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ROSETA

Refining and Optimising a behavioural intervention to Support Endocrine Therapy Adherence

Participant Information Sheet and Informed Consent Document

A large-print version of this sheet is available on request.

You have been invited to take part in a research study called “ROSETA”. In this information sheet we will explain why we are doing the research, what the study will involve and how we will use the information we have about you. This is to help you decide if you would like to take part.

Please read this information carefully and discuss it with others if you like. Take time to decide whether or not you wish to take part.

Once you have read this information, your researcher will talk to you about the study again and you will be able to ask questions.

If you have more questions about the study or what taking part would mean for you, you may find the answers in the **additional information** here https://ctru.leeds.ac.uk/roseta/. You don't have to read any of the extra information before agreeing to take part, if you don't feel you need to.

How to contact us

If you have any questions about this study, please talk to your researcher:

<<Enter PI/nurse name and contact details/website link>>

Thank you for reading this information sheet.

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Summary of the ROSETA Optimisation trial

What is the ROSETA Optimisation trial?

Some patients with breast cancer struggle to take their medications regularly and may even stop altogether. The ROSETA Optimisation trial is testing how well four ways (called interventions) support women with breast cancer in taking hormone therapy (e.g., Tamoxifen, Raloxifene, Anastrozole, Letrozole, Exemestane, Bisphosphonates). We are testing what, if any, is the best combination of the interventions.

What interventions are you testing?

SMS text reminders to support taking medication.

A leaflet providing information about the medication.

A website to provide useful resources for managing side effects of the medication.

A skills programme known as Acceptance and Commitment Therapy (ACT) which encourages approaching experiences with openness and awareness, and to support you to engage with your values. This is led by a therapist and involves learning and practising skills at home.

Who can take part?

We hope that around 500 women aged 18 and over will take part, who have been diagnosed with breast cancer and prescribed medication to reduce the risk of the cancer returning. They must have access to a mobile phone and a computer or smart device that can access the internet. Taking part is completely voluntary.

Who is organising the trial?

The trial is being run by the University of Leeds. The Chief Investigator is Professor Sam Smith, a researcher interested in the factors affecting the use of cancer medicines.

What is involved?

We will:

- Confirm your eligibility and ask if you consent to take part.
- Ask you to complete a total of up to 4 questionnaires over a period of up to 12 months.
- Ask you if you are willing to be interviewed after around 6 and 12 months, to discuss your experiences of taking part. The interviews are optional, so you can take part in ROSETA without being interviewed.

You will be randomly allocated either to one or more of the interventions in addition to your usual care, or to your usual care alone. If you are randomly allocated to the ACT sessions, you will attend a total of 5 remote sessions and will be asked to complete home practice tasks.

Will I get the results?

You can choose to receive a copy of the results by email at the end of the trial.

Part 1 - overview

What is the purpose of the study?

We aim to see how best to support women with breast cancer in taking their medication by testing combinations of four different interventions. If the new interventions support women in taking their medication, this may benefit women with breast cancer in the future. However, we currently do not know what the best intervention is or whether this is better than usual care. This is why we need to run this study.

Why have I been chosen?

We are inviting you because your hospital records show you have previously been diagnosed with breast cancer and have been prescribed medication to reduce the risk of it returning. Your hospital is supporting this study.

Do I have to take part?

No, your participation in ROSETA is voluntary and you may withdraw your consent to take part at any time, without giving us a reason.

If you decide not to take part, your treatment and care will not be affected in any way.

How do I take part?

If you decide to take part, please contact us using the details on the first page of this information sheet. You will have the opportunity to discuss the study in more detail and ask any questions you may have.

Your researcher will confirm whether you are eligible to take part. If you are eligible, you will be asked to give consent, but you are still free to withdraw at any time and without giving a reason.

After you have consented, you will receive an email with a link to complete questionnaires. You must complete these questionnaires before you can be randomly allocated to a group. This should take no longer than 45 minutes to complete.

