School of Psychology and Clinical Language Sciences
Earley Gate, Whiteknights
Reading, Berkshire
RG6 6AL
United Kingdom

Title of Study: Developing and Validating Two New Patient-Reported Outcome Measures of Recurrent Urinary Tract Infection Symptoms and Impact

Participant Information Sheet (Part 1 of 2)

Supervisor: Dr Katherine Finlay
Email: katherine.finlay@reading.ac.uk

Researcher: Abbi Newlands
Email: a.f.newlands@student.reading.ac.uk

We would be grateful if you could assist us by participating in our two-part study which aims to develop and validate two new patient-reported outcome measures of recurrent urinary tract infection (rUTI).

What is a patient-reported outcome measure and why develop new ones?

A patient-reported outcome measure (PROM) is a type of measurement tool (e.g. questionnaire) which can be used to gain insight into a patient's own perspective on certain aspects of their health. For example, a PROM may seek to understand a patient's views on how severe they feel their symptoms are, or how much their condition has interfered with their lifestyle. PROMs are typically designed to be used in conjunction with clinical outcome measures, e.g. results from a urine dipstick test, in order to build a more whole picture of the patient's health and health-related quality of life.

There are many generic PROMs which effectively measure, e.g., health-related quality of life and psychological symptoms such as anxiety; however, there are no existing validated rUTI-specific PROMs. Condition-specific PROMs can be especially useful in gathering information about aspects of health which may be unique to or present differently in the relevant patient population. In this study, we aim to develop and validate two new rUTI-specific PROMs: one measuring rUTI symptoms and symptom intensity, and one measuring rUTI impact. Our intention is that these measures could be used to assess effectiveness of treatments and interventions. They will not be used for diagnostic purposes, but instead to bring in the patient perception.

What will my participation involve?

Your participation will take approximately 1 hour, which will be divided evenly across two parts (30 minutes each). This is Part 1, and Part 2 will take place tomorrow, in approximately 24 hours' time from now. When it is time for you to start the Part 2 survey, you will be emailed your unique survey link and be asked to follow the exact same procedure as today.

After signing the consent form and completing the demographics form, you will be guided through a series of questionnaires to complete. Two of these questionnaires will be the rUTI symptom and impact PROMs we have developed, and others will be existing standardised questionnaires which measure similar concepts of symptom intensity and health impact. Because

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of this, **there may be some questions which appear to be asking you the same thing; please continue to answer all the questions in this case**.

Please continue to answer all the questions even if you are not currently experiencing UTI symptoms.

What will the rUTI PROMs ask me about?

The rUTI symptom PROM will ask you about how often you experience UTI symptoms and if they have been different in the past 24 hours compared with your typical experience. You will then be asked to rate the severity of the UTI symptoms and UTI pain or discomfort that you have experienced in the past 24 hours. Importantly, you should still complete all the questions on this questionnaire even if you feel that you have not experienced any symptoms in the past 24 hours.

The rUTI impact PROM will ask you to think about the past two weeks and rate your agreement with statements about the impact of your rUTI on your personal wellbeing, socialising, working and completing daily activities, sexual activity, and satisfaction with your UTI-related medical care. We use the term "work" to include full-time and part-time employment, volunteering, caring responsibilities and home management, and/or education responsibilities.

Please be aware that the PROMs are not intended to be used as diagnostic tools, but rather to understand how patients perceive their experience of living with rUTI. The PROMs will not be used to diagnosed rUTI.

Are there any risks involved?
The aim is for our PROMs to be able to accurately capture a picture of how rUTI patients perceive their condition and its impact on their life. Because of this, you may find that some of the questions are of a personal nature. Reflecting on your personal experience of your rUTI symptoms and their impact may induce negative feelings, thus the study may include a mild risk of anxiety, concern or other emotional reactions. This is not the intention of the study, and we hope that you feel able to continue in the event that this happens. If you are concerned about any of the questions in the study then you may choose to discontinue your participation at any time.

Are there any benefits involved?
All participants who take part in both parts of the study and provide their email address will be entered into a prize draw. One winner will be randomly selected using a random name generator and will receive an Amazon gift voucher of value £25 (GBP).

How will my data be stored?
Your data will be kept confidential and securely stored in a password-protected folder on the University of Reading server, only accessible to the research team. Your data will only be identified with an anonymous number. Information linking that number to your name and any personal information will be stored securely and separately from the data you provide us. This separate file containing your name and personal information will not be retained for longer than is necessary to complete this research project and publish the results. The non-personal data collected from this study will be preserved and made available in anonymised form, so that they

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can be consulted and re-used by others. Consent forms will also be stored securely and destroyed after a period of 5 years from the study's completion.

Do I have to take part?
Taking part in this study is completely voluntary; you may withdraw at any time without having to give any reason.

Please feel free to contact us using the contact details at the top of this page if you have any questions.

This application has been reviewed by the University Research Ethics Committee and has been given a favourable ethical opinion for conduct (code: 2021-043-KF).

Thank you for your help.

