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Supporting women with adherence to adjuvant endocrine therapy (SWEET): feasibility study of the HT&Me intervention

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ABSTRACT

Purpose: Women with estrogen receptor-positive breast cancer are recommended daily oral adjuvant endocrine therapy for at least 5 years, but up to 50 % discontinue early. We assessed an evidence-based, theoretically-informed, patient-centred intervention (HT&Me) to support adjuvant endocrine therapy adherence and improve quality-of-life, in terms of patient acceptability and feasibility to deliver within the UK National Health Service.
Methods: This single arm study aimed to recruit 45 women with stage I-III breast cancer within 14 weeks of first adjuvant endocrine therapy prescription. After completing baseline questionnaires, participants received the HT&Me intervention comprising: (i) a short animation; (ii) two personalised nurse/practitioner consultations (in-person or online); (iii) an interactive web-app; and (iv) regular email reminders. Participants completed follow-up questionnaires at 8 weeks. A sub-sample of participants (n = 20) and health professionals (n = 14) participated in semi-structured interviews.
Results: We recruited 51 participants. Participants varied in digital confidence at recruitment (low/moderate, 28 % (n = 14); high, 61 % (n = 31)). HT&Me was demonstrated as feasible to deliver. Overall, 69 % (n = 35) engaged with the web-app; 87 % (n = 40/46) found HT&Me helpful; and 80 % (n = 36/45) reported it motivated them to keep taking endocrine therapy. Both consultation formats were considered acceptable. Completion of outcome measures was high. Health professionals considered HT&Me addresses an important unmet need.
Conclusions: HT&Me is feasible, acceptable and helpful to women. Findings provided valuable insights for design and delivery of the full-scale randomised controlled trial assessing effectiveness now underway (ISRCTN24852890). HT&Me offers potential to improve adjuvant endocrine therapy adherence, thereby reducing recurrence risk for women with estrogen receptor positive breast cancer.
Study registration ISRCTN number: ISRCTN29401613

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1. Introduction

The majority of women with breast cancer have estrogen receptor positive (ER + ve) disease and are recommended to take endocrine therapy daily for at least five, and for some, up to 10 or 15 years (NICE, 2009). In women with early-stage ER + ve disease, adjuvant endocrine therapy (AET) reduces risk of breast cancer recurrence by 40–50 % which, in turn, reduces risks of breast cancer death and all-cause mortality (Davies et al; Goss et al., 2016). However, it is well recognised many women do not take AET as recommended (Murphy et al., 2012). Poor adherence, either in the form of sub-optimal implementation (e.g. skipping doses) or early discontinuation (e.g. stopping before five years), is associated with significantly increased risk of recurrence, worse disease-free survival and increased risk of death (Inotai et al., 2021). Non-adherent women also report poorer health-related quality-of-life (HRQoL) (Moon et al., 2019) and, from a health service perspective, non-adherence results in significantly higher medical costs, due to breast cancer recurrence (Cahir et al., 2017).

Medication adherence is recognised to be a complex behaviour (Peh et al., 2021). Determinants of AET (non)adherence are similarly multi-faceted and complex, encompassing patient-related factors (e.g. lower perceived necessity of taking AET, more treatment concerns), healthcare system/healthcare professional-related factors (e.g. perceived lower quality health professional interaction/relationship) and socio-economic factors (e.g. lower levels of social, economic or material support) (Todd et al., 2024). Some studies show evidence for the role of medication-related factors such as polypharmacy and side-effects attributed to AET, which can include severe hot flushes and night sweats, arthralgia, and depressed mood (Moon et al., 2017).

Medication adherence is potentially modifiable. A range of interventions to improve adherence to AET have been tested, with a recent systematic review and meta-analysis showing a statistically significant positive effect on adherence of intervention versus usual care (Bright et al., 2023). Specifically, in the US, policy interventions lowering the cost of AET consistently increased AET adherence, whereas those seeking to educate patients about side-effect management were generally ineffective. Interventions aimed at increasing psychological/coping strategies, communication and medication reminders had mixed effectiveness. However, some effective intervention components (such as reducing medication costs) are not relevant in all healthcare settings. Therefore, there remains a need to test rigorously-developed interventions seeking to target multiple adherence determinants in different patient populations and healthcare settings.

In this study we aimed to assess the feasibility and acceptability of the HT&Me intervention, designed to reduce poor AET adherence and improve cancer-specific HRQoL (Stewart et al., 2023) within the UK National Health Service (NHS), where healthcare is free at the point of delivery to all citizens. The study was a precursor to a large-scale randomised controlled trial (RCT) of clinical effectiveness and cost-effectiveness.

2. Methods

2.1. Study design

A multi-method non-randomised, single arm, feasibility study was undertaken (ISRCTN ref: 29401613). The study received ethics and governance approval from the South Central - Hampshire A Research Ethics Committee (22/SC/0150). Written, informed consent to participate was obtained from all participants and health professional interviewees. All procedures were performed in compliance with relevant laws and institutional guidelines.

2.2. Feasibility outcome measures

The main feasibility outcomes were: (i) recruitment and retention of the target population, assessed via the CONSORT diagram of the flow of participants through the study (Fig. 1); (ii) acceptability of the intervention, measured using: participant questionnaires; web-analytics; semi-structured interviews with participants and health professionals; (iii) feasibility of delivering the intervention, measured by the number and timings of consultations delivered, health professional interviews and assessment of intervention fidelity; and (iv) research process acceptability, assessed via questionnaire response rates, data completeness and interviews. The ultimate goal of this feasibility study was to identify changes to the intervention or study processes needed prior to the RCT.

