A realist evaluation of ‘paste’ and ‘dry’ compression bandages

The ROSE Protocol – Version 2.3 (18 December 2024)

IRAS ID 328315

This protocol has regard for the HRA guidance

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NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST

Research Protocol Summary

TITLE:	A realist evaluation of 'paste' and 'dry' compression bandages
Short title:	ROSE study
IRAS number	328315
R&D No	10604
Study design	Realist evaluation
Research Question	When, for whom and in what circumstances are two different types of compression bandages selected in the treatment of lower limb ulceration?
Objectives	To understand when, for whom and in what circumstances are two different types of compression bandages selected; to add to the body of knowledge that pertains to leg ulceration care and guide staff to select the appropriate compression bandage for each patient.
Patient population	Patients with bilateral leg ulceration who are in existing compression bandages or are about to be started with compression bandages.
Patients Sample size	40 patients
Sponsor	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Founder	Milliken Healthcare Products, LLC ("Milliken")
Chief Investigator	Dr Fania Pagnamenta
Co-investigators	Research Nurse Noala Parr, Professor Monique Lhussier, Professor Tim Rapley
Organisations where research will take place	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Planned timeline	Study start date: 1 December 2024 Study end date: 1 April 2026
Protocol version, date	Version 2.3 18 December 2024

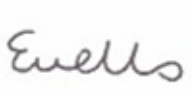
Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: 

Date: 23/12/2024

Name (please print): Emily Wells
Position: Research and Development Officer (NJRO)

Chief Investigator:

Signature: 

Date: 01/12/2023

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Study Protocol

Project summary

This study aims to provide explanations of when, for whom and in what circumstances are two different types of compression bandages (paste or dry) selected in the treatment of lower limb ulceration.

Compression bandages are used in the treatment of leg ulceration. A leg ulcer develops when blood vessels are not working as they should; they are painful, distressing and have a considerable impact on quality of life. They require frequent dressing changes, but with correct treatment can heal within three months. Evidence that compression is the gold standard to heal leg ulceration exists, but comparative data between different brands of compression bandages does not. Selection of a compression system is often based on nurses' preference, based on their acquired knowledge and skills of product application. This study aims to understand when, for whom and in what circumstances two very different product types should be selected to treat individual patient's lower limbs.

Patients have been the primary inspiration for this project. They often report that they are unable to tolerate compression bandages and when questioned in more detail, it appears that different systems have not been considered.

This study will use a research technique called 'realist evaluation', which acknowledges that leg ulcer care is complex, and is undertaken in a complex health care system. The process commences with listing what we think is happening (initial theories) and refine this through the analysis until the most plausible explanation is found.

The study is divided into two concurrent parts:
Patients who require bilateral compression bandages (registered with a Newcastle upon Tyne GP) will be selected from the caseload of District Nurses and Ambulatory Clinics.

(i) Opinions on the ease of application will be sought from Community Nurses and District Nurses who are applying the compression bandages to the recruited patients
(ii) Opinions on comfort will be sought from the recruited patients.

Background information

Venous leg ulcers affect 1.5% of the population and 3% of people aged over 80. They are painful, distressing and have a considerable impact on quality of life. They restrict day-to-day living including working, shopping, cooking, and socialising with family and friends. Leg ulcers develop from a range of comorbidities, such as venous or arterial disease, heart failure, rheumatoid arthritis but also through traumatic incidents like skin tears or insect

bites. Most people with leg ulcers are treated by nurses; compression bandages are the gold standard for treatment (SIGN 2010). The financial burden placed on the NHS for leg ulceration has been estimated at £3.2 billion per year.

Additionally, compression bandages are also used to prevent leg ulceration, for instance after traumatic incidents where skin tears have been sustained or in chronic oedema, due to cardiac failure or after a leg ulcer has healed, to prevent re-occurrence.

There are a whole range of compression bandages on the market. In the 2022-2023 financial year, in the Newcastle upon Tyne Hospitals NHS Foundation Trust, the cost of compression bandages was in excess of 171k (159k in community care and 12k in acute care). Ensuring that the correct bandage to maximise healing for this patients' group is a national priority.

This study is concerned with understanding when, for whom and in what circumstances are two different types of compression bandages selected in the treatment of lower limb ulceration.