What will happen to me if I take part?

The best way of finding out whether any of the interventions are as effective as usual care is in a randomised study. ‘Randomised’ means that a computer will allocate you randomly to a group. A group can be a combination of interventions, one intervention or no interventions. All groups will receive the usual care provided by their hospital. Neither your doctor nor you will choose which group you receive. In this way, a fair comparison can be made.

You will be asked to complete a similar set of questionnaires at 4, 8 and 12 months after you have been randomised. You may receive the 12-month questionnaires slightly earlier depending on when you were recruited into the study. This is to monitor any changes throughout the study, and we are interested in everyone’s responses regardless of what group you have been randomised to. The questionnaires will take no longer than 45 minutes to complete.

You will receive reminders to complete questionnaires by text, email and/or phone. Not everyone will receive the same reminder

message, and some people will also receive a notification that their questionnaire is due soon. This is to find out how best to support participants in completing questionnaires. Who receives what is decided by a computer that will allocate you randomly.

If you have agreed to being contacted about the optional interviews, a researcher may email you after around 4 and 12 months to ask you if you would like to take part in the interviews. A separate information sheet will be provided about this.

In the unlikely event that during this study you lose the ability to make your own decisions, you will no longer receive the interventions and we will stop sending you questionnaires. We will keep any information we have collected up to that point and it will be used to help with our research, but we will not collect any more information about you.

What do the interventions involve?

Remember that you may receive a combination of interventions, one intervention or no interventions.

SMS text reminders: You will receive a total of around 40 SMS messages over a period of approximately 4 months. You can select whether to receive these in the morning, afternoon or evening.

Information leaflet: You will receive this by email around 1 week after joining the study to read as you wish.

Website: You will receive access to this around 1 week after joining the study to use as you wish. You will have access to the website for around 12 months.

ACT sessions: You will attend 5 sessions remotely with a ROSETA therapist over a period of around 4 months once your sessions begin. There may be a short waiting list until you can start your sessions. You will receive 4 module booklets containing home practice tasks and audio files that you will be encouraged to complete between sessions. During the sessions, and in the booklets, you may be asked to reflect on your own thoughts and feelings. Each module should take no longer than 90 minutes to complete. Each support session will last around 25 minutes. Your ROSETA therapist will contact you directly to make your appointments. You can request printed booklets if you wish and you have the option of whether or not the sessions are audio-recorded. Recordings help us to monitor whether the sessions are delivered correctly by the ROSETA therapist.

What are the possible benefits of taking part?

Although we don't know which intervention, if any, helps women with breast cancer, you might personally find them useful to you. You will be contributing to important research that may benefit women with breast cancer in the future. You may also enjoy learning more about health research.

What are the possible disadvantages and risks of taking part?

We do not expect there to be any risks in taking part. Agreeing to take part in this

study will mean giving up some of your time to complete questionnaires.

Some questionnaires ask about how you are feeling, and this may upset some people. Your researcher will provide you with details of organisations that you can contact if the research upsets you in any way. Some of these are listed below:

Your local mental health team: https://www.nhs.uk/service-search/mental-health/find-an-urgent-mental-health-helpline

Samaritans: 116 123 (24-hour free telephone line), jo@samaritans.org

If any aspect of the study upsets or distresses you, please discuss this with your researcher, your GP, or dial 111 for further advice.

You should always tell your doctor about any health events you have experienced during your time on the study or afterwards (such as having to go to hospital for any reason).

What happens when the research study ends?

At the end of the study participants will no longer have access to the SMS messages, ACT sessions with a therapist and the website. The results will be published in a medical journal, but no individual participants will be identified. You can request that you receive a summary of the results by email.

What will happen if I don't want to carry on with the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, we would like to know the reason if you are willing to say, because this can be useful when we produce the results of the study.

Before deciding to stop, you should talk to your researcher. They can advise you and may be able to deal with any concerns you may have. If you decide to stop taking part at any time, it will not affect the standard of care you receive.