2.3. Participants and recruitment

The study took place in five NHS Hospital Trusts in England. Inclusion criteria were: aged 18+; female (self-reported); diagnosis of ER + invasive breast cancer; stage I-III disease; treated with curative intent; within 14 weeks of first oral AET prescription; completed surgery and chemotherapy (if applicable); access to an email address and willingness to use a support package with a web-based component. Eligible patients who wanted to participate, but who did not have access to an appropriate device to enable internet access, were offered an electronic tablet for the study duration. It should be noted that the study was limited to females as breast cancer in men is very rare, and almost all evidence on adherence to endocrine therapy, and determinants of this, comes from studies involving women only. Exclusion criteria were: male, evidence of metastatic disease, not had surgery for breast cancer, prescribed adjuvant CDK4/6 inhibitor, cognitive impairment sufficient to preclude participation, unable to read and understand English or had previously been prescribed AET for another breast cancer. Inclusion and exclusion criteria for the large RCT have been revised since completion of the feasibility study to include those prescribed adjuvant CDK4/6 inhibitors, which are now approved for use in England. We aimed to recruit 45 women. Given our goal and outcomes, a formal power calculation was not applicable. Therefore, the sample size was determined pragmatically; it was informed both by Billingham et al. (2013) (which states that the average feasibility study sample size is 36) and our desire to explore acceptability and feasibility in a patient population broadly representative of women with early-stage breast cancer in the UK, recruited from multiple hospitals. Eligible participants were identified, approached and consented by research delivery teams in these Trusts. Staff were asked to record details of those approached and, for those who declined, the reason. Informed consent was taken either in writing (if recruitment was in person) or remotely (in this event, consent was audio-recorded).

2.4. The HT&Me intervention

HT&Me is intended to support women's self-management of AET and improve HRQoL. Development followed a systematic and rigorous process (Stewart et al., 2023). In brief, the intervention, following the Perceptions and Practicalities Approach (PaPA) (Horne et al., 2019), comprises four components: (i) a brief animation explaining how AET works and why it is important to take daily; (ii) two personalised consultations about AET with a study nurse/practitioner trained in HT&Me delivery; (iii) access to an interactive web-app comprising information, personalised support and interactive tools to encourage adherence and support HRQoL; and (iv) brief nudge messages (by email) encouraging adherence and signposting to the web-app for information and support (Fig. 2).

2.5. Study process

Recruited participants were asked to complete baseline questionnaires (see Data Collection). The first consultation was scheduled with the participant, and a confirmation letter sent which included a link to view the animation prior to the appointment. As HT&Me seeks to

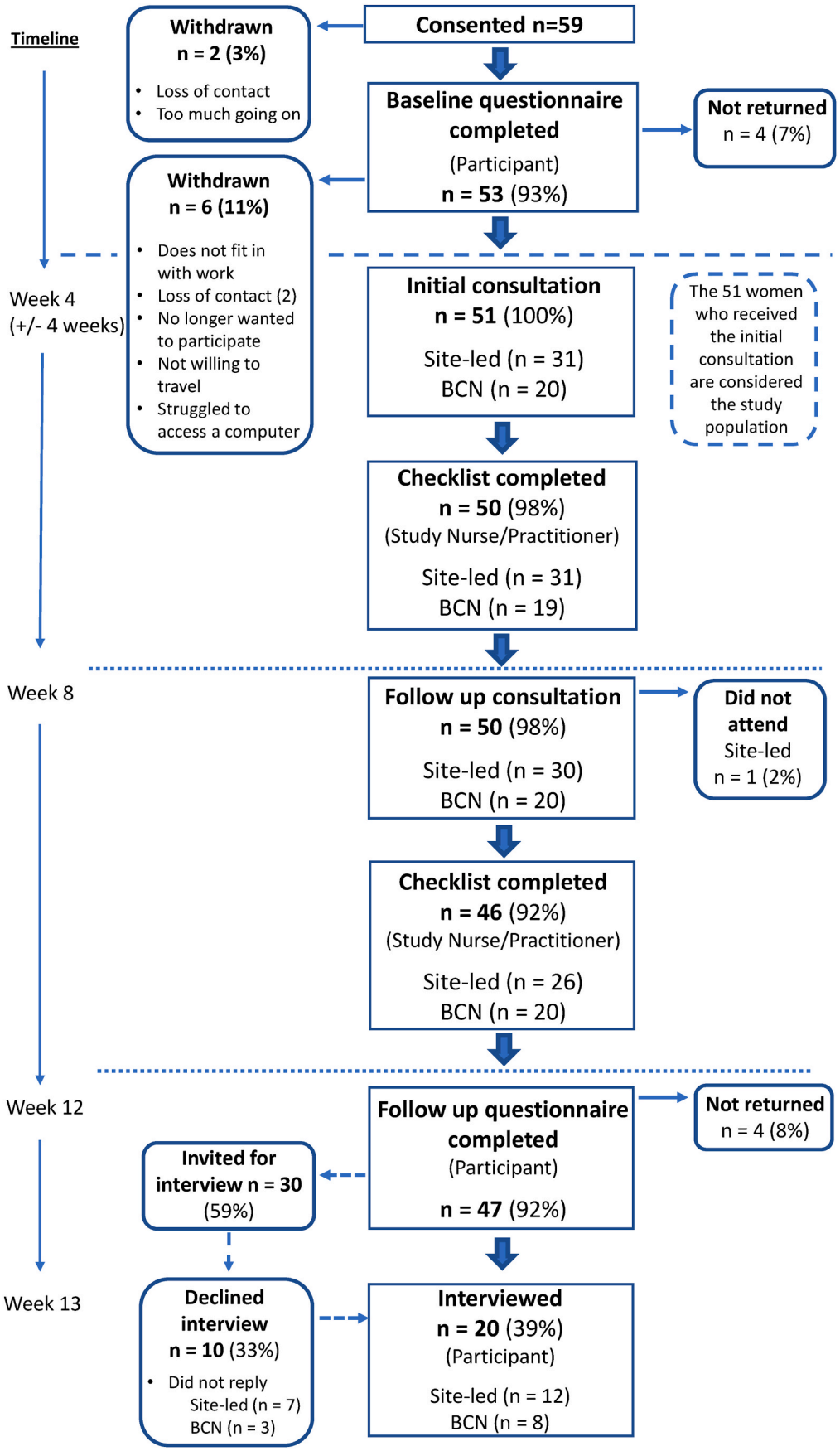

Fig. 1. CONSORT diagram.

