Healthcare Professional (HCP) Information Sheet

FINESSE – Optional Interview

Short Title: FINESSE – A research study to improve treatment for men with early prostate cancer

Scientific Title: The FINESSE Study: A randomised phase 3 trial evaluating the role of finasteride in increasing compliance with active surveillance, in men with a new diagnosis of low and intermediate risk prostate cancer, when compared with usual care.

Thank you for expressing your interest in taking part in a telephone interview for the FINESSE Trial. Please take time to read the information carefully.

Consent will be taken verbally before your interview begins by the researcher. You should only consent after reading this information sheet carefully, asking any questions you might have, and having received satisfactory answers.

What is this interview study about?

The purpose of interviewing healthcare professionals who have been involved in the FINESSE trial is to understand your views about the drug finasteride and to hear your thoughts on the use of active surveillance instead of surgery, as a way of monitoring patients diagnosed with low/intermediate risk localised prostate cancer. Weare keen to hear about your involvement in the trial so far, i.e. how you have supported trial patients and any problems or issues you have experienced. Finally, should finasteride be more widely available in the future, we are interested in any advice or recommendations you may have to ensure the NHS can provide the care and support needed to patients who have low/intermediate risk localised prostate cancer.

Who can take part?

You have been invited to take part as a healthcare professional who has supported patients taking part in the FINESSE trial.

What would taking part involve?

You are being invited to take part in a one-to-one interview. The interview will be with a researcher from Leeds University called Elizabeth (Liz) Travis, and it will be arranged at a time of your choice. During this interview Liz will ask you about your views of the FINESSE trial and the support you have provided to trial

participants. The interview will last 30 to 60 minutes, depending on how much you want to say. The interviews will be via telephone. You can take a break if you'd like, you can skip any interview questions you'd prefer not to answer, and can stop the interview at any time, without giving a reason why. The interview will be audio recorded, to help the researcher remember what you have said but they will check you are happy for them to do this first.

Do I have to take part?

Taking part is up to you. If you change your mind, you can stop the interview at any time. You do not have to give a reason. You can also ask us to take your interview data out of this study up to two weeks after the interview.

What are the advantages and disadvantages of taking part?

You could help to improve the support and treatment patients who have low/intermediate risk localised prostate cancer receive in the future.

How will my information be used?

We will need to use information already recorded in your FINESSE research records for this study.

This information will include your name and contact details (e.g., email and phone number). We will only use this information to arrange an interview with you, do the research and to check your records to make sure that the research is being done properly.

We will only collect and use information that we need for this study. Anything you tell us is confidential, unless you tell us something that suggests you, or someone else, are at risk of harm. We might use quotes from your interview in reports or presentations on the research findings, but we will never use your name or any details that could identify you.

With your permission, the interview will take place via telephone. The interview will be audio recorded via the videoconferencing software used to conduct the interview (e.g. Microsoft Teams) or using an external encrypted digital recorder.

We will keep all information about you safe and secure by:

- Using encrypted recording devices when not using videoconferencing software
- Temporarily storing an audio recording of your interview within the cloud of the corresponding videoconferencing software, before securely storing at the University of Leeds.
- Restricting access to the study team.
- Deleting recordings in the cloud after storage at the University of Leeds.

Who can see my data?

We will keep all information about you safe and secure. The interview will be typed into a written format called a transcript and it will be anonymised – this means your name and any details that could identify you will be taken out. This will be done either using inbuilt software, or it will be transcribed by an external company who has a data sharing agreement with the University of Leeds. The transcript will be stored securely at the University of Leeds. We will write our reports in a way that no one can work out that you took part in this study. No personal information about you will be shared, so nobody will be able to identify you from the information we share.

How long will you keep my data?

The audio recording will be destroyed once we have transcribed the interview. We will store your name and contact details for up to 12-months after this study has ended, to send you a summary of what we find. We will then delete this information.

How will we use your information after the study ends?

Once we have finished the study, we will store the anonymous interview transcript for at least 5 years after the study ends. Other researchers may need to check the results and our analysis. The study data will then be fully anonymised and securely archived or destroyed.

What are my choices about how my information is used?

You can stop being part of the study at any time, before the interviews have started, without giving a reason. If you have already been interviewed, you can ask us to take your interview data out of this study up to two weeks after the interview.

Where can I find out more about how my information is used?

If you would like more information, please also refer to the main FINESSE Study Patient Information Sheet you were given on joining the trial, and/or visit the links below.

The University of Leeds' Research data management policy

QMUL Information Governance and Data Protection. -governance/data-protection

Who has approved the study?

The study has been approved by the HRA Research Ethics Committee (REC), who are an independent group of people, that check all interview materials before the research starts to protect your interests.

Who is funding the FINESSE study, and who else is involved?

The research is funded by Yorkshire Cancer Research, and the National Institute for Health and care Research (NIHR) provides support services within the NHS hospitals involved. The medicines for this trial are being sponsored by the NHS Commissioners.

The Chief Investigator of the study is Professor James Catto (University of Sheffield), and his co-investigator is Professor Peter Sasieni (Queen Mary University of London).

Sheffield Teaching Hospital NHS Foundation Trust (STHNFT) is organising this research, is the sponsor for the study and employs the Trial Radiologist.

Leeds Teaching Hospital NHS Foundation Trust employs the Trial Pathologist.

The University of Leeds employs a Trial Behavioural Scientist – Professor Samuel Smith.

The study is being co-ordinated and managed by the Cancer Prevention Trials Unit at Queen Mary University of London.

None of the staff involved in the study will receive payment specific to their involvement in this research.

Will the use of my data meet UK GDPR rules?

UK GDPR stands for the United Kingdom General Data Protection Regulation. In the UK we follow the UK GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better. Universities and the NHS are funded from taxes, and they are expected to do research as part of their role. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If you would like more information about how your data will be processed in accordance with UK GDPR, please visit the links below:

The University of Leeds' Research data management policy

Queen Mary of London Governance

Where can I get further information and support?

Please contact Dr Elizabeth (Liz) Travis on e.a.travis@leeds.ac.uk who is the researcher conducting the interviews. She will be very happy to answer any questions you may have.

For more information generally about the trial, you can also visit the FINESSE study website at: www.finessetrial.org

What happens next?

Please think carefully about whether you wish to take part in this interview study. If you do wish to take part, please get in touch and we can arrange a suitable date and time for you to complete the interview.

Thank you for considering participating.