ISRCTN10487576 https://doi.org/10.1186/ISRCTN10487576

The ROSETA pilot trial – investigating strategies to improve medication adherence in women with early-stage breast cancer

Submission date
29/11/2021

Recruitment status
No longer recruiting

Registration date
16/12/2021

Overall study status
Completed

Last Edited
03/02/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breast cancer is the most commonly diagnosed cancer in women worldwide. In the UK, approximately 55,000 cases occur per year, with 11,000 cancer-related deaths. The majority of breast cancers are oestrogen receptor positive (ER+) tumours. Adjuvant hormonal therapies (HTs) have drastically improved cancer outcomes for women with ER+ tumours and are routine care for this group. However, adherence to these therapies is inadequate. Systematic reviews have highlighted the proportion of women taking these medications as prescribed ranges from 31% to 73%.

Medication side-effects are a frequently reported explanation for low adherence to HTs among breast cancer survivors. A health economic model indicated that if an intervention could be developed that was effective at improving 10% of breast cancer survivors' adherence to tamoxifen from low (80%) it would be likely to be cost-effective according to NICE thresholds if it could be delivered for £3397 per patient.

To develop such an intervention, the researchers have undertaken substantial preparatory research to design a model they believe explains non-adherence to medication in this context. The following factors are included:
1. Memory and forgetting
2. Medication schemas
3. Psychological flexibility
4. Living with side-effects

Along with patients and clinicians, four new interventions for women have been designed for women who are taking hormone therapy medication. The four different interventions aim to support women in taking their medication in different ways. The interventions are:
1. SMS text message reminders to support daily medication taking
2. An information leaflet explaining how the medications work.

3. A website to provide useful resources for managing side effects.
4. A skills programme known as Acceptance and Commitment Therapy (ACT). This is led by a psychologist and involves learning and practicing skills at home.

The aim of this study is to establish the feasibility of evaluating four intervention components targeting medication adherence in women with early-stage breast cancer.

Who can participate?
Women aged 18 or over with early-stage (1-3a) breast cancer who have been prescribed adjuvant Hormone Therapy and completed curative hospital-based treatment.

What does the study involve?
80 women from breast cancer services at eligible NHS Trust sites will be randomly allocated into 8 conditions comprising of four intervention components targeting different barriers to medication adherence in this population, which participants will be randomised to receive different combinations of, ranging from all four to none. The components are:
1. SMS text reminders to target forgetting
2. Information leaflet to target medication beliefs
3. ACT psychotherapy sessions to provide support for emotional distress
4. Access to side-effect management website providing information on managing side effects

Timing and duration of intervention components will vary: the information leaflet and website will be provided at randomisation, text reminders will be delivered at increasing intervals until follow-up (4-months post-randomisation), ACT will be delivered weekly with the first session occurring within 4 weeks post-randomisation. The ACT intervention component takes a guided self-help approach, involving 5 sessions delivered by practitioner psychologists. All five sessions will take place via videoconferencing or telephone.

Follow-up data will be routinely collected or obtained via online platforms prompted by reminders. Participants will be asked to complete a series of questionnaires before entering the study and at 2 and 4 months following randomisation to the study. The questionnaires will be looking at issues around health, well-being, and medication.

Following completion of the study, all participants will be invited to participate in an interview with a researcher. The interviews will ask questions to assess acceptability and fidelity of the individual intervention components, overall trial experience, and barriers/enablers to participation and responding to questionnaires.

Similarly, the therapists delivering the ACT intervention will also be invited to participate in interviews. Interviews will be used to understand fidelity of training and delivery including any barriers to this, and the acceptability of delivering the intervention within an NHS setting.

What are the possible benefits and risks of participating?
It is hoped that participants will benefit from taking part and that the interventions will be helpful, but as the interventions are new we cannot be sure this will be the case. The main benefits should be stated to be helping the researchers learn more about the treatment options for women with breast cancer who have been prescribed hormone therapies, the effectiveness and acceptability of the different intervention components, and how they may help in managing treatment side effects and quality of life. It will also help the researchers to inform the design of the optimisation phase of the ROSETA project.

Where is the study run from?
Clinical Trials Research Unit, The University of Leeds (UK)

When is the study starting and how long is it expected to run for?
From January 2019 to April 2023

Who is funding the study?
The National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
302050

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50714, IRAS 302050

Study information

Scientific Title
Refining and Optimising a behavioural intervention to Support Endocrine Therapy - The ROSETA Pilot Trial

Acronym
ROSETA

Study objectives
To undertake a randomised fractional factorial pilot trial to establish the feasibility of evaluating four intervention components targeting medication adherence in women with early-stage breast cancer.