prevent nonadherence, consultation 1 was intended to be delivered within eight (and, ideally four) weeks of recruitment to support the early establishment of good medication-taking habits. It was delivered face-to-face or remotely by a study nurse/practitioner or breast care nurse affiliated to the clinical or research team at the recruiting hospital ("site-led model"), or remotely by videocall by a study nurse employed by the UK charity, Breast Cancer Now ("BCN-model"). Three Trusts used the site-led model only, one both the site-led and BCN model, and one the BCN model only.

During consultation 1 (approximately 30 min) participants' beliefs, and any emerging concerns regarding AET were discussed and addressed. Participants were introduced to the web-app and given login details. After one month, they were invited to a second, follow-up consultation (approximately 15 min) delivered by telephone or video-call, during which beliefs and concerns were revisited, and relevant sections of the web-app highlighted. It should be noted that the timeline in the feasibility study was compressed to enable assessment of feasibility of delivery. In the RCT, women will receive the intervention for 18 months, with consultation 2 being delivered three months after consultation 1. Follow-up questionnaires will be administered at 6, 12 and 18 months. Nudge messages will be sent monthly (via email or text) throughout the duration of the RCT (18 months). Four weeks after consultation 2, participants were sent follow-up questionnaires (see Data Collection). Approximately one week following consultation 2, a sub-sample of participants (sampled to provide representation across sites and delivery models) were invited to participate in a semi-structured interview. Throughout the duration of the feasibility study, it was intended participants would be sent three nudge messages via email encouraging them to take their AET and reminding them to visit the HT&Me web-app. Nudges were sent at the point of HT&Me web-app registration, 10 days later, and 21 days later.

At the end of the study, semi-structured interviews were conducted with key health professionals including principal investigators at Trusts, and those responsible for participant recruitment and/or delivering HT&Me. The study was considered to have ended when all questionnaires were returned and interviews conducted.

2.6. Data Collection

Baseline and follow-up (8 weeks) questionnaires captured data on the primary outcomes for the RCT: i) adherence (Medication Adherence Report Scale - 5 (MARS-5)) (Chan et al., 2020), and ii) cancer-specific HRQoL (Functional Assessment of Cancer Therapy - General (FACT-G)) (Cella et al., 1993). They also captured data on secondary outcomes and postulated mediators (Supplementary Table 1). In separate questionnaire booklets at baseline and follow-up, we collected data on health service resource use in the four weeks before baseline, and in the eight weeks between baseline and follow-up. Furthermore, at baseline, participants were asked how confident they felt using IT devices (e.g. laptop/computer, smartphone, tablet). The follow-up questionnaire collected data on satisfaction with HT&Me, overall and for each element (e.g., consultations, sections of web-app), and willingness to be randomised if the study had been an RCT. Questionnaires could be completed by participants either on paper or online.

To assess intervention fidelity, after each consultation, study nurses/practitioners completed a brief checklist covering issues discussed. Study nurses/practitioners were asked to audio-record consultations, with the participant's permission; 50 % of recordings of consultation 1 (n = 15) and 2 (n = 18) were reviewed. These were purposively selected to ensure breadth across hospital Trust and delivery model. These were scored against pre-defined assessment criteria assessing adherence to content, study nurse/practitioner competence and overall impression of the consultation. These criteria were adapted from a previously published checklist (Mars et al., 2013), using Walton et al., 2020 'developing quality fidelity and engagement measures for complex health interventions' as a framework (Walton et al., 2020).

Interviews with participants (n = 20; 12 site-led model, 8 BCN model) explored experiences of HT&Me and were conducted by a member of the study team (LMcG or SJS) by video call (n = 5) or telephone (n = 15); they lasted 43 min on average (range 27–69 min).

