Patient Information Sheet

To examine whether a Complex Intervention protocol decreases Toxicity in patients following Radiotherapy or Surgery for colorectal cancer with electronic data collection; a feasibility of data collection

The CITRuS trial

Invitation to participate

You are being invited to take part in a research study. You have been diagnosed with bowel cancer and we would like to ask you to help us by participating in a study which involves your doctors at this hospital. This study is inviting patients with cancer of the bowel to answer a short series of questions using a computer, tablet or smartphone before treatment and at monthly intervals over a 2 year period after treatment. This will tell us more about how the cancer and your treatment have affected your daily life.

Before you make the decision as to whether you would like to take part or not, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with other people if you feel the need to. You are welcome now and at any stage of the research study to ask us (clinical care team here at the hospital and the research team) about anything that is not clear or if you require any information. It is important that you take your time to decide whether you would like to take part in this study.

What is the purpose of the study?

At the moment, all of the information on how patients feel before and after their cancer treatment is collected by their medical team. It is recognised that when patients personally report their own symptoms these often differ from those documented by their doctors. Over time, this could potentially lead to inaccuracies about how a doctor describes the effects of a cancer or its treatment to a patient when the patient is deciding what treatment to select. This study may help to discover how colorectal cancer affects patients individually and how the treatment they undergo affects their personal lives. This may help your doctors to describe the effects of treatment more accurately to future cancer patients. It may also help your doctors identify current patients who need extra help or support through their treatment journey. We are aiming to identify what symptoms may benefit from further therapy and to use the information that has been collected to develop interventions that we can test during a future part of this study. We want to find out whether answering these questions using a computer, tablet or smartphone is acceptable. We are also testing one set of questions in a process called “validation” to see if they will be useful in this format for future patients.

What would taking part involve?

If you are diagnosed with, or treated, for colorectal cancer your anonymised details are entered into the confidential colorectal database. This is a secure database from which anonymous data is taken out to determine the effectiveness of patient treatment**s** and outcomes.

If you opt to enter the CITRuS trial you will be able to securely view your personal data on this database if you choose. You will not be able to see anyone else's data and they will not be able to see yours. You will not be able to edit your data but you can contact the study team, via email or phone if you think anything needs adding or changing.

If you opt to enter the study, you will complete online consent using a computer, tablet or smartphone. You will be asked to answer several questionnaires at study entry and during follow up via an online platform. The initial questions may take up to 45 minutes to answer but you will have a week over which you can return to the questions to answer them. The follow-up questionnaires will be at monthly intervals for the first two years and will be related to your health and well-being. The questions that we ask you are predominantly taken from standardised international patient reported outcome measures (PROMS) questionnaires which have been used in trials with many patients. One set of questions will be taken from standardised questionnaire but arranged or asked in a different way to see if these are more helpful or quicker to fill in, this is the set of questions which this trials aims to put through the validation process. This may result in a little overlap in questions but we hope it may benefit future patients by enabling them to answer fewer questions. We expect that the questions will take approximately 45 minutes to answer the first time and then 15 minutes per month thereafter.

Once you have approved the consent form, you will then be asked to give your email address so that you can gain access to your clinical details on the database if you wish. Then when you are outside the hospital setting you can use your computer, tablet or smartphone to access a webpage and answer a series of questions at monthly intervals +/- 7 days over a 2 year period. You will be followed up by your clinical care team for up to 5 years, as is standard practice after cancer treatment. We may contact your hospital clinical team for updates regarding your health as it relates to your colorectal cancer. In the event of your death we may contact your GP asking for details on the cause of death and date of death if these are not available in the hospital. You will receive email reminders to prompt you to log on during the correct time frame. If you don't have an email address or internet access you can still join the study, a username will be allocated to you and when you attend the hospital for a follow-up, you can use the free WiFi at the hospital or your local library.

Why have I been invited?

As you are an adult patient with colorectal cancer and are being treated with radiotherapy or surgery with the intention of removing your cancer entirely at one of the hospitals involved in this study this makes you an eligible candidate to participate in the study.

Do I have to take part?

Taking part is entirely voluntary and it is up to you to decide whether or not you wish to participate in this study. If you decide to participate you will be given access to an electronic copy of this information sheet to keep and will be asked to approve an online consent form after reading this document. We can provide you with a paper copy of the consent form if required. It is important to note you can withdraw from the study at any time and do not need to give a reason for withdrawal. Please be reassured that deciding to withdraw will not affect the standard of care you receive.

What are the possible benefits of participating?

