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Patient Information Sheet (Questionnaire)

The AUTONOMY study

Invitation to take part

You are being invited to take part in a new research study. Before you decide, it is important for you to understand why the study is being done and what it will involve for you. Please take some time to read through the following information carefully and discuss it with others if you wish. Take some time to consider if you would like to take part, and ask the researcher if anything is unclear, or you would like more information.

The purpose of this research study

In the UK, older adults make up the biggest proportion of cancer patients. Cancer treatments are increasingly complex, and there may be more than one type of treatment option available. Some of these treatments can have an impact on an individual's ability to live their lives, while others may be less good at curing the cancer, but better at helping people to live a normal, happy life. It is important to balance the benefits of treatments with the impact this may have on how a person lives their life. Knowing what patients prefer helps doctors to offer the best treatments to their patients. This study will create a new decision tool which can help patients and doctors to jointly make the right treatment choices. The tool will also help doctors to understand what a patient prefers in terms of their choice to have a longer life, or a better quality of life.

Why you have been invited to participate

We are inviting people (aged over 70 years old) who have had a recent or previous diagnosis of potentially curable invasive cancer and been offered a choice of standard therapy (usually surgery) versus fitness adapted therapy (systematic hormone therapy, radiotherapy, stent,

"watch and wait") to complete a questionnaire. Your participation in this study is entirely voluntary.

Do I have to take part?

It is entirely your decision whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part but then later change your mind, you are still free to withdraw at any time and without giving a reason. Your care will not be affected in any way.

What will happen to me if I take part?

If you are interested in taking part, you can have a short conversation with a member of the research team, and they will go through the details of the study and answer any questions that you may have. You can then take some time to think about the study and whether you wish to take part. If you do agree to take part, you can complete the consent form and questionnaire before returning these to us in the enclosed Freepost envelope. The questionnaire will take approximately 20-30 minutes to complete.

What will be discussed in the questionnaire?

The questionnaire aims to explore patients' experiences and perspectives on cancer treatment decision-making. Specifically, this will cover how people weigh-up their treatment options, including considerations of quality of life versus length of life. When completing the questionnaire, you may share your thoughts on factors influencing your treatment choices and what matters most to you in terms of balancing potential treatment benefits and side effects.

We recognise that some of these topics are deeply personal, and you are encouraged to share as much or as little as you feel comfortable. If you experience distress at any point, you are free to skip questions. Support resources are available, and the researcher can guide you to additional support if needed. Your well-being is our priority.

What are the possible disadvantages and risks of taking part?

There are no specific risks associated with taking part in this study, but you may be inconvenienced in terms of the time taken to complete the questionnaire. You are free to decline to answer any questions you feel uncomfortable with.

What are the possible benefits of taking part?

The information you give will not have any direct benefit on the care you currently receive, but it could help to improve clinical practice and cancer treatment decision-making for older patients in the future.

What is patient data?

When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. The information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number), it is called patient identifiable information. It is important to all of us that this identifiable patient information is kept confidential to the patient and only the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

What sort of patient data does this research study use?

There are lots of different types of health research studies. If you agree to take part in this project, a member of the study team may look at your medical history and ask you some questions to check if you are able to participate. As part of this study, you are being asked to complete a questionnaire. A member of the study team will analyse data taken from each completed questionnaire, and combine this with the information from everyone else in the project.

How does this research study use information about you?

We will only use information that we need for the research study. This information will include your name and contact details. The study team are members of the clinical team who already have access to participant information. 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. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

Will my taking part in this research study be kept confidential?

Yes. All information that is collected as part of the study will be kept strictly confidential. However, if you disclose involvement in criminal activity, including harm to yourself or others, the research team may be required to report this to the appropriate authorities. If you have any concerns about confidentiality, please discuss this with the research team before participating.

If you agree to take part, a copy of your signed consent form will be stored securely in a locked room at [name of hospital/GP surgery and department].

Your name will not be passed to anyone outside the project team who is not involved in the research study. Any information collected will have your name removed so that you cannot

be recognised by it. You will be allocated a number which will be used to identify you. Only the members of the study team will be able to identify you from this number.

Any research data that we analyse for the study will be securely stored at the Medical School (The University of Sheffield).

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow GDPR rules and data protection legislation. All research using patient data must follow UK law and rules. All research studies must also take account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

Who has reviewed the research study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC) to safeguard your welfare, dignity, rights and wellbeing. The London – Harrow REC has reviewed this research study.

What happens to my data after the study has ended?

At the end of the study, we will save some of the data in case we need to check it. The final report must be written up in a way that means no-one can work out who took part. At the end of the study, if you wish, we can send a copy of the results to you. We will make sure that no-one can work out who you are from the reports we write.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely stored for a minimum of 5 years. Arrangements for confidential destruction will then be made.

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. 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 information about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/patientdataandresearch
- by contacting any members of the research team
- by sending an email to: j.morgan@sheffield.ac.uk or autonomystudy@sheffield.ac.uk

Who is organising and sponsoring the research study?

The study is sponsored by Doncaster and Bassetlaw Hospitals NHS Foundation Trust in collaboration with the University of Sheffield. The sponsor is responsible for looking after your information. We will keep all information about you safe and secure by:

- Storing any data electronically on a password protected cloud storage system
- Storing any physical paperwork (such as original consent forms and completed questionnaires) in a locked cabinet in a locked office

What will happen if I don't want to continue with the research study?

You are free to withdraw at any time and do not need to give a reason. If you decide to withdraw, you have two options:

- If you withdraw your full consent, we will use your data up to the date on which you withdrew consent. We would not collect any information about you after this date.
- Complete withdrawal from the study with any information you have given destroyed if you wish.

What if I am unhappy with any aspect of the research study?

If you have any concerns or complaints about any aspect of this project, please contact a member of the study team:

Dr Jenna Morgan, NIHR Advanced Fellow in Surgical Oncology, Division of Clinical Medicine, Faculty of Health, University of Sheffield Medical School, Beech Hill Road, Sheffield S10 2RX. E-mail: j.morgan@sheffield.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the Sponsors of this study:

Emma Stoner, Research Development Lead, Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust. E-mail: e.stoner1@nhs.net Tel: 01302 644429

If you would prefer to speak to someone outside of the department, you can contact the Patient Experience Team on 01302 642764 or PALS (Patient Advice and Liaison Service) at dbth.pals.dbh@nhs.net or by written communication to: Patient Advice and Liaison Service, Doncaster Royal Infirmary, Armthorpe Road, Doncaster, DN2 5LT.

Please retain this information leaflet for future reference and thank you for taking the time to consider this study.