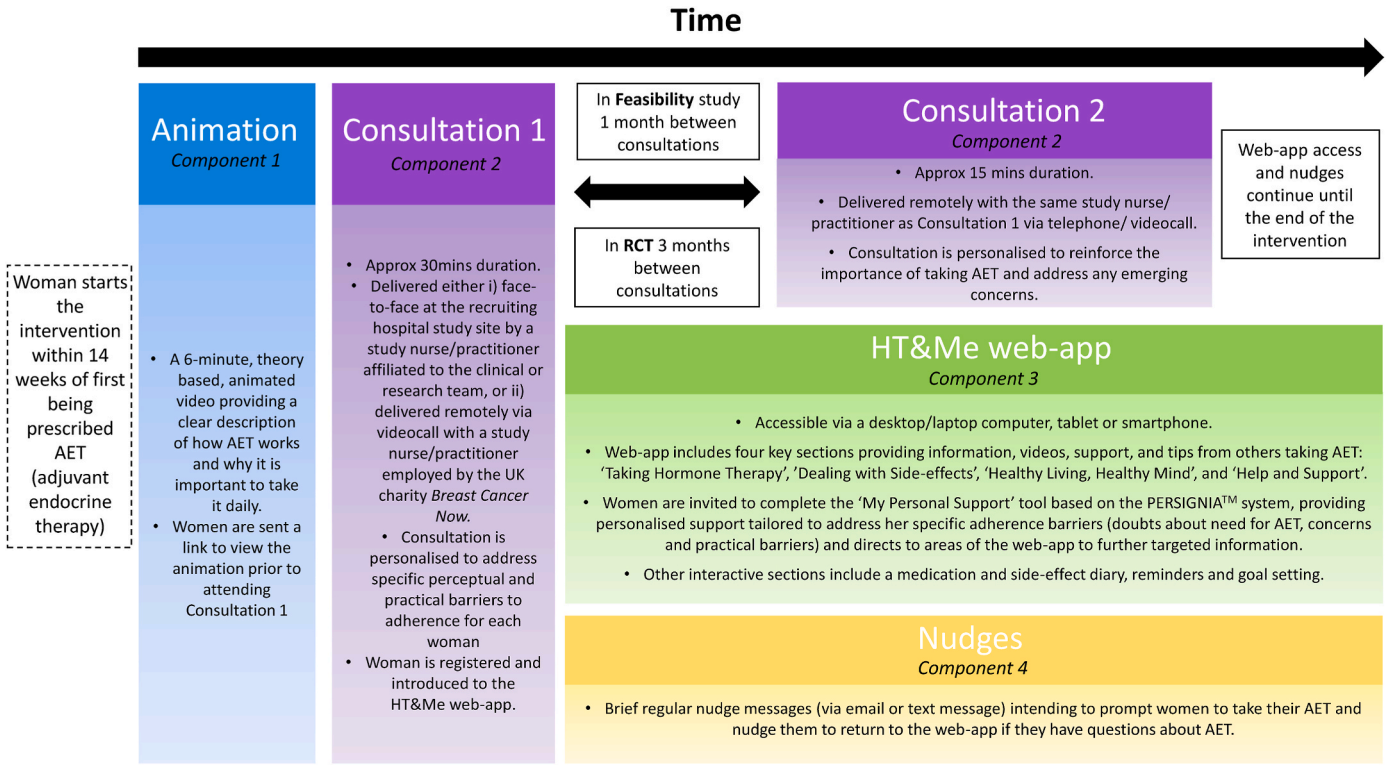

Fig. 2. Overview of HT&Me intervention, showing components and timelines.

Interviews with health professionals (n = 14), also conducted by LMcG or SJS, took place by videocall (n = 11), telephone (n = 1) or face-to-face (n = 2) (Supplementary Table 2). Informed by Normalisation Process Theory (NPT) (May et al., 2009), these interviews explored acceptability of the training package, experiences of intervention delivery, the feasibility and acceptability of the recruitment processes, and study logistics. They lasted for an average of 44 min (range 22–60 min). All interviews were audio-recorded and transcribed.

2.7. Data analysis

2.7.1. Quantitative analysis

Statistical analyses were performed using STATA versions 15 and 17 (College Station, Texas). Participant characteristics were summarised by numbers and percentages. Completion rates of individual instruments and (sub)scales included in baseline and follow-up questionnaires were computed. Participants' views of HT&Me were summarised as percentages who agreed with each in a series of statements.

Web analytic data was summarised to capture HT&Me web-app usage over the study duration (from the date the first participant was registered to the web-app until the last follow-up questionnaire was completed). Use of the web-app was defined as visiting a page beyond the homepage. Data reports the number of visits, by how many participants, to each core section of the web-app.

2.7.2. Qualitative analysis

Interview transcripts were checked against recordings for accuracy. Thematic analysis using principles of the Framework Method (Gale et al., 2013) was conducted, supported by NVivo (Version 14). Initial codes were discussed to form the basis of a working analytical framework which was iteratively developed and revised. Transcripts were coded independently by LMcG and SJS applying the analytical framework. A similar analytic process was conducted for health professional data. The data summary was reviewed and refined until a coherent narrative of participants' and health professionals' experiences was produced.

3. Results

3.1. Participant recruitment and retention

The recruitment target was 45 participants; 59 participants were recruited and consented between December 2022–August 2023; eight withdrew before attending consultation 1 (reasons for withdrawal are presented in Fig. 1 and are as follows: loss of contact (n = 3), too much going on (n = 1), no longer wishing to participate (n = 1), study participation not fitting in with work (n = 1), not being willing to travel to the hospital (n = 1), and struggling to access a computer (n = 1)). The text which follows refers to the remaining 51 participants who were considered the study population.

Demographic and clinical characteristics of the study population are presented in Table 1. Age ranged from 35 to 85 years, 14 % were from non-White ethnic groups, and 10 % had no formal educational qualifications while 41 % had completed college/university. Of clinical variables, 63 % had T1 tumours and 37 % T2 tumours (no T3 tumours); 16 % had chemotherapy, 76 % underwent lumpectomy, and 51 % had had radiotherapy. Two-thirds were initially prescribed letrozole and 24 % tamoxifen. 61 % reported being highly confident using technological devices, with more than one quarter reporting low or moderate confidence (28 %). Three participants took up the offer of a tablet to enable study participation. For characteristics of participants and the professional titles of health professionals who were interviewed see Supplementary Table 2.

Health professionals found the study straightforward to recruit to and felt recruiting to a full-scale RCT would be feasible.

Table 1
Demographic and clinical characteristics of feasibility study participants (n = 51).