You can still complete questionnaires, if you agree to this.

If you tell us that you want to stop completing the questionnaires, we will stop asking you to complete them. You can still take part in the study if you stop these, and you can change your mind later and start completing them again, if you wish.

If you decide to stop participating in the interventions or completing the questionnaires, to make sure the research is still reliable, we will need to keep the information we have already collected about you, and include it in the study analysis.

Unless you clearly tell us you don't want us to, we will continue collecting information about your health from routine hospital visits, via your GP or through other contact between you and your hospital. We will only do this if the information is relevant to the study. We will also keep collecting information about you from central sources of healthcare data such as NHS Digital. We do this to help ensure the results of the study are valid. If you are not happy with this, you can ask us to stop collecting more information about you at any time.

Will my taking part be kept confidential?

There are a few things you should know about how your confidentiality will be affected if you agree to take part in this study.

- Your **GP, and the other doctors involved in your healthcare, will be kept informed** of your participation in this study. This is because they might need to know you took part when they treat you for anything in future.
- When you are communicating with the research staff or your ROSETA therapist, if you mention anything that makes them think you might be in some danger or come to some harm, they may be obliged to **pass on that information to your usual care team**. They will only do this if they really think it is necessary, and they will be careful to keep your information secure and confidential, and only tell the minimum number of people required.
- Your **healthcare records may be looked at by authorised individuals** from the research team, the University of Leeds (the study Sponsor) or other authorised bodies to check that the study is being carried out correctly. This will only be done in line with your hospital's policies to ensure your records are secure.
- We would like to **collect a copy of your completed consent form**, if you agree to take part in the study. This is so that we can check you have definitely agreed to take part. This means people in the study team who are authorised to deal with consent forms will see your name. However, these people are trained to treat your information with care, and the consent form will be stored securely at all times.
- If you receive **ACT sessions**, we will ask your permission for the sessions to be audio recorded for the purpose of supervision (to support your therapist in delivering ACT) and to ensure the study is being conducted properly.
- If you receive access to the side-effect management website, data around your website usage will be tracked via google analytics, including pages visited, links clicked, and videos watched. Only the University of Leeds will have access to these tracking data.
- As part of this study, we will use some of your information (your name, date of birth, gender, NHS or CHI number, and postcode) **to obtain information about you in central sources of healthcare data such as standard NHS patient registries** held by NHS Digital, or equivalent.
- At the end of the study, we will make all the study data available for other researchers to carry out more research in the public interest. We will only share your information in such a way that researchers outside the

University of Leeds will not be able to identify you. We will only share your information for worthwhile research with all appropriate approvals.

- For those study participants who were referred via **Be Part of Research**: the CTRU will provide information to Be Part of Research to confirm who has signed up to the study. This is for the purpose of ensuring you will not be contacted about this study again, or other research that you may have become ineligible to take part in.

What if I am harmed by taking part in the study?

Every care will be taken in the course of this clinical trial. However, in the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available and you may have to pay your related legal costs. Your hospital where you receive your treatment has a duty of care to you whether or not you agree to participate in the trial and the University of Leeds accepts no liability for negligence on the part of your hospital's employees. If you wish to complain about any aspect of the way you have been treated please contact your researcher in the first instance.

Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

How we will use your information

If you decide to take part in this study, some information about you will need to be collected and used. Use the reference numbers to find the relevant section in the **additional information** here https://ctru.leeds.ac.uk/roseta/.

We will use information about you and your health to run the study, produce the study results, and to help make sure you and other people taking part in the study are safe **(1)**.

The University of Leeds will have overall responsibility for how your information is used in this study **(2)**

We will keep all your information secure at all times **(3, 4)**.