Research question and study aim

This research asks: *'When, for whom and in what circumstances are two different types of compression bandages selected in the treatment of lower limb ulceration?'*

This study aims to provide explanations of when, for whom and in what circumstances are two different types of compression bandages selected in the treatment of lower limb ulceration. The premise is that all systems under review in this study work equally well, but it is unclear which system works best in the right patient, at the right time and in the hand of the right clinician.

The secondary objectives are 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.

Theoretical framework

A realist evaluation will be undertaken, which contends that intervention impacts (Outcomes) occur when certain causal processes (Mechanisms) are 'triggered' in the most favourable environments (Contexts). CMO configurations are used as explanatory theories that are refined and tested with empirical data.

Study Design

Developing Initial Programme Theories (IPTs)

A key element in realist synthesis is the formulation of 'educated guesses' theories, which are explanatory statements based on the available literature, in addition to the researcher team clinical expertise and experience. An initial meeting will take place prior to the beginning of the study with 1 District Nurse, 1 TVN (community); 1 Registered Nurse from the Ambulatory Clinics and the research team to develop these initial statements and they will be refined by the research team into Initial Programme Theories. These IPTs will be tested and refined with data collected below.

Sample and recruitment

a) Patient recruitment

40 patients will be recruited for having bilateral leg ulceration and being treated in compression bandages or being in compression bandages for the prevention of leg ulceration (re-)occurrence.

b) Nurse recruitment

The nurses who are applying the compression bandages to the recruited patients will be asked questions about the ease of application. It is not possible to estimate how many nurses will be recruited, as a number of nurses will be looking after the above 40 patients, as per standard care.

- Nursing questionnaire for comfort at application, during wear and on removal, fluid handling (see Appendix 3)
- Nursing questionnaire asking ease of use/application (see Appendix 3).

Participant inclusion/exclusion criteria

Patient Inclusion

- Age ≥ 18 years of age
- Patient living in Newcastle upon Tyne, with a Newcastle GP.
- Patients with **existing** bilateral leg ulceration or legs that require compression bandages to prevent ulcer (re)-occurrence.
- Patients with **new** bilateral leg ulceration or legs that require compression bandages to prevent ulcer (re)-occurrence.

Patient Exclusion

- Patient younger < 18 years of age
- Patients in nursing homes
- Patients with leg ulcerations that do not necessitate compression bandages.
- Patients with leg ulcerations that require a specific type of compression bandages (i.e. lymphoedema)

Nurse Inclusion

- Registered Nurse bandaging the recruited patient participant.

Nurse Exclusion

- Nurse associate (NA)
- Assistant practitioner (AP)
- Healthcare assistant (HCA)

Recruiting and Screening

Patients will be existing patients on the Newcastle upon Tyne Hospitals NHS Foundation Trust District Nursing's workload. Potential patients participants will be identified using Systm1, the electronic documentation system used by District Nurses in Newcastle. A list of potential participants will be drawn by the administrative team within District Nurses.

During the course of standard care, District Nurses will ask permission for the Research Nurse to contact them via telephone, letter or email. With agreeing, the District Nurse will enter the following text in the patient electronic documentation: "Mr/Mrs/Ms [Patient name] has agreed for the Research Nurse to contact him/her regarding the ROSE study". Upon contact, the Research Nurse will give potential patient participants the PIS and seek informed consent.

Thus Nurse participants will be involved in the recruitment process, and it is hoped that this will enhance their willingness to be recruited to the study alongside their patients.

Nurse Participants will be contacted by the Research Nurse who is a NuTH employee, through the existing nursing management structure.

In accordance with Good Clinical Practice, participation in this study is voluntary and any decision not to participate will not have any impact on how the subject's clinical treatment is performed. Patients will have a minimum of 24h to decide whether to participate or until the following visit by the District Nurses team (compression bandages are changed 2-3 times per week).

Following recruitment, a participant will be considered enrolled once he/she signs and dates the informed consent form. Once enrolled, the participant will be assigned a unique subject number, which will not contain information that could identify him/her (such as name or date of birth). The unique participant number will be used to label study data throughout the study.

All District Nurses in the organisation will be sent the Patient Information Sheet by their managers so that they will be well informed about the study aim and objectives. The research nurse might observe the application of compression bandaging. Patients receive care by a group of District Nurses, it is not unusual for patients to see 10-12 different District Nurses during the course of their treatment. Nurse participation is voluntary.

Study setting

The geographical area covered by this study is within the city of Newcastle; care to this area is provided by the Newcastle upon Tyne Hospitals NHS Foundation Trust Community services.

