PARTICIPANT INFORMATION SHEET

You are being invited to take part in the above research study. 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. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

Key points:

- We are a team of researchers who are looking into how we can improve the detection of urinary tract infections (UTIs) in people who live in care homes.
- UTIs don't always cause clear symptoms for people who live in care homes and urine tests that are currently available do not give accurate or quick results.
- It can therefore be challenging for doctors and nurses to be sure whether someone has a UTI or not.
- We have some ideas about new ways that might help show us if someone really has a UTI but we don't know yet whether these will work. This study will help to explore these new ideas.
- Taking part in the study would involve giving a series of small samples of your urine for research tests at the beginning of the study.
- If you get a possible UTI over the next 6 months you would give another set of small urine samples for research tests.
- You would receive care as usual from the NHS whilst you are in the study and if you got a possible UTI.
- You do not have to take part in the study if you do not want to, and this will not affect the care that you receive from your care home or the NHS in the future.

1. What is the study title?

The full title of the study is 'Feasibility cohort study on predictors of diagnosis and prognosis of urine infection in care home residents.' However, we usually refer to the study by its short name which is DISCO UTI.

2. Who is doing the study?

The study is being carried out by a team of researchers from the University of Southampton, the University of Oxford and the University of Bristol, as well as other researchers from across the UK. We are interested in the health of older people who live in care homes.

3. What is the study about?

We are looking at how we can improve the detection of urinary tract infections (UTIs) in people who live in care homes. This is a common illness but it can be challenging for doctors to be sure whether someone in a care home has a UTI or not.

4. Why is it important to be sure whether someone has a UTI?

It is important to know whether someone really has a UTI because if you don't treat an infection there can be serious consequences. However, giving antibiotic treatment when there isn't an infection can cause antibiotic resistance and side effects.

5. Why is it challenging to be sure whether someone in a care home has a UTI?

There are several reasons for this:

- UTIs don't always cause clear symptoms for people who live in care homes.
- UTIs sometimes just cause symptoms like confusion which can have lots of different possible causes.
- It may be hard for people living with dementia to say how they are feeling or to easily provide a urine sample.

- Many people who live in care homes have bacteria present in their urine even when they are well, but this not harmful and does not need treatment.

6. Can you do any tests for UTI?

Unfortunately, urine tests that are currently available do not give accurate or quick results. They also can't tell the difference between bacteria in the urine causing infection (needing treatment), and bacteria in the urine not causing infection (not needing treatment). As a result, many people in care homes probably get antibiotics when they don't actually need them.

7. How are you going to address these challenges around detecting a UTI?

We have some new ideas that we want to test:

- Working out which symptoms or signs mean a UTI is more likely
- Detecting new markers of infection in urine samples
- Trying out new bedside tests that give rapid results

Eventually, we want to conduct a very large study collecting information and urine samples from many people living in care homes over a long period of time. However, we need to work out the best way to do such a big study. DISCO UTI will help us to do this.

8. Why have I been invited to take part in DISCO UTI?

You have been asked to take part in this study because you are over 65 years of age and live in a care home. We will be including 100 people like you in DISCO UTI.

However, you will **not** be able to take part in the study for several reasons, including:

- You are not permanently living in the care home
- You have a urinary catheter, or regularly use an in-out catheter
- You have a weakened immune system
- You will not be able to provide an uncontaminated urine sample

Members of the research team will check whether you meet all of the criteria.

9. Do I have to take part?

No, you do not have to take part if you do not want to.

10. What will happen if I decide to take part in the study?

There are several stages to the study.

1. Consent and baseline assessment

The first thing that will happen is that you will be asked to give your consent to take part in the study. Next the researcher will record some information about you including your medical problems, medications and whether you have had UTIs in the past. Finally, you will be asked to provide a small sample of your urine which will be sent for research tests. A researcher or care home worker can support you to collect the sample if you need.

2. Weekly urine samples for 4 weeks

25 participants will be asked to provide another small sample of urine once a week for the next four weeks. We will select participants to ensure that we have a good mix of gender and presence or not of bacteria in the urine at baseline. We will make it clear to you and your care home whether you have been selected to provide repeat samples. Each of these samples will be sent for research tests.