This trial will also have an embedded Study Within a Trial (SWAT), a self-contained research study that has been embedded within the host trial with the aim of evaluating ways of delivering follow-up trial processes. The overall aim of the SWAT is to understand the impact of SMS pre-notification and reminder messages in the context of clinical trials using online data capture for patient-reported questionnaires.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/10/2021, Wales REC 3 (Health and Care Research Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +44 (0)29 2078 5735; REC3@wales.nhs.uk), ref: 21/WA/0322

Study design
Randomized controlled fractional factorial pilot trial with an embedded Study Within a Trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
The study will evaluate four intervention components in a pilot trial with a nested process evaluation recruiting women with early stage (1-3a) breast cancer who have been prescribed hormone therapy. The four intervention components are:
1. SMS text message reminders to support habit formation
2. A written information leaflet to improve knowledge and address medication beliefs
3. Acceptance and Commitment Therapy (ACT)-based psychotherapy sessions to address psychological distress
4. A website which provides information to support side-effect management

The study will use a fractional factorial design. This trial design has 8 conditions, with all women receiving the usual care provided by their NHS service. Conditions are formed by systematically varying different combinations of the four intervention components. Participants will be randomised with an equal chance of being allocated to any of the eight conditions. Details of what women will receive if they are allocated to each experimental condition are as follows:
1. Usual care, text reminders, information leaflet, ACT, and website
2. Usual care, text reminders, and information leaflet
3. Usual care, text reminders, and ACT
4. Usual care, text reminders, and website
5. Usual care, information leaflet, and ACT
6. Usual care, information leaflet, and website
7. Usual care, ACT, and website
8. Usual care

The process evaluation will use both quantitative and qualitative data collection methods. It will involve all trial participants as well therapists delivering the ACT intervention component and the research nurses screening and recruiting for the trial.

Recruitment:
There will be three recruitment routes into the trial.
1. Recruitment route one
The research nurse (RN) or delegate will screen patient records for eligible patients who will be attending their discharge/holistic needs/end of treatment summary meeting in the upcoming

week(s). A member of the patient's care team will introduce the RN or delegate, who is trained in taking consent. Potential participants will have the opportunity to ask the RN or delegate any questions. If the patient feels the study has been adequately explained and has had the opportunity to ask any questions, they may consent to the study at this meeting. However, all potential participants will be given the opportunity to receive the study information via email to think about whether they wish to take part and discuss with family and/or friends.
If the patient is happy to take part in the study at the initial meeting, the screening questionnaire will be discussed with the patient to ensure they meet the eligibility criteria and the RN/delegate will complete the screening log. Once eligibility is confirmed and the patient has consented to participate in the trial, the RN will register the patient via the CTRU online system and a participant number will be generated. Once registered, participants will be emailed a link
to register themselves to receive the baseline questionnaire, which they are required to complete and return. If the visit took place remotely, study information will be emailed to them. If preferred, consent can be taken over the phone or using e-consent.
If the patient wishes to take time to consider whether they wish to participate before agreeing to consent, patients are instructed to telephone or email their RN/delegate if they decide they would like to take part, have any further questions or do not wish to take part (in this instance no further contact would be made). If the RN/delegate has not heard from the patient a week after the initial conversation, they will contact the patient to enquire whether they wish to take part or not.
The study information that all potential participants will receive includes an invitation letter, participant information sheet (including a step-by-step guide for how to participate and what is involved, together with the research nurse's or delegate's contact details) and guidance on how to use the e-consent system should they wish to.
2. Recruitment route two
Patients discharged following hospital-based treatment who self-refer to their oncologist to discuss problematic medication side effects and/or adherence problems within 12 months of completing their hospital treatment will be invited to participate. Eligibility will initially be assessed by the oncologist, who will briefly discuss the study with the participant, and if they are potentially interested, the oncologist will email (via secure NHS email) their contact details and name (with the patient's verbal consent) to the RN or delegate. The RN or delegate will telephone potentially eligible patients to discuss the study with them and answer any questions. Patients who have been screened as eligible and are interested in participating will then be emailed the study information detailed in recruitment route one.
If on receipt of the information the participant is still happy to take part, they will be instructed to telephone or email their RN/delegate if they have any further questions or do not wish to take part (in this instance no further contact would be made). Consent can be taken over the phone or via email. If the RN/delegate does not hear back within 7 days of sending out the study information, they will contact the patient via telephone and/or email to see if they are still interested in the study.
3. Recruitment route three
The RN or delegate will retrospectively screen patient records for potentially eligible patients who have completed hospital treatment within the last 12 months (including completion of radiotherapy/chemotherapy/surgery). The RN or delegate will post/email the same study information documents outlined in recruitment route one to potentially eligible patients. The patient is asked to call or email the RN/delegate if they are interested in the study or have any questions. If the RN/delegate does not hear back within 7 days of sending the study information documents they will contact the patient via telephone and/or email to see if they are interested in participating. If the patient is happy to be screened for eligibility, the RN/delegate will run through the screening questionnaire with them or re-arrange the call for a more suitable time. Patients who have been screened as eligible and are interested in participating will be able to