Criteria for Withdrawal/Discontinuation/exit

- The duration of patient participation in the study is 8 weeks.
- Patient participation in the study will be terminated immediately in case of discomfort or intolerance to zinc or calamine or any allergen present in the dry bandages as per standard procedure.
- Each participant has the right to withdraw from the study at any time without prejudice. In addition, the investigator may advise that a participant be discontinued from the study at any time if the investigator considers it necessary for any reason; however withdrawal decisions remain with the participant at all times.
- The investigator may withdraw a subject at any time, for any reason.
- The reasons for withdrawal and discontinuation for any subject shall be recorded.
- Any data and information collected for the subject up until the time of withdrawal or discontinuation, may still be included in the study registry, unless the participant has asked that their data are not to be used. The site shall document all requests by participants regarding their data use.
- Where participants lose capacity to consent during their time in the study, they will be withdrawn from further follow up; however data collected until this point will be retained for use. No further data would be collected, or any other research procedures conducted in relation to the participant.

Compression bandage selection procedure

The choice to apply 'full compression' versus 'reduced compression' will be dictated by the aetiology of the ulcer, wound assessment etc as per standard care. However, one leg will be bandaged in 'paste' compression and one leg in 'dry' compression, through a process of randomisation, using pre-prepared sealed envelopes.

The two types of compression bandages that will be used in this study are 'standard care' and are:

a) **Paste bandages:**

S_3F – full compression (F): AndoFlex TLC Calamine (Milliken, USA) - a two-layer compression bandage. The first layer is a soft foam layer impregnated with Calamine. The second layer is a cohesive short-stretch bandage.

S_3R – reduced compression (R): AndoFlex TLC Lite Zinc (Milliken, USA), a two-layer compression bandage. The first layer is a soft foam layer impregnated with Zinc. The second layer is a cohesive short-stretch bandage.

b) Dry bandages:

S_1F– full compression: UrgoK2 (URGO, France) - a two-layer compression bandage. The first layer is a short stretch bandage that provides 80% of the compression and a second layer, a long stretch bandage.

S_1R - Reduced compression (R): UrgoK2 Lite (URGO, France) - a two-layer compression bandage. The first layer is a short stretch bandage that provides 80% of the compression and a second layer, a long stretch bandage.

S_2F – full compression: Coban2 (3M, USA) - a two-layer compression bandage. The first layer is a foam bandage, and the second layer is a cohesive short-stretch bandage.

S_2R – Reduced compression (R): Coban2 Lite (3M, USA), a two-layer compression bandage. The first layer is a foam bandage, and the second layer is a cohesive short-stretch bandage.

Timeline

Each patient participant will be consented at time of recruitment. A patient information sheet will be offered. Each leg will be randomised to either S_1F/S_1R, S_2F/S_2R **or** S_3F/S_3R. The Research Nurse will visit each patient participant where they receive their treatment at Week 0, Week 1, Week 4, and Week 8. All participants will have demographic data obtained and the following outcome measures (Table 1):

Weeks	**0**	**1**	**4**	**8**
Baseline measures *(demographics, medical history, vascular history; nursing teams and setting)*	✔			
Visual analogue pain score *(pre, during and after dressing change)*	✔	✔	✔	✔
Visual analogue pruritus score	✔	✔	✔	✔
EQ-5D-5L	✔			✔
VEINES-QoL	✔			✔
Patient and Nurses Experience questionnaire		✔	✔	✔
Nurses technical questionnaire		✔	✔	✔
Photo(s) of both legs	✔	✔	✔	✔

Table 1. Outcome measures

a) Baseline measures (see Appendix 1)
b) Visual analogue pain score (see Appendix 2)
c) Visual analogue pruritus score (see Appendix 2)

d) VEINES-QoL is a patient reported outcome measure score that focuses on lower limb health (see Appendix 2)
e) EQ-5D-5L is a general quality of life measurement tool (see Appendix 2)
f) Patient questionnaire for comfort at application, during wear and on removal, fluid handling (see Appendix 3).

During the recruitment process the research team will acts as a contact point and coordinator for patients requiring information and support. If concerns are raised on participants (mental) wellbeing based on the home visits or outcome of the assessments, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

Data analysis

Refining Programme Theories

Excel/word documents will be used to store data. The data collected from the recruited participants will be analysed collectively, using descriptive statistics where appropriate and inductively bringing together the various data sources in emerging themes. This will demonstrate how theories evolve in the course of the study. Engagement, involvement, and collaboration between each member of the research team will take place to refine theories to understand when, for whom and in what circumstances are two different types of compression bandages selected in clinical practice. It is hoped and expected that at the end of the study, new guidance for nursing staff will be developed to guide the selection of compression bandages.