3. Reassessment if you get a possible UTI

For the six months following your baseline assessment, your care home will be asked to contact the research team every time they think that you might have a UTI. They will also contact your GP, who will investigate you and treat you as they normally would.

We can put up a poster in your room to remind the care home staff to contact the research team in these instances. However, this would be

visible to anyone coming into your room. If you would prefer there to be no poster, you do not need to sign this optional part of the consent form.

Your care home will be asked to support you in collecting another urine sample which will be sent for research tests. If your GP has also asked for a urine sample, we will make sure that this is done first.

A member of the research team will also come to your care home to record more information like your symptoms and whether the illness has meant that you need additional care or support. They will ask the care home whether you have had any care from your GP or other healthcare provider over this period.

A member of the research team will return to your care home 14 and 28 days later to see how you are getting on and to collect a further urine sample. They may ask to see your care home records to find out what has happened to you between the visits.

If you develop a further possible UTI over the 6 months of the study, all of these steps would be repeated again.

4. Interview

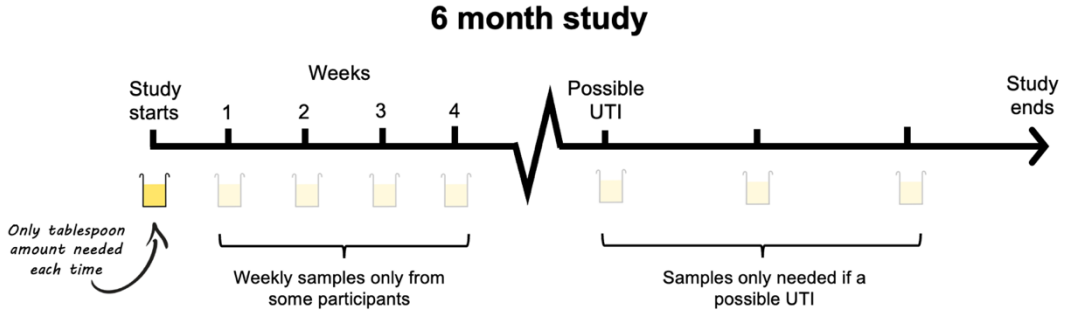
You will be asked at the end of the study whether you would like to speak to a researcher about your experiences of being involved in the study. We will invite participants to ensure that we have a good mix of participants who took part in the different aspects of the study.

11. What happens if I become more forgetful or confused during the study?

When you provide consent at the beginning of the study, we will ask your permission for you to remain in the study if you do become confused. If possible, we will check this decision with a family member or relative at the time. If the confusion settles we will remind you that you are taking part in the study.

12. How do I provide a urine sample?

If you need help providing a urine sample, you will be offered support by a care home worker or a member of the research team. For each sample we only need 15ml (around 1 tablespoon) of urine for all the research tests to be able to be carried out. Some participants may only need to give one sample at the beginning of the study.



13. What are the research tests?

We will be doing a few different research tests on each of the samples that you provide.

Some of these will be carried out in a laboratory:

- Culture test – we will see if any bacteria grow from your urine sample. This test will be carried out in the Public Health Wales laboratory in Cardiff.
- Biomarker tests – we will see if we can detect different biological molecules that may be higher in infections. These tests will be carried out in a University of Southampton research laboratory.

Some of the tests will be carried out in the care home by the research team. These will involve running a test on a fresh sample of urine which will look for the presence of bacteria, or other markers of infection.

14. Will I get the results of the research tests?

We will not give you, your care home or your GP the results of any of the research tests. This is because we do not know how good the new tests will be at detecting a UTI. We do not want to cause you harm by giving you or your GP an inaccurate or unhelpful result.

Urine culture tests are available as part of usual NHS care. If your GP or other healthcare provider wants a culture test they will send one themselves, and will receive the result directly.

15. Will the results of the test be shared with anyone other than the research team?

The central laboratory run by Public Health Wales will combine your study code with the results of the specialised culture tests they run. The companies who have created the new rapid bedside tests for UTI may also be given data about your sample tested on their device, but they will not be given any data about you. Neither Public Health Wales nor device manufacturers will receive your name or any other identifiable information about you from this study.

