THE LOCALLY RECURRENT RECTAL CANCER – QUALITY OF LIFE (LRRC-QOL) STUDY

We are writing to you to invite you to take part in a research study called the Locally Recurrent Rectal Cancer – Quality of Life (LRRC-QoL) research study to develop an international questionnaire to measure quality of life specifically for patients with locally recurrent rectal cancer.

The study is part of an international collaborative study coordinated by a research team based at the University of Leeds in the United Kingdom.

Participation in the study is voluntary and will not affect the medical care you receive. Please read this patient information leaflet explaining the study and what participating in it would involve before deciding whether you would like to take part.

If you have any questions at all regarding the study please get in touch with your doctor or medical team. Alternatively, you can contact the research team who are based at the University of Leeds in the United Kingdom, via email: LRRCQoL@leeds.ac.uk.

LRRC QoL

PelvEx Collaborative

BOWEL RESEARCH UK.

UNIVERSITY OF LEEDS

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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.

There are many questionnaires which currently exist that are used to assess quality of life, however, these tools have not been validated for this specific group of patients. Validation means checking that the questionnaire is applicable across relevant patient groups.

The **LRRC-QoL** is a questionnaire that has been designed specifically to assess quality of life in patients with locally recurrent rectal cancer. The **LRRC-QoL** was developed in patients from the UK and Australia. This study aims to translate and validate the **LRRC-QoL** for use in New Zealand and other countries internationally.

WHAT WOULD TAKING PART INVOLVE?

You have been provided with this participation pack containing:

- This information leaflet,
- A consent form,
- A demographics form,
- A copy of the **LRRC-QoL** questionnaire to complete and return,
- Three other quality of life questionnaires to complete and return,
- A copy of the **LRRC-QoL** questionnaire **to keep** and complete during the interview with the researcher,
- A self-addressed stamped envelope.

If you choose to participate, it will involve completing the LRRC-QoL questionnaire during an interview via telephone or Microsoft Teams with a researcher from the United Kingdom.

The aim of the interview is to give us a better understanding of how you interpret the questions in the LRRC-QoL questionnaire. Completing and returning the additional questionnaires will allow us to better understand the impact of locally recurrent rectal cancer on your quality of life.

Completing the questionnaire and discussing this in the interview will involve reflecting upon your experience of locally recurrent rectal cancer. Should you find this at all distressing please inform us and the interview will be stopped.

WHAT ARE THE BENEFITS OF TAKING PART?

There are no personal benefits to taking part. However, this study will deliver wider benefits in that it will provide information regarding quality of life in patients being treated for locally recurrent rectal cancer in many centres internationally. It will also allow the **LRRC-QoL** to be used in future international research.

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.

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 do not need to explain why you would like to stop participating and withdrawing from the study will in no way affect your treatment for locally recurrent rectal cancer.

WHAT WILL HAPPEN IF I WOULE LIKE TO PARTICIPATE?

If you would like to participate in the study, please complete the consent form and questionnaires provided to you. Following this, 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.

The responses you provide to the questionnaires and information provided by your medical team concerning your treatment and pattern of locally recurrent rectal cancer, will be stored in a database using an anonymous identifier.

This database will be stored at the University of Leeds in the United Kingdom where the research team are based.

WHAT WILL HAPPEN TO MY DATA?

Your name and telephone number will be stored on an encrypted file server at the University of Leeds solely to enable us to contact you for the purposes of this study. This information will be destroyed following the interview.

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.

Audio-recordings of the interviews will be destroyed once they have been transcribed. The transcripts and the database will be held securely on an encrypted file server at the University of Leeds with strict limits on who can access it.

The database of questionnaire responses will also 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.

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

WHAT ARE MY CHOICES ABOUT MY 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. 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.

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.

This information may include demographic data, clinical data, scores from the questionnaires you complete and the themes and ideas identified during 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 and quality of life. 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/).

WHO IS ORGANISING AND FUNDING THIS 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/