PURPOSE

Pressure ulcer quality adjusted life years (PUQALY): an item reduction survey

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Principle investigator: Professor Claire Hulme

Contact us:

Researcher:	**Researcher:**	**Insert details of local R&D contact here:**
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What is the purpose of the study?

Pressure ulcers (bed sores) happen to people with poor health who are unable to move about much. The Department of Health want to try and make sure that a lot fewer people get pressure ulcers in the future. The University of Leeds has been involved in a large research study with people who have pressure ulcers. As part of this we have developed a new questionnaire that measures the impact of pressure ulcers on a person's quality of life. This is based on the kinds of problems people with pressure ulcers have, for example pain and discomfort, unpleasant smell and so on. It is important for us to find out which of these problems affect people with pressure ulcers most. We would like your help in testing this new questionnaire. This will help measure which new treatments are best value for money in the future.

What do I have to do if I agree to take part in the study?

If you agree to take part the nurse will ask you to complete a survey. The survey asks about you pressure ulcer and your quality of life and should take about 20-30 minutes to complete. Having an ulcer impacts on health and how people get by in their lives. The questions are designed to help us understand this better.

Do I have to take part in the study?

No. It is up to you to decide if you want to take part in the study. If you decide to take part you will be asked to sign a consent form. If you think you want to take part and then change your mind you can without giving a reason. This will not make any difference to the medical care you receive.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, family member, or member of your healthcare team. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

When and where will the study take place?

Study participation will be at a time that suits you and will be either at your home or in the hospital if you are still a patient. This will be a 'one off' and you will not be asked to

participate again for this study. If you are in hospital you can complete the survey there but if you prefer to complete it at home then the nurse will give you a survey pack which includes a reply-paid envelope so you can post back your completed questionnaires.

What other information will be collected in the study?

We may also ask you about your pressure ulcer and about your general health.

Will there be any effects on my treatment?

No. Your treatment will be the same whether you take part or not.

Will the information obtained in the study be confidential?

Yes. It will not be possible to connect your answers in the questionnaires to the report we write about the study. The questionnaires will have a number and not a name to identify them for the researchers. The completed questionnaires will be kept secure and stored in our locked cupboards at the University.

Will anyone else be told about my participation in the study?

It is usual in studies to let your family doctor know that you have taken part in a study. We will check this with you first.

Who is funding this study?

The money to pay for this study has come from the department of health through the National Institute of Health Research.

What if I wish to complain about the way in which this study has been conducted?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not affected in any way because you have taken part in a research study.

If you have any complaints or concerns please contact the project co-ordinator (Karen Vinall-Collier). Otherwise you can contact David Meads.

Our contact details are on the front of this leaflet.

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PARTICIPANT CONSENT FORM

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The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I have read and understood the participant information sheet, dated 20.6.13. I have had the opportunity to ask questions and discuss this study. I have received satisfactory answers to all of my questions.	
I understand that I am free to withdraw from the study at any time and without having to give a reason. The relationship with my healthcare providers, level of services received or my legal rights will not be affected.	
I understand that if I decide to drop out of the study in the middle of the interview my questionnaire will be destroyed.	
I understand that any information I provide, including personal details, will be confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give may be included in published documents but it will not be possible to identify me personally.	
I agree to take part in this study.	
Participant Signature …… Date:	
Researcher Signature …… Date:	

Thank you for agreeing to take part in this study