give consent over the phone, followed by e-consent. Once consented, they will be registered by the RN on the CTRU online system and a participant identification number will be generated. They will then be emailed a link to register themselves to receive the baseline questionnaire, which they are required to complete and return.

Screening and registration:
Regardless of recruitment route, if patients agree to take part their eligibility will be confirmed through screening questions before completing the consent process.

All potentially eligible patients will be screened for eligibility, the data obtained from screening will include reasons why the participant did not go on to be randomised i.e. if ineligible and the reasons why, this will be sent to the CTRU. The screening information will not contain any identifiable information and will only include a trial number for those participants who go on to be eligible and consent/ be randomised in to the study.

Once consented, all participants will be registered by the RN via an online system and given a participant identification number. They will then be emailed a link to register themselves to receive the baseline questionnaire, which they are required to complete. Once this is done an authorised member of staff at the trial research site will randomise the participants using the telephone randomisation service which will be available within working hours (Monday-Friday, 9am-5pm, excluding Christmas, Easter, and bank holidays). Randomisation will be performed by an authorised staff member at the Clinical Trials Research Unit in Leeds.

The intervention components:
1. Usual care:
All participants will receive treatment as usual which will be the standard care offered to women at this stage of their treatment for breast cancer and is likely to differ by recruiting site. Women in this population will be invited to attend an end of treatment summary meeting with a Breast Cancer Nurse. This meeting includes a holistic needs assessment and women are often provided with information about local services. Follow-up is patient-initiated, whereby the majority of patients are discharged from hospital follow-up, but are given contact details of a Breast Cancer Nurse that they can speak with if they have any problems or concerns. The Breast Cancer Nurse can make referrals to an oncologist or surgeon as needed. The content of treatment as usual programmes will be monitored at a site level, and usual care accessed will be monitored via participant self-report.
2. SMS text reminders:
The content of the SMS reminders has been co-developed with experts in behaviour change and /or medication adherence, and women who have experienced breast cancer. Over a four month period there will be 42 SMS messages delivered to participants randomised to conditions 1, 2, 3, and 4. These include an opening message, 36 messages aiming to make medication taking more habitual, a closing message, and 4 messages informing participants they can stop the SMS messages by emailing the trial email address at any time (one per month).
Information about the delivery of the SMS messages will be routinely collected.
3. Written information leaflet:
Participants randomised to conditions 1, 2, 5, and 6 will be sent a 6-page patient information leaflet, which aims to target specific adjuvant hormone therapy medication beliefs, immediately after they have been randomised. The content of this leaflet will include explanations of how AET works, supplemented by diagrams, information about the benefits and side effects of AET and answers to common concerns. The leaflet will also indicate that it has been codesigned by researchers and breast cancer survivors, and will include quotes from breast cancer survivors. They can then read this information leaflet as they wish. Participants will self-report whether or not they have received and read the information leaflet at 2 and 4 month follow ups.

