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Participant Information Leaflet and Agree to Contact Form

PURPOSE

PUQOL Project Pre-test: patient interviews

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project 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 the study?

The development of pressure ulcers, also called a bed sores or pressure sores, can have a major impact on patients' quality of life and well-being as well as severely compromise all areas of functioning. However, there is currently no formal way of assessing quality of life outcomes from the patients' perspective in healthcare and in research, as there is no quality of life questionnaire for use with patients with pressure ulcers.

The Pressure Ulcer Quality of Life (PUQOL) project will develop a questionnaire that will assess important quality of life outcomes in patients with pressure ulcers that will be suitable for use in NHS clinical practice and in research. Specifically, the questionnaire will provide us with important information about the experienced suffering of patients with pressure ulcers and the impact pressure ulcer treatments have on patients' quality of life. This information will be obtained in order to improve patient healthcare and patient quality of life.

This study is the second phase of the development of the questionnaire and involves interviews with patients like yourself. Patients will complete the provisional version of the questionnaire and upon completion, will be asked to answer a series of questions about the questionnaire. The provisional questionnaire will be modified based on all patients' answers and recommendations.

Why have I been invited?

You have been chosen to take part because we wish to talk to people who have experience of having a pressure ulcer. Any person who has a pressure ulcer ranging from a small red area to a more severe ulcer, from hospitals and within the community around the United Kingdom, will be asked to participate.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part we will then ask you to sign a consent form to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What will happen to me if I take part?

If you agree to take part, you will be asked to complete a questionnaire which will take approximately 20 minutes to complete. It would involve choosing an answer to a set of questions on a scale. An example of a question that you might be asked is:

> In the past week, for how many days did your pressure ulcer cause you pain or ache? (*please tick one box*)
>
> None at all ☐ between 1-3 days ☐ between 4-5 days ☐ between 6-7 days ☐

While completing the questionnaire, you will be required to mark any questionnaire items that are annoying, upsetting or intrusive, or misunderstood. After completion of the questionnaire, the interviewer, Claudia Gorecki, will ask you some questions about the items

you marked to clarify ambiguities and/or misunderstandings in the questionnaire wording. You will also be asked questions relating to the time it took to complete, ease of response options, and general questionnaire content. All people who take part are being asked the same questions. Completion of the questionnaire and the follow-up interview could possibly take up to an hour so participants who agree to take part in the study would need to be available for up to an hour. We will make sure the interview took place in as private a place as possible, either in your own home or on the ward where you are admitted, at a time convenient for you. No further involvement is required.

The discussion that you have with the interviewer about the questionnaire, with your permission, will be tape recorded and transcribed to help us analyse it. The tape recording will be used only by researchers involved in the project and it will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed. In addition to the information collected during the interview, we may need to access your medical records to obtain further information about your pressure ulcer and the treatments that you have received.

Expenses and payments

We anticipate that there will be no extra expenses for you as a result of taking part in this study, as interviews will be conducted in your own home or on the hospital ward where you are admitted at a time convenient for you.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and by completing the questionnaire, you will need to reflect on your personal experience of having a pressure ulcer and how the pressure ulcer and treatments have impacted on your life. There is a possibility that you may find this distressing. The interview can be stopped at any point if you feel you do not want to continue. If necessary, a referral can be made to your nurse or other healthcare professionals if you are distressed by the content of the questionnaire or by the discussion that will follow completion.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the information we get from the interviews will help to develop a questionnaire that covers all the important issues that people with pressure ulcers have to deal with and the perceived benefits of treatments from the perspective of the sufferer.

Will my taking part in this study be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first. Details are included in Part 2.

This completes part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

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

Taking part in this study is entirely voluntary and you are free to change your mind at any point up to, during or following the interview. You will not be able to be identified in the study results but if you wish to withdraw any data already collected prior to publication of the results then arrangements can be made for the interview tape to be destroyed and your discussion excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Data Protection Act 1998.

Claudia Gorecki and her supervision team have a duty of confidentiality to you as a research participant, and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your medical records, will have your name and address removed so that you cannot be recognised from it. All information obtained is strictly confidential and will be kept in locked cupboards and will

only be accessible by members of the research team. No names or details that would identify specific people will be included in the findings from this study. Findings, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be used to modify and update the provisional questionnaire to produce a preliminary version of the questionnaire which will then be further tested for its usefulness. Information from this study will be included in a final report for the whole project and published in a scientific journal.

Who is organising and sponsoring the research?

This study is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. This study is also phase 2 of the PUQOL project that is funded by the National Institute of health Research as part of a larger pressure ulcer programme aimed to reduce the impact of PUs on patients and develop methods to capture outcomes important to patients such as quality of life.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the *(name of REC)* Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please let your district nurse or tissue viability nurse who provided you with this information leaflet know. They will complete the Agree to Researcher Contact Form at the end of this leaflet and

send it back to the researcher, Claudia Gorecki, who will phone you upon receiving the form to discuss this study further and arrange a time for the interview.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Claudia Gorecki on 0113 3437632 or the study supervisor, Dr Jane Nixon on 0113 3431488 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

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PATIENT AGREEMENT TO RESEARCHER CONTACT

Name of researcher: Claudia Gorecki
Clinical Trials Research Unit
University of Leeds
LS2 9PH
0113 3437632

Name of consultant/nurse: _____

Contact number: _____

PURPOSE

PUQOL Project-Preliminary test: patient interviews

Please the tick relevant box

Please initial the boxes:

- I have read the information sheet and kept a copy. ☐
- I am happy to be contacted by telephone by the above named researcher to discuss the study further ☐

OR

- I am happy for my nurse to arrange a time for me to meet with the researcher on the ward ☐

Please complete your contact details in the space provided

Patient name _____

Address _____

_____Postcode_____

Telephone Number _____Preferred contact time _____

OR

Hospital name _____ Ward _____

Date and time of visit_____

Thank you for completing this form. Please return to Claudia Gorecki at CTRU, University of Leeds, Clinical Trials Research House, 71-75 Clarendon Road, Leeds, LS2 9PH or phone 0113 343 7632

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PURPOSE

PUQOL Project Pre-test: patient interview consent form

Name of researcher: Claudia Gorecki
Address: Clinical Trials Research Unit, University of Leeds, Clinical Trials Research House, 71-75 Clarendon Road, Leeds, LS2 9PH; **Telephone:** 0113 3437632

	Please initial box after each question
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected.	☐
3. I understand that the above named researcher may ask my nurse additional information about my pressure ulcer history and relevant treatment. I give permission for the researcher to verbally obtain this information for the above study and any further research that may be conducted in relation to it, provided that strict confidentiality is maintained.	☐
4. I agree that my interview will be tape recorded and typed out, maintaining anonymity.	☐
5. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous.	☐
6. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication.	☐
7. I understand that a copy of this Consent Form will be sent to the CTRU	☐
8. I agree to take part in the above study.	☐

Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Name of Person taking consent	Date	Signature

(When completed, 1 for patient, 1 for patient file; 1 for CTRU)