The ROSE Study: A Realist Evaluation of 'Dry' And 'Paste' Compression Bandages

INFORMATION SHEET FOR NURSES

You are invited to take part in a research project undertaken by a team of researchers from the Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) and Northumbria University.

Before you decide whether or not to take part, it is important that you understand why the study is being carried out and what taking part will involve. Reading through this leaflet and discussing it with others if you wish, will help you decide whether or not you would like to take part in the study. Please contact the researcher named below if you would like to ask any questions.

Study clinical researcher
Dr Fania Pagnamenta – Nurse Consultant

Noala Parr – Research Nurse

Title of the study
A realist evaluation of 'dry' and 'paste' compression bandages**.**

What are the aims of the study?
This study aims to provide explanations of when, for whom and in what circumstances are dry or paste compression bandages, commonly used for the treatment of lower limb ulceration, best used for?

Why have I been chosen as someone who might take part?
You are invited to take part in the study, because you are a nurse who has been dressing a patient with a leg ulcer that has agreed to take part to the study.

Do I have to take part?
No. It is entirely up to you whether or not you would like to take part. If you decide not to take part in the study this will not affect how you treat your patient. If you decide to take part in the study, you may stop at any time point, without giving a reason.

What will participation involve?
If you take part, you will be asked to sign a consent form. We will be using an electronic tablet instead of a paper document and you will be asked to sign the consent form on the tablet.

You will be asked to complete one short questionnaire about how easy it is to apply compression bandages used in the study at the time of you visiting/treating a patient who has been recruited to this study. If you are visiting the patients a number of times, you can choose to complete the same questionnaire again as the way your opinion of the compression bandage's ease of application might have changed since the previous visit. The research nurse may observe the application of the bandages.

Will my taking part in the study be kept confidential?
Yes. The completed questionnaire will only be read by members of the research team. We will be using REDCap, which is a secure, web-based application to store data. Access will be restricted to named authorised individuals.

Your information will be destroyed 5 years after the study is complete.

Small quotes of your own words may be used in study reports, publications or presentations. However, your name will be removed from the information presented and any information that could lead to you being identified, or that you would like removed will not be included. If you decide to share any information that suggests that you or others are at risk of harm, this may have to be disclosed. A summary of the research findings will be shared with you if you would like to see a copy.

Additionally, if the researchers observe any events or behaviour that risked your safety or wellbeing, then confidentiality would be broken in order to escalate this to the relevant authorities in line with Trust policies and procedures.

What are the benefits of taking part in the study?
Your views will help us to understand when, for who and in what circumstances leg ulcers are best cased for. Some people find the discussion to be a useful process in itself from a professional point of view.

What are the disadvantages of taking part in the study?
We don't anticipate any disadvantages. You do not have to talk about anything you do not wish to and are able to withdraw from taking part in the research, without giving a reason.

What if I decide I no longer wish to take part in the study?
You are free not to complete the questionnaire at any time without giving a reason. If you decide not to participate any further, please tell the research nurse either by telephone, email or on their visit to a recruited patient.

What will happen to the results of the study?
The study findings will be used to help us to understand for whom these two types of compression bandages work best for; to add to the body of knowledge that pertains to leg ulceration care and guide staff to select the right compression bandage for each patient.

Findings will be written up into a report and shared across the Trust and NHS. They will also be written up and published in journal articles and presented at conferences. We may use direct quotations in these publication as well as photographs. All will be anonymised.

The information obtained from this work will be for research purposes and will not directly result in a change in standard of care practice within the NHS Trust.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South West - Central Bristol Research Ethics Committee.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

What are my rights as a participant in this study?
You can find out more about how we use your information:

- At www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to nuth.dpo@nhs.net
- By ringing us on 0191 2138946

Who is organising and funding the research?
This research is sponsored by the Newcastle upon Tyne Hospital NHS foundation Trust. Funding for this study has been provided through an unconditional grant from Milligan Healthcare Inc.

Payment
There will be no payment given to you for participating to this study.

Who to contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask question later, you may contact any of the following:

- Dr Fania Pagnamenta - Nurse consultant – fania.pagnamenta@nhs.net 0191 2824954.

If you wish to contact someone independent about this research, please contact:

- Mrs Cheryl Teasdale – Associate Director of Nursing - Cheryl.teasdale@nhs.net 0191 2137187.

Complaining

You can contact:

- the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202.

  or

- NuTH Patient Relations Department to:

  Telephone: 0191 223 1382 or 0191 223 1454

  Email: nuth.patient.relations@nhs.net

  Address: Patient Relations Department

  The Newcastle upon Tyne Hospitals NHS Foundation Trust

  The Freeman Hospital

  Newcastle upon Tyne NE7 7DN