16. What will happen to my urine samples after the research tests have been carried out?

All urine tested at your care home will be safely disposed of after any tests carried out there. However, if there is any urine remaining after the tests have been carried out in the laboratory, we will freeze and store it at a licensed facility. This means that it could potentially be used in another research project in the future. Any future research would need to have ethical approval. Future research may involve commercial organisations. Samples will be stored anonymously which means that they could not be linked back to you.

17. What happens if I am asked to take part in an interview?

The interview will last around one hour and will take place in person in the care home towards the end of the six-month study period. You will be able to ask a family member to join the interview if you want to. The

interview will be audio-recorded on a digital recording device. We will want to know things that went well in DISCO UTI as well as things that could have gone better. This will help us plan the bigger study in the future. The researcher may make notes during the interview. You will not have to answer all the questions that you are asked if you don't want to. You can also ask for the interview to be stopped at any point.

18. What will happen after the interview?

After the interview the audio-recording will be transferred securely to a University approved professional transcription company, which has the facility to provide secure downloading of audio files and guarantees that information in the transcripts will remain confidential. The company will transcribe the interview and transfer it back to the research team. It will be checked against the original recording by a researcher and any information that could identify you will be removed. The anonymised transcript from your interview will then be compared to interview transcripts from other participants and analysed together.

19. What are the possible benefits of taking part?

There will be no direct benefit to you taking part in the research. However, the information gained from the study will be useful when planning further research in care homes, which may help people like you in the future.

20. Will I be reimbursed for taking part?

You will not receive any payment for taking part in this study.

21. Are there any possible disadvantages from taking part?

Taking part in the study will involve some of your time – to answer questions and to provide urine samples at each of the study visits. Overall, we hope that this won't be too inconvenient for you.

22. Will my GP be informed that I am taking part in the study?

We will notify your GP that you are taking part in the study. There may also be instances where the research team may ask the care home to

contact your GP – for example if they are worried that you are unwell when they see you at a study visit.

23. Will my taking part in the study be kept confidential?

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

24. What will happen to my data?

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 and the University of Oxford are the 'Data Controllers' for this study, which means that we are responsible for looking after your information and using it properly. The Universities 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).

25. What will happen if I don't want to carry on with the study?

Taking part in the study is voluntary and you can change your mind at a later stage. Withdrawal from the study will not affect the care you receive from your care home or the NHS. If you withdraw from the study, we will destroy all your identifiable samples, but will use the data we collected up to your withdrawal.

26. What will happen to the results of this study?

We will publish the study findings through journal articles, reports, presentations and conference papers. We also hope to present the work to people who play an important role in care homes – like residents, staff and charities. We might use anonymised direct quotations from your interview in presentations and publications, if you take part in one. You will not be able to be identified in any written or verbal reports from the study. We will also send you a summary of the findings of the study if you would like this. Some of the research being undertaken will also be written up in a PhD thesis.

27. What if there is a problem?

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

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).

28. How have patients and the public been involved in this study?

Care home staff and relatives of those living in care homes have provided feedback on the design of the study and the information sheets that care homes and participants read. We will be asking for their help throughout the study, including how the results of the study are shared with care home residents, care home staff and the wider public.

29. Who is organising and funding the study?

The research is being organised by the Primary Care Research Centre at the University of Southampton and the Nuffield Department of Primary Care Health Sciences at the University of Oxford. The research is being funded by the National Institute for Health and Care Research School for Primary Care Research. Dr Abigail Moore is completing some of this work as part of her PhD which is being funded by the Wellcome Trust.

30. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Newcastle & North Tyneside 2 Research Ethics Committee.

Further information and contact details:

Please ask the research study team if you have any questions or you do not understand the information we have provided on the contact details below:

Principle Investigator:	Dr Abigail Moore
Telephone:	01865 289300
Email:	discouti@phc.ox.ac.uk
Website:	www.southampton.ac.uk/primarycare/disco.page#home

Thank you for reading this information and considering taking part in this study.