4. Side effect self-management:
The website will contain sections on managing side effects, patient stories (including videos) and signposting for further information/places of support. Participants randomised to conditions 1, 4, 6, and 7 will receive the website address and their unique log-in details immediately following randomisation. Data will be collected about each participants receipt of website details and their website use, including pages visited, whether videos were watched and the percentage of the video viewed on a per participant level.
The data collected on a participant's website registration and usage is collected by google analytics and will be obtained and summarised by the research team at the CTRU. Only the University of Leeds will have access to the tracking data.
5. Acceptance and Commitment Therapy (ACT):
The ACT component is a guided self-help program consisting of four modules with home practice. Participants in conditions 1, 3, 5, and 7 will take part in five sessions with a psychologist – one introductory session plus four modules, each corresponding to a different ACT-based skill: Mindfulness and unhooking; Following your values; Taking an observer perspective; Recap, reflection, and staying committed. Each module consists of a participant manual containing information about the relevant ACT skill, alongside home practice exercises to complete. All sessions will take place via videoconferencing or telephone, and the first session will take place within 4 weeks of randomisation. Within these support sessions, the therapist and the patient will discuss the module completed over the past week, their experiences of the home practice exercises, and can discuss and problem solve any difficulties that arose. One week after the fourth module there will be one closing 15-minute support session, in which module 4 and any associated difficulties will be discussed. Session attendance and engagement with home practice tasks will be monitored.
Suitably qualified Health and Care Professional Council (HCPC) registered practitioner psychologists will be identified at the site eligibility stage, if they are interested in delivering the ACT intervention they will undergo a training programme in the ACT intervention prior to patient recruitment. This will be delivered by Dr Graham, who has expertise in ACT applied to chronic disease. Training will take place over twohalfdays and will be delivered remotely via videoconferencing.Trainingwillinclude general teaching about ACT and practice of intervention-specific therapy methods.Practitioner psychologists will be trained in groups where feasible. The practitioner psychologists delivering the intervention will be offeredfortnightlygroup supervision (60 min), for the duration of the interventionbyphone or video call, with Dr Graham. The practitioner psychologist canalsoaccess local clinical supervision if they wish, as part of their standard clinical practice.

Assessment:
Regardless of which condition they are allocated to, participants will complete an electronic questionnaire at baseline, as well as at 2 and 4 months follow-up. Questionnaires will measure medication adherence (which will also be assessed using NHS digital prescribing and dispensing data), quality of life, mood, medication beliefs, habits, and psychological flexibility.

The same questionnaires will be collected at 2 and 4 months and it is anticipated that these will take approximately 30-45 min to complete. At 4 months there will be additional questionnaires relating to the process evaluation and relating to the intervention components received by the participants. These will be;
1. Acceptability Questionnaire (AQ) to assess acceptability of individual intervention components
2. A single general acceptability item from the AQ to assess overall trial acceptability
3. Items assessing self-reported adherence to the intervention components

Attempts will be made to chase non-responseas part of standard practiceandtheSWAT (study within a trial).DuringtheSWAT, participants will be randomised to receive a SMS pre-notification

versus no pre-notification,the day before follow-up assessments are emailed out.Participants who have received the questionnaires but have not returned it after96 h will be randomised to receive one of two types of SMS reminder (a simple prompt versus a message to increase knowledge of trial processes). Seven days after the SMS reminder, theSWATwillendand standard practice will commence.

On the day standard practice begins, participants who have notreturned their follow-up assessments will receive an emailreminder from a researcher. Ifthereisstill no response72 h later,a furtheremail reminder will be sent. No further attempts will be made.

Participants will be asked to consent to the secure sharing of their personal identifiers (which will include full name, date of birth, gender,and NHS number) with NHS Digital toaccesstheirprescribing and/or dispensing data. A data access request will be submitted to NHS digital by the research team at the CTRU for the period covering the participant's time within the trial. This will be a single, one-off request for all consenting participants.

Following their involvement in the trial, participants from conditions 1-7 will be invited to take part in a semi-structured interview with a member of the research team from the University of Leeds, where they will discuss their experiences of trial recruitment and participation and give feedback on the intervention and trial acceptability. Allinterviewswill beapproximatelyone hour in lengthand will beconducted viavideo conferencing software (e.g.Microsoft Teamsor Zoom).

After the trial, therapists who delivered the ACT intervention component will also be invited to take part in a semi-structured interview to discuss the fidelity of the training and delivery of the ACT sessions. All interviews (including those with participants) will take place remotely, via videoconference or over the phone.

All Research Nurses involved in the study will be invited to take part in a questionnaire at the end of the trial, where qualitative and quantitative data will be collected. This aims to establish the barriers and facilitators to recruiting to this trial. The survey will be hosted on Qualtrics.

