IRAS number: 272685

INTERNATIONAL VALIDATION OF THE LOCALLY RECURRENT RECTAL CANCER – QUALITY OF LIFE QUESTIONNAIRE

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

- The aim of this study is to measure quality of life in patients with locally recurrent rectal cancer.
- 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.

You can participate in the study either online or via telephone or via post. If you would like to participate in the study online, the consent form can be found at:
https://lictr.leeds.ac.uk/redcap/surveys/?s=KM3A7DPXCE

If you would like to participate in the study via post or telephone, please let your medical team know and they will be able to provide you with a study information pack.

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← HOW TO CONTACT US

LRRC QoL

PelvEx Collaborative BOWEL RESEARCH UK. UNIVERSITY OF LEEDS PELICAN cancer foundation CURING BELOW THE BELT CANCERS IMPACT

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 validate the **LRRC-QoL** and to measure quality of life in the first year following diagnosis and treatment for locally recurrent rectal cancer.

WHAT WOULD TAKING PART INVOLVE?

Taking part in the study will involve completing quality of life questionnaires at the start of the study and then the **LRRC-QoL** questionnaire at 3, 6 and 12 months.

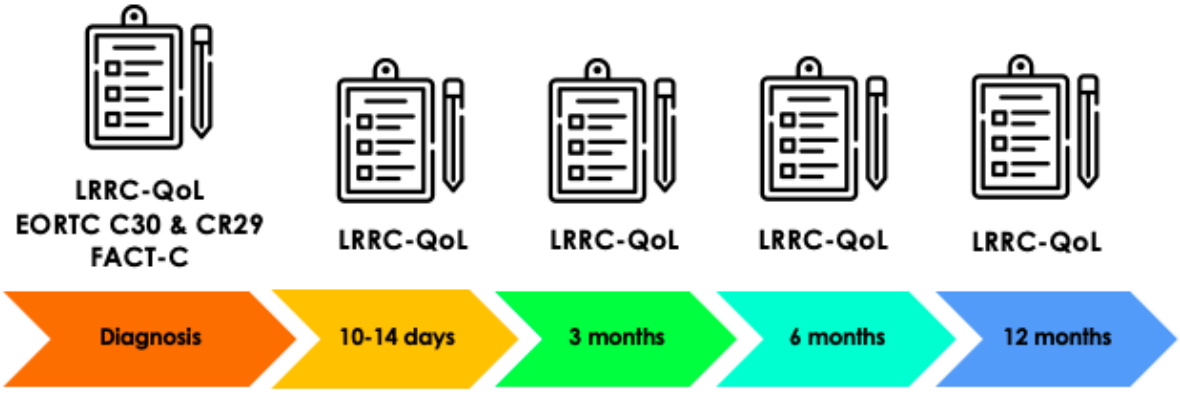
There are three different ways you can take part, online, via telephone or via post:

- If you would like to participate in the study **online**, the online consent form can be found at: https://lictr.leeds.ac.uk/redcap/surveys/?s=KM3A7DPXCE
- If you would like to participate via **telephone**, please let your medical team know and we will contact you to go through the consent form and questionnaires with a researcher over the phone.
- If you would like to participate via **post**, please let your medical team know and you will be provided with a participation pack containing:
    - a consent form,
    - a demographics form,
    - the **LRRC-QoL** questionnaire,

- three other quality of life questionnaires to complete,
- a self-addressed stamped envelope for you to return these documents to the research centre.

You also have the option to complete an additional questionnaire 10-14 days following the return of this questionnaire pack. Completing this additional questionnaire will enable us to establish whether the **LRRC-QoL** is a valid measure of quality of life.

Participating in this study is voluntary and will not affect your treatment for locally recurrent rectal cancer.



WHAT WILL HAPPEN IF I WANT TO PARTICIPATE?

Completing the consent form, demographics form and questionnaires typically takes 30-45 minutes. Completing the **LRRC-QoL** questionnaire at 10-14 days, 3, 6, and 12 months typically takes around 10 minutes. Returning the consent form and questionnaires either online or via telephone or via post will enter you into the study.

Following you entering the study, your medical team will be contacted to provide some information regarding your treatment and pattern of locally recurrent rectal cancer. This information will be transferred to the research team and entered onto a database using an anonymous identifier. The University of Leeds CTRU Secure File Transfer system will be used to contact your medical team and to transfer this information.

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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 ARE THE BENEFITS OF TAKING PART?

The study will deliver wider benefits as it will provide information regarding quality of life in patients who are being treated for locally recurrent rectal cancer in many centres internationally. This information can be used to inform shared decision-making between patients and their medical team regarding their care. The study will also allow the **LRRC-QoL** to be used in future international research. There are no personal benefits to taking part in the study.

WHAT ARE THE RISKS OF TAKING PART?

This study will not affect or alter your treatment. You may find that completing the questionnaires causes you to experience emotional distress in reflecting upon your experience of locally recurrent rectal cancer. If this should happen at any time please inform us and you can withdraw from the study if you would like to.

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. Withdrawing from the study will in no way affect your treatment for locally recurrent rectal cancer.

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/

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, email address and/or home address will be stored on an encrypted file server at the University of Leeds solely to enable us to contact you for the purposes of the study. This information will be destroyed following the final time the research team contact you. The online consent form and questionnaires will be collected and stored securely on an online database called REDCap. Any paper-based consent forms, and questionnaires will be stored securely in a locked cabinet at the CTRU. There are strict limits on who is given access to the CTRU.

Paper questionnaires will be entered onto a database 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.

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. The results of this study will be analysed and published in a PhD thesis and recognised medical journals. Reports about the study will be written in a way 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 and scores from the questionnaires you complete. 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/).

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