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Consent Form (Part 1 of 2)

Please tick the box after each statement to confirm you have read it and agree:

1. I have read and had explained to me the accompanying Information Sheet relating to the study "Developing and Validating Two New Patient-Reported Outcome Measures of Recurrent Urinary Tract Infection Symptoms and Impact." ☐

2. I have had explained to me the purposes of the study and what will be required of me, and any questions I have had have been answered to my satisfaction. ☐

3. I understand that the Recurrent UTI Symptom Scale and the Recurrent UTI Impact Questionnaire are not used to diagnose recurrent UTI or any other medical condition, and are simply measures of patient experience. ☐

4. I agree to the arrangements described in the Information Sheet in so far as they relate to my participation. ☐

5. I have had explained to me what information will be collected about me, what it will be used for, who it may be shared with, how it will be kept safe, and my rights in relation to my data. ☐

6. I understand that participation is entirely voluntary and that I have the right to withdraw from the project any time, and that this will be without detriment. ☐

7. I understand that the data collected from me in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others. ☐

8. I understand that this project has been reviewed by the University Research Ethics Committee and National Research Ethics committee where relevant, and has been given a favourable ethical opinion for conduct. ☐

9. By providing my email address below, I agree to be contacted for the purposes of receiving a link to Part 2 of the study which will take place approximately 24 hours after finishing Part 1. ☐

Name: ……

Email address: ……

Signed: ……

Date: ……

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Title of Study: Developing and Validating Two New Patient-Reported Outcome Measures of Recurrent Urinary Tract Infection Symptoms and Impact

Participant Information Sheet (Part 2 of 2)

Supervisor: Email:
Dr Katherine Finlay katherine.finlay@reading.ac.uk

Researcher: Email:
Abbi Newlands a.f.newlands@student.reading.ac.uk

Thank you very much for returning to complete Part 2 of our study. This page will firstly remind you of the general aims and background of the study, as well what your participation will involve today.

This study aims to develop and validate two new patient-reported outcome measures of recurrent urinary tract infection (rUTI).

What is a patient-reported outcome measure and why develop new ones?

A patient-reported outcome measure (PROM) is a type of measurement tool (e.g. questionnaire) which can be used to gain insight into a patient's own perspective on certain aspects of their health. For example, a PROM may seek to understand a patient's views on how severe they feel their symptoms are, or how much their condition has interfered with their lifestyle. PROMs are typically designed to be used in conjunction with clinical outcome measures, e.g. results from a urine dipstick test, in order to build a more whole picture of the patient's health and health-related quality of life.

There are many generic PROMs which effectively measure, e.g., health-related quality of life and psychological symptoms such as anxiety; however, there are no existing validated rUTI-specific PROMs. Condition-specific PROMs can be especially useful in gathering information about aspects of health which may be unique to or present differently in the relevant patient population. In this study, we aim to develop and validate two new rUTI-specific PROMs: one measuring rUTI symptoms and symptom intensity, and one measuring rUTI impact. Our intention is that these measures could be used to assess effectiveness of treatments and interventions. They will not be used for diagnostic purposes, but instead to bring in the patient perception.

What will my participation involve?

Your participation today will take approximately 30 minutes. You will be asked to follow the same procedure as you followed yesterday in Part 1.

Just like yesterday, you will be guided through a series of questionnaires to complete. Two of these questionnaires will be the rUTI symptom and impact PROMs we have developed, and others will be existing standardised questionnaires which measure similar concepts of symptom

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intensity and health impact. Because of this, **there may be some questions which appear to be asking you the same thing; please continue to answer all the questions in this case**.

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Please be aware that the PROMs are not intended to be used as diagnostic tools, but rather to understand how patients perceive their experience of living with rUTI. The PROMs will not be used to diagnosed rUTI.

Are there any risks involved?
The aim is for our PROMs to be able to accurately capture a picture of how rUTI patients perceive their condition and its impact on their life. Because of this, you may find that some of the questions are of a personal nature. Reflecting on your personal experience of your rUTI symptoms and their impact may induce negative feelings, thus the study may include a mild risk of anxiety, concern or other emotional reactions. This is not the intention of the study, and we hope that you feel able to continue in the event that this happens. If you are concerned about any of the questions in the study then you may choose to discontinue your participation at any time.

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All participants who take part in both parts of the study and provide their email address will be entered into a prize draw. One winner will be randomly selected using a random name generator and will receive an Amazon gift voucher of value £25 (GBP).

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necessary to complete this research project and publish the results. The non-personal data collected from this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others. Consent forms will also be stored securely and destroyed after a period of 5 years from the study's completion.

Do I have to take part?

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Please feel free to contact us using the contact details at the top of this page if you have any questions.

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Consent Form (Part 2 of 2)

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2. I have had explained to me the purposes of the study and what will be required of me, and any questions I have had have been answered to my satisfaction. ☐

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9. By providing my email address below, I agree to be entered into a prize draw in which one winner will be randomly selected to win an Amazon gift voucher of value £25 (GBP). I understand that I will not be contacted for other purposes. ☐

Name: ……

Email address: ……

Signed: ……

Date: ……