Intervention Type
Behavioural

Primary outcome measure
Eligibility, recruitment, retention and follow up rates, as well as availability and feasibility of outcome and process data, to inform the design of the optimisation phase of the ROSETA project, will be measured using data on the following, collected throughout the duration of the recruitment, intervention and at 2 and 4 months post-randomisation:
1. Number of patients identified as potentially eligible
2. Number and proportion of patients approached for eligibility screening
3. Number and proportion of patients agreeing to detailed eligibility screening and reasons for non-agreement
4. Number and proportion of eligible patients out of those potentially eligible and reasons for ineligibility
5. Number and proportion of patients consenting to randomisation out of those eligible and reasons for non-randomisation
6. Number of participants randomised per site per month
7. Questionnaire completion rates at each time-point
8. Number of items of missing data per questionnaire at each time-point
9. Number and proportion of randomised participants lost-to-follow-up
10. Number, proportion, type, and timing of participant withdrawals out of those randomised

and reasons for withdrawal
11. Number and proportion of participants with successful linkage to NHS Digital prescribing and /or dispensing data
12. Number and proportion of participants completing adherence questionnaires (MMAS-8 and Voils DOSE)

Secondary outcome measures
1. Acceptability of the intervention to participants and establish intervention component adherence measured using the following:
1.1. Short Message Service (SMS) text receipt at 2 and 4 months
1.2. Self-reported receipt and reading of information leaflet at 4 months
1.3. Receipt of website log in details and website use 2 and 4 months
1.4. ACT session attendance (clinician reported) between randomisation and 4 weeks
1.5. ACT module content engagement (clinician reported) between randomisation and 4 weeks
1.6. ACT module content engagement (patient reported) between randomisation and 4 weeks
1.7. Acceptability Questionnaire at 4 months
1.8. Qualitative interviews with participants and therapists at the end of the study
2. Estimate of the variability of planned outcome measures measured using the following:
2.1. NHS prescribing and/or dispensing data at all timepoints
2.2. Morisky adherence measure at all timepoints
2.3. Voils DOSE-Nonadherence measure- Extent Scale all timepoints
3. Estimate of the cost of developing and delivering each intervention component measured using NHS Reference Costs and Personal Social Services Research Unit cost data at the end of the study
4. Levels of burden among patients and healthcare professionals delivering intervention components measured using the following:
4.1. Acceptability Questionnaire at 4 months
4.2. Trial experience questionnaire (SPFQ) across all time points
4.3. Qualitative interviews with participants and therapists at the end of the study

SWAT:
1. Questionnaire response rates and completeness measured using the following:
1.1. Proportion of participants in each SWAT group who return the questionnaire within 96 h, 7 days, and 1 month of them being administered
1.2. Number of days between the questionnaire being sent to participants and it being returned by participants to the research team
1.3. Proportion of non-mandatory questionnaire items missing at all timepoints
1.4. Proportion of non-mandatory questionnaire measures with complete data at all timepoints
2. SWAT Intervention Cost measured using the cost of SWAT intervention per participant retained at one-month

Overall study start date
02/01/2019

Completion date
30/04/2023

Eligibility

Key inclusion criteria

Current inclusion criteria as of 10/01/2023:
1. An informed consent form (signed and dated)
2. Capacity to provide informed consent
3. Women with early stage (1 to 3a) breast cancer according to the TNM / American Joint Committee on Cancer (AJCC) staging system.
Note. Women being treated for a second primary breast cancer or a breast cancer local recurrence are eligible for the study, providing the most recent cancer is being treated with adjuvant endocrine therapy, and they meet all eligibility criteria. Women with bilateral breast cancer are permitted, providing at least one breast is affected by hormone receptor-positive disease'
4. Aged ≥18 years at time of screening for ROSETA's pilot study
5. Have sufficient proficiency in English to be able to adhere to all intervention components and data collection required
6. Treated with curative intent
7. Completed their hospital-based treatment (e.g., surgery, radiotherapy and/or chemotherapy) for the current breast cancer within the last 12 months.
Note. Women are still eligible for the study if they are being treated with monoclonal antibody-based therapy such as trastuzumab, kadcyla, pertuzumab, and phesgo
8. Currently prescribed oral adjuvant Hormone Therapy (tamoxifen, raloxifene, anastrozole, letrozole, exemestane)
9. The participant is willing to complete the study questionnaires*
10. The participant is willing to be audio recorded during the therapy sessions*
11. The participant is willing and able to attend all ACT sessions either via video conference or telephone*
12. The participant is willing and able to complete home practice tasks*
13. Access to a mobile phone to receive SMS messages*
14. Willing to receive frequent SMS messages*
15. Access to a computer or smart device that can access the internet*
*Source data for these items will be either partially or completely patient self-report.

