ROSETA

Refining and Optimising a behavioural intervention to Support Endocrine Therapy Adherence

Participant Information Sheet Additional Information

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

Who has organised, reviewed and funded the research, and who will be supervising?

The study is being organised and supervised by the University of Leeds. It is funded by the National Institute for Health and Care Research. A group of women with a previous diagnosis of breast cancer helped in the design of the study. All research is looked at by an independent group of people called a Research Ethics Committee, to protect the safety, rights, wellbeing, and dignity of those taking part. This study has been reviewed and approved by the Yorkshire & The Humber - South Yorkshire Research Ethics Committee.

Will any travel or other costs be refunded?

Taking part in this study will not require any additional hospital visits than usual. You will receive the interventions and questionnaires to complete from home.

What if relevant new information becomes available?

Sometimes during the course of a study, new information becomes available. If this happens your researcher will tell you about it, and you will be able to decide whether you want to continue in this study.

Why are you collecting information about me from my hospital medical notes and central sources of healthcare data such as standard NHS patient registries held by NHS Digital, or equivalent?

We do this because it is a more efficient way to collect certain data about your health. By using data collected from routine health visits, we can reduce the burden (such as the number of hospital visits) on you and your hospital. When we do this linking, we will only use the details mentioned (your name, date of birth, gender, NHS or CHI number, and postcode) to identify you, and we will follow strict rules when working with other organisations to maintain confidentiality and to protect your information.

How can I raise a complaint about something that has happened in the study?

If you are concerned about any aspect of this study, you should speak with your researcher who will do their best to answer your questions. If you still have concerns, you may wish to contact your local Patient Advice and Liaison Service, or, if you wish to complain formally you can do this through the NHS Complaints Procedure. Details for this can be obtained from your NHS Trust.

What if I have a problem?

We will not routinely monitor your questionnaire responses for the purposes of detecting concerns about mental wellbeing or risk to yourself.

If you feel you are in crisis or at risk of harming yourself, or anyone else, then you should contact your local mental health crisis line (you can find the number here: https://www.nhs.uk/service-search/mental-health/find-an-urgent-mental-health-helpline). Alternatively, you can make an emergency appointment with your GP, or access any of the following resources. In an emergency, please attend your local accident and emergency department, or call 999.

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

Samaritans is a registered charity aimed at providing emotional support to anyone in emotional distress, struggling to cope, or at risk of suicide throughout the UK and Ireland.

Shout – 85258 (24hr free text line)

Shout 85258 is part of a registered charity offering free, confidential, 24/7 text messaging support for anyone who is anxious, stressed, depressed, suicidal or overwhelmed, and who need immediate support in the UK.

Stay Alive (downloadable phone app)

This app is a pocket suicide prevention resource for the UK, packed full of useful information and tools to help you stay safe in crisis. You can use it if you are having thoughts of suicide or if you are concerned about someone else who may be considering suicide.

In addition to the resources, the app includes a safety plan, customisable reasons for living, and a LifeBox where you can store photos and memories that are important to you.

You can also read the strategies for staying safe, explore the tips on how to stay grounded when you're feeling overwhelmed, try the guided-breathing exercises and support your own wellness by creating your own interactive Wellness Plan.

Mind - (website with further resources)

https://www.mind.org.uk/information-support/

Mind is a registered charity that provides advice and support to empower anyone experiencing a mental health problem. Using the above link, you can access resources including:

- Tips for living with a mental health problem.
- Side by Side - a supportive online community for those experiencing mental health issues.

- Confidential mental health information services.
- Guides to understand which mental health service is right for you.

You may also find it helpful to contact Macmillan Cancer Support, an independent cancer information charity (freephone: 0808 808 00 00; address: 89 Albert Embankment, London, SE1 7UQ; website www.macmillan.org.uk) or get more information from the charity, Cancer Research UK at https://www.cancerresearchuk.org/about-cancer. If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published various resources to help people learn more about clinical trials. Contact UKCRC: Tel: 0207 395 2271; email: info@ukcrc.org; website www.ukcrc.org.

How will you use my information?

This section explains what information will be collected, who it will be shared with and what it means for you.

If you would like more detailed explanations about anything, including why we need to do things in a certain way, you can find it in our comprehensive guide. You do not have to read it before taking part in this study, but you might want to look at specific sections if you have particular questions. This is available at https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/ or you can ask for a printed copy from your researcher. This can also be made available in large print or other formats, if you need them.

All of these documents have been written with the help of patients and the public to help make sure they are clear and accessible. As in the participant information sheet, whenever we say 'we' or 'us', we mean the study team at the Clinical Trials Research Unit, University of Leeds (https://ctru.leeds.ac.uk/).

