

The RAPPORT Study: Reduce Anxiety for Patients with Physicist appointments in Radiotherapy

Principal Investigator: Charlie Martin, Principal Physicist, University Hospitals Dorset NHS Foundation Trust

We invite you to take part in a research study:

- Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.
- Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, contact the research team using the email address below and at the end of this information sheet.

To take part in the study please email RAPPORT@uhd.nhs.uk.
You will also be asked at your CT appointment if you want to take part.

What is the purpose of the study?

- Many people having radiotherapy treatment can feel anxious.
- The study will try to find out if an extra appointment with a different member of staff (a medical physicist) can help in patients having radiotherapy treatment.
- This could help improve quality of life and comfort during treatment.
- Medical physicists normally work 'behind the scenes' and are involved in all parts of radiotherapy treatment. They make sure the equipment is set up, working properly, and safe. They also find ways to develop or improve the way radiotherapy treatment is given, and they plan the radiotherapy treatment you will receive. Their technical knowledge of the radiotherapy process means they are well placed to answer any questions people may have about the technical parts of their radiotherapy treatment before it starts.

Why have I been invited to take part?

- You are being invited to participate in this study because you have been identified as someone about to receive radiotherapy at the Robert White Centre in Dorchester where this study is taking place.

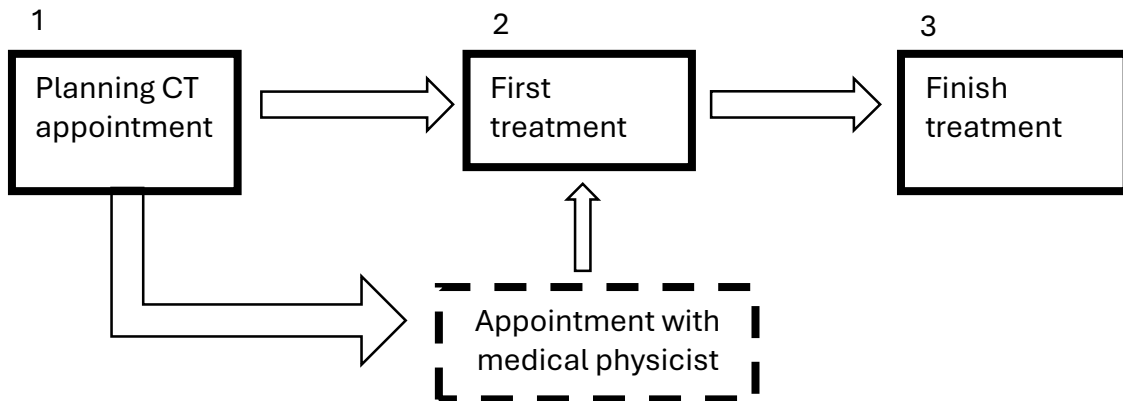
Do I have to take part?

- No, it is up to you to decide.
- Participation is completely voluntary.
- You should only take part if you want to and choosing not to will not disadvantage you in anyway. If you choose not to take part or leave partway during the study, your care will not be affected.
- Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part.
- If you would like to take part, please use the contact details at the end of this information sheet. Or you can tell staff when you attend for your radiotherapy planning CT appointment. We will ask you to sign a consent form. You will be given a copy of this information sheet and the consent form to keep.
- You are free to change your mind at any point. Please let us know by contacting the Research Centre on 0300 019 8500.

What will happen if I take part?

- If you choose to take part in the study, you will be randomly placed into 1 of the 2 study groups. You will either have your treatment as normal, or you will have an extra appointment with a medical physicist on the day of your first radiotherapy treatment.
- You will be told which group you are in before your first treatment appointment, so you know whether to expect the extra appointment or not.
- The purpose of the extra appointment is to give an overview of the treatment planning that has been done for you, and to answer any technical questions you have about your treatment. Some examples of these could be:
 - Is my treatment plan customised for me?
 - How does the treatment machine work?
 - Will radiotherapy make me radioactive?
 - How often does something go wrong during treatment?
 - Does anyone check the treatment machine?
- The medical physicist in the appointment **will not** be able to answer questions on your side effects, your specific diagnosis, or other medical questions. The appointments with your Consultant or treatment staff should be used for these questions.

- If you choose to participate, we will ask for your consent at the planning CT appointment, and to fill in a study registration form. You will be asked to fill in questionnaires at three different times: at your planning CT appointment, on the day of your first radiotherapy treatment, and on the day of your last treatment, shown by the numbers 1-3 in the picture below.



