliance with trial allocation   
*For example: participant did not attend an appointment and this was not re-scheduled, or the appointment was not be scheduled for another reason*
- 2. Participant found to be ineligible after randomisation   
*N.B: this does not automatically mean the participant should be withdrawn. Please contact the Trials Office for advice.*
- 3. Missed trial assessment   
*(e.g. questionnaire not completed at required timepoint)*
- 4. Incorrect version of trial document used
- 5. Inappropriate sharing of patient identifiable data
- 6. Other reason, please specify:

4. Please give further details of the protocol deviation  
(This question cannot be left blank, further details must be provided)

Form completed by

Printed name:

Signature:

Date signed:

-    -