You can find more general information from the NHS about how people's information is used in research at www.hra.nhs.uk/patientdataandresearch. Please feel free to ask for a printed copy of this if you cannot access this online version.

1. What information will be collected, and what will it be used for?

If you agree to take part in this study, we will need to collect and use some information about you and your health. The information we will collect will include:

- Information from you and from your hospital medical notes
- Information about you held in central sources of healthcare data such as standard NHS patient registries held by NHS Digital, or equivalent
- Your contact details
- If randomised to receive access to the side-effect management website, we will collect anonymised data around your website usage.

We will only use what we need to run the study, to produce the results of the study and to make sure you and other people taking part in the study are safe.

This research is in the public interest, which means our results will be used to improve the healthcare of patients in the future. Because of this, if you agree to take part in the study, we will be able to use information about you, including sensitive information about your health, ethnicity and sex life.

Specifically, the ways we will use information about you are**:**

- We will use information from you and your medical notes to run the study, to produce the study results and to confirm it is safe and appropriate for you to join the study. We will also collect information about your health from your researcher and your medical notes to help make sure you and others are safe.

- We will collect a copy of your signed consent form so that we can be sure you have agreed to take part in the study.
- We will collect information about you and your health directly from you on study questionnaires. We will use this information to produce the study results.
- We will collect prescribing and dispensing information about your medication held in central sources of healthcare data such as standard NHS patient registries held by NHS Digital, or equivalent. To do this, we will securely send your full name, your date of birth, gender, your NHS or CHI number and postcode to central sources of healthcare data such as NHS Digital**,** and they will return the information about you that we need for the study. We do this because it means we can do the study while taking up less of your time, and less of your hospital's time.
- We will send you intervention materials, study questionnaires, reminders to complete study questionnaires, a thank you for completing your study questionnaires, and potential study updates. To do this, we will need to collect your email address and phone number. If you are randomised to receive the ACT sessions, your contact details will also be sent securely to the member of staff who will be delivering ACT so that appointments can be made with you. This is likely to be the NHS Trust where you received your breast cancer treatment.
- We are collecting information about your postcode as it allows us to calculate the level of deprivation that exists within your neighbourhood. We need this to show that a broad range of people have taken part in the trial.
- If you are randomised to receive the ACT sessions and you consent to be audio-recorded during the sessions, we will collect the audio-recordings for the purpose of supervision (to support your ROSETA therapist in delivering ACT) and to ensure the study is conducted properly. They will be interested in how the ROSETA therapist is delivering the sessions and will not be analysing anything that you say. The recordings will be stored securely for a minimum of 5 years.
- If you are randomised to receive access to the side-effect management website, we will collect anonymised data around your website usage via Google analytics, including pages visited, links clicked and videos watched. Only the University of Leeds will have access to the tracking data.

2. Who is collecting my information?

Your information will be collected by the Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research, University of Leeds. You can find out more about our work at https://ctru.leeds.ac.uk/.

The University of Leeds has overall responsibility for what information is collected, how it is collected, and making sure people's information is used securely and correctly. If you want to contact someone within the University about how your information has been or will be

used, see section 9, below. See the **comprehensive guide** for more about what this means for you.

We will make sure we follow the principles of data protection in everything we do. This means we will keep your information secure, keep it only for as long as we need it, only use the minimum information we need for specific, necessary purposes, and we will be open, transparent and fair with you about how we use your information. You can find out more about how we follow the principles of data protection in the **comprehensive guide.**

3. Will my information be kept secure?

We will take all necessary measures to ensure that information about you is sent and stored securely by us or by anyone acting on our behalf.

Your researcher will enter most of the information needed for the study directly into our secure study database. Your researcher will also send us some information by 'secure file transfer'. This means information is sent by the internet in a very secure way. This will include your completed consent form, so that we can be sure you have agreed to take part in the study. This will be sent separately to any other study forms. This will also include data that only identifies you by your allocated study number, initials and date of birth.

Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

4. Who will see my information in the research team?

We will make sure that the only people at the University of Leeds who can see your information are people who need to run or analyse the study.

See **the Participant Information Sheet** for more on who may see your medical notes and other confidential information, if you agree to take part in this study.

