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INFORMATION SHEET

PURPOSE

A patient-reported outcome measure of health-related quality of life for pressure ulcer patients (PU-QOL): Qualitative 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?

At present, very few studies have been conducted to inform us about what it is like for a person to live with a pressure ulcer. Pressure ulcers, also called a bed sore or pressure sore, have many causes and although the aim is to prevent them, a small number of people still go on to develop them. This project is designed to 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 health-related quality of life.

In other disease areas, quality of life questionnaires exist and patients may often be asked to fill in quality of life questionnaires as part of their routine hospital care or clinic appointment.

While healthcare professionals and researchers in other disease areas are becoming more familiar with these questionnaires, quality of life questionnaires are rarely used with pressure ulcer patients to assess the impact of the pressure ulcer or their treatments on patients' quality of life. This study forms part of a larger project aiming to develop and evaluate a self-report measure of quality of life for use with patients suffering from pressure ulcers. The questionnaire will be used to inform healthcare professionals about the perceived benefit of PU treatments from the perspective of the patient and the effect it has on their quality of life. This is the first phase of the questionnaire development process involving interviews with patients like yourself, to determine which quality of life related issues are of most importance to patients.

Why have I been invited?

We are interested in talking to people who have experience of having a pressure ulcer. Any person from *(Trust name)* who has a pressure ulcer ranging from a small red area to a more severe ulcer will be asked to participate.

Do I have to take part?

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 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?

You will be contacted to arrange a suitable interview date and time. The researcher (Claudia Gorecki) will then meet with you to go through the interview process before the discussion begins. The discussion should last around 1 hour and will take place in the ward where you are admitted at *(hospital name*). The discussion will be tape recorded. The tape recording will be used only by researchers involved in the project to write notes on the discussion and will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed.

During the interview you will be asked a few questions about your current life circumstances and asked to describe and provide information about your experience of your pressure ulcer and the treatments that you received as part of your care. We also would like to ask for permission to ask your nurse details about your pressure ulcer such as whether it is a red area or blister or much more severe; how long you have had it, and details about the treatments that you have received such as the type of dressing applied. The information will be confidential between you, the team looking after you and the researcher.

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 while you are an in-patient in the hospital at a convenient time for you.

What are the possible disadvantages and risks of taking part?

The study requires approximately one hour of your time. You will be asked to think about and discuss 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 discussion.

What are the possible benefits of taking part?

There are no direct benefits to you taking part. We hope that the information we get from the interviews will help to identify all the important issues that patients with pressure ulcers have to deal with and identify the perceived benefits of treatments from the perspective of the patient. This information will then be used to formulate questions which will be put together to form a quality of life questionnaire for healthcare professionals to use in addressing quality of life impacts in patients with pressure ulcers and to provide them with a better understanding of how pressure ulcers and their treatments impact on a patients quality of life from a patient's perspective.

Will my taking part in the study be kept confidential?

Yes. 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. The 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?

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 Caldicott principles and the Data Protection Act 1998. Claudia Gorecki and her supervision team have a duty of confidentiality to you as a research participant and we will do their very best to meet this duty. Claudia Gorecki will store the interview tapes in a locked cabinet. Tapes will be identified by study number only and any references to names will be removed during transcription. Any identifiable data will only be accessed by the researchers. The tape recordings will be disposed of securely once data analysis is completed.

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/publication. The study results will be used to construct items on a questionnaire and published in a scientific journal.

Who is organising and sponsoring the research?

This project is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. The researchers and nurses are not being paid for inclusion of patients in this study.

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 your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by *(name of REC)* Research Ethics Committee.

Further information and contact details

Thank you 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 tissue viability nurse who provided you with this information sheet.

Development of a Patient-Reported Outcome measure of HRQOL for Pressure Ulcer Patients (PU-QOL): Qualitative patient interview consent form

PURPOSE

Name of researcher: Claudia Gorecki

Clinical Trials Research Unit

University of Leeds

Leeds

LS2 9NG

Telephone: 0113 3437632

Please initial the boxes:

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights 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. ☐

4. I agree that my interview will be tape recorded and typed out. ☐

5. I understand that my interview will be coded so that only the above named researcher will be able to link my interview with my personal details. ☐

6. 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.

Claudia Gorecki	_____	_____
Name of Person taking consent	Date	Signature

One copy for patient; one copy for researcher