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

Submission date
14/02/2025

Recruitment status
Recruiting

Registration date
20/03/2025

Overall study status
Ongoing

Last Edited
20/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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 (paste or dry) 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.

Who can participate?
Adult 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.

What does the study involve?
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 refining this through the analysis until the most plausible explanation is found.

The study is divided into two concurrent parts:
1. 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
2. Opinions on comfort will be sought from the recruited patients

What are the possible benefits and risks of participating?
Participants will be offered to try two different types of compression bandages and at the end of the study, choose the one they like the most.

Risks not provided at registration.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
December 2024 to April 2026

Who is funding the study?
OVIK Health LLC

Who is the main contact?
Dr Fania Pagnamenta, fania.pagnamenta@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
328315

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10604

Study information

Scientific Title
A realist evaluation of ‘paste’ and ‘dry’ compression bandages: The ROSE study

Acronym
ROSE

Study objectives
To understand when, for whom, and in what circumstances two different types of compression bandages are selected; to add to the body of knowledge that pertains to leg ulceration care and guide staff in selecting the appropriate compression bandage for each patient.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/01/2025, South West - Central Bristol Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8197, (0)207 104 8269, (0)207 104 8194; centralbristol.rec@hra.nhs.uk), ref: 23/SW/0141

Study design
Realist evaluation study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Community, Home, Other therapist office

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Patients with/without leg ulceration who require compression bandages

Interventions
This is a non-interventional study. The research nurse will visit the participant at the place where they normally have their wound dressed, for example at their home or the ambulatory clinic, to collect information on the medical history of the participant's legs. At this visit, participants will be asked to complete a questionnaire on their general quality of life. The research nurse will ask questions about pain and how itchy their legs are.

The research nurse will visit the participant on the first day of the study (Day 1), after one week (Week 1), after four weeks (Week 4) and after eight weeks (Week 8) which is the last day of the study. If they usually have their wound dressed at home, the research nurse will visit at home during the study.

On each visit, the research nurse will ask them to complete questionnaires on how much pain they have and how itchy their legs are. The research nurse will collect information on the wound at each visit and take photographs.

Their legs will be bandaged using two types of bandages. One leg will be bandaged using a dry bandage and one leg will be bandaged using a wet bandage. A wet bandage is a bandage that has either zinc or calamine on the first layer; a dry bandage has no wet component. Both systems are currently used, but it is unknown which system works best under which circumstances.

Which leg receives what treatment will be decided using a process called ‘randomisation’, which means that each leg will have the same chance of being treated either with a wet bandage or a dry bandage. The Research Nurse will open a sealed envelope which will tell her what type of bandage to apply to the left leg and what bandage to apply to the right leg. The Research Nurse will have no prior knowledge of the instructions contained in the envelope.

Intervention Type
Other

Primary outcome measure
This study aims to provide explanations of when, for whom, and in what circumstances two different types of compression bandages are selected for 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. These data will be collected by the Research Nurse using questionnaires during study visits on the first day of the study (Day 1), after one week (Week 1), after four weeks (Week 4) and after eight weeks (Week 8).

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.

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's clinical expertise and experience. An initial meeting will take place before 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 (IPTs). These IPTs will be tested and refined with the data collected below.

Secondary outcome measures
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. These data will be collected by the Research Nurse using questionnaires during study visits on the first day of the study (Day 1), after one week (Week 1), after four weeks (Week 4) and after eight weeks (Week 8).

Overall study start date
01/12/2024

Completion date
01/04/2026

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients younger than 18 years of age
2. Patients in nursing homes
3. Patients with leg ulcerations that do not necessitate compression bandages.
4. Patients with leg ulcerations that require a specific type of compression bandages (i.e. lymphoedema)

Date of first enrolment
15/01/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle Joint Research Office

Sponsor details
A partnership between The Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University, c/o Regent Point
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
OVIK Health LLC

Results and Publications

Publication and dissemination plan
Findings will be introduced in NuTH clinical practice, advancing knowledge translation. Impact will be maximised regionally and nationally, through the following presentation:
1. 2-3 international clinical conferences (2025)
2. Regional wound care networks and the Shelford Tissue Viability Group

3. 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.

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated during and /or analysed during the current study are not expected to be made available due to the confidentiality of treatment.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.2	17/01/2024	17/02/2025	No	Yes
Participant information sheet	version 2.2	17/01/2024	17/02/2025	No	Yes
Protocol file	version 2.3	18/12/2024	17/02/2025	No	No