5. Who else will see my information?

There are some specific situations where we will need to share information with other people or other organisations. We will always do this carefully and only when it's really necessary. We will avoid sharing information that could identify you whenever possible. We will never sell your information, or pass it on to people who will sell it. We will only share information when it is necessary for the study, necessary to protect your safety or the safety of others, or in the public interest. Information we share will not be used to make decisions about future services available to you, such as insurance.
We will share your information for the following reasons. You can find out more about these in the **comprehensive guide.**

- To run and analyse parts of the study, we need to share your information with collaborators (such as doctors, statisticians or other experts) outside the University of Leeds.
- To obtain additional information from your NHS medical records, we need to share your information with central sources of healthcare data such as NHS Digital or other information providers. They will send us information about you that we need for the study. This is an important way we can do the study while saving time and money for you and for the NHS.
- To keep you and other people safe, we will need to share some information about health-related events you may have with authorised organisations. None of these organisations will be able to identify you from this information.
- To report to authorised people about the progress of the study, we will need to share some basic information with some authorised organisations, including the Research Ethics Committee that has approved this study. None of these organisations will be able to identify you from this information.
- To allow the content of audio-recorded interviews to be typed up.
- To allow other researchers to carry out future research in the public interest. We will only share your information for worthwhile research with all appropriate approvals. 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 may also use study information for additional research projects within the University of Leeds. We will only agree to do this for worthwhile projects with all appropriate approvals, and we will not share any clearly identifiable information with researchers outside the original study team.
- Due to storage space limitations, we will store information securely away from the University of Leeds for a period after the main part of the study is over. The archiving companies we use to do this for us will only store your information and will not access it or see your details.

See **the Participant Information Sheet** for more on who may see your medical notes and other confidential information if you agree to take part in this study.

6. Can I see my information, or ask you to correct it?

Usually, when an organisation or a company has information about you, you can ask to have access to that information at any time, or ask them to correct it if it needs correcting. However, this does not apply in the same way to information used for research in the public interest, because allowing people to access or change their information could harm the quality of the research. You therefore cannot ask to access or correct information we have about you. However, most of the information we will collect will also be in your medical notes, which you can get access to if you want to. You should speak to your researcher if you would like more information about care you have received.

If you have provided us with contact details for use in the study (email address and phone number) it is important that we find out about any changes to these. Please let your researcher know about any changes so that they can let us know. Otherwise, we might lose contact with you or send messages for you to your previous contact details.

7. How long will my information be stored for?

If you agree to take part in this study, we will need to keep your information for at least **5 years** after the end of the study. We need to do this in order to comply with laws and other rules about research, which say it must be possible to check the results of the research for a period of time after it has finished. We will keep your information secure during all this time. For practical reasons, we may ask reputable archiving companies to store information securely on our behalf, away from the University of Leeds.

At the end of this period, we will securely destroy your information.

8. What will happen if I stop taking part in the trial?

If you decide you would like to stop participating in the interventions or completing the questionnaires, we will need to keep the information we have about you to make sure the results of the study are reliable.

Usually, when an organisation or a company has information about you, you can ask them to delete it, or not use it for a certain purpose. However, this does not apply in the same way to information used for research, because it would harm the quality of the research if people could delete or remove their information. We also need to comply with laws and other rules about research that say we need to keep all information used in research for a period of time after the research finishes. If you agree to take part in this study, it will therefore not be possible for us to remove or delete your information later on, although you can ask us to collect no further information after a given time.

Some other things you should know about what will happen to your information if you stop taking part:

- If you stop participating in the interventions or completing the questionnaires, you should discuss this with your researcher. If you still occasionally go to your hospital for routine visits, we would like to hear from your researcher about these visits, if they are relevant to this study. This way, you can still contribute to the study and help make the study results more reliable, without giving any more of your time. However, you can tell your researcher that you do not want any more information sent to us, and they will make sure your wishes are respected.
- In this study we will get some information from your electronic medical records held in central sources of healthcare data such as standard NHS patient registries held by NHS

Digital, or equivalent. If you ask to stop participating in the interventions or completing the questionnaires, we will continue doing this. Again, this means we can make sure the results of the study are reliable, without you having to give any more of your time. However, you can tell your researcher at any time that you would like us to stop doing this, and they will make sure your wishes are respected.

If you want to know more about what might happen to your information if you stop taking part in the study, including *why* we need to use your information in the ways we do, please see the **comprehensive guide.**

9. What if I have concerns about how my information is being used?

Your researcher should be your first contact for any questions about your participation in this study. If you have questions that they cannot answer, and which are not answered by any of these documents, you can contact the University of Leeds Data Protection Officer (the University's main contact for anything to do with how your information is used). You can do this using any of the details below. If you do contact them, please mention the name of this study (ROSETA) and the Clinical Trials Research Unit.

- Email: DPO@leeds.ac.uk
- Telephone number: +44 (0)113 343 7641
- Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT

If you are not happy with the response to any queries or complaints, or believe your information is being used incorrectly or unlawfully, you should contact the Information Commissioner's Office:

- General website: ico.org.uk
- ICO contact webpage: ico.org.uk/global/contact-us
- Telephone number: 0303 123 1113
- Postal address: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF