UNIVERSITY OF Southampton

Participant Information Sheet

Study Title: MultICath

A non-inferiority randomised controlled trial to compare mixed (multi/single-use) catheter management with single-use catheter management by intermittent catheter users over 12 months

Researcher:
ERGO number: 46424

You are being invited to take part in the above research study called **MultICath**. You have been invited to take part because you use intermittent catheterisation. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. You may like to discuss it with others but it is up to you to decide whether or not to take part. You do not need to decide straight away. Your decision will not affect the care you receive from your doctors and nurses.

Please read the information below carefully including the section 'What about Covid-19?' and ask questions if anything is not clear or you would like more information. There are contact details for the research team at the end of this sheet.

Summary
Most people in the UK who do Intermittent Catheterisation (IC) use catheters which are thrown away after each use (single-use). Although this is safe, easy and convenient we know from catheter users that if catheters that can be cleaned and re-used (multi-use) were available this would give more choice. We call using multi-use catheters some of the time and single-use catheters at other times 'mixed-use'.

When intermittent catheterisation was introduced to the UK in the early 70's, catheters were usually cleaned and re-used, often for several days or longer. Multi-use of catheters is still commonplace in many countries around the world including Australia and Canada.

The purpose of the MultICath trial is to test the safety and acceptability of mixed-use with a cleaning method that we have developed with catheter users especially for this trial.

What is the research about?
We know from IC users and health care experts that there are advantages and disadvantages to both multi-use and single-use catheters:

Single-use catheters often have built-in lubrication and are convenient as they are simply thrown away after use. However, users need to be sure to always have a supply and may need to carry many catheters with them when away from home. In addition, they are relatively expensive and they create waste.

Multi-use catheters are used more than once so there is less need to carry as many catheters, and users are less likely to be 'caught short' without a means of catheterisation. At a time when plastic waste is a major environmental issue, multi-use catheters create less waste and they may be more cost effective. However, users must clean their catheters regularly.

It is possible that using multi-use catheters some of the time and single-use catheters at other times (mixed-use) would offer the flexibility and advantages of both types. But, before mixed-use can be recommended in the UK, we need to compare mixed-use with only single use to find out if it is safe and acceptable to users.

Urinary tract infection (UTI)
It is a commonly held thought that use of sterile catheters prevents bacteria entering the bladder and causing urinary tract infection (UTI) and keeps bacteria out of the urinary tract. In fact, IC users often have several different types of bacteria in their bladder and develop UTIs even when they only use sterile catheters. Current research does not show that re-using a catheter causes more UTI than only using sterile ones.

As well as finding out about mixed-use and urinary tract infections (UTI), we also want to find out what users think about mixed-use of catheters and if they find it acceptable to clean and re-use their catheters.

To do a sufficiently thorough comparison, we need about 520 people who do intermittent catheterisation to agree to take part in the MultICath trial. Half of the group (approx. 260 people) will be asked to continue to use single-use catheters only and the other half will be asked to use both multi-use and single-use catheters.

Why have I been asked to participate?

You have been invited because you use intermittent catheterisation and expect to do so for at least the next 12 months.

Do I have to take part?

No. You do not have to take part unless you want to and your decision will not affect the care you receive. It is your decision and you do not need to decide straight away. A member of our research team will contact you and go through this information sheet with you. You will be given time to think about your decision. You will then have a chance to have further questions answered. There are contact details for the research team at the end of this sheet. You are welcome to contact us at any time with a question.

What will happen to me if I take part?

If you agree to take part we will ask you to sign a consent form.

You will then be asked to do IC using either:

a) Single-use catheterisation only using your usual catheters - we call this the 'control' group OR
b) Mixed-use catheterisation using a combination of single-use catheters (of your own) and multi-use catheters (which we give you) – we call this the 'intervention' group

You cannot choose which option you have. If you take part you will be assigned one of these options by chance using a computer program. This is called randomisation.

What will I have to do?

You will need to commit to do intermittent catheterisation according to the regime selected for you for 12 months and 2 weeks. If mixed-use is chosen for you, you need to be willing to use a multi-use catheter for some of your daily or weekly catheterisations. You will be encouraged to use multi-use catheters as often as you can and want, but at your convenience.

Regardless of which group you are in (control or intervention) you will have a researcher in regular contact to support you. If you are selected to continue with your usual catheters (control group) this contact will be by phone or video conference) as you prefer.

If you are selected to do 'mixed use' in the intervention group, most or all of this contact will also be by phone or video conference as you prefer. However, there may be the option for one visit from a researcher at your home to teach you how to use the multi-use catheters. This will depend on local Covd-19 restrictions, based on where you live.

You will be given all the items needed including a booklet and access to a video tutorial with comprehensive information about how to use the multi-use catheters.