There are some specific situations where we need to share information with other people or other organisations. **(5)**

You can usually ask organisations to give you a copy of information they hold about you, or to correct your information. However, this does not apply when your information is used for research in the public interest like this, because allowing you to access or change the information could harm the quality of this research. Your contact details are different though - it's vital that you tell your researcher if these change at any point. **(6)**

To comply with laws and other rules about research, we need to keep your identifiable information until at least **5 years** after the study has finished. **(7)**

You can usually ask organisations to delete your information or restrict how your information is used. However, allowing you to delete or restrict your information could harm the quality of this research, which is being done in the public interest. If you stop taking part in the study, we will therefore need to keep the information we already have about you. **(8)**

If you have questions or concerns about how your information is used that aren't answered by this document or by talking to your researcher, you can contact the University of Leeds Data Protection Officer. If you are still not happy, you can contact the Information Commissioner's Office. You can find out how to contact these people in the **Additional Information** **https://ctru.leeds.ac.uk/roseta/** . For any questions or concerns that are not to do with how your information is used in this study, please contact your nurse or doctor as you usually would. **(9)**

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Participant ID:	Initials:
Date of Birth:	NHS/CHI/Hospital Number:
ISRCTN: 17334319	Principal Investigator:

PARTICIPANT CONSENT FORM

Please initial each box

1. I confirm that I have read and understand the information sheet dated **23/10/2025 (V6.0)** for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that if I withdraw from the above study, the data collected from me up until that point will be retained and analysed. ☐

3. I understand that my healthcare records may be looked at by authorised individuals from the study team, the Sponsor, the Leeds Clinical Trials Research Unit or relevant third parties in order to check that the study is being carried out correctly. ☐

4. I agree for my details (which will include my full name, date of birth, gender, NHS/CHI number, and postcode) to be shared with central sources of healthcare data such as NHS Digital so that the research team can obtain prescribing and dispensing data for my adjuvant endocrine therapy medication. ☐

5. I consent to the secure transfer, storage and use of paper and electronic personal information for the purposes of this study, to the Leeds Clinical Trials Research Unit, or relevant third parties. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication. ☐

6. I understand that if during this study my clinical care team determine that I have lost my ability to make my own decisions, I will be withdrawn from the study and no further data will be collected. I agree that data collected up until this point will remain on file and will be included in the analysis. ☐

7. I agree for my email address to be passed to the CTRU so I can receive study questionnaires as well as requests and reminders to complete. I agree for my email address to also be used to send details of the interventions for which I will receive. ☐

8. I agree for my mobile telephone number to be passed to the CTRU so I can receive the SMS intervention, if so randomised, and reminders to complete questionnaires. ☐

9. I agree for my website usage to be tracked if I am randomised to receive the website intervention. ☐

10. I agree to a copy of this Consent Form being sent to the CTRU. ☐

11. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study. ☐

12. I understand that information collected about me in this research may be used later for other research in the public interest. Information would only be shared outside the original research team in a way that means I could not be identified. ☐

13. I agree to take part in the study. ☐

The following points are OPTIONAL.

Even if you agree to take part in this study, you do not have to agree to this section

	Please tick ✓ Yes	No
If randomised to receive Acceptance and Commitment Therapy (ACT), I give consent for the sessions to be audio-recorded.	☐	☐
I would like to be contacted about the results of this study using the contact details I have provided.	☐	☐
I am happy to be contacted by a member of the research team about taking part in two semi-structured interviews. I understand that taking part in this is separate to the main study and is not mandatory.	☐	☐

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Face-To-Face Consent

Participant- Please sign and date:

Signature……

Name (block capitals)……

Date……

Please now return this form to the Research Nurse/delegate

To be completed on receipt by the Research Nurse/delegate;

Research Nurse/delegate:

I have explained the study to the above participant and they have indicated their willingness to participate. I have placed a copy of this consent form in their medical notes.

Signature……

Name (block capitals)……

Date……

OR:

Telephone Consent

Research Nurse/delegate:

I have explained the study and read the statements to the above named participant. They have indicated their willingness to participate and agreed to each compulsory statement, so I have initialled and signed on their behalf.

Signature……

Name (block capitals)……

Date……

(Note for Research Nurse/delegate: 1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)