Demographic Characteristic	Study Participants n (%)	Clinical Characteristic	Study Participants n (%)
Age		Post Menopausal[b]	
<40	2 (4)	Yes	32 (63)
40–49	6 (12)	No	13 (25)
50–59	12 (24)	Not reported	6 (12)
60–69	20 (39)	**Tumour**[c]	
70–79	9 (18)	1	32 (63)
80+	2 (4)	2	19 (37)
Ethnicity		**Node**[d]	
White	44 (86)	0	39 (76)
Non-White[a]	7 (14)	1	11 (22)
Highest Education Level		Unassessed	1 (2)
No formal qualifications	5 (10)	**Surgery Type**	
O Level/GCSE	11 (22)	Lumpectomy	39 (77)
A Level	9 (18)	Mastectomy	12 (24)
College/University qualification	21 (42)	**Radiotherapy**[e]	
Not reported	5 (10)	Yes	26 (51)
Current Employment Status		No	25 (49)
Employed/self-employed	20 (39)	**Chemotherapy**	
Unemployed/Unable to work	3 (6)	Yes	8 (16)
Homemaker	3 (6)	No	43 (84)
Retired	20 (39)	**Initial Hormone Therapy Prescribed**	
Not reported	5 (10)	Anastrozole 1 mg 1/day	5 (10)
Relationship Status		Exemestane 25 mg 1/day	1 (2)
		Letrozole 1.5 mg 1/day	33 (65)
Married/Civil Partnership/ cohabiting	34 (67)	Tamoxifen 20 mg 1/day[f]	12 (24)
Separated/Divorced	7 (14)	**Number of Comorbidities**[g]	
Single	4 (8)	None	23 (45)
Widowed	1 (2)	1/2	25 (49)
Not reported	5 (10)	3+	3 (6)
Confidence using a Computer, Tablet and/or Smartphone			
Low	3 (6)		
Moderate	11 (22)		
High	31 (61)		
Not reported	6 (12)		

[a] Asian or British Asian Indian (n = 1); Black or Black British Caribbean (n = 1); Any other background (not stated) (n = 5).
[b] Defined by the NHS as no period within the last 12 months.
[c] Participant staging after neo-adjuvant chemotherapy (n = 1); Participant staging using tissues removed during surgery (n = 1).
[d] Participant had micrometastases (n = 3).
[e] Data correct as of April 2024. Variable captures the additional participants who had radiotherapy since the baseline CRF was initially completed (n = 11).
[f] Includes tamoxifen 40 mg 1/day prescribed as dosing error (n = 1).
[g] Comorbidities include: high blood pressure, heart condition, arthritis, diabetes mellitus, osteoporosis, anxiety/depression, asthma, hypothyroidism, glaucoma, osteopenia, skin disorder, ulcerative colitis, sleep apnoea, and epilepsy.

> *"I actually found it quite easy to recruit to compared to other studies. I had very few women decline it … most of them could either see that it would be useful for research in the future or they were like, actually, this will be useful for me … because it was only the two consultations and we were being flexible about the timing and also like whether it was in person, it wasn't that inconvenient for them"* (Clinical Research Practitioner)

In terms of retention, 50/51 (98 %) participants attended consultation 2; with only one participant lost to follow-up (Fig. 1). 47 participants (92 %) completed the follow-up questionnaire, with 43 (72 %) completing the separate follow-up health economic booklet.

3.2. Acceptability of the intervention to participants and health professionals

Table 2 summarises the follow-up questionnaire data on participants' views of HT&Me. The overall intervention was found to be helpful by 87 % (n = 40/46). Most reported HT&Me increased their knowledge about AET (91 %, n = 40/44) and understanding of why taking AET was important (86 %, n = 38/44); 80 % (n = 36/45) felt it motivated them to keep taking their AET; and 75 % (n = 30/40) said it helped them to manage side-effects. Regarding individual components, 93 % (n = 42/45) found consultation 1 helpful, 90 % (n = 36/40) the animation and 86 % (n = 37/43) the HT&Me web-app. When asked about specific aspects of the HT&Me web-app, participants most often reported the 'Taking Hormone Therapy' (86 %, n = 37/43) and 'Help and Support' (88 %, n = 36/41) sections were helpful.

These findings were echoed in interviews both with participants and health professionals. Some participants, and almost all health professionals, described HT&Me as filling a gap in service provision. For additional quotes from interviews see Supplementary Table 3.

> "*I didn't really get any other information support from anybody else. So, the quick guidance on the side-effects and everything honestly it was so helpful. It really was. So, as a guidance, yours was the only one that I've really seen.*" (Participant 1)

> *"It certainly helps ladies understand what they're getting involved in. It helps them identify their symptoms and what things can be put in place to help minimise or people to talk to"* (Research Nurse)

3.2.1. Animation and consultations

Participants spoke positively about each component of HT&Me in interviews. They found the animation clear and informative. Consultations were considered informative and useful, regardless of mode of delivery. Those whose consultations were delivered remotely by BCN nurses generally found the remote nature of the appointment acceptable; for some it was more convenient. None of these participants were concerned the nurse was not part of their NHS hospital team. In interviews, a few participants described technical difficulties joining video calls for their consultations, but outlined how these problems were suitably resolved by the study nurse/practitioner. The consultation lengths were judged to be appropriate by both participants and health professionals. Participants described the timing of HT&Me in their care pathway to be appropriate.

> "*It's [HT&Me] like having a chat and a personal assistant to help you with your hormone therapy, especially if you're struggling*" (Participant 3)

> *"Everyone I've talked to, often in the second consultation, when they've looked at the website a bit more, really, have really liked it, and found it really helpful"* (BCN Nurse)

Table 2
Participants' views of the HT&Me intervention, from follow-up questionnaire: numbers of participants who responded to (N), and agreed with (n), each statement and associated percentages (%)[a].

