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PURPOSE

Pressure UlceR Programme Of ReSEarch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

PATIENT INFORMATION SHEET

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

You have been invited to take part in a research study. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with your relatives or carers if you wish. Ask us if anything is unclear, or if you would like more information. Part 1 tells you the purpose of this study and what taking part involves. Part 2 gives you more detailed information about the study. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study is part of a larger study which is trying to find a better way of identifying patients who are at risk of developing pressure ulcers (bed sores) and those who already have pressure ulcers. A group of experts and patients have worked together to work out a list of questions to ask about you and this study is to check whether we can use this list to give reliable and consistent answers. We hope that the answers to these questions will give a good indication of whether you are at risk of a pressure ulcer or not, or if you have a pressure ulcer.

Why have I been chosen?

This study is looking for people like you who are in hospital or under the care of community nursing services. Hospital patients and patients within the community will be asked to take part. The study includes people with different levels of walking and movement ability. This includes people who are able to move easily, as well as people who have difficulty moving or are unable to move. It will also include some people who already have a pressure ulcer.

Do I have to take part?

No, you do not have to take part. Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide. If you are interested we will describe the study to you and go through this Information Sheet. If you agree to take part you will be asked to sign the Consent Form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this Information Sheet and of the signed Consent Form to keep. If you do not wish to take part this will not affect the care that you are currently receiving. If you decide to take part you are free to change your mind and withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive.

What if I would like to take part but I have trouble with or am unable to write to fill in the Consent Form?

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, a 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.

What will happen to me if I take part?

If you agree to take part in the study, two nurses will undertake an assessment that will involve asking you some questions relating to your health and refer to relevant sections of your nursing and medical records. Both nurses will also look at your skin in the areas which are exposed to pressure. This includes having a quick check of your elbows, heels, and bottom, which are the areas that are most at risk of getting a pressure ulcer. The nurses will also look at your pressure ulcer if you have one. A nurse will come and repeat the assessment a few days later at a time convenient to you. The questions and skin check will take about 20 minutes and will take place in your own home, or on the hospital ward 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 for taking part. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. However, we hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with your healthcare practitioner (e.g. Nurse or Doctor) or other healthcare professional who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. In the unlikely event that you think you have been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from your healthcare practitioner or PALs (Patient Advice and Liaison Services).

Will my taking part 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. No names or details that would identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Involvement of your General Practitioner (GP) / Other Healthcare Practitioner

Your GP will be informed that you are participating in this study. If you are under the care of a Hospital consultant (inpatients only), they will also be informed of your participation.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to 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 during or following completion of the study without giving a reason. A decision to withdraw at any time will not affect the standard of care you receive, nor will it affect your relationship with the medical and nursing team who are looking after you. Should you choose to withdraw, then your existing data (until withdrawal) will remain on file and will be included in the final study analysis unless you specifically withdraw consent for this.

Will my taking part in this study be kept confidential?

If you decide to participate in the study, the clinical information collected about you during the course of the study will be anonymised and kept strictly confidential. We will record your date of birth and initials on all study forms. If you agree to the second assessment the study nurse will record your NHS ID, hospital number (hospital patients only) and address and telephone number (community patients only). This will be held only by the study nurse who will destroy this information immediately following your second assessment. A copy of the Consent Form you sign, which will include your name, will be sent to the Clinical Trials Research Unit. They do not put your name on computer. They simply check that the consent form has been signed and dated properly and will securely file the form.

All information will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. The study team have a duty of confidentiality to you and will do their very best to meet this duty. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible to members of the research team. No names or details that would identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds, which is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee in order to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds West Research Ethics Committee (reference 12/YH/022).

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified in any report or publication. If you would like to obtain a copy of the published results, please ask your local contact person (see contact details below). We hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

Further information and contact details

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org. If you want further information about the study, now or in the future, please contact (*insert name*) below.

Your contact telephone numbers: (*to include local collaborator*)……
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