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 d d – m o n – y y y y

1.4 CONSENT

1. Date informed consent form received from participant d d – m o n – y y y y

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: 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 CRF completion.

Eligibility Form

Version: 1.1 —Date 30.11.2023

Form #2

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+	☐	☐
2. Female	☐	☐
3. Diagnosis of ER positive invasive breast cancer, stages 1-3 and treated with curative	☐	☐
4. Completed surgery for breast cancer	☐	☐
5. Within 14 weeks of first oral adjuvant endocrine therapy (AET) prescription (tamoxifen or aromatase inhibitor) post breast cancer completion surgery	☐	☐
6. Completed chemotherapy (if applicable) ☐	☐	☐
7. Able to access the internet	☐	☐
8. Has access to an email address	☐	☐
9. Are willing to use a support package with a web-based component.	☐	☐

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

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 .

Participant demographics form

Version: 1.0—Date 10.10.2023

Form #3

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:

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 CRF completion.

TNO: ☐☐☐☐ **Initials:** ☐☐☐

4.1 ELIGIBILITY AND BASELINE ASSESSMENTS

1. Has the participant completed the baseline questionnaire?

☐ **Yes** ☐ **No**

2. ELIGIBILITY *all answers must fall in unshaded boxes*	**Yes**	**No**
1. Has a designated individual completed and signed an Eligibility Form?	☐	☐
2. Does the participant meet all of the eligibility criteria?	☐	☐

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:

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 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)* d d – m o n – y y y y

2. Date of surgery *(date of main tumour excision)* d d – m o n – y y y y

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

- ☐ Local excision/ lumpectomy
- ☐ Mastectomy
- ☐ **Mastectomy with Reconstruction**
- ☐ **Sentinel Node Biopsy**
- ☐ Axillary sample
- ☐ Axillary clearance

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

Please complete one section

If only % staining was reported:

% stained cells: ☐☐☐ (0—100)

If ER was reported as Allred score:

Allred (Quick) Score: ☐ (0, 2 - 8)

N.B. An Allred / quick score of 8 always equates to 67-100%

% stained cells (tick one):

<1% ☐ 1-10% ☐ 11-33% ☐ 34-66% ☐ 67-100% ☐

If ER was reported as H-score:

H-score: ☐☐☐ (0—300)

% stained cells: ☐☐☐ (0—100)

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 ☐ *(if T0 or Tx review eligibility)*

N: 0, 1, 2 or 3 ☐

M: 0 or x ☐ *(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: d d – m o n – y y y y
- ☐ 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:** d d – m o n – y y y y

☐ CDK4/6i planned but not yet **received**

☐ No

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

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.

☐ Yes (Please detail below) →

☐ No

Date **prescribed** (DD/MON/YYYY)	Drug name	Route
	☐ Zolendronic acid ☐ Ibradronic acid ☐ Other *(please detail below)* ☐	☐ Oral ☐ IV

6. Has the participant received ovarian suppression?

☐ Yes *(Please provide details)* →

☐ 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)	Type of ovarian suppression
☐	Surgical
☐	Medical (i.e. GNRH agonist)

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)*
	☐ Tamoxifen ☐ Letrozole ☐ Anastrozole ☐ Exemestane ☐ Other (please detail) ☐	☐ Consultant/ Hospital led ☐ 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
		☐ Tamoxifen ☐ Letrozole ☐ Anastrozole ☐ Exemestane ☐ Other *(please detail below)*	☐ Toxicity ☐ Other *(please detail below)*
		☐ Tamoxifen ☐ Letrozole ☐ Anastrozole ☐ Exemestane ☐ Other *(please detail below)*	☐ Toxicity ☐ Other *(please detail below)*

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
		☐ Tamoxifen ☐ Letrozole ☐ Anastrozole ☐ Exemestane ☐ Other *(please detail below)*

4. Has the participant had a previous breast cancer?

☐ 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 CRF completion.

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: d d – m o n – y y y y

☐ No → If no, please complete a *death form*

☐ Unknown → *Please specify*

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 →

Please detail the reason this was not completed where known.

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 CRF completion.

Event Form

Version 1.0 10.10.2023

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

d d – m o n – y y y y

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: d d – m o n – y y y y

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 CRF completion.

Withdrawal Form

Form #8

Version: 1.0—Date 10.10.2023

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: d d – m o n – y y y y

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: d d – m o n – y y y y

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: d d – m o n – y y y y

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: d d – m o n – y y y y

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: 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 CRF completion.

Notification of Death Form

V1.0 10.10.2023

Form #9

TNO: ☐☐☐☐ **Initials:** ☐☐☐

9.2 DETAILS OF DEATH

1. Date of death

d d – m o n – y y y y

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:

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 CRF completion

Protocol Deviation Form

V1.0 10.10.2023

Form #10

TNO: ☐☐☐☐ **Initials:** ☐☐☐

10.1 SITE DETAILS

Site:

Principal investigator:

10.2 DETAILS OF PROTOCOL DEVIATION

1. Date of protocol deviation d d – m o n – y y y y

2. Date site became aware of the protocol deviation d d – m o n – y y y y

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: 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 CRF completion