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Patient Information Sheet – CaDeT Interview

Trial Title: Multicentre Trial of the clinical and cost-effectiveness of a novel urinary catheter design in reducing catheter-associated urinary tract infection compared with the traditional Foley design for adults requiring long-term catheterization.

We'd like to invite you to take part in an interview to hear about your feelings about trying a new cather design and thoughts on the trial. Please read the information below carefully and ask questions if anything is not clear or if you would like more information before you decide to take part in the trial.

If you would like more information, please contact:

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Why are we doing the CaDeT trial?

A modified catheter, called an Optitip catheter, has design features which are intended to reduce infection and other problems (see diagram below). The Opititp catheter is already used by some patients, however, we do not know for certain if it is more effective than a traditional catheter, called a 'Foley' catheter. The CaDeT trial is a randomised trial looking at whether the Optitip catheter reduces the number of Urinary Tract Infections (UTIs) and other catheter-related symptoms compared to the Foley catheter. This trial will include around 310 patients.

Why have I been invited to take part in an interview?

You have been invited to the trial/ use of the Optitip catheter and we want to understand your thoughts and feelings about the trial to improve catheter use and the design of future research. We would like to hear from people who took part and declined in the trial.

What will happen if I take part?

The qualitative researcher will contact you to arrange a convenient time to talk. You can choose to consent to the interview verbally (which will be recorded) or in writing. The discussion with be a private one-to-one with an independent researcher.

You are free to change your mind at any time if you decide you don't want to be interviewed. Withdrawal from the interview trial won't affect your participation in the main trial.

The interview will last approximately 30 min via telephone or video call (your preference). All interviews will be audio-recorded. We record the interviews so that they can be written into words and looked at with other interviews to identify similarities, differences and patterns.

What are the possible benefits and risks of taking part in this interview?

Possible benefits:

- You will be compensated for your time with a £15 voucher.
- You will be helping to further our knowledge by sharing your thoughts on the Optitip catheter and this may benefit other catheter users in the future.
- Your experiences may help us improve the way we design and deliver future research

Possible risks/disadvantages:

- There are no anticipated risks or disadvantages to taking part in the interview

Other questions you may have about the trial

What happens if I can't make the time or change my mind?

If you're unable to make a scheduled interview please contact the trial team.

You can change your mind and stop participation before or during the interview without giving a reason and without consequence. If you decide to stop taking part during the interview, all information received to that point will be used in data analysis unless requested otherwise. If you withdraw after the interview, where data analysis has already begun, it may not be possible to withdraw your data because it would have been anonymised (i.e. identifying information removed) and merged with other participant interview data.

What will happen at the end of the trial?

At the end of the trial, the results will be analysed, but this can take a further 6 months. The results will then be published in a medical journal. No directly identifiable personal data will be used in any reports or publications that come from the CaDeT trial. We will send you a summary of the trial results unless you have told us that you would prefer not to receive this. The summary will also be available to members of the public on the Southampton Clinical Trials website: www.southampton.ac.uk/ctu/index.page

Who is organising and funding the trial?

This trial is being coordinated by the Southampton Clinical Trials Unit. The trial is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme. https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/health-technology-assessment/

The Sponsor is the University Hopsital Southampton NHS Foundation Trust.

What happens if something goes wrong?

If you decide to take part in the CaDeT interview and feel concerned at any point, you should contact trial team as soon as possible. The trial team will do their best to help you and answer your questions. If you wish to complain, or have any concerns about the way you have been approached or treated during the CaDeT interview, please contact the R&D department at University Hospital Southampton NHS foundation Trust by email to sponsor@uhs.nhs.uk. If you remain unhappy and wish to complain formally, you can do this through the normal NHS complaints procedure. Details can be obtained through the following NHS web site:
http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx

Please be aware that if you are harmed as a result of taking part in the CaDeT interview, there are no special compensation arrangements. The University Hopsital Southampton NHS Foundation Trust provides clinical trials indemnity insurance for negligence in its management or design of the trial. NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. If you are harmed because of someone's negligence, you may be able to take legal action but you may have to pay your own legal costs.

Confidentiality and data protection

What happens to the interview recording?

The interviewer will call and audio-record you using Microsoft Teams, which is a University of Southampton approved software. Microsoft Teams is compliant with a range of regulatory security standards.

Recordings from Microsoft Teams are encrypted when stored (in SharePoint) and also in transit (moving from SharePoint to a folder) to protect it from unauthorised viewing.

The interview recording will be labelled with a code number not related to any of your personal information and securely sent through an online portal to McGowan Transcriptions who will type out everything said in the interview. The company used to do this has an agreement to keep everything you say in the interview secret. We will remove any names, places etc which would identify you or any other individuals.

The digital recording and the typed up record (transcript), identified only by the code number, will be kept in a secure folder within Univserity of Soutampton as per Research data management policy (https://www.southampton.ac.uk/~assets/doc/calendar/Research%20Data%20Management%20Policy.pdf).

Once transcripts have been error checked, the original interview recording will be deleted.

We will analyse the text of the interview to identify the most important points. These will be compared with other interviews. A scientific article will be written based on this information and will be sent to a scientific journal for publication. The results may also be presented in reports and conference presentations. Some selected quotes from your interview may be used in these publications, but your

name and any identifiable information will never be mentioned. The transcripts will be kept for up to 10 years on a securely encrypted, password-protected university computer in case we need to check them.

Will my details be kept confidential?

Yes. Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the Southampton Clinical Trials Unit and Glasgow Caledonian University Hub may be given access to data about you for monitoring purposes and/or to carry out an audit of the trial to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the trial correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

If you opt to take part in the qualitative interviews, your contact details will be shared securely with the CaDeT trial team at Southampton Clinical Trials Unit and stored securely. The qualitative researcher at Southampton Clinical Trial Unit will access your contact details to share information about the qualitative interview with you and to organise the interview. Non-identifiable data, managed by the Southampton Clinical Trials Unit, will be held on servers located within and outside of the UK. Access will be strictly controlled and all current Data Protection Regulations will be abided by. This data is described as 'pseudonymised' because your initials will be stored on the server.

You can find out more about how we use your information by contacting the Southampton Clinical Trials Unit: https://www.southampton.ac.uk/ctu/contact.page; telephone: 02381 205154; email: ctu@soton.ac.uk

Thank you for taking time to read this information sheet.