HT&Me Component found helpful	*% Agree (n/N)*
Animation video about hormone therapy	90 (36/40)
Initial nurse appointment	93 (42/45)
Follow-up nurse phone call	91 (39/43)
HT&Me Web-app	86 (37/43)
Receiving text/email messages to remind me about the Web-app	74 (31/42)
Overall HT&Me support package	87 (40/46)
Section of HT&Me Web-app found helpful	
"Taking Hormone Therapy" section	86 (37/43)
"Dealing with side-effects" section	83 (34/41)
"Healthy living, Health mind" section	83 (34/41)
"Help and Support" section	88 (36/41)
"My Hormone Therapy Diary" tool	82 (28/34)
"My Goals and Plans" tool	72 (23/32)
"My Personal Support" tool	73 (24/33)
The overall HT&Me support package …	
Increased my knowledge about hormone therapy	91 (40/44)
Increased my understanding of why taking hormone therapy is important	86 (38/44)
Motivated me to keep taking my hormone therapy	80 (36/45)
Helped me to talk to my doctor about hormone therapy	62 (18/29)
Helped me with any emotional concerns about hormone therapy	69 (25/36)
Made me feel more anxious	8 (3/40)
Helped me to manage any side-effects	75 (30/40)
Was relevant for me	77 (33/43)
Was overwhelming	8 (3/37)
Was trustworthy	88 (37/42)
Was an unwelcome reminder of cancer	19 (8/43)
Was easy to understand	93 (41/44)
Was easy to use	93 (39/42)
Took too much effort	18 (7/40)

[a] Who endorsed "somewhat helpful" or "very helpful"; % of participants who responded, not including those who responded N/A. Other response options were "neither helpful nor unhelpful", "somewhat unhelpful", "very unhelpful".

3.2.2. Web-app

Participants used a range of devices (e.g. smartphone, tablet, laptop) to access the HT&Me web-app. On the follow-up questionnaire, 93 % (n = 41/44) of participants agreed the web-app was easy to understand; 93 % (n = 39/42) found it easy to use (n = 39/42); and 88 % (n = 37/42) thought it trustworthy. These findings were supported in interviews with participants, even among those who lacked confidence, using digital devices and applications; some of these participants found the introduction to the web-app from the nurse/practitioner helpful. One participant who borrowed a tablet to join the study bought her own tablet at the end of the study.

> "*I'm not the best with obviously computers and technology and [study nurse/practitioner] talked us through everything and showed us which places to go on the website … on the websites and filling bits in and doing whatever, I probably would have struggled but because I was shown how to do it, it was a lot easier*" (Participant 10)

Fewer participants answered follow-up questions on web-app sections which included the interactive tools (*My Hormone Therapy Diary;* n = 43 respondents, *My Goals & Plans*; n = 32, *My Personal* Support; n = 33) but, of those who did respond, at least 70 % found them helpful. Similarly, in interviews some participants commented positively.

> *"I get a text at 9:00 every morning […] it's irritating, but I think it's good because, I mean, normally I would have my breakfast about 8:00, so if I haven't had it by 9:00 it would remind me."* (Participant 7)

In terms of web-app usage, web-analytics data suggested 69 % (n = 35) of participants clicked beyond the HT&Me homepage. All seven key sections ('*Taking Hormone Therapy', 'Dealing with Side-effects', 'Healthy Living, Healthy Mind' and 'Help and* Support*', 'My Hormone Therapy Diary', 'My Goals and Plans'* and *'My Personal* Support*'*) of the HT&Me web-app were visited by participants throughout the duration of the study. The most frequently visited section was the interactive '*My Hormone Therapy Diary'* which was visited a total of 233 times by 27 participants. '*My Personal* Support*'* was visited 74 times by 23 participants, '*My Goals and plans'* was visited 77 times by 17 participants; 3 participants set daily reminders to take AET; 4 set monthly reminders to order their prescription. The '*Dealing with side-effects'* section was visited 202 times by 34 participants, and the '*Taking Hormone Therapy'* section was visited 149 times by 35 participants. '*Healthy living, Healthy mind'* was visited 77 times by 27 participants and '*Help and* Support*'* was visited 34 times by 14 participants.

3.2.3. Nudge messages

Due to an initial technical fault, few participants received the three

planned nudge messages. However, those that did found them acceptable and, in some cases, found they helped motivate them to continue with their AET.

> *"They didn't bombard us, so it was fine. […]it was just a gentle reminder to say that if we needed to have a look just remember that it was there as a quick guide again. So yes, I think what we got was ideal"* (Participant 1)

3.3. Feasibility of delivering the intervention

Of the 51 study participants, consultation 1 took place within four weeks of recruitment for 45 % (n = 23), between four and eight weeks for 33 % (n = 17), and after eight weeks for 22 % (n = 11).

As noted above, a technical problem was uncovered with the automated system for delivering the nudge messages and only a small number of participants received these.

Health professionals reported finding HT&Me easy and enjoyable to deliver. The training was highly rated. Assessment of intervention fidelity via consultation recordings revealed a mean fidelity score of 95 % for consultation 1 (range 80 %–100 %) and 99 % for consultation 2 (98 %–100 %).

However, a key barrier to intervention delivery on a larger scale raised by several health professionals was the ongoing challenge of capacity within the NHS. Related to this, there was considerable support for the BCN model.

> *"We were hoping that the breast care nurses would be able to help [with recruitment]. But I think just, general workload, we've had lots of sickness, a lot people being off, maternity leave, etc …."* (Clinical Research Practitioner)

> *"Talking about going forward, it would be great to be able to say to patients in the clinic, "You're starting on this treatment, we've got a bit of education and help to support you with it. You'll be contacted by [the BCN] team." And then that, sort of, takes it off us in terms of doing anything extra with our resource to know … you'll do the rest"* (Consultant Medical Oncologist)

Health professionals identified several issues which helped with study delivery, including the ability to consent participants remotely, and ongoing support provided by the central study team. Despite capacity issues, health professionals generally agreed a RCT would be feasible to deliver.

