ISRCTN15089342 https://doi.org/10.1186/ISRCTN15089342

ENABLE: Medication brand changes in hormone therapy for breast cancer

Submission date
19/06/2024

Recruitment status
Recruiting

Registration date
25/06/2024

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Annually, 55,900 women are diagnosed with invasive breast cancer. After completing surgery, chemotherapy or radiation, around 44,720 (80%) are prescribed hormone therapy (HT) drugs (tamoxifen, anastrozole, letrozole, exemestane). These drugs help in preventing the cancer coming back (recurrence) or spreading to other parts of the body (metastasis). When patients are prescribed HT they take it as a daily tablet, usually for five years and in some cases for up to ten. HT medication produces a considerable amount of side effects: hot flashes, depression, low sexual desire, joint pain, low energy and tiredness among other bothersome symptoms. As a consequence, some women stop taking the medication early (discontinue) or do not take it as prescribed (poor adherence). Around 50% of women have poor adherence by five years. There are many factors that influence women to completely stop or not take their HT drugs as indicated. Our preliminary research has identified that changing the medication brand name (generics) can be challenging for patients. It is common practice for community pharmacies to dispense a different generic of the same drug when patients collect their prescriptions. This can negatively impact many patients, who experience: new side effects, lack of information on generics, feel unsupported, and encounter disbelief from healthcare professionals. This affects in turn women's confidence in taking their medication, e.g. when women search for their preferred brand, they do not take the medication or stop taking it if they cannot find a brand that suits them. Pharmacists suggest that training and guidelines would be needed for them to support these patients. However, to date no effective intervention exists to address patients' concerns with HT generic switching.
Aim: Supported by a breast cancer patient advisory group and key stakeholders, we will co-produce an intervention to improve medication consultations about HT brand changes.

Who can participate?
WP1 Community Pharmacists in London; Pharmacist representatives of professional bodies; owners or managers of community pharmacies; WP2 community pharmacists in London; WP3 Community pharmacists located in Barnet, Camden, Enfield, Haringey and Islington.
WP1 Women with breast cancer, taking HT medication or had taken these drugs in the last 12 months (and) has/had concerns about changing medication brands. WP3 Women diagnosed with early breast cancer [stage 1-3], taking HT medication, and have/had concerns about medication brand changes. Patients participating in co-development workshops will be recruited in London;

patients participating in the testing of the intervention will be recruited by community pharmacies located in the boroughs above.

What does the study involve?
WP1 Community Pharmacists will participate in 2 co-development workshops as researchers; Community pharmacists (owners or managers) and pharmacists representatives will participate in interviews about the barriers and facilitators of implementing the intervention; WP2 Community pharmacists will provide feedback after testing an e-learning package; WP3 Community pharmacists will attend an online training; recruit and consent 4 patients, collect data; deliver a medication consultation, take feedback notes; and participate in a follow-up interview.
WP1 Breast cancer patients will participate in 2 co-development workshops as researchers. WP3 Breast cancer patients will be recruited by community pharmacies, and will complete a diary (to record medication symptoms) for a minimum of 1 month and a maximum 3 months; attend a medication consultation with the community pharmacist; and a follow-up interview with the research team.

What are the possible benefits and risks of participating?
All participating pharmacists might find it useful to reflect on the management of HT medication consultations. They will have the opportunity to contribute their views on the prototype intervention and potentially help community pharmacists to better manage medication consultations and improve patients' adherence in the future. In addition, Pharmacists delivering the intervention they will gain research experience and gain CPD recognition. Potential risks: We do not envisage any significant risks arising for pharmacists. The main issue would be time constrains.
Patients: We cannot promise the study will benefit them immediately, but they might find it useful to explore a way of thinking around their HT medication brand that might help them better understand symptoms and side effects, and become more confident when discussing with pharmacists about new symptoms attributed to certain brands. Potential risks: During follow-up interviews, there might be cases when women feel upset when discussing their previous experiences and decisions made regarding therapy, whereby changing medications brands, describing new side effects or troubles in accessing a preferred brand could be upsetting.