Urine Samples

During the trial, we will ask you to provide urine sample at the start of your time on the trial, at 6-months and at the end of your participation in the trial (at 12 months). If you suspect a UTI during the trial, we will also ask you to provide an additional urine sample at this time for our central laboratory to analyse. We will provide you with the urine specimen pots and appropriate pre-paid packaging to post them back to our laboratory. The urine specimen pots will be pre-labelled with a unique trial identifier and no identifiable details (e.g. name, date of birth) will be given to our laboratory testing the urine sample. After testing, your urine sample will be discarded via clinical waste disposal routes following the central laboratory disposal policy.

As part of the study, you will be asked to do the following:

At the start of the trial

- Tell us about your ethnicity (this is optional), medical history, usual intermittent catheterisation practice (including catheter size and type) and quality of life.
- If you are randomised to do mixed use, with the help of the researcher learn how to use and clean the multi-use catheters – we will give you everything you need for doing this.
- Provide a urine specimen.
- After randomisation, you will enter a two-week learning period to help you become familiar with the catheter, diaries and questionnaires you will need to complete.

Every month during the trial

At a pre-arranged contact *(which will take no more than 40 minutes)*, tell your researcher about:

- Any symptoms of UTI you have had during the preceding month.
- How you have found using your catheters and how often you catheterise.
- Anything unusual that has happened during the month e.g. if you have had to visit your GP – we will give you an Event Diary in which to record these things.
- How many of each catheter type you have been using – we will give you a Catheter Diary to use if you need help to remember this information.

Throughout the study

- Contact us at any time if you think you have a UTI, complete a UTI questionnaire and send a urine specimen to our laboratory in a special Royal Mail container which can be posted into any standard letterbox. They do not have to be taken to a Post Office counter. If you cannot get to the letterbox we may be able to arrange collection of your specimen from your home.

Record any relevant events in the Event Diary e.g. if you have to visit your GP for any related matter.

At 6 months after your involvement in the trial starts and at the end of the trial:

When requested by your researcher:

- Send a urine specimen to our laboratory above.
- Tell us about your quality of life and experiences of IC during the trial by completing some short questionnaires (*this contact will take approximately one hour).*

At the end of the trial, we will be inviting some multi-use participants to tell us in more detail about their experiences in a short interview with a researcher – see 'Optional interview' below. (*This will be a separate contact and will take approximately one hour).*

Your participation in MultI*C*ath will end once the researcher has completed the end of study contact unless you are asked, and agree, to take part in the optional interview. All activities related to this study will be done whenever possible without any face to face contact (unless you are in the intervention group and, subject to local restrictions, opt for a visit or are attending a clinic).

After the trial

After your participation in the trial has finished, if you have been using multi-use catheters, you will need to revert to your previous intermittent catheterisation regime with your usual single-use catheter as prescribed under the guidance of your GP or medical practitioner. The multi-use catheters may not be available after the trial has ended.

Optional Interview

If you are asked to use multi-use catheters in the trial, you may also be offered the opportunity to take part in a short interview with a researcher. The aim of this interview is to help us to understand how patients invited to take part in the MultICath trial felt and their experiences of re-using catheters in the trial in even further detail. The interview will last around 45-60 minutes and will be done by phone or video conference. This is entirely optional. You do not have to take part in an interview if you don't want to. There is a box on the attached consent form for you to initial, if you are interested learning more about the interview study.

If you are interested in taking part in the optional interview and you provide consent to receive information about the optional interview, a researcher (either from the London School of Hygiene and Tropical Medicine or the University of Southampton) will contact you directly. You will be sent a separate information sheet and have any questions you may have about the optional interview answered. Please note not everyone who offers to be interviewed will be selected**.**

Expenses and equipment

We will provide the multi-use catheters and other items that you need for taking part in the study. You may keep any items you have at the end of the study.

Is there anything I need to know about the catheters?

In this trial we are using a catheter that is licensed (CE marked) for reuse. It is called the Cliny catheter and comes with a small storage kit. Unlike most intermittent catheters which are made from polyvinyl chloride (PVC – a type of plastic), the Cliny catheter is made from Silicone. Silicone is used for some other urinary catheters. The Cliny catheter is not currently available on the NHS although it is used in several countries including Australia, South Africa and Japan.

Although some intermittent catheters are uncoated or 'plain', most are coated and do not require additional lubrication. The Cliny catheter is a plain, uncoated catheter. This means that men will need to lubricate the catheter before passing it. Women may wish to do this although some women prefer not to or use water. We will provide lubricant as needed throughout the trial. Please note, you should not try to re-use your coated catheters.

Are there any benefits to my taking part?