Whilst participating in this study may not benefit you personally, the information gathered will help in finding out the aspects of patients' quality of life which are affected by colorectal cancer. It is important to note that the doctors and team caring for you will not automatically have access to view the data you enter as part of the trial. If you have entered significant symptoms or any concerns have been raised by completing the questionnaires, please do discuss these with a member of your healthcare team.

Findings from this trial will allow the development of a second part of this trial which will lead to interventions which may improve the quality of life of future bowel cancer patients.

What are the potential disadvantages and risks of participating?

As the study does not involve medical treatments, exposure to radiation or medication there are no physical risks associated with participating. The study only consists of completing a series of questionnaires at regular intervals. It is recognised that whilst there are no physical risks associated with participating, answering some of the questionnaires will require you to reflect on your treatment and the decisions you made and may cause some worry. You will receive emails regularly regarding the study and you will need to set aside time each month to answer the questions online.

Who is organising the research?

This feasibility study is primarily being organised and coordinated by the doctors and research team at the Royal Surrey County Hospital. If you agree to participate in the study, following giving your consent, your GP will be informed of your participation. The study is being sponsored by the Royal Surrey NHS Foundation Trust. GUTS and Bright, are two cancer charities that provide funding to the Royal Surrey, which pays for admin support for the trial.

Who has reviewed the study?

This study has been ethically approved by an independent group of people called the Research Ethics Committee. This has been done to protect your interests.

What will happen if I decide to withdraw from the study?

If you consent to the study and then decide you would no longer like to participate, you have the absolute right to withdraw at any given time and without giving any reason. To withdraw, you simply need to click the 'withdraw' button on your patient questionnaire portal and follow the onscreen instructions. This will automatically cancel any future reminder notifications and permanently close your patient portal, subsequently withdrawing you entirely from the study. Alternatively, you can contact a member of the research team using the details below to ask to be withdrawn from the study.

Any data which identifies you will be destroyed should you decide to withdraw from the study; Any data collected to date, before your withdrawal, could still be used in the study. If for any reason you are withdrawn from the study as a result of losing mental capacity we will keep and use identifiable data collected up to the point at which you were withdrawn from the study.

What will happen to the results of the research study?

All of the information which is gathered from this study will be stored confidentially electronically. Any data which is reported will be anonymised, protecting any personal information. We will produce a final report summarising the main findings and from time to time we may be able to send updates on the progress of the trial. There is an option on the Consent form for you to complete if you would like to receive these updates. The results from this study may be presented at appropriate conferences and may be reported in scientific and medical journals.

Non-identifiable data will be shared with collaborators at the University of Surrey and Inta-Care, a data analytics company, as part of developing interventions for the second part of the study.

What if I want to complain about the way data is handled?

If you wish to raise a complaint on how we have handled your personal data, you can contact the RSCH Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Patient Advice and Liaison Service (PALS), in writing to PALS, Royal Surrey County Hospital, Egerton Road, Guildford, GU2 7XX or email rsc-tr.PALS@nhs.net. We welcome and value your feedback on our services as we recognise that this helps us to identify those aspects of our service where we can improve.

For full details on our complaints procedure please see link below.

Alternatively, you can contact our complaints team by emailing your complaint to rsc-tr.Complaints@nhs.net or writing to the Chief Executive, Royal Surrey County Hospital, Egerton Road, Guildford, Surrey, GU2 7XX. https://www.royalsurrey.nhs.uk/patients/compliments-complaints/

Contact for Further Information

If you have any further questions regarding anything to do with this study and your potential participation, please do not hesitate to contact a member of the research team who will be more then willing to answers any queries. Please contact any of the following:

Helen Minnaar – CITRuS Trial Project Manager

Royal Surrey County Hospital
Egerton Road
Guildford
Surrey
GU27XX
Email: rsch.citrustrial@nhs.net
Telephone: 01483 571122 Ext: 3435

Dr A. Stewart DM, MRCP, FRCR - Consultant Clinical Oncologist
Royal Surrey County Hospital
Egerton Road
Guildford
Surrey
GU27XX
Secretary Telephone: 01483 571122 Ext. 2556

Thank you for taking the time to read this information leaflet.

Appendix 1 - General Data Protection Regulation from the Health Research Authority

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your:

- First and last names
- NHS/ hospital identifiable number
- Contact details – email address
- Date of Birth

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to rsch.citrustrial@nhs.net or
- by ringing us on 01483 571122 ext 3435
- by contacting the Head of Information Governance, Royal Surrey County Hospital NHS Foundation Trust, Egerton Road, Guildford, GU2 7XX. Tel: 01483 571122. Email: rsc-tr.InformationGovernance@nhs.net