> *"Patients are desperate for anything you know, especially anything as well put together as HT&Me. And so from that sort of clinical side, absolutely great, you know, I don't think you're gonna have any problems in expanding this to a much larger population when it comes to the actual full-blown trial"* (Consultant Breast Surgeon)

3.4. Research process acceptability and feasibility

3.4.1. Acceptability of measures

Approximately half of participants completed questionnaires on paper and half electronically. Instrument and (sub)scale completion rates were high both at baseline and follow-up; adherence to AET and HRQoL could be computed for 90 % of participants at baseline and 92 % at follow-up. For completion rates for (sub)scales and other postulated mediators, see Supplementary Table 1. Participants who were interviewed did note the questionnaires were lengthy, but said they were happy to complete them. This was reiterated by the health professionals who suggested the participants did not struggle with what they were asked to do in terms of study processes.

Slightly over half of respondents to the follow-up questionnaire (57 %, n = 29) indicated they would have been willing to be randomised either to the intervention or usual care.

3.5. Changes made to the support package

Interview data from both participants and health professionals, and web-analytics, highlighted areas for improvement. To address these, small changes were made to both HT&Me (changes to the frequency of prescription reminders, the addition of 'index' and 'favourites' pages, correcting the technical problem with nudge message delivery) and study processes (changes to the study nurse/practitioner training, introducing additional strategies to include more underrepresented groups, streamlining questionnaire booklets, collection of richer web-analytic data) prior to finalising the RCT protocol (Supplementary Table 4).

4. Discussion

Interventions effective at reducing poor adherence to AET in different healthcare systems are urgently needed. In this study, the evidence-based and theoretically informed HT&Me intervention, which is tailored to women's needs and designed for delivery within the UK NHS, was found to be both feasible and acceptable to women with breast cancer and health professionals.

Development of the multi-modal HT&Me intervention was stimulated by poor adherence to AET which has been recognised as an important issue internationally (Murphy et al., 2012), and the lack of capacity within the NHS to provide individualised support for patients prescribed these treatments. The patient-initiated follow-up approach which has been increasingly implemented over the past decade (Moore et al., 2022) means most women with early-stage breast cancer are discharged from routine hospital-based follow-up so lose regular contact with their breast cancer team. At the same time, primary care practitioners often lack expertise to support those who may be struggling. In the current study, the HT&Me intervention was acceptable to both participants and health professionals using both the localised, site-led, and the remote, centralised, BCN model. Our findings highlight the helpfulness of the HT&Me web-app, and the value placed by participants on the nurse consultations as a core component of HT&Me.

Health professionals considered HT&Me complemented standard care, and both they and some participants in the study felt the intervention could help reduce the burden upon health professionals, freeing up their time for other priorities. Although capacity to deliver HT&Me at hospitals was raised as an issue, the BCN model offers a feasible alternative. Encouragingly, fidelity of intervention delivery was very high irrespective of who delivered the consultations. Some participants preferred the convenience of not having to return to the hospital for consultation 1 and no participant raised concerns about having appointments with a nurse who was not part of the hospital breast cancer team; this may be because the BCN practitioner was an experienced breast cancer nurse who had previously worked within the NHS. However, the remote centralised approach was not without challenges; some participants needed support logging into video-calls for BCN-led consultations and, from a governance perspective, each hospital Trust involved needed to formally agree to patients under their care interacting with someone who works outside the health service. Given each Trust has different processes and procedures, it is likely to be challenging to streamline these. One strategy to address this could be to develop a template agreement with the RCT sponsor and encourage Trusts to adopt this.

Health professionals supported testing HT&Me in a large nationwide RCT. The RCT will ensure that there is a sufficient spread of Trusts using the BCN-model and the site-led model and, in the quantitative process evaluation, we will compare whether the effect of the intervention on adherence and HRQoL varies by model. The RCT process evaluation will also monitor the proportion of consultations that are delivered within the "target" time windows, as well as capturing other implementation-related data, including feasibility to deliver the intervention within current NHS contexts, and whether this varies between the two models.

Although one of the core components of HT&Me is a web-app, in designing the intervention and implementing the study we were conscious of attempting to minimise the exclusion of participants who lacked devices, data or confidence and skills to use an intervention with a web-based component. While we did not undertake a formal assessment of digital literacy in this feasibility study, our preceding optimisation studies (Stewart et al., 2023) identified and mitigated digital barriers helping to ensure that HT&Me was accessible and acceptable to those with varying levels of confidence and ability in using digital tools. In the current study, we offered a tablet to participants who wanted to take part but lacked a device; this offer was taken up by three participants at one Trust, which is located in a city with many areas of socio-economic disadvantage. We also: encouraged recruiting staff not to make assumptions about which participants would not be 'capable' of, or interested in, using the web-app; provided paper guides for using HT&Me; and offered questionnaires for completion in paper or electronic format. Over a quarter of participants recruited reported having low to moderate confidence in their IT ability at baseline, and several of these participants spoke in interviews about being surprised at how easy they found using the web-app. E-health and m-health interventions are growing in popularity in cancer (Wanchai et al., 2022) as they potentially offer a cost-effective method for providing patient support (Elbert et al., 2014; Gentili et al., 2022). Being conscious of issues around digital exclusion is important for intervention developers and researchers if inequalities in cancer outcomes are not to be exacerbated.