Where is the study run from?
London Metropolitan University (UK)

When is the study starting and how long is it expected to run for?
March 2024 to March 2026

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

Who is the main contact?
Prof Yolanda Eraso, y.eraso@londonmet.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327926

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56605, NIHR206589, IRAS 327926

Study information

Scientific Title
Medication brand changes in hormone therapy for breast cancer. A community pharmacy intervention development to improve patients' adherence and quality of life

Acronym
ENABLE

Study objectives
It is possible to co-develop a community pharmacy intervention to improve medication consultations about hormone therapy brand switching in women with breast cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/07/2024, West Midlands – South Birmingham REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8121; southbirmingham.rec@hra.nhs.uk), ref: 24/WM/0137

Study design
Interventional qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Pharmacy

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
Hormone therapy for breast cancer

Interventions
WP 1: Intervention development
1a. A rapid scoping review of the literature to identify the best available evidence on patient medication diary interventions for cancer patients.
1b. Two co-design Workshops:
Co-production workshops with BC patients and pharmacists
i. WS1: Develop content for a patient self-management diary;
ii. WS2: Develop content for a medication consultation guide for pharmacists and training content.
1.c Qualitative interviews with pharmacists: We will explore the views of pharmacist representatives of professional bodies and owners of community pharmacies about the barriers and facilitators of implementing the intervention.

WP 2: Design of e-learning resource for pharmacists
2a. E-learning package design: A Web-developer specialist will collaborate in the design of an e-learning package based on the educational content of the prototype intervention.
2b. Qualitative interviews with pharmacists: Feedback will aim to establish the appropriateness of the educational intervention as a learning tool.

WP 3: Testing and optimisation studies
We will test the intervention to gather feedback from participants and optimise the different components as follows:
3a. Deliver of the e-learning package to 5 community pharmacists in North Central London ICS. Participants will access the e-learning for 1 month.
3b. The 5 trained pharmacists will recruit 20 (4 each) BC patients from their CPs. Eligible patients will receive a self management diary and will attend a medication consultation with the pharmacist. Follow-up interviews with participants.
3.c Integration of feedback to produce ENABLE, and a protocol for a feasibility study.

Intervention Type
Behavioural

Primary outcome measure
Qualitative interviews to optimise the usability, practicality and acceptability of the intervention for community pharmacists and breast cancer patients. Using behavioural analysis constructs from the Theoretical Domains Framework and the Person-Based Approach for intervention development conducted 2 or 3 weeks after the testing of the intervention in WP3

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/03/2024

Completion date
31/03/2026

Eligibility

Key inclusion criteria
WP1 - 1.c Qualitative interviews with pharmacists:
1. Pharmacists who are owner or manager of a community pharmacy, chain and independent;
2. pharmacists with a representative role in professional pharmaceutical bodies, e.g. Local Pharmaceutical Committee, Community Pharmacy England, Royal Pharmaceutical Society.

WP2 - 2b. Qualitative interviews with pharmacists:
1. A pharmacist or pharmacist technician, permanent or locum (and)
2. Working in community pharmacies located in London (and)
3. Providing hormone therapy medication to clients

WP3 – Testing and optimisation studies
Pharmacists:
1. Pharmacists and pharmacy technicians; from the London boroughs of Barnet, Camden, Enfield, Haringey, or Islington
2. Providing Hormone Therapy medication to clients
3. Agree to participate in online training
4. Agree to recruit 4 patients from their pharmacy
5. Agree to deliver a medication consultation with recruited participants and audio record 1 consultation (with patient consent), and provide feedback notes of the consultation.
6. Agree to provide feedback in a study follow-up interview.
7. Is willing to provide written (signed and dated) informed consent.

Patients:
1. Women 18+ with early BC (stage 1-3);
2. Talking oral HT medication (tamoxifen, anastrozole, or letrozole) and had/have concerns about changing HT brands;
3. Not taking HT medication as neo-adjuvant or secondary metastatic BC;
4. Is willing and able to record notes on side effects and medication taken (diary) and attend a medication consultation with the CP;
5. Is willing and able to participate in a study follow-up interview (phone or video conference);

6. Is willing to provide a copy of the diary;
7. Is willing to be audio recorded during the pharmacy consultation;
8. Is willing to provide written (signed and dated) informed consent.

Participant type(s)
Patient, Health professional

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Key exclusion criteria
WP1 - 1.c Qualitative interviews with pharmacists:
1. locum, technician, assistants, pharmacist not owner or manager
2. Pharmacists without a representative role in professional pharmaceutical bodies

WP2 - 2b. Qualitative interviews with pharmacists:
1. Accredited Checking Technician, assistants

WP3 – Testing and optimisation studies
Pharmacists:
1. Locum, Accredited Checking Technician, pharmacy assistants.

Patients:
1. Male
2. Currently or recently (last 6 months) involved in another research study where medication adherence is a primary outcome;
3. Have had in the last 6 months a medication review about changing brands of HT drugs.

Date of first enrolment
27/08/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

5 community pharmacies located in North Central London
London
United Kingdom
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Sponsor information

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Sponsor type
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ROR
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Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Conference presentations and a knowledge exchange workshop.
3. Publication on website within one year of the end of study

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.3	17/03/2025	07/07/2025	No	No