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PRESSURE 2

Pressure **RE**lieving **S**upport **SU**rfaces: a **R**andomised **E**valuation 2

CONSULTEE INFORMATION SHEET

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

We are currently carrying out a research study in this hospital called PRESSURE 2. The study is comparing two different types of mattresses which are commonly used in hospitals. As a relative, carer or friend of a patient, we would like you to consider their participation in this research study. As he/she is unable to tell us whether they would be willing to take part themselves, we are asking you, as someone who has a close personal relationship with the patient, to consider this invitation on their behalf and respond as you think they would respond.

Please consider the patient's past or present wishes and feelings regarding research of this nature. You may have personal views on participation in this particular research project but we are asking you to advise on their views.

The patient has been invited to take part in a research study called PRESSURE 2. Before you decide if he/she should take part, we would like to explain why the research is being done and what the study will involve.

Please read this information carefully and discuss it with others if you like. A clinical research nurse or registered healthcare professional will also talk to you about the study and answer any questions.

This document is split into two parts:

- Part 1 tells you about why we are doing the study and what will happen if the patient takes part.

- Part 2 gives you more detailed information about what the study involves.

Please take time to decide whether or not you think the patient should take part.

How to contact us

If you have further questions about this study, please talk to

<<Enter PI, nurse/registered healthcare professional name >>

<< Contact details for site>>

Thank you for reading this information sheet

Part 1

What is the purpose of the study?

This study will compare two types of mattresses which are already widely used in hospitals to help prevent Pressure Ulcers. The mattresses are called High Specification Foam and Alternating Pressure .Alternating Pressure Mattresses are made up of pockets of air which inflate and deflate at different times to help relieve pressure on the skin. They are powered by electricity and make a small amount of noise. High Specification Foam mattresses (with no moving parts) are specially designed to distribute weight better and are routinely used for most patients in hospitals.

We would like to find out which mattress is best at helping to prevent pressure ulcers in hospitals and community based care settings (so the patient won't need the mattress at home when they leave hospital). We will also be looking at how quickly existing pressure ulcers heal, patients' quality of life and how cost effective the mattresses are.

What is a pressure ulcer?

A pressure ulcer (sometimes called a bedsore) is an area of damaged skin usually caused by being in one position or unable to move a part of the body for a long period of time. They are often caused by having to stay in bed due to another illness or injury. Special mattresses are one of the things used to try and prevent pressure ulcers occurring. Pressure ulcers vary in size and severity from a small red patch to deeper wounds; they can be painful and have a big impact on patients. This trial is an important part of finding out how pressure ulcers can be prevented.

Why has this patient been chosen?

The patient has been approached because he/she is over 18, is expected to be in hospital for a few days or more and a nurse has identified that the patient has at least **one** of the following factors:

1. Reduced mobility, (e.g. the patient finds it difficult to get out of bed and needs help to move around)
2. The early signs of a pressure ulcer.
3. Soreness or pain in one of the areas which it is common to get a pressure ulcer.

What will happen if I decide the patient should take part?

If you decide the patient should take part then you will be asked to sign a Consultee Declaration Form. This is to show you have been consulted about the research and are happy for the patient to be part of the study.

A clinical research nurse or registered healthcare professional will ask you questions about the patient's health so that health questionnaires can be completed. The clinical research nurse or

registered healthcare professional will fill out the questionnaires but will be happy to show them to you.

The clinical research nurse or registered healthcare professional will also need to examine the patient's skin. This will involve looking at areas of his/her body where pressure ulcers occur most commonly, including buttocks, heels, elbows, hips and lower back. If the patient already has a pressure ulcer the clinical research nurse or registered healthcare professional will measure it by drawing around the area onto a clear sheet.

The patient will then be given one of the mattresses to sleep on for the rest of their hospital stay. You won't be able to pick which mattress they are given as it will be selected for them at random. The patient will use that mattress for the rest of their hospital stay, unless you, the patient or the ward nurse specifically asks for a change. The patient's care will continue as normal throughout the trial.

How is their condition monitored?

Every week day that the patient stays in hospital, a clinical research nurse or registered healthcare professional will check that they are still on the correct mattress. If the patient is on an Alternating Pressure Mattress, they will also check that it is working properly. The patient will not be disturbed to make these checks.

The clinical research nurse or registered healthcare professional will visit the patient twice a week to check the their skin to see if any pressure ulcers have developed and to check how any existing pressure ulcers are healing. At two visits the clinical research nurse or registered healthcare professional will re-do some of the health questionnaires to see if anything has changed. If the patient is in hospital for longer than 30 days, the clinical research nurse or registered healthcare professional will visit them once a week to look at their skin until;

1. their mobility has improved and they are less likely to develop a pressure ulcer.
2. they are discharged from hospital, or
3. up to a maximum of 60 days.