- The main questionnaires you will be asked to fill out are for you to rate how anxious you are feeling. There will also be questions about your experience of your radiotherapy treatment so far. You will be asked some questions about your personal circumstances, such as what your marital status is, and what level of education you have attained as part of the study registration form.
- As well as the information you give us, we will collect some information from your medical records such as what treatment we are giving you, and technical details from each of your treatment sessions.
- Completing the questionnaires will take around 10-15 minutes on each occasion, but it may take longer than this.

What are the possible risks of taking part?

- Whilst some people find it helpful to have more information about their treatment, some may find this makes them feel worse or worry more.
- If you feel this is you, then the radiotherapy review team are available to support you. You will be given information at the start of your treatment on support services and staff will refer you to the review team if asked, or if they feel you need it.
- Your radiotherapy (and any other associated care) will not be affected by this study.
- You can stop your participation in the study at any point, and you do not need to give a reason.

What are the possible benefits of taking part?

- If you are randomly put into the test 'arm', you will have an extra appointment with a member of staff (medical physicist). This is specifically to talk through any technical questions you have around your treatment, the equipment, or radiotherapy and radiation in general.

What if there is a problem?

- If you have any concerns about any aspect of this study, please ask to speak to the Principal Investigator (Mr Charlie Martin) who will do their best to answer your questions. Please use the study email address in the first instance to ensure your message is seen quickly.
- If you remain unhappy and wish to make a formal complaint, you can contact the concerns team for University Hospitals Dorset NHS Foundation Trust on 0300 019 8499 or alternatively email them at patientexperienceteam@uhd.nhs.uk.
- Alternatively, you contact the Research and Development Department at ResearchOffice@uhd.nhs.uk or 0300 019 8500.
- We value your feedback – if you have any suggestions as to how the study could be improved, please get in touch using the details above or the study email address at the end of this information sheet.

How will we use information about you?

- We will need to use information from you and from your medical records for this study. The information will include your name and contact details, as well as demographic information such as age, marital status, and level of education attained.
- University Hospitals Dorset NHS Foundation Trust is the Sponsor for this study and is responsible for looking after your information. We will keep all information about you safe and secure on Trust computers and/or locked filing cabinets.
- 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 (study ID) instead.
- 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.
- We will keep your study data for a maximum of ten years. The study data will then be destroyed.

What are your choices about 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.

- You have the right to ask us to remove, change or delete data we hold about for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Will my taking part in the study be kept confidential?

- Yes.
- All information which is collected about you during the course of the study will be kept strictly confidential.
- Your data will be given a unique study number, and any information that could be used to identify you will not be shared with the Sponsor or any of the collaborators.
- The only personally identifiable information collected will be from the registration form. All other research data collected about you will be identified by your study number. Your identifiable data will only be accessible to members of the research team at UHD who have been granted permission to do so because they need this to contact you, via password protected accounts.

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
 - <https://www.uhd.nhs.uk/services/research-and-development/public>
 - By asking one of the research team at your hospital
 - By sending an email to information.governance@uhd.nhs.uk
 - By ringing the research team on 0300 019 8500
 - By sending an email to RAPPORT@uhd.nhs.uk
- University Hospitals Dorset NHS Foundation Trust will keep identifiable information about you from this study for no longer than required and a maximum of 10 years after the study has finished.

What will happen if I don't carry on with the study?

- You are free to withdraw from the study at any time.
- This will have no impact on the on-going care that you receive.
- You are not required to give us a reason for withdrawal; however we would be grateful for any feedback, as this may help us to improve the study in the future.
- If you choose to withdraw, we will use the information collected up to that point. As described in 'How will we use information about you?' your study ID

will be used in the database, and therefore it will not be possible to identify you in the study dataset.

What will happen to the results of the research study?

- The results will be written up as part of a thesis, published in academic journals and presented at conferences. No personal identifiable data will be shared with any external organisation, or in any publication.
- You will be asked on the study consent form if you would like to receive a summary of the results after the study has closed.

Who is organising and funding the study?

- The research is being conducted as part of a doctoral research project in conjunction with the University of Manchester and University Hospitals Dorset NHS Foundation Trust. As 'Sponsor' University Hospitals Dorset NHS Foundation Trust takes overall responsibility for managing the study.
- Funding has been provided by NHS England through the Higher Specialist Scientist Training (HSST) program, run by the National School of Healthcare Science (NSHCS).

Further information and contact details

- If you have any questions, you can contact the trial team on the email below.

To join this study or find out more please email:

RAPPORT@uhd.nhs.uk

Thank you for taking the time to read this information.