Duration of the project

Recruitment will take place over the course of 17 months, starting on the 1 December 2024 and ending on the 1 April 2026. First patient will be recruited on the 1 December 2024; last patient will be recruited on 31st January 2026.

Definition of the end of the study

The end of the study is defined as the date of the final visit of the last patient participant.

Ethics

This study is considered low risk for participants as compression bandages are commonly used in this patient population.

NHS Research Ethic Service (RES) review will be sought prior to the study commencement. HRA approval will be sought prior to study commencement. No other regulatory approvals will be required for this study.

Funding

Milliken Healthcare Products, LLC has provided an unconditional grant for this study, worth £71,481.63. All compression bandages used in this study are standard care and will be purchased through the current procurement route.

Funding includes research nurse time; administrator time to facilitate site contracts and approvals and open access fees for rapid publication.

Patient and Public Involvement

For the duration of this study, we will establish an 'Advisory Group' that will contribute to the management of the research. This group will comprise one or two patients; a district nurse; wound care nurse specialist (Tissue Viability) to monitor progress, provide guidance and help with problem-solving.

The research team will discuss issues as they arise with all or single members of the advisory Group.

Safety

There is no anticipated personal safety risk associated with taking part in this study. Appropriate precautions are in place to ensure medical and personal information is kept safe through adhering to appropriate governance regulations.

Participants will be allocated compression bandages that are used for its intended licensed purpose, are considered standard care in the Trust and that are available via NHS procurement routes.

Apart from being allocated to a different type of compression bandage per leg, all patients will be commenced on a compression therapy; therefore, all patients will receive the indicated clinical care they would receive if they were not in the study; they will be cared for in exactly the same manner as they normally would bar that usually both legs would be compressed using the same product for ease of procurement. However, in standard care, it is not unusual to be prescribed two different brands of compression bandages. Some bandage types may be more comfortable at controlling symptoms such as pruritus.

Participants cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research.

Anticipated problems

The main risks associated with this study are with recruitment and they have been mitigated by working within one Trust (the Newcastle upon Tyne Hospitals NHS Foundation Trust).

Informed consent forms
Consent forms have been designed. 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.

An interpreter service will be used, if the patient has currently been using this service.

Reporting of safety events and device complaints
This study involves the use of licensed Class I CE Mark post-market compression bandages currently used in standard practice and is not expected to pose additional medical risks to the patients beyond those of a routine clinical treatment.

Anticipated risks can be associated to misuse (e.g. poor compression bandage application techniques) and allergy to the bandages components.

In the very unlikely event that a Serious Adverse Event (SAE) has to be reported, a form has been devised. For the purpose of this study, a SAE has been defined as: an adverse event that led to death; led to a serious deterioration in the health of the subject, users, or other persons as defined by; either resulted in a life-threatening illness or injury, a permanent impairment of a body structure or a body function, or in-patient or prolonged hospitalisation, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or a body function; or led to foetal distress, foetal death or a congenital abnormality or birth defect.

Planned hospitalisation for a pre-existing condition, or a procedure required by the protocol without serious deterioration in health, is not considered a Serious Adverse Event.

Data storage & archiving arrangements
The following data will be stored on NHS, password protected computers,

- personal addresses, postcodes and so forth will be used to contact patients and the GP surgery
- direct quotations from respondents will be used for publication
- digital photographs of their wound, consent will be sought for publication as well as for clinical reasons (standard care)
- storage of data: for data analysis.

Any paper files will be stored in a locked room (Research Nurse's office).

There is a need to retain patient identifiable data to organise data collection. This is to allow identification of patients and ability to approach potential participants and provide a Patient Information Sheet and consent form.

We will be using REDCap, which is a secure, web-based application to store data. Access will be restricted to named authorised individuals.

Nothing that could reveal participants identity will be disclosed outside of this project.

Personal data be stored or accessed for 3 months or less after the study has ended. The research data generated by the study will be held for 5 years.

Dissemination of results and publication policy

Findings will be introduced in NuTH clinical practice, advancing knowledge translation. Impact will be maximised regionally and nationally, through the following presentation:

(i) 2-3 international clinical conferences (2025).

