IRAS number: 272685

QUALITY OF LIFE IN SURVIVORS OF LOCALLY RECURRENT RECTAL CANCER

WE WOULD LIKE TO INVITE YOU TO PARTICIPATE IN THIS RESEARCH STUDY:

- The aim of this study is to identify the issues which are relevant to and impact upon the quality of life of survivors of locally recurrent rectal cancer.
- Before you decide whether to take part, please read through this leaflet carefully. It is important that you understand why the research is being done and what it involves.
- Participation is entirely voluntary, if you choose not to take part this will not affect the treatment you receive from your medical team.
- Please do not hesitate to get in touch with any questions.

HOW TO CONTACT US:

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LRRC QoL

PelvEx Collaborative
BOWEL RESEARCH UK.
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WHAT IS THE PURPOSE OF THE STUDY?

Locally recurrent rectal cancer, meaning cancer which returns close to the origin site, affects approximately 10% of people following treatment of rectal cancer.

The extent of the burden that locally recurrent rectal cancer has on people's overall quality of life is poorly reported, particularly for survivors of the disease. This study aims to identify the issues which are relevant to and impact upon the quality of life of survivors of locally recurrent rectal cancer.

WHAT WOULD TAKING PART INVOLVE?

Taking part in this study will involve a one-off interview via telephone or Microsoft Teams with a researcher based at the University of Leeds in the United Kingdom. The interview typically takes around 1 hour to complete and will involve discussing your experience of surviving locally recurrent rectal cancer, survivorship issues and how they affect your quality of life. The interview will be arranged for a time that is convenient for you.

You have been provided with this participation pack containing:

- this information leaflet,
- a consent form,
- a demographics form,
- a self-addressed stamped envelope for you to return the completed questionnaires, demographics and consent form.

If you are interested in participating, please complete the enclosed demographics and consent form and return them to the University of Leeds Clinical Trials Research Unit (CTRU) using the self-addressed stamped envelope provided. Participating in the study is voluntary and will not affect your treatment or follow-up care.

Following the interview, you will be asked if you would be happy to be sent the LRRC-QoL questionnaire, which measures quality of life, to complete and return to the research team.

WHAT WILL HAPPEN IF I WANT TO TAKE PART?

After you have returned your consent form to us (the research team), we will contact you via telephone to arrange a convenient time for the interview. The interview will be audio-recorded and transcribed (writing down what has been said during the interview). Your name will be removed from the research data and replaced with an anonymous identifier. If using Microsoft Teams for the interview, you will be asked to turn off your video before recording starts. **Video will not be recorded.**

After the interview, your medical team will be contacted to provide some information regarding your treatment and pattern of locally recurrent rectal cancer. Your full name will be used to enable us to identify you to your medical team who will then securely send us this information. This information will be entered onto the database using an anonymous identifier.

WHAT ARE THE BENEFITS OF TAKING PART?

This study will deliver wider benefits in that it will provide information regarding the issues that people face following surviving locally recurrent rectal cancer and how this affects their quality of life.

This information can then be used in discussions with patients during their treatment and follow-up regarding the late and long-term effects from their cancer and treatment which they make experience. This information may also be used to guide shared decision-making between patients and their medical team.

WHAT IF I NO LONGER WANT TO PARTICIPATE?

Participating in the study is voluntary, you can decide to stop participating (withdraw your consent) at any time, including during the interview. You may find that completing the questionnaire or taking part in an interview causes you to experience emotional distress in reflecting upon your experience of locally recurrent rectal cancer. The interview will be conducted in a sensitive manner, however should you experience any discomfort or distress, please inform us and the interview can be stopped or paused and you may withdraw from the study.

You do not need to explain why you would like to stop participating and withdrawing from the study will in no way affect the follow-up care you receive.

WILL MY TAKING PART BE CONFIDENTIAL?

Only your medical team and the research team will know about your participation in the study. Even though we will protect your confidentiality at all times we do have a duty of care toward you. This means that if a researcher believes that you might be a danger to yourself (e.g. you are thinking about harming yourself) or others we are obliged to alert appropriate services.

WHO IS ORGANISING AND FUNDING THE STUDY?

Funding for this study has been provided by Bowel and Cancer Research and by the Pelican Cancer Foundation.

We (the research team) are based at the Clinical Trials Research Unit at the University of Leeds. https://ctru.leeds.ac.uk/

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BOWEL RESEARCH UK.

HOW WILL MY DATA BE USED?

WHERE WILL MY DATA GO?

This research is in the public interest, which means our results will be used to improve the health 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. If you would like more information regarding this, please see: https://ctru.leeds.ac.uk/privacy/

Your name, telephone number and/or email address will be stored on an encrypted file server at the University of Leeds solely to enable us to contact you for the study or with updates regarding the study. This information will be destroyed following the final time the research team contact you. Audio-recordings made on Microsoft Teams will be temporarily and securely stored on Microsoft servers within the European Union, on part of their Office365 service accessible only by the research team. This recording will then be downloaded to secure CTRU servers to allow the audio-recording to be transcribed. Audio-recordings of the interviews will be permanently deleted once they have been transcribed.

We (the research team) will take all available steps to keep the recording of any interview carried out for this project private. However, we will not be able to protect from other members of your household from overhearing the interview if they are present or from any software running on your computer, tablet or smartphone.

The information provided by your clinical team regarding your treatment and pattern of locally recurrent rectal cancer will be stored on a database using an anonymous identifier. The transcripts and databases of clinical data and questionnaire responses will be held securely on an encrypted file server at the University of Leeds with strict limits on who can access it. All of the computers storing patient data must meet special security arrangements. The consent form, demographics form and questionnaire you complete will be stored securely in a locked cabinet at the CTRU. There are strict limits on who is given access to the CTRU.

WHAT ARE MY CHOICES ABOUT MY PATIENT DATA?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

WHAT WILL HAPPEN TO MY DATA AFTER THE STUDY?

Following the end of the study, this data will be securely archived for 15 years. Only non-identifiable data will be archived. The results of this study will be analysed and published in a PhD thesis and recognised medical journals. Reports about the study, which may include quotations from interviews, will be written so that no-one will be able to identify you from these reports. Following the end of the study, your medical team will be sent information regarding the study results to pass on to you.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad.

This information may include demographic data, clinical data, scores from the questionnaire you complete and data related to the themes and ideas identified during the interviews. Any information shared will not identify you and will not be combined with other information in a way that could identify you. Information will only ever be shared for the purpose of further health and care research concerning locally recurrent rectal cancer, quality of life and survivorship. This data cannot be used to contact you or to affect your care. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

GENERAL DATA PROTECTION REGULATION (GDPR)

In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules. An NHS research ethics committee checks how the privacy of people who take part will be protected before the research starts.

WHO CAN I CONTACT IF I HAVE A COMPLAINT ABOUT HOW MY DATA IS HANDLED?

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer (DPO) who will investigate the matter, they can be contacted via the following:

- Tel: 0113 243 1751
- Email: DPO@leeds.ac.uk
- Post: University of Leeds, Room 11.72, EC Stoner Building, Leeds, LS2 9JT

If you are not satisfied with their response or believe your data is being processed in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

CONTACT DETAILS

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