- You may have an opportunity to try an alternative way of managing your IC which is unlikely to be available to you otherwise.
- During the trial you will be under closer follow-up than usual and may learn more about IC from the information we will give you.
- Whichever group you are allocated to (mixed-use or single use), you will be helping to improve our understanding of IC with multi-use catheters.
- If we find that re-using catheters causes no more infection than using single-use catheters only and IC users prefer them at least some of the time, re-use of intermittent catheters may become part of clinical practice giving catheter users more choice.

Are there any risks involved?

- It is possible that you might experience a UTI, but this is a risk with all catheter use. There is not enough research evidence at the moment to be sure that the infection risk from multi-use catheters is not worse than single-use catheters and that is why we are doing the trial.
- If you are asked to carry out mixed-use, it is possible that you might experience some discomfort or skin soreness when testing Cliny catheters, which is also a risk with all catheter use. We will be asking you for feedback about this throughout the trial.

Throughout the trial, you will be able to contact your named researcher or one of the team whenever you wish and we will contact you at least every month.

What about Covid-19?

We recognise that the COVID-19 pandemic might make people cautious about trying new catheter regimes and contact with our researchers. We have spoken with several intermittent catheter users and using their feedback have modified the study to take account of their concerns.

The changes we have made include reducing the face to face contact between the researcher and participant so that whenever possible contact is by phone or video conference. This may be essential if the area in which you live does not permit our researchers from visiting you at home. If a face to face visit from the researcher is required, we will follow government guidance to reduce the risk to you and our research staff. We will also keep the visit time to a minimum. If you have any concerns about this please feel free to ask the researcher at any point before or during the research.

If you do require a face to face visit at a time when face to face visiting is not allowed in your area, it is still possible for you to take part. It may be that we retain your contact details and get back to you when the rules change or delay your start in the trial. We would only do this with your permission.

Will my participation be confidential?

Yes. If you agree to take part in this study, only individuals connected to the trial would have access to these records and all identifiable information would remain strictly confidential. Any information from which you could be identified, such as your name and address, will be held securely on paper and electronically at the research site (usually a hospital, university or GP Practice). You will be allocated a trial number, which will be used as a code to identify you on trial forms. Information about you which leaves the site will not include your name or address. Your contact details will be kept securely so we can stay in touch to check how you are during the trial. If you are interested in the optional interview, your contact details will be transferred securely to the London School of Hygiene and Tropical Medicine (LSHTM) who are carrying out the interview study to contact you about this extra bit of research.

The information that we collect during your participation in the trial will be available to people authorised to work on the trial. An authorised person from the Newcastle Clinical Trials Unit will look at some parts of your medical records, and the data collected for the trial. This is to ensure the high quality of the work being carried out. Your medical records may also be looked at by representatives of regulatory authorities and by authorised people from the University of Southampton, to monitor the trial and ensure that it is being carried out correctly. Everyone who sees information has a duty to ensure that nothing that could reveal your identity is disclosed outside the research site. By signing the study consent form you agree to this access for the current study and any further research that may be conducted in relation to it. If you withdraw from the current trial, the data collected from

you until the point of withdrawal can be used for this current trial and any further research that may be conducted.

The National Institute for Health Research, which is funding this study, requires that after completion of the study we must share the data we collect with the rest of the research community. This is so that it can be used to help inform other research and policy development. No information that can identify you will be shared and your confidentiality will be maintained. We will use secure electronic systems for transferring data.

In line with the Sponsor regulations, at the end of the study your data will be securely stored for 10 years. Arrangements for confidential destruction will then be made.

Will my GP be informed of my involvement?

With your permission your GP and other doctors who are treating you will be informed that you are taking part in the MultICath trial.

What happens if I change my mind?

You can change your mind and withdraw from the study at any time even after signing the consent form. You do not have to give a reason for withdrawing (although it is useful for us to know the reason). A decision not to take part at any stage will not affect the care you receive from your doctors and nurses.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

The results will be presented at research meetings and published on the National Institute for Health Research website and in scientific journals. We will also make the results widely available to the public using the study website.

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Who has reviewed the trial?

All research in the NHS is reviewed to make sure it is safe and fair for the patients involved. An independent group of people called an NHS Research Ethics Committee (REC) do this. The South Central- Hampshire Research Ethics Committee have reviewed this trial and approved our plans.

Where can I get more information?

If you have any further questions concerning this study please contact:

Local Principal Investigator	**Local Researcher**
Professor Mandy Fader	Margaret Macaulay, Miriam Avery or Jackie Broadbridge
University of Southampton Clinical Academic Facility, University Hospital Southampton Southampton, SO16 0DY	University of Southampton Clinical Academic Facility, University Hospital Southampton Southampton, SO16 0DY
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What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

You can also talk to the Patient Advice and Liaison Service (PALS) in your hospital. Details can be obtained from the Patient Advice and Liaison Service (PALS http://www.pals.nhs.uk/) at your local hospital. Their contact number is 02381 206325.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research.

This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for thinking about taking part in our research.