(ii) Regional wound care networks and the Shelford Tissue Viability Group.;

(iii) 1-2 clinical academic journal articles. Open access fees for these papers have been included in the proposed funding to ensure they reach a wide audience and to ensure transparency of the research.

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APPENDIX 1: BASELINE MEASURES

To determine the demographics and characteristics of the patients, the following baseline data will be collated:

Patient details

- Age
- Sex
- BMI [BMI will be calculated using weighing scales if available or by using the Mid Upper Arm Circumference (MUAC) technique when weighing scale are not available].
- Mobility status: does not walk / walks with assistance (stick/frame) / walks without assistance.

Medical history and status:

- Significant comorbidities, including CEAP Clinical score, Peripheral Arterial Disease, Diabetes (type I, type II, +/- neuropathy), Heart failure, Eczema, Rheumatoid Arthritis , Psoriasis, Other dermatitis, , Multiple Sclerosis, Cancer
- Any previous leg ulcers within last 2 years.

Index leg and ulcer status

- Leg ulcer aetiology determining need for compression bandaging: Venous, Mixed, Skin tear, Management of oedema, Lymphoedema, other traumatic wounds.

Compression care characteristics

- Location of regular leg care: home (self-care) / home (district nurse)/Ambulatory care
- Frequency of care (change of compression bandaging: …. per week.
- Specific dressing used on wound.
    - no
    - Yes, which?
- Skin care product used on index leg before application of compression bandaging.
    - No
    - Yes, namely: Hydromol

Nursing teams and setting

- Where and by whom is the patient been seen?
  (Which DN team; Ambulatory clinics)

APPENDIX 2. OUTCOME MEASURE TOOLS AND ASSESSMENTS

This appendix contains:

- The VEINES Quality of Life questionnaire (from Lamping et al, 2003)
- Visual analogue pain scale and the visual analogue pruritis scale (Jonker et al, 2020)
- EQ-5D-5L quality of life score (from Herdman et al, 2011)

VEINES QoL questionnaire

INSTRUCTIONS
HOW TO ANSWER:
Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

Below are some questions about your views about your legs. This information will help keep track of how you feel and how well you are able to do your usual activities.

1. During the past 4 weeks, how often have you had any of the following leg problems?

	(check one box on each line)	Every day	Several times a week	About once a week	Less than once a week	Never
1.	Heavy legs	1	2	3	4	5
2.	Aching legs	1	2	3	4	5
3.	Swelling	1	2	3	4	5
4.	Night cramps	1	2	3	4	5
5.	Heat or burning sensation	1	2	3	4	5
6.	Restless legs	1	2	3	4	5
7.	Throbbing	1	2	3	4	5
8.	Itching	1	2	3	4	5
9.	Tingling sensation (e.g.pins and needles)	1	2	3	4	5

2. At what time of day is your **leg problem** most intense ? *(check one)*

1 On waking
2 At mid-day
3 At the end of the day
4 During the night
5 At any time of day
6 Never

3. Compared to one year ago, how would you rate your **leg problem** in general now? *(check one)*

1 Much better now than one year ago
2 Somewhat better now than one year ago
3 About the same now as one year ago
4 Somewhat worse now than one year ago
5 Much worse now than one year ago
6 I did not have any leg problem last year

4. The following items are about activities that you might do in a typical day. Does your **leg problem** now limit you in these activities? If so, how much ?

	(Check one box on each line)	I do not work	YES, Limited A Lot	YES, Limited A Little	NO, Not Limited At All
a.	Daily activities at work	0	1	2	3
b.	Daily activities at home (e.g. housework, ironing, doing odd jobs/repairs around the house, gardening, etc...)		1	2	3
c.	Social or leisure activities in which you are standing for long periods (e.g. parties, weddings, taking public transportation, shopping, etc...)		1	2	3
d.	Social or leisure activities in which you are sitting for long periods (e.g. going to the cinema or the theater, travelling, etc...)		1	2	3

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **leg problem**?