As soon as one of these conditions is met their participation in the main part of the PRESSURE 2 trial will be complete. There will be one final follow up visit 30 days after the patient has completed the main part of the trial. With your permission this may mean the clinical research nurse or registered healthcare professional visiting them at home to look at their skin and re-do the health questionnaires.

Photographs

If the clinical research nurse or registered healthcare professional finds a pressure ulcer then he / she will ask to take a photograph of it. They will always ask your permission before taking a photograph and you can say no at any point. The patient can also refuse at any time.

If you would prefer for the patient not to be photographed then you can opt out of photography but still continue with other parts of the trial. The photographs will only be of the patients skin and pressure ulcer (not their face) so they cannot be identified from the photographs.

A small selection of patients in the trial (1 in 10) will be visited by another senior nurse/registered healthcare professional (an expert in skin damage). If the patient is chosen, the senior nurse/registered healthcare professional will check the patient's skin to see if there are any pressure ulcers, photograph an area of skin on the patient's torso (for example the patient's back or buttocks) and one of the patient's limbs (for example the patient's heels). The photographs will be looked at by pressure ulcer experts who will not know what mattress the patient has been given.

Does the patient have to take part?

No. Taking part in Pressure 2 is completely voluntary and you may withdraw your consent for the patient to take part at any time, without giving a reason. If you do not feel it is appropriate for the patient to take part, it will not affect the care that they are currently receiving in any way.

If you agree for the patient to take part you will be asked to sign a Consultee Declaration Form to show that you have been consulted about the patient participating in the study and have agreed it is appropriate for them to take part. You will be given a copy of this Information Sheet and of the signed Consultee Declaration Form to keep. You are still free to withdraw the patient at any time and without giving a reason.

If you do not feel able to advise on the patient's views you can suggest someone else who has a close relationship with them. You can also ask the clinical research nurse or registered healthcare professional to nominate a consultee, such as a doctor or nurse who is not involved in this study and who knows the patient. If a nominated consultee is approached they will probably discuss the patient's wishes with you before they give advice.

What are the possible disadvantages and risks of taking part?

As both mattresses are already widely used and have been tested for safety there are no anticipated risks involved. However we are asking the patient to give up some of their time to take part. The clinical research nurse or registered healthcare professional will look at the patient's skin including intimate areas such as their buttocks and lower back and with your permission these areas may be photographed. You can opt out of this part if you think the patient would prefer not to be photographed.

What are the possible benefits of taking part?

In addition to any skin inspections which the nurses on the ward do as part of the patient's routine care, a qualified clinical research nurse or registered healthcare professional with enhanced expertise in skin assessment will inspect the patient's skin regularly for any signs of damage. If a pressure ulcer is found by the clinical research nurse or registered healthcare

professional then the patient's healthcare team will be informed immediately so that it can be treated quickly.

Information from this study will help us to improve pressure ulcer prevention in the future and ultimately benefit other patients.

Will taking part be kept confidential?

Yes. If you decide you would like the patient to participate in PRESSURE 2 then the information collected about them will be handled in accordance with the assent that you have given and also the 1998 Data Protection Act. Please refer to Part 2 for further details.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you, please continue to read the additional information in Part 2 before making a decision.

Part 2

What will happen if I don't want the patient 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. If you decide you want to withdraw the patient from the study, it will not affect the standard of care they receive. If the patient withdraws consent during the trial, any information we have collected about them up to that point will be kept, unless you request otherwise.

What if there is a problem?

It is very unlikely that the patient will come to any harm as a result of taking part in this study, as both types of mattresses are already used widely across the NHS every day. If you have a concern about any aspect of this study, you should ask to speak with a nurse or doctor at the hospital. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details about how to complain can be obtained from staff on the ward or by contacting your local Patient Advice and Liaison Service (PALS) http://www.pals.nhs.uk/ or Patient Advice & Support Service (PASS) (Scotland).

In the unlikely event that the patient is harmed by taking part in this research project, compensation arrangements are in place. If you have grounds for legal action you may have to pay your legal costs. Any claims will be subject to UK law and must be brought in the UK.

Will taking part in this study be kept confidential?

Yes. The hospital team will make a note of some of the patient's personal details to allow the clinical research nurse or registered healthcare professional to monitor them in hospital and follow them up at home. This will include their name, NHS number, hospital number, ward, address and telephone number. These details will be recorded on a paper research form and will be kept securely in a locked cupboard, in a locked room.

