Participant Information Sheet

Qualitative study to find out what urologists think about the acceptability and feasibility of the OPEN trial

Invitation

You are invited to take part in a qualitative research study linked to the OPEN trial. Before you decide we would like you to understand why this research is being done and what it would involve for you. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

Part 1 tells you the purpose of this interview study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of this study?

OPEN is a pragmatic, multicenter, surgical randomised controlled trial where 500 men with recurrent bulbar urethral stricture will be assigned to endoscopic urethrotomy or open urethroplasty. Detailed qualitative research with clinicians and patients is a vital component of the requisite feasibility exercise undertaken prior to the commencement of a high quality RCT. The purpose is of this qualitative study is to explore and address feasibility and acceptability issues raised by the OPEN trial from the surgeon's perspective.

We would like you to help us answer the following questions:

- How do surgeons conceptualise the role of RCTs in the assessment of surgical interventions?
- How do surgeons understand and respond to their involvement in an RCT like OPEN?
- What incentives and barriers are there to surgeons' participation?
- What are the specific feasibility and acceptability issues raised by the OPEN trial from the surgeon's perspective?

Why have I been invited?

You have been invited to take part in this study because you have been asked to participate in the OPEN trial led by your colleague Professor Robert Pickard at Newcastle University. We are aiming to interview approximately 12 urologists.

Do I have to take part in an interview?
No. It is up to you to decide. We will describe the interview process and answer any questions you may have. If you take part you are free to withdraw at any time without giving a reason.

What will happen to me if I take part?
A researcher from Newcastle University's Institute of Health and Society will contact you to check that you are willing to participate in this qualitative study. If you are, they will arrange for you to have a single semi-structured interview at a time and place convenient to you. You can be interviewed face-to-face or over the phone and the interview will last between 30 minutes and one hour.

What will I have to do?
Before the interview starts you will be asked to sign a consent form, a copy of which you will be given to keep for your records. Interviews will be audio-recorded and names and settings will be kept confidential. You can ask the interviewer to pause the recording at any time during the interview and you are also free to stop the interview should you wish to do so. At the end of the interview the interviewer will check that you are happy for the conversation to be included in the study. The audio-recording will be transcribed and anonymised ahead of being analysed, and upon request we can send you a copy of the anonymised transcript for your information.

Expenses and payments
There is no payment for participating in this study.

What are the benefits of taking part?
The results of this qualitative research strand will feed into the larger OPEN trial, helping to streamline the recruitment process.

What are the disadvantages of taking part?
The interview will take between thirty minutes and one hour of your time.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

This completes Part 1 of the information sheet. If the information in Part 1 has interested you and you are thinking about taking part, please read the additional information in **Part 2** before making a decision.

Part 2

What will happen if I don't want to carry on with the interview study?
If you change your mind about having an interview you can withdraw from the study at any time, including during the interview, and without giving a reason.

What if there is a problem?
If you have a concern about any aspect of this study, you should speak to the lead researcher Dr Tim Rapley first who will do his best to answer your questions (email tim.rapley@ncl.ac.uk, phone 0191 222 5665).

Will my taking part in the study be kept confidential?
Yes. We will abide by the Medical Research Council's guidelines on Good Research Practice and follow Newcastle University's Research Governance guidelines.

Records obtained while you are in this study will remain strictly confidential. Transcripts will be anonymised so that you cannot be recognised from any of the information we collect from you. Audio-recordings and anonymised transcripts will be securely stored at Newcastle University for the duration of the study. At the end of the study the recordings will be destroyed. The anonymised transcripts will be held for a maximum of 15 years in line with MRC guidelines, and then they will also be destroyed. Only the researchers and those employed on the study will have access to the recordings.

What will happen to the results of the research study?
The study results will be published on the National Institute for Health Research Health Technology Assessment Programme website and in scientific journals. They will also be presented at research meetings. You will not be identified in any report or publication but we may wish to use your anonymised quotations.

Who is organising and funding the research?
The OPEN qualitative study strand is led by Dr Tim Rapley, who is a medical sociologist at Newcastle University's Institute of Health & Society. It is sponsored by the Newcastle Upon Tyne Hospitals NHS Foundation Trust and funded by the National Institute for Health Research Health Technology Assessment programme.

Who has approved the study?
This study has been reviewed and given favourable opinion by the Newcastle and North Tyneside 1 Research Ethics Committee.

What do I do now?
You will be contacted by a member of the research team. Please let them know whether you would like to take part.

Further information and contact details
If you have any further questions concerning this study please contact:

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Fax: 0191 222 6043
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Thank you for thinking about taking part in our research.

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Consent Form for Surgeon Interview

OPEN: Clarifying the management of men with recurrent urethral stricture: a pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy.

Qualitative study to find out what urologists think about the acceptability and feasibility of the OPEN trial

Identification Number ☐☐-☐☐☐

Name of Chief Investigator Professor Robert Pickard

Name of Lead Researcher, Interview Study Dr Tim Rapley

Name of Local Principal Investigator ……..

By initialing each box and signing this form:

1. I confirm that I have read and understand the information sheet dated 15 February 2013 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I agree to the audio recording of my interview. ☐
4. I understand that I will not be personally named in any report and that anything I say will be treated in confidence ☐
5. I agree to take part in the above study. ☐

Name of Surgeon	Date	Signature

Name of Person taking consent	Date	Signature

When completed: 1 copy for interviewee; 1 original for researcher.