	(check one box on each line)	YES	NO
a.	Cut down the **amount of time** you spent on work or other activities	1	2
b.	**Accomplished less** than you would like	1	2
c.	Were limited in the **kind** of work or other activities	1	2
d.	Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

6. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors or groups? *(check one)*

1 Not at all
2 Slightly
3 Moderately
4 Quite a bit
5 Extremely

7. How much leg pain have you had during the past 4 weeks? *(check one)*

1 None	4 Moderate
2 Very mild	5 Severe
3 Mild	6 Very severe

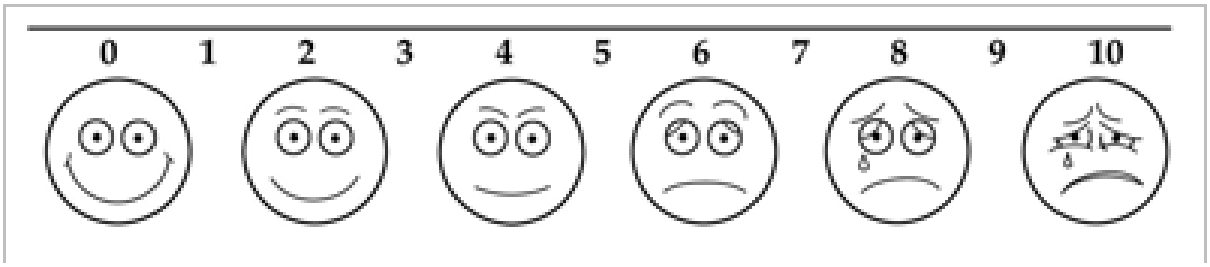
8. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your **leg problem**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

	(check one box on each line)	**All of the Time**	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a.	Have you felt concerned about the appearance of your leg(s) ?	1	2	3	4	5	6
b.	Have you felt irritable ?	1	2	3	4	5	6
c.	Have you felt a burden to your family or friends ?	1	2	3	4	5	6
d.	Have you been worried about bumping into things ?	1	2	3	4	5	6
e.	Has the appearance of your leg(s) influenced your choice of clothing ?	1	2	3	4	5	6

Visual analogue pain

Pain visual analogue scale Instructions:

"Please think about any **leg pain** you may have had over the past **2 weeks** and put a cross along the scale that best describes it."

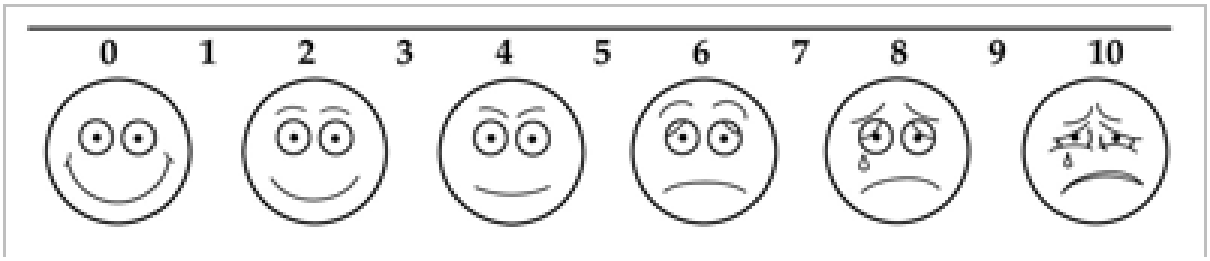


Pain free **Extreme pain**

Pruritus visual analogue scores

Pruritus visual analogue scale Instructions:

"Please think about any **leg itching** you may have had over the past **2 weeks** and put a cross along the scale that best describes it."



Not itchy at all **Extremely itchy**

Quality of life: EQ-5D-5L

Under each heading, please tick the **ONE** box that best describes your health today.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work ,study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderate anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

APPENDIX 3. PATIENT AND NURSE'S EXPERIENCE

PATIENT AND NURSE QUESTIONNAIRE – CLINICAL EXPERIENCE

Bandage used: <u>Right Leg</u> **S1F/S1R, S2F/S2R or S3F/ S3R** (circle what applies)	S1F = UrgoK2 S1R = UrgoK2 Lite S2F = Coban2 S2R = Coban2 Lite S3F = AndoFlex TLC Calamine S3R = AndoFlex TLC Lite Zinc
FOR THE PATIENT TO COMPLETE	
Please rate the following as your overall experience of wearing this bandage *(please circle)*:	
Has this bandage helped with your pain?	Yes No N/a
Has this bandage improved your comfort?	Yes No N/a
Has this bandage improved your ability to wear normal footwear and clothes?	Yes No N/a
Has this bandage stayed in place?	Yes No N/a
Has this bandage improved your skin condition?	Yes No N/a
Has this bandage improved your skin irritation?	Yes No N/a
Please add any further comment of your personal experience	