Previous inclusion criteria:
1. An informed consent form (signed and dated)
2. Capacity to provide informed consent
3. Women with early-stage (1 to 3a) breast cancer according to the TNM / American Joint Committee on Cancer (AJCC) staging system.
4. Aged ≥18 years at time of screening for ROSETA's pilot study
5. Have sufficient proficiency in English to be able to adhere to all intervention components and data collection required
6. Treated with curative intent
7. Completed their hospital-based treatment (e.g., surgery, radiotherapy and/or chemotherapy) for the current breast cancer within the last 12 months.
8. Currently prescribed oral adjuvant Hormone Therapy (tamoxifen, raloxifene, anastrozole, letrozole, exemestane)
9. The participant is willing to complete the study questionnaires
10. The participant is willing and able to attend all ACT sessions either via video conference or telephone.
11. The participant is willing and able to complete home practice tasks
12. Access to a mobile phone to receive frequent SMS messages
13. Willing to receive frequent SMS messages
14. Access to a computer or smart device that can access the internet

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
52

Key exclusion criteria
Current exclusion criteria as of 10/01/2023:
1. Stopped taking adjuvant hormone therapy if it is clinically contraindicated according to clinical recommendation
2. Women with metastatic breast cancer
3. Currently or recently (last 6 months) involved in a similar research study where medication adherence is a primary outcome*
4. Currently attending psychotherapy/psycho-oncology/psychology/counselling services, for any clinical reason*
5. Need for treatment for a severe mental health disorder or crisis, which is likely to interfere with participation (e.g., active psychosis, bipolar disorder, significant issues with addiction or self-harm or expressing active suicidal ideation with active plans and intent*)
Note, if concerned about the possible presence of risk of suicidal ideation with active plans and intent, then this can be assessed with the following questions, with patients ineligible if they answer 'yes' to 5.3.
Recently (in the last month):
5.1. Have you had any thoughts about ending your life?
5.2. (if yes) Have you thought about how you might go about it?
5.3. (if yes) Do you intend to carry out this plan?
6. Patients with a scheduled date for breast reconstruction surgery that is within their intervention delivery and follow-up period. Note: Women planning to have a breast reconstruction but who have not scheduled a date for surgery are permitted
7. Auditory problems that would prevent the patient from participating in a telephone or video call, or hearing audio clips*
*Source data for these items will be either partially or completely patient self-report.

Previous exclusion criteria:
1. Stopped taking adjuvant hormone therapy if it is clinically contraindicated according to clinical recommendation
2. Currently or recently (last 6 months) involved in a similar research study where medication adherence is a primary outcome
3. Currently or recently (last month) been referred to a psycho-oncology service
4. Currently attending, or on a waiting list for, psychotherapy/psycho-oncology/psychology /counselling services, for any reason

5. Current diagnosis of an active major mental health disorder likely to interfere with participation (e.g., active psychosis, significant issues with addiction, or self-harm)
6. Known element of risk (e.g. the clinical team is aware that the patient has made a recent attempt to end their life, or has recently disclosed plans to do so) as determined by three clinical screening questions below:
6.1. Recently (in the last month), have you had any thoughts about ending your life?
6.2. Have you thought about how you might go about it?
6.3. Do you intend to carry out this plan?
7. Auditory problems that would prevent the patient from participating in a telephone or video call, or hearing audio clips

Date of first enrolment
20/05/2022

Date of final enrolment
16/12/2022

Locations

Countries of recruitment
United Kingdom

Study participating centre
Queen Elizabeth Hospital
Lewisham and Greenwich NHS Trust
Stadium Rd
London
United Kingdom
SE18 4QH

Study participating centre
The Queen Elizabeth Hospital
Kings Lynn NHS Foundation Trust
Gayton Rd
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Whiston Hospital
St Helens and Knowsley Teaching Hospitals NHS Trust
Warrington Rd
Rainhill

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United Kingdom
L35 5DR

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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journal
2. Internal report
3. Conference presentation
4. The results will inform the design of the definitive randomised controlled trial

Intention to publish date
30/11/2024

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 01/07/2022:
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.
CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.
The CTRU encourages a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.
The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from CTRU-DataAccess@leeds.ac.uk. Data will be shared according to a controlled access approach. Data will only be shared for participants who have given consent to use of their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications	process evaluation protocol	24/04/2023	26/10/2023	Yes	No
Basic results		25/04/2024	25/04/2024	No	No
Other publications	Process evaluation results	05/12/2024	07/01/2025	Yes	No
Results article		04/01/2025	03/02/2025	Yes	No