Our web-analytics and interview data indicate some participants did not engage with the HT&Me web-app Although web-analytic data is a crude measure of individuals' engagement with any website or web-app, reasons for non-engagement could be due to some of the issues highlighted for improvement (Supplementary Table 4). Moreover, as became clear during the study, sometimes study nurse/practitioners suggested to participants the support package was only for participants who were struggling with side-effects which may have meant those who were not experiencing side-effects did not use it. Further, only a few participants received the regular nudge messages reminding them to log back into the web-app. Those participants that did use the web-app used it thoroughly, accessing all key sections, including using some of the interactive features (which include many of the behavioural change techniques forming the "active ingredients" of HT&Me) (Stewart et al., 2023). The collection of web-analytic data has been much expanded in the RCT; we are undertaking passive tracking of interaction patterns, such as login frequency, time spent on each page, which pages are viewed and how often, to provide a more comprehensive overview of HT&Me user behaviour and engagement. In addition, whilst the RCT is underway we are interviewing a proportion of participants to ask about their use of HT&Me as part of our process evaluation.

Breast cancer treatment pathways are complex and while most women with early-stage disease have surgery and radiotherapy, a variety of other treatments may be utilised - depending on features such as age, stage, and receptor status (NICE, 2025). Although women with stage I-III disease were eligible, and our study exceeded the recruitment target, it was noteworthy the participants recruited had earlier stage disease. For example, no recruited participants had T3 tumours. We also excluded patients receiving CDK4/6 inhibitors alongside AET as these drugs were only approved in the early disease setting (NICE, 2025) after our study had obtained ethical approval. Women with larger tumours, who undergo chemotherapy, and/or are suitable for CDK4/6 inhibitors with AET, are at higher risk of recurrence (NICE, 2025, and adherence to AET is arguably more important for them. This highlights the importance of ensuring Trusts in our RCT - and, indeed, other ongoing or future studies of interventions to support AET adherence - seek to recruit participants across the full range of increasingly complex breast cancer treatment pathways. This will be achieved by emphasising this in the Site Initiation Visits (where participating sites are onboarded to the study), having very clear eligibility criteria and through discussion at monthly Trust drop-in sessions.

Measuring adherence to AET is challenging; straightforward and acceptable biomarkers are lacking and monitoring via devices such as electronic pill bottles, may be viewed as an intervention in itself. Best practice recommends using a combination of an objective measure (such as AET prescribing or prescription encashment records) and a subjective measure (i.e. self-report) (Lam and Fresco, 2015), to reduce the misclassification inherent in using either measure alone. Here we tested only the feasibility of collecting self-reported AET adherence, using the MARS-5, and found adherence could be measured for at least 90 % of participants. In the RCT, we propose to adopt best practice and collect self-reported adherence as well as accessing community prescription encashment data held by the NHS (Emanuel et al., 2019). In a parallel study, we have demonstrated feasibility of obtaining historical encashment data for individual patients with stage I-III breast cancer.

There were a number of strengths and limitations to this feasibility study. Strengths included the multi-site design, and the fact participants recruited had a range of socio-demographic characteristics and varied in confidence in engaging with digital devices. However, despite efforts to achieve a more ethnically diverse sample, participants were mostly white. A number of recruitment strategies will be employed in the RCT to attempt to address this issue: for example, the development of a recruitment animation, featuring a diverse range of women and regular discussions about the importance of diversity at meetings with site teams. There will be careful ongoing monitoring of the characteristics of participants throughout the trial. Further, although hospitals were asked to record details of all those approached about the study, it was impossible to accurately determine recruitment rates, or reasons for non-participation, as screening logs were poorly completed.

While the findings highlight that the study was feasible to deliver and acceptable and helpful to women with early-stage breast cancer, there are likely to be limitations in the extent to which these findings can be generalised to the male breast cancer population, some of whom are also prescribed endocrine therapy. It is worth noting that male breast cancer incidence is low and there has been only limited exploration of both levels of, and barriers to, adherence in this population; such data is a prerequisite for considering whether HT&Me could be adapted to a male population. We also note that acceptability and engagement with the intervention are largely self-reported and could be affected by social desirability bias. In the RCT we will triangulate the web-app analytic data with questionnaire responses regarding acceptability. Further, our questionnaire items relating to use of specific elements of HT&Me were completed by fewer participants compared to the rest of the questionnaire; the reasons for this are not known but may reflect usability issues or, simply, placement of these items later in the questionnaire. All interviewed participants were currently taking AET as prescribed, which may have influenced the generally very favourable view of HT&Me which emerged in interviews. It should be noted that, as interviews were conducted by study team members, this may have introduced social desirability bias; however those conducting the interviews were experienced qualitative researchers, and made it clear to participants that there were no right or wrong answers and they could speak freely. Finally, it should be noted that the follow-up period was a much shorter period than is planned for the RCT (8 weeks vs 18 months). It is possible that, in the RCT, women's views of, and engagement with, different aspects of the intervention, and the follow up questionnaires, may differ from those reported here, as may their ET adherence patterns.

5. Conclusion

The HT&Me intervention has been shown to be feasible to deliver, acceptable and helpful to women. HT&Me offers the potential to increase AET adherence and consequently improve outcomes for those with hormone-sensitive breast cancer by reducing the risk of recurrence and improving HRQoL. This feasibility study provided an opportunity to optimise both HT&Me and study processes ahead of a full-scale RCT. The lessons learned have informed the design and processes of the RCT,

which is now underway to test the effectiveness and cost-effectiveness of HT&Me (McGeagh et al., 2025).

CRediT authorship contribution statement

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All authors have declared no competing interests, with the exception of the following:

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Appendix A. Supplementary data

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