FOR THE NURSE TO COMPLETE	
Prior to last bandage application, was the leg washed with Hydromol mixed in warm water?	Yes No N/a
Prior to last bandage application, was the leg debrided using a debridement cloth or tenatome?	Yes No N/a
Looking at the leg, has this bandage helped improve the leg's skin condition?	Yes No N/a
Looking at the leg, has this bandage reduced the leg's skin irritation?	Yes No N/a
Looking at the leg, has this bandage helped with wound healing?	Yes No N/a
Looking at the leg, has this bandage helped with wound malodour?	Yes No N/a

Bandage used: <u>Left Leg</u> **S1F/S1R, S2F/S2R or S3F/ S3R** (circle what applies)	S1F = UrgoK2 S1R = UrgoK2 Lite S2F = Coban2 S2R = Coban2 Lite S3F = AndoFlex TLC Calamine S3R = AndoFlex TLC Lite Zinc
FOR THE PATIENT TO COMPLETE	
Please rate the following as your overall experience of wearing this bandage *(please circle)***:**	
Has this bandage helped with your pain?	Yes No N/a
Has this bandage improved your comfort?	Yes No N/a
Has this bandage improved your ability to wear normal footwear and clothes?	Yes No N/a
Has this bandage stayed in place?	Yes No N/a
Has this bandage improved your skin condition?	Yes No N/a
Has this bandage improved your skin irritation?	Yes No N/a
Please add any further comment of your personal experience	

FOR THE NURSE TO COMPLETE	
Prior to last bandage application, was the leg washed with Hydromol?	Yes No N/a
Prior to last bandage application, was the leg debrided using a debridement cloth or tenatome?	Yes No N/a
Looking at the leg, has this bandage helped improve the leg's skin condition?	Yes No N/a
Looking at the leg, has this bandage reduced the leg's skin irritation?	Yes No N/a
Looking at the leg, has this bandage helped with wound healing?	Yes No N/a
Looking at the leg, has this bandage helped with wound malodour?	Yes No N/a

NURSE QUESTIONNAIRE – PROFESSIONAL OPINIONS ON APPLICATION

Bandage used: <u>Right Leg</u> **S1F/S1R, S2F/S2R or S3F/ S3R** (circle what applies)	S1F = UrgoK2 S1R = UrgoK2 Lite S2F = Coban2 S2R = Coban2 Lite S3F = AndoFlex TLC Calamine S3R = AndoFlex TLC Lite Zinc
On a scale of 1-6 (1 = worst, 6 = best) please rate the following as your overall clinical experience of using this compression system compared to previously used compression system *(please circle)*:	
How easy is it to apply? (i.e. speed, technique required such as simple spirals and visual indicators for correct tension, cutting, tapes)	1 2 3 4 5 6
How easy is it to remove? (i.e. Wear time – appearance of the bandage post wear – slippage, unwind, worn out areas)	1 2 3 4 5 6
How 'neat' does it look once it has been applied?	1 2 3 4 5 6
Is it easy to learn how to apply it?	1 2 3 4 5 6
Is it easy to teach others to apply?	1 2 3 4 5 6
Do you like using this bandage	Yes No N/a

Bandage used: <u>Left Leg</u> **S1F/S1R, S2F/S2R or S3F/ S3R** (circle what applies)	S1F = UrgoK2 S1R = UrgoK2 Lite S2F = Coban2 S2R = Coban2 Lite S3F = AndoFlex TLC Calamine S3R = AndoFlex TLC Lite Zinc

On a scale of 1-6 (1 = worst, 6 = best) please rate the following as your overall clinical experience of using this compression system compared to previously used compression system *(please circle)***:**	
How easy is it to apply? (i.e. speed, technique required such as simple spirals and visual indicators for correct tension, cutting, tapes)	1 2 3 4 5 6
How easy is it to remove? (i.e. Wear time – appearance of the bandage post wear – slippage, unwind, worn out areas)	1 2 3 4 5 6
How 'neat' does it look once it has been applied?	1 2 3 4 5 6
Is it easy to learn how to apply it?	1 2 3 4 5 6
Is it easy to teach others to apply?	1 2 3 4 5 6
Do you like using this bandage	Yes No N/a

General questions:

Do you have an 'all-favourite' bandage that you find easier to apply?	Yes No N/a
Which one do you prefer? Why?	Name brand: _____