The Clinical Trials Research Unit (CTRU) at the University of Leeds will also be sent some information about the patient. The team at the University of Leeds will only be sent the clinical and questionnaire information collected about the patient. This clinical and questionnaire information will be entered onto a secure database held at the Clinical Trials Research Unit at the University of Leeds, in accordance with the 1998 Data Protection Act. The information will not include the patient's name and will be kept strictly confidential. The patient will be given a study number, which will be used along with their date of birth and initials to identify them on study documents.

A copy of the Consultee Declaration Form you sign, which will include your name and the patient's name, date of birth and NHS number will be sent to the Clinical Trials Research Unit. They will not put your names onto the database. They will check that the Consultee Declaration Form has been signed and dated properly and also check that the patient hasn't already been registered on the study prior to securely filing the form.

No other personal information about you or the patient will leave the hospital. The anonymised information collected about the patient may be shared with other research teams to answer new research questions in the future. However their name and other personal details will not be shared.

In addition any photographs taken will be transferred immediately by secure email and stored on a secure database at the CTRU. Once confirmation of receipt is received by the clinical research nurse or registered healthcare professional, the photographs will be deleted from the camera straightaway. The photographs will only be used for analysis and will be kept for a period of 5 years before being destroyed.

Involvement of the patient's healthcare team

With your permission, the patient's GP and hospital Consultant (if applicable) will receive a letter letting them know that they are taking part in the study.

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 patients will be identified. If you would like to obtain a copy of the published results, please ask the contact person named on the first page of this information sheet.

Who has organised and funded the study?

PRESSURE 2 is being funded by the National Institute for Health Research and is being organised by the Clinical Trials Research Unit at the University of Leeds.

Who has reviewed the study?

The study has been reviewed by the NHS National Institute for Health Research before funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This committee exists to protect the safety, rights, wellbeing, and dignity of patients (Ethics ref: **13/YH/0066**). This research has also been reviewed by patients and carers.

Further information about research

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations in the UK) have published a booklet entitled 'Understanding Clinical Trials'. For a copy contact UKCRC: Tel: 0207 670 5452 or visit their website www.ukcrc.org

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Participant ID:	Initials:
Date of Birth:	NHS/Hospital Number:
ISRCTN:	Principal Investigator:

PRESSURE 2

CONSULTEE DECLARATION FORM

Please initial each box

1. I confirm that I have been consulted about the patient's participation in the PRESSURE 2 study and have read and understood the information sheet (version 6, 25.09.15). I have had the opportunity to ask questions and have had these answered satisfactorily. ☐

2. I understand that the patient's participation is voluntary and that I am free to withdraw them from the study at any time without their medical care or legal rights being affected. ☐

3. I understand that if I withdraw the patient from the above study, the data already collected from them will be used in analysing the results of the study unless I specifically withdraw consent for this. ☐

4. I understand that relevant sections of the patient's healthcare records and data collected during the study may be looked at by authorised individuals from the study team, where it is relevant to their study participation. The Sponsor or other regulatory bodies may also access the patient's healthcare records in order to check that the study is being carried out correctly. ☐

5. I understand there will be secure storage of the patient's personal information (both paper and electronic) for the purposes of this study. This information will include name, NHS number, hospital number, ward, address and telephone number. I understand that any information that could identify them will be kept confidential and that no personal information that could identify them will be included in the study report or other publication. This information will be confidentially destroyed at the end of the study. ☐

The following point is **OPTIONAL**. Even if you agree to the patient taking part in this study, you do not have to agree to this section.

Please initial

Yes ☐ No ☐

6. I agree to allow the clinical research nurse, registered healthcare professional or senior expert nurse to take photographs of pressure ulcers (where present) and parts of the patient's body that are vulnerable to the development of pressure ulcers, including both left and right buttocks and the lower back region.

7. I understand that information and results arising from this study may be used to develop new research. ☐

8. I understand that a copy of this Consultee Declaration Form, containing the patient's name, date of birth and NHS number, will be passed to the Clinical Trials Research Unit (University of Leeds), where it will be filed securely. The patients NHS number will be used to ensure he/she has not already been registered on the study. ☐

9. I understand that the patient's GP and hospital consultant will be notified of the patient's participation in this study. ☐

10. In my opinion the patient would have no objection in taking part in this study ☐

_____
Name of Patient

_____	_____	_____
Name of Consultee	Date	Signature

Relationship to patient: _____

I have given written information and a verbal explanation to the consultee named above who has freely given their Declaration for the patient to participate.

_____	_____	_____
Name of Person Taking Consent	Date	Signature

1 copy for consultee 1 for patient records; 1 copy CTRU; original stored in Investigator Site File